

Early satiation and nausea are independent determinants of poor quality of life in patients with type 2 diabetes mellitus with and without diabetic gastroparesis

Erken doyma ve bulantı diyabetik gastroparezisi olan ve olmayan tip 2 Diabetes Mellituslu hastalarda kötü hayat kalitesinin bağımsız belirleyicileridir

Özlem Özer Çakır^{1*}, Gülsüm Gönülalan², Murat İsmailoğlu³, Hüseyin Ataseven⁴, Ali Demir⁴, Hakkı Polat⁴

1.Alanya Alaaddin Keykubat University, School of Medicine, Department of Gastroenterology and Hepatology, Alanya, Turkey

2.Konya Numune State Hospital, Department of Endocrinology and Metabolism, Konya, Turkey

3.Nevşehir State Hospital, Department of Nuclear Medicine, Nevşehir, Turkey

4.Necmettin Erbakan University, Meram school of Medicine, Department of Gastroenterology and Hepatology, Konya, Turkey

ABSTRACT

Aim: We aimed to show the relationship between presence of diabetic gastroparesis and demographic features, symptom severity, quality of life.

Patients and Method: Patients with type 2 Diabetes Mellitus (DM) were enrolled in this study. Patients were interviewed face to face in terms of demographic profile, the Patient Assessment of Upper Gastrointestinal Disorder Symptoms (PAGI-SYM), and the Patient Assessment of Upper Gastrointestinal Disorders QOL (PAGI-QOL).

Results: A total of 51 patients with type 2 DM were included in this study. The mean age of the type 2 DM patients without and with diabetic gastroparesis were respectively 53.35±6.98 and 57.04±9.41 (p=0.192). The most severe of symptoms based on PAG-SYM score was bloating in both patients with and without diabetic gastroparesis (2.69±2.21 and 2.57±2.22). In this study, nausea was correlated with poor quality of life based on PAGI-QOL but not with delayed gastric emptying (coef: 0.351, 95% CI: 0.035-0.667, P=0.030). Also, nausea score was correlated with impaired quality of life (coef: 0.207, 95% CI: 0.085-0.330, p<0.001). Both early satiation and early satiation score were significantly correlated with poor quality of life (coef: 1.061, %95CI:0.699-1.424, p<0.001 and coef:1.136, 95%CI:0.791-1.480, p<0.001) in our study.

Conclusion: Early satiation and nausea are statistically significant independent predictors of poor quality of life in patients with Type 2 DM with and without diabetic gastroparesis. Also, nausea, abdominal pain, bloating and pyrosis were significantly associated with PAGI-SYM scores.

Key words: Diabetic gastroparesis, quality of life, PAGI-SYM, PAGI-QOL

ÖZET

Amaç: Biz diyabetik gastroparezi varlığı ile demografik özellikler, semptom ciddiyeti ve hayat kalitesi arasındaki ilişkiyi göstermeyi amaçladık.

Hastalar ve Yöntem: Bu çalışmaya Tip 2 Diyabetes Mellituslu (DM) hastalar alındı. Hastalara yüz yüze demografik profili, üst gastrointestinal sistem bozuklukları semptom ciddiyeti (PAGI-SYM) ve hayat kalitesi (PAGI-QOL) hasta değerlendirilmesi ile ilgili sorular soruldu.

Bulgular: Bu çalışmaya Tip 2 DM'li toplam 51 hasta alındı. Diyabetik gastroparezisi olmayan ve olan Tip 2 DM'li hastaların ortalama yaşları sırasıyla 53.35±6.98 ve 57.04±9.41 (p=0.192) di. Diyabetik gastroparezisi olan ve olmayan hastaların her ikisinde de PAGI-SYM skoruna göre en ciddi semptomu şişkinliği (2.69±2.21 ve 2.57±2.22). Çalışmamızda bulantı PAGI-QOL temel alınarak kötü hayat kalitesi ile koreleydi, fakat bulantı uzamış mide boşalma zamanı ile korele değildi (coef: 0.351, 95% CI: 0.035-0.667, p=0.030). Bulantı skoru bozulmuş hayat kalitesi ile koreleydi (coef: 0.207, 95% CI: 0.085-0.330, p<0.001). Erken doyma ve erken doyma skorunun her ikisi de kötü hayat kalitesi ile güçlü koreleydi (coef: 1.061, %95CI:0.699-1.424, p<0.001 ve coef:1.136, 95%CI:0.791-1.480, p<0.001).

Sonuç: Erken doyma ve bulantı diyabetik gastroparezisi olan ve olmayan Tip 2 DM'li hastalarda istatistiksel anlamlı olarak kötü hayat kalitesinin bağımsız belirleyicileridir. Ayrıca bulantı, karın ağrısı, şişkinlik ve pyroz PAGI-SYM skorlarıyla anlamlı derecede ilişkiliydi.

Anahtar kelimeler: Diyabetik gastroparezi, hayat kalitesi, PAGI-SYM, PAGI-QOL

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*Özlem Ozer Cakir, MD, (Faculty of Medicine, Department of Gastroenterology and Hepatology, Alanya, Turkey, Telephone: +90 242 5106135
E-mail: tansozlem@yahoo.com

Diabetic gastroparesis is a complication of diabetes mellitus and characterized by gastroduodenal motor abnormalities in absence of mechanical obstruction [1-3]. Diabetic gastroparesis is associated with poorly glycemic control [4]. Patients with type 1 or 2 diabetes mellitus have classic symptoms of gastroparesis that including early satiety, postprandial fullness, abdominal pain, bloating, pyrosis, regurgitation, abdominal swelling, nausea, vomiting, and retching [4]. Symptoms associated with gastroparesis are demonstrated by 5 to 12% of patients with diabetes [5,6]. One study showed that association between self-reported glycemic control and psychological distress and development of gastrointestinal symptoms in diabetics [7].

Previous studies suggested that diabetic gastroparesis impaired quality of life (QOL) scores on all main domains assessed including physical, emotional, mental, social and bodily functions [8,9]. We aimed that a comparison in terms of quality of life and symptom severity between type 2 diabetes mellitus (DM) patients with and without diabetic gastroparesis in this study.

PATIENTS AND METHODS:

Study Design

The inclusion criteria for the study included absence of gastric outlet obstruction or mechanic bowel obstruction, absence of previous stomach and/or bowel surgery, absence of ileus and/or motility disorder, absence of hypothyroidism and/or psychological distress and absence of pregnancy or breast-feeding, not usage of drugs that affect gastric motility or that are gastroprotective, not usage of psychiatrics (including sedative, antidepressant).

The study was approved by the local ethics committee and all subjects provided written informed consent. A total of 51 type 2 DM (Diabetes Mellitus) patients consecutively were enrolled in this study from December 2011 to February 2012.

Each patient was suitable for inclusion criterias and mental status in the study. All patients underwent face to face a physical examination, and detailed medical histories and questionnaires were recorded.

Patients: A total of 51 patients with type 2 DM were included in this study. All patients were made with 4-hours gastric emptying scintigraphy (GES) for diagnosing gastroparesis. According to this, 30 of 51 patients had delayed gastric emptying.

Questionnaires: All patients were asked face to face based on the Patient Assessment of Upper Gastrointestinal Symptom Severity Index (PAGI-SYM), Patient Assessment of Upper Gastrointestinal Disorders-Quality of Life (PAGI-QOL) to fill out a composite questionnaire to evaluate their symptoms on the initial visit.

PAGI-SYM, patients are asked to assess the severity of their symptoms during the previous 2 weeks using a Likert scale with a range of 1 to 5, where no symptoms=0, very mild=1, mild=2, moderate=3, severe=4, and very severe=5 [10]. The PAGI-SYM includes the 9 symptoms of the Gastroparesis Cardinal Symptom Index, which asks about nausea, retching, vomiting, stomach fullness, inability to finish meal, excessive fullness, loss of appetite, bloating, and abdominal distension [11,12]. Seven subscales (nausea, vomiting, early satiety, post-prandial fullness, bloating, abdominal pain(upper/lower), pyrosis) were analysed in this study.

Patient Assessment of Upper Gastrointestinal Disorders-Quality of Life (PAGI-QOL). The PAGI-QOL and PAGI-SYM were developed to assess quality of life in patients with dyspepsia, GastroEsophageal Reflux Disease (GERD), or gastroparesis. The PAGI-QOL consist of 30-items that cover five domains: Daily Activities, Clothing, Diet and Food Habits, Relationships, and Psychological Well-Being [13]. A score per dimension as well as a total score can be calculated. The PAGI-QOL scores range from 0 (highest QoL) to 5 (lowest QoL). The higher scores of PAGI-QOL have the poorer the quality of life [10,13].

Gastric Emptying Study

All patients underwent a 4-hours Gastric emptying scintigraphy (GES) which was performed using test meal consisting of egg substitute (equal to 2 large egg), two slices bread, strawberry jam (30 gm), 120 ml water with 500 mCi Tc-99m DTPA ingested within 10-15 min. Then gastric emptying time was performed on supine position by 1 min images at time 0, 1, 2, and 4 hrs and geometric mean attenuation correction.

Patients were asked to stop any prokinetic and narcotic pain medications 3 days before the study. GE was measured at 0, 1, 2, and 4 hours. Delayed GE was defined as greater than 10% retention at 4 hours [14, 15]. Normal GE was defined as 10% retention or less at 4 hours. Normal value of 4-hours gastric emptying time

was T1/2: 55±15 minutes. Gastric emptying time-activity curves were obtained, and gastric emptying time was calculated by a single blinded nuclear medicine specialist.

Statistical Analysis

Data analysis was performed by using SPSS for Windows, version 11.5 (SPSS Inc., Chicago, IL, United States). Whether the distributions of continuous variables were normally or not was determined by Kolmogorov Smirnov test. Data were shown as mean ± SD or median (min-max), where applicable.

While the mean differences between groups were compared by Student's t test, otherwise, Mann Whitney U test was applied for comparisons of the medians. Degrees of association between continuous variables were evaluated by Spearman's Rank Correlation analyses. Categorical data were analyzed by Pearson's chi-square or Fisher's exact test, where appropriate.

Determining the best predictor(s) which affect on PAGY-SYM and PAGY-QOL scores were evaluated by stepwise linear regression analyses. Any variable whose univariable test had a p value <0.10 was accepted as a candidate for the multivariable model along with all variables of known clinical importance. Coefficient of regression, 95% CI confidence interval and t-statistic for each independent variable were also calculated. Because of not normally distributed, logarithmic transformation was used for PAGI-SYM and PAGI-QOL in regression analyses. A p value less than 0.05 was considered statistically significant.

RESULTS

The mean age of the type 2 DM patients without and with diabetic gastroparesis were 53.35±6.98 and 57.04±9.41, respectively. 12 (56.6%) of 21 in patients without diabetic gastroparesis and 20 (66.7%) of 30 in patients with diabetic gastroparesis were female. There were no statistically significant differences between groups in terms of age and gender, respectively (p=0.192, p=0.489). There were no statistically significant differences between groups regarding to diabetes duration and presence of diabetic complications, respectively (p=0.916 and p=0.498).

There was no significant difference between patients with and without diabetic gastroparesis in terms of the frequency of symptoms (p:0.368). Nausea (n:8/11, 38.1%/36.7%), vomiting (n:3/5, 14.3%/16.7%), bloating (n:14/21, 66.7%/70%), early satiety (n:4/8, 19%/26.7%), upper abdominal pain (n:6/8, 28.6%/26.7%), post-prandial fullness (n:5/9, 23.8%/30%) and pyrosis (n:13/15, 61.9%/50%) were seen in patients without/with diabetic gastroparesis. Symptom frequency in patients with and without diabetic gastroparesis were demonstrated in Table 1.

Table 1. Symptom frequency in patients with and without diabetic gastroparesis

Variables	without diabetic gastroparesis (n=21)	with diabetic gastroparesis (n=30)	P-value
Nausea	8 (38.1%)	11 (36.7%)	0.326†
Vomiting	3 (14.3%)	5 (16.7%)	1.000¶
Early satiety	4 (19%)	8 (26.7%)	0.739¶
Post-prandial fullness	5 (23.8%)	9 (30%)	0.626†
Bloating	14 (66.7%)	21 (70%)	0.881†
Abdominal pain	6 (28.6%)	8 (26.7%)	0.881†
Pyrosis	13 (61.9%)	15 (50%)	0.400†
Weight loss	6 (28.6%)	2 (6.7%)	0.052¶

† Pearson's chi-square test, ‡ Mann Whitney U test, ¶ Fisher's exact test

There was no statistically significant difference between patients with and without diabetic gastroparesis in terms of mean symptom scores (p>0.05).

A statistically significant difference was not seen between groups regarding to median scores of daily activities, clothing, diet and food habits, relationship and psychological well-being (p>0.05). There was no statistically significant difference between groups in terms of median PAGI-SYM and PAGI-QOL scores, respectively (p= 0.185 and p=0.096) It was shown in Table 2.

There was no statistically significant correlation between gender with PAGI-SYM and PAGI-QOL in all patients (p>0.05). Both of PAGI-SYM and PAGI-QOL were not shown a significant positive correlation with presence of diabetic complication (p>0.05).

There was a statistically significant positive correlation between PAGI-SYM and BMI (r=0.341, p=0.014). It was shown that significant positive correlation between PAGI-SYM and nausea score, abdominal pain score, bloating score, pyrosis score and post-prandial full-

ness score, respectively ($p=0.003$, $p=0.005$, $p<0.001$, $p<0.001$ and $p<0.001$). There was no statistically significant correlation between PAGA-SYM and early satiety and vomiting scores ($p>0.05$). In all patients, PAGA-SYM showed statistically significant positive correlation with relationship score, daily activities score and psychological well-being score, respectively ($p=0.022$, $p=0.013$ and $p<0.001$) (Table 3).

Table 2. Scores of PAGA-SYM and PAGA-QOL

Variables	without diabetic gastroparesis (n=21)	with diabetic gastroparesis (n=30)	P-value
Age	53.35±6.98	57.04±9.41	0.192†
Gender (F/M)	12F (56.6%)/ 9M (43.4%)	20F (66.7%)/ 10M (33.3%)	0.489‡
BMI (kg/m ²)	32.25±5.99	31,48±5,29	0.529¶
PAGA-QOL	Mean ± SD (Min-Max)	Mean ± SD (Min-Max)	
Daily activities	1.22±2.18 (0-5)	2.33±2.54 (0-5)	0.100
Clothing	0±0 (0-0)	0±0 (0-0)	1.000
Diet and food habits	1.49±2.31 (0-5)	1.69±2.39 (0-5)	0.721
Relationship	1.25±2.18 (0-5)	2.50±2.54 (0-5)	0.062
Psychological Well-being	2±2.48 (0-5)	2.83±2.52 (0-5)	0.196
PAGA-QOL total score	5.96±6.76 (0-20)	9.31±7.6 (0-20)	0.096
PAGA-SYM	Mean ± SD (Min-Max)	Mean ± SD (Min-Max)	
Nause	0.80±1.34 (0-5)	0.75±0.94 (0-3)	0.326
Vomiting	0.72±0.35 (0-1)	0.61±0.57 (0-2)	0.358
Early satiety	0.72±0.40 (0-1)	0.75±0.45 (0-1)	0.331
Post-prandial fullness	1±0.46 (0-1)	1±0.48 (0-1)	0.635
Bloating	2.57±2.22 (0-5)	2.69±2.21 (0-5)	0.331
Abdominal pain (Upper/lower)	0.57±1.24 (0-5)	0.62±1.37(0-5)	0.329
Pyrosis	1.56±2.01 (0-5)	1±1.69 (0-5)	0.139
PAGA-SYM total score	6.09±3.07 (0-12)	5.66±2.49 (0-9)	0.185

† Pearson's chi-square test, ‡ Mann Whitney U test, ¶ Fisher's exact test

There was a statistically significant positive correlation between PAGA-QOL and relationship score, daily activities score and psychological well-being score, respectively ($p<0.001$, $p<0.001$ and $p<0.001$).

The variables that were determined at the univariate statistical analysis as $p<0.10$ were included in the regression model. After backward stepwise method, it was shown that nausea, bloating, abdominal pain and

pyrosis were important predictors for PAGA-SYM. Multivariable linear regression analysis showed that there was no statistically significant positive correlation between presence of gastroparesis and PAGA-SYM ($p=0.818$) but nausea, bloating, abdominal pain and pyrosis independently predict PAGA-SYM (Table.4).

Table 3. Correlation of demographic, clinic features and symptom scores with PAGA-SYM and PAGA-QOL in all patients

	PAGA-SYM		PAGA-QOL	
	R	P†	R	P†
Age	-0.053	0.714	0.173	0.226
BMI	0.341	0.014	0.050	0.730
DM duration	-0.206	0.146	-0.072	0.615
Nause score	0.410	0.003	0.272	0.054
Vomiting score	0.094	0.511	0.183	0.200
Abdominal pain score	0.388	0.005	0.217	0.127
Bloating score	0.509	<0.001	0.241	0.088
Early satiety score	0.149	0.296	0.234	0.098
Pyrosis score	0.538	<0.001	0.115	0.421
Post-prandial fullness score	0.517	<0.001	0.059	0.682
Relationship score	0.320	0.022	0.864	<0.001
Daily activities score	0.347	0.013	0.864	<0.001
Psychological well-being score	0.438	<0.001	0.839	<0.001

† Spearman's Rank Correlation analyses.

BMI: Body mass index, DM: Diabetes mellitus.

After backward stepwise method, independent variable was PAGA-QOL and dependent variables were early satiety, nausea, relationship and psychological well-being. As multivariable linear regression analysis, early satiety, nausea, relationship and psychological well-being were independent predictor of PAGA-QOL. However, presence of gastroparesis was not statistically significant associated with PAGA-QOL ($p=0.801$).

Nausea, abdominal pain, bloating and pyrosis scores were independent predictors of PAGA-SYM. At the same time, presence of gastroparesis was not significant related with PAGA-SYM ($p=0.105$).

Nausea, early satiety, relationship and psychological well-being scores were independent predictors of PAGA-QOL. But also, it was shown that presence of gastroparesis was not significant associated with PAGA-QOL ($p=0.494$) (Table 4).

Table 4. Predictive ability of symptoms and presence of gastroparesis on PAGA-SYM and PAGA-QOL by multivariable linear regression analysis.

	Coefficient	95% Confidence Interval		t-statistics	P-value
		Lower	Upper		
PAGA-SYM					
Presence of gastroparesis	0.135	-0.029	0.299	1.653	0.105
Nause score	0.210	0.143	0.278	6.289	<0.001
Abdominal pain score	0.208	0.145	0.272	6.636	<0.001
Bloating score	0.222	0.183	0.261	11.495	<0.001
Pyrosis score	0.241	0.191	0.292	9.623	<0.001
PAGA-QOL					
Presence of gastroparesis	0.103	-0.197	0.403	0.690	0.494
Nause score	0.207	0.085	0.330	3.416	<0.001
Early satiety score	1.136	0.791	1.480	6.645	<0.001
Relationship score	0.119	0.006	0.232	2.120	0.040
Psychological well-being score	0.300	0.190	0.409	5.512	<0.001

DISCUSSION

This study showed that early satiety and nausea were independent predictors of poorer quality of life in patients with and without diabetic gastroparesis. Also, nausea, abdominal pain, bloating and pyrosis were significantly associated with PAGA-SYM.

The most common symptom was bloating in groups (66.7% in patients without diabetic gastroparesis and 70% in patients with diabetic gastroparesis) compared with nausea (38.1%/36.7%), vomiting (14.3%/16.7%), bloating (66.7%/70%), early satiety (19%/26.7%), upper abdominal pain (28.6%/26.7%), post-prandial fullness (23.8%/30%) and pyrosis (61.9%/50%) were seen in patients without/with diabetic gastroparesis.

Severity of symptoms were determined based on the PAGA-SYM. Nausea (0.80 ± 1.34), vomiting (0.72 ± 0.35), early satiety (0.72 ± 0.40), post-prandial fullness (1 ± 0.46), bloating (2.57 ± 2.22), abdominal pain (0.57 ± 1.24) and pyrosis (1.56 ± 2.01) based on PAGA-SYM score were seen in patients without diabetic gastroparesis. Severity ranking of symptoms in patients with diabetic gastroparesis were seen as follows: Nausea (0.75 ± 0.94), vomiting (0.61 ± 0.57), early

satiety (0.75 ± 0.45), post-prandial fullness (1 ± 0.48), bloating (2.69 ± 2.21), abdominal pain (0.62 ± 1.37) and pyrosis (1 ± 1.69). There was no statistically significant difference between patients with and without diabetic gastroparesis in terms of PAGA-SYM total score ($p=0.185$).

Previous study showed that nausea and vomiting were correlated with worse quality of life in patients with gastroparesis, but also patients with diabetic gastroparesis had greater nausea than idiopathic gastroparesis [16]. Another study suggested that, nausea and vomiting were significant symptoms of gastroparesis. Vomiting was greater in diabetic gastroparesis compared with idiopathic gastroparesis. Therefore, they said that nausea and vomiting were related significantly on quality of life [17].

Cherian et al showed that, abdominal pain was a frequent symptom in patients with gastroparesis, comparable with nausea and vomiting. At the same study suggested that, abdominal pain was correlated with worse quality of life but not with gastroparesis [18]. One study suggested that moderate-severe abdominal pain was common in gastroparesis and associate with worse quality of life in their study [19].

Nausea was correlated with worse quality of life based on PAGA-QOL but not with delayed gastric emptying (coef: 0.351, 95% CI: 0.035-0.667, $P=0.030$) in this study. Also, nausea score was correlated with impaired quality of life (coef: 0.207, 95% CI: 0.085-0.330, $p<0.001$). Both of early satiety and early satiety score were stronger correlated with worse quality of life (coef: 1.061, 95%CI:0.699-1.424, $p<0.001$ and coef:1.136, 95%CI:0.791-1.480, $p<0.001$) in our study. But this study showed that other symptoms including vomiting, post-prandial fullness, bloating, abdominal pain and pyrosis were not correlated with quality of life. For all that, presence of gastroparesis was not related with symptom severity and/or quality of life based on PAGA-SYM and PAGA-QOL in this study.

The quality of life was assessed based on PAGA-QOL. Comparing the quality of life in patients without and with diabetic gastroparesis were described as follows: daily activities (1.22 ± 2.18 and 2.33 ± 2.54), clothing (0 ± 0 and 0 ± 0), diet and food habits (1.49 ± 2.31 and 1.69 ± 2.39), relationship (1.25 ± 2.18 and 2.50 ± 2.54) and psychological well-being (2 ± 2.48 and 2.83 ± 2.52). Scores of daily activities, relationship and psychological well-being in patients with diabetic gastroparesis

were higher than in patients without diabetic gastroparesis. According to this results, presence of diabetic gastroparesis was related to poorer quality of life, regardless of symptom severity. But this association was not statistically significant, the number of the patients in our study was small that may cause this results. This situation was limitation of our study. There is a need for larger studies to clarify the predictive role of diabetic gastroparesis on quality of life. To now, there some studies about comparing the quality of life in patients with idiopathic and diabetic gastroparesis in literature. Therefore, our study is novel study that comparing the quality of life in patients with and without diabetic gastroparesis. This is the first study that was investigated symptoms, symptom scores, quality of life in patients with type 2 DM.

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