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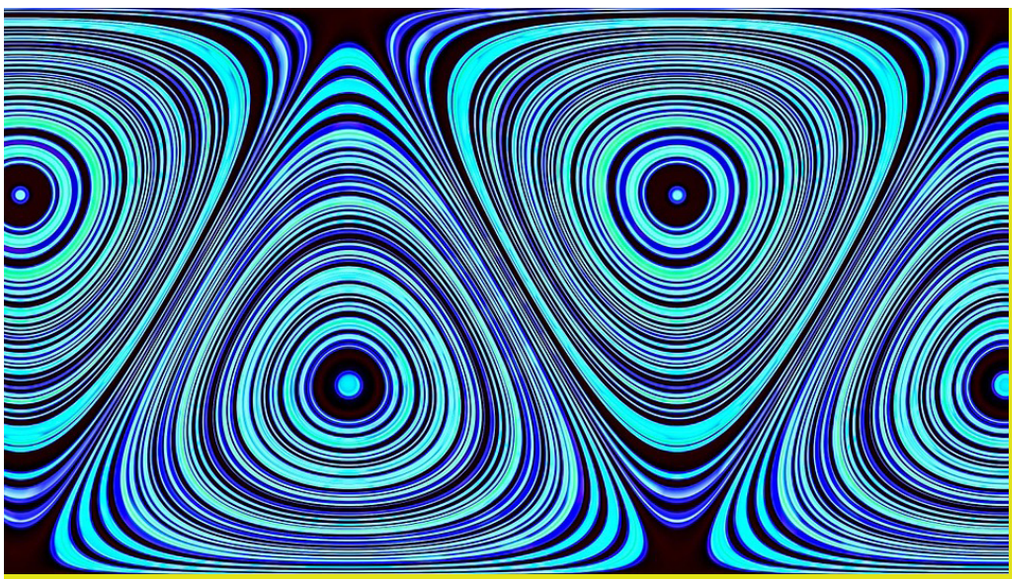

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RESEARCH ARTICLE

CARE NEEDS OF WOMEN WITH SUSPECTED OR DIAGNOSED WITH OVARIAN CANCER DURING HOSPITALIZATION: A MULTICENTER CROSS-SECTIONAL STUDY

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ABSTRACT

Purpose: This study aimed to identify care needs of women with ovarian cancer and suspected ovarian cancer during hospitalization according to the Roy Adaptation Model (RAM).
Material and Methods: This cross-sectional and descriptive study was carried out two university hospitals in İzmir, in Turkey. The sample included 100 women with ovarian cancer or suspected ovarian cancer in hospitalized. Care Needs of Women with Ovarian Cancer Questionnaire was used. We used descriptive statistics and content analysis.
Results: This study used RAM to examine care needs across four compliance domains: physiologic, self-concept, role functions, and interdependence. The diagnoses of “disturbance in sleep pattern and fatigue” were evaluated within the physiological mode; the diagnoses of “lack of knowledge regarding diagnosis and treatment process” were evaluated within the self-concept mode; the diagnoses of “decrease in continuity of family processes, inadequacy in fulfilling roles” were evaluated within the role function mode; and the diagnosis of “change in perception of femininity” was evaluated within the interdependence mode.
Conclusion: According to RAM, the nurse's interventions tailored to the patient's needs can effectively ensure the patient's compliance with the treatment process and meet their needs.

Keywords: Care needs, nursing care, Roy Adaptation Model, ovarian cancer

INTRODUCTION

Ovarian cancer is the eighth deadliest cancer for women, and the recurrence rate is 80% within two years of initial treatment (1). The final diagnosis of ovarian cancer is usually determined surgically (2). Therefore, patients are admitted to hospital for surgery. During treatment process, needs of patients should be considered because of side effects of the treatments and advanced stage disease (3). When there is a mismatch between perceived needs of patients and suitability of service provided, unmet needs are revealed (4). Women are expected to have unmet needs due to symptoms of illness, suspection of cancer and admission to hospital.

Women with ovarian cancer have many physical, psychological, spiritual, sexual, emotional needs during diagnosis and treatment (3,5,6). Fitch and Steele (2010) stated that women with ovarian cancer have difficulty in managing these needs and cannot seek help from clinical professional (7). Unmet needs can also lead to inability to access the best medical care, complementary and alternative treatment and

health care (8). In addition, unmet needs were found to be cancer spread, lack of information to help heal, uncertainty about the future, lack of energy and concerns about people close to them (3).

It is understood that women with ovarian cancer have very a lot of care needs. Most studies have examined needs that a year occurred after diagnosis or treatment (6,8). For any reason, hospitalization is stressful for patients. Also, women who are hospitalized with ovarian cancer or suspicion have to deal with stressors such as uncertainty, fear and creating burden for their families (7,9,10). However, it was determined that there was a deficiency in determining needs of patients after admission to the hospital. A study examining needs of women with ovarian cancer during hospitalization could not be reached. Failure to meet needs of patients increases patient care costs, reduces quality of life, adversely affects the diagnosis and treatment process and patient satisfaction (11).

The Roy Adaptation Model, one of the most frequently used models in nursing, defines humans as systems that can adapt to changing environmental conditions. Adaptation problems occur when individuals cannot cope with environmental stimuli. These stimuli are categorized into three categories: focal, contextual and residual stimuli. In this system, the nurse takes an active role in ensuring the individual's adaptation to changing environmental conditions (12). Patients are affected biologically, psychologically and socially due to multiple drug therapies and surgical intervention in ovarian cancer treatment. By determining the care needs of patients with ovarian cancer according to RAM, it is expected that positive results will be achieved in patients' compliance with both surgical intervention and medical treatment. Determination of these needs are necessary to facilitate the adaptation of women to the preoperative and postoperative period, to increase the awareness of health professionals in this patient group, to plan care for patients, and to increase satisfaction of patient. Therefore, our purpose was to determine needs of women with ovarian cancer or suspicion.

MATERIAL AND METHODS

Design

A cross-sectional and descriptive study was performed to determine needs of women with ovarian cancer or suspicion.

Participants

Data were collected between July 2017 and September 2019 from inpatients from the gynecologic and gynecologic oncology clinics of two university hospitals in İzmir, Turkey. Eligible participants included women who were between 18-65 years, diagnosed with an adnexal mass, pelvic mass, peritoneal carcinoma and ovarian cancer and preoperative period in the study. Women who have a history of psychiatric disease were excluded from the sample (13,14). The sample size of the study was determined as 90 in G Power 3.0 program based on in one group, medium effect size (0.5), significance level of 0.01 and power 99%. During this study, 133 women with suspected or diagnosed ovarian cancer were screened for participation. Of these, nine patients refused to participate in the study, while 24 others were excluded because they did not meet the sampling criteria. A total of 33 patients were excluded. 100 women participated in the study.

Data Collection

The first researcher collected the data for this study in the patient room in the gynecologic oncology and gynecologic and obstetric wards. The second researcher was involved in the evaluation and interpretation of the data obtained. The data of the study were collected by face-to-face interview method. Data on laboratory findings were obtained from the patient file. Data collection took an average of 20-25 minutes.

Descriptive Information Form and the Care Needs of Women with Ovarian Cancer Questionnaire were used. These forms were preparead in light of the literature and Roy's Adaptation Model (RAM) and taking opinions of three experts by two researchers. The Descriptive Information Form consisted of questions that included descriptive features such as age, educational status, health problems. Care Needs of Women with Ovarian Cancer Questionnaire which was created based on RAM, included 67 questions related to the physiological, self-concept, role function and interdependence modes. This form consisted of 30 open and 37 closed-ended questions about the presence of symptoms, information resources, the role of femininity and motherhood. To determine the functionality of the prepared questionnaire form and the scales used, a pre-test was performed with a total of five patients. After the pre-test, a rearrangement of the forms was not

Table 1. Descriptive features of women

	n	%
Age		
20-34*	15	15.0
35-49	31	31.0
50-64	32	32.0
65 ve older	22	22.0
Educational status		
Illiterate	14	14.0
Literate	4	4.0
Primary school	55	55.0
Secondary school	13	13.0
University**	14	14.0
Marital status		
Married	75	75.0
Single	25	25.0
Menopause status		
Menopause	54	54.0
Not menopause	46	46.0
Diagnosis		
Adnexal mass	78	78.0
Ovarian cancer	18	18.0
Peritoneal carcinoma	4	4.0
Time passed after the previous surgical operation (mounth)		
Not undergone surgery	82	82.0
0-12 months	6	6.0
13 months and more	12	12.0
Total	100	100.0

* A person aged 18 was included in the 20-34 age group.

** 5 associate degree graduates were included in the university group.

required and the patients who had taken the pre-test were excluded.

According to the RAM, basic nursing knowledge is aimed at understanding people's adaptation to different life situations. The main purpose of the model is to maintain homeostasis (12). Women admitted to the hospital change from a healthy individual to a patient. The reason why content of form is structured according to the model is that it emphasizes holistic care of nursing. Thus, appropriate interventions for individual can be planned and evaluated by giving point of view to the collected data.

Data Analysis

The quantitative data were analyzed using the IBM SPSS Statistics 23 program (IBM Corp., Armonk, NY, USA). The data were presented as mean ± SD, percentages, min and max. For open-ended questions, free-text analysis was conducted using traditional content analysis principles. The patients'

free-text responses were categorized by two researchers who are experts on this topic.

Ethical Considerations

Research ethics board approval (Dokuz Eylul University Non-Invasive Research Ethics Committee, Decision No: 2017/02-18, Date: 09.02.2017) and permission was obtained from the hospitals. The participants gave both oral and written informed consent.

RESULTS

The mean age of the women was 51 years, 55% of women are primary school graduates and 54% of the participants were in menopause (Table 1). Almost half of women (40%) have chronic disease, and 54% have a chronic disease, including hypertension, diabetes and asthma. The most prevalent diagnosis was adnexal mass (78%.) The mean time to diagnosis was 6.4 months and previous surgery was 45.3 months.

It was determined that 21% of women had dyspnea, distension of 63%, loss of appetite of 36%, pain of 52% and sleep problems of 39% (Table 2).

Women's findings regarding the self-concept mode needs are given in Table 2 and 3. 15% of the women stated that they made the decision about the treatment themselves, 48% with their families, 37% with their physician. The majority of women (88%) stated that they were informed about diagnosis and treatment only by the physician, 7% of them stated that they were informed by physicians and nurses, and 5% of them were informed by physicians, nurses or the internet. It was found that women wanted to be informed by physicians most. 73% of the women stated that they wanted to get face-to-face information and 17% of them stated that they would like to additionally receive brochures (Table 2). Women stated that they needed information about the presence of the cyst, the surgical procedure and the recovery process (Table 3).

One-third of women stated that the illness and hospital process affected femininity perception, 57.6% of them had motherhood role and 26.7% of them had a significant effect on the spouse role. Almost all of the participants (98%) were accompanied by their relatives.

Themes and sub-themes related to women's perception of femininity, role of motherhood, interaction with spouse, family and friend relationships are given Table 3.

The majority of women whose femininity perception is affected stated that their perception of femininity is negatively affected. One participant stated:

‘I will not feel as a wife. When my uterus is removed, I will feel like an eunuch.’

Some of the women reported that they feel like a burden to their children during the hospital process and that is why they feel sorry. A woman told:

‘My daughter is heart patient. Although she is sick too, she takes care of me.’

A few of the participants came from different city. For this reason, they stated that they were separated from their spouses. In addition, due to the presence of female patients in clinic, husbands are not admitted to clinic except visit hours. Particularly, spouses working in shifts cannot attend visiting hours. A participant said:

'Visit hours do not match my husband's working hours. Therefore, my husband cannot come here. We're just talking on the phone. I miss him so much.

Several of women stated that she was angry because of uncertainty and her caregiver did not understand her. Only a few of women reported that they took care of their grandchildren before they got sick, but they could not take care of their grandchildren because they are in the hospital now.

DISCUSSION

The discussion will consist of physiological, self concept, role function and interdependence modes sections.

Care Needs of Women in the Physiological Mode

In our study, most of the women had problems with the gastrointestinal system such as pain, abdominal bloating, changes in taste, loss of appetite, nausea, vomiting, weight loss, decreased skin turgor and constipation. The symptoms of ovarian cancer patients were found to be substantially associated with their impaired physical performance in the American Cancer Society's Cancer Survival Study I (15). The most common unmet needs of women with ovarian cancer were in the symptom dimension (16). Among patients with ovarian cancer, ascites-induced abdominal distension, decreased appetite, weight loss, constipation, pleural effusion; dyspnea due to pulmonary congestion; nausea and vomiting due to decreased stomach motility may ocur (7,17,18). Our findings are similar to those of other research. It is understood that women have many problems in the physiological mode. Ovarian cancer is typically diagnosed in late stages.

Table 2. Care Needs of Women in the Physiological Mode and Self Concept Mode

Physiological Mode	**n**	**%**	**Self Concept Mode**	**n**	**%**
Oxygenation			**Her requested information source**		
Dyspnea	21	21.0	Physician	71	71.0
Nutrition			Physician and nurse*	23	23.0
Presence of abdominal distension	63	63.0	Internet	3	3.0
Loss of weight	47	47.0	Sufferers who the same disease	2	2.0
Loss of appetite in the last week	36	36.0	No wish to receive information	1	1.0
Changes in taste in the last week	23	23.0	**Preferred method of accessing information**		
Nausea in the last week	29	29.0	Face to face	73	73.0
Vomiting in the last week	11	11.0	Face to face and brochure	17	17.0
Elimination			Face to face and telephone	3	3.0
Constipation	24	24.0	Face to face, brochure and telephone	2	2.0
Activity and rest			Through relatives	4	4.0
Fatigue in the last 24-hour			Internet	1	1.0
Not tired	51	51.0	**Understanding the given information/education**		
A little tired	34	34.0	Use of medical term	12	38.8
So tired	15	15.0	Giving much information and using medical term	9	29.0
Sleep problems			Having anxiety	6	19.4
No sleep problems	61	61.0	Having hearing problems	2	6.4
Have sleep problem	39	39.0	Pain	2	6.4
Protection			**Coping with pain**		
Decreased skin turgor	37	37.0	Not using any method	53	53.0
Hemoglobin level			Taking drug	17	17.0
Low (<12 g/dL)	43	43.0	Nonpharmacological method (music, massage, shower, walking)	16	16.0
Albumin level			Sleeping	14	14.0
Hypoalbuminaemia (<3.5 g/dL)	15	21.1			
Senses					
The presence of pain					
No pain	48	48.0			
In the pelvic area	40	40.0			
In the abdominal	9	9.0			
In the waist	3	3.0			
Fluid and electrolytes					
Edema of the lower extremities	18	18.0			

* Patients who wanted to get information from doctors and nurses through their relatives were included in the group that wanted to get information from doctors and nurses.

Table 3. Themes and sub-themes related to the information, role function and self conception needs

Information needs		**Role function and self conception needs**	
Themes	**Sub-themes**	**Themes**	**Sub-themes**
Information content	-Presence of cysts in the ovary -The size of the cyst -Presence of cancer -Ascites in the abdomen -Reproductive effects -Malign-benign distinction	**Perception of femininity**	-Loss of femininity -Feeling like a man -Loss of reproductive -Feeling of being half human
	- Laparoscopic/laparotomy surgery - To be taken organs - Recovery time - Discharge time	**Role of motherhood**	-Missing her children -Sadness for seperation -Feeling of inadequacy -Feeling of being a burden for her children
Information need	-Benign or malign -Reproductive effects	**Interaction with spouse**	-Feeling strong. -Strengthening spouse communication -Fear of disfavor -Communication problem -Missing her husband
	- To be taken organs - Duration of surgery - Laparoscopic/laparotomy surgery - Duration of surgery - Physician who will do surgery -Anesthesia type	**Family and friend relationships**	-Sadness because of losing care role -Anger -Decreased social relations -Keeping diagnosis secret
	-Waiting for pathology result / worry / -Getting rid of disease -The time of learning the pathology result -Effect of surgery on movement -Time to start feeding -Effect of surgery on menopause -Effect on working condition -Duration of report -Time to recover the caring role		

Table 3. Continue

Information needs		**Role function and self conception needs**	
Themes	**Sub-themes**	**Themes**	**Sub-themes**
The effects of the disease and hospitalization	-Loss of family caregiver roles -Can not get permit for work -Decreased activity -Decreased self-care -Pain -Insomnia -Discomfort from distension -Fear of cancer -Fear of death -Uncertainty -Sadness -Anxiety due to hospitalization -Anxiety and concern due to privacy -Relaxation due to reduced uncertainty -Feeling less responsible -Shock -Acceptance	**Perception of femininity**	-Loss of femininity -Feeling like a man -Loss of reproductive -Feeling of being half human

Many symptoms occur due to ascites and mass in the abdomen in advanced stage (19,20). Nutritional disorders related to cancer and pressure of mass are seen in these patients and immune response decreases. This situation facilitates the emergence of preoperative and postoperative complications in women. It may also adversely affect the effectiveness of treatment. The findings of this studies support this result. The length of hospital stay of patients with ovarian cancer developing malnutrition and response to treatment decreases, postoperative complication development and morbidity rates increase (21,22). Therefore, nurses should carefully evaluate the physiological mode care needs of hospitalized women with adnexal mass, and plan nursing interventions to prevent, early recognise and reduce problems.

One-third of the women in our study stated that they felt a little tired and 39% had sleep problems in the hospital. Fatigue and decreased sleep quality were the most prominent symptoms among women with ovarian cancer (3,8,23). It is thought that the causes of sleep and fatigue problems among these women are caused by malnutrition, abdominal ascites and mass pressure and psychological problems. Women reported a decrease in physical activity and self-care during the hospital process. In other studies, it is understood that self-care is an important problem in women with ovarian cancer (7,24). Nurses should definitely plan an intervention to solve sleep, fatigue, physical activity and self-care problems of women with ovarian cancer.

Care Needs of Women in the Self Concept Mode

In the study, it was found that half of the women made the decisions regarding the diagnosis and treatment process with their family, while only 15% of the women stated that they made their own decisions. Nowadays, the decision-making process of patients is supported by the concept of informed consent. It was determined that the most important factors affecting the patients' decision-making were the recommendations of the health Professional (25). It is stated that the beliefs, preferences, beliefs of patients about decision making, power dynamics, communication style and doctor factors affect the decision-making process of ovarian cancer treatment (26,27). Pozzar et al. (2018) found that patients were influenced by doctor referral, interpersonal relationships, family and friends' recommendations when deciding on ovarian cancer treatment (27). Both these research results and other research results show that women with ovarian cancer are very open to the guidance of health workers and their families in the decision-making process. For this reason, nurses should support women to make right decision for themselves in the decision-making process.

It was determined that women needed information about diagnosis and treatment, characteristics of the mass, operation, recovery process, physical and social effects. In our study, women stated that they needed information about malignancy status of the mass, effect of the disease on reproduction, organs to be taken by surgery, duration of the surgery, time of surgery, physician who will do surgery and type of anesthesia to be given. Women stated that they were given too much information and had difficulty understanding the information given because medical terms were used. More than half of women in our study stated that they understood the information given. Women express a lack of knowledge at various stages of their illness (28). The information need is one of the unmet needs of patients with gynecological cancer. The information provided should be tailored to the patient's education and information needs (29,30). Rietveld et al. (2018) found that 35% of ovarian cancer survivors were satisfied with the information they received during the diagnosis and treatment process. Women reported that they mostly recevied information about illness, medical tests and treatment (8). In another study, it was found that obtaining information about the test results of women with ovarian cancer made women feel better (7). Nurses should determine information need and characteristics of the patient from the beginning of the hospitalization. The nurses should provide information considering patient characteristichs such as education, age, etc. The nurse should test whether the information provided by the nurse meets the needs of the patient and whether the patient perceives the information correctly. The nurse should remember that given information will be reduced the patient's anxiety and the treatment process will be positively affected.

The patients stated that they wanted to meet with the person they were asked for information face to face. In a study conducted with women surviving gynecological cancer, it was determined that the most frequently preferred method of getting information about women was one-to-one interviews, followed by brochures and internet resources. In other studies, it was found that women mostly preferred the brochure

method, followed by a one-to-one interview with the healthcare professional and internet resources (31). In a study comparing written and verbal preoperative information in gynecologic oncology surgery, it was found that written information increased patient satisfaction; decreased pain score, length of hospital stays and daily analgesic use. Also, it was found that hospitalization of patients with endometrial cancer on the day before surgery reduced preoperative evaluation and preparation time (32). It is understood from the results of the research that women need different education methods. However, it is understood that getting information by face to face interview method is an indispensable method. When planning an education, nurse should determine the training methods appropriate to the needs of the woman and plan her training accordingly.

Half of women stated that they had pain, but half of the women stated that they did not know how to cope with pain. Therefore, nurses should consider how patients can cope with pain, which is an important problem. It was determined that presence of postoperative pain decreased patient satisfaction (33). Nurses should teach how to cope with pain in hospitalize patients and include positive method coping with pain in the preoperative training content (34,35). Pain management in preoperative education will contribute to decrease of pain scores, shortening of hospital stay and increasing satisfaction with surgical procedure in postoperative period (32,36).

In this study, the participants stated that the meaning of the disease and the reactions to the disease were negative. Shock, uncertainty, sadness, fear of death, decrease in activity, stress, anxiety was negative emotions expressed by the participants. Women with ovarian cancer experienced emotional problems such as feeling sad and depressed, worrying about outcome of treatment was out of control, uncertainty, shock, treatment-related anxiety, feeling bored or useless, and fear of death (7,9,28,37). Studies have shown that women experience a sense of uncertainty due to relapse and fear of death (3,6,9). Negative emotions and reactions of women in our study may result from the negative meaning of cancer. Nurses should be aware of the negative feelings these women may experience. Nurses should be involved in a team work involving psychologists and psychiatrists to help patients cope with these negative emotions (38).

In our study, women mostly want to know the status of benign/malignant masses related to diagnosis and tests. Women with a pelvic mass usually refer to units such as internal medicine, gastroentrology and are consulted to gynecologists as a result of tests. Surgery is required to differentiate benign/malignant pelvic masses and patients are usually referred to gynecological oncology requiring advanced expertise. Referring patients to a gynecological oncologist may cause anxiety for the patient and lead to going distant hospitals (39). This causes uncertainty in women and causes them to experience anxiety. The nurse should be aware of the underlying causes and feelings of anxiety and uncertainty of the hospitalized women for surgery.

Care Needs of Women in the Role Function and Interdependence Modes

It is understood that women with adnexal masses had intense problems regarding femininity, motherhood, spouse, friendship perception and relationships. In our study, almost half of the women stated that their perception of femininity was affected. Women stated that they experienced feelings of losing their femininity, being like men, losing reproduction and being half human. Having strong social support have been shown that increased women's self-esteem and decreased levels of depression and anxiety. In addition, abdominal scars, hair loss, weight gain, ovarian and uterine losses, which are symbolic organs of female identity, significantly affect body image (40). Childbearing, which is perceived as a part of the perception of femininity, is one of the important issues that cause concern among women with ovarian cancer. Campos et al. (2012) stated that most women with ovarian cancer and borderline tumors discuss fertility options with their physicians, but very few seek information on fertility conservation (41). In Turkish culture, fertility is an important role attributed to women by society. The belief that 'a woman without a uterus is not a woman' is common in Turkish society (42). It should help women develop positive coping methods and highlight their strengths. Nurses should support self-care in order to cope with changes in the woman's physical appearance. In addition, fertility desires of young women should be evaluated and health professionals should discuss appropriate treatment options and the effect of treatment on fertility.

More than half of the women stated that the role of motherhood was affected. Women expressed that they felt longing for their children and felt sadness and inadequacy due to being separated and being a

burden for their children. Tan et al. (2021) found that that because the disease is genetic inherited, women with ovarian cancer are fearful for the future and concerned about their daughters (28). Women with ovarian cancer stated that they received support from their families and especially their children in symptom management (43). It is stated that children are seen as a source of power and motivation for gaining the sense of being normal of the patients, but psychological stress rate is high in the mothers with cancer (37). Women also describe the treatment process as 'a struggle for all of us' regarding their maternal role and want to see their children grow up (43).

A quarter of women stated that their partner roles and relationships were affected. Women stated that they missed their husbands during fear of disfavor, communication problems and hospital stay. However, some women stated that they felt stronger and their relationships were strengthened in this process. In studies, while some of the women stated that they received adequate support from their spouses, some of them stated that their relationship with their spouses was negatively affected during the diagnosis and treatment process (9,10,13). It was found that women could not perform their role as spouses and avoid close relationships due to feelings of shame and fear (7,44). In addition, disharmony associated with sexual function and body image leads to social withdrawal (13). In addition, women stated that they were especially afraid of their husbands' disliking themselves and that they were worried about their appearance (9,44). In contrast to these studies, women stated that they missed for their spouses. This situation is thought to be caused by the fact that male caregiver is not allowed to stay in the hospitals where the studies are conducted. In addition, while previous studies included outpatient treatment, our study only addressed the hospital process and did not reveal any side effects associated with chemotherapy (13). Nurses should be aware of women's missing for their husbands and children during the hospital process and plan their visit hours appropriately to improve the psychological well-being of patients.

Women who expressed that family relations were affected during the hospital process mentioned negative feelings such as hiding the disease and decreasing social relations. Patients with ovarian cancer; reported negative effects such as the burden of ovarian cancer and treatment on family and friends, lack of support, loss of relationship and difficulty in maintaining it (10). Holt et al. (2014) stated that before the diagnosis, some women with gynecological cancers shared their concerns with their relatives, while others conceal their concerns until the diagnosis of cancer was confirmed (45).

The caregivers of the patients were determined as children, mothers, siblings and other family members. To have someone to care for patients in hospitals in Turkey it is usually requested by both health professionals and patients. In Turkish culture, there is a perception that the patient should have caregiver. It was determined that women who without caregivers felt lonely and worthless (46). Hospital caregiver can be a good practice for women to feel safe. However, it can also cause anxiety because patients feel they are burdening their relatives. Nurses should be aware that women hospitalized for adnexal mass or ovarian cancer often experience problems in the modes of role function and interdependence. It should also consider individuality when identifying women's problems and planning their care.

Limitations

The strength of our study is that the study was conducted in two hospitals. However, the limited sample size may affect the generalization of the study results. Secondly, scales that evaluate care needs are usually focused on needs after post-treatment. There is no specific scale developed to assess the care needs of women with ovarian cancer that has been validated and reliable.

The questionnaire created in this study was created based on the researchers' experiences and literature knowledge. Therefore, there is a need to develop a special scale that measures the needs of women with ovarian cancer in the preoperative period. Thirdly, considering that their care needs may be affected, patients who had a previous gynecological operation were also included in the study. However, this situation may have limited the care needs of patients who underwent surgery more than once.

CONCLUSION

In conclusion, women admitted to gynecological oncology service due to the diagnosis or suspicion of ovarian cancer have many needs related to physiological, self, interdependence and role function modes. It is seen that gastrointestinal symptoms, sleep problems and fatigue come to the forefront in relation to physiological modes. Women have stated that they have the most information needs in self

concept mode. Face to face interviews were the first choice of women as receiving information. In addition, in role function and interdependence modes, women expressed that missing their spouses and children and affecting their perceptions of femininity. Nurses should be aware of gastrointestinal symptoms in patients, determine the factors that decrease and increase appetite by performing nutritional control, evaluate whether the patient is getting enough calories, and cooperate with the dietician when necessary. From the moment of hospitalization, nurses should evaluate the patients' sleep quality and plan sound, light, and sleep hygiene procedures in a way that doesn't disrupt their sleep. Nurses should evaluate patients' fatigue daily and make environmental arrangements to minimize energy expenditure. Furthermore, it's crucial to strategize the patients' visiting hours and relatives scheduling to fulfill their role-function and interdependence needs.

Future research is needed to explore what care needs of women with ovarian cancer or suspicion are in the hospital. It is recommended to develop a scale that can measure the care needs of women with ovarian cancer. Roy Adaptation Model can be used while developing the scale. The use of the model in patients with suspected or diagnosed of ovarian cancer guides the nurse in determining the needs in the modes of physiology, self-concept, role function and interdependence and in providing individualized health care.

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RESEARCH ARTICLE

IMPACT OF HEMOGLOBIN–ALBUMIN–LYMPHOCYTE–PLATELET (HALP) SCORE ON MORTALITY IN ABOVE-ANKLE AMPUTATION OF DIABETIC FOOT INFECTION

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ABSTRACT

Purpose: Diabetic foot ulcers are one of the important reasons for amputations. The hemoglobin–albumin–lymphocyte–platelet (HALP) score is a marker of the inflammatory and nutritional status of the individual. Aim of this study is to investigate the relationship between the HALP score and mortality in patients undergoing above-ankle amputation due to diabetic foot infection.
Material and Methods: The demographic data (age, sex), deaths during hospitalization, laboratory values and mortality through 3-6-9-12 months were recorded. Chi square and t test were used for categorical comparison and logistic regression tests were used for mortality risk estimation.
Results: The mortality rates in hospital and in the 3rd, 6th, 9th, and 12th months were 13.1%, 37.7%, 48.5%, 53.8%, and 56.2% respectively. HALP score below 21.55 was associated with a 2.975 times higher risk for 1-year mortality (odds ratio: 2.975; 95% CI: 1.252–7.069; p = 0.014). Female gender, HALP score below 21.55, and age over 65 predict 20.2% overall 1-year mortality risk (Nagelkerke R^2 = 0.202).
Conclusion: The HALP score is a novel risk factor for mortality in patients undergoing amputation for diabetic foot ulcers. Also; older age and female gender are independent risk factors for 1-year mortality.

Keywords: Diabetic foot, risk factor scores, prognosis, amputation, mortality

INTRODUCTION

Amputations due to diabetes mellitus (DM) not just represent a medical concern but are public health issues at large, posing a substantial economic burden to nations (1). A study conducted in the United Kingdom revealed that 8.6% of adults had DM, with the risk of lower-extremity amputation increased by 23-fold (2). Alarmingly, approximately half of non-traumatic amputations are caused by diabetes-related complications (3). Studies have shown that the 5-year mortality rate for diabetes-related amputations can be up to 55% (4,5). The lifetime risk of the development of diabetes-related foot ulcers in patients with diabetes is 25% (6). Diabetic foot ulcers are one of the important reasons for amputations (7). Foot ulceration and amputation are closely related in patients with DM. In addition, 85% of amputations in patients with diabetes develop after an active foot ulcer (8).

The underlying factors for diabetic foot ulcers are neuropathic, neuroischemic, ischemic, or nonischemic–nonneuropathic (9). A multicenter study found that more than 63% of patients had the triad of trauma, neuropathy, and deformity, with edema,

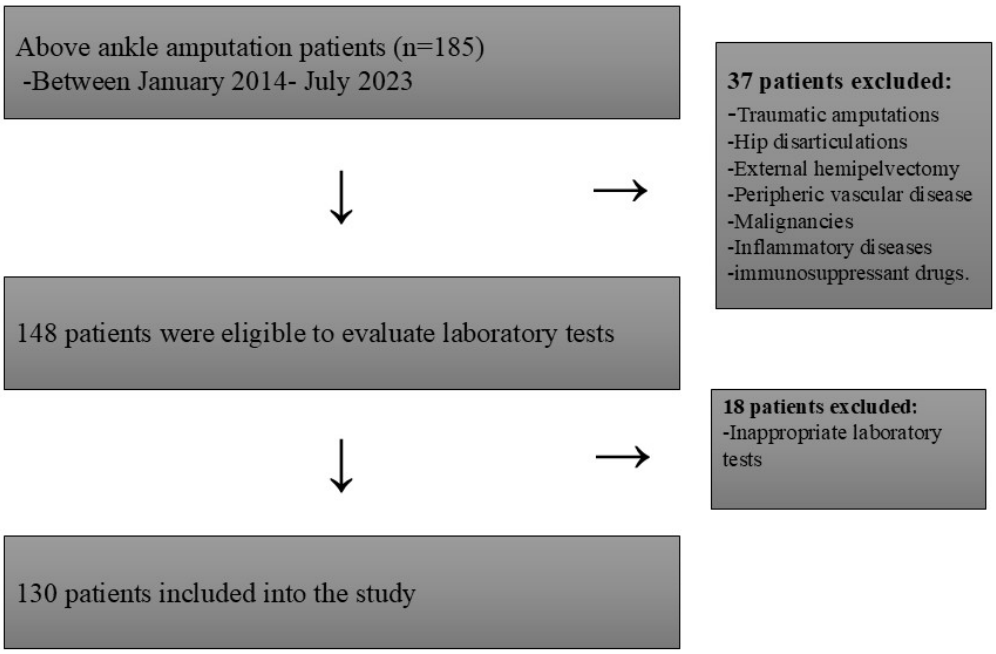

Figure 1. Flowchart of patient's selection criterias

ischemia, and callus formation involved in the etiology (10).

Wagner's classification for diabetic foot ulcers is still widely used (11). These ulcers are evaluated between grades 0 and 5. Grade 0 ulcer indicates the presence of deformity or cellulitis without an open lesion. Grade 1 ulcer indicates a superficial ulcer; grade 2 indicates those that have reached the tendon ligament, joint capsule, or deep fascia without abscess or osteomyelitis. Grade 3 ulcer indicates an ulcer that reaches deep tissues, including abscess, osteomyelitis, and joint sepsis besides grade 2. Grade 4 describes a localized gangrenous condition of the forefoot or heel, whereas a grade 5 ulcer describes a diffuse gangrenous condition of the entire foot (11). Wagner type 0-1-2 ulcers usually necessitate debridement and antibiotic treatments, whereas Wagner type 3-4-5 ulcers may require debridement and amputation at various levels (12). Most of these patients visit emergency departments prior to amputation, leading to their hospitalization for subsequent follow-up and surgical interventions (13). The hemoglobin–albumin–lymphocyte–platelet (HALP) score is a marker of the inflammatory and nutritional status of the individual and is used to assess prognosis across many malignancies and diseases (14,15). The HALP score is calculated using the following formula: hemoglobin level (g/L) × albumin level (g/L) × lymphocyte count (/L)/platelet count (/L) (14,15,16). However, despite its significance, no study to date has investigated the relationship between the HALP score, which indicates the nutritional and inflammatory status of the patient, and above-ankle amputations due to diabetic foot ulcers.

Hence, this study aimed to investigate the relationship between the HALP score and mortality in patients undergoing above-ankle amputation due to diabetic foot infection.

MATERIAL AND METHODS

This retrospective study was conducted at the Department of Orthopedics and Traumatology and Emergency Medicine, Niğde Ömer Halisdemir University Medical School, between January 1, 2014, and July 1, 2023. The study protocol was approved by the Non-Invasive Clinical Research Ethics Committee of Niğde Ömer Halisdemir University (Date: 29.08.2023, Decision No: 401670, Protocol No: 2023/51). The study was conducted following the criteria of the Declaration of Helsinki.

This retrospective study included patients who underwent above-ankle amputation due to diabetic foot infection. The inclusion criteria were as follows:

Table 1. Comparison of age and gender with patients'mortality status

Variables	n (total=130)	Deceased at 1-year	Survival at 1-year	p
Age, years mean (SD)	67.3 (15.6)	72.44 (13.3)	64.75 (15.1)	0.01*
Gender, n (%)				
female (expected count)	37	25 (18.1)	10 (16.9)	0.004**
male (expected count)	93	36 (42.9)	47 (40.1)	

* t test; ** Chi-Square test (continuity correction) SD, standart deviation

(a) a diagnosis of DM type 1 or 2, (b) above-ankle amputation(knee disarticulations,below knee and above knee amputations) due to Wagner type 3-4-5 diabetic ulcer, (c) appropriate laboratory tests 1 week before above-ankle amputation. The exclusion criteria were as follows: amputation levels other than above the ankle, also hip disarticulation and external hemipelvectomy, individuals without available laboratory data within 1 week prior to surgery, individuals with acute traumatic amputations, amputations due to peripheral vascular diseases without diagnosis of diabetes, malignancies, active and chronic inflammatory diseases, and individuals using immunosuppressant drugs.

The study was conducted with 185 patients who underwent above-ankle amputation due to diabetic foot infection between January 1, 2014, and July 1, 2023. All patients admitted from the emergency department or orthopedic outpatient clinics were included. Of these, 55 patients who did not meet the inclusion criteria were excluded. The study was completed with 130 patients. Flowchart of the patients selection criterias is shown in Figure 1.

The demographic data (age, sex), deaths during hospitalization, and laboratory values were recorded. The laboratory values, including hemoglobin and albumin levels, lymphocyte and platelet counts, and C-reactive protein (CRP) level, were obtained within 1 week before amputation. The following formula was used to determine the HALP score: Albumin (g/L) × Hemoglobin (g/L) × Platelet count (/L)/lymphocyte count (/L)(14,15,16). The dates of patient deaths were obtained through the national death notification system, and their mortality status was determined in the 3rd, 6th, 9th, and 12th months. Patients were divided into two main groups: deceased and living patients. Comparisons of categorical and noncategorical variables were made between the groups.

To calculate the 1-year mortality risk, regression analysis using both univariable and multivariable methods were done. Prior to creating a model for multivariable regression analysis, variables deemed statistically significant in categorical comparisons underwent univariable regression analysis. Patients were divided into two groups based on the age variable in the 1-year mortality risk estimation: those under 65 and those above 65.

Statistical Analysis

A retrospective design was used to collect data, and statistical analyses were performed using SPSS software (IBM SPSS Statistics Version 22, SPSS Inc., IL, USA. In the realm of descriptive statistics, the categorical data were expressed as frequencies and percentages, and the continuous data were expressed as mean ± standard deviation or median (minimum-maximum). Independent sample t test and chi-square analysis were used to compare categorical and non-categorical variables such as HALP scores, age and gender. The Kolmogorov–Smirnov test was used to evaluate whether noncategorical data showed normal distribution. The analysis results indicated that the continuous variables had a normal distribution. Therefore, the Pearson correlation test was conducted to examine the relationship between continuous data. The optimum threshold value of the HALP score for 1 year mortality prediction was determined by receiver operating characteristic (ROC) analysis and Youden index maximization (sensitivity+specificity-1). As the study had a retrospective design, it included all data that met the inclusion criteria; however, *a priori* power analysis was not performed. Youden index maximization (sensitivity+specificity-1) and receiver operating characteristic (ROC) analysis were used to find the optimal threshold value of the HALP score for mortality prediction. One-year mortality risk was estimated using binary logistic regression analysis with 95% confidence interval. To calculate the 1-year mortality risk, regression analysis using both univariable and multivariable methods were done.

Table 2. Univariable analysis for 1 year mortality risk prediction

Variables	Exp(B)	95%CI for Exp(B) Lower-Upper	Sig
HALP score <21.55	2,975	1,252-7.069	0.014
Gender (female)	3.264	1.392-7.653	0.007
Age >65	2.913	1.347-6.300	0.007

Table 3. Multivariable analysis for 1 year mortality risk prediction

Variables	Exp(B)	95%CI for Exp(B) Lower-Upper	Sig
HALP score <21.55	3,156	1,236-8.059	0.016
Gender (female)	2,977	1.215-7.297	0.017
Age >65	2,441	1.074-5.551	0.033

Model summary for Block 0: Begining Model, -2 Log likelihood:163.447; Block 1: Method = Enter, -2 Log likelihood 144.049. Hosmer and Lemeshow test sig.: 0.984; Nagelkerke R square: 0.202

Prior to creating a model for multivariable regression analysis, variables deemed statistically significant in categorical comparisons underwent univariable regression analysis. Patients were divided into two groups based on the age variable in the 1-year mortality risk estimation: those under 65 and those above 65. *P* value <0.05 indicating the significance level were used in all statistical analyses. In this study, a post-hoc power analysis was conducted between two independent groups to determine the prognostic value of the HALP score on 1-year mortality (Group 1: n = 57, Group 2: n = 61).The test's statistical power was determined to be 85.4% based on a medium effect size (Cohen's d = 0.5) and a significance threshold of 5% (α = 0.05).

RESULTS

The study included 130 patients who met the inclusion criteria. The mean age of these patients was 67.3 ± 15.6 years (range = 20–97 years). Of these patients, 37 (28.5%) were female and 93 (71.5%) were male. Patients (n=130) were compared by gender for 1 year mortality, statistically significant difference was found between male and female gender (p=0.01). Chi-squared analysis showed that the mortality rate was higher for female gender than male gender. Also, it was shown that the mean age of patients who deceased at 1 year was higher than the patients survived at 1 year and this difference was statistically significant(p=0.004). These associations are shown in Table 1.

The optimal cut-off point for the HALP score was determined to be 21.55. As a result, in the univariable analysis, patients with a HALP score below 21.55 had a 1-year mortality risk that was 2.975 times than that of patients with a score above 21.55. (odds ratio=2.975, 95% CI [1.252-7.069]; p=0.014). Female gender had a 3.264 times 1-year mortality risk than male gender (odds ratio=3.264, 95% CI [1.392-7.653]; p=0.007). The 1-year mortality risk for individuals over 65 is 2,913 times than for those under 65. (95% Confidence Interval [1.347-6.300] = 2.913; p = 0.007). Table 2 displays these findings. The constructed multivariable model is shown Table 3. The model with being a female gender and a HALP score of less than 21.55 and older than 65 age estimates a 20.2% overall 1-year mortality risk (Nagelkerke R square: 0.202).

The mean survival time was 331.7 ± 525.18 days (range = 1–2304 days). The mortality rates of the patients in hospital and in the 3rd, 6th, 9th, and 12th months were 13.1%, 37.7%, 48.5%, 53.8%, and 56.2%, respectively. These mortality rates are shown in Table 4.

Table 4. Patients' mortality rates in various periods

	n (130)	%
In-hospital mortality	17	13.1
3rd-month mortality	49	37.7
6th-month mortality	55	48.5
9th-month mortality	60	53.8
12th-month mortality	61	56.2

Table 5. Correlation between 3rd-, 6th-, 9th-, and 12th-month mortality and the HALP score

HALP score			Mean	SD	p*
3rd-month mortality	Yes	49	15.0698	9.3784	0.087
	No	81	19.0227	16.76499	
6th-month mortality	Yes	55	14.3147	9.12868	0.02
	No	67	20.2236	17.80826	
9th-month mortality	Yes	60	14.3678	8.9635	0.015
	No	60	20.9895	18.56099	
12th-month mortality	Yes	61	14.3052	8.90192	0.01
	No	57	21.5951	18.85299	

SD, Standard deviation, * t test

The HALP scores showed no statistically significant difference between those who died and those who did not die during the 3-month mortality (p = 0.087). Although the 3-month mortality in patients with low HALP scores was higher, it was not statistically significant. However, statistically significant differences were found in 6-month mortality (p = 0.02), 9-month mortality (p = 0.015), and 12-month mortality (p = 0.01). Hence, patients with low HALP scores had higher 6-, 9-, and 12-month mortality. The relationship between the 3-, 6-, 9-, and 12-month mortality of the patients and the HALP score is depicted in Table 5.

The study found a weak negative correlation between the age of the patients and the HALP scores (p = 0.029, r = –0.192). A weak negative correlation was also observed between the CRP levels of the patients and their HALP scores (p = 0.012, r = –0.223). The relationship between the HALP score and age, and the CRP level is presented in Table 6.

Table 6. Correlation between HALP score with age and CRP level

Variable		HALP score
Age	r	–.192*
	p	.029
	n	130
CRP	r	–.223*
	p	.012
	n	127

Correlation is significant at the 0.05 level (two-tailed), CRP: C-reactive protein, HALP: hemoglobin–albumin–lymphocyte–platelet

DISCUSSION

Laboratory findings are the independent factors for investigating the prognosis of diseases (17). To the best of our knowledge, this study was novel in examining the correlation between HALP scores and above-ankle amputation prognosis after diabetic foot infections. The main finding of this study was that patients who underwent above-ankle amputation due to diabetic foot ulcers and patients with a low HALP score had higher mortality rates in the 6th, 9th, and 12th months.

A meta-analysis conducted by Zhang et al. showed that diabetic foot ulcers occurred more frequently in the male population (18). Nather et al. investigated limb loss in diabetic feet and reported that it occurred almost equally in male and female patients, the mean age of the patients was 60 years, and most were in their fifth and sixth decades (19). An epidemiological study conducted by Hicks et al. reported that the mean age of patients with diabetic foot ulcers was 62.9 ± 0.1 years and 59% of the patients were male (20). The mean age of the patients in our study was 67.3 ± 15.6 years and male sex was predominant, consistent with previous studies.

In a prospective cohort study, advanced age was shown to be an independent risk factor (21). In a meta-analysis, it was shown that older age is a higher risk for mortality (22). In the study conducted by Seghieri et al. on 165,650 patients, it was shown that mortality was higher in female (23). A study conducted in California showed that the mortality rate was 37.7 in female and 29.7 in male per 1000 amputations (24). In our study, we showed that older age and female gender are independent risk factors for 1-year mortality, similar to the literature.

In a study conducted in Nigeria involving 336 patients, the in-hospital mortality rate of patients followed up

due to diabetic foot ulcers was found to be 21.4% (25). A study conducted in Turkey involving 401 patients found the in-hospital mortality rate of patients hospitalized due to diabetic foot infections to be 3%. While selecting these patients, all diabetic foot infections were evaluated regardless of whether they required amputation (17). A study conducted in the United Kingdom reported an in-hospital mortality rate of 8.4% in patients with diabetic foot infection who did not undergo amputation and 7.2% in the group in which amputation was performed due to diabetic foot infection (26). Malyar et al. found the in-hospital mortality rate to be 2.8% in patients who had isolated diabetic foot syndrome (27). A study conducted in Brazil involving 654 patients found the in-hospital mortality rate of patients with diabetic foot lesions to be 12% (28). In the present study, the in-hospital mortality after above-ankle amputation was 13.1%. The demographic characteristics, socioeconomic characteristics, glycemic monitoring, and so forth, might affect the results regarding in-hospital mortality rates of diabetic foot infections.

Vuorlaakso et al. found 1-year overall survival to be 41.7% in patients undergoing major amputation due to diabetic foot infection (29). In a 430-patient prospective cohort study, the 1-year mortality from hospital admission after diabetic foot infection was 8.9% (21). Another study reported that the presence of diabetic neuropathic ulcers or related amputations had a higher 5-year mortality than many malignant diseases (30). A prospective study including 347 patients in a multidisciplinary foot center reported a 1-year death rate of 9% in patients with a diabetic foot infection (31). Consistent with previous studies, the present study also found that patients who underwent major amputation for diabetic foot ulcers had high mortality rates at follow-up up to 1 year.

Many reliable biomarkers have been investigated to evaluate the prognosis of diabetic foot ulcers; some of these are neutrophil-to-lymphocyte ratio (32,33), platelet-to-lymphocyte ratio (34), and matrix metalloproteinase-1/ tissue inhibitors of matrix metalloproteinase-1 ratio (35). However, the nutritional status of patients is not evaluated using these biomarkers. Nutritional status is an essential predictor in determining the prognosis of diabetic foot ulcers and should be given importance because it affects diabetic foot ulcer outcomes (36,37,38). The HALP score is used to evaluate prognosis in many diseases and malignancies because it shows nutritional status (39,40,41). A retrospective study showed that the Geriatric Nutritional Risk Index and the HALP score, which are used to evaluate geriatric malnutrition, had similar nutritional results (42). No study to date has explored the correlation between the HALP score and prognosis in diabetic foot ulcers. This study showed that the 6th-, 9th-, and 12th-month mortality rates were higher in patients with low HALP scores. Furthermore, we showed that 2,975 times increased risk is found for 1 year mortality for those with HALP scores lower than 21.55.

Forster et al. found that poor nutritional status was associated with advancing age (43). Agarwalla et al. reported that malnutrition was common in older age groups (44). The present study found a negative correlation between the HALP score and advancing age. Thus, a negative correlation existed between age and nutritional status, consistent with previous studies. In addition, high serum CRP levels have also been shown to be associated with low nutritional status (45). A prospective cohort study conducted with 237 patients showed a statistically significant correlation between inflammatory markers, including CRP, and malnutrition (46). Similarly, the present study found a negative correlation between CRP and HALP scores.

Limitations

This retrospective study was conducted in a single center with a limited number of patients, which represents an inherent limitation. Furthermore, The differing metabolic impacts of various amputation levels on the body constitute one of the most critical limitations of this study which focuses on evaluating mortality. Additionally, the lack of evaluation of the vascular status of the extremity and the treatments administered accordingly constitutes another major limitation of this study.

CONCLUSION

The HALP score is a novel risk factor in patients undergoing amputation for diabetic foot ulcers. Also, older age and female gender are independent risk factors for 1-year mortality. Prospective studies including long-term follow-up are needed for a better understanding of the predictive capabilities of the HALP score.

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Conflict of interests: No conflict of interest was declared by the authors.
Ethical approval: The study protocol was approved by the Non-Invasive Clinical Research Ethics Committee of Niğde Ömer Halisdemir University (Date: 29.08.2023, Decision No: 401670, Protocol No: 2023/51). The study was conducted following the criteria of the Declaration of Helsinki.
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RESEARCH ARTICLE

EVALUATION OF DYSPHAGIA AND MALNUTRITION IN OLDER PATIENTS WITH STROKE

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ABSTRACT

Purpose: The study was aimed at investigating the dysphagia and malnutrition status in individuals with stroke and determining the relationship between the variables.
Material and Methods: The sample of this descriptive and analytical study consisted of 180 ≥65-year-old individuals with stroke who met the inclusion criteria, and who were treated in the neurology inpatient clinic of a state hospital. Data were collected using the Descriptive Information Form, Eating Assessment Tool-10, Bedside Water Swallowing Assessment Test, Mini Nutritional Assessment Form and Modified Barthel Index.
Results: The mean age of the participants was 74.40±6.87 years. According to the results of the Eating Assessment Tool-10 and Bedside Water Swallowing Assessment Test, approximately 73% of them experienced dysphagia. The mean score the participants obtained from the Mini Nutritional Assessment Form was 15.41±5.01, and 64.4% of them were diagnosed with malnutrition. There was a very high level of negative relationship between the scores the participants obtained from the Mini Nutritional Assessment Form, and the scores they obtained from the Eating Assessment Tool-10 ($r=-0.806$, $p<0.001$) and Bedside Water Swallowing Assessment Test ($r=-0.815$, $p<0.001$).
Conclusion: In the study, the swallowing and feeding behaviors of the participants who had a stroke were negatively affected.

Keywords: Stroke, older adult, dysphagia, malnutrition, nursing

INTRODUCTION

Stroke is a chronic disease that affects a great number of people both in Turkey and in the other countries of the world and has many negative effects on health. Stroke ranks first among the diseases that cause disability and workforce loss. It is reported that the prevalence of stroke in the world is more than 60 million, and it is estimated that approximately 16 million people are diagnosed with stroke every year (1-4). Since stroke is common, it is the leading cause of long-term disability in adults and adversely affects their independence levels while they perform activities of daily living. One of these activities is feeding behaviors (1,5).

Dysphagia is among the main reasons for changes in feeding in stroke patients. It is stated that dysphagia is observed in 42-67% of patients in the first three days after stroke, that 70% of them may recover after the first week, but that dysphagia continues for more than six months in 11-19% of them (6,7). If necessary precautions are not taken to identify and eliminate dysphagia, the patient may inevitably suffer from dehydration, aspiration pneumonia, and especially from malnutrition. Patients with stroke who do not

receive adequate nutrition due to dysphagia experience weight loss, a decrease in serum albumin value, deterioration in skin integrity, and retardation of healing (7,8). Thus, malnutrition worsens prognosis and increases mortality. Older patients who are dependent on others for nutrition have special nutritional needs due to dysphagia that occurs in the period following a stroke (9,10). In a study conducted with older patients who had a stroke, of the participants, 20.7% were diagnosed with dysphagia. Dysphagia continued after discharge in 50.9% of the participants diagnosed with dysphagia and 30.5% of them were fed through nasogastric tube (11).

Malnutrition is a serious health problem, especially for those in the geriatric age group. Delays in the diagnosis and treatment of malnutrition bring about negative consequences such as deterioration in general well-being, dependence on others in performing activities of daily living, tendency to infections due to suppression of immunity, increased risk of falls and fractures, pressure sores, anemia, deterioration in cognitive functions and even an increase in mortality (12-15). In addition, the duration and frequency of hospitalization increases in older patients with malnutrition (16,17). Therefore, early diagnosis and appropriate treatment of malnutrition is of great importance, especially in older patients (12,15).

Since nurses are health professionals who observe all the activities of daily living in the patient and interact with the patient for a long time, their monitoring the patient's feeding, identifying the factors affecting this activity, and being sensitive about malnutrition will ensure the early detection of possible complications (7). Although dysphagia and malnutrition are of great importance for patients with stroke because they pose a high risk of morbidity and mortality, screening is often neglected, which leads to delays in the diagnosis of malnutrition.

Therefore, it is important to evaluate the nutritional status of individuals with stroke and to address and analyses the risk factors related with malnutrition. Although studies on the evaluation of dysphagia and malnutrition in elderly patients with stroke are available in Turkey (7, 9, 18, 19), the number of such studies is not sufficient. In this context, this study is expected to contribute to the determination of dysphagia and malnutrition in stroke patients and to the planning of patient care. The present study was conducted to investigate the dysphagia and malnutrition status of individuals with stroke treated in the neurology inpatient clinic and to determine the relationship between the variables.

MATERIAL AND METHODS

Study Design and Participants

The population of this descriptive and analytical study consists of individuals with acute stroke who were treated in the neurology inpatient clinic of a state hospital between March 01, 2023 and August 31, 2023. In determining the minimum number of older adults with stroke to be included in the sample, power analysis was performed, and the minimum sample size to represent the universe was calculated as 172 people (significance level: 0.05, confidence interval: 1-α =0.95, margin of error: 0.20 and power: 1-β=0.80). Considering the possibility of withdrawals, or losses due to incorrectly or incompletely responded questionnaires during the study, it was decided to include more people in the sample. Thus, 180 people were included in the sample.

The inclusion criteria were as follows: being treated in the neurology inpatient clinic due to the diagnosis of ischemic stroke, being ≥65 years old, not having hearing impairment, being able to communicate verbally, having the cognitive ability to answer questions, and agreeing to participate in the study after being informed about the study. Individuals who had a previous stroke history, and who were diagnosed with hemorrhagic stroke were not included in the sample.

Measures and Procedure

Descriptive Information Form: The form prepared by the researchers in line with the literature consists of 15 items. Of the items, nine question the respondent's characteristics such as sex, age, marital status, educational status, etc., and six question the respondent's health behaviors and disease-related characteristics.

Eating Assessment Tool-10 (EAT-10) : The EAT-10 developed by Belafsky et al. (20) is used to assess symptoms and severity of dysphagia and the patient's response to treatment. The EAT-10 consists of 10 items. Responses given to each item are rated on a scale ranging from 0 to 4. The possible total score that can be obtained from the EAT-10 varies between 0 and 40. A score of ≥3 is considered as abnormal. Demir et al. (21) conducted the validity and reliability study of the Turkish version of the EAT-10.

Table 1. Sociodemographic characteristics of the participants (n=180)

Sociodemographic characteristics	n	%
Age [**(**mean±SD (min- max)]=[74.40±6.87 (65-92)]		
65-74 years	109	60.5
75-84 years	59	32.8
85-96 years	12	6.7
Sex		
Men	94	52.2
Women	86	47.8
Education level		
Illiterate	60	33.3
Literate but not a graduate of any school	87	48.3
Primary school	33	18.4
Marital status		
Married	108	60.0
Single	72	40.0
Employment status		
Employed	5	2.8
Unemployed	175	97.2
Social security		
Yes	169	93.9
No	11	6.1
Body Mass Index (BMI)		
Normal weight	53	29.4
Overweight	92	51.1
Obese	35	19.5
BMI [mean ±SS (min.- max.) (kg/m^2)]	27.01±3.63 (19.50-40.30)	

The Cronbach's Alpha coefficient of the EAT-10 was 0.90, 0.91 and 0.99 in Belafsky et al.'s study, Demir et al.'s study and the present study, respectively.

Bedside Water Swallowing Assessment Test (BWSAT): This test is a widely used method to evaluate swallowing function by having patients drink small amounts of water. While the patient drinks water, whether he or she can drink without hesitation, coughing, change in voice, whether water leaks from the corner of the mouth, or whether there is laryngeal movement is observed and whether there is a decrease in oxygen saturation is measured by using a pulse oximeter. Patients with 0-2 points are considered to have normal swallowing function, and patients with 3-6 points are considered to have dysphagia (22). In several studies, it has been reported that evaluating the test result together with oxygen saturation provides more accurate results. Therefore, it is recommended that while the BWSAT is performed, oxygen saturation should be measured with a pulse oximeter (19).

Mini Nutritional Assessment (MNA) Form: The MNA form developed by Vellas et al. (23) is considered as a simple and reliable measurement tool to determine the nutritional status of people over the age of 65. The MNA Form contains 18 items grouped in the following 4 sections: anthropometric assessment (BMI, weight, arm and calf circumferences), general assessment (lifestyle, medication use, mobility, symptoms of depression and dementia), brief nutritional evaluation (number of meals, food and fluid intake, autonomy in nutrition) and subjective assessment (health and nutrition). The MNA Form is a rapid assessment tool which takes approximately 10-15 minutes to answer. While a score obtained from the overall form ranging between 24 and 30 indicates normal nutritional status, a score between 17 and 23.5 indicates risk of malnutrition, and a score below 17 indicates

malnutrition. The validity study of the Turkish version of the MNA form was conducted by Sarıkaya (24). The Cronbach's Alpha coefficient of the MNA form was 0.68 in Sarıkaya's study and 0.81 in the present study.

Modified Barthel Index (MBI): The MBI was developed by Barthel and Mahoney (25). Küçükdeveci and Yavuzer et al. performed the validity and reliability study of the Turkish version of the MBI (26). Its Cronbach's alpha value was 0.93 in Küçükdeveci and Yavuzer et al.'s study. MBI is one of the most commonly used scales for measuring activities of daily living such as fecal-urinary incontinence, feeding, washing hands and face, dressing, transfer, toilet use, mobility and bathing. Scores obtained from the overall MBI range from 0 to 100. While a score ranging between 0 and 20 indicates total dependence, a score ranging between 21 and 61 indicates severe dependence, a score ranging between 62 and 90 indicates moderate dependence, a score ranging between 91 and 99 indicates mild dependence and a score of 100 indicates independence. The Cronbach's alpha coefficient of the MBI was 0.79 in the present study.
The researcher asked the participants the questions in the data collection tools personally in their rooms and the patient or his/her relative answered them. Height and weight measurements for the MNA evaluation were performed with the measuring instrument available in the clinic. Calf and arm circumference measurements were performed with a tape measure. Arm circumference was measured by bending the arm 90° at the elbow and marking the midpoint between the acromion process on the shoulder and the olecranon process at the elbow. The height of the participants who could not get out of bed was measured in bed with a tape measure. For newly hospitalized patients, the last weight measured at home was taken into consideration. For other patients, the patient bed weighing system was used Body mass index (BMI) is calculated according to the World Health Organization (WHO) criteria, by dividing the body weight in kilograms by the square of the body height in meters.

Data Analysis

The study data were analyzed using the SPSS (Statistical Package for the Social Sciences) (ver: 22.0). Whether the data were normally distributed was determined by the Kolmogorov-Smirnov test. The t-test was used for independent groups. The ANOVA was used if there were more than two groups. In the study, Pearson Correlation Coefficient analysis was used to reveal the relationship between the variables. In the correlation analysis, 0-0.39 was accepted as weak relationship, 0.40-0.69 as moderate relationship, 0.70-0.89 as strong relationship, 0.90-1.00 as very strong relationship. In the analysis of the data, the significance level was accepted as $p<0.05$.

Table 2. Participants' care status and disease-related characteristics (n=180)

Characteristics	n	%
Need for Assistance in Daily Care		
Yes	180	100.0
Presence of a Person Assisting in Daily Care		
Yes	171	95.0
No	9	5.0
People Assisting in Daily Care* (n=171)		
Children	83	48.5
Spouse	79	46.2
Nursing home staff	4	2.3
Relatives (uncle, aunt, etc.)	5	3.0
Duration of stroke disease		
1-4 days	51	28.3
5-8 days	75	41.7
9 days and more	54	30.0

*Percentages were calculated based on 171 elderly patients with stroke who reported having a daily care assistant

Table 3. Mean scores the participants obtained from the EAT-10, BWSAT, MNA Form, and MBI

SCALES (Ort±SS) (min-max)		
EAT-10 total (25.52±15.74) (0.00-40.00)		
Swallowing problems	**n**	**%**
Yes (abnormal swallowing)	132	73.3
No (normal swallowing)	48	26.7
BWSAT total (3.08±1.79) (0.00-6.00)		
Swallowing Function Status	**n**	**%**
There is dysphagia	130	72.2
Swallowing function is normal	50	27.8
MNA total (15.41±5.01) (4.00-25.40)		
Nutritional Status	**n**	**%**
Malnutrition	116	64.4
Situation at risk of malnutrition	57	31.7
Normal nutritional status	7	3.9
MBI total (27.50±25.31) (0.00-91.00)		
Dependency level	**n**	**%**
Fully dependent	93	51.7
Highly dependent	58	32.1
Moderately dependent	29	16.2

Abbreviation: EAT-10**:** Eating Assessment Tool-10, BWSAT: Bedside Water Swallowing Assessment Test, MNA: Mini Nutritional Assessment Form, MBI: Modified Barthel Index

Ethical Considerations

Before the study was started, ethics committee approval was obtained from *Sivas Cumhuriyet University, Non-invasive Clinical Research Ethics Committee (Approval date:* 18.01.23*; Number:*2023-01/39*)* and written permission from the hospital management where the study was to be conducted. During the data collection phase, all the individuals who agreed to participate in the study were informed about the study and their written consent was obtained. The principles of the Declaration of Helsinki were taken into account at every stage of the research.

RESULTS

The mean age of the participants was 74.40±6.87 years. Of them, 60.5% were in the age group of 65-74 years, 52.2% were men, 48.3% were literate, 60% were married, 97.2% were not employed and 93.9% had social security. According to their anthropometric measurements, the average Body Mass Index (BMI) score was calculated as 27.01±3.63 kg/m^2. Of them, 51.1% were overweight according to their BMI (Table 1).

In Table 2, the distribution of the care status and disease characteristics of the participants was given. All the participants needed help while doing their activities of daily living, and 95% of them needed help from someone with their care. Of the people who helped the participants with their care, 48.5% were their children and 46.2% were their spouses. The disease duration of 41.7% of participants is 5-8 days (Table 2).

The results of the scales used to determine the dysphagia, nutrition and dependency status of the participants were given in Table 3. The mean score the participants obtained from the EAT-10 was 25.52±15.74, and 73.3% of them had swallowing problems. The mean score they obtained from the BWSAT was 3.08±1.79, and 72.2% of them experienced dysphagia. The mean score they obtained from the MNA Form was 15.41±5.01. Of them, 64.4% suffered from malnutrition and 31.7% were at risk of malnutrition. The mean score they obtained from the MBI was 27.50±25.31, and 51.7% of them were fully dependent (Table 3).

In Table 4, the relationship between the mean scores the participants obtained from the MNA, EAT-10,

BWSAT and MBI was given. There were negative and very highly statistically significant relationship between the MNA scores, and the EAT-10 and BWSAT scores.

This finding indicates that as the participants' EAT-10 and BWSAT scores increased, in other words, as their difficulty in swallowing increased, their MNA scores decreased and their nutritional levels were negatively affected. However, there was a positive relationship between the participants' dependence levels and dysphagia levels. This finding indicates that patients with high level of dependency had more difficulty in swallowing (Table 4).

According to the comparison of the mean scores the participants obtained from the EAT-10, BWSAT Form and MNA form in terms of their sociodemographic characteristics, the variables such as age, education level, marital status and disease duration affected all scale scores. Accordingly, it can be said that the participants who were in the 86-96 age group, illiterate and/or single and whose stroke disease duration was 1-4 days had severer difficulty in swallowing according to the eating and drinking water test, and their nutritional scores were significantly worse (Table 5).

DISCUSSION

In patients with neurological disorders such as stroke, determining the factors affecting their nutritional status, monitoring their feeding behaviors and maintaining appropriate nutritional support are of great importance. The results of the present study indicate that more than half of the participants experienced dysphagia after stroke. In Abubakar and Jamoh's study (27) in which the presence of dysphagia in 94 patients with acute stroke was investigated, 34.4% of the participants had dysphagia. In Güçmen et al.'s study (9), dysphagia was observed in approximately 25% of the participants. In various studies, similar results were obtained (6,11). In the literature, it is reported that the prevalence of dysphagia after stroke ranges between 29% and 81% (28). This quite wide range shows that the result obtained in the present study is consistent with those in the literature.

Progressive dysfunction that develops due to neurological complications in older adults who have had a stroke is the main cause of nutritional deficiency, and the most serious of these deficiencies is dysphagia (14). Nurses play a key role in identifying and managing swallowing problems, and preventing complications that may develop due to difficulty swallowing (19, 29). In hospitalized patients, sometimes due to the short length of stay, the patient may be discharged before the healthcare team notices the early signs and symptoms of swallowing difficulty. Therefore, it is important to carry out careful monitoring of patients with appropriate measurement tools in order to prevent patients with dysphagia from being overlooked.

In the present study, the comparison of the mean scores the participants obtained from the EAT-10 and BWSAT in terms of their sociodemographic characteristics revealed that age led to a statistically significant difference in the frequency and severity of dysphagia. According to the results of the comparison, of the participants, those in the age group of 85-96 years experienced severer swallowing difficulties. In their study in which dysphagia and nutritional status of patients with stroke was investigated, Güçmen et al. (9) stated that older patients were at greater risk of dysphagia in the post-stroke period. In their study (30), Henke et al. evaluated dysphagia in patients in the acute phase of ischemic stroke and reported that age was a factor affecting dysphagia significantly.

Table 4. Relationship between the scores the participants obtained from the MNA Form, EAT-10, BWSAT, and MBI

Scales		1	2	3	4
1.MNA Total	**r**	-			
	p				
2.EAT-10 Total	**r**	-0.806	-		
	p	**0.000**			
3.BWSAT Total	**r**	-0.815	0.909	-	
	p	**0.000**	**0.000**		
4. MBI Total	**r**	0.81	-0.875	0.850	-
	p	**0.000**	**0.000**	**0.000**	

Abbreviation: 1.MNA: Mini Nutritional Assessment Form, 2. EAT-10**:** Eating Assessment Tool-10, 3. BWSAT: Bedside Water Swallowing Assessment Test, 4. MBI: Modified Barthel Index; r: Pearson correlation analysis

Table 5. Comparison of the mean scores the participants obtained from the EAT-10, BWSAT, MNA Form in terms of their sociodemographic characteristics

Variables	EAT-10	BWSAT	MNA
	Mean±SD	Mean±SD	Mean±SD
Age groups			
65-75 year	22.64±16.89	2.65±1.86	16.60±4.92
76-85 year	29.13±13.64	3.64±1.53	14.03±4.77
86-96 year	34.66±2.60	4.25±0.86	11.37±2.83
Test value	F=5.682	F=9.389	F=10.128
Significance level	**p=0.004**	**p=0.000**	**p=0.000**
Sex			
Men	24.71±16.08	2.91±1.85	15.20±5.22
Women	26.51±15.40	3.26±1.71	15.63±4.79
Test value	t=0.765	t=-1.320	t=-0.569
Significance level	p=0.445	p=0.253	p=0.570
Education level			
Illiterate	33.78±8.13	4.19±1.07	13.04±3.82
Literate	22.83±16.80	2.63±1.82	16.33±5.01
Primary school	17.34±17.22	2.18±1.80	17.39±5.43
Test value	F=16.353	F=23.259	F=11.944
Significance level	**p=0.000**	**p=0.000**	**p=0.000**
Marital status			
Married	23.46±16.39	2.63±1.77	16.34±4.99
Single	28.73±14.25	3.75±1.61	14.01±4.73
Test value	t=-2.225	t=-4.263	t=3.128
Significance level	**p=0.027**	**p=0.000**	**p=0.002**
Body Mass Index			
Normal weight	28.83±14.14	3.54±1.68	12.68±5.20
Overweight	23.84±16.29	2.85±1.81	16.60±4.55
Obese	25.17±16.23	2.97±1.82	16.40±4.34
Test value	F=1.711	F=2.608	F=12.535
Significance level	p=0.184	p=0.076	**p=0.000**
Duration of stroke disease			
1-4 days	17.70±17.77	2.23±1.98	18.05±4.83
5-8 days	25.21±15.59	2.92±1.68	15.99±4.50
≥9 days	33.50±8.71	4.11±1.17	12.10±4.00
Test value	F=15.348	F=17.647	F=24.484
Significance level	**p=0.000**	**p=0.000**	**p=0.000**

Abbreviation: F=ANOVA Analysis of Variance test value, t= T Test value in independent groups,
EAT-10**:** Eating Assessment Tool-10, BWSAT: Bedside Water Swallowing Assessment Test, MNA: Mini Nutritional Assessment Form, MBI: Modifiye Barthel Index

In the present study, another factor affecting the dysphagia process was the duration of the disease. Of the participants, those with a disease duration of 1-4 days experienced severer difficulty in swallowing. In the literature, it is reported that dysphagia is experienced intensely in the acute phase of the disease, but 70% of dysphagia can be resolved by the end of the first week (19, 14). In their study including 94 patients with acute stroke, Abubakar et al. (27) determined that the patients intensely experienced

dysphagia especially in the acute phase. However, in the literature, there are other studies indicating that there is no relationship between the level of dysphagia and the duration of stroke (9,14,31). The difference in the results obtained may have stemmed from the disease-related characteristics of the samples and the differences between the measurement tools used.

Another parameter investigated in the present study is the nutritional status of the participants. The Mini Nutritional Assessment Form was used to determine the nutritional levels of the participants, which demonstrated that 64.4% of them were malnourished and that 31.7% were at risk of malnutrition. It is stated that approximately 90% of patients with stroke are at risk of malnutrition (32) and the prevalence of malnutrition reaches up to 45% in the acute period (14). In the literature, results regarding this issue vary from one study to another. It has been reported that the rate of malnutrition diagnosed during hospital admission in patients with acute stroke ranges between 3.8% and 32%, that this rate reaches 7.5-35% at the end of the second week of hospitalization, and that the rate of malnutrition development approximately doubles within two weeks after the stroke (22, 33). In Çoban's study conducted with patients with stroke, malnutrition was detected in 66.1% of the participants in the age group of ≥65 years and in 12.2% of the participants in the age group of <65 years (34). In Mollaoğlu et al.' study in which 123 patients with a diagnosis of stroke were treated, according to the results of the MNA, 22.8% of the participants developed malnutrition and 50.4% were at risk of malnutrition (18). In a study conducted with 1650 patients over the age of 65 in Australia and New Zealand, according to the result of the subjective global assessment test, 60% of the participants were malnourished (35).

Although results vary from one study to another, it can be said that post-stroke malnutrition is a serious problem and affects many patients. In the literature, it is stated that mortality rates are higher in the first week following the stroke in patients whose nutritional status deteriorates after stroke, that patients' hospitalization durations increase due to complications and that their prognosis worsens, and the importance of monitoring nutrition in patients with stroke is emphasized (22, 33).

In the present study, according to the results of the comparison of the participants' sociodemographic characteristics and their mean score for the MNA, the variables such as age, educational status, marital status and disease duration led to a statistically significant difference on their malnutrition status, but the sex variable had no effect on their malnutrition status. Of the participants, those who were illiterate, who were in the age group of 85-96 years, who were single and whose disease duration was 1-4 days obtained significantly lower scores from the MNA. Several researchers state that as the level of education increases, so does the socioeconomic status of patients, which provides them with the opportunity to reach better nutritional conditions. In their study conducted to determine the malnutrition status in older people with stroke aged ≥65 years, Cin et al. (14) stated that there was a statistically significant relationship between the participants' education level and MNA scores. In her study conducted to determine the effect of post-stroke swallowing monitoring and training on swallowing function and complications related to difficulty swallowing, Savcı obtained similar results (19).

In the present study, the marital status variable led to a statistically significant difference in the prevalence of malnutrition and the mean scores they obtained from the MNA was high. This data can be explained by the fact that the regular eating habits of the single participants were not good enough in the pre-stroke period and that whether they were caregivers or not. In her study conducted to determine the malnutrition status of patients admitted to the neurological rehabilitation unit after stroke, Rüstemova Bayraktar observed that the marital status of patients with stroke did not make a significant difference on the presence and frequency of malnutrition (36).

In the present study, there were negative and very high-level statistically significant relationships between the MNA scores, and the EAT-10 and BWSAT scores. This finding indicates that as the EAT-10 and BWSAT scores of the participants increased, in other words, as their difficulty in swallowing increased, their MNA scores decreased and their nutritional levels were negatively affected. In the present study, it was also determined that there was a relationship between dependency level and malnutrition level. The level of malnutrition was higher in dependent patients. In Vanderwee et al.'s study conducted in Belgium (37), of the 2329 older patients included in the sample, 71% with difficulty swallowing suffered from malnutrition. In a study conducted in Turkey, nutrition of patients with stroke who had difficulty swallowing was affected and their risk of

malnutrition increased (14). Güçmen et al. (9) report that malnutrition develops when dysphagia is not controlled in patients who lose weight due to dysphagia. Of the 1662 patients included in Carrion et al.'s study, while 47.4% suffered from dysphagia, 30.6% suffered from malnutrition. Both conditions were associated with poor functional capacity (38). This finding supports the relationship between the malnutrition, dysphagia and dependency level obtained in the present study. Luo et al. (39) reported that of the patients with moderate and severe malnutrition, most were older patients with dysphagia and low albumin. In the same study, it was also determined that the nutritional risk level increased in patients with decreased functional independence. Acute decreased food and fluid intake associated with dysphagia is a contributing factor to increased malnutrition in subsequent processes (9). Dysphagia not only is a stroke-induced complication but also is a care problem that negatively affects patients' oral nutrition. Researchers report that malnutrition is an independent risk factor for dysphagia. In the present study, as in other studies in the literature, it was determined that patients with dysphagia were at a greater risk of malnutrition.

CONCLUSION

In the present study, most of the participants suffered from dysphagia-induced malnutrition. Poorly managed dysphagia may lead to the development of complications such as aspiration, dehydration, malnutrition, prolonged hospital stay, or readmission. Therefore, evaluation of the patient's swallowing function upon admission to the hospital, and planning and implementing individualized care including early precautions in the presence of dysphagia are of importance, because such interventions will prevent not only the development of malnutrition but also all possible complications (19).

In line with this result, it is recommended that the swallowing skills and feeding activities of older patients who have experienced stroke should be routinely evaluated with appropriate measurement tools, and that their feeding activities should be supported with individual nutrition programs. It is also recommended that multicenter studies with larger sample groups including high-risk older individuals should be conducted in order to generalize the results.

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Conflict of interests: The authors declare that they have no conflict of interest.

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RESEARCH ARTICLE

EVALUATION OF PRE-OPERATIVE AND POST-OPERATIVE PRACTICES OF PATIENTS UNDERGOING ABDOMINAL SURGERY ACCORDING TO ERAS PROTOCOL

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ABSTRACT

Purpose: This study was conducted to evaluate the pre-operative and post-operative practices of patients undergoing abdominal surgery, according to the Enhanced Recovery After Surgery protocol.
Material and Methods: The study was conducted in May-June 2022 as descriptive - cross-sectional. Patients who underwent abdominal surgery in the general surgery clinics of a university hospital in Istanbul constituted the population of the study. No sample was selected and 102 volunteer patients who met the inclusion criteria were included in the study.
Results: In the study, it was observed that although most of the pre-operative and post-operative practices of patients undergoing abdominal surgery had high compliance with ERAS protocols, practices such as pre-operative fasting time (10 hours and above in 96.1% of patients) and post-operative first oral intake time (10 hours or more in 97.1% of patients) were low, and patients undergoing open surgery were discharged in an average of 6 days, while patients undergoing minimally invasive surgery (laparoscopic) were discharged in an average of 3 days.
Conclusion: According to the results of the study, it was seen that compliance with all elements of ERAS protocols in clinics is still low. Regular auditing of compliance with the protocol and reporting of results in clinics is very important and it is recommended to support this research with larger-scale and multicenter studies.

Keywords: Surgery, surgical procedures, enhanced recovery after surgery, surgical nursing

INTRODUCTION

The Enhanced Recovery After Surgery Protocol (ERAS) is a concept pioneered by Danish Dr. Kehlet in the 1990s. This protocol, which proposes changes to the entire course of a patient from pre-operative to post-discharge, is used because of its benefits such as accelerating the time of oral food intake, providing early mobilization, reducing the length of hospital stay

and possible complications, and ensuring rapid return to activities of daily living after discharge (1,2). ERAS protocols, which provide many benefits for the patient, health care professionals and the medical institution, are an effective method to standardize and improve the quality of patient care and improve patient outcomes (3).

Adherence to the elements of ERAS protocols is important to ensure that all processes of a patient undergoing a surgical procedure, from hospitalization to home care, are successful and effective in patient care. Success in implementing ERAS protocols requires the involvement and effort of all members of a multidisciplinary team, including patients and their families. In addition, the entire team should take responsibility for designing and adhering to standard care pathways, providing regular supervision and monitoring results (4). Nurses, as an important part of the multidisciplinary team, are at the forefront of daily patient care and therefore have a major influence on ensuring compliance with the elements of the ERAS (5). In a study examining the role of the nurse in the successful implementation of ERAS protocols in patients undergoing abdominal surgery, it is stated that the role of the nurse is essential for patient education and successful use of ERAS (6). Therefore, trained professional nurses should continue to be assessors, implementers, observers and coordinators in all phases of ERAS protocols (7). However, there are gaps in the understanding and implementation of ERAS protocols by nurses and other health care professionals.

There are significant difficulties in the acceptance and implementation processes of ERAS (Enhanced Recovery After Surgery) protocols due to reasons such as the widespread preference of traditional practices in clinics, insufficient adoption of practices based on scientific evidence, and prioritization of personal experiences (8). In addition, the fact that healthcare professionals do not follow scientific updates closely and are resistant to changing their current practice habits also contribute to these difficulties. Although there are studies in the literature that comprehensively address the benefits of ERAS protocols, the extent to which these protocols are implemented in clinics, the factors that prevent implementation, and the effects of these factors on patients have not been sufficiently investigated (9). The lack of evidence regarding the applicability of ERAS protocols, especially in elective surgeries, creates a gap in the management of the surgical process. Therefore, our study aimed to evaluate the compliance of the pre- and postoperative practices of patients undergoing elective abdominal surgery with the ERAS protocol and to determine the obstacles encountered in this process. The study aims to fill these gaps in the literature regarding the integration of ERAS protocols into clinical practice. Based on this, our study aimed to evaluate the preoperative and postoperative practices of patients undergoing elective abdominal surgery according to the ERAS protocol.

MATERIAL AND METHODS

Study Design

This research is a descriptive, cross-sectional study.

Setting and Time of the Study

The study was conducted in the general surgery clinics of a university hospital in Istanbul between May 2022 and June 2022.

Population and Sample of the Study

Patients underwent abdominal surgery in the general surgery clinics of a university hospital in Istanbul between May 2022 and June 2022 were the population of the study. No sample selection was made and all patients who underwent abdominal surgery between May and June 2022 and met the inclusion criteria were included in the study. A total of 115 patients underwent abdominal surgery within two months and 3 of these patients were transferred to post-operative intensive care unit and 10 patients reject to be a volunteer to participate in the study. Therefore, a total of 102 patients constituted the study sample. According to the known universe sample calculation (Cochran formula), the sufficient sample size with a 95% confidence interval is 89 patients. Since 102 patients participated in this study, it has already exceeded the sufficient sample size of 89 with a 95% confidence interval. Therefore, the current sample size is sufficient for reliable results.

Criteria of Inclusion in the Study

- History of elective abdominal surgery
- Age above 18
- No severe vision and hearing problems
- Volunteering to participate in the study

Criteria of Exclusion from the Study

- Transfer from the operating room to the intensive care unit
- Communication problem

Table 1. Descriptive characteristics of the patients (N=102)

Characteristic		**Mean ± SD**	**Min-Max. (Median)**
Operation time		**3.68±2.18**	**1-10 (4)**
		n	**%**
Age	18-25	6	5.9
	26-35	4	3.9
	36-45	16	15.7
	45-55	17	16.7
	55-65	32	31.4
	Above 65 years	27	26.5
Gender	Male	53	52.0
	Female	49	48.0
Education status	Primary school	51	50.0
	Secondary School	12	11.8
	High School	21	20.6
	Two-year degree	2	2.0
	Bachelor's degree.	12	11.8
	Postgraduate	4	3.9
Presence of chronic disease	Yes	49	48.0
	No	53	52.0
Smoking status	Yes	31	30.4
	No	71	69.6
Previous hospitalization	Yes	71	69.6
	No	31	30.4
Previous operation	Yes	62	60.8
	No	40	39.2
Type of anesthesia	Epidural	1	1.0
	General	92	90.2
	Spinal	9	8.8
Type of operation	Open	76	74.5
	Minimally invasive surgery (laparoscopic)	26	25.5
Total		**102**	**100**

SD: Standard deviation

Data Collection Tools

Data were collected using the 11-question personal information form prepared by the researchers in line with the literature (8,10,11) and the questionnaire form containing information about the pre-operative ERAS practices with 11 questions and the information about the post-operative ERAS practices with 11 questions.

Collection of Data

Routine clinical pre-operative and post-operative practices of each patient who was planned for abdominal surgery and accepted to participate in the study were evaluated according to the form prepared by the researchers. Patients were followed up from admission to the clinic until discharge. The study

Table 2. Pre-operative practices (N=102)

Characteristic		**n**	**%**
Pre-operative information about the operation process	Yes	97	95.1
	No	5	4.9
Improving the pre-operative physical, emotional and nutritional status, informing and practicing about optimizing nutrition	Yes	80	78.4
	No	22	21.6
Pre-operative cessation of bad habits such as smoking and alcohol	2 weeks	16	15.7
	4 weeks	8	7.8
	6 weeks	3	2.9
	8 weeks	4	3.9
	No habit	71	69.6
Enema the night before surgery	Yes	44	43.1
	No	58	56.9
Duration of solid food withdrawal the night before surgery	10 hours and above	98	96.1
	8 hours	4	3.9
Duration of liquid food withdrawal the night before surgery	4 hours	1	1.0
	6 hours	1	1.0
	8 hours and above	100	98.0
Wearing compression stockings before surgery	Yes	99	97.1
	No	3	2.9
Low Molecular Weight Heparin (LMWH) status in pre-operative treatment	Yes	16	15.7
	No	86	84.3
Fluid supplementation status in pre-operative treatment	Yes	54	52.9
	No	48	47.1
Antibiotic status before going to surgery	Yes	33	32.4
	No	69	67.6
Pre-operative pre-medication status	Yes	24	23.5
	No	78	76.5
Total		**102**	**100**

questionnaire, nurse observation form and patient files were used for data collection and verbal statements of the patients were utilized. The questionnaire form including information about ERAS applications was filled out before discharge by interviewing the patients face-to-face for 10 minutes.

Statistical Analysis of the Data

The data obtained in the study were analyzed in SPSS 25 for Windows (SPSS, Chicago, United States). In descriptive statistics, variables were expressed as number and percentage (%), and continuous variables determined by measurement were expressed as mean, ± standard deviation and minimum-maximum.

Ethical Dimension of the Study

Ethical approval was received from the Istanbul Unıversity Cerrahpaşa Social Sciences and Humanities Research Ethical Committee (Date:

Table 3. Post-operative practices (N=102)

Characteristic		**n**	**%**
The use of analgesic in post-operative treatment	Yes	101	99.0
	No	1	1.0
Time of post-operative removal of the urine catheter	2 to 6 hours	3	2.9
	7 to 12 hours	-	-
	13 to 24 hours	6	5.9
	25 to 48 hours	10	9.8
	Above 48 hours	56	54.9
	Not catheterized	27	26.5
Time of post-operative removal of the drain	2 to 6 hours	-	-
	7 to 12 hours	-	-
	13 to 24 hours	-	-
	25 to 48 hours	10	9.8
	Above 48 hours	80	78.4
	Not catheterized	12	11.8
Post-operative transition time to liquid food	4 hours	1	1.0
	6 hours	4	3.9
	8 hours	19	18.6
	10 hours and above	78	76.5
Post-operative transition time to solid food	4 hours	-	-
	6 hours	-	-
	8 hours	3	2.9
	10 hours and above	99	97.1
Post-operative blood glucose monitoring status	Yes	41	40.2
	No	61	59.8
Time to first post-operative standing up	2 to 4 hours	1	1.0
	5 to 6 hours	16	15.7
	7 to 8 hours	22	21.6
	8 hours and above	63	61.8
Total		**102**	**100**

10.05.2022, Decision No: 2022/156) and institutional approval (06.05.2022-375455) were obtained. Before starting the study, patients were asked about their willingness to participate in the study and informed consent was obtained from those who agreed. The articles of the Declaration of Helsinki were followed at all stages of the study.

Table 4. Information status on discharge (N=102)

Characteristic		**n**	**%**
Status of pre-discharge written and oral training on discharge	Yes	101	99.0
	No	1	1.0
Time to be called for a follow-up appointment after discharge	7 days	67	65.7
	10 days	34	33.3
	15 days	1	1.0
Total		**102**	**100**
Discharge period (day)		**Mean ± SD**	**Min-Max. (Median)**
Open surgery patients (n: 76)		6.15 ± 4.51	1-10 (4)
Minimally invasive surgery (laparoscopic) (n: 26)		3.68±2.18	1-10 (4)

SD: Standard deviation

RESULTS

The patients who participated in the study were mostly in the 55-65 age group (31.4%). Of the patients, 52% (n: 53) were male and 50% were primary school graduates. 48% (n: 49) of the patients had chronic diseases and 30.4% (n: 31) were smokers. Of the patients, 69.6% (n: 71) had a history of hospitalization and 60.8% (n: 62) had a history of surgery. Of the patients, the most common last abdominal surgery procedure was calculous gallbladder (21.6% n: 22) and the most common reasons for hospitalization were colon surgery (15.7% n: 16) and gastric surgery (12.7% n: 13). Average operation time was 3.68±2.18 hours. It was observed that 90.2% (n: 92) of the patients underwent general anesthesia, 74.5% (n: 76) underwent open surgery, and 25.5% (n: 26) underwent laparoscopic surgery (Table 1).

It was found that 95.1% of the patients were informed about the operation process before surgery. Of the patients, 78.4% (n: 80) answered that prehabilitation was performed before surgery while 21.6% (n: 22) answered that it was not. Within the scope of prehabilitation, when patients with bad habits such as smoking and alcohol were asked how long ago they quit smoking and alcohol, 15.7% (n:16) of the patients said they quit two weeks before surgery, 7.8% (n:8) four weeks before surgery and 2.9% (n:3) six weeks before surgery. While 56.9% (n: 58) of the patients did not perform pre-operative mechanical bowel preparation, 43.1% (n: 44) did. When the patients were asked about the time of stopping solid food before surgery, 96.1% (n: 98) said that they stopped solid food 10 hours or more pre-operatively, 3.9% (n: 4) stopped before 8 hours pre-operatively, and 98% (n: 100) stopped liquid food before 8 hours. When asked, “Did you wear compression stockings before surgery?” 97.1% (n: 99) of the patients stated that they did. To answer the last four items in Table 2, the patient's file was reviewed and it was found that 15.7% (n:16) were started on Low Molecular Weight Heparin (LMWH) in preoperative treatment, 52.9% were given fluid supplementation, 32.4% (n: 33% (n: 33) received preoperative antibiotics and 67.6% (n: 69) did not receive antibiotics, 23.5% (n: 24) received preoperative pre-medication and 76.5% (n: 78) did not receive pre-medication (Table 2).

According to the patient files, 99% (n: 101) of the patients received postoperative analgesics, of which 74.8% were non-opioid analgesics and 25.2% were non-steroidal anti-inflammatory drugs (NSAIDs). When patients with urinary catheters were asked when the urinary catheter was removed post-operatively, the rate of removal was 2.9% (n: 3) in the first 6 hours, 5.9% (n: 6) in 7 to 24 hours, 9.8% (n: 10) in 25 to 48 hours and 54.9% (n: 56) after 48 hours. The post-operative drain removal rate was 9.8% (n: 10) in the first 48 hours and 78.4% (n: 80) after 48 hours. When the patients were asked about the post-operative transition time to liquid food, 76.5% (n: 78) answered 10 hours or later, 18.6% (n: 19) after 8 hours, and 3.9% (n: 4) after 6 hours, while the transition time to solid food was answered as 10 hours or later in 97.1% (n: 99) and after 8 hours in 2.9% (n: 3). When the patient files were examined to determine the status of post-operative blood glucose monitoring, it was seen that 40.2% (n: 41) of the patients who participated in the study had blood

glucose monitoring and 59.8% (n: 61) did not. When patients were asked when they were first mobilized post-operatively, 61.8% (n: 63) answered after 8 hours, 21.6% (n: 22) after 7-8 hours and 15.7% (n: 16) after 5-6 hours (Table 3).

When asked, “Were you given a written and oral training for discharge?”, 99% (n: 101) of the patients answered yes. 65.7% (n: 67) and 33.3% (n: 34) of the patients stated that they were called for a follow-up appointment after 7 days and 10 days, respectively. Of the patients, 102 who underwent abdominal surgery and participated in the study, 76 patients who underwent open surgery were discharged in an average of 6 days and 26 patients who underwent minimally invasive surgery (laparoscopic) were discharged in an average of 3 days (Table 4).

DISCUSSION

Although ERAS protocols provide many positive outcomes for the patient and the hospital, such as early recovery, early discharge, minimal complications and hospital costs, compliance with these protocols and their use in clinical practice is very low and progresses slowly (8,12,13).

In ERAS protocols, informing the patient before surgical intervention is the first important step and pre-operative education is recommended (14). This is because patients experience anxiety due to pre-operative uncertainty, pain and fear of death. Informing them about the surgery process and the post-operative period verbally and written and through tools such as brochures or videos and providing psychological support will reduce their anxiety (14–16). Studies on this matter have shown that most or all patients are informed about the surgical process (10,11,17,18). According to the findings of the study, it was understood that most of the patients were informed pre-operatively and the results obtained were similar to the ERAS protocol. This result showed that surgical clinic nurses mostly included pre-operative patient information in their practices because they were aware of the importance of education. However, it should be noted that this education is not exclusively performed by nurses; it is a multidisciplinary effort involving surgeons, anesthetists, and other healthcare professionals. The process of informing the patient begins with the decision for surgery and continues through pre-operative preparation and post-operative care. This multidisciplinary approach ensures that all aspects of the patient's journey are covered comprehensively. When evaluated in terms of ERAS protocols, it can be said that the pre-operative education observed in this study partially meets the expected standards, as it was provided to most patients. However, further investigation is needed to determine whether the education is comprehensive, timely, and effective in reducing pre-operative anxiety and improving post-operative outcomes.

According to the ERAS protocol, pre-habilitation and optimization of the general condition of all patients undergoing surgery is recommended. This includes cardiorespiratory assessment, smoking and alcohol cessation, nutritional optimization, anemia treatment, and cognitive evaluation to prevent delirium (14). In this study, the application of ERAS protocols was evaluated based on patients' perspectives. Most patients reported receiving information about improving their preoperative physical, emotional, and nutritional status and stated that they were guided on practices such as smoking cessation, nutritional supplementation, and blood glucose monitoring. However, while patients acknowledged being informed, they also indicated that follow-up on the implementation of these recommendations was limited. Furthermore, when asked about other critical pre-habilitation components, such as nutritional assessment, anemia treatment, and cognitive evaluation, some patients stated that they were not aware of whether these evaluations had been conducted. This suggests a possible gap in the comprehensive implementation of ERAS protocols. The lack of clarity in patient responses regarding these aspects may reflect the absence of standardized tools or procedures for assessing and communicating these elements during preoperative preparation. From the patients' perspective, the preoperative education and guidance they received were perceived as beneficial but lacked systematic follow-up and comprehensive evaluation, which are essential to fully meet ERAS protocol standards. According to the ERAS protocol, smoking and alcohol cessation four weeks or more preoperatively is recommended (19). In this study, the rate of smokers was lower than that of non-smokers. It was observed that most of the smokers quit smoking two weeks before surgery, while the number of smokers who quit four or eight weeks before surgery was low, thus not complying with ERAS protocols. This suggested that patients were informed about smoking cessation by nurses and other health care professionals in the clinic, but there was no follow-up and control of the

implementation and duration of cessation. The clinic has a smoking cessation protocol as part of its preoperative preparation, and patients are routinely informed by nurses and other healthcare professionals about the importance of quitting smoking before surgery. However, while many patients successfully quit smoking at least two weeks prior to surgery, follow-up and control of the implementation and duration of cessation remain limited. This highlights the need for a more structured follow-up process to ensure compliance with ERAS protocols and improve long-term cessation rates. Health care professionals, especially nurses, are largely responsible for following up and guiding patients in this regard.

According to the ERAS protocol, mechanical bowel cleansing should not be routinely performed even when bowel resection is planned (20). In this study, more than half of the patients did not undergo pre-operative bowel preparation in accordance with the protocols. In the clinic where the study was conducted, it was seen that routine bowel cleansing is not practiced before each surgery, and evidence-based practices have started to be adopted instead of traditional practices. Similarly, a study conducted in Turkey showed a gradual shift towards evidence-based practices in bowel preparation with increasing awareness of ERAS protocols among healthcare professionals (21). However, there are still some centers where traditional practices persist, highlighting the need for further education and standardization in preoperative care across the country.

The ERAS protocol recommends that clear liquids such as water, tea, coffee without milk or fruit juice without pulp can be consumed up to two hours pre-operatively and solid food (light meal) up to six hours pre-operatively. In addition, for metabolic satiety, patients should be given 800 ml of carbohydrate-rich liquid food until midnight before surgery and 400 ml until 2-3 hours before surgery (20). Studies on this matter have shown that most or all patients are starved after midnight before surgery (10,11,17,18). In this study, patients similarly reported fasting after midnight, with the average cessation duration for both solid and liquid food exceeding 10 hours. Many patients also stated that they stopped consuming solids and liquids simultaneously, which deviates from the ERAS protocol. This finding reflects the ongoing challenges in changing traditional practices in surgical care. Studies suggest several reasons for this resistance to adopting ERAS recommendations. Özkeçeci and Yavan (2020) found that healthcare professionals often fear aspiration or other intraoperative complications, leading them to favor prolonged fasting. Similarly, Kırık (2018) highlighted insufficient training and a lack of institutional policies supporting ERAS as barriers to implementation. Çelebi (2019) noted inadequate preoperative patient education, resulting in misunderstandings about appropriate fasting durations. The persistence of outdated practices in preoperative nutrition management underscores the need for significant changes in clinical protocols. Healthcare professionals, particularly surgeons, anesthetists, and nurses, must receive comprehensive training on the evidence-based benefits of ERAS protocols. One of the most important and fatal post-operative complications is venous thromboembolism (VTE). ERAS protocols recommend that every patient undergoing elective abdominal or pelvic surgery should receive VTE prophylaxis. For these cases, a combination of low molecular weight heparin (LMWH) or unfractionated heparin with compression stockings and/or intermittent pneumatic compression is advised, with prophylaxis continued throughout hospitalization (14,22). Despite these recommendations, studies in the literature have reported varying levels of adherence to these protocols (10, 11,17). For example, Yıldırım (2017) and Kırık (2018) observed that while the use of compression stockings was widespread, LMWH administration was often inconsistent, primarily due to concerns over bleeding risks and a lack of standardized guidelines in surgical clinics. Çelebi (2019) also noted that LMWH was frequently administered based on cardiology consultations rather than as a routine prophylactic measure in line with ERAS protocols. In this study, similar to the literature, the rate of patients wearin compression stockings was high, but the rate of LMWH administration was low. This discrepancy may be attributed to patient-specific factors, such as an increased risk of bleeding or co-existing conditions like cardiovascular diseases, which might require individualized VTE prophylaxis approaches. Additionally, the study revealed that LMWH administration in the clinic where the study was conducted was predominantly initiated based on cardiologist recommendations rather than a protocol-driven approach. This finding suggests potential gaps in interdisciplinary communication and adherence to

ERAS guidelines. To address these issues, clinical teams should prioritize training and standardizing VTE prophylaxis practices in alignment with ERAS protocols, ensuring that LMWH is appropriately prescribed unless contraindicated.

The main goal of perioperative fluid management is to maintain intravascular volume to ensure adequate tissue and organ perfusion and prevent electrolyte imbalances (14). ERAS protocols recommend avoiding too restrictive or too liberal fluid regimen to maintain fluid-electrolyte balance.(20). With conventional perioperative intravenous fluid regimens in abdominal surgery, patients should receive 3.5 to 7 liters of fluid on the day of surgery and more than 3 liters for 3-4 days post-operatively (14). In this study, fluid replacement therapy was evaluated and it was found that more than half of the patients were given pre-operative fluid supplementation that was continued post-operatively. For treatment in the clinic, ERAS protocol recommendations were followed.

Many studies and meta-analyses have identified the benefit of intravenous antibiotic prophylaxis to reduce Surgical Site Infections (SSI) (14,23). ERAS recommends that I.V. antibiotics (first generation cephalosporins or amoxy-clav) be administered within 60 minutes prior to skin incision and that additional doses may be administered during prolonged surgery, in severe blood loss and in obese patients (14,16,23). According to the findings of this study, less than half of the patients were administered antibiotics less than one hour before surgery, while most were administered antibiotics but not exactly one hour before the time of surgery. Although antibiotics were included in the pre-operative treatment protocol in the clinic where the study was conducted, it can be said that compliance with ERAS protocols in long-lasting abdominal surgeries is low because the time of administration to patients does not coincide with exactly 60 minutes before the operation time. This may reflect challenges in coordinating the timing of antibiotic administration in the operating room rather than in the clinic, where case flow and patient preparation processes may affect adherence to strict time frames. To address these challenges, it is crucial to ensure that antibiotic administration occurs in the operating room, where precise timing can be managed under sterile conditions. Regular staff training on ERAS guidelines and close monitoring of antibiotic administration timing can improve compliance.

ERAS protocols recommend avoiding unnecessary premedication before anesthesia (20). This is because long-term effective premedication may cause delayed return to full psychomotor function, mobilization and feeding, and increased delirium. Studies have shown that no pre-operative premedication was administered to most or all patients (10,11,17,18). In this study, it was observed that most of the patients who underwent abdominal surgery and participated in the study were not given premedication (anxiolytic or sedative agent) in the pre-operative period and compliance with the literature and ERAS was achieved in this regard.

One of the most important problems experienced by patients in the post-operative period is pain. Post-operative pain prolongs the recovery process and early discharge as it negatively affects the functions of many organs/systems, including the respiratory and circulatory systems (24). One of the key elements of ERAS is the control of post-operative pain and a multimodal analgesia approach is adopted. ERAS recommends avoiding the use of opioids for pain control (20). Although ERAS protocols do not recommend the use of intravenous opioids for pain control, they do indicate that opioids may be included in multimodal analgesia. For open abdominal surgery, thoracic epidural analgesia (TEA) is recommended to be initiated T7-10 pre-operatively and ideally maintained for 48 to 72 hours post-operatively. In addition, the routine use of paracetamol 4 mg/day and, if this protocol is inadequate, the use of nonsteroidal anti-inflammatory drugs in between is recommended (14,20). In this study, when the treatment protocol of the patients was examined, it was determined that postoperative analgesia was mostly applied and paracetamol and nonsteroidal anti-inflammatory drugs were mostly preferred. However, it is stated that continuous analgesic infusion should be used via epidural catheter and paracetamol should be applied in addition to multimodal analgesia approach in accordance with ERAS protocols (14,20). In the clinic where the study was conducted, the fact that TEA was not used sufficiently with continuous infusion and epidural analgesia was not widespread in the pain control protocol shows that full compliance with the ERAS protocol was not achieved. In order to ensure full compliance with ERAS protocols in pain management, training for health professionals should be increased and technical facilities should be developed.

Before major abdominal or pelvic surgery, Foley catheters are inserted to prevent urinary retention, increase patient comfort, and perform intake-output monitoring (IOM). However, the presence of a long-term post-operative urinary catheter increases the risk of urinary tract infection and prolongs hospitalization (25). According to ERAS protocols, the Foley catheter should be removed within 24 hours post-operatively in most of cases and individualized in patients at high risk of retention (14). In studies on this subject, it was found that urinary catheters of most of the patients were removed within 24 hours post-operatively (10,11,26). Likewise, ERAS protocols recommend avoiding the routine use of nasogastric tubes and drains in elective abdominal surgery. In this study, it was found that most of the patients had their drains and urinary catheters removed after 48 hours post-operatively and very few patients had their drains and urinary catheters removed within the first 24 hours. According to this result, compliance with the literature and ERAS protocols was low. This study was performed on patients who underwent abdominal surgery, and in the clinic, post-operative IOM and drain follow-up are important and frequently followed in major surgeries such as abdominal surgery. Therefore, it can be said that the rate of compliance with ERAS is low because catheters and drains are removed within the first post-operative 48 hours instead of the first post-operative 24 hours.

After major surgery, oral nutrition is usually introduced slowly and the process progresses gradually from liquid to solid foods. Studies have showed that prolonged fasting is associated with increased risk of post-operative infectious complications and delayed recovery (27). According to ERAS, patients should be encouraged and guided to take oral fluids in the second post-operative hour and solid food in the fourth hour (14). In this study, it was found that the time to start post-operative liquid and solid food intake was mostly 10 hours or more. According to this result, compliance with the ERAS protocols was found to be low. In the clinic where the study was conducted, after major surgery, such as abdominal surgery, oral intake is usually restricted until gas and stool output and bowel function are judged to have returned. However, it is aimed to switch to early feeding after minor surgeries. We considered that these were the reasons why the procedure for switching patients to oral food in clinics was not performed according to the protocol. This approach stands out as a general view of the current practice in the clinic and the recovery process of the patients. However, according to ERAS protocols, waiting for gas and stool discharge should not be a factor that prevents patients from switching to early feeding (20).

Instead of waiting for bowel functions to return to normal, the protocol recommends switching to early feeding to support the patient's general recovery process (14,20,27). As a result, one of the main reasons for non-compliance with ERAS protocols in the clinic is that patients are unnecessarily waiting for gas and stool discharge for post-operative feeding transition and symptoms such as nausea and vomiting are not taken into account. This situation has negatively affected the timing of the transition to feeding and reduced compliance with the protocol. In order to better comply with ERAS protocols, it is recommended that the recovery processes of the patients be evaluated more comprehensively and the transition to feeding be accelerated according to these evaluations.

Insulin resistance occurs as an inflammatory response to surgical intervention and hyperglycemia occurs due to increased glucose production. Hyperglycemia increases the risk of post-operative complications and decreases the rate of recovery (7). According to ERAS protocols, Especially diabetic patients should be well prepared pre-operatively and followed up post-operatively. (20). According to the findings of this study, nearly half of the patients had postoperative blood glucose (BG) monitoring, but more than half did not. It was considered that this result may occur because only patients with diabetes mellitus were monitored in the clinic and not all patients were routinely monitored for blood glucose.

Early mobilization is an important component of ERAS protocols to counteract the negative physiological consequences of post-operative surgical stress and immobilization (26,28). The current recommendation is for the patient to sit out of bed for 30 minutes on day zero and then for 6 hours a day and to start walking on day one (14). Early mobilization increases functional capacity and accelerates recovery in patients undergoing major abdominal surgery (28). Studies on the rate of early mobilization have reported that most patients are mobilized in the first 6 or 8 hours post-operatively and show high compliance with early mobilization (8,10,11,17,18,30–32). In this study, although it was observed that the patients were mobilized within the

first 6-8 hours in accordance with early mobilization protocols, the majority (61.89%) were mobilized after 8 hours. These findings contradict the results supporting early mobilization in the literature; because the literature states that early mobilization should be performed within the first 6-8 hours for most patients (8,10,11,17,18,30-32). The reason for delayed mobilization may be based on various factors. The delayed mobilization in this study is a situation that contradicts the literature. The reasons for the delay should be considered as pain management, clinical decisions, general condition of the patients and the effect of the treatment methods used in the hospital.

Improving these factors may contribute to greater compliance with ERAS protocols by accelerating the mobilization process. Nurses and other healthcare professionals need to cooperate more effectively for mobilization in accordance with ERAS protocols.

Post-operative discharged patients and their relatives face many problems in home care. The importance of discharge education is emphasized to solve these problems, improve the quality of patient care, and reduce readmission (33). Discharge education and post-discharge follow-up are important stages in ERAS protocols. According to ERAS recommendations, the patient's discharge home should be planned at the time of admission. In addition, patients should be fully informed about the entire surgical process and post-operative period, and patients discharged home should be phoned 24 to 48 hours later to inquire about their condition. On post-operative days seven to ten, the patient should be called for a follow-up visit for wound reassessment and suture removal (20,34). In this study, we found that almost all patients received discharge education before leaving the clinic and a follow-up appointment was scheduled on days seven to ten post-discharge. The discharge protocol at the clinic followed the recommendation of ERAS protocols.

According to studies on ERAS protocols, following the ERAS protocols has been shown to reduce length of hospital stay by up to two to three days compared to conventional care, with hospital stays is 9 days for open surgery, 7 days for laparoscopic surgery and 6 days for robotic surgery (35–36). Similar to the literature, this study showed that patients undergoing open surgery were discharged in an average of six days and patients undergoing laparoscopic surgery in an average of three days, and that compliance with ERAS protocols was effective in early discharge. These results show that ERAS protocols are successful in reducing hospital stay and complications (37-39).

Despite the valuable insights provided by this study, several limitations must be acknowledged. First, the study was conducted in a single clinic, which may limit the generalizability of the findings to other settings. Second, the data were collected retrospectively, which may introduce recall bias or missing information. Furthermore, although adherence to ERAS protocols was assessed, patient adherence and specific factors affecting adherence were not examined in depth. Given these limitations, larger, multicenter, and prospective studies are recommended.

CONCLUSION

As a conclusion, it was considered that most of the pre-operative and post-operative practices in abdominal surgery operations were appropriate according to ERAS protocols, although practices such as pre-operative fasting time and post-operative first oral food intake time were different from ERAS recommendations in the clinic where the study was performed. Despite these positive results, ERAS protocols have not yet been sufficiently adopted due to the difficulty of changing traditional practices. Therefore, an official ERAS protocol should be established in institutions and adequate training on the importance of multidisciplinary implementation of the protocol should be provided to all members of the team, especially nurses who have a major role in patient care. Because, the recognition and implementation of ERAS protocols by nurses, who accompany patients throughout the surgical process and play a key role, will improve the quality of care. An important component of the ERAS program is auditing compliance with the guidelines and monitoring the results. Regular monitoring of compliance with the guidelines and reporting of results is recommended, and the results of this study should be supported by larger-scale, multicenter studies.

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RESEARCH ARTICLE

DEMOGRAPHIC AND SEROLOGIC FACTORS PREDICT RHEUMATOİD ARTHRITIS-ASSOCIATED INTERSTITIAL LUNG DISEASE

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ABSTRACT

Purpose: Interstitial lung disease (ILD) stands as a prominent reason of morbidity and mortality in rheumatoid arthritis (RA). Certain demographic and serologic elements have been attributed in the risk of RA-ILD; however, the available data may not be sufficient to fully clarify this association. Our objective was to analyze the relationship of demographic features and serologic factors with RA-ILD.
Material and Methods: We examined clinical data from RA patients between January 2015-January 2020. Chest computed tomography (CT) examinations were assessed for ILD. The association between age, gender, smoking, RF and anti-CCP titers and the existence of RA-ILD was analyzed. The same factors were analyzed for the existence of usual interstitial pneumonia (UIP) pattern in RA-ILD patients.
Results: RA patients with ILD were notably older (p=0.005), male (p<0.001), and smokers (p=0.027). Higher RF titers were found in RA-ILD group (p=0.022). Although anti-CCP (cyclic citrullinated peptide) rates and titers were elevated in RA-ILD patients, the variation was not significant. Male sex was linked with the UIP pattern (p=0.029), but other factors did not vary significantly between UIP and non-UIP patterns.
Conclusion: Advanced age, being male, smoking, and elevated RF titers were spotted as significant indicators of RA-ILD. Except for male gender, no significant risk factor predicted UIP pattern.

Keywords: anti-cyclic citrullinated peptide, interstitial lung disease, smoking, rheumatoid arthritis, rheumatoid factor

INTRODUCTION

While bilateral polyarthritis is the primary presentation of rheumatoid arthritis (RA), most RA patients also develop extra-articular symptoms affecting various organs, including heart, eyes, lungs, and skin (1). Pulmonary involvement is common and can affect various lung components, incorporating air passages, lung tissue, pleural layers, and vascular structures. Interstitial lung disease (ILD) is a prevalent complication related to lungs in RA, identified through high-resolution computed tomography (HRCT) in approximately 60% of RA patients, with clinical significance evident in 10% of instances (1-3). RA patients with ILD are prone to have an unfavorable prognosis (2). Interestingly, patients may remain asymptomatic for long periods despite evidence of pulmonary involvement (4). Therefore, screening all RA patients for ILD is recommended, given its status as a leading cause of morbidity and mortality in RA. Despite its importance, there is still limited

Table 1. Comparative characteristics of RA patients with and without ILD

	RA-ILD (n=)	RA-no ILD (n=)	P value
Demographic parameters			
Age, mean ± SD	64.5 ± 9.3	60.1 ± 13.6	0.005
Male sex n (%)	33 (47)	32 (19.8)	0.000
Smoker, n (%)	38 (54.3)	63 (39)	0.027
Pack-years of smoking, mean ± SD	33 ± 18.5	25.8 ± 15	0.056
Autoantibody tests			
Rheumatoid factor positive, n (%)	52 (74.3)	112 (69.1)	0.229
Rheumatoid factor, median ± SD	69 ± 349	37 (205)	0.022
Anti-CCP positive, n (%)	39 (55.7)	84 (51.8)	0.308
Anti-CCP, median ± SD	177 ± 379	59.5 ± 370	0.126

understanding of the underlying causes and risk factors of RA-ILD (5). The pathogenesis of RA-ILD has been linked to factors such as autoantibodies, smoking, and gene mutations; nevertheless, the available evidence is insufficient to reach a conclusive conclusion (6).

Currently, HRCT imaging is the primary method for evaluating ILD in RA patients. HRCT is superior to chest radiography as it can identify subtle structural abnormalities in lung tissue during the initial phases of the disease (7). It also replaces the need for biopsy, as HRCT findings correlate well with histopathologic changes (8). The usual interstitial pneumonia (UIP) pattern identified in RA patients with ILD mirrors that seen in individuals with idiopathic pulmonary fibrosis (IPF) and is correlated with a more unfavorable prognosis in comparison to other patterns of RA-ILD (9).

Among the demographic and environmental factors studied, there is strong evidence to support cigarette smoking, advanced age and male gender are identified as risk factors for the onset of RA-ILD (3). Rheumatoid factor (RF), which is an autoantibody targeting immunoglobulin G (IgG) Fc fragments, particularly of the IgM class, is linked to RA-associated ILD (RA-ILD) (10). Elevated serum levels of RF, even when there is no evident clinical presence of RA, might contribute to lung injury and inflammation, thereby elevating the risk of ILD (11). Anti-citrullinated peptide antibodies (anti-CCP), specifically directed against citrullinated peptides, demonstrate higher specificity for RA compared to RFs. Elevated serum levels of anti-CCP IgG might be associated with RA-ILD, although additional validation studies are required (5,12).

In our present study, we explored the relationship between age, gender, smoking habits, and serum autoantibodies (RF and anti-CCP) and their association with RA-ILD within our patient cohort. We also evaluated the relationship between these factors and the observed ILD pattern.

MATERIAL AND METHODS

A total of 251 consecutive outpatients meeting standard diagnostic criteria for rheumatoid arthritis (13) were enrolled between January 2015 and January 2022. After excluding patients with rheumatologic comorbidities, congestive heart failure, and those with indeterminate ILD status, the study included 232 patients.

Each patient underwent a thorough clinical evaluation with careful review of their medical records. An experienced thoracic radiologist visually reviewed the most recent chest CT scans for evidence of ILD. Individuals with ILD were sorted into two categories depending on whether a UIP pattern was present or absent (Figure 1A and Figure 1B, respectively). Demographic information, encompassing age, gender, and smoking history, was obtained through a questionnaire during the initial visit. Antibody titers were determined through ELISA at the initial assessment, expressed in IU/mL, and considered

Table 2. Comparative characteristics of RA-ILD patients with UIP and non-UIP paterns

	UIP (n=13)	Non-UIP (n=57)	P value
Demographic parameters			
Age, mean ± SD	67.5 ± 7.9	63.7 ± 9.5	0.149
Male sex n (%)	10 (76.9)	23 (40.3)	0.029
Smoker, n (%)	8 (61.5)	30 (52.6)	0.71
Pack-years of smoking, mean ± SD	35 ± 13.8	32.5 ± 19.6	0.77
Autoantibody tests			
Rheumatoid factor positive, n (%)	10 (76.9)	42 (73.7)	0.186
Rheumatoid factor, median ± SD	144 ± 363	63 ± 347	0.094
Anti-CCP positive, n (%)	6 (46)	33 (57.9)	0.17
Anti-CCP, median ± SD	202 ± 587	149 ± 347	0.164

positive for RF at a threshold of 10 IU/mL and for anti-CCP at 20 IU/mL.

Patient age and gender were analyzed to assess their association with RA-ILD. The impact of smoking on RA-ILD was evaluated by examining both smoking status (former-current smoker versus never smoker) and cumulative smoking exposure (evaluated based on pack-years) in patients with and without ILD. Furthermore, age, sex, and smoking details were compared between RA-ILD patients with UIP pattern and RA-ILD patients with any pattern other than UIP. An analysis of autoantibody positivity and titers was conducted in RA patients with and without ILD. Similarly, RF and anti-CCP positivity and levels were compared among RA-ILD patients with a UIP pattern and those with a pattern other than UIP.

Demographic characteristics and autoantibody titers among RA patients were compared using chi-squared test and Mann-Whitney U test. A p-value below 0.05 was considered indicative of a statistically significant difference.

Ethical Considerations

Dokuz Eylül University Non-Interventional Research Ethics Committee approved this retrospective study (Date: 02.06.2021, Decision number: 2021/17-01), and the requirement for a consent form was waived.

RESULTS

In the present study, from the original cohort of 232 RA patients, 70 individuals (30%) were identified with RA-ILD by chest CT scan. Of these, 33 were male and 37 were female. Thirteen of the patients with RA-ILD had a UIP pattern. The overall mean age of the patient population was 61.4±13.6 years and 28% were male. Among the patients, 59% were either current or former smokers, while 41% had never smoked. Smokers within the group had a median pack-years of 30, ranging from 2 to 87. RF titers ranged from 7 to 1794 IU/mL, and anti-CCP titers ranged from 0.8 to 2001 IU/mL. The median of anti-CCP was 73.5 U/mL with an IQR of 188 U/mL, and the median value of RF was 44 U/mL with an IQR of 119 U/mL.

RA patients with ILD tended to be older (p=0.005) and male (p=0.000) compared to those without ILD. In addition, a substantially larger number of patients with ILD were smokers (p=0.027) and had more pack-years of smoking, even though this disparity was not significant (p=0.056). An increased percentage of RA-ILD patients tested positive for RF (p=0.229), and the median RF level was significantly elevated compared to those without ILD (p=0.022). Despite a more frequent occurrence of anti-CCP positivity and

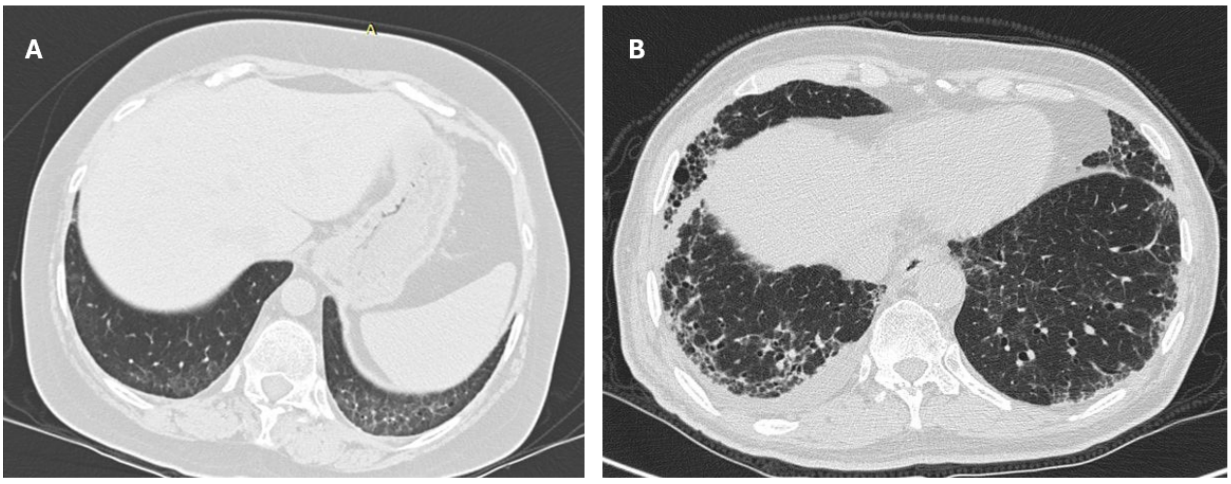

Figure 1. CT images of two patients with rheumatoid arthritis-associated interstitial lung disease. (A) Axial CT image of a 55-year-old male patient shows bilateral subpleural reticular opacities, honeycombing with peripheral and lower lobe predominance, consistent with a usual interstitial pneumonia pattern. (B) Axial CT image of a 49-year-old female patient shows bilateral subpleural ground-glass opacities, more prominent on the left, consistent with a non-specific interstitial pneumonia pattern.

higher antibody titers in patients with ILD, these distinctions did not achieve statistical significance. A summary of the comparative findings is presented in Table 1.

No statistically meaningful distinction in age was identified between patients exhibiting and not exhibiting a UIP pattern (p=0.149). The male gender exhibited a statistically pronounced correlation with the UIP pattern (p=0.029). The UIP pattern did not show a significant association with smoking status or pack-years of smoking. Although the median RF titer was higher in the UIP group than in the non-UIP group, this distinction was not statistically significant (p=0.094). The association of RF positivity with the UIP pattern was not more robust than what was noted for RF levels (p=0.186). Although anti-CCP titers were slightly higher in the UIP group (202 ± 587 vs. 149 ± 347 IU/mL), there was not a significant correlation between anti-CCP positivity or titer and ILD pattern. Comparative findings of patients with RA-ILD with and without UIP pattern are presented in Table-2.

DISCUSSION

In this study, we noted significant connections between RA-ILD and advanced age, male gender, and smoking. Additionally, we detected a significant correlation between higher RF levels and ILD in patients with RA. Although elevated anti-CCP titers were more common in RA-ILD patients, this association did not attain statistical significance. Male sex was correlated with the UIP pattern in RA-ILD, but we did not reveal a significant correlation between the UIP pattern and autoantibody titers.

ILD is a fatal outcome in patients diagnosed with RA. RA-ILD patients have a three times elevated risk of mortality in comparison to RA patients without ILD (14). Although the exact mechanisms contributing to the onset of RA-ILD remain elusive, certain demographic and external factors appear to play a noteworthy role in its occurrence in RA patients. Our study aligns with prior research, which have consistently found that ILD is more commonly seen in males, elderly patients, and smokers (5,6,14-16). Zhang et al. found that the onset of ILD is most common between the ages of 50 and 69, with a 59.9% elevate in the risk of ILD with each additional decade of age (14). Another study showed that individuals aged 65 years and older experience a quadruple increase in the incidence of ILD (17). Therefore, it is imperative to evaluate ILD in elderly RA patients.

Studies by Saag et al. have shown a correlation between cigarette smoking and the progression of RA-ILD (18). Another study also showed that the occurrence of ILD rose with the quantity of cigarettes consumed (19). In the present research, the frequency of ILD was significantly higher in smokers. While we observed a greater pack-years of smoking in ILD patients, we did not identify a significant correlation between pack-years and RA-ILD. One possible mechanism contributing to the association

between cigarette smoking and RA-ILD is that cigarette smoking facilitates protein citrullination in the lung. It is theorized that citrullinated proteins within the lung may initiate an autoimmune response, causing the generation of anti-CCP antibodies (20). Considering the correlation between elevated serum titers of anti-CCP antibodies and an elevated risk of RA-ILD, it is conceivable that smoking-induced protein citrullination in the lung might contribute to RA-ILD (1).

We compared anti-CCP and RF titers between RA-ILD group and RA patients with no evidence of ILD. We observed a significant elevation in RF antibody levels among patients with ILD, indicating a potential association between high RF levels and the pathogenesis of ILD. Nevertheless, we did not observe noteworthy disparities in the rates of positivity for anti-CCP or RF antibodies between individuals with and without ILD. Restrepo et al. found higher titers of anti-CCP and increased disease activity in RA-ILD patients, supported by the discovery of citrullinated proteins in lungs (5,21). Giles et al. also documented a correlation between higher titers of anti-CCP and the presence of ILD (22,23). However, Mori et al. found significantly elevated titers of anti-CCP in RA patients with airway disease but not in patients with ILD (24). In our study, although we observed higher positivity rates and increased titers of anti-CCP in RA-ILD patients, we did not detect a meaningful distinction compared to RA patients without ILD. Inui et al. did not identify a significant correlation between anti-CCP and ILD, aligning with the findings of our study (25). Additional investigation is required to tackle the diversity in data concerning the association between anti-CCP and RA associated ILD.

The most prevalent histopathological subtypes of RA-ILD include UIP and nonspecific interstitial pneumonia (NSIP) (26). UIP, which has been identified as more prevalent and associated with poorer survival outcomes compared to non-UIP ILD patterns, is a critical focus. The identification of ILD and its specific pattern relies primarily on HRCT scans. A crucial diagnostic criterion for definitively identifying the UIP pattern is the presence of honeycombing. While the presence of honeycombing in the absence of conflicting features such as widespread ground-glass opacities or significant mosaic perfusion indicates high specificity, its sensitivity in detecting the histopathologic UIP pattern may be limited. This radiologic presentation of UIP is referred to as "radiologic UIP", with reported survival rates akin to those of idiopathic pulmonary fibrosis (IPF) (27). In the field of RA-associated ILD (RA-ILD), there is a greater prevalence of patients exhibiting the UIP pattern in comparison to other ILDs associated with connective tissue diseases, where the NSIP pattern is more prevalent. However, our study showed a greater prevalence of the NSIP pattern than previous cohorts. These differences in findings may be due to differences in the methods used to diagnose ILDs, including clinical assessment, imaging studies, pulmonary function testing, or lung biopsy.

In our investigation, no significant relationship was found between rheumatoid factor (RF) and anti-CCP positivity/titer and ILD pattern (UIP versus non-UIP) in RA-ILD patients. Therefore, our results suggest that RF and anti-CCP antibodies may not serve as reliable biomarkers to diagnose ILD pattern, particularly UIP, in RA-ILD patients. Nevertheless, it is crucial to recognize specific limitations in our study, particularly the sample size, leading to a smaller number of patients for each RA-ILD pattern. This limitation could potentially lead to false negative results or underestimation of the observed associations.

CONCLUSION

In conclusion, this study enhances our comprehension of the features and risk factors associated with RA-ILD, potentially contributing to enhanced patient care. The findings underscore the significance of factors such as advanced age, male sex, and smoking as risk factors for ILD in individuals with RA. We also observed a notable association between elevated RF levels and the occurrence of ILD. It's worth noting that demographic and serologic markers, other than male gender, may not be reliable for predicting the UIP pattern. Nevertheless, further research should address limitations such as sample size for validation.

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Ethical approval: Dokuz Eylül University Non-Interventional Research Ethics Committee approved this retrospective study (Date: 02.06.2021, Decision number: 2021/17-01), and the requirement for a consent form was waived

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RESEARCH ARTICLE

TURKISH PROPOLIS MITIGATES OXIDATIVE STRESS AND ENDOPLASMIC RETICULUM STRESS IN CARDIAC DAMAGE CAUSED BY DOXORUBICIN IN RATS

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ABSTRACT

Purpose: This study examined the effects of propolis extracted with ethanol (EPE) or olive oil (OPE) on the endoplasmic reticulum (ER) and oxidative stress in doxorubicin (DXR)-induced cardiac damage in rats.
Material and Methods: Six groups of Sprague–Dawley rats were used in this research: Control, EPE, OPE, DXR, EPE+DXR, and OPE+DXR. The extracts were administered orally for two weeks (50 mg/kg/day), and DXR was injected 48 hours before sacrifice (15 mg/kg). Cardiac malondialdehyde (MDA) and glutathione (GSH) levels and catalase (CAT) activity were assayed spectrophotometrically, while cardiac glucose-regulated protein (GRP)78, pro-caspase 12, and serum troponin I levels were determined via ELISA.
Results: The DXR group presented elevated serum troponin I, indicating cardiac injury, increased MDA, decreased CAT activity, and reduced GSH, indicating oxidative stress, along with elevated GRP78 and decreased pro-caspase 12, indicating ER stress. Pretreatment with EPE or OPE significantly prevented DXR-induced increases in troponin I and MDA, as well as decreases in GSH, CAT activity, and pro-caspase 12, but did not significantly alter cardiac GRP78 levels. Compared with the EPE+DXR group, the OPE+DXR group presented higher levels of CAT activity ($p<0.01$).
Conclusion: Pretreatment with EPE or OPE may provide protection against DXR-induced cardiotoxicity by suppressing both oxidative and ER stress.

Keywords: cardiac injury, ethanol, GRP78, MDA, olive oil, pro-caspase 12, propolis

INTRODUCTION

Doxorubicin (DXR) is a potent chemotherapeutic agent employed in the management of a wide range of neoplasms. However, its clinical utilization is predominantly restricted by its cardiotoxicity, which has been observed in approximately 25% of patients undergoing therapy (1,2). The basic cellular processes responsible for DXR-induced cardiotoxicity are multifactorial and include mitochondrial damage, increased production of reactive oxygen species (ROS), oxidative damage to cellular components, calcium dysregulation,

endoplasmic reticulum (ER) stress and apoptotic cell death (3,4).

ER stress initiates a cellular response when unfolded or misfolded proteins accumulate within the ER lumen in response to various threats, such as oxidative stress, nutritional deprivation, calcium imbalance, genetic mutations, or viral infection (5). It has been reported that DXR therapy can induce ER stress in cardiomyocytes through the induction of ROS production and disruption of redox balance, which negatively affects protein folding processes in the ER lumen (6). To restore cellular homeostasis, the ER stress response stimulates ER-associated protein degradation and suppresses the protein synthesis machinery, but it increases the synthesis of chaperone proteins such as glucose-regulated protein (GRP)78 and GRP94, which are involved in protein folding processes in the ER. However, extended or severe ER stress can trigger apoptosis via three main pathways: caspase 12, C/EBP homologous protein and c-JUN NH2-terminal kinase (5).

Researchers are intensively investigating strategies to reduce the toxic side effects of DXR while maintaining its anticancer activity (7,8). Propolis, a natural bee product, has been shown to possess antioxidant, anti-inflammatory, and antitumour benefits and has emerged as a potential agent to mitigate or prevent DXR-induced cardiotoxicity (9). Previous studies have shown that propolis, administered intraperitoneally or orally, reduces DXR-induced cardiotoxicity primarily by decreasing oxidative stress (10-12). Its high polyphenolic content, which scavenges free radicals and prevents lipid peroxidation, contributes significantly to its therapeutic potential. Propolis and its biologically active constituents, including caffeic acid phenethyl ester (CAPE), chrysin, and artepillin C, have demonstrated efficacy in attenuating ER stress in various cell lines (13-15). Although the impact of propolis on ER stress within the context of DXR related cardiotoxicity remains to be fully clarified, CAPE has been shown to mitigate ER stress in rat cardiomyoblast H9c2 cells under in vitro DXR exposure (13).

As propolis is a complex mixture of phenolic acids and flavonoids, the cellular benefits of propolis are likely different from those of individual compounds (9). Therefore, the content, biological activity and protective efficacy of propolis extracts may be affected by regional variations in propolis and the solvents used in its extraction (16-18). Ethanol is the preferred solvent for propolis extraction, but alternatives such as water, olive oil, and propylene glycol are also used (19). Olive oil, a key constituent of the Mediterranean diet, attenuates oxidative damage and the inflammatory response and has been shown to reduce DXR-induced cardiotoxicity on its own (20, 21).

To date, studies on the cardiotoxicity of DXR have focused on ethanolic extracts of propolis, and no data are available on extracts prepared in olive oil. In our recent study, we reported that olive oil-based propolis was more effective at preventing DXR-induced hepatorenal oxidative stress than ethanol-based extracts were (22). The present study therefore focused on the influence of propolis extracts obtained using olive oil and ethanol on DXR-induced cardiotoxicity and compared their efficacy in alleviating ER stress and oxidative stress in myocardial damage.

MATERIAL AND METHODS

Ethical Considerations

This study was reviewed and approved by the Institutional Animal Experiments Ethics Committee of Ordu University (Date: 11.01.2023, Decision No: 2023/09).

Propolis extraction procedures

The raw Turkish propolis used in this study was obtained from accredited beekeepers operating in the Black Sea region of Turkey. The propolis was kept at -20°C until the extraction procedure was carried out. For the preparation of ethanol-based propolis extract (EPE), the propolis was ground and mixed with ethyl alcohol (96%) for a period of 36 hours. The procedure was performed in the dark at a temperature of 20–22°C. The aforementioned mixture was then filtered through filter paper (Whatman No. 1). Following evaporation of the solvent, a quantity of water was added until the ethanol concentration reached 2%. This resulted in the formation of a homogeneous mixture. For the preparation of olive oil-based propolis extract (OPE), the propolis was ground and stirred with extra-virgin olive oil for a period of 72 hours. This procedure was also carried out in the dark at 35°C. Thereafter, the sample was cooled to ambient temperature and subjected to filtration (18, 23).

Animals and study design

In this study, young adult Sprague–Dawley rats (aged between 2.5 and 3 months) were utilized. The animals were randomly allocated to six groups, with a total of seven animals per group.

- Control (n=7): The animals were given drinking water once a day for fourteen days by intragastric gavage (ig).
- EPE (n=7): Rats were given a daily dose of propolis extract prepared in ethanol (50 mg/kg, ig) for two weeks (12).
- OPE (n=7): Rats were given a daily dose of an extract of propolis processed in extra-virgin olive oil (50 mg/kg, ig) for a period of two weeks (12).
- DXR (n=7): For fourteen days, the animals were given daily drinking water (ig), and DXR injection (15 mg/kg) was performed intraperitoneally 48 hours before the termination of the study (24).
- EPE+DXR (n=7): Rats were given a daily dose of propolis extract prepared in ethanol (50 mg/kg, ig) for fourteen days. DXR was injected 48 hours prior to the termination of the study, in the same manner as in the DXR group.
- OPE+DXR (n=7): Rats received a daily dose of propolis extracted with olive oil (50 mg/kg, ig) for fourteen days. The administration of the DXR injection was conducted 48 hours prior to the conclusion of the study, employing the same methodology as was utilized in the DXR group.

The animals involved in the study were given unrestricted access to a regular laboratory diet as well as water. At the conclusion of the experiment on day 15, the rats were euthanized under general anesthesia (ketamine and xylazine, 80:10 mg/kg, ip). The animals were sacrificed after the heart and blood samples were taken quickly. Blood samples were maintained at a temperature of 20-22°C for about 30 minutes. Following this, centrifugation at 1000 g for 20 minutes was performed to obtain the serum. The serum samples and the heart tissue samples were preserved in a deep freezer (-80°C). On the day of the experiment, the serum samples were used for the measurement of troponin I, whereas the tissue samples were used for the following parameters after homogenization.

Troponin I measurement

To estimate the serum levels of cardiac troponin I (TNNI3/cTn-I), a commercially available ELISA kit was used (Elabscience, China), and the assay was conducted in strict accordance with the manufacturer's instructions. Serum troponin I concentrations were estimated via a standard curve.

MDA measurement

Prior to the measurements, the tissue was weighed and homogenized in 1.15% KCl (1:9). The homogenate was subjected to centrifugation at a speed of 1000 × g (10 minutes). The resulting top layer was then used to measure the MDA and GSH contents.

MDA measurements were performed via a spectrophotometric method (25). This method relies on the interaction between MDA and thiobarbituric acid (TBA), resulting in the formation of an MDA-TBA2 adduct that strongly absorbs at 535 nm. The results were calculated via a standard graph and expressed as a ratio to wet tissue weight.

GSH measurement

The spectrophotometric method for GSH involves the oxidation of GSH by the Ellman reagent (5,5′-dithiobis (2-nitrobenzoic acid)), which produces a yellow derivative (5'-thio-2-nitrobenzoic acid) that can be read at 412 nm (26). The results were determined from a standard graph and are presented relative to wet tissue weight.

CAT activity measurement

To determine the enzymatic capacity of CAT, the heart tissue was initially homogenized in 1:9 phosphate buffer. Next, the mixture was subjected to centrifugation at 1000 × g (10 minutes). The activity of the enzymes was determined by monitoring the decrease in hydrogen peroxide (H2O2) concentration at a wavelength of 240 nm over time via a spectrophotometer (27). The data are expressed as ratios relative to milligrams of wet tissue.

Measurement of GRP78 levels

Prior to the execution of the ELISA experiments, the cardiac tissues were homogenized in phosphate buffer solution (1:9 ratio), and then, the samples were subjected to a centrifugation process (5000 × g, 10 minutes) to yield the supernatant. GRP78 concentrations in tissue homogenates were evaluated by ELISA via appropriate commercial kits (BT-Lab, China). The assay procedure was conducted following the manufacturer's instructions. The results were calculated using a standard graph and are presented as the ratio of the total protein, which was determined according to the Bradford

method in the same homogenates (Thermo Scientific, USA).

Measurement of the pro-caspase 12 level

Cardiac levels of pro-caspase 12, the inactive form of caspase 12, were measured by ELISA method via a suitable commercial assay kit (BT-Lab, China) in tissue supernatants prepared by homogenization in phosphate buffer. The assay was carried out as described in the supplier's instructions. The amount of pro-caspase 12 was determined by means of a standard curve and is related to the amount of total protein in the sample.

Statistical evaluation

All the data are shown as the means ± standard deviations (SDs). The Kolmogorov–Smirnov test was utilized to confirm the normality of the variables. Statistical analysis was performed using one-way analysis of variance and Tukey's test (GraphPad Prism 4.0 software). Pearson's correlation analysis was employed to assess the interrelationships between the specified parameters. Statistical significance was considered for p values less than 0.05.

RESULTS

The impact of propolis extracts on the serum levels of troponin I in DXR cardiotoxicity

The serum concentration of troponin I in the control group was 823.41±71.75 pg/ml and did not change significantly in the EPE and OPE groups ($p>0.05$). DXR injection caused a significant increase in the serum troponin level in the DXR group (1730.34±184.39 pg/ml, vs control $p<0.001$). Two weeks of treatment with propolis extract significantly reduced DXR-induced troponin increases in the EPE+DXR group (1251.80±220.71 pg/ml, vs DXR $p<0.001$) and OPE+DXR group (1234.08±210.59 pg/ml, vs $p<0.001$ DXR); however, the values did not completely return to the control levels. The findings revealed that troponin levels in the EPE+DXR and OPE+DXR groups were comparable ($p>0.05$) (Figure 1).

Influence of propolis extracts on the oxidative stress response in DXR-induced cardiotoxicity

The oxidative stress status in cardiac tissue was evaluated by the MDA level, GSH level, and CAT activity. Two weeks of treatment with propolis extract prepared in ethanol or olive oil did not significantly affect cardiac MDA or GSH levels or CAT activity ($p>0.05$). As demonstrated in Figure 2, DXR injection significantly induced cardiac oxidative stress, as evidenced by elevated MDA levels (from 191.62±39.89 to 523.63±68.80 nmol/g tissue, $p<0.001$), GSH depletion (from 3.75±0.51 to 1.10±0.22 µmol/g tissue, $p<0.001$) and decreased activity of CAT (from 3.64±0.34 to 1.34±0.37 µmol H_2O_2 /min/mg tissue, $p<0.001$) compared with those in the control group. The alterations in these parameters that were induced by DXR approximated the control values to a significant degree in both the EPE+DXR and OPE+DXR groups. However, none of the parameters fully returned to the control levels (Figure 2). The effectiveness of the two extracts in reducing DXR-induced oxidative stress was similar, except for CAT activity. A comparison of the OPE+DXR and EPE+DXR groups revealed a significantly greater level of CAT activity in the OPE+DXR group ($p<0.01$) (Figure 2C).

The impact of propolis extracts on the ER stress response in DXR-induced cardiotoxicity

In the control rats, the GRP78 level in the heart tissue was 0.62±0.08 ng/mg protein and did not significantly change in the EPE- or OPE-treated rats (0.59±0.07 and 0.62±0.17 ng/mg protein, respectively). Compared with the control, DXR injection significantly increased the level of GRP78 in cardiac tissue to 0.81±0.09 ng/mg protein ($p<0.001$). Pretreatment with EPE slightly reduced the DXR-induced increase in GRP78 level in the EPE+DXR group (0.73±0.04 ng/mg protein); however, this decrease was not statistically significant ($p>0.05$). A comparable response was detected in the OPE+DXR group (0.69±0.10 ng/mg protein) (Figure 3A).

The cardiac level of pro-caspase 12, the inactive form of caspase 12, was 17.36±4.01 ng/µg protein in the control group, and two weeks of treatment with EPE or OPE did not cause any significant change in its level (16.02±2.78 and 16.72±4.29 ng/µg protein, respectively, $p>0.05$). A substantial decrease in pro-caspase 12 levels was evident in the DXR group compared with the control group (9.96±1.36 ng/µg protein, $p<0.01$). However, this value did not differ from that of the control in the EPE+DXR and OPE+DXR groups ($p>0.05$), both of which had significantly higher levels of pro-caspase 12 than the DXR group (14.62±1.91 and 14.78±2.21 ng/µg protein, respectively) (Figure 3B).

The correlations between the data

To evaluate the relationships between cardiac damage and stress parameters, correlation analyses between troponin I and both oxidative stress and ER stress parameters were performed. Significant correlations were detected between the serum troponin I concentration and the cardiac MDA level ($r = 0.8569$, $p < 0.0001$, positive), GSH concentration ($r = -0.8217$, $p < 0.0001$, negative), and CAT activity ($r = -0.7916$, $p < 0.0001$, negative) (Figure 4A-C).

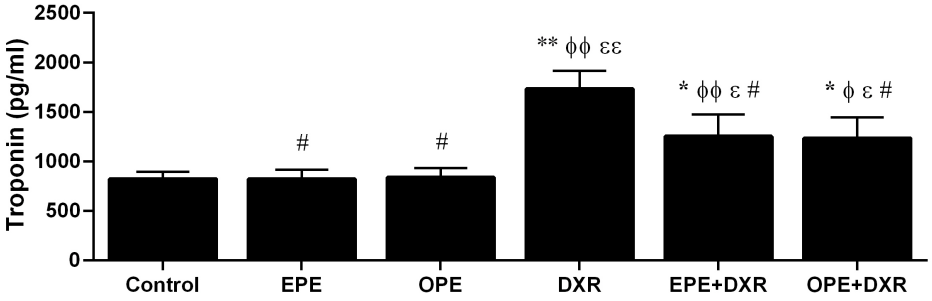

Figure 1. Serum troponin I levels in the control, ethanolic propolis extract (EPE, 50 mg/kg), olive oil propolis extract (OPE, 50 mg/kg), doxorubicin (DXR, 15 mg/kg), EPE+DXR and OPE+DXR groups. The data are presented as the means ± SDs (n=7). Statistical difference from the control *p<0.01, **p<0.001; from the EPE ϕp<0.01, ϕϕp<0.001; from the OPE εp<0.01, εεp<0.001; from the DXR #p<0.001.

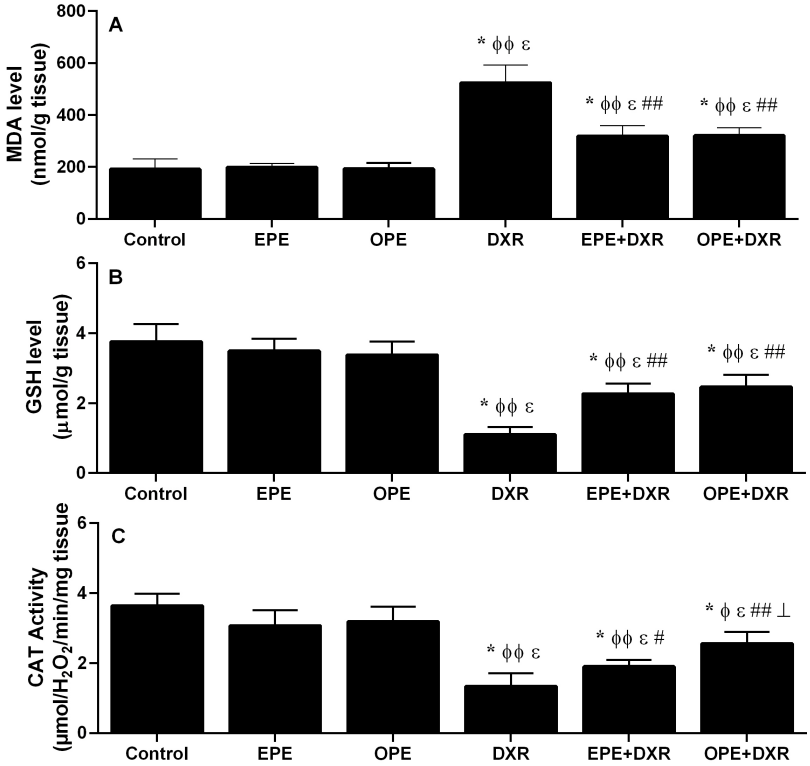

Figure 2. Changes in the cardiac oxidative stress response in the control, ethanolic propolis extract (EPE, 50 mg/kg), olive oil propolis extract (OPE, 50 mg/kg), doxorubicin (DXR, 15 mg/kg), EPE+DXR and OPE+DXR groups. The oxidative stress response was assessed by the tissue levels of MDA (A) and GSH (B) and the activity of CAT (C). The data are presented as the means ± SDs (n=7). Statistical differences from the control *p<0.001; from the EPE ϕp<0.01, ϕϕp<0.001; from the OPE εp<0.001; from DXR #p<0.05, ##p<0.001; from the EPE+DXR ⊥p<0.01.

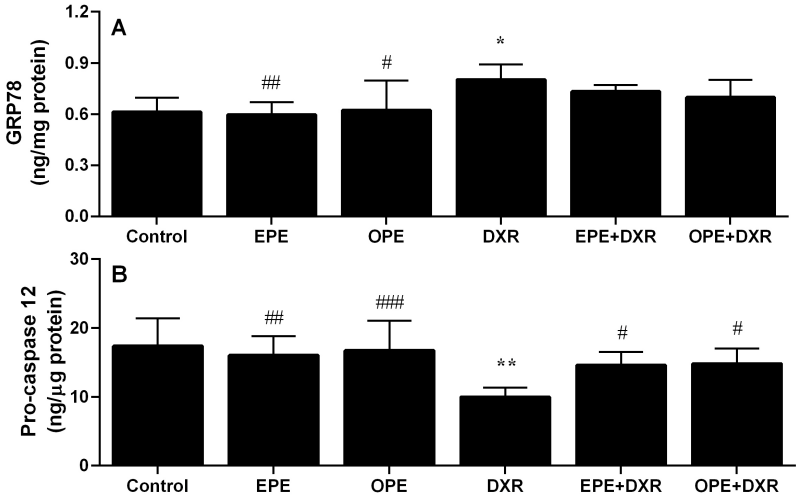

Figure 3. Changes in the cardiac ER stress response in the control, ethanolic propolis extract (EPE, 50 mg/kg), olive oil propolis extract (OPE, 50 mg/kg), doxorubicin (DXR, 15 mg/kg), EPE+DXR and OPE+DXR groups. The ER stress response was evaluated by determining the tissue levels of GRP78 (A) and pro-caspase 12 (B). The data are presented as the means ± SDs (n=7). Statistical difference from the control *p<0.05, **p<0.01; from the DXR #p<0.05, ##p<0.01.

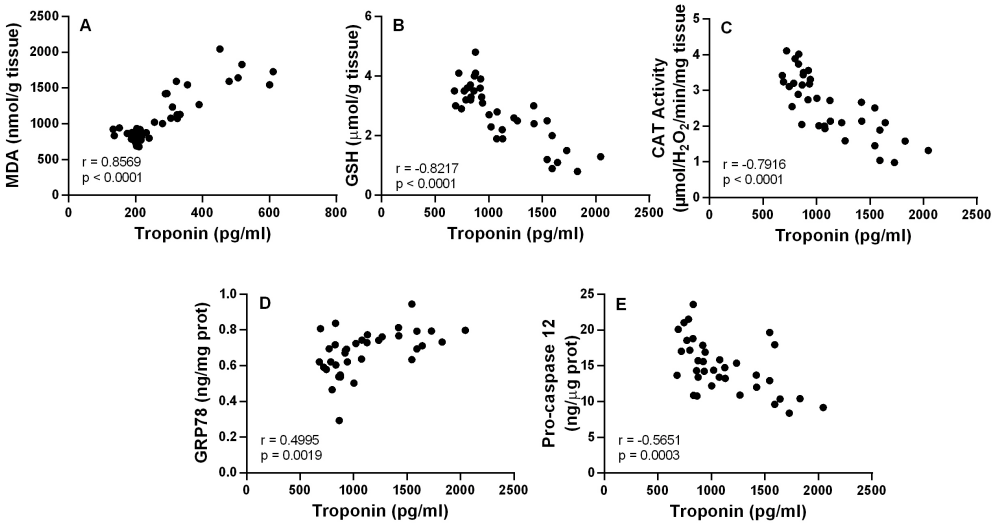

Figure 4. Correlations between serum troponin I concentrations and cardiac MDA levels (A), GSH levels (B), CAT activity (C), GRP78 levels (D) and pro-caspase 12 levels (E). Correlation analyses were performed via Pearson's correlation analysis.

According to the correlation analysis between serum troponin I and ER stress parameters, there was a positive correlation with GRP78 (r = 0.4995, p = 0.0019) and a poor correlation with pro-caspase 12 (r = -0.5651, p< 0.0003) (Figure 4D-E).

DISCUSSION

Several reports to date have indicated that ethanol based propolis can reduce DXR cardiotoxicity by decreasing oxidative damage, inflammation and cell death. However, its effects on ER stress have not yet been studied (3, 4, 28). In this study, the effects of Turkish propolis extracted with ethyl alcohol and olive oil on endoplasmic reticulum stress and the oxidative stress response during DXR-induced cardiotoxicity were investigated.

Given that the serum troponin level is a sensitive marker for DXR-induced cardiotoxicity (29), this study

utilized the serum troponin I level to evaluate cardiac damage. Consistent with expectations, the DXR group presented a substantial increase in troponin I levels. The groups treated with EPE for two weeks presented a lower level of DXR-induced troponin I increase. Although histological examination was not performed, which is a limitation of this study, the dose of propolis used and the treatment duration are effective in reducing DXR-induced cardiac damage. The attenuation of DXR-induced oxidative stress, as evidenced by lower levels of lipid peroxidation, higher levels of GSH and increased CAT activity after pretreatment with EPE, demonstrates the antioxidant properties of propolis as one of the protective mechanisms by which it protects against DXR-induced cardiotoxicity, which is consistent with previous studies (10-12).

The effects of propolis extracted with olive oil on cardiac damage during DXR toxicity were also investigated in this study. Our results demonstrate, for the first time, that OPE provides protection against DXR-induced cardiotoxicity and is as effective as EPE in reducing serum troponin I levels and oxidative damage. Importantly, the OPE treatment improved CAT activity better than the EPE treatment. In our previous study comparing the efficiency of olive oil and ethanol-based propolis extracts in DXR-induced hepatorenal damage, we demonstrated that the reduction in lipid peroxidation and the increase in SOD activity in the kidney and liver, as well as the increase in GSH levels in the liver, were greater in the oily extract group; however, the increase in CAT activity was similar in both extract treatment groups (22). These results suggest that the efficacy of OPE may vary depending on the tissue, with cardiac tissue providing less benefit than hepatorenal tissues from the treatment. The variations in cardiac CAT activity levels observed in the EPE+DXR and OPE+DXR groups may be attributed to differences in the biologically active components of the two extracts, as the active components of propolis not only scavenge free radicals but also possess the ability to activate antioxidant enzyme systems, including CAT, at the transcriptional level (34). However, content analyses of the extracts were not performed, which may be another limitation of the present study. On the basis of the literature knowledge that olive oil alone provides cardioprotection against DXR damage, the difference in the effectiveness of the extracts can also be attributed to the direct effect of olive oil (21). Nonetheless, the olive oil vehicle group (4 ml/kg/day) showed no changes in any of the parameters we assessed, including CAT activity (data not shown). The inefficiency of extra virgin olive oil in the vehicle group might be dependent on the lower volume of olive oil administered to the subjects than in the literature (10 ml/kg/day) (21). However, despite the higher levels of CAT activity, the similarity in lipid peroxidation and cardiac damage to those of the ethanolic extract group suggests that there was not a sufficient increase in the total antioxidant capacity of the tissue to reduce oxidative damage in the present study.

In our study, we also investigated how different propolis extracts affect ER stress in DXR-induced cardiac injury. Previously, it has been shown that propolis from different geographical regions or its components (e.g., artepillin C and chrysin) can inhibit ER stress (35-37). However, the effect of propolis on the cardiotoxicity of DXR has not been studied thus far. Consistent with previous reports (30,31,38,39), DXR-induced ER stress in this study was evidenced by increased GRP78 and decreased pro-caspase 12 levels. Compared with those in the DXR group, both the EPE+DXR and OPE+DXR groups presented slight decreases in GRP78 levels accompanied by significant increases in pro-caspase 12 levels, indicating alleviation of the ER stress response. Altgough Turkish propolis has demonstrated efficacy in mitigating ER stress in a lung cancer cell line (36), its impact on ER stress in nontumor cells remains unexplored. This study, therefore, represents the first attempt to elucidate the effect of Turkish propolis on ER stress in this context.

The dose of propolis used in our study is the lowest dose reported in the literature to be effective in treating DXR-induced cardiotoxicity (12). According to the present results, treatment with a low dose of propolis has been sufficient to alleviate oxidative stress and ER stress to some extent but is inadequate to completely prevent them. Nevertheless, the suppression of these two damage mechanisms by propolis appears to be successful in partly reducing tissue damage. The strong correlations between serum troponin I levels and lipid peroxidation ($r = 0.8569$), GSH levels ($r = -0.8217$), and CAT activity ($r = -0.7916$) indicate the role of oxidative stress inhibition in propolis-mediated cardioprotective effects (Figure 4). Similar relationships have been observed with ER stress parameters. The positive correlation between troponin I and GRP78 ($r = 0.4995$) and the negative correlation between

troponin I and pro-caspase 12 (r = -0.5651) suggest that the suppression of the ER stress response may also play a role in the cardioprotective effects of propolis (Figure 4). Although the correlations between troponin I and ER stress parameters were found to be statistically significant, the correlations between troponin I and oxidative stress parameters appeared to be much stronger. Therefore, while the suppression of ER stress may contribute to the cardioprotective effects of propolis, its antioxidant effect may be the predominant mechanism.

CONCLUSION

This study investigated the effects of treatment with various propolis extracts on oxidative stress and ER stress in DXR-induced cardiotoxicity. These results indicate that propolis treatment provides protection against DXR-induced cardiotoxicity by suppressing both oxidative stress and the ER stress response. Another finding of the study is that the propolis extract prepared in olive oil is as effective as the ethanolic extract and even more successful in preserving endogenous CAT activity. These results may have several potential clinical implications. First, propolis extracts could be developed as cardioprotective adjuvants for patients undergoing DXR chemotherapy, potentially allowing higher therapeutic doses while minimizing cardiac damage. Second, the comparable efficacy of the olive oil-based extract offers opportunities for use in pediatric patients or those with alcohol sensitivity or religious restrictions. Future research should focus on determining optimal dosage regimens and investigating whether these protective effects are replicated in humans.

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RESEARCH ARTICLE

TURKISH VALIDITY AND RELIABILITY STUDY OF 'THE CHILDREN'S TRUST IN GENERAL NURSES SCALE'

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ABSTRACT

Purpose: This research was a methodological study aiming to prove the validity and reliability of the Children's Trust in General Nurses Scale (CTGNS) in Turkish language.
Material and Methods: Our sample included a total of 221 students aged between 9 and 12 from 13 primary and secondary schools in the city center. An informed consent form and a family data collection form were sent to all families for data collection. The Turkish trust scale form and student data collection form were filled by the students. The content validity index was calculated, the Kaiser-Meyer-Olkin value and Bartlett's test were examined. For construct validity, exploratory factor analysis (EFA) was conducted to identify the scale's underlying structures, and confirmatory factor analysis (CFA) was performed to test the fit of the hypothesized model. For reliability, Cronbach's Alpha value (α) from internal consistency analysis was checked.
Results: The average age of the students was 10.35 ±0.97 years. The internal reliability Cronbach's Alpha value of the scale was found to be 0.72. The results of the Kaiser-Meyer-Olkin test and Bartlett's test were statistically significant. After the exploratory factor analysis, the scale was found to consist of three subscales: honesty, reliability, and emotionality. These subscales explained 56.76% of the total variance collectively, with the honesty subscale accounting for 19.53%, the reliability subscale for 19.15%, and the emotionality subscale for 18.02% of the variance. As confirmatory factor analysis revealed that the compatibility values of the scale with 9 items were RMSEA=0.068, $p<0.005$, chi-square($\chi 2$) =69.23.
Conclusion: The study on the validity and reliability of 'The Children's Trust in General Nurses Scale (CTGNS)' in the Turkish language demonstrated that the scale is valid and reliable for use in Türkiye.

Keywords: child, nurse, trust, validity, reliability

INTRODUCTION

Trust, defined as 'belief and attachment without fear, hesitation or doubt' (Turkish Language Association Dictionaries), is an essential substance that forms the basis of human relations (1, 2). Erikson describes trust as a psychodynamic process and the basic sense of belief in oneself and the world (3). Trust, due to its intangible nature, has a feature that can only be determined by feelings in relationships. The feeling of trust and insecurity is a significant issue, particularly in the field of healthcare (4, 5). It is known that nurses working in health services are seen as reliable individuals in the eyes of adults due to their roles (6). Parents' trust in nurses is acknowledged, but when exploring the pediatric literature for information on children and trust in pediatric nursing practice, it becomes evident that this essential element needs to be formally recognized (6). In research-centered pediatric nursing (7), nurses participate in studies for healthy physical, cognitive, emotional, and social

growth and development of children within the family and society, as well as to protect them from diseases and to maximize their health (8). Pediatric patients experience varying degrees of stress due to their fears of physical harm, surgery, and separation from the family during their hospitalization (9).

Trust is not only a psychological concept but also a critical component within the context of healthcare. In pediatric nursing, trust plays a pivotal role as children's trust in nurses directly influences their cooperation and the quality of care during treatment processes. Studies suggest that establishing trust-based therapeutic relationships with children enhances their engagement and collaboration in care activities (10). Furthermore, trust in healthcare professionals is emphasized as a foundation for positive health outcomes and effective treatments. Therefore, pediatric nurses' ability to build trust with children contributes not only to psychological comfort but also to the overall effectiveness of the treatment process and patient satisfaction (11).

On the other hand, children aged 9-12 begin to distinguish good from bad, right from wrong, compassion from cruelty, generosity from selfishness, and they can make decisions about right and wrong situations. At this age, children's sensitivity to behaving correctly and honestly increases (12). According to the principle of honesty, which is included in the ethical principles of nursing, telling the truth in practice leads to respect, open communication, trust, and sharing responsibility. It is important for nurses to tell the truth in order to maintain the patient's trust since the patient-nurse relationship can be seriously damaged when the patient is lied to, and distrust can develop when the nurse ignores the patient's trust relationship. It has been observed that there is a similar attitude between children's trust in nurses and fear. Although it is assumed that a close relationship is assumed to exist between these two emotions, they are entirely different from each other structurally and conceptually. While trust in nurses includes certain expectations, fear of nurses has negative effects on them (13). While trust is seen as an important variable in terms of the personality and social development of the child, most of the research has been aimed at examining the trust of adults (14, 15).

Despite the abundance of scales translated into Turkish to measure trust in nurses, no scale has been found appropriate for use in children (15). The lack of a valid and reliable tool to measure children's trust in nurses presents a significant gap in pediatric healthcare, hindering the development of interventions to enhance trust in nurse-child relationships. To address this, we conducted the Turkish validity and reliability study of "The Children's Trust in General Nurses Scale," introducing this essential tool to our country's pediatric health literature for the first time. We hope that this scale will play a significant role in future studies across various pediatric settings in Turkey, contributing to the assessment and self-evaluation of pediatric nurses who work closely with children and families, particularly those involved in family-centered care (16).

What is already known about this topic?

Trust, defined as 'belief and attachment without fear, hesitation or doubt', is one of the essential substances that form the basis of human relations (1).

What this paper adds?

The adaptation and validation of the Turkish version of CTGNS is a significant contribution to this study.

The result of this study might show us that different countries in the nursing field can use CTGNS.

The implications of this paper:

This study aimed to conduct a validity and reliability study of 'The Children's Trust in General Nurses Scale' (CTGNS) for the Turkish population, which developed to measure children's level of trust towards nurses.

In this way, it may be possible to evaluate the effectiveness of interventions in the treatment environment and to increase the quality of family-centered care by determining the reasons for children's trust in nurses and the results of the different foundations of the child's trust in nurses.

MATERIAL AND METHODS

Research Design

This study aimed to conduct a validity and reliability study of 'The Children's Trust in General Nurses Scale' (CTGNS) for the Turkish population, which was developed to measure the level of trust children have towards nurses.

Participants and Sample

The study population included 13 primary and secondary schools in the city center. The sample size is usually 5 to 10 times the number of items. The sample of this methodological study consisted of 221 students and their families. The students’ ages were

between 9 and 12. The data was collected from December 2018 to March 2019 using the CTGNS, which consists of 9 items, The Parent Data Collection Form and The Student Data Collection Form. Sample participations were selected using the 'Simple random sampling' method. Inclusion criteria were as follows: no history of mental illness or cognitive impairment, ability to communicate normally with language, and informed consent. Exclusion criteria were as follows: children who do not want to participate.

Instruments

The study data was collected using the parent data collection form, the student data collection form, and The Children's Trust in General Nurses Scale (CTGNS).

The Children's Trust in General Nurses Scale: Developed by Ken J. Rotenberg (17), this scale was designed to measure children's trust in nurses. The original version of the scale consists of 9 items that assess the three bases of trust (Honesty/Reliability/Emotionality) on a 1-5 Likert Scale. It was initially validated with 128 students in England attending 5th and 6th grades of primary school. The scale's total score ranges from 9 to 45 points, while the sub-scores for each item range from 3 to 15 points. Higher scores indicate higher levels of trust in nurses. The Cronbach's alpha value for the scale was found to be 0.72.

Parent data collection form

The CTGNS researchers created this form based on literature. It includes questions regarding the frequency of children's visits to health institutions in the last year and the children's level of trust or fear towards nurses. Parents are requested to provide answers the questions like "How much does your child trust nurses?" and "How much is your child afraid of nurses." The fear and trust questions are scored on a scale of 1 to 5 points, while the visit question is scored on a scale of 1 to 4 points. The correlation between the CTGNS and the Parent Data Collection Form was examined.

Student data collection form

This form also created by the researchers, collects students' demographic data, including their name, age, class, and gender, alongside assessing their level of trust and fear towards nurses. Students are requested to provide answers the questions like "How much do you trust nurses?" and "How much are you afraid of nurses? The fear and trust questions presented to the students were scored on a scale of 1 to 5 points. The correlation between the CTGNS and the Student Data Collection Form was analyzed.

Procedure:

Application of Data Collection Tools

The schools, where permission was obtained for the study, were visited by the researchers one week before the application day, and the necessary permission documents and family data collection forms were sent to the families through the children. At the end of a week, the researchers revisited the schools and applied the data collection forms to the students whose consents were obtained by explaining the study to them during and between classes.

Language Adaptation and Assessment of Data Collection Tools

The translation of the CTGNS into Turkish was carried out independently by researchers and three translators who were fluent in English. All the translations were examined and then incorporated into a single form by the researchers. This Turkish form was back translated by a native English-speaking translator who could understand and speak both languages, residing and working in Turkey. After the back-translation, the items were reviewed by comparing the original and back-translated forms. Once compared in terms of grammar, the forms were made ready for expert opinions.

Content Validity

A total of 10 pediatric nursing specialists with experience working with children were selected for the scope validity of the scale. The selection criteria for experts were working experience ≥10 years; bachelor's degree or above; extensive working experience in the children; and voluntary participation in this study. The experts calculated the scale's content validity index (CVI) value using the Davis technique.

Analysis

Statistical analysis of research data was performed on SPSS and LISREL software packages. Percentages, means, and standard deviations of demographic data were calculated through descriptive statistics. For validity analysis, language

and content validity, construct validity (exploratory and confirmatory factor analyses), and correlations were examined. Internal consistency alpha value, scale item correlations, and test-retest were used for reliability analysis. The reliability of the scale over time was assessed using the test-retest technique. The test-retest procedure was conducted four weeks after the initial application. A group of 20 students, selected through simple random sampling from those who participated in the study, was re-administered the same scale. Statistical calculations were performed to determine the correlation between the scores obtained in the first application and the retest scores, using Pearson's correlation coefficient (r) to assess the reliability coefficient of the scale.

Ethical considerations:

Ethical approval was obtained from the Pamukkale University Non-Interventional Clinical Research Ethics Committee (Date: 24.07.2018, Decision No: 15). Necessary permissions were obtained via email from Ken J. Rotenberg, the developer of the scale. Written consent was obtained from the City Provincial Directorate of National Education for the schools where the research would be conducted, as well as from the families and children who participated.

RESULTS

The mean age of the children participating in the study was 10.35+0.97 and half of them were male 50.2% (n=111).

Distribution of children were given in the Table 1. The answers to the CTGNS are given in the Table 2.

The answers given to the question "How often did you take your child to any health institution in the past year (12 months)?" were as follows: 10% (n=22) never and, 16.3% (n=36) more than five times.

The answers given by the children to the question "How much do you trust the nurses?" were as follows: 10.9% (n=24) I do not trust them at all and, 6.3% (n=14) I trust them very much.

The answers given by the children to the question "How afraid are you of the nurses?" were as follows: 45.7% (n=101) not afraid at all and, quite afraid, 2.3% (n=5) very afraid.

The answers to the question "How much does your child trust the nurses?" by the families participating in the research were as follows: 10.4% (n=23) does not trust at all, 3.2% (n=7) trusts very much.

Table 1. Descriptive Characteristics of the Students Participating in the Study

Descriptive Characteristics (n=221)	Mean ± SD	Min.	Max.
Age	10.35+0.97	9	12
		n	%
Gender	Female	110	49.8%
	Male	111	50.2%

Table 2. The responses of the children to the CTGNS

	The responses of the children (n=221)				
Scale Items	**a- 5 point**	**b- 4 point**	**c- 3 point**	**d- 2 point**	**e- 1 point**
Item 1 (Honesty)	14	28	78	83	18
Item 2 (Reliability)	13	33	24	111	40
Item 3 (Honesty)	7	28	32	96	58
Item 4 (Reliability)	15	28	22	105	51
Item 5 (Emotionality)	18	60	51	67	25
Item 6 (Emotionality)	22	35	35	79	50
Item 7 (Emotionality)	29	39	46	71	36
Item 8 (Honesty)	27	69	53	48	24
Item 9 (Reliability)	25	38	36	69	53

The answers to the question "How afraid is your child of nurses?" by the families were as follows: 44.8% (n=99) not afraid at all and, 2.7% (n=6) very afraid.

In additional questions given by children and their parents for compare correlation to CTGNS are given in the Table 3.

Table 3. Correlations Between the Measures and CTGNS (with Means and SDs)

	Mean+SD	RelTN	HonTN	EmTN	CRTN	CRFN	PRTN	PRFN	FVMC
CTGNS									
Total scale	30.35±5.90	0.78 **P<.01**	0.79 **p<.01**	0.81 **p<.01**	0.26 **p<.01**	-0.16	0.14 **p<.05**	-0.10	-0.02
Reliability (RelTN)	10.66±2.62		0.38 **p<.01**	0.43 **p<.01**	0.20 **p<.01**	-0.08	0.10	-0.14	-0.01
Honesty (HonTN)	9.93±2.43			0.51 **p<.01**	0.28 **p<.01**	-0.13	0.15	-0.02	-0.05
Emotional (EmTN)	9.76±2.40				0.15 **p<.05**	-0.18	0.07	-0.08	0.00
Child reported									
Trust in nurses (CRTN)	2.74±1.01					-0.23	0.37 **p<.01**	-0.10	0.05
Fear of nurses (CRFN)	1.80±0.94						-0.17	0.42	0.06
Parent reported									
Trust in nurses (PRTN)	2.71±0.90							-0.36	0.10
Fear of nurses (PRFN)	1.79±0.92								0.12
Frequency of Visiting									
Medical Centres (FVMC)	2.76±0.84								

Validity Analysis

The forms, which were evaluated by 10 selected experts, were reevaluated through the Davis technique. In our study, exploratory and confirmatory factor analyses were examined for the construct validity of the CTGNS. In addition, as a result of the literature review, it was seen that the trust scales developed on children were insufficient and in order to increase the validity of the scale, the original developers of the scale correlated the total scale with the trust reported by the child and the child's trust reported by the family (17).

A positive correlation was found between the total score and subscale scores of the CTGNS and the children's trust towards nurses in the statements of their families (r=0.78, 0.79, 0.81, p<.01).

The KMO value was 0.74 and Bartlett's was found as $X2$=312.48, p=0.00 (Table 4). After the exploratory factor analysis, the scale explained 56.76% of the total variance in three sub-dimensions (Table 5). It explained 19.53% of the variance in the honesty sub-dimension, 19.15% in the reliability sub-dimension, and 18.02% in the emotional sub-dimension of the CTGNS.

The CFA was used to examine whether the structure of the CTGNS, which has 3 sub-dimensions and 9 items, was confirmed or not. For the acceptability of the CFA results, the t-values of the scale were calculated, the standard analysis and error variances were examined, and the other fit indices of the scale (Table 6) were examined (Chi-square (χ2)=69.23, sd=24, value=0.00000, RMSEA =0.093).

Reliability Analysis

The Cronbach's Alpha value (α) of internal consistency of the scale, which consists of a total of 9 items, was found to be 0.72. Item-total scale reliability is given in Table 7. Considering the total correlations of the 9 items of the scale, item reliability coefficients were found to be between r=0.33-0.47 except for the 7th item. In various studies, a item-total correlation value of 0.20 or higher is considered acceptable. In order to avoid deviating from the intended characteristics measured by the original scale, item 7 was not removed from the scale (17,18,19). The same scale was applied again to a group of 20 students selected by simple random sampling among the students participating in the research. The correlations obtained from the test-retest results were found to be positive and significant (Table 8).

Table 4. Kaiser-Meyer-Olkin Test and Bartlett's Test

KMO ve Bartlett's Test		
Kaiser-Meyer-Olkin Value		0,74
Bartlett's Testi	Chi-square	312,48
	Degree of freedom	36
	Significance	0,00

Table 5. Factor Analysis Results of CTGNS-TR

Factors	Standard Deviation	t-values	Error Variance
Factor 1 (Honesty)			
Item 1	0.51	6.64	0.74
Item 3	0.56	7.36	0.69
Item 8	0.63	8.29	0.90
Factor 2 (Reliability)			
Item 2	0.52	6.63	0.73
Item 4	0.62	5.56	0.79
Item 9	0.68	8.42	0.54
Factor 3 (Emotionality)			
Item 5	0.40	4.95	0.84
Item 6	0.63	9.29	0.94
Item 7	0.27	3.47	0.93

Notes. CTGNS-TR = Turkish version of the children trust in general nurses scale

DISCUSSION

In order to adapt the scale to the Turkish language, translation and back translation was performed by expert translators. Then ten pediatric nursing specialists were selected for the scope validity of the scale. The CVI value of the scale was calculated as '1' as a result of the CTGNS and content validity index (CVI) evaluations, which were scored by the experts using the Davis technique. In addition, the statements were not found to be problematic by the experts and there was no request for correction. In the Davis technique, the value of the scale is expected to be greater than 0.80 to be acceptable. The value obtained as a result of CTGNS's content validity calculation showed that the scale has the power to represent the qualities it tries to measure at a very high level (20, 21).

In the original scale study, the total scale score was associated with the child-reported trust in nurses score and the family-reported children's trust in nurses score (17). A positive correlation was found between the feeling of trust in the nurse in the children's expressions and the trust in the nurse in the expressions of the families. A negative correlation was found between the children's trust towards nurses in the expressions of the families and the children's fear towards the nurses in the expressions of the families. In the original study in which the scale was developed, the desired positive significance between the correlations was also found in the validity study of the scale in Turkish.

Contrary to the positive relationship between the frequency of children's visits to a health center over the last year (12 months) and the original scale total scores, a negative relationship was found in the Turkish validity study of CTGNS. Obtaining a result contrary to the result found in the original scale can be associated with the fear of medical procedures in secondary school children in Turkey and the image of nurses in our country. Many studies have shown that the fear of medical procedures in children varies depending on the severity of the disease and the procedures, as well as the length of hospital stay (22, 23). In addition, the high workload of nurses in our country. The fact that they also loaded with duties outside their job descriptions scope cause the disruption decrease in their work quality. Therefore, it gives the impression that nurses do not fulfill their duties fully and on time, causing the image of nurses to degrade in the society (24, 25, 26).

The factor analysis suitability required for the construct validity of the CTGNS was measured with the Kaiser-Meyer-Olkin (KMO) test and Bartlett's tests (27, 28). KMO test result values of 0.80 and above are considered excellent. The calculated KMO value of 0.74 for CTGNS was between 0 and 1. Chi-square ($X2$) =312.48 and p=0.00, which were found with the Bartlett's test were considered statistically significant. The results showed that the CTGNS had sufficient sample size for factor analysis, with sufficient correlation between the variables (27, 28).

After the exploratory factor analysis of the CTGNS, which consists of a total of 9 items, the total scale explained 56.76% of the total variance in 3 sub-dimensions. Scale sub-dimensions were above the 5% variance value, which is considered valid for EFA. Since the sub-dimension eigenvalues of the CTGNS were found to be 1 and above, which is accepted in

the scale validity and reliability studies, the rate of value explained by the scale was accepted as sufficient. As a result of the analysis, whereas James P. Stevens (1996) accepted 75% and above, Robin K. Henson and J. Kyle Roberts (2006) accepted as 52% and above, most sources state the sufficient variance value to be between 40% and 60% (21, 29). The T-values calculated by CFA were found to be greater than 2.56 for each item. With this result, the items were found to be significant at the level of '0.01' and so no items were removed from the scale. Error variances were examined by performing CTGNS standard analysis after t-values. A high rate of error was detected for item 6 and item 7 error variances of CTGNS. In some studies, it was observed that items with high error variances, but significant t-values were not removed from the scale. In order to preserve the initial structure of the scale, the 6th and 7th items of the CTGNS continued to be used as in the original research scale (21, 30).

As a result of standard analysis and examination of t-values, the chi-square of CTGNS with preserved items was calculated as ($\chi 2$) =69.23, degrees of freedom (sd)=24, and p value was 0.00. The P value indicates the significance of the difference between the expected and observed covariance values, that is, the $\chi 2$ value. The p value is expected to be insignificant in confirmatory factor analyses. The

Table 6. Goodness of Fit Test Results of CTGNS-TR

Fit Measure	Good Fit	Acceptable Fit	CTGNS-TR
GFI	0.95 ≤ GFI ≤ 1	0.90 ≤ GFI ≤ 0.95	0.93
AGFI	0.90 ≤ AGFI ≤1	0.85 ≤ AGFI ≤ 0.90	0.88
RMSEA	0 < RMSEA < .05	0.05 ≤ RMSEA ≤ 0.10	0.09
RMR	0 ≤ RMR ≤ .05	0.05 ≤ RMR ≤ 0.08	0.09
SRMR	0 ≤ SRMR ≤ .05	0.05 ≤ SRMR ≤ 0.08	0.07
CFI	0.95 ≤ CFI ≤ 1	0.95 ≤ CFI ≤ 0.90	0.91
NFI	0.95 ≤ NFI ≤ 1	0.95 ≤ NFI ≤ 0.90	0.87
NNFI	0.95 ≤ NNFI ≤ 1	0.95 ≤ NNFI ≤ 0.90	0.87
	x^2/df	**2.88**	

Notes. CTGNS-TR = Turkish version of the Children trust in general nurses scale; GFI = Goodness of Fit Index; AGFI = Adjusted Goodness of Fit Index; RMSEA = Root Mean Square Error of Approximation; RMR = Root Mean Square Residuals; SRMR = Standardized Root Mean Square Residual; CFI = Comparative Fit Index; NFI = Normed Fit Index; NNFI = Non-normed Fit Index; df = Degree of Freedom"; x^2 = Chi-square.

Table 7. Item-total Score of CTGNS-TR

	Scale Mean if Item Deleted	Scale Variance if Item Deleted	Corrected Item-Total Correlation	Cronbach's Alpha if Item Deleted
Item 1	27,07	29,50	0,39	0,69
Item 2	26,76	29,14	0,36	0,70
Item 3	26,58	28,44	0,45	0,68
Item 4	26,68	28,85	0,37	0,69
Item 5	27,26	29,22	0,33	0,70
Item 6	26,90	27,52	0,42	0,68
Item 7	27,14	29,31	0,27	0,71
Item 8	27,48	27,46	0,47	0,68
Item 9	26.96	26,830	0,45	0,68

significant p value obtained in the study was due to the large sample size, as in many studies. Since χ2, which is one of the fit indices, was not examined alone in the validity and reliability studies of the scale with a sample size of 200 and above, the χ2/sd value of the CTGNS was calculated. The χ2/sd value was found to be 2.88. Since this value was less than 3, it was accepted that the scale showed a perfect fit (21, 30). CTGNS (21, 30, 31, 32), whose other fit indices were examined and found to have an acceptable fit, was then compared with the fit indices obtained from the scale in the original study. It was observed that CTGNS could not reach the fit indices of the original scale, but it yielded close values (17). The difference in value between these fit indices was attributed to the result of revealing the scale factor pattern in the original research as a result of various quantitative and qualitative studies and determining the experimental evidence of the construct validity of the scale. It is accepted as normal since cross-cultural validity and reliability studies have certain differences (30).

Overall, the analyses and calculations helped us conclude that the CTGNS was a valid tool in the Turkish language. However, it is also important to question whether a measurement tool is reliable as much as it is valid (33). Reliability analysis was performed to demonstrate the reliability of CTGNS. The CTGNS Cronbach Alpha coefficient, consisting of 9 items, was found to be 0.72. A decrease in the number of items in the scales may cause a decrease in the alpha value. Since the calculated CTGNS Cronbach Alpha value was greater than the limit value of 0.60 used in many studies, and also greater than the value of 0.70, which was accepted for validity analyses, it was accepted that the CTGNS had internal consistency within itself (33, 21). Then, item-total score correlations were examined. Considering the total correlations of the CTGNS consisting of 9 items, item reliability coefficients were found to be between r=0.33 and 0.47, except for the 7th item. With values of 0.30 and above, it was observed that the items distinguished children well. Since none of the items were below 0.20, they were not removed from the scale. The 7th item, showing the value of 0.27, was found to be in the range of 0.20 to 0.30, which can be used in the scale in mandatory situations (26). In addition, a value of 0.20 and above is considered sufficient for item-total correlation in various studies (18,19). Item 7 was not removed from the test in order to not deviate from the characteristics of the CTGNS that were intended to be measured in the original scale (17).

Table 8. Test-retest Results of CTGNS-TR

	r	p
CTGNS-TR	0.95	.000
Reliability	0.89	.000
Honesty	0.90	.000
Emotionality	0.97	.000

Finally, a test-retest process was applied for the CTGNS reliability analysis. The Pearson coefficients (r) used for iterative measurements of the scale against time were found to be positive and statistically significant. With this result, it was determined that the CTGNS provided similar measurement values at different times (33, 34).

During the Turkish adaptation of the scale, intercultural differences were taken into account. Significant cultural differences, such as expectations related to healthcare services, societal norms regarding health, and perceptions of the role of healthcare professionals, were considered. Some of the cultural differences encountered include the structure of the healthcare system in Turkey, access to healthcare services, the public's perspective on healthcare workers (especially nurses), and differences in family decision-making processes.

Linguistic differences were one of the most prominent challenges in the cultural adaptation process. Some healthcare terms and expressions used in Turkey may have different meanings compared to their counterparts in the UK. During the translation of these terms, commonly used expressions in Turkish and public comprehensibility were prioritized, and explanations were added where necessary to ensure they were aligned with the local language. Additionally, some English terms were too specific to be directly translated into Turkish, so the most appropriate local equivalents were found and used.

Considering that cultural differences may affect the validity and reliability of the scale, the adaptations made ensured that the results were best suited to the characteristics of Turkish society.

The Turkish version of the CTGNS was determined to be a valid and reliable scale. The scale is the first measurement tool to measure nurse-child trust in the pediatric nursing literature in our country. CTGNS, which has been translated into Turkish, can be used as a simple objective measurement tool by pediatric nurses who are in close contact with children and families in future studies to be conducted in the field of pediatric nursing. In this way, it may be possible to evaluate the effectiveness of interventions in the treatment environment and to increase the quality of family-centered care by determining the reasons for the trust of children in nurses and the results of the different foundations of the child's trust in nurses.

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RESEARCH ARTICLE

INVESTIGATION OF GLASS CEILING SYNDROME AMONG RADIATION PROFESSIONALS: A COMPARATIVE ANALYSIS

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ABSTRACT

Background and Purpose: This study investigates the perception of the glass ceiling syndrome among radiology, nuclear medicine, and radiation oncology technicians in healthcare institutions in Turkey.
Methods: A comparative approach was used to examine the prevalence and impact of the glass ceiling on female workers. Data was collected via questionnaires from 311 participants in Turkey, and analyzed using descriptive statistics, chi-square analysis, and independent sample tests.
Results: The results indicate that 78.1% of the participants were women, 64% were medical imaging technicians and 65.3% were employed in private institutions. A significant difference was found in the total and subscale scores of the glass ceiling scale (excluding mentoring) based on gender ($p<0.05$).
Conclusion: This study enhances understanding of gender dynamics among radiation workers and highlights the need for targeted interventions to address the glass ceiling syndrome. The findings provide key insights for promoting workforce equity and organizational development in healthcare institutions.

Keywords: Gender disparities, radiology, nuclear medicine, radiation oncology, glass ceiling syndrome

INTRODUCTION

The term "glass ceiling syndrome (GCS)" refers to the invisible barriers that impede the career advancement of women and minority groups in the workforce, encompassing social, organizational, and individual factors. These deep-rooted prejudices hinder the professional development of these underrepresented groups, reflecting discrimination related gender and racial origins, as well as to disability, age, and sexual orientation.

The term "glass ceiling," originating in the United States during the 1970s, serves as a powerful metaphor to describe the unseen yet significant barriers encountered by individuals aspiring to reach leadership roles within organizations (1). Initially, the glass ceiling primarily refered to the challenges faced by women, but it later evolved to encompass a variety of dimensions, including discrimination based on race, disability, age, and sexual orientation. This phenomenon underscores the persistence of barriers that impede the upward mobility of women and minority groups, perpetuating inequality within organizational hierarchies.

The GCS is not merely a manifestation of individual limitations but a systemic issue rooted in attitudinal and organizational biases. Defined as "attitudinal or organizational biases that prevent qualified individuals from advancing to management-level positions", the glass ceiling reflects deep-seated prejudices that obstruct the professional growth of underrepresented groups. Some studies emphasize its various dimensions, including disability, age, and sexual orientation, alongside gender and racial inequality (2). Yıldız et al. reported a bias against female employees in the information technology sector, with male counterparts asserting that women will encounter significant challenges in this field (3). A similar study revealed the effects of gender discrimination, one of the problems working women face regarding promotion, on GCS (4). Gül and Oktay (2009) illustrate how married women, whether mothers or not, experience fewer promotional opportunities and rewards compared to their male counterparts, elucidating the intersectional nature of the glass ceiling (5). Cortis and Cassar (2005) highlight that the barriers encapsulated by the term "glass ceiling" are often difficult to identify and address explicitly (6).

Despite advancements in education and shifts in societal perceptions of gender roles, women continue to face significant disparities in career progression compared to their male counterparts, particularly in leadership positions. In Turkey, and in many other regions worldwide, women are markedly underrepresented in management positions across diverse sectors, including healthcare. This disparity is pronounced among female healthcare workers in radiation-related fields such as radiology, nuclear medicine, and radiation oncology, in which women encounter multiple barriers, ranging from organizational biases and cultural stereotypes to a lack of mentorship and support.

This research aims to evaluate the perception of the glass ceiling among female healthcare professionals in healthcare institutions in Turkey, in fields such as radiology, nuclear medicine, and radiation oncology and seeks to identify the specific obstacles contributing to the GCS. By revealing the relationship between socioeconomic status and the sub-dimensions of the GCS, this study provides insights into the factors that perpetuate gender inequality in radiation-related fields**.** The study aim to shed light on the underlying factors contributing to this effect, and contribute to foster a more inclusive and equitable work environment for female healthcare professionals in Turkey.

MATERIAL METHOD

Study Group

The research was reviewed and approved by Izmir Economy University, Health Sciences Research Ethics Committee (Date: 06.08.2024, Decision No: B.30.2.IEUSB.0.05.05-20-306). Power analysis was used to decide the size of the sample, which was drawn from employees the public and private sectors. The analysis determined a sample size of approximately 311 using simple random sampling, where the bound of error coefficient obtained from previous studies was 0.2 and the population variance was 4, with a total population of 1512 radiation professionals.

The prevalence and impact of GCS was evaluated with employees working in three fields, radiology, nuclear medicine, and radiation oncology departments in both private (205, 65.9%) and public (105, 34.7%) institutions in different provinces of Turkey. Accordingly, the sample consists of 243 female (78.1%) and 68 male (21.9%) radiation workers. The majority, 200 participants (64.3%) had an associate degree. The distribution of professional roles within the sample is as follows: 199 (64%) were medical imaging technicians, 84 (27%) were radiotherapy technicians, 22 (7.1%) were radiation safety officers and 11(3.5%) were nuclear medicine technician. Strikingly, only 36 (11.6%) occupied managerial positions.

Glass Ceiling Scale Data Collection and Analysis

For the purposes of this research, following an extensive review of the relevant literature, a survey form was meticulously designed. The survey was administered to radiation workers between March 6 and April 18, 2024. Participants completed the survey online, and their participation was entirely voluntary.

The survey instrument comprised two sections. The first section contained questions about socio-demographic characteristics, and the second included questions designed to measure perceptions of the GCS. The responses were given using a 5-point Likert scale. Following a preliminary review of the dataset, responses were coded such that ‘I Strongly Disagree’ was assigned a value of 5 points. Reverse-coded items (questions 13-22) were adjusted accordingly, ensuring that higher scores indicated a higher level of perceived GCS. The full

Table 1. Cronbach's Alpha Coefficient of GCS and subscales

Scales	C Alpha Coefficient
All questions (GCS) (1-30)	0.785
TMR: Taking on Multiple Roles (1-5)	0.851
WPP: Women's Personal Preferences and Perceptions (6-12)	0.871
PIC: Perceptions of Informal Communication (13-15)	0.728
PD: Professional Discrimination (16-19)	0.886
M: Mentoring (20-22)	0.873
P: Prejudice (23-30)	0.924

questionnaire has been included as supplementary file (Appx 1).

Data were initially classified as discrete and continuous (n=311). The survey instrument was subsequently divided into subscales, and the reliability of the instrument was evaluated using Cronbach's alpha coefficient (Table 1). We calculated frequency tables (f, %) of categorical variables (Table 2) and descriptive statistics (mean ± std) of continuous variables of scores and demographic characteristics (Table 3). The normality of the continuous subscales was evaluated using the Kolmogorov-Smirnov test, which guided the determination of hypothesis testing methods. Hypotheses were tested using an independent two-sample t-test, which was applied to the total score of the GCS, while the Mann-Whitney U test was utilized for the subscales and other variables. Spearman and Pearson correlation coefficients were used according to the normality test and scale. All statistical analyses were performed using IBM SPSS 26.0 software. Although the significance level is generally set as 5%, it can also be set as 10% in some special cases (α = 0.05 and α = 0.10).

RESULTS

In the study examining radiation professionals' GCS, the internal consistency coefficient (Cronbach Alpha Coefficient) was first examined as the validity and reliability coefficient of the survey (Table 1). High Cronbach Alpha Coefficient values were found for the entire questionnaire and each subscale (r>0.70). This coefficient was used to examine whether the 30 questions in the scale collectively explained a homogeneous structure. A higher alpha value (maximum of 1) indicates that the scale itemsare consistent and measure the same construct.

In the first part of the survey, a frequency table of the radiation workers' demographic characteristics was created (Table 2). The majority in the sample were women (78.1%), predominantly employed as medical imaging technicians (64%) in private institutions (65.3%). This high percentage of women is one of the limitations of the study; however, this reflects the wider trends workers in this field throughout Türkiye.

Within the 30-item Glass Ceiling Scale, questions related to perceptions of informal communication (PIC), professional discrimination (PD), and mentoring (M) were reverse-coded. For the analysis, these items were re-coded before performing

Table 2. Descriptive statistics of discrete variables f (%)

Variables	f (%)	Variables	f (%)
Gender		**Institution**	
Female	243 (78.1)	Public	108 (34.7)
Male	68 (21.9)	Private	203 (65.3)
Management		**Education**	**f (%)**
Yes	277 (89.1)	High school	56 (18.0)
No	34 (10.9)	Bachelor's degree	198 (63.7)
Children		Associate degree	40 (12.9)
Yes	235 (75.6)	Postgraduate	17 (5.5)
No	76 (24.4)	**Position**	**f (%)**
Marital Status		Radiation Safety Officer	18 (5.8)
Married	94 (30.2)	Radiotherapy Technician	83 (26.7)
Single	207 (66.6)	Medical Imaging Technician	199 (64.0)
Divorced	10 (3.2)	Nuclear Medicine Technician	11 (3.5)

Table 3. Descriptive Statistics of Variables, GCS and Subscales

Variables	X±Sd (Median)	Min-Max
Age	27.29±8.72	18-57
Experience	6.15±7.93	1-32
Management	4.86±4.72	0-20
GCS	106.95±13.85 (108)	67-150
TMR: Taking on multiple roles	18.28±5.15 (19)	5-25
WPP: Women's personal preferences and perceptions	28.06±5.96 (29)	7-35
PIC: Perceptions of Informal Communication	8.39±3.40 (8)	3-15
PD: Professional Discrimination	11.07±4.91 (11)	4-20
M: Mentoring	7.51±3.52 (7)	3-15
P: Prejudice	33.62±7.08 (6)	8-40

statistical calculations. Consequently, a higher score on the Glass Ceiling Scale indicates a greater perception of obstacles, discrimination, difficulties, and prejudice, thereby reflecting a stronger perception of the GCS. The possible GCS scale scores range between 30 and 150, and scores closer to 150 indicates a greater perception of obstacles, discrimination, difficulties and prejudice.

The average score on the Glass Ceiling Scale was approximately 107 (106.95 ± 13.85). The average age of the participants was 27.29 years, their average length of professional experience was 6.15 years, and the average time spent in managerial positions was 4.86 years (Table 3).

An examination of the correlation coefficients between the scales and variables using the correlation matrix (Spearman correlation) revealed that gender was the only variable significantly associated with both the GCS and its subscales, except for Mentoring (Table 4). However, a noteworthy case emerged regarding the PIC and PD variables. Although these variables were not statistically significant at the 0.05 level, their p-values were very close to this threshold. Consequently, a significance level of 0.10 was considered appropriate. From a statistical point of view, this relationship is expected to become stronger as the sample size increases. In such large samples, there is a high probability that a significant relationship will emerge between these two variables and gender. No significant correlations were observed in the correlation matrices (Spearman and Pearson) between GCS and its subscale scores and any other variable except for gender. Therefore, in alignment with the study's objectives, statistical analyses primarily focused on the role of gender.

The Kolmogorov-Smirnov test, conducted with a 5% error margin, indicated that only the total score (GCS) followed a normal distribution ($p > 0.05$), and not the other subscales ($p<0.05$). It should be noted that in this test, the H_0 hypothesis established that the data came from a normal distribution. In this case, rejecting the H_0 hypothesis indicates that the data did not come from a normal distribution and non-parametric tests should be used. In particular, normal distribution was not found for the variables of age, experience, and years in management($p<0.05$). Consequently, an independent two-sample t-test was conducted to determine whether the mean GCS score differed between gender groups. To assess whether the mean subscale scores varied between the groups, an independent two-sample Mann-Whitney U test, a non-parametric test, was performed (Table 5).

Hypothesis tests were conducted to identify the differences between the gender groups in GCS and subscale scores, and t-test showed a statistical difference according to gender in GCS means ($p <$

Table 4. Correlation values (r) of scales with gender

Correlation (Gender)	p-value	r
GCS	0.000*	-0.439
TMR: Taking on multiple roles	0.001*	-0.191
WPP: Women's personal preferences and perceptions	0.023*	-0.129
PIC: Perceptions of Informal Communication	0.052**	-0.110
PD: Professional Discrimination	0.051**	-0.111
M: Mentoring	0.166	-0.079
P: Prejudice	0.000*	-0.357
p: *<0.05, **<0.10		

Table 5. Hypothesis tests of the Glass Ceiling Scale and its subscales

	Female (f=243) X±Sd(M)	Male (f=68) X±Sd(M)	Test value	p-value
GCS	110.06±12.54(110)	95.82±12.61(95)	8.27*	0.000*
TMR: Taking on multiple roles	18.81±4.92(19)	16.37±5.50(16)	6069.5**	0.001*
WPP: Women's personal preferences & perceptions	28.56±5.53(29)	26.28±7.06(28)	5783.5**	0.023*
PIC: Perceptions of Informal Communication	8.58±3.37(9)	7.72±3.45(7.5)	6993.5**	0.052**
PD: Professional Discrimination	11.37±5.02(11)	10.00±4.39(9.5)	6989.0**	0.051**
M: Mentoring	7.67±3.59(7)	6.94±3.25(6.0)	7360.0**	0.165
P: Prejudice	35.05±6.11(37)	28.52±7.98(30.0)	4200.5**	0.000*

p-value: *<0.05, **<0.10; Test value: * t test, ** Mann Whitney U test

0.05). In addition, the results of this test showed that women (110.06) had higher scores than men (95.82). Similarly, a statistical difference based on gender in subscale score medians was determined using Mann Whitney U test. A difference was observed based on gender, particularly in taking on multiple roles (TMR), women's personal preferences and perceptions (WPP) and P subscale medians, showing that this perception was higher in women ($p < 0.05$). No difference was observed based on gender in M subscale median ($p > 0.05$), but the difference based on gender in PIC and PD subscale medians only narrowly exceeded the 5% significance level and reached a statistically acceptable result at 10%. Here, it was concluded that women had a higher perception than men.

Since only gender had a relationship with the GCS score, it was decided not to examine the statistical differences between the groups for other categorical variables. This study reveals that gender plays an important role in the perception of the glass ceiling, and that women have higher GCS perception in all subscales except mentoring (M). However, unlike gender, GCS perception is not related to position, education, institution, age, experience or length of management experience.

DISCUSSION

Despite the increase in the number of women in the workforce in Turkey and globally, they continue to face significant barriers to reaching senior management positions. According to TUIK (Turkish Statistical Institute) 2022 data, 79.3 percent of managerial positions in Turkey are held by men, and only 20.7 percent by women (7). The United Nations Gender Social Norms Index Report further highlights that gender biases persist worldwide, even in developed countries (8).

In this study, 76% of the 311 participants agreed or strongly agreed that women's career development was negatively impacted by societal norms assigning excessive familial responsibilities to women. The dual burden of family roles and the demanding work tempo of managerial positions hinders women's career progression, and advancement is further affected by maternal duties, which often result in prolonged absences from the workplace. Similar findings were reported by Öztürk and Bilkay (2016), who concluded that women bear a disproportionate share of family responsibilities, leading to a higher likelihood of men occupying senior management positions (9). Additionally, Kıraç et al. found that, among female employees, 63.7% believed that women should be given more opportunities for promotion, 46.4% believed that women were assigned too many family responsibilities, and 32.8% believed that senior management positions were more often given to men (10). Kılıç and Çakıcı (2016) found that married women have a lower perception of the GCS compared to single women, and that the perceived impact of "Family Life," a sub-dimension of the GCS, was found to vary according to profession, age, and number of children (11).

Age is another factor influencing the perception of the glass ceiling. Kurtaran et al. found that female healthcare workers under 25 and those aged 26-35 experienced greater occupational discrimination, compared to those aged 46-55 (12). Additionally, female healthcare workers with higher levels of education reported more professional discrimination than those educated to only primary level.

In this study, it was determined that radiation workers, especially women, had high glass ceiling scale scores, both overall, and in all subscales. Statistically, it was found that gender discrimination was found in all except the mentoring (M) subscale of the glass ceiling scale score.

Several factors contribute to women's greater difficulty in competing for high-level positions. One critical factor is the misalignment between social expectations of the role of women and the realities of working life. Women often face obstacles such as responsibilities towards their spouses and children, which may conflict with the demands of work-related travel, prolonged meetings, and professional social events (13).

Chapman et al. emphasized that career development for female radiation oncology specialists is adversely affected by gender discrimination and societal gender perceptions in Japan and the United States (14). Thus, even in technologically advanced countries, this discrimination reflects social injustice and negatively impacts scientific progress and patient outcomes.

Many studies worldwide indicate that women in the health sector receive lower salaries and have fewer promotion opportunities than men (15-17). Research in Turkey confirms that GCS is prevalent in the healthcare sector, making it difficult for women to reach managerial positions. Despite women's high labor force participation rate in the health sector, their representation at management levels remains low. This study further supports these findings, demonstrating that women in radiation-related fields face significant barriers, particularly in informal communication and professional discrimination, which often hinder their upward mobility. Similarly, Çankaya and Çiftçi's (2022) study explores the prevalence of GCS in healthcare and its effects on female employees (18). Kalafatoğlu and Torun (2022) analyze the difficulties and gender wage gaps that women face in reaching managerial positions in healthcare (19). A previous study, Soysal and Baynal (2016), also examines the GCS experienced by women in Turkey's healthcare sector and its impact on career development (16).

Consequently, the literature clearly shows that the glass ceiling remains a significant issue. The results of this study, emphasize the need for targeted interventions addressing the specific barriers faced by women in radiation-related healthcare fields. To address this problem, it is important to create more opportunities for women in both public and private institutions, and to develop supportive work environment to help them balance home and work responsibilities. These measures could create a more equitable representation in managerial roles and promote the overall advancement of women in the workplace.

Through this research, we seek to identify actionable insights and recommendations to promote gender equity and inclusivity within the fields of radiology, nuclear medicine, and radiation oncology. The results underscore the need for comprehensive strategies to address and mitigate the effects of the GCS. Essential steps toward fostering a more inclusive and equitable work environment are implementing mentorship programs, promoting gender-sensitive organizational policies, and creating support networks. By recognizing and dismantling the barriers, healthcare institutions can ensure that all employees, regardless of gender, have the opportunity to achieve their full potential.

Addressing the GCS is crucial for promoting gender equality and enhancing women's professional growth in radiation-related healthcare roles. This research provides a foundational understanding of the challenges faced by female healthcare workers in Turkey and offers actionable strategies to create a more supportive and equitable professional environment.

However, the demographic composition of the sample, predominantly women and employees from private hospitals, limits the generalizability of the findings to the broader population of radiation professionals in Turkey. Future research should aim to include a more balanced representation of genders and occupational settings to provide a more comprehensive understanding of the glass ceiling syndrome in these fields.

A thorough understanding of the underlying causes of these barriers is essential for organizations to implement effective strategies that promote inclusive environments and ensure equal opportunities in leadership advancement. Furthermore, fostering a more inclusive organizational culture can enhance equity in career progression, enabling employees to reach their full potential. Ultimately, such efforts would contribute to the overall improvement of the healthcare system.

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Supplementary Material 1. Survey of the study

SECTION I			
	Demographic Information		
Age:	…….		
City of Employment:	……		
Gender:	□ Female	□ Male	□ Other
Marital Status:	□ Single	□ Married	□ Divorced
Children:	□ Yes	...(number of children)	□ No
Education Level:	□ Primary School		
	□ High School Graduate		
	□ Associate Degree Graduate		
	□ Bachelor's Degree Graduate		
	□ Postgraduate (Master's/PhD)		
Workplace:	□ Private	…….	
	□ Public	……	
Professional Experience:	……. years		
Position at the Workplace:	□ Radiation Safety Officer		
	□ Nuclear Medicine Technician		
	□ Radiotherapy Technician		
	□ Medical Imaging Technician		
Management Role:	□ Yes	□ No	
Duration as a Manager:	……. years		

SECTION II					
	Glass Ceiling Barriers Scale (GCBS)				
	Strongly Disagree	**Disagree**	**Neutral**	**Agree**	**Strongly Agree**
Women should choose less demanding jobs to maintain a healthy balance between work and family life.					
Working life prevents women from fulfilling their family duties.					
Being married or having children negatively affects women's job performance.					
The current or future thought of having children limits women's career goals.					
Working life makes it difficult for women to balance work and family.					
Women are reluctant to seek promotions or higher positions.					
Women think they cannot cope with the challenges they may face in achieving their career goals.					
Women think they cannot cope with the challenges they may face in achieving their career goals.					
Women accept the negative biases against them in the workplace.					
Female employees abandon their career plans due to the feeling of not dedicating enough time to their spouses and children.					
Women cannot accept the requirements and necessities of career advancement.					
Women do not aspire to rise further for fear of harming their family life.					
Men are given more opportunities than women for career advancement.					
Women struggle to enter male-dominated communication networks.					
Cultural values prevent women from participating in off-work activities, especially with male-dominated senior management.					
The business world operates according to men's rulesHigh-level positions in institutions are predominantly given to men.					
High-level positions in institutions are predominantly given to men.					
It is believed that senior positions are not suitable for women in institutions.					
The distribution of tasks within the institution is different for men and women.					
There are not enough female role models to guide women in career advancement.					
Women cannot find female mentors in institutions with male-dominated senior management.					
There is no one to help women overcome obstacles in their career development.					
Women are not as determined as men in their careers.					
Due to emotional decision-making, women are unsuccessful in senior positions.					
Women lack the capacity for quick and logical decision-making.					
Women dislike long working hours, intercity, or international travel.					
Women cannot adapt to harsh working conditions.					
Communicating with women in the workplace is difficult.					
Women cannot show as much resilience to workplace challenges as men.					
Men are more suited for senior management positions than women.					

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RESEARCH ARTICLE

ACUTE EFFECTS OF PROPRIOCEPTIVE NEUROMUSCULAR FACILITATION COMPARED TO ACTIVE RANGE OF MOTION EXERCISES ON RESPIRATORY AND HEMODYNAMIC RESPONSES IN CRITICALLY ILL PATIENTS: A PILOT STUDY

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ABSTRACT

Background and Purpose: Proprioceptive Neuromuscular Facilitation (PNF) is a widely used rehabilitation approach. However, limited studies examine the effect of PNF in a critical care setting. We aimed to investigate the acute effects of PNF-based exercises compared to active range of motion (ROM) exercises on respiratory and hemodynamic responses in critically ill patients.
Methods: Twenty-one spontaneously breathing non-intubated critically ill patients were randomly assigned to either PNF-based (n=10) or active ROM exercise group (n=11). Respiratory rate (RR; breath/min), peripheral oxygen saturation (SpO_2; %), heart rate (HR; beat/min), systolic blood pressure (SBP; mmHg), diastolic blood pressure (DBP; mmHg) and mean blood pressure (MBP; mmHg) were measured using bedside monitoring system. The dyspnea severity and perceived exertion of patients were evaluated using the 0-10 numeric rating scale. Data was recorded before, immediately after, and 5 minutes after each exercise session.
Results: There were no clinically significant differences between groups in RR (breath/min), SpO_2 (%), HR (beat/min), SBP (mmHg), DBP (mmHg), and MBP (mmHg), the severity of dyspnea and perceived exertion (P>0.05).
Conclusion: In the treatment of spontaneously breathing non-intubated patients, PNF technique can be applied safely in terms of respiratory and hemodynamic responses, similar to active ROM exercises.

Keywords: Critically ill patients, Proprioceptive Neuromuscular Facilitation, Physiotherapy

INTRODUCTION

Critical illness survivors and disability-adjusted life-years are increasing, though the mortality rates for critical illness have reduced in the last 20 years (1, 2). Critically ill patients are frequently exposed to physical, mental and cognitive intensive care unit-related consequences, especially because of prolonged immobilization (3). Current studies have

indicated that skeletal muscle weakness is one of the most common clinical manifestation (4). Its development is significantly associated with delayed functional recovery and reduced health-related quality of life in a longer-term perspective (5). Consequently, there are common impaired functional status and reduction quality of life (6).

Physical therapy is an integral part of a multidisciplinary approach in intensive care units. To prevent functional impairment and enhance recovery, initiating early mobilization and rehabilitation is highly recommended as soon as the vital status of patient has been stabilized (7). Emerging evidence has demonstrated that early mobilization was effective to prevent the intensive care unit-acquired weakness, improve muscle strength, physical function, and decrease the length of stay (8). Standardized early mobilization activities include sitting, transfers, standing and ambulation, as well as bed mobility exercise such as range of motion (ROM) exercises (9). Research has proven that all these activities are well tolerated in critically ill patients (10-12).

Proprioceptive Neuromuscular Facilitation (PNF) has gained considerable interest in the field of patients with neurological and musculoskeletal disorders, with safety and efficacy (13-15). PNF, which was originally developed by Kabat, is a widely used physiotherapy approach in rehabilitation (16). The primary aims of PNF are to improve neuromuscular control and function through optimal resistance, irradiation, tactile stimulation, body position and mechanics, verbal command, visual stimuli, approximation, stretch, timing and movement patterns. It is based on functional and diagonal movements conducted in daily activities. PNF imposes, both physically and mentally, awareness of individual during the performed movement (17).

A common condition in critically ill patients may face a respiratory problem resulting from instability of the respiratory system (18). A recent systematic review conducted by Mankad reported that PNF techniques of respiration play an effective role in improving hemodynamic and respiratory function for mechanically ventilated patients (19). Alternatively, limb muscle proprioceptive play an important role in respiratory activity (20). To date, we have found only several study that applied PNF-based physiotherapy for upper and lower extremities in mechanically ventilated critically ill adults (21-23); however, the impact and safety of the PNF technique in critical illness are still unexplored. In addition, there is a clinical concern that the PNF technique may cause cardiovascular overload, as its close-to-maximal loads and isometric contractions may lead to hemodynamic differences with increasing in blood pressure during exercise (24, 25). This is particularly important for older individuals due to increased vascular resistance with aging (26). Given those individuals being admitted to intensive care unit, we aimed to investigate the acute changes promoted by PNF-based exercises compared to active ROM exercises on respiratory and hemodynamic responses in spontaneously breathing non-intubated critically ill patients.

MATERIALS AND METHODS

The present prospective randomized controlled trial was performed in a 14-bed Anesthesia Intensive Care Unit of Dokuz Eylul University Medical Faculty Hospital, Izmir, Turkey between April 2018 and January 2020.

The study was approved by Dokuz Eylul University Non-Interventional Research Ethics Committee (Date: 15.06.2017, Decision No: 2017/16-16) and conducted in accordance with the Declaration of Helsinki. Written informed consent was obtained from participants.

Subjects

A convenience sample of 21 critically ill patients were enrolled in this study. Inclusion criteria were extubated for at least 24 hours, the ability to perform at least 3 of the following Standardized Five Questions for awakening and comprehension of patients: (1) Open (close) your eyes, (2) Look at me, (3) Open your mouth and put out your tongue, (4) Nod your head, and (5) Raise your eyebrows when I have counted up to 5 (27), and the patients receiving 0 (zero) score from Richmond Agitation and Sedation Scale (28). Exclusion criteria were having subarachnoid hemorrhage, neuromuscular disease, fractures of the upper or lower extremities, cardiorespiratory disease influencing rehabilitation management, hemodynamic instability (heart rate < 40 beats/min and > 130 beats/min, mean blood pressure < 60 mmHg and > 110 mmHg, oxygen saturation ≤ 90%, respiratory rate > 40 breath/min, temperature ≤ 36ºC and ≥ 38.5ºC) (12).

Study protocol

Patients were randomly assigned to each of two treatment groups using sealed opaque envelopes just

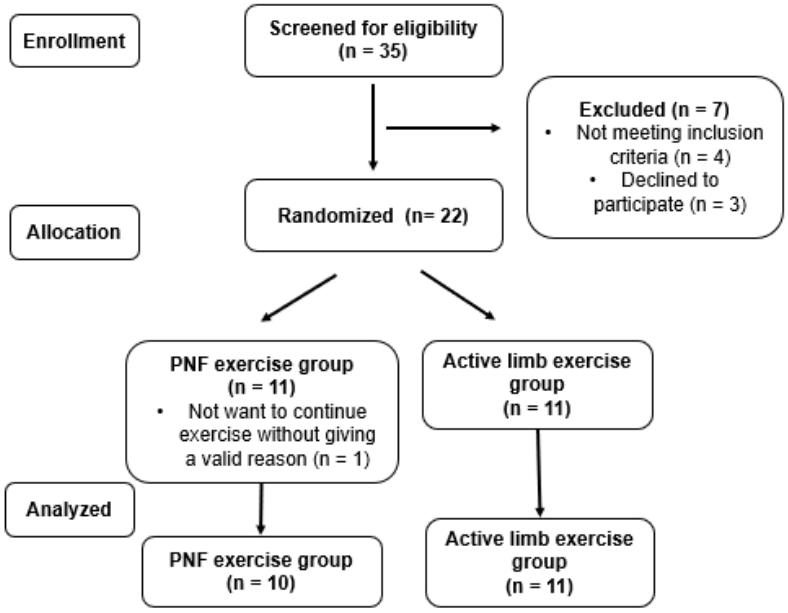

Figure 1. Flow diagram of patients

before the treatment. Two sequentially numbered envelopes were prepared for allocating the participants either to the PNF-based exercise group, or the active ROM exercise group. An envelope was opened by an intensive care nurse who was blinded to our study. According to the group assignment, treatment proceeded.

All treatments and assessments were made by the same physiotherapist, who had 2 years of experience in intensive care unit. Participants received 30-min physiotherapy session.

PNF-based exercise

The PNF-based exercises included dynamic reversal techniques of PNF. It combined the active resisted and concentric contractions of muscle groups. This technique aims to improve the active control of motion, coordination, muscle strength and endurance of upper and lower extremities in diagonal and spiral directions, and to prevent or reduce fatigue (17).

The exercises were applied bilaterally to the patients positioned supine with a 30-degree head tilt in the four patterns: flexion – abduction – external rotation into extension – adduction – internal rotation and the extension – abduction – internal rotation into flexion – adduction – external rotation for the arm diagonal patterns; flexion – adduction – external rotation with knee extension into extension – abduction – internal rotation with knee extension and extension – adduction – external rotation with knee extension into flexion – abduction – internal rotation with knee extension for the leg diagonal patterns. Each pattern was performed in the three phases: (1) the extremity was placed passively in a starting position following a stretch stimulus in an elongated position, (2) moving actively through the desired motion against optimal resistance, (3) moving back to opposite direction against optimal resistance without relaxation after the end of the desired motion. The optimal resistance, is applied with the intensity of resistance that does not interfere with conducting the pattern and overcoming of the patient, was provided by the physiotherapist (17). Each pattern was repeated 10-12 repetitions, with rest intervals of 30 s between repetitions.

Active range of motion exercises

The exercise protocol consisted of flexion, extension, abduction, adduction, internal and external rotations range of motion for all upper and lower extremity joints. These exercises aimed at promoting skeletal muscle function and control (29). Each movement was applied 10-12 repetitions, with a 30 s rest between repetitions in the supine position with the head of the bed elevated by a 30-degree angle.

Outcome measures

Respiratory and hemodynamic responses were obtained from bedside monitoring systems (Samsung SyncMaster 710v). Respiratory responses included respiratory frequency (RF; breath/min) and peripheral oxygen saturation (SpO_2; %) measurements. For hemodynamic evaluation, heart rate (HR; beat/min),

Table 1. Sociodemographic and health profile of patients

	PNF-based exercise group (n = 10)	Active ROM exercise group (n = 11)	*P**
Age (years)	64.30 ± 15.63	73.73 ± 12.32	0.139
Gender (n, %)†			
Female	5 (50.0)	5 (45.5)	1.000
Male	5 (50.0)	6 (54.6)	
Body mass index (kg/m²)	26.68 ± 5.27	27.46 ± 4.40	0.719
GCS (score)	14.90 ± 0.31	15.00 ± 0.00	0.343
Oxygen support (n, %)†			
High flow oxygen therapy	2 (20.0)	0	0,047
Nasal cannula	6 (60.0)	3 (27.3)	
Oxymask	2 (20.0)	4 (36.4)	
No support (breathing room air)	0	4 (36.4)	
ICU length of stay (days)	7.00 ± 4.39	5.09 ± 1.86	0.227

*Independent t-test
†Chi-square test
GCS: Glasgow Coma Scale; ICU: Intensive Care Unit

systolic blood pressure (SBP; mmHg), diastolic blood pressure (DBP; mmHg) and mean blood pressure (MBP; mmHg) was used.

The patient's severity of dyspnea and perceived exertion were measured through the numeric rating scale (30). The scale consists of 0 (no shortness of breath or exertion) and 10 (worst shortness of breath or extreme exertion) numerical sequence.

Outcomes were recorded at pre-treatment, the end of treatment and at a five-minute follow-up (recovery).

Statistical analysis

The statistical analyses were carried out using the statistical package for social sciences (SPSS) software. The Shapiro-Wilk test was employed to confirm data-distribution normality. Independent t-tests and chi-square tests were used for comparison of sociodemographic and health profile between groups. Repeated-measures ANOVA was performed to evaluate the effects of PNF-based exercises and active ROM exercises on respiratory and hemodynamic responses by time (before, immediately after, and recovery) as the within-subjects effect and group (PNF group or active ROM exercise group) as the between-subjects effect. *P*-value were accepted less than 0.05 for statistical significance.

RESULTS

Of 35 spontaneously breathing non-intubated critically ill patients admitted to the intensive care unit, 21 subjects participated: PNF-based exercise group (n = 10) and active ROM exercise group (n = 11). The flow diagram of patients is shown in Figure 1.

Sociodemographic and health profiles of patients are summarized in Table 1. There were no differences between PNF-based exercise and active ROM exercise groups concerning length of intensive care unit stay and ventilatory support ($P > 0.05$).

No significant changes in RR (breath/min), SpO_2 (%), HR (beat/min), SBP (mmHg), DBP (mmHg), MBP (mmHg), the severity of dyspnea (score) and perceived exertion (score) in spontaneously breathing non-intubated patients treated with PNF-based exercises compared to active ROM exercises (Table 2, $P > 0.05$).

DISCUSSION

To the best of our knowledge, this is the first study investigating the acute effects of PNF technique on respiratory and hemodynamic responses in intensive care units. We found that the PNF-based exercises and active ROM exercises observed similar changes in respiratory and hemodynamic variables of spontaneously breathing non-intubated critically ill patients. None of the severity of dyspnea and perceived exertion changes was also statistically significant. Our results indicated that PNF-based exercises could be all well-tolerated in awake and spontaneously breathing non-intubated patients when compared to active ROM exercises.

Physical rehabilitation is one of the cornerstones for critical illness management. It is becoming more widely recognized that physical-based rehabilitation interventions improve the pulmonary and muscular function of critically ill patients, as well as functional independence. Active mobilization including ROM exercises is recommended safely in international guidelines (31).

Table 2. Changes in respiratory and hemodynamic responses at before, immediately after, and recovery of exercise session

		Intervention groups		Repeated-measures ANOVA		
		PNF-based exercise group (n = 10)	Active ROM exercise group (n = 11)	Group effect	Time effect	Interaction effect
Respiratory frequency (breath/min)	Before	23.80 ± 3.96	21.36 ± 5.44	F = 0.303	F = 1.119	F = 2.652
	Immediately after	23.30 ± 5.53	24.18 ± 6.43	*P* = 0.588	*P* = 0.326	*P* = 0.099
	Recovery	24.10 ± 3.90	22.18 ± 5.41	ηp^2 = 0.016	ηp^2 = 0.056	ηp^2 = 0.122
Peripheral oxygen saturation (%)	Before	98.30 ± 1.94	97.54 ± 2.97	F = 0.693	F = 0.544	F = 0.127
	Immediately after	98.20 ± 1.39	97.27 ± 3.16	*P* = 0.415	*P* = 0.585	*P* = 0.881
	Recovery	98.40 ± 1.34	97.45 ± 3.01	ηp^2 = 0.035	ηp^2 = 0.028	ηp^2 = 0.007
Heart rate (beat/min)	Before	85.20 ± 17.69	89.00 ± 22.44	F = 0.035	F = 0.698	F = 1.564
	Immediately after	86.60 ± 16.93	88.09 ± 18.69	*P* = 0.853	*P* = 0.504	*P* = 0.222
	Recovery	86.30 ± 17.32	85.54 ± 18.28	ηp^2 = 0.002	ηp^2 = 0.035	ηp^2 = 0.076
Systolic blood pressure (mmHg)	Before	121.60 ± 19.53	124.90 ± 25.33	F = 0.130	F = 0.481	F = 0.006
	Immediately after	121.40 ± 18.93	124.81 ± 22.44	*P* = 0.722	*P* = 0.622	*P* = 0.994
	Recovery	119. 80 ± 16.27	122.72 ± 22.88	ηp^2 = 0.007	ηp^2 = 0.025	ηp^2 = 0.000
Diastolic blood pressure (mmHg)	Before	64.20 ± 7.59	62.54 ± 13.14	F = 0.022	F = 0.736	F = 1.569
	Immediately after	62.50 ± 10.40	64.09 ± 15.46	*P* = 0.883	*P* = 0.486	*P* = 0.221
	Recovery	63.40 ± 10.53	65.81 ± 15.17	ηp^2 = 0.001	ηp^2 = 0.037	ηp^2 = 0.076
Mean blood pressure (mmHg)	Before	87.00 ± 13.44	88.27 ± 20.18	F = 0.208	F = 0.029	F = 0.513
	Immediately after	84.40 ± 16.28	90.45 ± 21.99	*P* = 0.654	*P* = 0.971	*P* = 0.603
	Recovery	85.90 ± 16.12	88.18 ± 13.89	ηp^2 = 0.011	ηp^2 = 0.002	ηp^2 = 0.026
The severity of dyspnea (0 – 10)	Before	1.30 ± 2.75	0.50 ± 1.58	F = 0.390	F = 0.412	F = 0.412
	Immediately after	1.00 ± 1.88	0.60 ± 1.57	*P* = 0.540	*P* = 0.547	*P* = 0.547
	Recovery	0.70 ± 1.63	0.50 ± 1.58	ηp^2 = 0.021	ηp^2 = 0.022	ηp^2 = 0.022
Perceived exertion (0 – 10)	Before	2.20 ± 3.29	1.60 ± 2.59	F = 1.276	F = 1.224	F = 1.290
	Immediately after	3.20 ± 2.89	1.20 ± 2.09	*P* = 0.273	*P* = 0.299	*P* = 0.283
	Recovery	2.00 ± 2.66	1.00 ± 2.10	ηp^2 = 0.066	ηp^2 = 0.064	ηp^2 = 0.067

Physical exercise requires an increase in cardiac output and metabolic oxygen consumption to maintain both muscle perfusion and venous return during skeletal muscle contractions (32). Based on our study, respiratory frequency, peripheral oxygen saturation, heart rate, systolic, diastolic and mean blood pressure were not observed to increase statistically in response to PNF-based exercises and active ROM exercises. Our results are in accordance with a previous study, which performed in healthy elderly women. The authors demonstrated that PNF-based exercise did not change diastolic and systolic blood pressure (33). There is also similar evidence that PNF did not alter heart rate, SBP and DBP responses in healthy sedentary women and swimmers (34, 35). However, Gultekin et al. found that hemodynamic responses (HR, SBP and DBP) increased after PNF exercises in university students (36). Cornelius et al. (37) and Rahman et al. (38) observed that PNF did not alter significant changes in DBP while the authors reported a significant increase in SBP. This acute increase in SBP may be explained by Valsalva maneuver. The number of repetitions in exercise protocol might also result in lower metabolic demands.

Fatigue and dyspnea are distressing symptoms for many critically ill patients (39) and identified as barriers for a cessation to early rehabilitation (40). Physiotherapy in the early period should be instigated to combat these issues. In recent reviews, PNF respiratory exercises performed in critically ill patients showed better respiratory function (19, 41). However, the effectiveness of PNF-based exercise performed on the upper and lower extremities on the severity of dyspnea and perceived exertion is not still known. Liu et al. revealed that patients with chronic obstructive pulmonary disease received 5 days per week for 6 weeks pulmonary rehabilitation and 10-minute PNF stretching combined with aerobic training have reduced dyspnea and improved pulmonary function (42). Consistent with this study, we found that PNF-based performed on the upper and lower extremities and active ROM exercises reduced in the severity of dyspnea of patients, there were only minor but not statistically significant differences between groups. Our finding suggests that PNF-based and active ROM exercises can be safely used in non-intubated critically ill patients.

There are a few limitations to our study. Firstly, the time interval between onset of rehabilitation and admission to intensive care unit was very broad: 7.00 ± 4.39 days for PNF group, 5.09 ± 1.86 days for active ROM exercise group. Secondly, the sample size was relatively small due to the difficulty of accessing patients who would be cooperative to active exercises in the level three intensive care unit and the cancellation of the data collection process during the COVID-19 pandemic. Thirdly, our study design did not include critically ill patients who are mechanically ventilated. Thus, further research should address respiratory and hemodynamic responses of PNF-based exercise in mechanically ventilated patients.

CONCLUSION

Our findings suggest that the PNF-based exercise did not significantly affect acute respiratory and hemodynamic effects compared to active ROM exercises in awake, spontaneously breathing non-intubated critically ill patients. No changes were noted in the severity of dyspnea and perceived exertion. We observed that PNF-based exercise is well-tolerated and can be safely used in intensive care unit setting for awake, non-mechanically ventilated, non-intubated critically ill adults. The long-term effectiveness and functional outcomes of PNF technique in critical illness could be worth examining for future research.

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Conflict of interest: The authors report there are no competing interests to declare.
Ethical approval: The study was carried out with the approval of Dokuz Eylul University Non-Interventional Research Ethics Committee (Date: 15.06.2017, Decision No: 2017/16-16).
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Peer-review: Externally peer-reviewed.

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RESEARCH ARTICLE

APPLICATION OF THE ANALYTIC HIERARCHY PROCESS FOR THE SELECTION OF BENEFICIARIES AND PROVIDERS OF OCCUPATIONAL REHABILITATION SERVICE

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ABSTRACT

Purpose: The aim of this study is to select the beneficiaries and providers of Occupational Rehabilitation Service for Turkey.
Material and Methods: This research conducted to select the beneficiaries and providers for occupational rehabilitation used the Analytical Hierarchy Process (AHP), which is a multi-criteria decision making technique. This research conducted based on expert opinion, the results of 4 components were evaluated according to criteria of relevance, human orientation and cost.
Results: It was determined that the highest weight was “workers who have had a occupational disease” with 0.444 and the lowest weight is “workers who have had a accidents/disease for non-work reasons” with 0,232. “Ministry of Health” is selected as the highest weighted alternatives with 1.21. ‘With the commission decision that can give fitness of the work’ is also the highest weighted alternatives with 0.51. ‘Case Manager’ is the alternative with the highest level of importance with 0,29.
Conclusion: Occupational rehabilitation isn’t a service defined and implemented by the Health Implemetation Comminique (HIC) or any other legislation. It can be implemented with in the existing health system in Turkey. This servise may help to reduce lost of work and economic and social cost caused by occupational accident and disease.

Keywords: Occupational rehabilitation, return to work, occupational health, occupational safety, AHP.

INTRODUCTION

Work related injures and diseases are the major public health problem in the world. The Labour Organisation (ILO) reports that 2.3 million work-related accidents or illnesses occur worldwide every year, and that 6,000 workers die every day as a result of these occupational accidents and diseases (1). The impact of accidents and injuries on the global economy is also very high. The European Agency for Health and Safety at Work reported that occupational accidents and diseases caused 2.8 million deaths worldwide, resulting in a total loss of 67.8 million years of life, while injuries and diseases caused a total of 55.5 million years of disability (2). When all these are evaluated on the basis of the average production of an employee, it is estimated that the total cost of fatal and non-fatal work-related incidents accounts for 3.9% of global Gross Domestic Product. Occupational rehabilitation is defined as a multidisciplinary field of study that removes health-

related physical or Metal limitetin and / or limitations related to the working life of individuals from working age, thus supporting effective participation in working life by increasing work-worker fitting (3–5). This service accelerates work adaptation and return to work, reduces lost working days and ensures sustainable employment. In this way, economic and social costs arising from occupational accidents and occupational diseases are minimised (7,8).

According to the Social Security Institution statistics for 2022, 588,823 people had work accidents and 1,517 of these people died after work accidents. 953 people were diagnosed with occupational diseases and 8 of them died. As a result of non-fatal work-related accidents and diseases, some of workers are separated from employment with temporary incapacity for work and some with permanent incapacity for work and disability. Not only very high economic cost of lost working days and loss of working capacity, but also it hinders sustainable employment and causes social exclusion. For this reason, a occupational rehabilitation-return-to-work service that reduces the loss of working days as a result of work-related accidents and diseases, supports the sustainable employment of the employee and prioritises the principle of fitness for work becomes essential.

MATERIAL AND METHODS

AHP is defined as “measurement through pairwise comparisons and relies on the judgments of experts to derive priority scales”. The method is widely used and flexible tools for complex decisions (9-11). The principles and priorities of this method were firstly defined by Thomas L. Saaty in the 1970s (11–13). The method includes 6 steps summarized below (14-15);

Research Questions

In Turkey, there isn't any occupational rehabilitation service with a legislative basis and implementation. The questions of this research are as follows;

- Who should benefit from occupational rehabilitation?
- Who should be the occupational rehabilitation service provider?
- Who should be decision maker on occupational rehabilitation-return to work?
- Which organisations/experts should be members of the commission that will decide on return to work?

In this research, with these questions are aimed to select the beneficiaries and providers of Occupational Rehabilitation Service for Turkey.

Expert Selection

This research conducted to select the beneficiaries and providers for occupational rehabilitation used the AHP, which is a multi-criteria decision making technique. In the research conducted based on expert opinion. Six experts were selected for this research. The AHP method can be applied to only one person, case or situation, and it can also be applied to multiple persons or situations. Six experts worked as decision makers in this study. Three of the experts have a bachelor’s degree in engineering. These experts have been working on occupational rehabilitaton and occupational health and safety issues at public institutions for minimum ten years. The other experts have a bachelor’s degree in medicine and these experts have been working on occupational health, occupational rehabilitation and return to work in universities as an academician for minimum ten years.

Data Collection and Analysis

At this step, the data was collected through online forms created according to the hierarchical structure. Where necessary, experts were consulted through face to face or telephone call to ensure that the form was completed correctly.

The results of 4 components of the research questions were evaluated according to criteria of relevance, human orientation and cost. In the data analysis, Microsoft Excel programme was used for the calculations.

Defining the problem and determining the alternatives

The aim of this study is to select service components for occupational rehabilitation under three criteria are relevance, human orientation and cost. A quetionnaire with 4 question was prepared according to Saaty’s scale (9-point). Six experts who have been working on occupational rehabilitation answered the questionnaire as a decision maker.

Establishing the decision hierarchial structure

Figure 1 shows the established selection model with a total of 18 alternatives for 3 criteria and 4 questions.

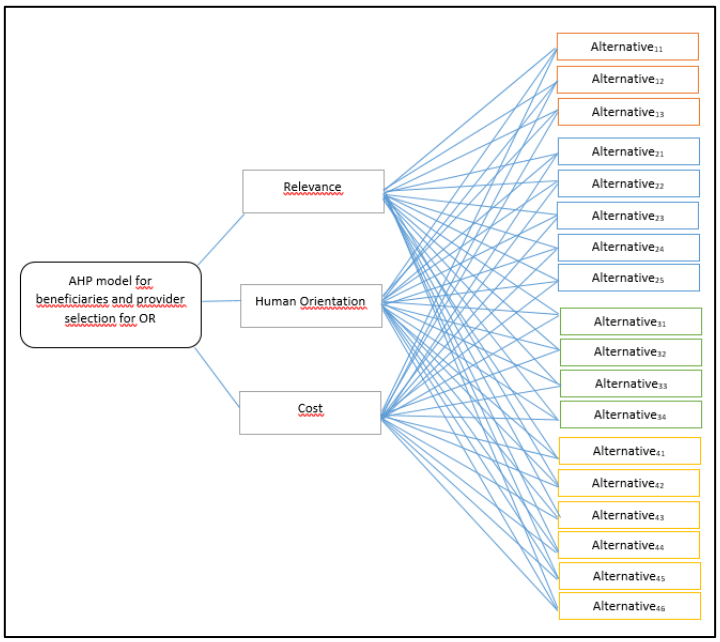

Figure 1. The hierarchical structure of AHP for selection

Table 1. Saaty's Scale

Importance	Definition	Explanation
1	Equal importance	Two criteria contribute equally to the objective
3	Moderate importance	Experience and judgement slightly favor one criterion over another
5	Strong importance	Experience and judgement strongly favor one criterion over another
7	Very strong or demonstrated importance	A criterion is favored very strongly over another; its dominance is demonstrated in practice
9	Extreme importance	The evidence favoring one criterion over another is of the highest possible order affirmation
2,4,6,8	Intermadiate	Can be use if necessary

Resource: Suitability Index (16)

Constructing pairwise comparision matrix

After establishing the hierarchial structure, three criteria were compared pairwise. In n-element matrix, there are (n-1)/2 comparisons. The Saaty Scale, given below, was used for comparisons.

According to the Saaty's scale given above, the nxn dimensional pairwise comparison matrix to be prepared for n number of criteria is as follows;

The cells shows the values indicating the degree of importance of the i-row element according to the j-column element. In the evaluation of the pairwise comparison matrix, the value of each target according to itself should be aij=1 since i=j. In other cells, if aij=k, aji=1/k.

Normalisation, Calculating weights/eigenvectors

ti: sum of column i.

For normalisation, it is obtained by dividing each cell in the pairwise comparison matrix by the column sum. Criteria weights are calculated by averaging the normalised matrix rows. Eigenvector (criteria weight) is a mathematical expression calculated as;

$$\frac{1}{n}\sum_{i=1}^{n}\frac{a_{1i}}{t_i} \quad (1)$$

Calculation of Consistency ratio and Consistency Index

In the consistency calculation, the λmax value is first calculated by dividing the product of the pairwise comparison matrix and the eigenvector matrix by the relevant eigenvector and taking the average of the values obtained. The consistency index (CI) is then calculated from the λmax value obtained.

$$CI=\frac{\lambda max-n}{n-1} \quad (2)$$

The calculation of the consistency ratio, the Random Consistency Index values determined by Saaty according to the number of criteria were used.

After the normalisation, weighting and calculation of criteria weights and consistency index, it is needed to determine whether the responses from the experts can produce a consistent decision. In order to ensure expert's individual responses are consistent and measure the degree of this, consistency ratio (CR) is calculated. Consistency measurement is a the significant step for the AHP analysis. If the consistency rate is less than 10%, this indicates that the answers may reveal a consistent decision.

$$(CR) = \frac{CI}{RI} \quad (3)$$

Ranking the alternatives

The alternatives are analysed by pairwise comparisons according to the criteria. The final step of the AHP method is the calculation of the final priority weights and ranking of the alternatives. The final weight is defined as the contribution of each sub-criteria to the final output. The final weight calculation is based on the additive summation used by Saaty. Therefore, the final priority weight of each sub-criteria is obtained by summing up all local weights. The final weight is the sum of the local weights of the main criteria multiplied by the local weights of the respective sub-criteria. The weighted sum of the criteria, sub-criteria and their scores gives the total score of each alternative and the alternative with the highest value is selected as the best alternative.

Ethical Considerations

Ethical approval was obtained from the Science and Engineering Ethical Committee of Ankara Yildirim Beyazit University (Date: 01.04.2024, Decision No: 2024-10).

RESULTS

The experts were asked 4 components to select beneficiaries and providers for occupational rehabilitation services and responses were given according to the criteria of relevance, human orientation and cost. The alternatives that are expected to be evaluated according to the criteria of relevance, human orientation and cost are given in Table 4.

Table 4 shows the expert selections for the 4 components. For Q1 *"Who should benefit from occupational rehabilitation?",* it was determined that those who had occupational accidents/occupational diseases should benefit from occupational rehabilitation services first with regard to the criteria of relevance and human orientation. According to the cost criterion, non-occupational accidents/illnesses have the highest weight. Considering the total weights, it was determined that the highest weight was "Workers who have had a occupational disease" with 0.444 and the lowest weight is "Workers who have had a accidents/disease for non-work reasons" with 0,232.

For Q2 *"Who should be the occupational rehabilitation service provider?",* "Ministry of Health" has the highest weight according to the criteria of relevance and human orientation. According to the cost criterion, "Ministry of Health" and "Turkish Employment Agency (İŞKUR)" are the highest weighted alternatives. According to the total score, "Ministry of Health" is selected as the highest weighted alternatives with 1.21.

For Q3 *"Who should be decision maker on occupational rehabilitation-return to work?",* according to the criteria of relevance (0,51), human orientation (0,52) and cost (0,52), 'With the commission decision that can give fitness of the work' is the highest level of importance. According to all score, 'With the commission decision that can give

Table 2. Pairwise Comparision Matrix

Criteria (C)	C1	C2	C3	.	.	Cn
C1	1,00	a12	a13	.	.	a1n
C2	a21	1,00	a23	.	.	a2n
C3	a31	a32	1,00	.	.	a3n
.	.	.	.	1,00	.	.
.	.	.	.	.	1,00	.
Cn	an1	an2	an3	.	.	1,00
Total	t1	t2	t3	.	.	tn

Table 3. Random Consistency Index (17)

Matrix Size (n)	Random Consistency Index
1	0,00
2	0,00
3	0,58
4	0,90
5	1,12
6	1,24
7	1,32
8	1,41
9	1,45
10	1,49

Table 4. Criteria-based Alternative Selection Table

Response/criteria	Relevance	Human Orientation	Cost	1-Cost	Total Score
Q1. Who should benefit from occupational rehabilitation?					
R1 Workers who have had a occupational accidents	0,45	0,33	0,54	0,46	0,421
R2 Workers who have had a occupational disease	0,45	0,33	0,3	0,7	0,444
R3 Workers who have had a accidents/disease for non-work reasons.	0,09	0,33	0,16	0,84	0,232
Q2. Who should be the occupational rehabilitation service provider?					
R1 Ministry of Health	0,6	2,72	0,34	0,66	1,21
R2 ÇASGEM	0,1	0,36	0,04	0,96	0,26
R3 SGK	0,1	0,76	0,18	0,82	0,36
R4 İŞKUR	0,1	0,67	0,33	0,67	0,32
R5 Private Sector	0,1	0,49	0,12	0,88	0,29
Q3. Who should be decision maker on occupational rehabilitation-return to work?					
R1 SGK	0,11	0,08	0,08	0,92	0,18
R2 İŞKUR	0,19	0,2	0,2	0,8	0,25
R3 with physician report	0,19	0,2	0,2	0,8	0,25
R4 with a commission decision that can give fitness of the work	0,51	0,52	0,52	0,48	0,51
Q4. Which organisations/experts should be members of the commission that will decide on return to work?					
R1 İŞKUR	0,2	0,08	0,2	0,8	0,22
R2 SGK	0,2	0,14	0,1	0,9	0,25
R3 Ministry of Health	0,2	0,23	0,2	0,8	0,27
R4 ÇASGEM	0,06	0,05	0,05	0,95	0,15
R5 Relevant Employer, occupational physician and OHS expert	0,14	0,14	0,11	0,89	0,21
R6 Case Manager	0,2	0,36	0,34	0,66	0,29

fitness of the work' is also the highest weighted alternatives with 0.51.

For Q4 *"Which organisations/experts should be members of the commission that will decide on return to work?",* it was determined that 'Turkish Employment Agency (İŞKUR)', 'Social Security Institution (SGK)', 'Ministry of Health' and 'Case Manager' are the alternatives with equal level of importance according to the criterion of relevance while 'Case Manager' is the alternative with the highest level of importance according to the criteria of human orientation (0.36) and cost (0.34). According to all criteria, 'Case Manager' is the alternative with the highest level of importance with 0,29.

DISCUSSION

In this study, it was aimed to select the occupational rehabilitation beneficiaries and providers based on the criteria of relevance, human orientation and cost. According to the results of the study, occupational rehabilitation services for Turkey should be provided after occupational accidents and occupational diseases as a priority. Ministry of Health should be also service provider as a priority. It was also found that occupational rehabilitation and return to work should be decided by a commission including case managers.

Occupational rehabilitation services designed to assist workers in returning to work after occupational accidents and disease thereby enhancing their quality of life, preventing long-term disability and reducing societal and economic costs. A systematic review by Cullen et al. (2018) analyzed the effect size of numerous interventions and found that workplace-based programs, especially those integrating ergonomic and psychosocial components, significantly improve return-to-work rates (18). Similarly, Vogel et al. (2017) demonstrated that early intervention and multidisciplinary approaches in occupational rehabilitation are associated with shorter disability durations and higher employment retention. These findings show the effectiveness of

comprehensive occupational rehabilitation services in facilitating successful reintegration into work(19). A study by the OECD (2010) found that comprehensive return-to-work programs not only reduce the economic burden of disability but also improve overall workforce productivity. By facilitating faster recovery and reducing absenteeism, these return to programs help both workers and employers maintain a stable workforce, which in turn has positive effects on the broader economy (20).

In addition, occupational rehabilitation services are associated with the retention rates. A study by Jeong et al. (2018) stated that the relationship between workplace health interventions and employee retention. The study suggests that employees who got occupational rehabilitation service by their employers during recovery are more likely to remain with the company long-term. This not only benefits workers but also provides significant advantages for employers in terms of reduced recruitment and its costs (21).

Occupational rehabilitation services vary in practice from one country to another (22). In Canada and Australia, vocational rehabilitation services are provided as part of health care. In the USA, vocational rehabilitation is carried out by a structure called RETAIN (Retaining Employment and Talent After Injury/Illness Network). This occupational rehabilitation service covers diseases and injuries such as cancer or disabilities other than occupational accidents/occupational diseases (23). In European countries, vocational rehabilitation is implemented in quite different structures. In Austria, Denmark, Finland, Germany, Netherlands, Norway and Sweden, occupational rehabilitation service covers everyone and any situation that takes them away from work. The most important actor in occupational rehabilitation is the employer and the processes are coordinated by him/her.

In Belgium, France, Iceland, Iceland, Italy, Luxembourg, Switzerland and the UK, occupational rehabilitation is mainly implemented to accelerate return to work after diseases (24). However, recent studies show that with COVID-19, practices have also been developed in France and the UK after more illness and occupational accidents/occupational diseases (25-26). In many countries, the occupational rehabilitation service is provided by private facilities or occupational therapists as a case manager (27).

Limitations

This study has several limitations. First, occupational rehabilitation was not well-known concept in our country. Therefore, the number of experts working in this field is quite limited. Occupational rehabilitation is an unpracticed service in Turkey and there is no legislation on this issue. Therefore, evaluations of the service provider include a priori evaluations of the system. Second, while the AHP method enables structured decision-making based on expert opinion, the derived judgments reflect the context-specific experiences and professional interpretations of the selected informants. As occupational rehabilitation lacks formal legislative and institutional recognition in Turkey, there may be instances where the judgments obtained differ from internationally established scientific findings or normative approaches. This contextual specificity should be considered when generalizing the results or drawing comparisons with broader global practices.

As a result of this research, it was selected the occupational rehabilitation beneficiaries and providers based on the criteria of relevance, human orientation and cost. This study is novel in terms of identifying/selecting the beneficiaries and service providers in occupational rehabilitation services. Occupational rehabilitation isn't a service defined and implemented by HIC or any other legislation. Occupational rehabilitation service can be implemented with in the existing health system in Turkey. This servise may help to reduce lost of work and economic and social cost caused by occupational accident and disease.

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RESEARCH ARTICLE

INVESTIGATION OF FACTORS AFFECTING DISASTER PREPAREDNESS BELIEFS AMONG PUBLIC INSTITUTION EMPLOYEES: A CROSS-SECTIONAL STUDY

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ABSTRACT

Objective: Disasters affect the whole society, may cause great loss of life and property and may threaten public health at a significant level all over the world. The aim of this study is to reveal the disaster preparedness beliefs of public employees and effective factors.
Methods: This study was conducted with a total of 322 public employees. The data were collected face-to-face between June-September 2023 with the General Disaster Preparedness Belief scale developed based on the Health Belief Model and a descriptive form.
Results: The total score of general disaster preparedness belief was 106.80±17.42. There was no significant difference was found between the socio-demographic characteristics of the employees and the total scale score, and the disaster preparedness belief, motivation and obstacles to disaster preparedness were found to be high in those who were not prepared for disaster, did not have an emergency/disaster kit and did not receive disaster training.
Conclusion: General Disaster Preparedness Belief score of public employees is close to the middle level. Public employees have high perceptions of obstacles related to disaster preparedness. The perception of barriers should be reduced and the perception of benefits should be increased in this group with high level of education.

Keywords: Disasters, disaster preparedness, health belief models

INTRODUCTION

The term “disaster” has many definitions. The Centre for Research on the Epidemiology of Disasters (CRED) defines a disaster as "an unexpected and often sudden event that causes great damage, destruction and human suffering, exceeding local capacity to the extent that it requires external assistance at national or international level"(1). According to the disaster classification in the International Emergency Events Database (EM-DAT), disasters are divided into two groups: natural and technological. Approximately two-thirds of the disasters registered in the database are natural disasters(2). The EM-DAT report states that in 2022, 387 natural disasters were recorded. These events affected 185 million people, and 31 thousand lost their lives, resulting in an estimated economic loss of 223.8 billion(1).

The diversity and significance of natural disasters vary across countries. Turkey ranks third worldwide in human loss from earthquakes and eighth in the number of people affected (3).Due to its location,

technological structure, geological structure and climate characteristics, natural disasters occur more frequently than technological disasters(4). According to the records in the EM-DAT database, 208 natural disasters occurred in Turkey between 1923 and 2023, resulting in approximately 136 thousand lives lost and 85 billion dollars of damage(5).

In recent years, the number, magnitude and impact of disasters on society have increased worldwide due to global climate change and human-induced factors. To reduce the negative impact of disasters, countries should establish strategies for the prevention, preparation, response and recovery phases of disaster management(6). It is crucial to take necessary measures in the risk reduction phase before the disaster and carry out activities to prevent losses in the preparation phase(5). Disaster preparation is the responsibility of every individual(7). Making the necessary preparations to reduce the damages caused by disasters and taking precautions increases a society's resilience against disasters (8).

Disaster preparedness is a dynamic and ongoing process that includes education and training, development of plans and policies, recruitment of volunteers, equipment, public training, exercises and evaluation(9,10). Being prepared is essential to reduce the effects of disasters and save lives, especially in countries with high disaster risk(11). Health professionals are integral in disaster preparedness; in particular, nurses assume a critical role at every stage of the disaster management process. In disaster preparedness studies, nurses are essential in determining the needs and resources of society, creating and maintaining the disaster nursing workforce, using nursing roles, and providing cooperation (6). However, studies show that nurses in our country are not competent in disaster management (12).

Major disasters in recent years have made the deficiencies in disaster planning and preparedness even more evident(9). The COVID-19 outbreak and the physiological, economic and psychological losses from the earthquake of June 2023 in Kahraman Maraş, Turkey, have shown the necessity of disaster preparedness. The Health Belief Model (HBM) is important in increasing the awareness and motivation of individuals and explaining healthy behaviors. The measurement tool for general disaster preparedness based on this model addresses disaster preparedness beliefs(13).

Previous studies show that disaster belief is generally at a moderate level(14,15). Individuals with different socio-demographic characteristics may change their approach to disaster preparedness activities. This study aims to contribute to the literature by revealing the disaster preparedness beliefs of highly educated public employees and the associated determinants.

MATERIALS AND METHODS

Type of Research

This descriptive and cross-sectional study examined the disaster preparedness beliefs of individuals working in a public institution and the factors affecting them.

Population and Sample of the Study

The population of the study consists of public employees working in a public institution in Denizli, Turkey. There was no sample selection. A total of 400 people working in the public institution were included in the study. The study was completed with a total of 322 people and 80.5% of the sample was reached. The reasons for not participating in the study included employees being on leave (n=14) and not wanting to participate.

Data Collection Tools

The data collection tools included the Public Employees Introductory Information Form (Appendix 1) and the General Disaster Preparedness Belief Scale (Appendix 2).

Introductory Information Form

The researchers prepared this form within the scope of the literature (16,17). The form consists of questions about age, gender, education level, marital status, number of children, income, occupation, previous disaster experience, emergency/disaster preparedness, having a disaster kit, and disaster training.

General Disaster Preparedness Belief Scale (GDPB)

This scale developed by Inal et al. 2018 (8) is based on the Health Belief Model, and it measures people's behaviors, attitudes, and beliefs in preparation for disasters and emergencies. The Health Belief Model (HBM) posits that individuals consider their perceptions of risk, anticipated benefits, barriers, and personal beliefs when making health-related

decisions. This model is also effectively applied to understanding beliefs regarding health behaviors such as disaster preparedness. Therefore, the scale is based on this theoretical framework to assess individuals' beliefs and preparedness levels concerning the measures they would adopt in response to disasters (18). The Cronbach alpha value of the scale, which consists of 31 items and six sub-dimensions, is 0.86. In the same year, İnal and Doğan (2018) aimed to improve and retest the psychometric properties of the scale, adding 14 more items by expanding the same structure. The 45 items and six sub-dimensions of the scale include perceived susceptibility (6 items), perceived barriers (14 items), perceived usefulness (6 items), perceived severity (4 items), self-efficacy (10 items) and enablers (5 items). Cronbach's alpha value of the expanded five-point Likert-type scale is 0.93. Positive statements in the scale are scored as (1) Strongly disagree, (2) Disagree, (3) Undecided, (4) Agree, and (5) Strongly agree, while negative statements are reverse scored. The minimum score is 45 points, and the maximum is 225 points. Questions 4, 6, 8, 9, 17–30, 31, 35, 37, 38, 42, and 44 are reverse scored (13). As a result, the 45-item scale improved on the 31-item scale. Since the 45-item scale is better in terms of validity, reliability and other psychometric properties, it is recommended that researchers use it. In particular, the scale provides more information about behaviors related to disaster preparedness (13). Therefore, it was used in the study, and the Cronbach alpha value was 0.85. The General Disaster Preparedness Belief Scale, developed within the framework of the Health Belief Model, is designed to assess individuals' beliefs regarding disaster preparedness. An increase in both total and subscale scores signifies a strengthened belief in the importance of disaster preparedness, suggesting a heightened awareness of potential risks and an increased likelihood of engaging in preventive behaviors, including health-related actions and psychological readiness. In contrast, a decrease in scores reflects a diminished belief in preparedness, indicating a reduced perception of disaster risks and a lower propensity to adopt preventive measures or cultivate psychological resilience. Higher scores typically denote strong preparedness beliefs and enhanced resilience, while lower scores suggest weaker preparedness beliefs, which may correspond to greater vulnerability in the event of a disaster. Overall, variations in the scores provide critical insights into the efficacy of preparedness interventions and highlight areas in need of further educational efforts or targeted action (13,18).

Data Collection Method

The study was conducted in a public institution in Denizli, Turkey. The researchers collected the data face-to-face with questionnaires for 12–20 minutes on average. Several visits were made during the data collection period to reach the employees who were on report and on leave. The study data were collected between June and September 2023 using face-to-face interview method.

Ethical Issues

Permission was obtained from the authors for the scale used in the study. The participants were informed about the purpose of the research and the content of the forms, that the collected information would be kept confidential, and that they could exercise their right to withdraw from the research at any time. Their consent was obtained. Ethical permission was obtained from the Non-Interventional Clinical Research Ethics Committee of Pamukkale University (Date: 31.05.2023, Decision No: 374391). The study was kept confidential since the institution did not want to be identified.

Data Evaluation

Data were evaluated using the Statistical Package for the Social Sciences (SPSS Inc, Chicago, Illinois) 21.0 program. Descriptive statistics were presented as mean ± standard deviation for continuous variables and frequency and percentage for categorical variables. The normal distribution of the data was determined by the Kolmogorov-Smirnov test. Data were analyzed using independent-samples t-test and one-way ANOVA. A value of $p<0.05$ was accepted as significant in the analyses.

RESULTS

Table 1 gives descriptive information about public employees. The mean age of the participants was 41.73±0.55, and 95.0% were undergraduate and master's degrees. Of the public employees, 21.4% had previous disaster experience, and 24.2% had received training.

The total score of the General Disaster Preparedness Belief Scale of public employees was 106.80±17.42. The mean scores of the sub-dimensions were as follows: Perceived susceptibility 12.26±3.11,

Table 1. Socio-demographic and disaster-related characteristics of public employees (n=322)

Variables		n	%
Age	39 years and under	148	46.0
	40 years and older	174	54.0
Mean (SD)		41.73±0.55	
Gender	Male	187	58.1
	Female	135	41.9
Marital status	Married	236	73.3
	Single	86	26.7
Education status	High school	16	5.0
	University	286	88.8
	Postgraduate	20	6.2
Children	Yes	236	73.3
	No	86	26.7
House ownership	Self-ownership	184	56.1
	Renting	138	43.9
Ever experienced any disaster	Yes	69	21.4
	No	253	78.6
6 February 2023 earthquake experience	Yes	11	3.4
	No	311	89.8
Emergency/Disaster preparedness	Yes	42	13.0
	No	280	87.0
Having an emergency/disaster kit	Yes	58	18.0
	No	264	82.0
Emergency/Disasters training	Yes	78	24.2
	No	244	75.8
Subjects trained *n=101	First aid	48	47.5
	Community disaster volunteer	14	13.9
	Basic disaster awareness	32	31.7
	Other	7	6.9

* Since there are multiple responses, the number n exceeds the sample size.

Table 2. Total and subscale mean scores of general disaster preparedness beliefs

Scale and Subscales	Number of items	X ±SD	Min-Max
Perceived Susceptibility	6	12.26±3.11	6-22
Perceived Severity	4	7.78± 2.89	4-19
Perceived Benefits	6	11.86±3.91	6-30
Perceived Barriers	14	33.30±8.91	14-70
Cues to Action	5	14.03±3.68	5-25
Self-Efficacy	10	27.54±5.30	14-46
GDPB	45	106.80±17.42	64-157

GDPB, General Disaster Preparedness Belief. X: Average, SD: Standard Deviation, Med: Median, Min: Minimum, Max: Maximum

Perceived severity 7.78± 2.89, Perceived benefits 11.86±3.91, Perceived barriers 33.30±8.91, Cues to Action 14.03±3.68, Self-efficacy 27.54±5.30 (Table 2).

Table 3 compares the mean scores of public employees in GBDP and its sub-dimensions with various variables. A statistically significant difference was found between public employees aged 40 and older and the sub-dimensions of perceived susceptibility and perceived severity ($p<0.01$). A statistically significant difference was determined between the gender variable and perceived severity ($p<0.01$), perceived benefits ($p<0.05$) and self-efficacy sub-dimensions ($p<0.001$). No significance was found between marital status, presence of children and residence ($p>0.05$).

A statistically significant difference was determined between those who had never experienced a disaster and perceived susceptibility ($p<0.01$). A statistically significant difference was found between those who were not prepared for emergencies/disasters and the mean scores of perceived susceptibility, self-efficacy ($p<0.01$), perceived barriers ($p<0.05$) sub-dimension and total scale score ($p<0.01$). A statistically significant difference existed between those who did not have an emergency/disaster kit and perceived susceptibility($p<0.01$), as well as between the most recent earthquake and perceived severity sub-dimension score ($p<0.05$). There was a statistically significant difference between the status of receiving disaster training and perceived severity ($p<0.05$), cues to action, self-efficacy sub-dimension scores ($p<0.001$), and total scale score ($p<0.05$). A significant difference was found between the total score of GDBP and those who did not receive disaster

training, were unprepared for disaster and did not have an emergency/disaster bag (p<0.05) (Table 4).

DISCUSSION

This study determined the disaster preparedness beliefs of public employees with a scale developed and expanded based on the Health Belief Model. Public employees with high levels of education had middle levels of disaster preparedness beliefs. The GDBP was at a moderate level in studies conducted in our country involving nurses in a research hospital, (16)parents with a high level of education working at a university(14), individuals participating through social media (15), and academic and administrative staff at a university(19).

In a study conducted in Iran using the cultural adaptation of the scale, earthquake preparedness belief was found to be low (20). Only 20% of the participants were university graduates; the low level of education compared to our study may be the

Table 3. Evaluation of socio-demographic variables according to General Disaster Preparedness Belief Scale scores of public employees

Variables	Susceptibility	Severity	Benefits	Barriers	Cues to Action	Self-Efficacy	GDBP
Age							
39 years and below	11.77±2.9	7.38±2.9	11.79±4.0	32.66±9.5	14.41±3.7	27.56±5.5	105.60±17.5
40 years and above	12.67±3.1	8.13±2.7	11.92±3.8	33.85±8.2	13.71±3.6	27.52±5.1	107.83±17.2
p value	**p< 0.01**	**p< 0.01**	0.771	0.302	0.237	0.087	0.253
Gender							
Male	12.47±3.1	8.19±2.8	11.49±3.7	33.93±9.5	13.93±3.8	26.54±4.9	106.56±18.1
Female	11.97±2.9	7.22±2.8	12.37±4.1	32.43±7.8	14.18±3.4	28.94±5.4	107.14±16.4
	0.150	**p< 0.01**	**p< 0.05**	0.125	0.534	**p< 0.001**	0.767
Marital status							
Married	12.23±3.0	7.87±2.7	11.94±3.7	33.05±8.1	14.10±3.6	27.41±5.3	106.61±16.8
Single	12.33±3.3	7.54±3.1	11.66±4.3	34.01±11.1	13.86±3.7	27.91±5.2	107.33±19.1
p value	0.800	0.397	0.602	0.460	0.608	0.447	0.757
Education status							
High school	11.87±3.4	7.68±3.8	11.12±3.9	33.62±11.2	12.81±2.9	26.62±4.7	102.75±16.5
University	12.26±3.1	7.79±2.8	11.77±2.9	33.54±9.1	14.25±3.8	27.63±5.2	107.27±17.3
Postgraduate	12.5±3.4	7.85±2.4	13,75±4.9	33.15±11.5	13.65±4.1	26.95±6.3	107.85±23.3
p value	0.834	0.986	0.069	0.983	0.060	0.664	0.599
Children							
Yes	12.33±3.0	7.89±2.8	11.78±3.7	33.22±8.1	14.01±3.6	27.52±5.2	106.89±16.9
No	12.04±3.1	7.50±3.2	12.09±4.3	33.52±10.9	13.80±3.7	27.60±5.4	106.56±18.6
p value	0.464	0.315	0.558	0.820	0.495	0.908	0.888
House ownership							
Self-ownership	12.37±3.2	7.80±2.8	11.70±3.8	32.58±8.7	14.23±3.7	27.70±5.1	106.41±16.9
Renting	12.10±2.91	7.76±2.9	12.07±4.0	34.27±9.0	13.76±3.5	27.33±5.5	107.33±18.1
p value	0.441	0.913	0.402	0.093	0.254	0.537	0.643

Mann-Whitney U was used as a statistical test. p < 0.05 and below was considered statistically significant.

Table 4. Evaluation of variables related to disasters according to General Disaster Preparedness Belief Scale scores of public employees

Variables	Susceptibility	Severity	Benefits	Barriers	Cues to Action	Self-Efficacy	GDBP
Ever experienced any disaster							
Yes	11.30±2.8	7.62±3.5	11,78±4,5	32,50±10,1	14,52±4,2	26,86±5,4	104,60±18,5
No	12.52±3.1	7.83±2.7	11,88±3,7	33,52±8,5	13,90±3,5	27,73±5,2	107,40±17,1
p value	**p< 0.01**	0.645	0,858	0,443	0,270	0,246	0,262
Emergency/Disaster preparedness							
Yes	10,90±3,0	8,66±3,6	11.30±3.5	30.00±11.2	13.07±4.1	25.04±5.3	99.00±20.0
No	12,46±3,1	7,65±2,7	11.95±3.9	33.80±8.4	14.18±3.5	27.92±5.2	107.97±16.7
p value	**p< 0,01**	0.094	0.289	**p< 0.05**	0.107	**p< 0.01**	**p< 0.01**
Having an emergency/disaster kit							
Yes	11.24±2.9	7.98±2.9	12.32±3.5	30.79±8.4	13.58±3.6	26.62±4.6	102.55±16.4
No	12.48±3.1	7.74±2.8	11.76±3.9	33.85±8.9	14.13±3.6	27.75±5.4	107.74±17.5
p value	**p< 0.01**	0.581	0.291	**p< 0.05**	0.302	0.107	**p< 0.05**
Emergency/Disasters training							
Yes	12.,08±3.1	8.38±2.8	11.66±3.7	32.35±9.6	12.87±3.2	25.69±5.0	103.06±19.7
No	12.31±3.0	7.59±2.9	11.93±3.9	33.61±8.6	14.40±3.7	28.13±5.2	108.00±16.4
p value	0.585	**p< 0.05**	0.593	0.310	**p< 0.001**	**p< 0.001**	**p< 0.05**
6 February 2023 earthquake experience							
Yes	11.81±3.7	11.09±4.3	11.09±3.1	35.18±14.6	14.45±3.7	25.90±4.1	109.45±22.9
No	12.27±3.0	7.67±2.7	11.89±3.9	33.24±8.6	14.02±3.6	27.60±5.3	106.71±17.2
p value	0.700	**p< 0.05**	0.423	0.672	0.715	0.217	0.703

reason. Efeoğlu et al. 2021 (21), emphasized that the perceived barrier is low, while self-efficacy and perceived benefit beliefs are high in those with more education. Higher monthly income and occupational status were positively associated with GDBP (19).

In our country, disaster preparedness beliefs are insufficient in highly educated individuals. The socio-demographic characteristics of public employees do not explain their GDBP beliefs—only age and gender show differences on some subscales. The subscales in the HBM interact with individuals' disaster and emergency health preparedness levels. The information obtained provides an opportunity to convey messages that inform and educate about protective measures(22).

Workers 40 and older are more likely to have been caught in a disaster or impacted and to have a higher susceptibility to the fear of disaster and its consequences. In terms of gender, while men have a higher perception of severity about disasters, women have a higher belief that disaster preparedness will reduce the risk and be protective, belief in the benefits of being prepared, and belief in being able to do what is necessary. In other words, although men take disasters seriously, women have a more constructive approach to disaster preparedness. Wirtz and Rohrbeck (2017) (23), found that perceived self-efficacy had a moderate effect on starting preparedness activities, but recognizing others taking action had a strong effect. Women are more prominent in disaster preparedness. In other similar studies, age, gender, marital status and earthquake preparedness scores were not correlated (15,21,24). In a study conducted in a different culture, gender and marital status were important determinants of earthquake preparedness(20). Cultural structure is also important in terms of socio-demographic variables in an individual's disaster preparedness beliefs.

In this study, the determinants of general disaster preparedness beliefs were having an emergency/disaster kit and receiving disaster training. Previous disaster experiences were not effective with GDBP. This may be related to the low number of public employees with disaster experience. On the contrary, some studies emphasize that previous experience is a vital determinant increasing the belief in disaster preparedness(19,20, 24). A study of the different effects of disaster experience in Japan found that experience related to disaster damage increases the preparedness of households, and one of the strongest motivation sources for disaster preparedness is direct and recent disaster experience (25).

This study found that the recent K. Maras (06 February 2024) earthquake disaster increased the fear of disaster and the perception of severity, revealing the belief about the consequences of the disaster on general disaster preparedness. Others who did not directly experience the disaster experienced the sadness and anxiety of this situation but did not turn to preparedness behavior. In order to be prepared, negative experiences such as experiencing disasters and loss of life and property should not be expected.

Within the scope of health protection and empowerment, individuals and policymakers should try to acquire disaster preparedness behavior. Disaster preparedness is a way of life in disaster management (26) and a dynamic approach to health promotion(27). The main goal of the activities in the preparedness phase is to eliminate the negative consequences that may arise by taking precautions in a timely, appropriate and effective manner(28).

In this study, the number of public employees who stated they were prepared for disaster was low. However, while the general GDBP scores, susceptibility belief, and self-efficacy perception of the employees who were unprepared for disaster were high, the perception of perceived barriers was also high. Public employees who want to be prepared for disaster and transform it into behavior have insufficient belief in its usefulness and face obstacles. Among the cultural barriers to earthquake preparedness in Turkey, a combination of high fatalism, high anxiety and high distrust of the system is linked to a lack of action to mitigate damage(24). It is essential that individuals' perceptions of barriers are low to increase their belief in disaster preparedness.

Perceived self-efficacy is an important motivational factor in disaster preparedness(29). Individuals with high self-efficacy feel more empowered to take better care of themselves and their families during disasters(24). In acquiring a positive behavior, individuals should perceive the benefits of the behavior more than the obstacles. Perceived benefit is the extent to which an individual believes they can prevent the risk if they change their behavior(30). The perception of GBDP, susceptibility and self-efficacy beliefs of public employees who state they are unprepared for disasters can be directed toward

positive health behavior and an increase in perceived benefit belief through planned and effective training. Knowing and understanding the benefits of being prepared for disasters will enable them to be more prepared.

Having an emergency/disaster bag is essential in disaster preparedness. However, this study found that few public employees have a disaster kit. Public employees who do not have a disaster kit adopt this practice more as an enabler, see it as an important motivation in the belief of disaster preparedness and have a higher GDBP. The barrier perception of this highly educated group was also found to be high. In future studies, revealing the obstacles will be beneficial in transforming them into positive behaviors.

Similarly, in this study, public employees who stated they did not receive any disaster training had higher belief in cues to action, self-efficacy and GDBP. Public employees with high levels of education who did not receive any training on this subject think that the training increases the beliefs of cues to action, motivators and preparedness. Still, they believe it does not increase their severity toward disasters. The necessity of training for disaster preparedness cannot be disputed. In a study, it was determined that the training program increased the general disaster preparedness beliefs and psychological resilience of the students in the intervention group. Researchers recommend the development and implementation of training programs(31). Having received disaster training before is positively associated with general disaster preparedness(19). However, training should be persuasive to individuals, provide communication between practitioners and individuals, and ensure active participation in disaster preparation. In this context, emergency and disaster scenario drills involving practitioners and the public, along with skills training approaches, can improve perceived self-efficacy and knowledge of and compliance with response procedures(29). The use of mass media and technology can be important to support disaster preparedness education.

Promoting continuous behavioral change toward disaster preparedness and using cultural factors compatible with individuals' worldviews, values, and norms can effectively reduce individual perceptions of barriers. Research in Portugal and the Netherlands highlighted three main strategies expected to promote a "soft" cultural shift toward disaster preparedness over time. These strategies are promoting measures built on already existing cultural values and daily routines, organizing preparedness-related activities as part of daily life events, and improving perceived self-efficacy by showing how individuals can use their unique skills in disaster situations(29).

The results of this study can be generalized to the public institution where the data were collected. Our study has shown that although public employees in this institution have high levels of education, their disaster preparedness beliefs are not at the expected level.

Limitations

The study was conducted among public employees with a high level of education. A limitation of the study is that the name of the public institution where the study was conducted was not specified, as it was not requested by the institution. The results of the study can be generalized to this public institution in Denizli province.

CONCLUSION

The GDBP of the public employees with higher education level who participated in our study are close to medium level. The socio-demographic characteristics of public employees were not related to their GDBP. Those who were not prepared for disasters, did not have an emergency/disaster kit, and did not receive disaster training had firm belief and motivation to prepare for disasters but also high barriers to disaster preparedness. This study reveals the necessity of reducing the perception of barriers and increasing the perception of benefits in this group with high education levels.

The results obtained from the sub-dimensions of general disaster awareness based on HBM should be considered by practitioners and policymakers in the preparation of training and intervention programs. An educational approach that motivates individuals more, reduces their perception of obstacles, ensures their active participation and is appropriate for their cultural characteristics should be adopted in disaster preparedness. Nurses who work more with individuals and society should guide the disaster preparedness phase, identification of risks, implementation of interventions and preparation before disasters occur. Behavioral theoretical models related to disaster preparedness are recommended to improve the disaster preparedness behaviors of individuals and organizations.

Abbreviations: CRED, Centre for Research on the Epidemiology of Disasters; EM-DAT, International Emergency Events Database; GDPB, General Disaster Preparedness Belief Scale; HBM, Health Belief Model.

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RESEARCH ARTICLE

THE RELATIONSHIP BETWEEN MENSTRUAL POVERTY AND DEPRESSIVE SYMPTOMS IN WOMEN AGED 15-49 IN BALÇOVA DISTRICT OF IZMIR

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ABSTRACT

Purpose: The aim of this study is to examine the relationship between menstrual poverty and depressive symptoms in women aged 15-49 living in the Fevzi Çakmak and Çetin Emeç neighborhoods of Balçova, İzmir.

Materials and Methods: This cross-sectional study was conducted among women aged 15-49 living in Balçova between December 2022 and August 2023. A total of 304 women were recruited using a cluster sampling method. Data were collected through face-to-face interviews. The dependent variable was the presence of depressive symptoms, and the independent variable was menstrual poverty. Additional variables included socio-demographic characteristics, economic status, household features, and health perception. Data analysis was performed using Chi-square tests, t-tests, and logistic regression.

Results: According to the Patient Health Questionnaire-9 (PHQ-9) scale, 41.1% of women reported moderate depressive symptoms, and 20.1% experienced moderately severe depressive symptoms. Over the past year, 70.4% of the participants experienced menstrual poverty. Women who experienced menstrual poverty were 2.1 times more likely to report depressive symptoms compared to those who did not (OR=2.1, p=0.012, 95% CI=1.1-3.8). Age and household income were also found to be significant risk factors for depressive symptoms.

Conclusion: The study indicates that menstrual poverty negatively impacts the mental health of women in Balçova. Policymakers are urged to address this issue and develop supportive interventions for women.

Keywords: depressive symptoms, menstrual poverty, poverty, hygiene products

INTRODUCTION

Despite the advances brought by globalization and technological development, poverty remains a persistent sociological issue. Poverty can be broadly defined as the condition in which an individual is unable to meet their basic needs (1). Worldwide, approximately 1.2 billion people experience multidimensional poverty, with women disproportionately affected compared to men (51.3% versus 49.7%) (2).

The impoverishment of women is further compounded by factors such as gender inequality, violence, disparities in education and employment, household inequalities, and low wages. One significant manifestation of this phenomenon is menstrual poverty, which refers to the lack of access

to menstrual hygiene products, clean water, and sanitary facilities (3). Gender-based disparities, discriminatory social norms, cultural taboos, poverty, and limited access to essential services often leave women's menstrual health and hygiene needs unmet. It is estimated that globally, around 500 million women experience menstrual poverty (4). Furthermore, 1.25 billion women and girls lack access to safe, private toilets, with 526 million lacking access to any toilets at all (5).

One of the earliest studies on menstrual poverty was conducted by Crichton and colleagues, examining the hygiene-related challenges and psychosocial impacts experienced by adolescent girls in Kenya during menstruation. The study revealed that many girls face significant difficulties during their menstrual periods due to shame and social stigma (6). In another study conducted among 1,603 young Venezuelan migrant women living on the northwestern border of Brazil, 46.4% reported a lack of access to hygiene kits, 61% stated they could not find clean water to wash their hands, and 75.9% had difficulty accessing safe toilets (7).

In Turkey, two key studies provide substantial data on menstrual poverty. The first is a study published by the Deep Poverty Network during the COVID-19 pandemic, and the second is a 2022 study on menstrual poverty in Turkey conducted by the We Need to Talk Association (8).

Menstrual poverty can lead to elevated levels of stress and anxiety, which in turn may increase the risk of developing depressive symptoms. In a study conducted among young women in Barcelona, Spain, the relationship between menstrual poverty and mental health was explored. The findings revealed that 15.3% of the participants experienced menstrual poverty, and these women were more likely to report poor mental health outcomes (9).

Despite the growing recognition of menstrual poverty as a public health issue, studies investigating its mental health implications remain limited. Therefore, this study aims to address this gap by examining the association between menstrual poverty and depressive symptoms.

The objective of this study is to assess the prevalence of menstrual poverty and its relationship with depressive symptoms among women aged 15-49 living in the Fevzi Çakmak and Çetin Emeç neighborhoods of Balçova, İzmir.

MATERIALS AND METHODS

This study was designed as a cross-sectional investigation, with the target population consisting of women aged 15-49 residing in Balçova. According to data from the Turkish Statistical Institute's (TÜİK) Address-Based Population Registration System, as of December 31, 2021, there were 20,525 women in this age group living in Balçova. The minimum sample size was calculated as 264 women, based on a 50% prevalence, a 6.0% margin of error, and a 95% confidence interval. To account for a design effect of 1.2, the final target sample was adjusted to 317 women.

Balçova's neighborhoods were categorized into two groups according to socioeconomic status. Çetin Emeç neighborhood was selected to represent the lower socioeconomic group, while Fevzi Çakmak neighborhood was chosen to represent the higher socioeconomic group. The number of women aged 15-49 in both neighborhoods was approximately 2,805 and 2,869, respectively. The study aimed to recruit 160 women from each neighborhood. Streets were considered as clusters, and participants were selected by random sampling from households on these streets. A total of 304 women (95.8% of the target sample) were successfully enrolled in the study.

The primary outcome variable was the presence of depressive symptoms, while the primary independent variable was menstrual poverty. Depressive symptoms were assessed using the Patient Health Questionnaire-9 (PHQ-9), a validated tool originally developed by Kroenke et al. in 2001 (10), with its Turkish version validated by Uğur Bilge and colleagues (11). The PHQ-9 is scored from 0 to 27, with the following categories: 1-4 (no depressive symptoms), 5-9 (mild), 10-14 (moderate), 15-19 (moderately severe), and 20-27 (severe). Menstrual poverty was assessed by asking participants, "In the past year, have you experienced difficulty in purchasing menstrual products (e.g., sanitary pads, tampons, menstrual underwear, menstrual cups, menstrual discs)?" Those who responded affirmatively were classified as experiencing menstrual poverty (4). Additional independent variables included age, marital status, education level, employment status, spouse's employment and education level, household structure, perceived income-expenditure balance, perceived health status relative to peers, and family and work-related relationships.

Table 1. Distribution of Participants' Socio-demographic Characteristics

Characteristic	n (%)
Age group (n=303).	
15-24	27 (8.9)
25-29	23 (7.6)
30-34	42 (13.8)
35-39	62 (20.4)
40-44	77 (25.3)
45-49	72 (23.7)
Educational level (n=304)	
No diploma	24 (7.9)
Primary school	57 (18.8)
Middle school	42 (13.8)
High school	97 (31.9)
University	84 (27.6)
Marital status (n=304)	
Married	211 (69.4)
Unmarried	93 (30.6)
Spouse's educational level	
No diploma	12 (5.7)
Primary school	41 (19.4)
Middle school	48 (22.7)
High school	57 (27.0)
University	53 (25.2)
Employment status (n=303)	
Unemployed	181 (59.8)
Insecure job	50 (16.5)
Secure job	72 (23.7)
Spouse's employment status	
Unemployed	22 (10.4)
Insecure job	75 (35.5)
Secure job	114 (54.1)
Income-expenditure perception (n=302)	
Less income than expenditure	211 (69.9)
Equal income and expenditure	68 (22.5)
More income than expenditure	23 (7.6)
Health status compared to peers (n=304)	
Better	107 (35.2)
Same	153 (50.3)
Worse	44 (14.5)
Family relationships (n=303)	
Good	222 (73.3)
Moderate	80 (26.4)
Poor	1 (0.3)

Data were collected via face-to-face interviews using a pre-tested structured questionnaire, either at participants' homes or at community centers provided by Balçova Municipality. Data collection occurred between December 2022 and August 2023.

All statistical analyses were conducted using SPSS version 26.0. Descriptive statistics were reported as percentages, means, and standard deviations. For univariate analyses, Chi-square and t-tests were employed. Multivariate analyses were conducted using Multiple Logistic Regression to explore the relationship between depressive symptoms and other variables. The logistic regression model was constructed using variables that were found to have a significant association with depressive symptoms in the univariate analyses.

Ethical approval for the study was granted by the Non-Interventional Research Ethics Committee of Dokuz Eylül University (Date: October 26, 2022, Approval No: 2022/34-40). Informed consent was obtained from all participants, and necessary permissions were obtained from the Balçova Municipality.

RESULTS

Of the 304 women reached, 153 (50.3%) resided in Çetin Emeç neighborhood and 151 (49.7%) in Fevzi Çakmak neighborhood. The mean age of participants was 37.6 ± 8.3 years (range 15.0-49.0), with the majority being high school graduates (31.9%) and married (69.4%). Additionally, the average number of children was 1.5 ± 1.1 (range 0-4), with 59.5% of the women not employed and 16.5% engaged in insecure employment. Most of their spouses were high school graduates (27.0%) and employed in secure jobs (54.1%). A majority of the women (85.8%) lived in nuclear families, 69.9% reported their income as less than their expenses, and 50.3% stated their health status was the same as their peers. Socio-demographic, health, and family relationship characteristics of the participants are displayed in Table 1.

Of the participants, 99.6% reported using sanitary pads during menstruation, and 22.4% also used tampons. A total of 70.4% of the women reported difficulties in purchasing menstrual products over the past year, and these women were considered to be experiencing menstrual poverty. Reasons for menstrual poverty and the challenges faced during menstruation periods are shown in Table 2. According to the PHQ-9 scale, a majority of women (41.1%) experienced moderate depressive symptoms (Table 2).

Univariate analysis revealed that the presence of

depressive symptoms was significantly higher among those experiencing menstrual poverty (p<0.001). Additionally, age group, education level, employment status, spouse's education and employment status, and income-expenditure perception significantly affected depressive symptoms (p<0.05) (Table 3).

Multiple Logistic Regression Analysis results are presented in Table 4. The presence of menstrual poverty significantly increases the risk of depressive symptoms by 2.1 times compared to those without menstrual poverty (p=0.012, 95% CI=1.1-3.8). Additionally, being under 35 years of age (OR=2.3, p=0.004, 95% CI=1.3-4.2) and having an income lower than expenses (OR=2.6, p=0.002, 95% CI=1.4-4.7) also significantly increase the risk of experiencing depressive symptoms. Cronbach's alpha coefficient was calculated as 0.853 for 9 questions.

Table 2. Distribution of Menstrual Poverty and Related Characteristics

Characteristic (n=304)	**n** (%)
Menstrual products used*	
Sanitary pads	303(99.6)
Tampons	68 (22.4)
Menstrual underwear	0 (0.0)
Menstrual cups	0 (0.0)
Menstrual discs	0 (0.0)
Presence of menstrual poverty	
Yes	214(70.4)
No	90 (29.6)
Reasons for difficulty purchasing products*	
Economic reasons	168(55.3)
Price increases	162(53.3)
Spouse's prioritization	28 (9.2)
Challenges in accessing items/facilities during menstruation*	
Clean toilet paper	119(39.1)
Safe toilet	97 (31.9)
Garbage bin	27 (8.9)
Soap	15 (4.9)
Clean water	2 (0.7)
Activities with difficulty during menstruation*	
Going outside for daily tasks	144(47.4)
Participation in social activities	130(42.8)
Going to work	34 (11.2)
Going to school	24 (7.9)
Presence of depressive symptoms	
No depressive symptoms (0-4 points)	35 (11.5)
Mild depressive symptoms (5-9 points)	62 (20.4)
Moderate depressive symptoms (10-14 points)	125(41.1)
Moderately severe depressive symptoms (15-19 points)	61 (20.1)
Severe depressive symptoms (20-27 points)	21 (6.9)

* Multiple options could be selected by participants

DISCUSSION

This study examined the prevalence of menstrual poverty and its association with depressive symptoms among women aged 15-49 living in two neighborhoods of Balçova District. In our study, 70.4% of women experienced menstrual poverty in the past year. Two separate studies conducted in the United States reported menstrual poverty prevalence rates of 64% among women aged 18-69, mostly unemployed high school graduates, and 14.2% among university-enrolled women aged 18-24 (4,14). Another study conducted in the United Kingdom found that 11% of girls aged 14-21 experienced menstrual poverty (22). In 2024, it was reported that 42% of women aged 13-55 in Jordan experienced menstrual poverty (23). A study conducted in Turkey found that 42.5% of women occasionally struggled to access hygiene products, 22.6% frequently faced difficulties, and 8.5% always encountered such challenges (31).

In our study, the primary reason for menstrual poverty was identified as the rising costs of hygiene products (53.3%). Similar studies in the United Kingdom and Ghana also identified price increases as the main cause of menstrual poverty (24, 25). Additionally, studies conducted in various regions of Asia and Africa in 2020 indicated that women from lower socioeconomic backgrounds were more likely to experience menstrual poverty (26). It can be assumed that tax policies on hygiene products, which contribute to price increases, make it more challenging for women to access these items. In 2018, several European Union countries, including the United Kingdom, France, Spain, and the Netherlands, reduced taxes on hygiene products. In 2019, Germany lowered the tax rate from 19% to 7%, and in 2021, the United States completely eliminated taxes on these products (31). In Turkey, menstrual product taxes were reduced from 18% to 8% in 2022. However, in 2023, VAT rates on hygiene products such as soap, toilet paper, and paper towels were raised from 8% to 20% (32).

Furthermore, in our study, 47.4% of women reported difficulties leaving the house during menstruation, 42% could not participate in social activities, 11.2% faced challenges attending work, and 7.9% experienced difficulties attending school. A UNESCO report from 2014 indicated that 1 in 10 young women could not attend school due to a lack of access to menstrual products and resources (33). Developing effective policies to manage the costs of menstrual hygiene is crucial for women's health and participation in social life.

Table 3. Relationship Between Socio-demographic Characteristics and Depressive Symptoms

Characteristic	Depressive symptoms present (Moderate-severe) n (%)	p Value [a,b]
Menstrual poverty		
Yes (n=214)	163 (76.2)	**<0.001[a]**
No (n=90)	44 (48.9)	
Neighborhood		
Fevzi Çakmak (n=151)	105 (69.5)	0.840[a]
Çetin Emeç (n=153)	102 (66.6)	
Age group		
35 and below (n=112)	85 (75.9)	**0.026[a]**
Above 36 (n=192)	122 (63.5)	
Educational level		
Primary school and below (n=81)	64 (79.0)	**0.006 [b]**
Middle school and high school (n=139)	96 (69.0)	
University and above (n=84)	47 (55.9)	
Marital status		
Married (n=211)	145 (68.7)	0.723[a]
Unmarried (n=93)	62 (66.6)	
Employment status		
Unemployed (n=181)	128 (70.7)	**0.006[a]**
Insecure job (n=50)	40 (80.0)	
Secure job (n=72)	39 (54.6)	
Spouse's educational level		
Primary school and below (n=53)	38 (71.6)	**0.001[a]**
Middle school and high school (n=105)	81 (77.1)	
University and above (n=53)	26 (49.0)	
Spouse's employment status		
Unemployed (n=22)	11 (50.0)	**0.012[a]**
Insecure job (n=75)	60 (79.9)	
Secure job (n=114)	74 (64.9)	
Family structure		
Nuclear family (n=260)	177 (68.7)	0.934[a]
Extended family (n=43)	29 (67.4)	
Income-expenditure perception		
Less income than expenditure (n=211)	159 (75.3)	**<0.001[a]**
Equal income and expenditure (n=68)	33 (48.5)	
More income than expenditure (n=23)	13 (56.5)	
Health status compared to peers		
Better (n=107)	68 (63.5)	0.430[a]
Same (n=153)	107 (69.9)	
Worse (n=44)	32 (72.7)	
Family relationships		
Good (n=222)	149 (67.1)	0.381[a]
Moderate (n=80)	57 (71.2)	

[a] *Pearson chi-square test p value.* [b] *Mantel-Haenszel chi-square test p value.*

According to the Patient Health Questionnaire-9 (PHQ-9), used in our study, 41.1% of women exhibited moderate depressive symptoms, 20.1% had moderately severe depressive symptoms, and 6.9% had severe depressive symptoms. The adaptation of HSA-9 into Turkish was conducted by Bilge et al. (2016). As a result of the reliability analysis, the Cronbach's Alpha internal consistency coefficient was calculated as 0.842 (11). In the present study, the Cronbach's Alpha coefficient was

Table 4. Effect of Menstrual Poverty on the Risk of Depressive Symptoms - Logistic Regression Analysis Results

Characteristic (Reference group)	P Value	OR (95% CI)
Menstrual poverty (No)	**0.012**	2.1 (1.1-3.8)
Age group (Above 36)	**0.004**	2.3 (1.3-4.2)
Educational level (University and above)	0.061	2.0 (0.9-4.5)
Middle school and above	0.283	1.4 (0.7-2.5)
Employment status (Secure employment)	0.835	1.1 (0.4-2.9)
Unemployed	0.610	0.8 (0.4-1.6)
Income-expenditure perception (Equal or more)	**0.002**	2.6 (1.4-4.7)

calculated as 0.853. The value between the two scales is similar. In a study conducted in Mexico, depressive symptoms were observed in 25.6% of women, while in North Carolina, 31.2% of Latin women, farmers, and those facing economic difficulties exhibited severe depressive symptoms (12, 13). Additionally, a study conducted in Kenya found that economic conditions, abuse, and violence increased depressive symptoms in 57% of women (27). In studies conducted in Turkey, the prevalence of depressive symptoms ranged from 10.2% to 28.3% (28). The differences in prevalence may be attributed to variations in the quantitative and qualitative characteristics of the study samples or differences in analysis methods.

Although few studies have examined the association between menstrual poverty and depressive symptoms in women, the limited available research suggests that menstrual poverty increases depressive symptoms in women, consistent with our findings. Similar to our study, significant associations between menstrual poverty and the risk of depressive symptoms have been found in studies conducted in the United States, Spain, and France (4, 9, 15). Similar results were also observed in a study conducted in a refugee camp in Jordan (23). Menstrual products are considered basic necessities, and our findings support the significant relationship between unmet basic needs and the likelihood of deteriorating mental health. The stigma surrounding menstruation, insufficient toilets and privacy measures, as well as the lack of clean water, sanitation, and hygienic menstrual products, may contribute to stress, social isolation, depression, and anxiety, further exacerbating difficulties during menstruation (34).

Our study also found that being aged 35 or younger and having household income lower than expenses increased the risk of depressive symptoms. Similarly, studies conducted in Sweden and the United States have shown that as age decreases, the prevalence of depression and anxiety increases (16, 29). Another study conducted in Finland, Poland, and Spain found a significant relationship between depression and low socioeconomic status (30). Despite these results, longitudinal studies covering the lifespan of adults are needed. Another study conducted in Turkey found a significant relationship between income-expenditure perception and depression. Therefore, considering that period poverty parallels economic status, these results may also apply to individuals experiencing period poverty (35). Besides income, access to healthcare services, education, menstrual taboos, discrimination, and social, societal, and economic participation have also been identified as factors that increase period poverty (36).

Although univariate analyses in our study indicated a significant relationship between educational and employment status and depressive symptoms, multivariate logistic regression analysis did not yield significant results. In contrast to our findings, other studies have identified significant associations. For instance, a study conducted in Indonesia in 2022 found that the risk of depression increased as educational attainment decreased (20). Another study conducted in the United Kingdom found a significant relationship between depression and job loss (21).

Our study has certain limitations. It was conducted among women living in the Fevzi Çakmak and Çetin Emeç neighborhoods of Balçova District in İzmir, and thus, the results can only be generalized to women living in this specific area. The reliance on self-reported data regarding income-expenditure perceptions and menstrual poverty is another limitation of the study. Additionally, the cross-sectional nature of the study limits the ability to assess causality between menstrual poverty, depressive symptoms, and related factors.

Another limitation is the absence of a validated and reliable scale for identifying menstrual poverty. Although our measurement is consistent with the limited number of studies in the literature, developing a scale specific to this issue could help mitigate this limitation. The fact that the research was conducted by a single researcher and data were collected face-to-face contributes to consistency. Given the limited research on this topic globally, our study is important in contributing to the literature.

CONCLUSION

In our study, 41.1% of women experienced moderate depressive symptoms, 20.1% had moderately severe symptoms, and 6.9% exhibited severe depressive symptoms. The prevalence of menstrual poverty in the past year was 70.4%. The most common reason for difficulty in accessing menstrual products was economic hardship. Among women, 39.1% struggled to access clean toilet paper, and 31.9% faced difficulties accessing a safe toilet. During menstruation, 47.4% of women had trouble leaving the house for daily activities, 42.8% had difficulties participating in social activities, 11.2% faced challenges attending work, and 7.9% had issues attending school. The presence of menstrual poverty significantly increased the risk of depressive symptoms. Additionally, being aged 35 or younger and having income lower than expenses also increased the risk of depressive symptoms.

Menstrual poverty is not an issue of privilege or biological sex but a matter of human rights. All women have the right to access clean and sufficient menstrual products, safe toilets, clean water, and soap. Issues such as poverty, education, health, hygiene materials, and gender equality have inspired the framework for the United Nations Sustainable Development Goals. Therefore, it is crucial for all countries to combat poverty in all its dimensions. Current studies show that many young women cannot afford hygiene products to meet their menstrual needs, which may negatively affect their mental health. To support these women, improving access to affordable hygiene products and considering these results when formulating tax policies is essential. Budget allocations and comprehensive audits for the provision of clean water, toilet paper, and trash bins in all public restrooms, particularly in public schools, dormitories, and universities, are crucial. Additionally, menstrual products, encompassing a wide variety of options (e.g., not only sanitary pads but also tampons, menstrual cups, and period underwear), should be provided free of charge in all public restrooms, especially in public schools, dormitories, and universities. It is important that institutions, NGOs, and local governments providing financial, clothing, and food support to families also consider offering menstrual product support. Furthermore, the presence of depressive symptoms should be taken into account when menstrual poverty is present.

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RESEARCH ARTICLE

INVESTIGATION OF LATERAL TRUNK FLEXOR MUSCLE PERFORMANCE IN INDIVIDUALS WITH CHRONIC NECK PAIN: A CASE-CONTROL STUDY

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ABSTRACT

Purpose: To investigate lateral trunk flexor muscle performance and thoracolumbar mobility in individuals with chronic neck pain (CNP) compared to asymptomatic controls.
Materials and Methods: This case-control study included 20 participants with CNP and 20 asymptomatic controls. Pain and disability variables in the CNP group were assessed via Visual Analogue Scale (VAS) and Neck Disability Index. Lateral trunk flexor muscle performance was evaluated on endurance, strength, and thoracolumbar rotation range basis using the side-bridge lateral trunk flexor endurance test, hand-held dynamometer, and bubble inclinometer, respectively. Group differences were analyzed using the Independent Sample's t-test.
Results: The individuals with CNP reported pain intensity scores of 6.32 at rest and 6.63 during activity, on the VAS. Additionally, their neck disability index value was found to be 45.6%, indicating a moderate disability level. Compared to the asymptomatic controls, the CNP group demonstrated significantly lower lateral trunk flexor endurance, strength, and thoracolumbar rotation, with large effect sizes ($p<0.05$, Cohen's $d>0.71$).
Conclusion: Individuals with CNP exhibit reduced lateral trunk flexor muscle performance and thoracolumbar mobility compared to asymptomatic individuals. These observations suggest that interventions focused on improving trunk muscle strength, endurance, and mobility may be advantageous in managing CNP.

Keywords: chronic neck pain; lateral trunk muscle performance; thoracolumbar rotation.

INTRODUCTION

Chronic neck pain (CNP) is a prevalent musculoskeletal disorder that significantly impacts individuals' daily lives and socioeconomic factors (1). The underlying causes of CNP are multifactorial including muscle strength imbalances between superficial and deep layers of the cervical musculature, poor posture, and psychosocial factors (1,2). While these factors emphasize the localized impact of CNP, emerging research suggests that its effects may extend beyond the cervical region (3–5).

Trunk muscle performance plays a crucial role in maintaining spinal stability and controlling head and neck movements (6). Weakness or dysfunction in these muscles can lead to altered biomechanics, increased spinal loading, and ultimately, the development and persistence of neck pain (6). Schweigart et al. explained their experimental model for determining head rotation perception in space, attributing head perception to two main factors: head-on-trunk rotation and stationary trunk biomechanics (7). From a clinical perspective, Falla et al. reported that individuals with CNP walk with increased stiffness in the trunk region (8). Also, Christensen et al. showed alterations in axio-scapular muscle activity during the acute phase of neck pain (9). In addition to this evidence, regional interdependence theory describes the human body as an interconnected system with compensation mechanisms that are neurological, fascial, and biomechanical in nature (10,11). The theory supports the idea that muscle strength imbalances and pain may arise in compensating body parts, regardless of their proximity to the painful area (10). Ghamkar et al. provided findings supporting the theory, revealing altered muscle strength in pain-free regions, such as the shoulder, trunk, and scapulothoracic area, in individuals with neck pain (11). Moreover, growing evidence from systematic review and meta-analysis suggests that a combined therapeutic approach targeting both the cervical and thoracic regions may be more effective for managing CNP than focusing on the neck alone (12). This approach recognizes the interconnectedness of the cervical and thoracic spine and the potential for muscular alteration of the trunk to contribute to neck pain.

Overall, this research highlights that CNP is not just a localized issue; it has broader implications for movement control, muscle function, and potentially spinal health. However, the specific performance of the lateral trunk muscles, which are critical for maintaining spinal alignment, postural control, and daily functional activities, has not been extensively studied in this population.

The aim of this study was to compare lateral trunk flexor muscle strength and endurance and thoracic rotation between individuals with and without CNP. We hypothesized that individuals with CNP would exhibit decreased lateral trunk flexor strength and endurance as well as reduced trunk rotation range of motion compared to asymptomatic individuals.

MATERIALS AND METHODS

Design

This case-control study was conducted at Dokuz Eylul University. Ethical approval was obtained from the Dokuz Eylul University Non-invasive Research Ethics Committee (Number: 2023/04-01, Date: 15.02.2023), and all procedures adhered to the Declaration of Helsinki. Participants provided informed consent before participating in the study.

Participants

The total sample size was calculated using the pilot data set (The CNP group n=9, mean age=37.44±13.22 years, mean body mass index (BMI)=24.96±4.54 kg/m2; the control group n=9, mean age=41.66±6.87 years, mean BMI=26.87±3.53 kg/m2). The total sample size was 38, with an effect size of 1.22, a power of 0.95, and two tails, using G*Power for Windows (v3.1.9.4, Düsseldorf University, Germany). In the pilot sample, we evaluated all independent variables of thoracolumbar range of motion, lateral trunk endurance, and lateral trunk flexor strength. However, the reference value for the sample size calculation was based on the right lateral trunk strength, which represents the variable with the smallest difference between the pilot groups (13).

The study recruited participants from the Neurosurgery Outpatient Clinic at Dokuz Eylul University. Individuals experiencing neck pain lasting over six months were included in the CNP group. Exclusion criteria for this group included previous or current spinal pain (except neck pain), neurological deficits related to neck disorders, any history of spinal trauma or surgery, and diagnoses of neurological or musculoskeletal conditions that could affect trunk muscle performance. The control group consisted of asymptomatic individuals with no current or history of spinal pain, as well as no history of trauma, surgery, or diagnosed conditions that could impact trunk muscle function.

A total of forty-seven participants were assessed for eligibility, two participants from the CNP group were excluded regarding the criteria of current low back pain (n=2), and five participants from the control group were excluded regarding the criteria of low back pain (n=4), and history of spinal trauma (n=1). Forty participants were enrolled in the study, comprising twenty in the CNP group and twenty in the control group.

Measurements

The Visual Analog Scale (VAS) was used to assess participants' neck pain severity at rest and during activity. Participants were asked to indicate their pain intensity on a 100-mm visual analog scale, where 0 represented no pain and 100 indicated the worst imaginable pain (14). Additionally, the Neck Disability Index (NDI) was used to evaluate self-reported neck pain-related disability. The NDI scores range from 0 to 100, with higher values indicating greater functional impairment (15).

The side-bridge lateral trunk flexor endurance test

The participant was positioned in a side-lying posture on their dominant side, with their legs extended and resting on their forearm and elbow. The shoulder was abducted to a 90-degree angle, and the elbow was flexed at a 90-degree angle. The test instruction was to 'lift your hip off the bed and maintain a straight line between your shoulder, hip, and feet while placing the hand of your free arm on the contralateral shoulder (16). Throughout the assessment, the examiner monitored the participant's alignment to ensure their entire body remained straight. If the participant deviated from the test position, verbal commands were provided to correct their posture and continue the trial. The test concluded if the participant was unable to maintain a straight posture for more than three seconds or if they experienced excessive fatigue or discomfort, at which point the time was recorded (16) (Figure 1).

Figure 1. The side-bridge lateral trunk flexor endurance test

The muscle strength of lateral trunk flexors

The lateral trunk flexor muscle strength of each side was evaluated using a handheld dynamometer (Lafayette Instrument, UK), positioned at the mid-trunk by the examiner. Participants were securely positioned on a plinth using straps, with their knees and hips flexed at 90 degrees and their hands crossed over their chest. The examiner stood perpendicular to the participant and provided resistance to lateral trunk flexion using the handheld dynamometer to minimize actual trunk movement. Participants were instructed to exert maximal effort to bring their shoulder towards the ipsilateral iliac crest and sustain that position for 5 seconds. Trials exhibiting excessive movement were excluded, with excessive movement defined as any detectable movement or rotation in the transverse plane. Adequate rest periods (minimum 30 seconds) were provided between trials. Three trials were conducted, and the average strength value was recorded in kilograms for each side. The measurement procedure demonstrated excellent inter-rater reliability, with an intraclass correlation coefficient (ICC) of 0.88 reported (17) (Figure 2).

Figure 2. The muscle strength of lateral flexors

The side-lying thoracolumbar rotation measurement

The trunk rotation measurements were performed as outlined by Iveson et al. Participants were positioned in a side-lying posture with their hips and knees flexed to 90 degrees (18). They then rotated their trunk posteriorly toward the treatment table, attempting to approximate their scapulae to the surface. Measurements were obtained using a bubble inclinometer (Baseline, USA) placed across the medial clavicles, and the average of three trials was used for analysis. The intra-rater reliability for the measurements was consistent for both right and left side rotation, reported as ICC=0.95 for the right side and ICC=0.94 for the left side (18) (Figure 3).

Figure 3. The side-lying thoracolumbar rotation measurement

Statistical Analyses

Statistical analyses were performed using IBM® SPSS Statistics 25 with data from 40 participants. The Shapiro-Wilk test and descriptive statistics confirmed that the data were normally distributed. Demographic characteristics were compared between groups using the Independent Samples t-test, and descriptive variables were presented as means and standard deviations.

The Independent Samples t-test was performed to compare trunk muscle performance variables (lateral trunk flexor endurance and strength, thoracolumbar rotation angle) between the CNP and asymptomatic groups. The statistical significance level was set at $p<0.05$. Effect sizes were calculated according to the Cohen's d and were interpreted as follows: 0 to 0.40, small effect; 0.41 to 0.70, moderate effect; and 0.71 or higher, large effect (13,19).

RESULTS

The demographic variables of the groups, as well as the pain intensity and disability level variables for the neck pain group, are presented in Table 1. The age, weight, and BMI values of the neck pain group were higher ($p<0.05$), while there was no significant difference between the groups in terms of height ($p>0.05$). The individuals with CNP reported pain intensity scores of 6.32 at rest and 6.63 during activity, on the VAS. Additionally, their neck disability index value was found to be 45.6%, indicating a moderate disability level (Table 1).

The comparison of lateral trunk flexor muscle performance between the chronic neck pain and asymptomatic groups was presented in Table 2. Lateral trunk flexor endurance, lateral trunk flexor strength, and thoracolumbar rotation degrees were lower in the CNP group compared to the asymptomatic group ($p<0.05$) for both sides. The effect size was large for all differences ($d> 0.71$) (Table 2).

DISCUSSION

This study demonstrated that individuals with chronic neck pain exhibited significantly reduced performance in several key areas related to trunk function compared to asymptomatic controls. Specifically, individuals with CNP had lower endurance and strength in their lateral trunk flexors, as well as decreased thoracolumbar rotation. These findings align with existing research suggesting that CNP is often associated with impaired neuromuscular function, not only in the neck region but also affecting the trunk with a new perspective in terms of lateral trunk flexor muscle performance.

The findings of altered lateral trunk muscle endurance and strength in the CNP group are consistent with previous studies that have reported impairments in trunk flexor endurance in individuals with CNP (3,20). Previous research has predominantly focused on trunk flexor endurance rather than isometric muscle strength (3,20). Additionally, our study reveals that both endurance and strength measures of the lateral

Table 1. Demographic and pain-related variables of the groups

Variables	The CNP Group (n=20)	The Asymptomatic Group (n=20)	
	Mean (SD)	Mean (SD)	p[a]
Age, year	43.2 (6.19)	37.25 (9.86)	0.028*
Weight, kg	69.95 (8.47)	62.88 (11.36)	0.032*
Height, cm	162.75 (4.64)	161.2 (5.23)	0.328
BMI, kg/m^2	26.44 (3.21)	24.15 (3.74)	0.045*
The pain intensity at rest, cm on VAS	6.32 (1.54)	-	-
The pain intensity at activity, cm on VAS	6.63 (1.65)	-	-
Neck Disability Index, %	45.6 (8.98)	-	-

Abbreviations: CNP, Chronic Neck Pain; [a], Independent Samples t-Test; SD, Standard Deviation; BMI, Body Mass Index; *,$p<0.05$

Table 2. Comparison of lateral trunk flexor muscle performance between the chronic neck pain and asymptomatic groups

Variables		The CNP Group (n=20)	The Asymptomatic Group (n=20)		
		Mean (SD)	Mean (SD)	p	Cohen's d
Endurance of lateral trunk flexors, second	right	12.40 (5.24)	34.57 (16.01)	<0.001*	1.861
	left	11.71 (3.03)	33.42 (15.18)	<0.001*	1.983
The strength of lateral trunk flexors, kg	right	10.71 (2.03)	14.54 (2.86)	<0.001*	1.544
	left	10.71 (2.77)	14.39 (2.55)	<0.001*	1.382
The range of motion of thoracolumbar rotation °	right	50.46 (8.59)	66.35 (10.38)	<0.001*	1.667
	left	50.94 (8.78)	65.10 (9.83)	<0.001*	1.519

Abbreviations: CNP, Chronic Neck Pain; SD, Standard Deviation; *, p<0.05 in Independent Samples t-test.

trunk flexors were lower in individuals with CNP compared to asymptomatic controls. The underlying reasons remain unclear, but these alterations could be attributed to neurophysiological adaptations. Elgueta-Cancino et al. demonstrated that the motor cortex representation of the deep neck flexors is directly connected to the trunk, face, and neck regions in the motor homunculus (21). If we accept the involvement of deep neck flexors in our CNP group, we can speculate that this involvement initiates a change in the neurophysiological patterns of the trunk muscles due to their connection through the motor cortex. Yalcinkaya et al. also reported that lumbar motor control could be affected in individuals with CNP through changes in the contractile properties of the transversus abdominis (4). If we consider the role of transversus abdominus during trunk rotation and lumbopelvic control (22), we can hypothesize that impairment of the lateral trunk flexor muscles may lead to a decrease in thoracolumbar rotation observed in our study.

The trunk musculature provides proximal stability, enabling the transfer of force and angular momentum between the limbs (23). As a result, the trunk is often characterized as a critical 'powerhouse' due to its ability to transmit, absorb, and redirect kinetic energy during functional tasks (24). Moghaddas et al. showed that individuals with CNP exhibited reduced thoracolumbar rotation during functional tasks such as overhead reaching (25). In parallel, we found that a decreased active range of motion in thoracolumbar rotation was present in the CNP group compared to the asymptomatic group. Joshi et al. showed that thoracic mobility was reduced in the neck pain population and revealed an association between thoracic kyphosis and postural alterations in the cervical spine (26). More specifically, Falla et al. reported that individuals with CNP exhibit decreased thoracic rotational movement during walking (8). These findings indicate the importance of adequate thoracolumbar rotation for optimal movement. The reduction in trunk mobility may be linked to compensatory protective mechanisms employed to minimize spinal loading and pain, as suggested by Van Der Hoorn et al., who found reduced trunk residual rotation in individuals with low back pain (27). Further research is needed to explore the long-term consequences of these adaptations and to develop targeted interventions that address both trunk muscle function and thoracolumbar mobility in individuals with CNP. Also, the lateral trunk muscles facilitate the force transfer between the upper and lower extremities (23). Our findings of decreased endurance and strength could point out superficial muscles of the trunk region may compensate for the current pain and this overuse frame of CNP leads to muscle imbalance, coordination, and poor postural stability through the axis of the lateral trunk region. Research that further explores the mechanical coupling between the thorax, neck region, and upper extremities might expand the knowledge of

disabilities or functional movement alterations due to CNP.

Several limitations should be considered when interpreting the findings. Firstly, the small sample size may have limited statistical power of our findings due to the limited (n=18) number of participants in the pilot findings. To reach a larger sample size estimation would have been preferable to impact the generalizability of the findings. Future studies with larger and more diverse samples are needed to confirm and expand upon our findings. Secondly, while our study focused on lateral trunk muscle performance, other muscle groups contributing to trunk stability and movement, such as the anterior and posterior trunk muscles, were not assessed. A comprehensive evaluation of trunk muscle function would provide a more complete understanding of the co-occurring mechanisms employed in neck pain conditions. Also, using novel instruments such as electromyography or ultrasonography could have provided a more detailed edge of the underlying neuromuscular alterations. In addition, the measurement of thoracolumbar rotation angle may obscure distinct contributions of thoracic, lumbar, and even neck mobility to the observed findings due to the biomechanical coupling mechanism of the spine and the rib cage. Therefore, future research could examine the long-term results of data isolating the thoracic region, such as a 3D motion analysis system. Finally, the cross-sectional design of this study limits our ability to draw definitive conclusions about the cause-effect relationships between CNP, trunk muscle function, and thoracolumbar mobility. Longitudinal studies are necessary to investigate the long-term effects of CNP on these variables. Additionally, exploring the potential influence of other factors, such as pain duration, psychosocial factors, and physical activity levels, would provide a more comprehensive understanding of CNP's impact on trunk function.

CONCLUSION

This study provides evidence of reduced lateral trunk flexor muscle performance and thoracolumbar mobility in individuals with chronic neck pain compared to asymptomatic individuals. These findings highlight the potential importance of addressing trunk muscle function and thoracolumbar mobility in the management of CNP.

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RESEARCH ARTICLE

DOES THE PREGABALIN SHOW NEUROPROTECTION IN A HEAD INJURY RAT MODEL?

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ABSTRACT

Purpose: Traumatic brain injury (TBI) encompasses both primary and secondary injury mechanisms that contribute to its overall pathogenesis. Pregabalin is used in the treatment of neuropathic pain. Treatments targeting excitotoxicity may be useful in the posttraumatic period. Purpose of this study is to examine the possible neuroprotective effects of pregabalin administered in a rat model of head trauma.
Materials and Methods: 32 male Wistar rats were used. The rats were randomly assigned into four distinct groups, each consisting of eight subjects: a sham group, a trauma group, and groups receiving treatment with methylprednisolone (MPSS) and pregabalin. In Brain Samples, assessment of malondialdehyde (MDA), glutathione peroxidase (GPx), and superoxide dismutase (SOD) enzyme activities were evaluated
Results: Pathological analysis showed that pregabalin treatment lessened the trauma-induced damage to the brain tissue. There was a notable statistical discrepancy in MDA levels when comparing the trauma group with the others (P=0.000). Both the Pregabalin and MPSS groups exhibited elevated GPx and SOD levels relative to the trauma group, with the differences being statistically significant (respectively GPx and SOD; P=0.002, P=0.001).
Conclusion: Pregabalin and MPSS protected the brain against traumatic injury by attenuating lipid peroxidation and inflammatory process

Keywords: Pregabalin, Rat model, Head injury, Antioxidant

INTRODUCTION

Traumatic brain injuries cause the highest morbidity and mortality rates among all traumatic injuries worldwide. In the United States of America, there are 1.4 million cases of head trauma and 50000 deaths per year (1,2). TBI encompasses both primary and secondary injury mechanisms that contribute to its overall pathogenesis. While primary injuries occur instantaneously due to mechanical forces and are beyond our control—leading to disruptions in the functionality of blood vessels, neurons, and their axonal connections—secondary injuries present an opportunity for intervention (3). The secondary injury phase is characterized by a cascade of deleterious processes, including oxidative stress, excitotoxicity, mitochondrial dysfunction, inflammatory responses, damage to the blood-brain barrier and subsequent brain oedema (4,5). Among these secondary mechanisms, excitotoxicity plays a crucial role; it refers to the pathological consequences arising from excessive or prolonged stimulation of neurons by excitatory neurotransmitters such as glutamate, ultimately leading to neuronal cell death (6).

Pregabalin is used in the treatment of neuropathic pain associated with various medical conditions, including diabetic neuropathy, neuralgia, and complex regional pain syndrome, as noted by Tassone DM (7). Although its chemical composition resembles that of gamma-aminobutyric acid (GABA), pregabalin does not function like GABA nor does it interact with GABA receptors. Research indicates that pregabalin binds to the α2-δ subunit of voltage-gated calcium channels. This strong binding action results in a reduction of Ca2+ influx at presynaptic nerve terminals, subsequently diminishing the release of several neurotransmitters, including glutamate and noradrenaline, as reported by Joshi I and Shneker BF (8,9).

Treatments targeting excitotoxicity may be useful in the posttraumatic period. The aim of this research is to examine the possible neuroprotective effects of pregabalin administered in a rat model of head trauma. For this purpose, the effects of pregabalin were evaluated by biochemical and pathological analysis.

MATERIALS AND METHODS

Experimental groups

The research was conducted at the Experimental Animal Laboratory of Ankara Training and Research Hospital, under the auspices of the Experimental Animal Ethics Committee of the same institution (Date: 01.11.2024, Approval No: 0086). A total of thirty-two male Wistar rats, weighing between 240 and 305 grams, were included in the study. Animals were divided into 4 groups, each of eight animals, with all assignments carried out blindly to ensure objectivity.

The sham group underwent only a scalp incision. In the second group, designated as the trauma group, the rats experienced closed head trauma. The third group, referred to as MPSS, received an immediate single dose of MPSS sodium succinate (Prednol, Mustafa Nevzat, Istanbul, Turkey) at 30 mg/kg via intraperitoneal injection right after the trauma incident. Finally, the fourth group, labeled as the pregabalin group, was administered pregabalin at 30 mg/kg via gavage (10,11,12).

Type of surgery

Surgery was performed under general anaesthesia. The anaesthetist anaesthetised the rats with a mixture of IM ketamine hydrochloride (Ketalar; Pfizer, Istanbul, Turkey) and xylazine (Rompun; Bayer, Istanbul, Turkey) (50 mg/kg ;10 mg/kg). The procedures were performed in prone position. Animals were subjected to closed head trauma using the method described by Marmarou et al: A blunt object weighing 500 g was freely dropped from a height of 1 m through a copper tube onto a metal disk above the animal's skull (13). After induction of head trauma, the metal disk was removed. Twenty-four hours after the study began, the animals were humanely sacrificed via using 100 mg/kg of ketamine hydrochloride (Ketalar; Pfizer, Istanbul, Turkey) intraperitoneal injection.

The cranial bones and overlying scalp were carefully extracted as a single unit. After midline separation, one brain hemisphere was assigned for pathological evaluation, while the contralateral hemisphere was reserved for biochemical assays.

Evaluation of Pathological Sections

The samples were fixed in 10% formalin and processed using standard protocols with a LEICA ASP 300S. After embedding in paraffin, 4-µm sections were cut on a LEICA RM 2255 microtome, stained with hematoxylin and eosin (H&E), and examined under an OLYMPUS BX51 microscope.

Measurement of MDA, GPx, and SOD enzyme activities

Tissue samples underwent homogenization with 1 ml of distilled water using an Ultra Turrax tissue homogenizer. The resulting homogenates were utilized to assess levels of MDA, SOD, and GPx activity. All procedures were conducted at a temperature of 4°C. The protein content in the brain samples was quantified employing the Lowry method as outlined by Lowry et al (14). The extent of lipid peroxidation in the brain was evaluated by measuring MDA concentration. MDA levels were quantified using the NWLSS NWKMDA01 assay provided by Northwest Life Science Specialties, with results expressed as micromoles per gram of protein. GPx activity in the brain was determined through a colorimetric assay kit based on the protocol developed by Paglia and Valentine (15). GPx concentrations were reported as milliunits per gram of protein. Furthermore, SOD activity was analyzed with a specialized superoxide dismutase assay, with results expressed in units per gram of protein.

Statistical analysis

Each experimental group comprised 8 specimens, necessitating non-parametric analyses as per established guidelines (16). Data are presented as median ± IQR (25th–75th percentiles). Intergroup comparisons were first evaluated with the Kruskal-Wallis test; where significance was reached ($p < 0.05$), post hoc Mann-Whitney U tests with Bonferroni-adjusted p-values were applied for subgroup contrasts. Statistical procedures were executed in IBM SPSS software (Version 23, Armonk, NY).

RESULTS

Pathological examination

Pathological assessment revealed pronounced perivascular and interstitial edema in injured brain regions, with no such changes detected in the sham group (Figure 1a). In contrast, the trauma group exhibited extensive edema formation (Figure 1b). However, rats administered pregabalin or MPSS showed a significant attenuation of perivascular edema relative to untreated controls (Figure 1c). Furthermore, the efficacy of pregabalin in reducing edema was comparable to that of MPSS (Figure 1d).

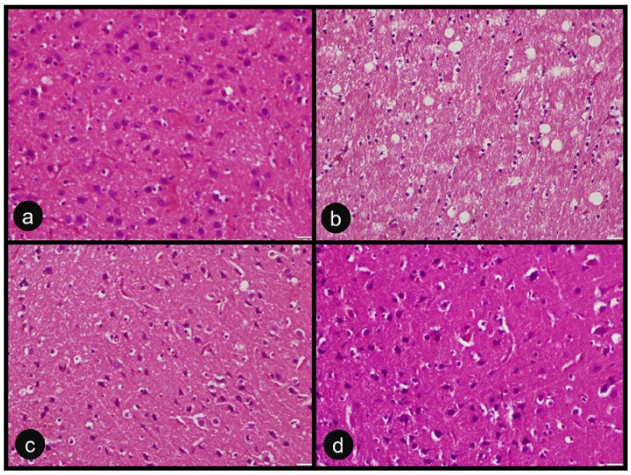

Figure 1. This figure displays tissue sections stained with H&E staining, highlighting clear differences in pathology among the various study groups. Image (a), representing the Sham group, shows undamaged brain tissue, serving as a normal reference point. Conversely, image (b), from the trauma group, demonstrates pronounced swelling around blood vessels and within the interstitial spaces, indicating substantial pathological alterations. Image (c), depicting the MPSS group, reveals a moderate degree of perivascular fluid accumulation, implying a limited beneficial impact from the treatment. Finally, image (d), from the pregabalin group, shows only slight perivascular edema, suggesting a more positive outcome with this therapeutic approach.

MDA Activity

There was a notable statistical discrepancy in MDA levels when comparing the trauma group with the others (P=0.000). It was observed that trauma caused a significant increase in MDA activity. In addition, the evaluation indicated that there was a significant difference between the pregabalin group and the trauma group when considering the MDA level (P=0.001). Furthermore, while there was a significant variation in MDA levels between the MPSS group and the trauma group, this incompatibility was not evident when comparing the MPSS group with the pregabalin group (P=0.001 for the trauma vs. MPSS; P=0.161 for the pregabalin vs. MPSS). These findings are illustrated in Figure 2.

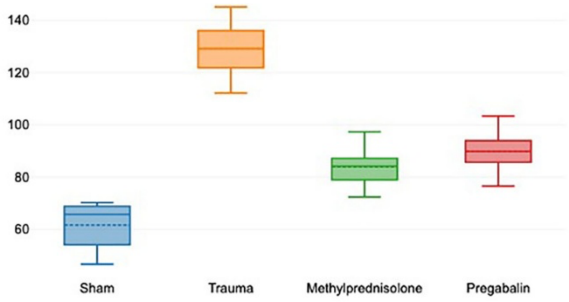

Figure 2. Box plot showing median MDA levels in brain tissue. Lipid peroxidation content is expressed as micromoles per gram protein.

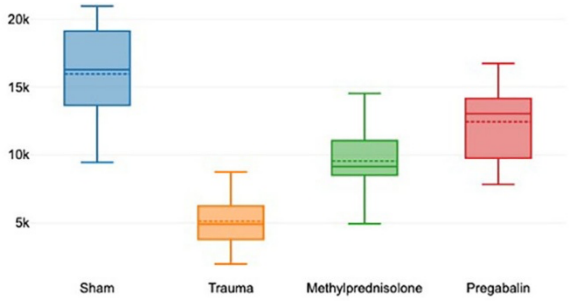

Figure 3. Box plot showing median SOD levels in brain tissue. SOD content of the brain is expressed as milliunits per gram protein.

GPx Activity

In the study, the levels of GPx was found to be significantly lower in trauma group tissue compared to others (P=0.000). Both the Pregabalin and MPSS groups exhibited elevated GPx levels relative to the trauma group, with the differences being statistically significant (P=0.002). However, no statistically significant difference was observed in GPx levels when comparing the Pregabalin group to the MPSS group (P=0.6; see Figure 3).

SOD Activity

A significant reduction in SOD levels was found in the trauma group when comparison done to the others (P=0.000). The group receiving pregabalin demonstrated a statistically significant difference in SOD activity relative to the trauma group; however, the difference was non-significant between the pregabalin group and the MPSS group (P=0.001 for the trauma comparison, and P=0.074 for the MPSS comparison) as illustrated in Figure 4.

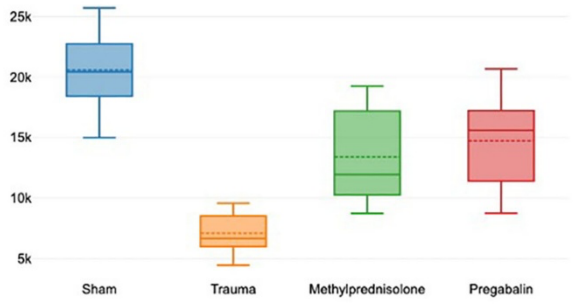

Figure 4. Box plot showing median GPx levels in brain tissue. GPx content of the brain is expressed as units per gram of protein.

DISCUSSION

Immediately after trauma to the central nervous system, primary damage is followed by a series of auto destructive mechanisms that lead to secondary damage. The resulting secondary damage causes progressive degeneration of the parenchyma, leading to chronic neurodegeneration (17). One of the main secondary mechanisms after traumatic injury is the attack of free radicals on the cell membrane (18), by the process of lipid peroxidation all cellular components, including unsaturated fatty acids, are affected and damaged (19). A frequently used biomarker that is an indicator of the overall level of lipid peroxidation is the plasma MDA concentration (20). In our study, higher MDA activity was detected in the trauma group exposed to trauma than the others.

Metabolic surges can lead to the reduction of oxygen into reactive species such as superoxide, hydrogen peroxide, and hydroxyl radicals, triggered by various stimuli (20). The enzyme SOD plays a crucial role in neutralizing superoxides by converting them into hydrogen peroxide. Subsequently, hydrogen peroxide is further reduced to water through the action of cytosolic antioxidants, specifically catalase and GPx (21). Brain tissue is very vulnerable to oxidative damage due to its fast metabolism, high content of polyunsaturated fatty acids and relative lack of antioxidant defenses (22). In our research, we observed a notable reduction in tissue levels of SOD and GPx in the pregabalin and MPSS group compared to non-drug the traumatic animals. Pathological examination revealed that traumatic brain injury induced pronounced perivascular edema, which was substantially attenuated by pregabalin treatment.

MPSS has been identified as a noteworthy antioxidant and anti-inflammatory compound that mitigates secondary injury following trauma, as noted by Kahraman S (23). Its efficacy in enhancing blood circulation and subsequently lowering lactate buildup in damaged tissues is contingent upon elevated glucocorticoid levels in those tissues, according to Braughler JM (24). Additionally, MPSS is effective in inhibiting lipid peroxidation and the formation of free radicals in the aftermath of traumatic events, leading to improved neurological outcomes, as highlighted by Bracken MB (25). Prior paper written by Kalayci M and Yang YB demonstrated that spinal cord injury markedly elevated levels of MDA in spinal cord tissues, while concurrently decreasing the antioxidant enzymes levels such as SOD and GPx. Their findings also indicated that treatment with MPSS not only reduced tissue MDA levels but also prevented the decline in SOD and GPx enzyme activities in affected tissues. tissues (25). Our research corroborated these findings, revealing that in the group treated with MPSS, there was a notable elevation in the tissue levels of GPx and SOD, alongside a decrease in MDA levels. These results align with the previous observations made by Kalayci M (26).

Oxidative stress following head trauma can be characterized as a disturbance in the delicate balance between the heightened generation of reactive

oxygen species and the inadequacy of the body's own antioxidant defense mechanisms (27). While ROS are typically produced naturally during metabolic processes within living cells, an overproduction can lead to detrimental cellular effects by harming essential cellular components, including proteins, lipids, and nucleic acids (28). The buildup of ROS is associated with lipid peroxidation in cell membranes, culminating in the generation of significant levels of MDA. Key antioxidant enzymes such as SOD, catalase, and GPx serve as primary protectants against cellular damage induced by reactive oxygen species (29). However, under conditions of pronounced oxidative stress, the activity of these enzymes may become diminished due to molecular injury.

Numerous studies have indicated that pregabalin offers protective effects on tissues exposed to oxidative stress by augmenting the activities of SOD, GPx, and catalase, as well as reducing MDA levels in a dose-dependent manner (11,12). In line with these findings, our research illustrated that traumatic injury led to a reduction in the activity of endogenous antioxidant enzymes alongside an increase in MDA levels within brain tissue. Notably, these alterations were substantially mitigated through the administration of pregabalin. Furthermore, the findings from our biochemical analysis corroborated the pathological observations of our study. To more comprehensively elucidate the mechanisms by which pregabalin affects TBI, additional investigations are warranted.

CONCLUSION

Pregabalin and MPSS protected the brain against traumatic injury by attenuating lipid peroxidation and inflammatory process. Moreover, the pathological evaluations were supported the biochemical analysis results. The lack of ultrastructural findings in our study is a shortcoming in terms of understanding the effective mechanism. Further studies may be needed to determine the neuroprotective activity of pregabalin in a time- and dose-dependent manner.

Acknowledgments No.

Author contribution Ömer Şahin: Idea-Concept-Design-Analysis-Literature review-Writing. Fatma Karaca Kara: Research-Data processing-Analysis-Literature review-Writing.

Conflict of interests: The authors have no conflict of interest to declare.

Ethical approval: This study was approved by Institutional Animal Experiments Ethics Committee of Ankara Training and Research Hospital, University of Health Sciences (Date: 01.11.2024, Approval No: 0086).

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RESEARCH ARTICLE

THE OUTCOME ASSESSMENT REQUIRES BOTH PERFORMANCE-BASED AND PATIENT-REPORTED MEASURES AFTER REVISION TOTAL KNEE ARTHROPLASTY

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ABSTRACT

Purpose: To investigate the correlation between performance-based and patient-reported measures and their relation with knee muscle strength in the assessment of revision total knee arthroplasty (rTKA) patients.
Materials and Methods: This cross-sectional study recruited 92 patients with rTKA. The outcome assessment was performed using three performance tests (the Timed Up and Go (TUG), 30-second Chair Stand Test (30CST), and 50-Foot Walking Test (50FWT)) and one patient-reported questionnaire (the Hospital for Special Surgery (HSS)). The maximum isometric muscle strength of knee flexors and knee extensors was assessed with Handheld Dynamometry (HHD).
Results: The total HSS knee score showed low significant associations with performance-based tests (all, $p< 0.05$), but no associations with knee muscles strength. The knee extensor strength showed moderate to strong significant associations with all performance tests, while the knee flexor strength had a low to moderate significant correlation with these performance tests (all, $p<0.05$).
Conclusion: Our findings, which show a low correlation between performance-based tests and patient-reported questionnaire, suggest patient perception fails to accurately capture the functioning at the late follow-up of rTKA. Therefore, performance-based tests should be included in the outcome assessment to determine an appropriate rehabilitation program and exercise training after rTKA. Moreover, the higher associations between functional tests and knee muscle strength than the associations of the questionnaire with these performance measures advocate this assertion. These findings could be crucial in informing the design and implementation of interventions tailored to this population.

Keywords: Performance-based tests, patient-reported outcomes, functioning, muscle strength, revision total knee arthroplasty

INTRODUCTION

The annual total number of revision total knee arthroplasty (rTKA) is projected to increase by 90% by 2050 (1). Despite its growing frequency, rehabilitation and outcome measurement strategies for rTKA are lacking in the existing literature. Namely, this population has no standardized rehabilitation protocol, and the outcome assessment method is

based solely on patient-reported measures (2). Nonetheless, James Lind Alliance Priority Setting Partnership has identified rehabilitation and assessment strategies for rTKA as one of the top 10 priority research areas for patients and clinicians (3). The loss of motor function and muscle strength is considerable following rTKA, leading to decreased functional independence (4, 5). Hence, it is necessary to study the outcomes of specified interventions in this population, which need to be evaluated with appropriate outcome measures to interpret the benefits of the intervention.

Revision TKA surgery is technically more complex compared to primary TKA and requires more extensive exposure to the knee extensor mechanism, which is the primary determinant of overall functional independence. However, rTKA surgical techniques directly affect quadriceps strength, thus potentially leading to functional impairments (6, 7). Therefore, rTKA patients may not have as good outcomes as those with primary TKA after surgery (4). On the other hand, rTKA patients who are increasingly demanding postoperative functional results expect an early return to daily life and optimal functional level following surgery (2, 8). Hence, it is essential to qualitatively evaluate these patients regarding their postoperative outcomes and functioning to offer them timely access to an appropriate rehabilitation program.

Many available methods, such as patient-reported questionnaires and performance-based tests, measure function and symptoms at the perioperative stage of joint arthroplasty (9, 10). However, in the literature, it has been shown that the methods for assessing the functional status of rTKA patients rely solely on patient-reported questionnaires (4, 8, 11). Nonetheless, outcome assessment of joint arthroplasty should also include reproducible objective measures and permit identifying the functional performance at a point in time and assessing changes over time in the clinical setting (10, 12). Besides, the relationship between assessment tools should be determined to better understand the circumstances under which to administer a particular instrument. Nevertheless, the existing literature did not investigate the relationship between patient-reported questionnaires and performance-based tests in rTKA patients. In addition, no study to our knowledge has concurrently measured knee muscle strength level to determine its relation to patient-reported and performance-based measures. Therefore, specifically, the two main objectives were (1) to determine the correlation between the patient-reported measure and performance-based tests in rTKA patients and (2) which of these outcome measures is more relevant to knee muscle strength level.

MATERIALS AND METHODS

Study design and participants

A total of 92 patients with rTKA operated by the same surgeon were recruited for analysis in this study. Inclusion criteria were that patients had an rTKA for reasons including aseptic loosening, infection, ligamentous instability, and had undergone rTKA surgery at least one year prior to allocation, were 40 years of age or older, could walk at least 50 m independently with or without an assistive device, and could understand the instructions of the tests. Patients were excluded if they had previous disorders (i.e. orthopedic or neurologic conditions) causing gait disturbance, had undergone rTKA surgery within one year, and had a body mass index (BMI) of 40 kg/m2 or above.

This study design was a cross-sectional correlational analysis of patients who had undergone rTKA. According to a priori power analysis, a sample size of 88 was needed to achieve 90% statistical power with a probability of a 2-tailed type I error of 0.05 in the correlation analysis (13). To prevent power loss due to early withdrawal, and increase its generalizability to the population, the study was planned to be completed with 102 patients. A total of 115 patients who were operated by the same surgeon at least one year prior were called for an initial telephone screening and to determine their eligibility. 14 patients having exclusion criteria as given previously, and further 9 patients who were not interested in participating were excluded. As a result, 92 rTKA patients who met the eligibility criteria were scheduled for an outcome assessment. A flowchart of the study is shown in Figure 1.

Ethical considerations

This study was approved by the Non-interventional Research Ethics Committee of Dokuz Eylul University (Date: 03.04.2019, Approval number: 2019/08-39). In accordance with the Declaration of Helsinki, written informed consent was obtained from all participants prior to enrollment in the current study.

Outcomes assessment

Patients were assessed at the mean time of 6 (2.81) years postoperatively (range from surgery 1 to 12 years). The tests were ordered in the following sequence because patients' perception of fatigue resulting from performance tests may influence their questionnaire scores. The testing order was the completion of the patients' demographic and clinical data followed by a patient-reported questionnaire of the Hospital for Special Surgery (HSS). After completing the questionnaire, knee muscle strength and performance-based tests were assessed randomly to avoid potential confounding effects. Between performance assessments, all patients were allowed 10 minutes of rest in a comfortable chair to minimize fatigue-related effects. Prior to the actual test, a practice trial was conducted for each performance assessment so that patients could familiarize themselves with the tests. During walking-based functional performance tests, patients were asked to walk as quickly but safely as possible, using walking aids (e.g., walker and/or cane) if needed. All patients were evaluated by the same physiotherapist with seven years of clinical experience in orthopedic rehabilitation and in performing outcome assessment.

The HSS is a reliable and valid scale that assesses patients with knee osteoarthritis and knee arthroplasty (14). The HSS subscales specifically assess knee pain, function, range of motion, strength, flexion deformity and instability. The total HSS score is obtained by subtracting the scores for walking aids, loss of knee extension and valgus/varus deformity from the total score of all other subscales.

A reliable and valid method, the Timed Up and Go (TUG) test measures patients' functional mobility and balance ability (15). The TUG measures the time spent on testing, including rising from a standard chair, walking 3 meters, turning around, returning to the chair, and sitting down. The participant was instructed to walk as fast as possible but safely at a set distance.

A valid and reliable method, the 30-second Chair Stand Test (30CST) assesses the lower extremity strength and endurance associated with ambulation abilities (16). According to the 30CST protocol, a chair with a seat height of 17 inches (43.2 cm) was used. The patients' starting position was standardized for all assessments, including buttock placement, back support, back straight, and crossing their arms across their chests to avoid compensation. Then, participants were asked to stand up repeatedly as quickly as possible but safely within 30 seconds. Along the test duration, the number of full chair stands completed was recorded.

A reliable and valid measurement method, the 50-Foot Walking Test (50FWT) is widely used to measure patients' performance and locomotion (16). Participants are asked for walking in a straight line (25 ft), then turning around and walking (25 ft) back to the starting position (totally 15.24 meters/50 ft). The 50 ft walk was performed as quickly as possible but at a safe pace. The time spent during the test was recorded.

Handheld Dynamometer (HHD) was used to assess maximal isometric knee muscle strength. Before the measurement, the participants were seated at the examination table with approximately 90 degrees of hip flexion and 60 degrees of knee flexion and crossed their arms across their chest. Before the testing, the participants were instructed according to the standardized static muscle strength assessment protocol of knee flexors and knee extensors (17). The transducer was placed on the 1-2 centimetres proximal of the medial malleoli, anteriorly for strength assessment of knee extensors, and posteriorly for strength assessment of knee flexors. Participants performed one repetition of a practice trial to be familiarized with the test, then three consecutive maximum contractions for each knee muscle strength measurement. All muscle strength values were converted to Newton meters (Nm) for analysis.

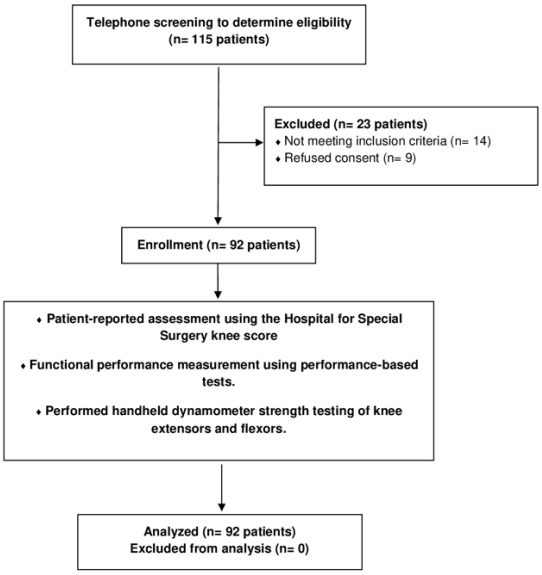

Figure 1. Flow diagram of study

Statistical analysis

The data was analyzed using the IBM® SPSS® (ver. 26.0; IBM Corp., Armonk, NY, USA) package program for Windows software. The normal distribution of the data was determined using the Shapiro-Wilk test. Descriptive statistics were described with numbers (percentages) and mean (standard deviation) values. The associations between the patient-reported questionnaire and performance-based measures and knee muscle strength were assessed using the Pearson's correlation coefficient. The correlation level was considered negligible if the coefficient was less than 0.10, low if it was between 0.10 to 0.39, moderate if it was between 0.40 to 0.69, and strong if it was greater than 0.70 (18). A value of $p<0.05$ was set as statistically significant.

RESULTS

No adverse events or complications were developed in participants during outcome assessments. Demographics and clinical characteristics of the patients are presented in in Table 1 and Table 2.

The total HSS knee score, showed low significant associations with TUG, 30CST, 50FWT. We found no significant associations between the total HSS knee score and knee muscles strength.

The HSS "Function" had low associations with 30CST, 50FWT, and knee extensors strength. There were low associations between the HSS "Muscle Strength" and TUG, 30CST, 50FWT, knee muscles strength. We found low associations between the HSS "Range of Motion" and 30CST, 50FWT, knee extensors strength. There was also a low correlation between the HSS "Deformity" and knee extensors strength. There were no significant associations between the other subscale of HSS knee score and the performance tests and knee muscles strength. The associations between patient-reported outcome and performance-based scores and knee muscles strength are presented in Table 3.

Both knee extensor and flexor strength were significantly correlated with performance-based tests but not patient-reported measure. In general, knee extensors strength was more strongly correlated with performance tests compared to knee flexors strength. The knee extensors strength showed a strong correlation with 30CST, and moderate associations with TUG and 50FWT. The knee flexors strength had moderate correlation with TUG, and low correlation with 30CST and 50FWT. The associations between knee muscles strength and performance-based scores are shown in Table 4.

The total HSS knee score showed low significant associations with TUG, 30CST, 50FWT. We found no significant associations between the total HSS knee score and knee muscles strength.

The HSS "Function" had low associations with 30CST, 50FWT, and knee extensors strength. There were low associations between the HSS "Muscle Strength" and TUG, 30CST, 50FWT, knee muscles strength. We found low associations between the HSS "Range of Motion" and 30CST, 50FWT, knee extensors strength. There was also a low correlation between the HSS "Deformity" and knee extensors strength. There were no significant associations between the other subscale of HSS knee score and the performance tests and knee muscles strength. The associations between patient-reported outcome and performance-based scores and knee muscles strength are presented in Table 3.

Table 1. Demographic characteristics of patients with revision-TKA

Variables	Mean (SD)
Age (years)	69.43 (8.98)
Height – cm	161.98 (7.35)
Weight– kg	81.58 (12.03)
BMI – kg/m^2	31.06 (3.87)
Time since surgery (years)	6.00 (2.81)
Sex (♀/♂), n, (%)	68/24 (73.90/26.10)
Side (right/left), n, (%)	61/58 (51.30/48.70)

Data are presented as number, percentage, and/or means and standard deviation (in parentheses); TKA: Total Knee Arthroplasty; BMI: body mass index; ♀: female; ♂: male

Table 2. Scores from the patient-reported questionnaire, performance-based measures, and muscle strength of patients with revision-TKA

Variables	Mean (SD)
HSS (total)	72.82 (13.38)
Pain	25.40 (5.90)
Function	11.97 (4.18)
ROM	15.19 (2.56)
Muscle strength	6.94 (2.58)
Deformation	4.30 (3.55)
Instability	9.45 (0.89)
TUG (sec.)	13.25 (6.02)
30CST (numbers)	10.63 (5.13)
50FWT (sec.)	29.63 (12.37)
Quad. (Nm)	106.40 (49.22)
Ham. (Nm)	116.60 (39.71)

Data are presented as means and standard deviation (in parentheses). TKA: Total Knee Arthroplasty; HSS: Hospital for Special Surgery; TUG: Timed Up and Go test; 30CST: 30-second Chair Stand Test; 50FWT: 50-Foot Walking Test; Quad.: quadriceps; Ham.: hamstring; Nm: Newton meter; sec.: second

Table 3. Correlations between patient-reported outcome and performance-based scores and muscle strength in patients with revision-TKA

Variables	TUG (r) 95% CI	30CST (r) 95% CI	50FWT (r) 95% CI	Quad. (r) 95% CI	Ham. (r) 95% CI
HSS (total)	-0.196*	0.191*	-0.316***	0.178	0.137
	-0.376/-0.016	0.011/0.371	-0.490/-0.142	-0.003/0.358	-0.046/0.318
Pain	-0.176	0.026	-0.118	0.048	-0.186
	-0.383/0.013	-0.169/0.222	-0.317/0.073	-0.155/0.259	-0.356/0.002
Function	-0.095	0.285**	-0.355***	0.308***	0.148
	-0.300/0.100	0.105/0.479	-0.549/-0.182	0.135/0.527	-0.042/0.339
ROM	-0.096	0.220*	-0.214*	0.239*	0.067
	-0.301/0.098	0.035/0.417	-0.413/-0.029	0.057/0.454	-0.125/0.260
Muscle strength	-0.222*	0.267**	-0.287**	0.314***	0.280**
	-0.429/-0.037	0.085/0.462	-0.484/-0.108	0.142/0.532	0.097/0.467
Deformation	0.023	0.183	-0.174	0.209*	0.139
	-0.177/0.225	-0.005/0.380	-0.373/0.014	0.024/0.426	-0.051/0.330
Instability	-0.054	-0.004	0.040	-0.036	0.096
	-0.257/0.144	-0.200/0.191	-0.155/0.237	-0.246/0.168	-0.095/0.286

TKA: Total Knee Arthroplasty; HSS: Hospital for Special Surgery; TUG: Timed Up and Go test; 30CST: 30-second Chair Stand Test; 50FWT: 50-Foot Walking Test; Quad.: quadriceps; Ham.: hamstring; r: Pearson's correlation coefficient; 95% CI: 95% Confidence interval with lower/upper bound
*0.01 < p ≤ 0.05, **0.001 < p ≤ 0.01, ***p ≤ 0.001

Table 4. Correlations between performance-based scores and muscle strength in patients with revision-TKA

Variables	TUG (r) 95% CI	30CST (r) 95% CI	50FWT (r) 95% CI
Quad.	-0.619***	0.853***	-0.578***
	-0.766/-0.476	0.760/0.953	-0.731/-0.429
Ham.	-0.540***	0.351***	-0.359***
	-0.642/-0.355	0.177/0.521	-0.518/-0.182

TKA: Total Knee Arthroplasty; TUG: Timed Up and Go test; 30CST: 30-second Chair Stand Test; 50FWT: 50-Foot Walking Test; Quad.: quadriceps; Ham.: hamstring; r: Pearson's correlation coefficient; 95% CI: 95% Confidence interval with lower/upper bound
*0.01 < p ≤ 0.05, **0.001 < p ≤ 0.01, ***p ≤ 0.001

Both knee extensor and flexor strength were significantly correlated with performance-based tests but not patient-reported measure. In general, knee extensors strength was more strongly correlated with performance tests compared to knee flexors strength. The knee extensors strength showed a strong correlation with 30CST, and moderate associations with TUG and 50FWT. The knee flexors strength had moderate correlation with TUG, and low correlation with 30CST and 50FWT. The associations between knee muscles strength and performance-based scores are shown in Table 4.

DISCUSSION

The primary findings of the current study were (1) patient-reported outcome showed low associations with performance-based tests of functional performance, (2) both knee extensor and knee flexor strength were significantly correlated with performance-based tests but not patient-reported measure. With respect to the performance-based tests, these findings are similar to previous studies in different populations with knee and hip arthroplasty that reported correlation coefficients with patient-reported questionnaires to be low (12, 19, 20). Showing generally moderate to strong correlation between muscle strength and performance tests, our findings are similar to other studies in primary TKA patients that reported moderate to strong correlation between lower extremity muscle strength and performance tests (7, 12, 21). On the other hand, to our knowledge, this is the first study that showed relationships between the performance-based tests and patient-reported questionnaires and their relevance to the knee muscle strength in patients with rTKA.

There could be some possible explanation for the current findings, which showed a low correlation

between the two types of assessment tools. Patient-reported questionnaires, having high internal consistency and ease of administration, assess the perception of ability to perform required daily living activities (9, 10). Nevertheless, these measures may not fully capture impairments in functional performance since they are influenced by many factors (i.e., patient's perception and experience, personality, cultural situations) (9). On the other hand, alternatively, performance-based tests, which measure the timing, counting, or distance, quantify a particular task mimicking daily living activities (22, 23). Thus, performance tests provide a continuous measure of difficulty instead of relying on the assessors' judgment to score and individuals' perception of performance (23). Therefore, using a combination of performance-based and patient-reported measures may be valuable to comprehensively measure functional recovery and patients' reports on their functional status after revision knee surgery, as these two methods assess tap into different aspects related to functioning. Our findings and also previous studies (10, 12), conducted on different populations support this assertion.

The quadriceps muscle strength is a significant determinant of gait, functional ability, and overall functional independence (7). However, rTKA directly affects knee muscle strength because more extensile exposure is required to the knee extensor mechanism during revision knee surgery (6). Therefore, identifying the lower extremity muscle strength and its correlation with functional performance is particularly important to determine the more efficient and accurate selection of therapeutic interventions in this population (24).

The current study showed associations between performance-based tests and knee muscles strength. A higher correlation was generally found for the knee extensors strength (quadriceps strength), but the knee flexors strength (hamstring strength) also affects the functional performance. Previous studies (25, 26) have shown a strong association between quadriceps strength and functional performance in TKA patients compared to other muscle groups, and this supports our findings. In addition, in agreement with previous studies (19, 21), conducted on TKA patients, the current study showed the highest correlation between knee extensors muscle strength (quadriceps muscle strength) and 30CST. This finding is clinically important because it implicates that this performance-based test is the potential predictor of knee extensors muscle strength. The 30CST, one of the performance-based tests, requires sit-to-stand but predominantly considerable balance level, muscle strength and endurance. These could be reasons for the results obtained in the current study. More, the current result suggests that this performance test can be used to determine the overall knee muscle strength when advanced equipment such as a handheld dynameter for assessment of knee muscle strength is not available. Our results showed no associations between the total score of HSS and knee muscles strength. This result is similar to the previous findings (19, 21), which reported no associations between patient-reported measures and muscles strength. On the other hand, some subscores of the HSS have low associations with knee muscle strength. However, inadequate associations suggest that both types of assessment tools examine independent dimensions and parameters of functional performance; therefore, neither should be used interchangeably in the outcome measure of rTKA patients. This result can be attributed to the fact that unlike the self-report of performance that is based on patients' perception of their ability, the performance assessment such as muscle strength testing with a dynamometer captures patients' actual ability to perform a specific task. Besides, previous evidence indicates that patients' perceptions and beliefs strongly influence pain perception rather than self-report of performance (27). Therefore, patients' perceptions and beliefs, namely psychological factors, may be misleading when scoring a questionnaire. Our results, showing that knee muscle strength has a low but significant correlation with the HSS "function", however, no correlation with the HSS "pain", confirm this assertion.

In clinical practice for assessing orthopedic patients, longer walk tests, such as the 2- and 6-minute walk test, have been used to assess functional mobility, and gait ability and endurance (22). However, performing such a long walk test might overburden patients with revision knee arthroplasty during the postoperative stage, especially if they use walking aids and have limited walking endurance or muscle weakness. Thus, a shorter walk test can be more appropriate and provide clinically practical assessment for patients with knee arthroplasty (22). In line with this assertion, the performance-based tests used in this study to assess functional performance were well received by patients, and all

of them could complete these tests safely during the postoperative period. More, the performance tests in this study, which involve sitting and standing, mainly assess quadriceps performance, a key factor in functioning for patients with knee arthroplasty. We, therefore, concluded that these performance tests can be easily used to assess the walking and functional ability of rTKA patients in the clinical setting.

Limitations

This study is a cross-sectional correlational analysis, and the same surgeon performed all surgeries at a single surgical center. These are the strengths of the current study. However, conducting the current study in a single-center surgery clinic is a limitation because it may influence the generalizability of our results. Another limitation was that as this study used a cross-sectional correlational analysis, it limited our ability to comment on causality and effect. More, patients with an extended follow-up period of 1 to 12 years after surgery were tested, which may have affected the functional status and therefore the current findings. Lastly, the parameters such as patients' expectation, preoperative functional level, and other muscles strength (e.g. the hip and ankle muscles) which possibly related to functional performance in rTKA patients were not evaluated. It may be relevant to investigate the impact of these parameters on function; therefore, further studies should be warranted.

CONCLUSION

The current findings demonstrate a low correlation between performance-based tests and patient-reported questionnaire. This implies that these assessment tools, although comparable, usually evaluate independent properties of functional performance; therefore, neither should be used interchangeably. Given that, a comprehensive assessment for rTKA patients should include a combination of these two assessment tools. In addition, the highest associations, especially between knee extensors strength and performance-based tests, suggest that these performance tests are clinically relevant surrogate measures of knee muscle strength. More, these findings could be crucial in informing the design and implementation of interventions tailored to this population.

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Conflict of interests: No potential conflict of interest was reported by the author(s)

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RESEARCH ARTICLE

VALIDITY AND RELIABILITY OF THE SINGLE-ITEM KINESIOPHOBIA SCALE IN PERSONS WITH NECK AND BACK PAIN

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ABSTRACT

Purpose: Kinesiophobia is a significant concern in individuals with neck and back pain. This study aimed to evaluate the measurement properties of the Single-Item Kinesiophobia Scale (SKS) including test-retest reliability and convergent validity.

Material and Methods: A total of 101 participants (n=38 with neck pain and n=63 with back pain) were included. The SKS was applied twice 7-14 days apart. Test-retest reliability was assessed using intraclass correlation coefficients (ICCs). Validity was examined through correlations with established measures: the Tampa Scale for Kinesiophobia (TSK), Neck Disability Index (NDI), Oswestry Disability Index (ODI), and Visual Analog Scale (VAS) during activity and rest. Floor/ceiling effects and score distribution were also analyzed.

Results: The SKS demonstrated moderate test-retest reliability [neck pain: ICC=0.56 (95%CI: 0.30–0.75), back pain: 0.52 (95%CI: 0.31–0.68)] in both groups. It showed moderate correlations with the TSK (neck pain: rho= 0.446; back pain: rho=0.555), but only small correlations with the VAS (rho=0.261–0.265) and the ODI (rho=0.278) in the back pain group. No significant correlations were found between the SKS and VAS or NDI in the neck pain group.

Conclusion: The SKS is a simple and feasible screening tool for kinesiophobia but should be used alongside comprehensive measures due to its moderate psychometric properties and limitations.

Keywords: Kinesiophobia, Pain, Neck Pain, Back Pain

INTRODUCTION

Kinesiophobia is characterized by an excessive, irrational, and debilitating fear of movement, driven by the belief that physical activity may lead to injury. Originally defined by Kori et al. (1990), kinesiophobia is considered a key component of the fear-avoidance model, in which individuals interpret pain as threatening and subsequently avoid movement or activity, leading to a cycle of physical deconditioning, increased disability, and chronic pain (1–4). This psychological factor is frequently observed in individuals with musculoskeletal pain, particularly those experiencing neck or back pain, and has been linked to poorer rehabilitation outcomes, delayed recovery, lower participation in physical activity, and poorer quality of life (5–11). It is also recognized as a mediator between pain and disability, emphasizing its importance as a treatment target in both physiotherapy and multidisciplinary pain

management (12). These findings highlight the clinical relevance of accurately identifying and treating kinesiophobia to optimize outcomes in patients with persistent pain.

The presence and severity of kinesiophobia have been generally assessed using multi-item scales, which provide detailed insights into patients' fear of movement from different aspects. The Tampa Scale for Kinesiophobia (TSK) is one of the most commonly used kinesiophobia measurement tools in different populations, and it includes 17 items (1). Shorter versions, such as the TSK-13, TSK-11 and TSK-4 have also been developed to improve feasibility while maintaining validity and reliability (13,14). In addition, the Kinesiophobia Causes Scale (KCS) has been proposed as a more comprehensive tool to assess the cognitive-behavioral origins of kinesiophobia (15). While these multi-item instruments provide a detailed insight into the complex nature of fear of movement, their length and time to complete may pose challenges, particularly in time-constrained clinical settings or for individuals with attentional or cognitive limitations.

To address these limitations, single-item scales have been proposed as efficient alternatives, offering a quick and straightforward way to capture essential psychological constructs without compromising clinical utility and overburdening respondents. In people with sciatica, a single substitute question for the TSK demonstrated comparable or superior predictive ability for leg pain severity and global perceived effect at one-year follow-up, and it was moderately correlated with TSK (16). However, for such short instruments to be useful in clinical decision-making, their measurement properties need to be rigorously evaluated.

The Single-Item Kinesiophobia Scale (SKS) was used as a brief, pragmatic tool to assess the presence and intensity of kinesiophobia (16). Despite its simplicity, evidence of its reliability and validity remains limited. Determining the psychometric properties of the SKS is essential to ensure its accuracy and consistency in measuring kinesiophobia in different populations and settings. Therefore, the aim of this study was to assess the test-retest reliability and convergent validity of the SKS in people with neck and back pain. By demonstrating its measurement properties, we hope to support the integration of the SKS into routine clinical practice, particularly in fast-paced or resource-limited settings where rapid yet valid screening is essential to guide rehabilitation and monitor progress.

MATERIALS AND METHODS

All participants provided written informed consent before inclusion in this cross-sectional, methodological study. The Non-interventional Clinical Research Ethics Committee of Izmir Katip Celebi University (Date: 21.04.2022, Approval Number: 0178) approved the study.

Participants

Although there is no universally accepted consensus, validation studies typically recommend a minimum sample size of 2 to 20 participants per item. As the SKS is a single-item scale, this would suggest a required sample size of 2 to 20 participants (17). In addition, the sample size was determined on the basis of the COSMIN guidelines, which were developed to ensure adequate quality in the evaluation of self-report scales. According to these guidelines, a minimum of 50 participants is recommended to obtain results of sufficient quality for test-retest reliability and construct validity (18). Therefore, this study planned to include 100 participants (n=50 with back pain and n=50 with neck pain).

Individuals with neck pain were eligible for inclusion if they: (1) had experienced chronic neck pain for a minimum of three months, (2) were between 18 and 65 years old, and (3) possessed sufficient proficiency in Turkish to understand and communicate effectively. Similarly, individuals with back pain were included if they: (1) had experienced chronic back pain for at least three months, (2) were within the age range of 18 to 65 years, and (3) had adequate Turkish language skills for comprehension and communication. Exclusion criteria for both groups consisted of: (1) a prior history of fractures or surgical procedures, and (2) the presence of any inflammatory or neurological condition.

Outcome measures

Single-Item Kinesiophobia Scale (SKS):

The SKS is designed as a single-item visual analog scale to assess kinesiophobia. Participants was asked to rate their fear of movement on a scale from 0 to 10. They were asked, "How much fear do you have that your neck/back pain would be increased by physical activity?" and rate from 0 (no fear) to 10 (very much fear) (16). The SKS was applied twice 7-14 days apart to assess test-retest reliability.

Table 1. Descriptive measures of the participants

	Neck pain (n=38)	Back pain (n=63)
Age	49 (43.5-58)	47 (37-60)
Sex: Female/Male, n (%)	25 (65.8%)/13 (34.3%)	40 (63.5%)/23 (36.5%)
Single-item Kinesiophobia Scale	5 (1-7.12)	5.5 (3-8)
Tampa Scale for Kinesiophobia	41.5±7.6	43.5±7.4
Neck Disability Index	34.1±14.5	NA
Oswestry Disability Index	NA	28.8 (18-42.2)
Visual Analog Scale-rest	4 (3-5)	5 (3-6)
Visual Analog Scale-activity	6 (5-7)	7 (6-9)

Values are presented as mean±standard deviation or median (interquartile range).
NA: not applicable, n: number

Tampa Scale for Kinesiophobia (TSK):
The TSK is a 17-item questionnaire designed to assess fear of movement and re-injury. It evaluates aspects related to work activities, injury/re-injury concerns, and fear-avoidance behaviors. Responses are recorded on a 4-point Likert scale, ranging from 1 (strongly disagree) to 4 (strongly agree). The total score varies between 17 and 68, with higher scores reflecting greater kinesiophobia. The Turkish adaptation of the scale has been validated and demonstrated to be reliable (19).

Neck Disability Index (NDI):
The NDI is a 10-item questionnaire designed to assess disability and functional limitations associated with neck pain. Higher scores reflect greater levels of disability. The Turkish version has been validated and proven to be reliable for individuals with neck pain (20).

Oswestry Disability Index (ODI):
The ODI measures functional impairment in individuals with low back pain (21). It includes 10 items covering aspects such as pain intensity, self-care, lifting/carrying, walking, sitting, standing, sleeping, pain fluctuation, travel, and social life. The total score is doubled and presented as a percentage, ranging from 0 (no disability) to 100 (maximum disability). Higher scores indicate greater disability levels. The Turkish adaptation has been validated and found to be reliable for individuals with low back pain (22).

Visual Analog Scale (VAS):
The VAS is a 10 cm scale used to measure pain intensity. Patients indicate their pain level at rest and during activity by marking a point on two separate 10 cm lines. The scale ranges from "no pain" at the starting point to "the worst pain experienced" at the endpoint (10). Pain intensity is determined by measuring the distance in centimeters from the starting point to the marked location, with higher scores representing greater pain severity (23).

Statistical analysis
Data analysis was performed using IBM SPSS Statistics for Windows (Version 25.0, Armonk, NY: IBM Corp.). The normality of data distribution was assessed through the Kolmogorov-Smirnov test and visual inspection of histograms. Descriptive statistics were reported as mean (standard deviation) for normally distributed continuous variables, median (interquartile range) for non-normally distributed continuous variables, and frequency (percentage) for categorical variables.

Test-Retest Reliability:
Relative test-retest reliability was assessed using the intraclass correlation coefficient (ICC) with a two-way random-effects model. Absolute reliability was examined through the repeatability coefficient and Bland-Altman analysis. ICC values were interpreted as follows: <0.25 indicating very low reliability, 0.26–0.49 as low, 0.50–0.69 as moderate, 0.70–0.89 as high, and ≥0.90 as very high reliability (24).

Table 2. Test-retest reliability of Single-item Kinesiophobia Scale

	Test	Retest	ICC (95%CI)
Neck pain (n=38)	5 (1-7.12)	3.5 (0-6.12)	0.56 (0.30-0.75)
Back pain (n=63)	5.5 (3-8)	5 (0-7)	0.52 (0.31-0.68)

Abbreviations: ICC: Intraclass correlation coefficients, 95% CI: 95% confidence interval

Convergent Validity:
The convergent validity analysis was based on predefined hypotheses, expecting a moderate to strong correlation between the SKS scores and other kinesiophobia, pain, and disability measures. Depending on the distribution of the data, either Spearman or Pearson correlation coefficients were computed. Correlations were interpreted as small (0.10–0.29), moderate (0.30–0.49), and strong (≥0.50) (25).

Table 3. Correlation coefficients between SKS, TSK, and other outcome measures

		TSK	NDI	ODI	VAS-activity	VAS-rest
Neck pain (n=38)	SKS	0.446**	0.031	NA	0.120	0.204
	TSK	1	0.386*	NA	0.216	0.320*
Back pain (n=63)	SKS	0.555**	NA	0.278*	0.265*	0.261*
	TSK	1	NA	0.437**	0.196	0.196

** p<0.01
* p<0.05
Abbreviations: SKS: Single-item Kinesiophobia Scale, TSK: Tampa Scale for Kinesiophobia, NDI: Neck Disability Index, ODI: Oswestry Disability Index, VAS: Visual Analog Scale, NA: not applicable

0	0.5	1

Floor and Ceiling Effects:
To assess floor and ceiling effects, the proportion of participants who obtained the lowest and highest possible scores on the SKS was calculated. A threshold of more than 15% was considered indicative of a floor or ceiling effect (26).

RESULTS

In total, 101 participants (38 persons with neck pain and 63 persons with back pain) were recruited in the study. The median age of the neck pain group was 49 (43.5-58) years and 47 (37-60) in the back pain group. The participants' median scores on the SKS were 5 (1-7.12) in the neck pain group and 5.5 (3-8) in the back pain group. The mean TSK scores were 41.5 (7.6) and 43.5 (7.4) in neck and back pain groups, respectively. All descriptive characteristics of the participants are presented in Table 1.
All participants were included in the test- retest analysis. The test-retest reliability (i.e., ICC) scores are presented in Table 2. ICC of the SKS was 0.56 (95%CI: 0.30 to 0.75) in the neck pain group and 0.52 (95%CI: 0.31 to 0.68) in the back pain group. It means that both groups showed moderate test-retest reliability.
Bland-Altman figures are presented in Figure 1, showing most of the participants are in between the lower and upper limit of agreement lines.
Correlation coefficients between SKS, TSK, and other outcome measures are presented in Table 3. In the neck pain group, the SKS showed a moderate correlation with the TSK (rho=0.446, p=0.005), confirming our hypothesis. However, no significant correlations were found between the SKS and the NDI, VAS during activity, or VAS at rest. The TSK, in contrast, showed a moderate correlation with the NDI (rho=0.386, p=0.17) and VAS at rest (rho=0.320, p=0.049), while the correlation with VAS during activity was nonsignificant. In the back pain group, the SKS demonstrated a strong correlation with the TSK (rho=0.555, p<0.001), and small but significant correlations with the ODI (rho=0.278, p = 0.027), VAS during activity (rho=0.265, p=0.035), and VAS at rest (rho=0.261, p=0.039). The TSK also showed a moderate correlation with the ODI (rho = 0.437, p<0.001), but nonsignificant correlations with both VAS measures (rho=0.196, p=0.125 for both). Overall, 25% of the a priori hypotheses were confirmed.
Six persons (15.8% of the sample) had a score of 0, and 4 persons (10.5%) had a score of 10 in the group of neck pain. In persons with back pain, seven persons (11.1% of the sample) had a score of 0, and 8 persons (12.7%) had a score of 10. Frequencies are presented in Figure 2-A and B.

DISCUSSION

This study investigated measurement properties of the SKS in those with neck pain and back pain. Our findings showed that the test-retest reliability of SKS is moderate in both study groups. The SKS showed a moderate correlation with the TSK in the neck pain group and a strong correlation in the back pain group. However, the overall validation results were mixed, with only 25% of a priori hypotheses confirmed, raising important considerations about the scale's comprehensiveness in capturing the complexity of kinesiophobia. Additionally, the SKS showed a floor effect in persons with neck pain.

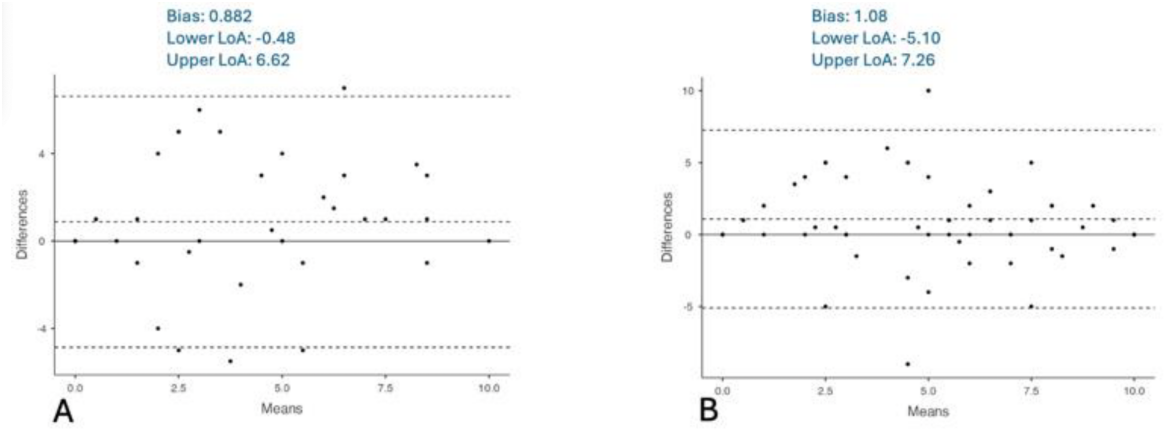

Figure 1. A) Bland-Altman plot of Single-item Kinesiophobia Scale in persons with neck pain B) Bland-Altman plot of Single-item Kinesiophobia Scale in persons with back pain

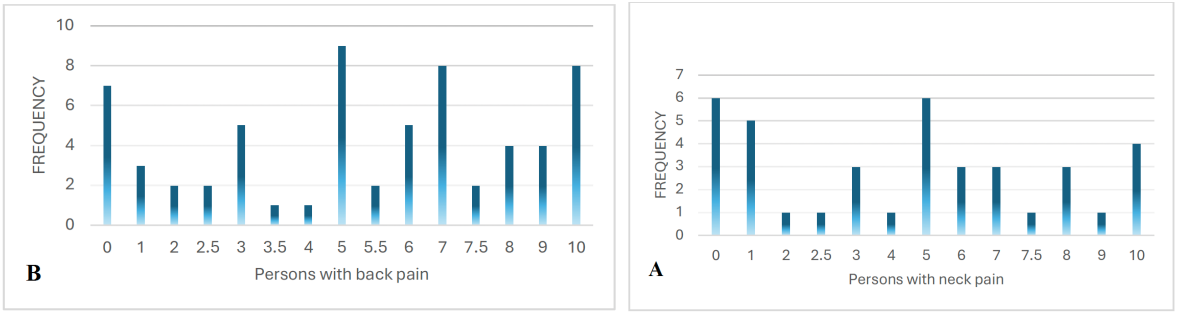

Figure 2. A) Frequency of answers in persons with neck pain B) Frequency of answers in persons with back pain

The SKS showed moderate correlations with the TSK in the neck pain group and strong correlations in the back pain groups, supporting its validity as a short measure of kinesiophobia. A similar correlation value (r=0.46) between the SKS and TSK was also reported in individuals with sciatica (16). This finding suggests that the SKS captures a general fear of movement construct, particularly in individuals with back pain.

The difference in the magnitude of correlations between SKS and TSK in the neck and back pain groups may stem from back pain being more closely associated with kinesiophobia. Alternatively, it could also be related to the slightly higher pain levels observed in the back pain group. In contrast, correlations with disability (NDI, ODI) and pain intensity (VAS) were either small or non-significant. However, higher correlations were found with the extended version (i.e., TSK), highlighting its sensitivity to the multifaceted nature of kinesiophobia, making it a more comprehensive tool for assessing its relationship with disability. These findings may reflect the limitations of a single-item measure in capturing the multidimensional nature of kinesiophobia, which often encompasses emotional, cognitive, and behavioral components contributing to pain-related disability in these populations (3, 27).

The reduced validity of the SKS in the neck pain group could be attributed to both clinical and methodological factors. Neck pain presentations may be more variable and less functionally impairing than back pain, resulting in a narrower range of kinesiophobia scores (7). Additionally, the smaller sample size in the neck pain group may have limited the statistical power to detect meaningful correlations. The lower mean scores in both SKS and TSK also suggest that individuals with neck pain may generally report lower kinesiophobia levels, consistent with previous studies that have reported more pronounced fear-avoidance behaviors in those with back pain (28).

The frequency analysis revealed potential floor effects in the neck pain group. Approximately 15.8% of participants with neck pain and 11.1% of those with back pain scored the minimum value (0). Although the threshold value of 15% was not reached, 10.5% of participants with neck pain and 12.7% of those with

back pain marked the maximum score of 10. The greater number of participants scoring 0 in the neck pain group, along with the lower SKS and TSK scores, support the notion that kinesiophobia is more pronounced in individuals with back pain (28). Increased floor and ceiling effect limits the scale's sensitivity to detect low-to-moderate levels of kinesiophobia or subtle changes over time. Such effects may restrict its utility for assessing changes in kinesiophobia in response to interventions. Although a 10-point numerical format enhances usability, it may not fully reflect the psychological dimensions of kinesiophobia.

This study has several limitations. First, although we aimed to recruit 50 participants per group; however, due to time and logistical constraints, we were unable to reach this target in the neck pain group. The lower correlation and reliability values in this group may be due to increased variability and reduced stability of the estimates resulting from the small sample size. Additionally, since we included only individuals with chronic pain, our findings cannot be generalized to those in the acute or subacute phases.

Despite these limitations, the SKS presents some practical benefits. Its brevity and simplicity make it appealing for use in busy clinical settings or for populations with time or cognitive constraints. However, it should be used as a preliminary screening tool rather than a standalone diagnostic measure. In research contexts where detailed profiling of psychological factors is required, more extensive, validated instruments such as the TSK or KCS may be more suitable. Comparing the SKS to these multidimensional tools in future studies could further clarify its utility.

CONCLUSION

In conclusion, while the SKS demonstrates moderate reliability and validity, its psychometric limitations warrant cautious interpretation. The scale's brevity is advantageous in clinical practice, but its limited sensitivity and narrow construct coverage restrict its utility as a comprehensive outcome measure. Clinicians and researchers should use the SKS cautiously, supplementing it with more comprehensive tools when a detailed assessment is needed.

Given that the SKS is a single-item scale, it holds strong potential for use in busy clinical settings. Its brevity allows for rapid administration without placing an additional burden on clinicians or patients. It can be easily integrated into routine assessments to quickly capture patients' perceptions, support clinical decision-making, and monitor changes over time. This makes the SKS especially valuable in time-constrained environments where comprehensive tools may not be feasible. However, to enhance its clinical and research applicability, future work should explore ways to broaden the scope of the scale. This could include adding complementary items or combining the SKS with brief contextual questions. Further research should also examine the responsiveness of the SKS to therapeutic interventions and assess whether it can predict meaningful functional or psychological outcomes over time.

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Conflict of interest: The authors have no conflicts of interest to declare.

Ethical approval: The Non-interventional Clinical Research Ethics Committee of Izmir Katip Celebi University (Date: 21.04.2022, Approval Number: 0178) approved the study.

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RESEARCH ARTICLE

TOTAL IMPLANTABLE CENTRAL VENOUS ACCESS PORT IMPLANTATION IN A HYBRID OPERATING ROOM: SINGLE CENTER RESULTS

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ABSTRACT

Purpose: This study retrospectively evaluated the impact of ultrasound (USG) and fluoroscopy (XrF) guidance on perioperative and postoperative complications during total implantable venous access port (TIVAP) implantation in a hybrid operating room setting.

Material and Methods: Patients undergoing TIVAP implantation between November 1, 2022, and August 31, 2024, were screened. Data collected included demographics, diagnosis, complications, and TIVAP duration. Exclusion criteria were procedures not performed by cardiovascular surgeons, absence of USG-guided puncture, and non-use of XrF. Postoperative chest radiographs were used to assess malposition, pneumothorax, and hemothorax. TIVAP duration and reasons for removal were recorded.

Results: 112 patients were included. No malposition, pneumothorax, venous thrombosis, arterial puncture, or acute bleeding were observed. Infection was the most common complication leading to TIVAP removal. 70 patients remain under follow-up.

Conclusion: This series demonstrates the effectiveness of USG and XrF guidance during TIVAP implantation by cardiovascular surgeons. The absence of periprocedural complications and malpositions and the low infection rate according to published data are probably attributable to the procedure being performed in a sterile hybrid operating room environment and USG and XrF guidance.

Keywords: Infection, Malposition, Port, Vascular access

INTRODUCTION

A total subcutaneous implantable venous access port (TIVAP) is a drug delivery system that is placed under the skin and provides long treatment duration, completely isolated from the external environment (1). The increase in the elderly patient population and oncological diseases has increased the need for long-term treatment with intravenous (IV) access. TIVAP has been used in increasing numbers since 1982 as an effective, safe, long-term solution for this situation (2). It can be used safely for many treatments including chemotherapeutics, IV nutritional preparations and blood products. The advantages of TIVAP are the low risk of infection and embolism and the treatment comfort for the patient and healthcare personnel. TIVAP consists of a subcutaneous reservoir and a catheter connecting the reservoir to the central venous circulation via a tunnel. The front side of the reservoir anterior of the body surface and the reservoir can be accessed

percutaneously with a small noncoring (Huber) injector tip. The tip of the injector penetrates this leak-proof septum and reaches the reservoir chamber, and from there, IV treatment can be provided via a catheter extending into the superior vena cava (VCS). Although TIVAP is considered the safest method of central venous access for long-term, intermittent treatments, the implantation procedure has complications such as infection, catheter migration, deep venous thrombosis, catheter malposition, arterial puncture, pneumothorax, hemothorax and cardiac tamponade (4). Complications can be divided into early and late. Early complications occur due to injury to adjacent structures during catheter insertion and reservoir implantation. Late complications occur due to trauma or misuse (5). The development of interventional methods enables TIVAP implantation with similar success and lower complication rates as surgery (6). There is evidence in the literature that the use of intraoperative ultrasonography (USG) and X-ray fluoroscopy (XrF) reduces the possibility of malposition compared to other implantation methods (7). In addition, current clinical TIVAP application guidelines do not include pneumothorax, hemothorax, air embolism, arterial puncture, etc. The emphasis is on USG-guided puncture for complications and correct catheter positioning, especially to prevent catheter thrombus complications. Guidelines recommend the use of XrF to position the catheter tip or to determine catheter localization by postoperative chest radiography with a high level of evidence (8) The European Society for Medical Oncology guidelines have stated that the ideal tip position is at the junction of the VCS and the right atrium (9).

The catheter tip can be positioned blindly based on patient height or by electrocardiographic monitoring from the catheter tip. Randomized controlled trials have shown that intraoperative X-rays in the hybrid operating room significantly reduce the need for re-positioning of the catheter tip compared to blind positioning (10). Perioperative and early infection rates have been reported to be lower in operating rooms where effective surgical sterilization can be achieved (11). In our study, we aim to evaluate the relationship between the use of USG and XrF, which are considered innovative in TIVAP implantation in the hybrid operating room that includes both of these advantages, and the complications and to contribute the retrospective results of our technique to the literature The results that will emerge can shed light on clinical practice guidelines, can be compared with data from centers using different techniques, can guide practitioners in updating their methods, and can increase the number and use of hybrid operating rooms.

MATERIALS AND METHODS

This study was approved by Dokuz Eylul University Non-Interventional Research Ethics Committee (Date: 18.09.2024, Decision No: 2024/31-14). The data of patients who underwent TIVAP implantation using USG and XrF in the hybrid operating room in our clinic between 01.11.2022 and 31.08.2024 were retrospectively reviewed. Electronic patient records were accessed to collect study variables such as patient age, gender, body mass index (BMI), oncological diagnosis requiring IV treatment, TIVAP implantation and removal dates, punctured side and preferred vein, complications (infection, malposition, pneumothorax, hemothorax, etc.), and TIVAP duration in the preoperative period. Patients who were not implanted by cardiovascular surgeons, who were not punctured according to USG guidance, and who were not used for XrF when placing the catheter into the VCS were excluded from the study. Patients who were checked by the nurse and who used low-profile titanium reservoir ports connected to a 7.8 French silicone catheter were included in the study. In patients who meet the conditions, malposition, pneumothorax, hemothorax will be evaluated in postoperative direct chest radiographs, TIVAP usage periods of the patients until 31.08.2024 assessed, and the reasons for revision or TIVAP removal until this date will be listed. Electronic patient records were confirmed a second time by the nurse. Complications were divided into three groups as perioperative (first 24 hours), early (first 30 days) and late (after 30 days). TIVAP-related infection was grouped as local or systemic infection. The complication rate that caused TIVAP revision or removal was determined.

Data were analyzed using the Statistical Package for the Social Sciences (SPSS), Version 20 (IBM, Corp., Armonk, New York, USA). Complication rates were reported as absolute numbers and percentages. Catheter survival was defined as the presence of a catheter initially implanted. The event was defined as “TIVAP removal due to complications.” In the patients included in the study, the reasons for the termination of TIVAP use, other than complications, were death and termination of treatment. For this reason, the

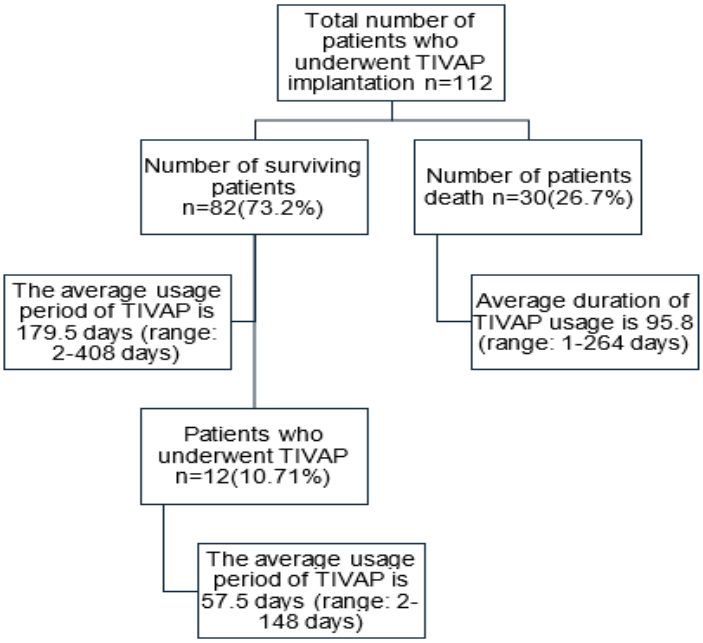

Figure 1. Overview of the usage times of patients who had TIVAP implanted at Dokuz Eylül University Hospital between 01.11.2022 and 31.08.2024.

duration of TIVAP use of the patients who died was analyzed separately. (Figure 1).

RESULTS

Demographic data of patients implanted with TIVAP at Dokuz Eylül University Hospital from November 2022 to August 2024 are shown in Table 1. (N=112)

During the study period, 134 patients were implanted with TIVAP. Twenty-two patients were excluded because electronic patient data were not available. All procedures were performed by cardiovascular surgeons.

For puncture, the right internal jugular vein (IJV) was preferred due to ease of access. The left IJV was preferred in 7 (6.2%) patients and the right subclavian vein was preferred in 1 (0.8%) patient. The left IJV puncture was performed in 4 patients with skin invasion in the pectoral region due to right breast cancer. The left side was preferred in the other 3 patients due to previous right IJV puncture. The only patient for whom the right subclavian vein was preferred had radiotherapy to the neck region due to laryngeal cancer. Data are summarized in Table 2.

By the end of the study, 82 (73.2%) survived. 30 patients died during the study period. The mean duration of TIVAP use among these patients was 95.8 (range: 1-264 days). The mean duration of TIVAP use among surviving patients was 179.5 days (range: 2-408 days). TIVAP was removed from a total of 12

Table 1. Characteristics and diagnoses of patients with cancer who had a TIVAP implanted at Dokuz Eylül University Hospital from November 2022 to August 2024 are summarized. (N=112)

Clinical Characteristics	**n (%)**
Sex	
Male	57(50,89)
Female	55 (49,10)
Body Mass Index (kg/m^2)	
Low(<18.5)	2(1,78)
Normal (18.5–24.9)	46(41,07)
High (25–30)	44(39,28)
Obese (>30)	20(18,60)
median	24,8
Oncological Diagnosis	
Breast cancer	14 (12,50)
Colorectal cancer	38 (33,92)
Esophageal-stomach cancer	11 (9,82)
Ovarian cancer	2 (1,78)
Pancreatic cancer	22 (19,64)
Lung cancer	2 (1,78)
Liver cancer	5 (4,46)
Prostate cancer	2 (1,78)
Other	16(14,28)

(10.71%) patients during the study period. A total of 10 (8.9%) complications were observed. In patients who developed complications, the duration of TIVAP use was significantly reduced by 57.5 days (range: 2-148 days). The TIVAP use duration scheme is shown in Figure 1.

No malposition was observed in any patient. Infection was determined as the factor that reduced the duration of TIVAP use the most and was observed in 6 (5.35%) patients. Other complications were reservoir-catheter separation in 3 (2.67%) patients, and kink at the reservoir-catheter junction in 1 (0.89%) patient. Systemic infection was observed in 2 (1.78%), and local infection was observed in 4 (3.57%) patients. Staphylococcus aureus was observed in 2 (1.78%) patients, Pseudomonas aeruginosa was observed in 1 (0.89%) patient, Candida was observed in 1 (0.89%) patient, Staphylococcus epidermidis was observed in 1 (0.89%) patient, and Staphylococcus hominis was observed in 1 (0.89%) patient. The overall median time to develop an infection was 84 days from the date of TIVAP placement.

No patient developed pneumothorax, venous thrombosis, arterial puncture or acute bleeding after the procedure. TIVAP was removed in 1 (0.89%) patient due to completion of chemotherapy treatment and in 1 (0.89%) patient due to pain in the pectoral region where the reservoir is located. 70 patients are still using TIVAP and are under follow-up. Complications are summarized in Table 3.

DISCUSSION

This study is a single-center retrospective analysis evaluating the efficacy and safety of TIVAP implantation using USG and XrF in a hybrid operating room. Our study results show that the use of USG and XrF in TIVAP implantations performed by cardiovascular surgeons is associated with low complication rates. In particular, the absence of perioperative complications and the low infection rate emphasize the advantages of this method.

Comparison with Literature

It has been shown in the literature that major complications (1.5%) in blind implantations result in more major complications than in TIVAP implantations performed with USG guidance. Similarly, the use of XrF eliminates the risk of malposition by ensuring correct positioning of the catheter. In line with this information, no major complications or malpositions were observed in our study. Structural deterioration in the catheter (kink, migration, etc.) is observed between 0.1% and 3.4% in the literature and is similar to our results (kink and reservoir catheter separation 2.67%) (13). The fact that no malposition was observed in our study once again demonstrates the importance of XrF use in this regard. The low complication rates obtained in our study are consistent with other studies in the literature and support that the use of USG and XrF is a safe and effective method in TIVAP implantation.

Table 2. Vein puncture localizations and localization preference reasons for TIVAP implantation at Dokuz Eylül University Hospital from November 2022 to August 2024 are summarized.

Puncture localization	n(%)	Description
Right IJV	103(%91,9)	Target puncture is preferred due to ease of access.
Left IJV	7(%6,2)	Due to skin-invasive right breast carcinoma and old right-sided puncture
Right Subclavian vein	1(%0,8)	Due to radiotherapy to the laryngeal region

Table 3. Time to complication and type of complication in patients undergoing TIVAP implantation.

Complication	Early(<30days)	Late(>30days)	Total Complications	Days to complication (Mean)
	n (%)	n (%)	n (%)	
Infection	2(1,78)	4(3,57)	6(5,35)	83,5
Reservoir-Catheter Separation	2(1,78)	1(0,89)	3(2,67)	24
Reservoir-Catheter Migration	1(0,89)	0(0)	1(0,89)	2

Infection Rates

In our study, the infection rate was found to be 5.35%. In a retrospective study including 516 patients performed in the radiology department, the infection rate was reported as 11.4% (14). In another retrospective analysis including 1406 patients and performed in a hybrid room, the infection rate (5.1%) was observed to be similar to this study (15). Infection, which is the most common complication of TIVAP implantation and reduces the duration of use the most, is related to the implantation conditions. The low infection rate in our study may be a result of the importance given to the sterilization of the operating room environment, the surgeon's application of the procedure and the catheter placement technique.

Complication Management

Other complications seen in our study (reservoir-catheter separation, kink) are complications observed in the long term and are generally due to surgical technical problems. Such complications can be minimized when performed carefully by experienced surgeons and appropriate catheter care techniques are applied. Early diagnosis and treatment of complications are important to improve the prognosis of patients. In addition, in the event of life-threatening complications such as cardiac tamponade and pneumothorax, the fact that the most effective diagnosis and most advanced treatments can be performed by the relevant surgeons in the hybrid operating room without the need for patient transport provides a significant advantage in terms of safety.

Strengths of the Study

The strengths of our study include including a relatively large patient population in a single center, evaluating the efficacy and safety of USG and XrF in TIVAP implantation, and analyzing complications in detail. In addition, the TIVAP implantation technique and operating room environment used in our study are more specific and standardized compared to other studies in the literature.

Limitations of the Study

There are also some limitations of our study. First of all, our study is a retrospective study. Prospective clinical studies should be planned for more definitive results. Second, since our study was conducted in a single center, the results may differ in different centers. Third, only the complication rates were evaluated in our study, and other important outcomes such as quality of life or satisfaction of the patients were not evaluated.

CONCLUSION

This series, which included a total of 112 patients, shows that TIVAP implantations performed using USG and XrF in a hybrid operating room are a safe and effective method. The absence of perioperative complications and the low infection rate were associated with TIVAP implantation being performed in hybrid operating rooms where imaging systems such as XrF were used and surgical sterile fields could be created. These results support that the optimal TIVAP implantation should be performed by cardiovascular surgeons in hybrid operating rooms.

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RESEARCH ARTICLE

AGE-RELATED DIFFERENCES IN FUNCTIONAL CAPACITY AND TECHNICAL PERFORMANCE IN YOUTH SOCCER PLAYERS WITH SIMILAR TRAINING AGES

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ABSTRACT

Purpose: Chronological age is the most straightforward method for classifying youth soccer players based on their date of birth. However, results concerning the effect of chronological age on functional capacity and technical performance are controversial in youth soccer. Therefore, the aim of the present study was to determine the differences in physical and soccer technical performance between U12 and U14 male soccer players with similar training ages. For this purpose, 84 soccer players were grouped according to their soccer age category (U12 and U14).
Material and Methods: Body weight, body mass index and body composition were measured by using a bioelectrical impedance analysis. Flexibility, static balance, and vertical jump performances were measured using the sit-and-reach test, Flamingo balance test, and vertical jump test, respectively. Moreover, soccer technical performance was evaluated using Mor-Christian passing test.
Results: The mean training ages of the U12 (4.28 ± 2.14 years) and U14 (5.00 ± 2.55 years) groups were similar ($p = 0.15$), whereas their chronological ages differed significantly (U12: 10.46 ± 0.78 years; U14: 12.09 ± 0.28 years; $p < 0.05$). Anthropometric measurements (height, weight and fat free mass), flexibility, static balance, vertical jump, and passing results were significantly higher in U14 compared to U12 soccer players ($p<0.05$).
Conclusion: U14 soccer players demonstrated superior physical and technical performance compared to U12 players, despite similar training ages. These findings suggest that age-related developmental factors play a key role in performance and highlight the need to consider individual maturity and physical characteristics in youth training and classification.

Keywords: Youth soccer, chronological age, training age, technical performance, functional capacity.

INTRODUCTION

Soccer, the world's most popular sport, has become even more popular according to Fédération Internationale de Football Association's (FIFA) Big Count that counts 265 million players across different levels, genders, and ages (1,2). It also has largest number of youth players, totalling 22 million (2). Given the vast range of participants globally, it becomes

important for standard frameworks to guarantee fair competition and support structured player development. Consequently, youth soccer age group classifications, determined by national and international soccer associations, follow FIFA's overarching guidelines and are based on chronological age (CA) (3).

The age range commonly used to define young athletes spans from 6 to 18 years, encompassing both prepubescent athletes (under the age of 12) and adolescent athletes (generally between 12 and 18 years). This range is commonly divided into subgroups such as U10, U12, U14, U16, and U18, based on birth year (4,5). CA has been identified as a key factor influencing both technical performance and functional capacity in youth soccer players (6,7). However, relying solely on CA may be insufficient to account for the great variability in biological maturation and training experience among youth soccer players. Differences in physical growth, motor skill acquisition, and athletic development can lead to considerable discrepancies in functional capacity and technical performance among players of the same CA. Therefore, investigating the effects of CA while controlling for training age is crucial for better understanding developmental pathways and optimize talent identification in youth soccer.

Soccer players require a high level of functional capacity, including various components such as explosive power, maximal strength, and aerobic endurance to perform successfully during matches (8). Although aerobic metabolism predominates over the course of a match, decisive actions such as short sprints, jumps, tackles, and one-on-one duels rely on anaerobic energy systems, and often distinguish successful teams from unsuccessful ones (9,10). These high-intensity actions, which have a critical influence on match results, must be developed from an early age (11). In addition to CA, functional capacity in youth players is influenced by both training age (12–15) and biological maturation (4). During puberty, increased secretion of growth hormone, testosterone, and insulin-like growth factor-1 (IGF-1) promotes muscle development, neuromuscular coordination, and energy metabolism. However, muscle mass and strength are not yet fully develop in younger athletes, resulting in gradual improvements in strength, power, and anaerobic performance with age (4).

Strength is a key determinant of soccer performance, particularly as adolescent players progress through developmental stages. Strength, which has been shown to have a strong correlation with CA, critically influences technical skill acquisition during the first two decades of life (16–18). Functional tests such as short sprints, vertical jumps (VJ), and squats effectively mirror soccer-specific strength capacities. Many studies have shown that CA positively impacts VJ performance in adolescent soccer players (6,19–21). However, biological maturation may act as a confounding variable, making it challenging to separate age-related and maturation-dependent effects (4,22,23).

Flexibility also plays an important role in soccer performance, as it underpins mobility, coordination, and technical execution (24,25). Yet, the influence of CA on flexibility in youth soccer players remains inconclusive; some studies report no significant age-related impact, while others note a decline in flexibility with increasing age in both athletes and non-athletes (18,26–28). This discordance may be due to differences in biological maturation, which complicate the interpretation of CA's impact.

Enhanced proprioception and balance are associated with improved technical and tactical soccer skills (29,30). Although balance is a crucial component of soccer performance, limited research has examined the specific influence of CA on balance development in youth players. As with strength and flexibility, biological maturity would likely play a crucial concerting role in the development of balance (4,22,23).

Finally, technical skills such as passing, shooting, dribbling, and ball control are essential to soccer success, as proficiency in these skills directly enhances a team's ability to score goals and win (31). Existing evidence indicates that CA plays a significant role in the development of these skills during adolescence (6,22,32), although this process may also be influenced by training content, biological maturation, and individual variability (6,32–34).

In summary, while CA remains the most straightforward method for classifying youth soccer players based on their date of birth (5), studies investigating its impact on functional capacity and technical performance are limited and inconsistent. Moreover, although CA offers a simple way to classify, it does not account for differences in training age. Studying players of similar training backgrounds may alow for a more accurate assessment of CA's effect on performance parameters. Thus, the aim of the present study was to determine the differences in

technical performance and functional capacity between U12 and U14 male soccer players with comparable training ages. The study was based on two hypotheses:

I. Older players, despite having similar training ages, would demonstrate higher functional capacity due to physiological and motor development advantages associated with aging.

II. Older players, despite having similar training ages, would exhibit higher technical performance as a result of age-related developmental factors.

MATERIALS AND METHODS

Subjects

A total of 84 registered male youth soccer players participated in the study. Players belonged to the U12 (n = 50) and U14 (n = 34) age groups, which are among the most commonly used categories in youth soccer (6). All players belonged to a local youth soccer club, which was training them under professional coaches.

A post hoc power analysis with α = 0.05 was conducted using G*Power 3.1.9.2 to evaluate whether the sample sizes were sufficient to detect significant differences in the study outcomes. Given the inclusion criteria and natural availability of participants at the time of data collection, group sizes were unequal (U12 = 50, U14 = 34), reflecting the actual distribution of players actively registered in the local youth soccer program. Despite this imbalance, post hoc power analysis using the Wilcoxon-Mann-Whitney test (A.R.E. method) indicated acceptable statistical power for both primary outcomes. For flexibility, an effect size of d = 0.623 yielded a power of 0.86 (noncentrality parameter δ = 2.74, df = 78.21, one-tailed). For VJ, an effect size of d = 0.575 resulted in a power of 0.81 (δ = 2.53, df = 78.21, one-tailed).

Training 3 sessions per week with a training experience of at least 2 years were the inclusion criteria of the study. On the other hand, players who had any musculoskeletal injuries over the last 6 months were excluded from the study.

This study followed a cross-sectional comparative design, with data collected from independent groups of players at a single time point.

Written and verbal information about the study was provided to all players and their families, and written informed consent was obtained prior to participation. The players were aware of the potential risks and benefits of the study. Ethical approval for the current study was given by the Eastern Mediterranean University Health Subcommittee, located in Famagusta, in February 2020 (approval number:2020/0050).

Procedures

Players' assessments were conducted over two consecutive training days, with a minimum 24-hour rest period between them to minimize fatigue and ensure recovery.

Day 1: All demographic and anthropometric data were collected. CA and training age were calculated as the difference between the current date and the player's date of birth or training start date, respectively (5). Body height was measured with a tape measure. Weight, body mass index (BMI) and body composition were measured by using a bioelectrical impedance analysis (Tanita SC 330). Subsequently, players completed flexibility, balance and VJ tests in that order. Prior to testing, all participants were warmed up in the same standardized way: 5-minutes of jogging at their own comfortable pace, at sub-maximal exertion, before 8-minutes of dynamic stretching on their lower extremities (lunging walks, hip circles, leg swings) (32). To minimize fatigue and ensure test reliability, a standardized rest period of 5 minutes was provided between each test. Tests were conducted indoors in the laboratory of the university, which allowed more consistent climate and testing surfaces, in the same order at the same time of day (2:00 PM) to avoid fluctuations in physiological responses due to differences in circadian rhythm.

Day 2: Soccer technical performance test was conducted. The same warm-up protocol from day 1 was repeated. The passing test was performed on an artificial turf soccer pitch, with players first receiving a familiarization trial. Measurements were performed by three physiotherapists and two sports scientists, with standardized verbal encouragement to ensure maximal effort.

Assessments- Physical Fitness Tests

Sit-and-Reach Test (SRT): SRT was used to assess flexibility of lower back and hamstring muscle groups. This test has been validated and demonstrated high reliability when standardized procedures are applied (35). Athletes sat on the floor with their knees straight, legs together, and soles of the feet positioned flat against a SRT standardized box. Once in that

position, athletes were requested to extend their arms with palms down and lightly touch the index fingers together. Then, athletes bent forward slowly and reached as far forward as possible while keeping the knees extended. Three attempts were performed and the mean is recorded in cm to reduce variability due to single outlier efforts and increase measurement reliability, as recommended in previous flexibility assessment protocols (36,37).

Static Balance Test: Flamingo Balance Test was used to assess static balance, which reflects the strength and neuromuscular control of the leg, pelvic, and trunk muscle. A balance board with a 50 cm length, 4 cm in height, and 3 cm width was used. Players were asked to stand on the long axis of the board, on their dominant foot, lift the non-dominant leg, and hold it with the hand on the same side. Athletes kept their balance by holding the instructor's hand then the stopwatch started when athletes were ready to maintain their balance on their own. The stopwatch stopped each time the players lost their balance (either by falling off the beam or by moving the held leg). The number of falls within one minute was recorded. If more than 15 falls occurred in the first 30 seconds, the test was over and a score of zero was given (38). The test was performed three times for both the dominant and non-dominant legs to evaluate possible asymmetries in static balance and postural control. The mean number of falls for each leg was calculated and used for further analysis.

Vertical Jump (VJ) test: The standing VJ test was used to evaluate lower-body muscular strength and power, following the protocol described by Salles et al. (39). The test was performed indoors on a flat surface. Athletes stood flat-footed and performed a countermovement jump with arm swing, aiming to achieve the highest possible jump. Each athlete completed three trials with a 60-second rest between repetitions. Jump height was measured using the wall and chalk method, where participants marked the wall at the peak of their jump after applying chalk to their fingertips. The difference between the standing reach height and the jump mark was recorded in cm. The best of the three trials was retained for analysis. To ensure standardization, the same observer gave standardized verbal encouragement during all trials.

Soccer ability skill test: The soccer ability skill test developed by Mor-Christian evaluates technical performance such as passing, dribbling and shooting performance (40). The present study used only the passing component of the test, as it has high test-re-test reliability (r=0.96) and acceptable validity (r=0.78) (41). Passing was selected due to its critical role in maintaining possession and organizing team play in soccer (31). The test was conducted on an artificial turf soccer pitch, suitable for the soccer skill evaluation. A goal of 91 cm wide and 46 cm high was made by placing 91 cm apart two cones of 45 cm high. A rope of 1.22 meters was put on the top of the two cones parallel to the ground to form the crossbar of the goal. Three cones were placed at a distance of 14 meters from the goal. The first cone was in the left and made a 45-degree angle with the goal line. The second cone was in the center and made a 90-degree angle with the goal line. The third cone was in the right and made a 45-degree angle with the goal line. The players made 5 passes with the dominant leg from each cones. The first pass from each cone was a trial and was not taken into account. The other 12 passes were taken into account (4 passes from each cone). If the ball passed between the goal posts or touched them, the pass was considered successful. 1 point was given for each successful pass and 0 point was accorded for unsuccessful passes. The highest possible score obtainable from this test was 12 points on condition that all the passes were successful (40).

Statistical analysis

The data obtained in the study were analyzed using the Statistical Package for Social Sciences (SPSS v24.0, IBM, Chicago, IL, USA). Shapiro-Wilk test was used to determine if the data were normally distributed. Non-parametric statistical tests were used for statistical analysis since the entire dataset did not follow a normal distribution. The variables used in the study were presented in numbers, percentages (%), and median and interquartile range (IQR). Comparison of continuous data between groups was analyzed with the Mann-Whitney U test. Statistical significance was accepted at a level of $p<0.05$. The effect size was calculated using the formula $r = z / \sqrt{N}$. Effect sizes were interpreted based on Cohen's criteria as small ($r \approx .10$), moderate ($r \approx .30$), and large ($r \geq .50$) (42).

RESULTS

A total of 84 soccer players participated in the study, including 50 players in the U12 group (59.53%) and 34 players in the U14 group (40.48%). The mean chronological ages of the U12 and U14 groups were 10.46 ± 0.78 and 12.09 ± 0.28 years, respectively, showing a statistically significant difference between

the groups ($p < 0.05$). In contrast, the mean training ages were 4.28 ± 2.14 years for U12 players and 5.00 ± 2.55 years for U14 players, with no significant difference observed ($p = 0.15$).

Anthropometric characteristics of adolescent soccer players by soccer age group were presented in Table 1. According to table 1, body weight, height and fat free mass (FFM) were significantly higher in U14 groups compared to the U12 group ($p<0.05$).

However, BMI and Fat percentage values were not significantly different between the groups ($p > 0.05$) (Table 1).

Physical performance parameters of adolescent soccer players by soccer age group were presented in Table 2. The total number of falls in the Flamingo Balance Test (dominant and non-dominant sides) was significantly lower in U14 players compared to U12 players ($p = 0.019$ and $p = 0.013$, respectively). The SRT and VJ test scores were also significantly higher in U14 players ($p = 0.010$ and $p = 0.035$, respectively). Moreover, passing test scores of U14 players were significantly higher than U12 players ($p = 0.03$) (Table 2).

DISCUSSION

The aim of this study was to compare physical fitness and technical performance parameters between U12 and U14 male soccer players with similar training ages. It was hypothesized that U14 players, despite similar training ages, would demonstrate higher functional capacity and technical performance due to physiological and motor development advantages associated with age. The major findings confirmed this assumption: U14 players were found to have

Table 1. Anthropometric Characteristics of Adolescent Soccer Players by Soccer Age Group

	Soccer Age Group	Median	IQR	MR	Z	P* (r)
Body Weight (kg)	U12 (n=50)	35.10	13.50	36.48	-2.743	**0.006 (0.30)**
	U14 (n=34)	41.75	12.53	51.35		
Height (cm)	U12 (n=50)	142.00	13.00	34.97	-3.435	**0.001 (0.37)**
	U14 (n=34)	150.00	9.25	53.57		
BMI (kg/m^2)	U12 (n=50)	17.20	3.70	39.50	-1.367	0.172
	U14 (n=34)	19.05	4.70	46.91		
Body Fat (%)	U12 (n=50)	15.40	6.70	43.60	-0.501	0.616
	U14 (n=34)	17.05	9.53	40.88		
FFM (kg)	U12 (n=50)	30.70	8.30	34.83	-3.495	**0.000 (0.38)**
	U14 (n=34)	35.00	7.05	53.78		

**Mann-Whitney U test. IQR: Interquartile range. MR: Mean Rank, r: effect size, BMI: Body Mass Index, FFM: Fat Free Mass*

Table 2. Physical Performance Parameters of Adolescent Soccer Players by Soccer Age Group

	Soccer Age Group	Median	IQR	MR	Z	P* (r)
Total Number of Falls in Flamingo Balance Test (Dominant)	U12 (n=50)	8.00	8.00	47.63	-2.344	**0.019 (0.26)**
	U14 (n=34)	4.00	9.25	34.96		
Total Number of Falls in Flamingo Balance Test (Non-dominant)	U12 (n=50)	9.00	8.50	47.95	-2.490	**0.013 (0.27)**
	U14 (n=34)	6.00	7.25	34.49		
SRT (cm)	U12 (n=50)	-2.00	10.00	36.86	-2.572	**0.010 (0.28)**
	U14 (n=34)	3.33	7.30	50.79		
VJT (cm)	U12 (n=50)	26.00	6.00	37.88	-2.110	**0.035 (0.23)**
	U14 (n=34)	27.00	5.30	49.29		
Mor-Christian Passing Test (#)	U12 (n=50)	5.00	3.00	30.47	-2.164	**0.030 (0.24)**
	U14 (n=34)	7.00	2.00	40.88		

** Mann-Whitney U test, IQR: Interquartile range. MR: Mean Rank, r: effect size, SRT: Sit-and-Reach Test, VJT: Vertical Jump Test*

significantly better static balance, flexibility, explosive power, and technical performance than U12 players.This is consistent with previous research showing that the physical and technical qualities of youth athletes appear to improve with age and development (1,4,6,7,11). Understanding these developmental differences is crucial for age-specific training and long-term player development strategies in soccer.

Actions such as quick sprints and high jumps requiring explosive power are important in winning duels within a match (43). VJ is a good functional test for fitness and talent selection (1,44). In the present study, VJ performance of U14 was significantly higher than U12 players' results, which is consistent with previous findings that VJ scores improve with increasing CA in adolescent soccer players (1,21,45). This age-related increase until the age of 18 is often attributed to greater muscle development, particularly in the lower limbs (16). Although muscle mass was not measured directly in the present study, significantly higher FFM, which is frequently used as an indirect indicator of muscle mass (46), was observed in the U14 group. However, training age (13,15) and maturity (6,22) are also highly correlated with explosive power. CA-induced muscle mass increase may affect positively explosive power in the current study. Therefore, we may suggest that explosive power is a biomotor ability affected by multiple factors. Also, practically, the evident improvement in VJ performance might have translated into improved match-related aspects such as quick accelerations and dueling ability in the air, which may favor the on-field performance of the older age group.

Lower limb is used intensively in soccer where hamstring flexibility is vital. Consequently, SRT is widely used in soccer practices (47,48). In boys, lower back flexibility decreases linearly starting from the age of 5 until the age of 12 where it becomes the lowest. Afterwards, it starts to increase until the age of 18 (4). In the current study, flexibility of U14 players was better than U12, which is consistent with this age-related trend. Feldman et al. hypothesized that the decrease of flexibility before puberty was due to environmental factors such as the beginning of primary school, decrease of physical activities, and increase of sitting time (48). While these explanations are rather contextual, their applicability may have limitations for adolescent athletes who are generally trained on a regular basis like those in our sample. According to the training ages reported in the current study, they were homogenous between groups, thus suggesting that training history did not influence flexibility differences. While earlier research has claimed that flexibility may regress as the training age becomes higher (12), the current findings suggest that CA may have a stronger influence on flexibility development, at least within the age range we examined. Furthermore, it is shown that biological maturation has relatively less effect on levels of flexibility during the period of adolescence (26,27). Taken together, the results can be interpreted in a way that improved flexibility in the older group is more so due to physical-dimensional alterations associated with age than training or differences in maturation.

Static, semi-dynamic, and dynamic balances are required to perform well soccer technical performance (29). However, to our knowledge, no study investigated the effect of CA on static postural stability in adolescent soccer players. Only one research investigating the relationship between CA and dynamic balance found no correlation between them in soccer players aged between 11 and 19 (49). According to Wu et al., CA and training age may improve movement control (14). Moreover, postural balance needs a well designed sensori motor system which includes proprioceptive, visual, and vestibular systems. While proprioceptive system reached maturity at 3 to 4 years, visual and vestibular systems reached adult level at 15 to 16 years (50). The development of such systems, with age, would have likely favored postural improvement, although no direct measure of this phenomenon in the present study leaves it an assumption. In our study, training age was comparable between groups, yet static balance was better among the older players. Thus, our findings tentatively suggest that CA might influence static balance, possibly due to the continued maturation of sensory systems involved in postural control. The present study provides preliminary insights wherein very few studies exist and calls for further investigation with direct neurophysiological assessments.

Mor-Christian standardized test battery is a simple, valid and reliable test to evaluate soccer technical performance (40,41). In the present study, passing test scores in U14 soccer players were significantly higher than U12 soccer players. Studies showed that CA and training experience contributed slightly to soccer technical performance in adolescent soccer players (6,32). On the other hand, adiposity and

heavier body weight had negative effects on technical performance, while biological maturity appears to have minimal effect (6). According to Meylan et al., chronologically older athletes tend to have more time to develop technical skills and typically possess greater fat-free mass (11). In our study, the training age and body fat percentage of both groups were similar; therefore, we attempted to control for the confounding effects of these factors, although the influence of unmeasured variables cannot be entirely excluded. Based on these findings, we suggest that the CA-related increase in FFM, along with potential developmental motor advantages associated with age, may have contributed positively to soccer technical performance. This highlights the multifactorial nature of technical skill development in youth soccer.

LIMITATIONS

Several limitations should be acknowledged. Biological maturation, which plays a key role as a determining condition for the athletes' physical development during adolescence, has not been assessed but might have influenced group comparisons. Future studies should take on board status of maturation to enhance interpretability. Although the group sizes were fairly close to one another, that slight imbalance may have affected statistical power. Moreover, technical performance was evaluated using only a passing test, which greatly limits one's view regarding the overall technical skill set. This one-dimensionality may compromise the intensity and generalizability of this research's claims regarding technical proficiency.

CONCLUSION

The current study demonstrated that U14 soccer players outperformed their U12 counterparts in several physical and technical domains, despite having similar training experience. These differences seem to be related more to age-related developmental changes instead of just training exposure. While chronological age remains a practical criterion for grouping young athletes, it may not fully capture the nuances of physical and technical development. Therefore, coaches and development programs should consider broadening their indicator systems for talent identification and training design to include biological maturity, anthropometric profiles, and motor performance. Such an individualized approach may assist with fairer competition structures and more effective long-term athlete development.

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RESEARCH ARTICLE

DETERMINING THE PRACTICES OF PARAPLEGIA PATIENTS CONCERNING THE SELF APPLIED CLEAN INTERMITTENT CATHETERIZATION

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ABSTRACT

Purpose: The aim of this study is to determine the practices of patients with paraplegia for Clean Intermittent Catheterization (CIC).

Material and Methods: This descriptive study was conducted on 145 patients with paraplegia who were hospitalized in a physical therapy and rehabilitation hospital, who applied CIC, who were 18 years of age and older, who could use their upper extremities, who were at least literate, and who agreed to participate in the study. In the research, a questionnaire consisting of 39 questions prepared by the researchers in line with the literature was used as a data collection tool. Institutional permission, ethics committee approval and patient consent were obtained before data collection. The data were evaluated by performing count, percentage, mean and standard deviation analyzes.

Results: The mean age of the patients was 36.43±13.29 years. CIC application periods are between 3 months and 20 years, and the number of CIC applications in a day is between 1-8. The applications for the pre-procedure, during and post-procedure steps of the patients who applied CIC with paraplegia were determined, and it was concluded that they did not have sufficient knowledge.

Conclusion: It can be recommended to plan trainings on the steps of the procedure during the hospitalization period for patients who apply CIC with paraplegia.

Keywords: Paraplegia, clean intermittent catheterization, practice, nursing care.

INTRODUCTION

Paraplegia is one of the health problems that occur as a result of spinal cord injuries that seriously affect the life of the individual in many ways (1-3). Paraplegia; is a clinical condition that develops due to spinal cord injury caused by head trauma, brain tumor, venous sinus thrombosis, ischemic or hemorrhagic cerebrovascular causes (4,5).

Paraplegic patients have a reduced resistance to infection and an increased risk of contracting a disease. In addition, paraplegic patients' quality of life is negatively affected in many ways. In individuals with neurogenic or non-neurogenic paraplegia, the bladder cannot function fully and the bladder capacity cannot be completely emptied. In this case, permanent or temporary bladder catheterization is

applied (6). Clean Intermittent Catheterization (CIC) application, which is temporary bladder catheterization, is one of the methods that ensure bladder emptying in bladder dysfunction in paraplegic patients (7-9). The prevalence of CIC in patients with paraplegia, was determined at the level of 62.6% (10). According to the Center for Disease Control and Prevention 2015 report; Infections related to catheter applications constitute 75% of urinary infections (11). The incidence of urinary infection is significantly reduced when CIC is applied to the individual with aseptic techniques (9). Compliance with the principles of asepsis, providing hygiene rules and bladder rehabilitation are among the subjects within the scope of nursing services. The nurse; has the responsibility to maintain the aforementioned issues effectively in patients and to provide information and education to the patient (12). It will be possible for patients to apply CIC on their own by preventing or reducing the risk of developing complications with the right methods in their hospital and out-of-hospital life, only with the nursing education given. It is necessary to look at the readiness of individuals for nursing education and to determine the practices of patients who apply CIC.

Although there are studies on patients with paraplegia and CIC applications, studies on the procedure steps performed by patients with paraplegic CIC in practice are limited. Therefore, in this study, it was aimed to determine the self-administered CIC of patients with paraplegia.

MATERIALS AND METHODS

This descriptive study was conducted in Physical Therapy and Rehabilitation. The data of the study was collected between October 2021 and April 2022. Inclusion criteria for the study; Patients who were diagnosed with paraplegia, performed CIC on their own, were literate, aged 18 and over, were conscious, had a stable clinical condition, could use their upper extremities, had no hearing and vision problems, and agreed to participate in the study. The sample number of the study was determined by the G*POWER 3.1 statistical analysis program; The significance level was calculated as 0.05, the power was 95%, and the effect size was 0.3 (medium effect size) based on 145 people. The sample of the study was terminated when the sufficient number of samples calculated in G*POWER, 145, was reached following the beginning of the research. This process took six months (October 2021-April 2022) to complete.

The patients' practices regarding the pre-, during and post-procedure steps of CIC are the dependent variables of the study. The introductory characteristics of the patients and some features of the use of CIC, such as how long, how often, etc., also constitute the independent variables of the study.

In the research, a questionnaire consisting of 39 questions prepared by the researchers in line with the literature was used as a data collection tool (3,4,6-9,13-16). The questionnaire form consists of five parts that will determine the introductory and characteristics of individuals regarding the use of CIC and their practices regarding the pre-, during and post-process steps of CIC. The form consists of eight questions about the introductory characteristics of individuals, three questions determining the characteristics of TAK use, 10 questions about the pre-processing steps of TAK, nine questions about the steps of TAK during the process, and nine questions about the post-processing steps of TAK. All questions in the questionnaire form, except age, height, and weight, consist of optional questions. The questionnaire form was pre-applied on 30 patients with paraplegia who fit into the sample group, and its intelligibility and effectiveness were tested. As a result of the application, the questions that were not perceived by the patients in the same sense, unclear and difficult to understand were changed and the questionnaire form was made ready for application. The data of patients with paraplegia who were pre-treated were not included in the study.

Institutional permission numbered E-26171210-929 from Provincial Health Directorate Scientific Study Commission regarding the place where the study will be conducted before data collection, and Clinical Research Ethics Committee dated 05.10.2021 decision numbered 2021-16/171 was taken. After explaining the purpose of the research to the patients and obtaining consent from the patients, a questionnaire form was given to the patients by the researcher, and they were asked to fill in. The study was carried out in accordance with moral, conscientious and medical rules according to the articles specified in the Declaration of Helsinki. Data were collected by the researcher through face-to-face interviews. It took 15-20 minutes for the participants to fill out the questionnaire.

RESULTS

Of the patients participating in the study, 29.7% were female and 70.3% were male. The mean age of the patients was 36.43±13.29 (min:18, max:70). Considering the education level of the patients; it was determined that the majority of them were high school (33.8%) and secondary school (32.4%) graduates (Table 1).

CIC application times of the patients; 0-3 years (32.4%), 4-7 years (35.9%), 8-11 years (24.8%), 12-15 years (2.1%), 16 years and above (4.8%). CIC was performed once a day (2.8%), twice a day (4.8%), thrice a day (5.5%), four times a day (31.7%), five times a day (7.6%), six (37.3%) a day, seven or more per day (10.3%). It was determined that the mean duration of CIC use of the patients was 2.11±1.04 years and the frequency of CIC use was 4.90±1.48 times a day. In CIC, men use 40 cm and women 20 cm long catheters. Men prefer catheters with CH 14/40 cm (40.7%) and women with CH 12/20 cm (15.9%) more than others (Table 2).

All of the patients stated that they prepared all the necessary materials before the procedure. Sterile gel-packed catheter (hydrophilic catheter) (100%), urine bag (73.1%), wet wipes (70.3%), disposable gloves (42.1%), urine drainage container (32.4%), protective cover / cloth in CIC application of patients (22.1%), napkin (19.3%), antiseptic solution (batikon etc.) (17.9%), warm water (9.7%), sterile sponge (gauze) (9.7%), mirror (9.7%), dirty bag / waste container (8.3%), towel (5.5%), soap (2.8%) and material tray (0.7%). All patients perform CIC using a sterile gel-packed catheter (hydrophilic catheter). The answers of the patients regarding the evaluation of their genital areas in terms of negativity (discharge, deterioration in tissue integrity, etc.) before the procedure; no (42.8%), sometimes (50.3%), yes (6.9%). Regarding whether the bladder fullness control is checked before the procedure, the patients; no 79.3%, sometimes 20%, yes 0.7%. It was determined that the majority of the patients (65.5%) did not wash their hands before the procedure (Table 3).

While applying the CIC application, women; dorsal recumbent (21.4%), semi fowler (13.1%), sims (6.9%), fowler (4.8%) and supine (2.1%) men; semi fowler (47.6%), supine (33.8%) and fowler (33.1%) positions are preferred. It was determined that the majority (71.7%) did not clean the genital area during the procedure. Data on catheter advancement distances during the procedure; until the entire catheter is inserted (60.7%), until the urine comes out (33.8%), up to half of the catheter (4.8%), and up to 3/4 (0.7%) of the catheter. Considering the patients' use of more than one CIC with the same catheter; While 54.5% stated that they did not implement it, 45.5% stated that they did. The amount of urine discharged at one time in CIC application was determined as 100-999 ml (31.7%), 1.000 ml and above (68.3%) (Table 4).

It was determined that the majority of patients did the genital area cleaning after the procedure with a yes response of 56.6%. Considering the level of washing hands of the patients after the procedure; it is seen that the majority give the answer sometimes (38.6%). Considering the state of bladder fullness control after the procedure; It was determined that the majority of the patients did not perform bladder fullness control, with a no response at the level of 78.6%. Post-procedure urine of the patients (in terms of color, smell, amount); no (13.1%), sometimes (64.8%) and yes (22.1%). Considering the responses of the patients to inform the healthcare professionals if they detect an abnormal situation; 29.6%, sometimes 56.6%, yes 13.8% (Table 5).

DISCUSSION

In this study, the number of male patients with paraplegia was higher than that of females with paraplegia. According to the studies, it has been determined that the rate of women in the prevalence of CIC application is lower than that of men (10,17). The data in the mentioned studies support the result of this study. It was determined that the age distribution of the patients with paraplegia in the study was between the ages of 18-70. While the majority of the patients (33.8%) with paraplegia were high school graduates at the education level, it was observed that there were also literate patients. According to the results obtained; The trainings to be planned regarding the CIC application should be planned in a way that appeals to individuals of all age groups and education levels.

Different results were obtained in studies investigating of patients with paraplegia who applied CIC (18,19). Considering the duration of CIC administration in this study; While there is a substantial number of patients between 0-3 years (32.4%), the majority consists of patients (35.9%) who practice between 4-7 years. It has been determined that there are also patients who have continued the application for 16 years or more. When we look at previous studies on the sustainability of

Table 1. Descriptive characteristics of patients who applied CIC with paraplegia (N:145)

Descriptive Characteristics	**n**	**%**
Sex		
Female	43	29.7
Male	102	70.3
Age (36.43±13.29 age, min:18-max:70)		
18-30 age	64	44.1
31-43 age	41	28.3
44-56 age	27	18.6
57-70 age	13	9.0
Education Status		
Literate	7	4.9
Primary school graduate	26	17.9
Secondary school gradute	47	32.4
High school	49	33.8
Associate degree	5	3.4
Licence	11	7.6

Table 2. Characteristics of patients with paraplegia regarding the use of CIC (N:145)

Features related to CIC use			**n**	**%**
CIC application times (2.11±1.04 year, min:3 ay-max:20 year)				
0-3 year			47	32.4
4-7 year			52	35.9
8-11 year			36	24.8
12-15 year			3	2.1
16 year and above			7	4.8
Number of CIC applications in a day (4.90±1.48 times, min:1-max:8)				
1 time			4	2.8
2 times			7	4.8
3 times			8	5.5
4 times			46	31.7
5 times			11	7.6
6 times			54	37.3
7 times and above			15	10.3
The number of the catheter used when applying the CIC*	**Women (n=43)**		**Men (n=102)**	
	n	**%**	**n**	**%**
CH 10/40 cm	-	-	2	1.4
CH 12/40 cm	-	-	35	24.1
CH 14/40 cm	-	-	59	40.7
CH 16/40 cm	-	-	6	4.1
CH 10/20 cm	1	0.7	-	-
CH 12/20 cm	23	15.9	-	-
CH 14/20 cm	18	12.4	-	-
CH 16/20 cm	1	0.7	-	-
* Percentages are based on N=145.				

CIC implementation; it becomes clear that these patients should be followed regularly in their lives outside the hospital and should be informed whether they continue the practice or not (19,21,22).

In this study considering the frequency of CIC application; It is seen that CIC is performed mostly 4 (31.7%) and 6 times (37.3%) a day by the patients with paraplegia.

Table 3. Responses of the patients regarding the pre-procedural steps of CIC (N:145)

Pre-Process Steps	n	%
The state of preparing all the necessary materials		
Preparing	145	100
Materials used in CIC application*		
Sterile gel-packed catheter (hydrophilic catheter)	145	100
Urine bag	106	73.1
Wet wipes	102	70.3
Disposable gloves	61	42.1
Urine drainage container	47	32.4
Protective cover / cloth	32	22.1
Napkin	28	19.3
Antiseptic solution (batikon etc.)	26	17.9
Warm water	14	9.7
Sterile sponge (gauze)	14	9.7
Mirror	14	9.7
Dirty bag / Waste container	12	8.3
Towel	8	5.5
Soap	4	2.8
Material tray	1	0.7
Evaluation of the genital area in terms of discharge, deterioration of tissue integrity, etc.		
Does not evaluate	62	42.8
Evaluates Sometimes	73	50.3
Evaluates	10	6.9
The state of controlling the fullness of the bladder		
Not checking	115	79.3
Checking sometimes	29	20.0
Checking	1	0.7
Hand washing status		
Not washing	95	65.5
Washing Sometimes	28	19.3
Washing	22	15.2

*More than one answer has been given. Percentages are based on N=145.

It was determined that the most preferred catheter number in male patients with paraplegia was CH 14/40 cm, and CH 12/20 cm in women with paraplegia. In the literatüre, similar to this study It has been determined that the duration of CIC administration should not exceed 4-6 hours, and the appropriate catheter diameter in adults is Fr 12-14 (20,21). Moreover, the type of catheter and the number of CIC applications affect the use level of the patients and the risk of complications that may develop (18,22). In addition to the majority of the individuals who perform the application at the appropriate frequency and with the correct catheter number, it is seen that other individuals need to be informed to be evaluated.

In this study, it was stated that all patients with paraplegia prepared all necessary materials before the procedure. Considering the answers to the questions asked about the materials used in CIC, it was determined that all the necessary materials were not prepared by all the patients, except the sterile gel-packed catheter (hydrophilic catheter) (100%). Different from the materials to be prepared, it was determined that wet wipes (70.3%) and soap (2.8%) were used. It is recommended to use soap-free, irritating and chemical-free products for cleaning the genital area (23). Considering the levels of wet wipes (29.3%) used for cleaning the genital area during the procedure, wet wipes (82.2%) and soap (1.7%) used for cleaning the genital area after the procedure; it is

seen that some of the individuals do not have sufficient knowledge about the materials that should be used in ensuring the cleaning of the genital area.

According to the studies, it was determined that the selected catheter type and the individual's with paraplegia CIC self-administration increase (18,24,25). Hydrophilic type catheter minimizes the risk of developing complications (20,26-28). In this study, the fact that all individuals perform CIC on their own and use a hydrophilic catheter is important in terms of the risk of complications that may develop. In CIC, a bag or container is needed for urine discharge (7,8,15,21). In this study; It was determined that the use of urine bag was at a higher level than the use of a urine emptying container.

The literature emphasizes that failure to clean the genital area, not complying with aseptic techniques, not paying attention to hand washing technique, and not performing CIC under hygienic conditions increase the risk of urinary infection (20,29). It has been determined that there are many complications that develop due to improper CIC application (8,14,30,31). In this study, when the data obtained on washing hands before the procedure, ensuring genital area cleaning during the procedure, ensuring genital area cleaning after the procedure, and washing hands are evaluated, the risk of developing complications related to CIC application is thought to be high. It was determined that cleaning the genital area during the procedure (28.3%) was less than after the procedure (81.4%).

Bladder fullness control, which has an important place in determining the frequency of CIC application, should be performed before and after the procedure (3,4,7,8,15,32). Considering the data obtained on this subject, it is seen that the vast majority of patients do not regularly check their bladder fullness. The push forward distance of the catheter and the application of the catheter without infection are important in terms of not causing the development of complications such as urethral perfusion, urethral bleeding, urinary system infection, etc. (3,4,6,7,8,13,14,29,33).

Table 4. The answers of the patients regarding the steps of the CIC application during the procedure (N:145)

Steps During the Process	**Women (n=43)**		**Men (n=102)**	
The position in which the application is carried out*	**n**	**%**	**n**	**%**
Half sits (semi fowler)	19	13.1	69	47.6
Sits (fowler)	7	4.8	48	33.1
Supine (supine)	3	2.1	49	33.8
Dorsal recumbent	31	21.4	-	-
Half side (sims)	10	6.9	-	-
Genital area cleaning status			**n**	**%**
Not doing			104	71.7
Doing Sometimes			18	12.4
Doing			23	15.9
Catheter push forward distance				
Until the entire catheter is inserted.			88	60.7
Until the urine comes			49	33.8
Halfway down the catheter			7	4.8
Up to 3/4 of the catheter			1	0.7
Multiple CIC applications with the same catheter				
Not applying			79	54.5
Applying			66	45.5
Maximum amount of urine discharged at one time in CIC application				
100-999 ml			46	31.7
1.000 ml and above			99	68.3
*More than one answer has been given. Percentages are based on N=145.				

Table 5. Responses of the patients regarding the post-procedure steps of CIC (N:145)

Post-Processing Steps	n	%
Genital area cleaning status		
Not doing	27	18.6
Doing Sometimes	36	24.8
Doing	82	56.6
Hand washing status		
Not washing	26	18.0
Washing Sometimes	56	38.6
Washing	63	43.4
The state of controlling the fullness of the bladder		
Not checking	114	78.6
Checking sometimes	30	20.7
Checking	1	0.7
Evaluation of urine (in terms of color, smell, amount)		
Not evaluation	19	13.1
Evaluating sometimes	94	64.8
Evaluating	32	22.1
Informing healthcare professionals when an abnormal situation is detected		
Not informing	43	29.6
Informing sometimes	82	56.6
Informing	20	13.8

It is revealed that it poses a risk for the complications that may develop in the patients when the push forward distance of the catheter (up to 60.7% of the entire catheter is inserted) is questioned.

In CIC application, it is emphasized that the genital area should be checked before the procedure (4,6,7,15). According to the results of a case report, it is important to regularly evaluate the genital area in terms of complications that may develop. According to the study, as a result of the data we obtained on the evaluation of the genital area in terms of negativity, we think that it may be late or not detectable in terms of early detection of complications that may develop in the genital area.

It is stated that in case the applied catheter is contaminated (inserting the catheter in the wrong area, using the same catheter more than once, etc.), it should be discarded and the procedure should be performed with a new catheter (3,4,6,34). More than one use of the same catheter is the cause of contamination and this This situation will bring along many complications (35,36). Considering the responses given to the situation of multiple CIC applications with the same catheter in the study, it was determined that the patients did not have sufficient knowledge on this subject. This situation may be due to many reasons such as economic reasons, laziness, difficulty in transportation, etc.

Urine output of 1000 ml or more at one time is not recommended, as it causes bladder collapse and cramping (4,6,7,8,15). The number of individuals with 1000 ml or more urine output at one time in CIC is 68.3%. gives us a serious warning in this regard. The importance of applying to a health institution in case of any problems related to the application and in terms of routine follow-ups is mentioned in patients who apply CIC (37,38). Findings that may indicate the presence of an abnormal situation in CIC application may also be possible by evaluation of urine. For this reason, the evaluation of urine (in terms of color, smell, amount) is of great importance (4,7-9,15). The data obtained on the status of urine evaluation and the level of notifying healthcare professionals in the detection of abnormal conditions suggest that it may increase the risk of being late in the intervention in case of a developing problem.

The research has some limitations. The reason for this is that it required time constraints as it was a master thesis work. In addition, the fact that the research data were collected according to patient with

paraplegia statements and only in one institution is a limitation in terms of the generalizability of the research result. The results obtained from the study can be generalized to the patients with paraplegia who applied to the mentioned institution on the specified dates.

As a result; The practices of patients with paraplegia regarding the pre-, during and post-procedure steps in CIC were determined. The study examined the application of CIC to patients with paraplegia during the pre-procedure, intra-procedure and post-procedure stages and found that they did not have sufficient knowledge. It may be recommended to plan and implement training on pre-, during and post-procedure steps during hospitalization for patients who undergo CIC with paraplegia.

CONCLUSION

It can be recommended to plan trainings on the steps of the procedure during the hospitalization period for patients who apply CIC with paraplegia and to study the knowledge levels of nurses about CIC. In addition, patients should be educated with brochures/booklets on the importance of fluid consumption, genital area cleaning, hand washing, use of a bladder and urine drain, bladder fullness control, the maximum amount of urine that should be emptied at one time, evaluation of urine, possible complications, and situations that should be reported to healthcare professionals. These trainings to be planned regarding CIC application should be planned to appeal to all age groups and education levels.

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RESEARCH ARTICLE

THE RELATIONSHIP BETWEEN PULSE PRESSURE AND DEMENTIA IN OLDER ADULTS: A CROSS-SECTIONAL STUDY

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ABSTRACT

Purpose: As a risk factor for cardiovascular disease, wide pulse pressure may be related to cognitive impairment across the lifespan.

Methods: A total of 313 patients with dementia and 1117 cognitively healthy individuals were included in this study. Blood pressure measurements, demographic data, comorbid conditions, laboratory findings, and parameters from a comprehensive geriatric assessment were evaluated.

Results: While the mean age of the patients and the number of drugs were higher; the frequency of female sex and years of education were lower in the dementia group than in the control group ($p<0.001$ for each). Also, the Mini Nutritional Assessment scores, estimated Glomerular Filtration Rate, folate, and 25 hydroxy vitamin D levels were lower in the dementia group than in the control group ($p<0.001$; $p<0.001$; $p<0.001$ and $p=0.001$, respectively). While the dementia group had wider pulse pressure than controls($p=0.006$); there were no differences between the groups in systolic, diastolic, and mean arterial blood pressure values. When confounding factors were adjusted, the pulse pressure and dementia was related($p=0.032$). In addition, pulse pressure was positively correlated with dementia($p<0.01$).

Conclusion: This study showed that dementia seems to be related to wider pulse pressure in older adults. Healthcare professionals should be aware of the importance of pulse pressure in geriatric practice.

Keywords: Dementia; Pulse Pressure; Mean Arterial Blood Pressure, Older Adults

INTRODUCTION

Hypertension (HT), one of the most common comorbidities, is highly prevalent in older adults (1). Dementia, a geriatric syndrome, is also one of the common comorbidities in older adults. It causes mental and physical disabilities in individuals and poses a significant limitation for their families and caregivers (2). Studies have shown that high blood pressure (BP) that is not treated at an early age is associated with an elevated risk of cognitive decline in older adults (3). Given that there is no definitive cure for many types of dementia, which becomes more common with advancing age, the management of the risk factors such as HT becomes even more important (4). Although the relationship between HT and dementia has been rather well-established over

decades, the association between BP and cognition is complex across the lifespan.

With advancing age, systolic BP tends to increase, while diastolic BP decreases (5,6). This phenomenon attributed to age-related aortic stiffening, which reduce the elastic reservoir capacity of vessel, leading to increased stroke volume during systole and a diminished aortic blood volume at the onset of diastole (7). Also, a drop in diastolic pressure occurs with advancing age due to decreased elastic rebound and increased pressure drop velocity in the arterial system (8). Such changes in older people lead to wide pulse pressure (PP), which may play a role as a cardiovascular risk factor (5). PP, in addition to being a cardiovascular risk factor, may also be associated with cognitive health (9), particularly given that wide PP may accelerate parenchymal aging and adversely affect cognitive functions by leading to cerebral hypoperfusion, micro bleeding, and neuroinflammation (10). Besides, wide PP is closely associated with orthostatic hypotension, which is associated with falls, sarcopenia, frailty, and dementia in the elderly (11–13) and increases mortality from all causes (5). Current guidelines have no recommendation for PP control, and there is no widely accepted value for normal PP (14–16). Moreover, and the relationship between wide PP and dementia has only been evaluated in a few conflicting studies thus far (17, 18). Therefore, this study sought to examine the potential association between PP and dementia in older adults.

MATERIALS AND METHODS

Participants

For this study, 5940 patients who applied to the geriatric outpatient clinic between January 2013 and February 2022 were screened. The patients with a diagnosis of infection, acute cerebrovascular disease, those with missing Comprehensive Geriatric Assessment (CGA) parameters and drug information in their files, and those whose BP was taken by a device other than Biolight1 BIOM69 (Australia) or by manual sphygmomanometer were excluded from the study. After applying the exclusion criteria, a total of 1,430 participants aged 60 years and above who provided informed consent were enrolled in the study.

Ethical Statement

Permission for our study was granted from Dokuz Eylul Non-Interventional Research Ethics Committee (Date: 2 March 2022, Decision no: 2022/08-21), and informed consent for the procedure was obtained from the participants or a proxy on behalf of the patient. The investigation conformed to the Declaration of Helsinki of 1975.

Comprehensive geriatric assessment (CGA)

Demographic characteristics of the patients and comorbid conditions including HT, diabetes mellitus (DM), peripheral vascular disease, coronary artery disease (CAD), cerebrovascular events, congestive heart failure, as well as the number of drugs, antihypertensive drugs, and other drug usage were recorded. Additionally, the Yesevage Geriatric Depression Scale, Lawton-Brody Instrumental Daily Living Activity Scale (IADL), and Barthel Index (BI), Mini Nutritional Assessment (MNA), FRAIL and FRIED scales were collected from patients' files. Dementia, also referred to as major neurocognitive disorder, was diagnosed using The Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria (19). Additionally, brain imaging was carried out in all the demented patients, and with the consent of the patients, cerebrospinal fluid (CSF) analysis was performed.

Evaluation of pulse pressure and mean arterial blood pressure

The Biolight1 BIOM69 (Australia) measured BP after the patient rested for at least 5 minutes in a quiet room, avoiding smoking or drinking tea or coffee for 30 minutes prior to measurement. While the PP was obtained by subtracting the diastolic BP from the systolic BP, mean arterial BP was calculated as, mean BP = PP x (1/3) + diastolic BP.

Laboratory evaluation

In the study, the estimated glomerular filtration rate (eGFR) level; 25-Hydroxy (OH) vitamin D, vitamin B12, low-density lipoprotein (LDL), folic acid, and thyroid stimulating hormone (TSH) results, which may be related to cardiovascular and cognitive health, were evaluated from the laboratory data of the patients. The tests were conducted with the auto-analyzer diagnostic modular system (Roche E170 and P-800), and Serum 25-OH Vitamin D was measured with the radioimmunoassay.

Statistical analysis

Statistical analyses were performed using Statistical Package for Social Sciences (SPSS) version 24.0 (SPSS Inc). Participants were divided into two

groups: those diagnosed with dementia and cognitively healthy individuals. Continuous variables were presented as mean ± standard deviation and categorical data were expressed as percentages (%). The distribution of continuous variables was evaluated using the Kolmogorov–Smirnov test and Skewness and Kurtosis values. Normally distributed continuous variables were compared using Student's t-test, whereas non-normally distributed continuous variables were analyzed with the Kruskal Wallis and Mann-Whitney U tests. Categorical variables were compared using Pearson's chi-squared or Fisher's exact test. To examine associations among non-normally distributed and/or ordinal variables, Spearman's rank correlation coefficients and their corresponding significance levels were computed. A 5% type I error rate was adopted to determine statistical significance. Binary Logistic Regression analysis was performed to reveal the relationship between dementia and PP, considering other related factors, and $p<0.05$ was considered statistically significant.

RESULTS

A total of 313 patients with dementia and 1117 cognitively healthy individuals were included in the study. The frequency of female sex was lower (54.3%) in the demented individuals who were older and less educated than in the controls ($p<0.001$). While the prevalence of HT was lower in the dementia group than in the control group (66.7% vs 60.3%; $p=0.036$); the use of anti-hypertensive medications usage was not significantly different. The eGFR, folate, and 25 OH vitamin D levels were lower in the

Table 1. Characteristics of Participants

	Control n=1117	Dementia n=313	p**
Demographic characteristics (*,%)			
Age (year)*	73.18 ± 7.33	76.78 ± 7.68	**<0.001**
Sex (female) %	67.1	54.3	**<0.001**
Education year*	8.01 ± 4.65	6.58 ± 4.61	**<0.001**
Number of drugs*	4.87 ± 3.21	6.23 ± 3.05	**<0.001**
Anti - hypertensive medications %	59.8	52.7	0.052
Comorbidities (%)			
Hypertension	66.7	60.3	**0.036**
Diabetes Mellitus	29.3	27.6	0.550
Congestive heart failure	5.5	6.7	0.409
Cerebrovascular events	5.7	7.1	0.355
Coronary artery disease	17.1	21.1	0.109
Peripheral vascular disease	5.1	5.4	0.818
Laboratory Results (*)			
eGFR mL/min 1.73 m2	75.86 ± 18.57	71.11 ± 18.98	**<0.001**
Vitamin B12 pg/mL	418.83 ± 301.33	428.36 ± 343	0.503
Folate ng/mL	9.34 ± 4.57	8.11 ± 5.01	**<0.001**
25 OH vitamin D ng/mL	22.58 ±11.84	20.26 ± 11.58	**0.001**
TSH m(IU)/L	1.89 ± 3.01	1.65 ± 1.41	0.212
LDL mg/dL	133.47 ± 29.24	134.68 ± 39.51	0.648
Comprehensive Geriatric Assessment (*, %)			
YGDS	3.24 ± 3.48	3.46 ± 3.5	0.272
BADL	92.22 ± 11.5	83.22 ± 18.19	**<0.001**
IADL	20.266 ± 7.69	11.17 ± 8.67	**<0.001**
MNA	12.63 ± 1.96	11.26 ± 2.33	**<0.001**
Frailty (%)	26.1	49.5	**<0.001**
Blood Pressure Measurements (mmHg) (*)			
Pulse Pressure	60.57 ± 15.03	63.22 ± 14.56	**0.006**
Systolic BP	134.12 ± 18.73	136.02 ± 16.84	0.087
Diastolic BP	73.55 ± 12.04	72.80 ± 10.22	0.272
Mean arterial BP	93.74 ± 12.78	93.87 ±10.82	0.854

BADL: Barthel Basic Activity of Daily Living; BP: Blood Pressure; eGFR: estimated Glomerular Filtration Rate; IADL: Lawton-Brody Instrumental Activity of Daily Living; LDL: Low Density Lipoprotein; MNA: Mini Nutritional Assessment; OH: Hydroxy; PP: Pulse Pressure; TSH: Thyroid Stimulating Hormone; YGDS: Yesevage Depression Scale . * Mean ± SD **Statistically significant p values ($p < 0.05$) are shown in bold characters

dementia group (p<0.001, p<0.001 and p=0.001, respectively).

The demographic characteristics, comorbidities, and laboratory findings of the study participants are summarized in Table 1. While the dementia group had a wider pulse pressure than controls (p=0.006); there was no difference between the groups in systolic, diastolic and mean arterial blood pressure values. When the regression analysis was performed according to age, sex, education year, HT, frailty, MNA score, eGFR, folate, and 25 OH vitamin D, the significance of the relationship between PP and dementia remained (OR:1.011, 95% CI 1.001-1.022, p= 0.032) (Table 2). A positive correlation was observed between PP and dementia (r = 0.080, p <0.01), whereas no significant associations were found with mean arterial BP, systolic BP, or diastolic BP. Table 3 shows the correlation analysis between the variables.

DISCUSSION

This retrospective and cross-sectional study demonstrated that wider PP was associated with dementia in older adults.

The lack of a curative treatment option for demented individuals has made it even more significant to take preventive interventions by regulating the accompanying risk factors such as HT in these patients (20, 21). With advancing age, PP increases due to the aforementioned changes in BP and the arterial system (5,22). Furthermore, recent evidence has suggested that PP may be related to cognitive impairment. The relationship between cognitive function and PP may be linked to the “biomechanical brain injury hypothesis”, which includes microvascular and neuronal damage (10). Accordingly, it has been shown that wide PP targets brain microvascular endothelial cells, leads to leaks in the blood-brain barrier and creates microvascular damage (22–24). Consequently, wide PP caused by age-related increased peripheral arterial stiffness may increase penetration into cerebral micro vessels and cause functional, structural, metabolic, and hemodynamic changes that may lead to neuronal dysfunction and cognitive decline (25). Additionally, microvascular damage in the brain impairs the function of the blood-brain barrier and increases its permeability, which increases the accumulation of β-amyloid in the cerebral cortex, the basis of the neurodegeneration process (26). Accordingly, the present study found that wider PP was associated with dementia in older adults.

On the other hand, there is no consensus on the relationship between PP and dementia in the available studies. In a meta-analysis, no relationship was found between PP and dementia (17). However, Qiu et al reported that both higher and lower tertiles of PP were associated with an increased risk of dementia especially among women in the categorical analysis (27). Accordingly, lower PP was associated with probable dementia in a recent study which defined probable dementia with Mini Mental State Examination Score ≤23 and that was conducted with 432 patients (28). Furthermore, Jung Y et al found a higher risk of dementia in older females with a wider PP but not in males (18), and suggested that this may be related to the lower education level, the stronger effect of apolipoprotein E and the increased frequency of depression in females, nevertheless, the underlying mechanism has not been fully accounted

Table 2. The Relationship Between Pulse Pressure and Dementia After Regression Analysis

	Dementia		
	OR	95% CI	**p***
Pulse Pressure	1.011	1.001-1.022	**0.032**

Model: Adjusted for age, sex, years of education, number of drugs, HT, Frailty, MNA, eGFR, folate, and 25 hydroxy vitamin D levels. CI: Confidence Interval; eGFR: estimated Glomerular Filtration Rate; HT: Hypertension; MNA: Mini Nutritional Assessment; OR: Odds Ratio. *Statistically significant p values (p < 0 0.05) are shown in bold characters.

Table 3. Correlation between blood pressure parameters and dementia

	Pulse Pressure	**Mean arterial BP**	**Systolic BP**	**Diastolic BP**
Dementia	**0.080****	-0.005	0.041	-0.040

BP: Blood Pressure. ** Correlation is significant at the 0.01 level (2-tailed).

for. The other research extracted from Hypertension in the Very Elderly Trial (HYVET) demonstrated that wider achieved PP, which was calculated as a mean of PPs from multiple visits during the trial, was associated with an increased risk of dementia in treatment groups (placebo and active) (9). Furthermore, in the study by Peters et al. (9), it was observed that achieved diastolic blood pressure did not predict subsequent dementia in the placebo group; however, a U-shaped association was identified in the active treatment group. In contrast, systolic blood pressure was not found to be associated with dementia. In our study, although the frequency of HT was different between the groups, there was no difference between the groups in systolic, diastolic and mean arterial BP values, probably due to proper anti-hypertensive treatment. These results support the notion that PP rather than mean arterial BP, systolic or diastolic BP may be associated with dementia. Within this context, as far as we are concerned, this is one of the first studies to thoroughly evaluate such a relationship in older adults naturalistically and in real-life conditions. However, prospective, cohort and follow-up studies that evaluate this relationship in subtypes of dementias, especially in AD and vascular dementia, are needed to elucidate this relationship in detail.

The study's strengths are the high number of patients and the measurement of BP of all patients with the same model and brand BP monitor. All the patients underwent CGA, and antihypertensive drug use was evaluated in detail. On the other hand, the retrospective and cross-sectional design are the limitations of the study. Another limitation of the study is the lack of differentiation between dementia subtypes, which may involve distinct pathophysiological pathways in relation to pulse pressure. Additionally, despite being under optimal conditions, all the measurements were based on single BP readings in the study.

CONCLUSION

This study demonstrated that wider pulse pressure may be related to dementia in older adults. Therefore, healthcare professionals dealing with geriatric patients should be aware of the importance of pulse pressure in the management of dementia and hypertension.

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