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What may be Related to Patient Satisfaction in Prostate Biopsies?

Prostat Biyopsilerinde Hasta Memnuniyeti Nelerle İlişkili Olabilir?

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ÖZET

Amaç: Prostat biyopsisi yapılan hastalarda hasta memnuniyetini etkileyen faktörleri araştırmak.

Gereç ve Yöntemler: Transrektal ultrasonografi (TRUS) eşliğinde prostat biyopsisi yapılmasına karar verilen, yaşları 48 ile 86 arasında değişen 241 hastanın 237'si prospektif olarak değerlendirildi. İşlem öncesinde hastaların yaşı, vücut kitle indeksi (VKI), prostat spesifik antijen (PSA) değerleri, prostat hacmi, pozitif parmakla rektal muayene (PRM) bulguları ve biyopsi endikasyonları kaydedildi. Biyopsi esnasında hisedilen ağrı düzeyi, görsel ağrı skorlama (VAS) ile puanlandı. Biyopsi sonrasında hasta memnuniyeti 4 puanlık ölçek ile değerlendirildi.

Bulgular: Değerlendirmeye alınan 237 hastadan 92'si işlemden memnun değil iken, 145 hasta memnundu. Grup 1 ve Grup 2'nin ortalama yaşları 65,9±8,1 ve 66,1±7,6 yıl, VKI 27,7±4,0 ve 26,3±3,9 kg/m2, PSA düzeyleri 58,6±304,6 ve 17,9 ± 68,1 ng/ml, Prostat hacmi 59,4 ± 51,8 ve 51,8 ± 28,7 cc Ortanca VAS skoru sırasıyla 4 (3-6) ve 4 (2,5-6) idi. PRM bulguları pozitif olan grubun memnuniyet düzeyi 3 (2-3) iken, negatif olan grubun 3 (2-3) olarak bulundu. Tümor varlığı pozitif olan grubun memnuniyet düzeyi 3 (2-3) bulunurken, tümor bulunmayan grubun memnuniyet düzeyi 3 (2-3) idi. Perinöral invazyon görülen grubun memnuniyet düzeyi 3 (2-3)iken, görülmeyen grubun memnuniyet düzeyi 3 (2-3) olarak bulundu.

Sonuç: TRUS eşliğinde yapılan prostat biyopsilerinde hastanın memnuniyet düzeyi ile hastanın yaşı, serum PSA düzeyi, prostat hacmi, hissedilen ağrı düzeyi, pozitif PRM bulgusu, pozitif tümor patolojisi veya histolojik olarak tumorün perinöral invazyonu arasında ilişki saptanmadı. BMI ile memnuniyet düzeyi arasında istatistiksel olarak anlamlı bir ilişki mevcuttu.

Anahtar Kelimeler: Hasta memnuniyeti, Ağrı düzeyi, Prostat biyopsisi, Pozitif tümor patolojisi, Perinöral invazyon.

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ABSTRACT

Objective: To investigate the factors affecting patient satisfaction in patients undergoing prostate biopsy.

Material and Methods: Two hundred thirty seven of 241 patients, aged between 48 and 86, those who are decided to undergo transrectal ultrasonography (TRUS)-guided prostate biopsy, were evaluated prospectively. Age, body mass index (BMI), prostate-specific antigen (PSA) values, prostate volume, positive digital rectal examination (DRE) findings and biopsy indications of the patients were recorded before the procedure. The level of pain felt during biopsy was scored by visualised pain scoring (VAS). Patient satisfaction was evaluated with a 4-point scale after biopsy.

Results: Of the 237 patients evaluated, 92 were dissatisfied with the procedure, while 145 were satisfied. The mean age of Group 1 and Group 2 were 65.9±8.1 and 66.1 ± 7.6 years, BMI were 27.7±4.0 and 26.3 ± 3.9 kg/m2, PSA level were 58.6 ± 304.6 and 17.9 ± 68.1 ng/ml, Prostate volume were 59.4 ± 51.8 and 51.8 ± 28.7 cc., The median VAS score was 4 (3-6) and 4 (2.5-6) respectively.

The satisfaction levels of positive DRE findings Group was 3 (2-3) while negative 3 (2-3), Tumor existance Group was 3 (2-3) while no tumor Group's Satisfaction levels 3 (2-3), Perineural invasion of tumor existance Group was 3 (2-3) while other Group's Satisfaction levels 3 (2-3).

Conclusion: In TRUS-guided prostate biopsies, no relationship was found between the patient's satisfaction level and the patient's age, PSA level, prostate volume, the level of pain felt, positive DRE finding, positive Tumor pathology or having perineural invasion of the tumor histologically. There is a statistically significant relationship between BMI and the level of satisfaction.

Keywords: Pain level, Prostate biopsy, Positive tumor pathology, Perineural invasion

INTRODUCTION

Prostate cancer is one of the most commonly diagnosed malignancies in men. It's incidence is increasing annually (1,2). Although it has an insidious onset, it often becomes symptomatic in advanced stages, such us anemia, bone pain, and renal failure due to bilateral ureteral obstruction are some conditions it causes in the advanced stages(1). Other symptoms it may cause are lower urinary tract symptoms (LUTS), such as nocturia and weak urine flow, erectile dysfunction and visible hematuria(3). The symptoms of prostate cancer are not specific to it and might be difficult to discriminate from benign prostate hyperplasia and inflammatory prostate diseases(4). Age, race, positive family history, dietary factors and obesity are some risk factors increasing prostate cancer risk(5).

Prostate-specific antigen (PSA) test, multiparametric magnetic resonance imaging screening and biopsies are utilized in the diagnosis of prostate cancer(1). Although an increased PSA value alone can detect prostate cancer in only 25-30% of cases, prostate cancer is diagnosed in 80% of cases by performing a biopsy after detecting an increased PSA value in the blood(1). An elevated PSA value must be detected in the blood at least twice or a palpable nodule must be detected in a digital rectal examination (DRE) to decide on a biopsy(6). PIRADS scoring system is used to evaluate multi-parametric magnetic resonance imaging (mpMRI) images (7). The location of suspicious tumoral lesions can be determined using mpMRI technology and the PIRADS scoring system (8).

The prostate biopsy is traditionally performed in cases of abnormal DRE, increased blood PSA, and clinical suspicion of prostate cancer, and it can be performed mainly through transrectal and transperineal approaches(9). Although TRUS guided prostate biopsy is the most commonly performed invasive urological procedure, it is considered that gold standard in diagnosis and generally 12 core biopsy samples are obtained during the intervention(10,11). With the development of MRI-guided prostate biopsy technology, it has become frequently practiced to take targeted biopsies from suspicious areas detected by MRI in addition to the standard 12-core biopsy(11).

Although transrectal ultrasonography (TRUS) guided biopsy is generally well tolerated, it can often cause pain and bleeding(12). TRUS-guided biopsy method can sometimes be problematic for patients due to the way it is applied and the fact that it may cause pain. Studies in the literature show that most patients feel discomfort due to pain during TRUS-guided biopsy(13).

Some anesthesia methods are used to reduce the pain felt by patients during TRUS-guided biopsy. The main methods are sedation, periprostatic nerve blockade, and intrarectal lidocaine application(14). Among the anesthesia methods applied before TRUS-guided biopsy, the gold standard is local anesthesia with periprostatic nerve blockade (PPNB) (4). However, Turgut et al. reported that PPNB caused needle-related pain and some other undesirable effects(15). There are some reports that prostate biopsy using intrarectal lidocaine gel does not cause such undesirable effects(16).

It has been shown in the literature that the pain felt during TRUS-guided biopsy is related to the preferred anesthesia method, prostate volume, biopsy sector and PSA level (4,10,13). There are also studies in the literature investigating patient satisfaction with the prostate biopsy procedure(17,18). In our study, in addition to the parameters in the studies in literature, we aimed to investigate the effects of age, BMI, PSA level, the presence of tumor, lymphatic invasion positivity, and VAS score on the level of patient satisfaction who undergo TRUS-guided biopsy.

MATERIAL AND METHODS

The study was designed to be prospective. The sample size was determined using the G-Power 3.1 program. Based on the group averages in the reference studies, a total of 237 patients were planned to be included in the study, with an effect size of 0.37, an α-error rate of 5%, and a study power of 80%.

After approval by the local ethics committee of our hospital (Approval no: 02/05/2023/3914), the study was initiated in accordance with the Declaration of Helsinki. The participants were informed about the study and gave written consent.

Between September 2018 and August 2023, 241 patients aged 48 to 86 years who underwent a TRUS-guided prostate biopsy at the University of Health Sciences, Sisli Hamidiye Etfal Training and Research Hospital, Urology Department were prospectively evaluated in our study. Four patients were excluded from the study because two of them had communication problems during the satisfaction score evaluation, the others had anal fissures and haemorrhoids.

Age, positive DRE findings, PSA values, prostate volume, body mass index and biopsy indications of the patients were recorded before the procedure. Urine culture, bleeding time, prothrombin time, and complete blood count tests were evaluated in all patients before the biopsy. Only patients whose test results were normal underwent the biopsy. Antibiotic prophylaxis and a cleansing rectal enema were given to all patients prior to biopsy, as recommended by guidelines. Lidocaine gel was applied to all patients 10 minutes before the biopsy, and all biopsies were performed by the same urologist. TRUS-guided biopsy was performed using an 18-gauge needle in the lateral decubitus position. No complications required hospitalization developed in any patient. The level of pain felt during the biopsy was evaluated with the Visual Analogue Scoring scale (VAS). Patients were about the intensity of the pain they felt during the biopsy; 0 meant no pain and 10 meant was the worst pain. After biopsy, the patient satisfaction scale was scored on a 4-point scale.

Patients were asked how satisfied they were with the biopsy. In response, they were to choose one of these options; 1-Not satisfied(1 point), 2-Somewhat satisfied(2 points), 3-Satisfied (3 points), 4-Very satisfied(4 points). Group 1 was created from patients who gave 1 and 2 points, and Group 2 was created from patients who gave 3 and 4 points. Variables belonging to the created groups were compared statistically. After the pathological analysis of the biopsy materials, the presence of tumor and perineural invasion were recorded. Two groups created according to patient satisfaction levels were compared using various parameters.

Statistical Analysis

Statistical analysis was performed using SPSS 25 for Windows (IBM, Armonk, NY) software. Descriptive statistics of evaluation results; for categorical variables number and percentage, for numerical variables mean, standard deviation, minimum, maximum, and median values were given. Homogeneous distribution of the data was evaluated by Shapiro-Wilk test. Student's t-test and The Mann–Whitney U test was used for continuous variables according to the normal distribution of the data. The ratio of the categorical variables between the groups was tested by Chi-

square analysis. P-value <0.05 was considered statistically significant.

RESULTS

A total of 237 patients were evaluated. Of these, 92 patients (38.8%) reported dissatisfaction while 145 patients (61.2%) reported satisfaction.

The mean age was 66.0 ± 7.8 (year). The median BMI was 26.9 ± 4.0 (kg/m$^{2)}$. The median PSA level and prostate volume of these patients were 33.7 ± 197.5 ng/mL and 54.8 ± 39.3 cc respectively (Table 1). Seventy-six of 237 patients(%32.1) had positive DRE findings and 75 (% 31.6) had tumor existence in the pathology results. Thirty-nine of 79 tumor positive patients(%52.0) had perineural invasion (Table 1).

Table 1. Evaluation of demographic and clinical variables of the patients (n=237)

Variables	n (%)	Median (IQR)	Mean ± SD
Age (Year)			66.0 ± 7.8
***BMI (kg/m^2)**		26.8 (24.4-29.4)	
***PSA level (ng/dl)**		6.9 (5.1-10.4)	
Prostate volume (cc)		45.0 (33.0-63.0)	
***Positive DRE finding**	76(%32.1)		
Tumor existance	75(%31.6)		
***Positive perineural invasion in patients with Pca**	39(%52.0)		

*BMI: Body mass index

*PSA: Prostate specific antigen

*DRE: Digital rectal examination

*Pca: Prostate cancer

The mean age of Group 1 and Group 2 were 65.9±8.1 and 66.1 ± 7.6 years respectively. There was no statistically significant difference between the two groups(P=0.858) (Table 2). The median BMI of Group 1 and Group 2 were 27.7±4.0 and 26.3 ± 3.9 kg/m^2 respectively. BMI rate of Group 1 found to be statistically significantly higher than Group 2 (P = 0.011) (Table 2). The median PSA level of Group 1 and Group 2 were 58.6 ± 304.6 and 17.9 ± 68.1 ng/ml respectively. There was difference between in two groups but it was not statistically significantly differance (P=0.210) (Table 2). The median Prostate volume of Group 1 and Group 2 were 59.4 ± 51.8 and 51.8 ± 28.7 cc respectively. There was difference between in two groups but it was not statistically significantly differance(P=0.209)(Table 2). The median VAS score of Group 1 and Group 2 were 4 (3-6) and 4 (2.5-6) respectively. There was no statistically significant difference between in two groups (P=0.957) (Table 2).

Table 2. Evaluation of the patients characteristics according to satisfaction levels

Variables		Group 1(Not Satisfied)	Group 2(Satisfied)	P value
Age (years),	mean±SD	65.9±8.1	66.1 ± 7.6	0.858^t
BMI (kg/m^2),	median (IQR)	27.4 (24.8-29.4)	26.4 (23.9-28.7)	**0.032^m**
PSA level (ng/ml),	median (IQR)	6.4 (4.8-9.4)	7.2 (5.1-11.1)	0.273^m
Prostate Vol.(cc),	median (IQR)	44.0 (340-67.5)	45.0 (33.0-60.0)	0.720^m
VAS score,	median (IQR)	4 (3-6)	4 (2.5-6)	0.957^m

BMI: Body mass index; PSA: Prostate-specific antigen; VAS: Visual analogue scale;
^{m} Mann-Whitney U test; ^{t} Student's t-test

Table 3. Comparison of satisfactory levels among patients according to different groups

Variables	Satisfaction levels, median (IQR)	P value
***DRE findings**		
Yes	3 (2-3)	0.965
No	3 (2-3)	
Tumor existance		
Yes	3 (2-3)	0.368
No	3 (2-3)	
Perineural invasion		
Yes	3 (2-3)	0.439
No	3 (2-3)	

*DRE: Digital Rectal Examination

The Satisfaction levels of positive DRE findings Group was 3 (2-3) while negative DRE findings Group 3 (2-3). There was no statistically significant difference between in two groups (P=0.965). The Satisfaction levels of tumor existance Group was 3 (2-3) while other Group's Satisfaction levels 3 (2-3). There was no statistically significant difference between in two groups (P=0.368). The Satisfaction levels of Perineural invasion of tumor existance Group was 3 (2-3) while other Group's Satisfaction levels 3 (2-3). There was no statistically significant difference between in two groups (P=0.439) (Table 3).

DISCUSSION

In addition to showing the quality of the healthcare service provided, patient satisfaction is also important in terms of accepting the patient's re-biopsy procedure and surgical treatment alternatives. In our study, we investigated whether there was a relationship between various parameters and patient satisfaction.

In a retrospective study of 100 patients conducted by Peters JL et al., they investigated the satisfaction levels of those who were sedated and those who were not sedated during transrectal biopsy, and they obtained a higher satisfaction score in those who were sedated (17). Awsare et al.in their study reported The use of propofol sedation for transrectal ultrasonography-guided prostate biopsy is associated with high patient satisfaction and acceptability (18).

Hossack et al., in their study with 476 patients, found that age was an effective factor in not accepting re-biopsy under local anesthesia. However, no difference was found between races. In our study, no significant difference was found between the patient satisfaction levels of two groups with different ages (19).

Again, in the same study, the difference in PSA level between the groups that could not tolerate local anesthesia and those that did was not found to be significant. In our study, no statistically significant difference was found between PSA groups in terms of satisfaction.(19). In the same study, it was concluded that patients with high VAS scores would significantly prefer General Anesthesia in case of re-biopsy compared to those with low VAS scores. One of the factors that can affect patient satisfaction is pain. Pain is an unwanted feeling. The main goal is to ensure that the patient does not feel as much pain as possible during the biopsy. In our study, no significant difference was found between the satisfied and unsatisfied groups in terms of VAS score (19).

In a study conducted by Yun et al. consisting of 71 patients, it was revealed that more pain was felt in patients with larger prostate size. In our study, no difference was found between the satisfaction levels of the two groups with prostate volumes below and above the average (20). Skyring at al. in their study involving 151 prostate cancer patients, regret about the treatment was found to be inversely proportional to the satisfaction felt in the decision-making process. If the patient was satisfied, regret about continuing the treatment process decreased (21). In a retrospective study by Hong et al. involving 1162 patients, penis size was found to be increased in those with low BMI and large nasal size (22). The study by Udo et al. showed that there was no correlation between Prostate Volume and BMI in

black population (23). In our study, a higher satisfaction rate was observed in those with low BMI compared to those with high BMI.

Up to date many studies have been conducted examining the relationship between patient satisfaction and acceptance of the treatment given, decision to continue the treatment, trust and loyalty to the health institution providing the service. However, there is no study in the literature examining the relationship between age, prostate volume, BMI, VAS score, presence of tumor, presence of lymphatic invasion in the presence of tumor, DRE positivity and patient satisfaction in TRUS-guided prostate biopsies. This study will be the first in the literature.

Satisfaction perception differs according to individuals. This is a limitation for this study. In future studies, the relationship between parameters and satisfaction levels can be investigated by using different anesthesia methods. It is useful to conduct new studies focusing on patient satisfaction in urological practices.

CONCLUSION

In TRUS-guided prostate biopsies, no relationship was found between the patient's satisfaction level and the patient's age, serum PSA level, prostate volume, the level of pain felt, having a positive tumor finding during the diagnosis of the tumor, detecting the presence of tumor in histological examination, or having perineural invasion of the tumor histologically, while BMI and it was determined between the satisfaction level. As the patient's BMI increases, the level of satisfaction with the procedure decreases.

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