Health-related quality of life in patients with functional dyspepsia

Kvalitet života i zdravstveno stanje bolesnika sa funkcionalnom dispepsijom

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Abstract

Background/Aim. Recent population based studies have proved that patients with functional dyspepsia (FD) have a significantly impaired health-related quality of life HRQoL as compared to general population. The aim of the study was to evaluate the impact of FD on (HRQoL) in patients treated in primary healthcare settings in Serbia. **Methods**. The study involved 1,448 patients with FD. The diagnosis was made by a general practice physician or gastroenterologist using the Rome III diagnostic criteria. The Serbian version of the questionnaire for the assessment of HRQoL of the U.S. Department of Health and Human Services' Centers for Disease Control and Prevention (HRQoL-4 item CDC) was used for data collection, while descriptive statistical measurements were applied to calculate standard deviation, frequency as well as multiple logistic regression model. **Results**. Out of the total number of patients, 41.8% assessed their health condition as seriously disordered or poor. The mean values of health disorder duration over the last 30 days was 11.8 days, disordered physical health 7.2 days, mental disorder 6.3 days, and activity limitation 5.1 days. Also, 29.7%, 15.2%, 12.8% and 10.7% of the patients reported ≥ 14 unhealthy days, ≥ 14 physically unhealthy days, ≥ 14 mentally unhealthy days and ≥ 14 activity limitation days, respectively. **Conclusion**. From patients' perspective, FD has a significant impact on HRQoL. In this study, 41.8% of the patients described their health status as fair or poor, and FD significantly affects all aspects of life, both mental and physical. The recognition of that impact is probably the most important step towards appropriate treatment and decreasing HRQoL impairment in patients with FD.

Key words:
dyspepsia; quality of life; depression; anxiety; surveys and questionnaires.

Apstrakt

Uvod/Cilj. Rezultati nedavno sprovedenih populacionih studija ukazuju na to da je kod bolesnika sa funkcionalnom dispepsijom prisutno značajno sniženje kvaliteta života u odnosu na opštu populaciju. Cilj ovog istraživanja bio je procena uticaja funkcionalne dispepsije na kvalitet života kod bolesnika lečenih u ustanovama primarne zdravstvene zaštite u Srbiji. **Metode**. U studiju je bilo uključeno ukupno 1 448 bolesnika sa funkcionalnom dispepsijom. Dijagnoza funkcionalne dispepsije postavljena je primenom ROME III kriterijuma od strane lekara opšte prakse ili gastroenterologa. Za prikupljane podataka korišćena je srpska verzija opšteg upitnika za procenu kvaliteta života povezanog sa zdravljem Centra za kontrolu i prevenciju bolesti iz SAD. U statističkoj obradi podataka primenjena je deskriptivna statistika sa izračunavanjem standardne devijacije, učestalosti i procenata kao i multipli logistički regresioni model. **Rezultati**. Od ukupnog broja bolesnika uključenih u studiju 41,8% je ocenilo svoje zdravstveno stanje kao ozbiljno narušeno ili loše. Srednja vrednost trajanja narušenog zdravstvenog stanja u poslednjih 30 dana iznosila je 11,8 dana, narušenog fizičkog zdravlja 7,2 dana, narušenog psihičkog zdravlja 6,3 dana i nemogućnosti obavljanja svakodnevnih aktivnosti 5,1 dan. Takođe, 29.7% bolesnika imalo je narušeno zdravstveno stanje ≥ 14 dana u toku prethodnog meseca. Čak 15.2% imalo je narušeno fizičko zdravlje ≥ 14 dana, 12.8% je imalo narušeno mentalno zdravlje ≥ 14 dana i 10.7% ograničenje u aktivnostima ≥ 14 dana u toku prethodnih 30 dana. **Zaključak**. Funkcionalna dispepsija značajno pogoršava kvalitet života ispitivanih bolesnika. Od ukupnog broja ispitanika uključenih u studiju 41,8% je ocenilo svoje zdravstveno stanje kao ozbiljno narušeno ili loše. Funkcionalna dispepsija negativno utiče na sve aspekte normalnog funkcionisanja. Prepoznavanje funkcionalne dispepsije je verovatno najvažniji korak ka odgovarajućem lečenju i sniženju njenog štetnog uticaja na kvalitet života.

Ključne reči:
dispepsija; kvalitet života; depresija; anksioznost; ankete i upitnici.

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Introduction

Functional dyspepsia (FD) is a functional gastrointestinal disorder (FGID) defined as the presence of symptoms thought to originate in the gastroduodenal region in the absence of any organic, systemic or metabolic disease that is likely to explain the symptoms [1]. According to the ROME III criteria, FD is defined as the presence of one or more of the following symptoms: bothersome postprandial fullness, early satiation, epigastric pain and epigastric burning without evidence of structural disease. Two main differences compared to the ROME II criteria are the duration of symptoms and characterization of FD as postprandial distress syndrome (B1a) and epigastric pain syndrome (B1b) [2]. The etiology of FD remains unclear. According to the biopsychosocial model, FD, like other FGID results from complex interactions between biological, social and psychological factors [3]. FD represents a serious public health problem, with prevalence ranging from 11% to 30% according to large population studies [4–6]. The importance of FD lies in the impairment of health-related quality of life (HRQoL), as confirmed by many studies [7–9]. The aim of this study was to assess the impact of FD on HRQoL in patients treated in primary healthcare settings in Serbia.

Data about FD-related HRQoL in the Eastern European countries have been scarce. The aim of this study was to assess the impact of FD on HRQoL in patients treated in primary healthcare settings in Serbia. The current study, to the best of our knowledge, is the first population-based study regarding HRQoL in the patients with FD ever conducted in Serbian primary health care settings. In addition, according to the iceberg concept, the majority of patients with FD should be treated in the primary healthcare setting. Understanding the nature of HRQoL impairment and risk factors for FD is important for improvement of treatment modalities.

Methods

This study measured HRQoL in patients with chronic non-transmittable diseases, selected from a large cross-sectional survey conducted in the primary healthcare facilities in Serbia from January-December 2011. Sampling was based on random selection of clusters of patients: at the first stage random selection of primary health care centers, and at the second stage, random selection of general practitioners. Patient inclusion criteria were FD as the main reason to visit the doctor. FD was diagnosed using the ROME III criteria by a primary care physician and/or gastroenterologists. The exclusion criteria included the evidence of structural disease, confirmed by upper endoscopy, such as peptic ulcer disease, malignant tumors, etc. These criteria ensured that only patients with FD were eligible for the study. All patients filled-in a questionnaire in the office of their general practitioner (GPs).

In our study, data collection was carried out by using the Serbian version questionnaire of the U.S. Department of Health and Human Services' Centers for Disease Control and Prevention (CDC) which supported population surveillance of health-related quality of life (HRQoL-4 item CDC).

We used the back-translation procedure to ensure the cross-cultural validity of the Serbian version and linguistic equivalence of translated items. This questionnaire, often used in surveys, prevention researches and population-based studies, has shown good measurement properties in several populations, languages and settings [10]. Collection of additional data included variables such as age, gender, education, the main reason to visit the doctor and medication adherence.

Data collection and statistical analysis

A total of 1,448 patients with FD were enrolled in this study. The patients self-rated their health status as excellent/very good, good and fair/poor using a questionnaire. In the last 30 days prior to receiving the questionnaire, the patients reported the following symptoms: pain limitation days, depression days, anxiety days, poor sleep days and days feeling well. Also, the patients reported more or equal to 14 days of physical and/or mentally unhealthy days as well as activity limitation days. Most patients used either over-the-counter (OTC) drugs or medications prescribed by a primary care practitioner or specialist.

Descriptive statistics with standard deviation, frequency and percentage were calculated. A multiple logistic regression model was applied with self-rated health status and ≥ 14 unhealthy days in the last 30 days as dependents variables, and sociodemographic characteristics as independent ones. The statistical analysis was performed using SPSS, version 20.

Results

The study group involved 1,448 patients with FD, 667 males and 781 females, mean age 50.7 years. Regarding the education level, 57% had lower education levels that included no education level or primary education level, and 43% had higher education levels that included secondary and tertiary education levels. Of all patients, 605 (41.8%) self-rated their health status as fair or poor.

Data on self-rated health status, a number of unhealthy or healthy days in past 30 days and number of patients who had ≥ 14 unhealthy or healthy days in that period are given in Table 1.

Deterioration of HRQoL was confirmed by the analysis of duration of symptoms over the last 30 days (Table 2). A total of 721 (49,8 %) patients were on medications prescribed by the gastroenterologist, 485 (33.5%) took medication prescribed by primary care practitioners and 162 (11.2%) of the patients were self-administering OTC drugs. Only 80 (5.5%) patients did not take any medications.

Using multiple logistic regression model, and after adjustment for age, sex and education level (Table 3) it was demonstrated that the female FD patients [odd ratio (OR) = 1.31, 95% confidence interval (CI) = 1.04–1.64], aged over 50 years (OR = 3.49, 95% CI = 2.77–4.41) and lower education levels (OR = 0.36; 95%, CI = 0.29–0.46) had a significantly higher prevalence of poor or fair health. The FD patients aged over 50 years (OR = 2.0; 95%, CI = 1.47-2.73) and with lower education levels (OR = 0.47,95%, CI = 0.34-

Table 1
Perceived health status of patients with functional dyspepsia (n = 1,448)

Parameters	Patients, n (%)	Days, $\bar{x} \pm$ SD
Self-rated health		
exellent, very good, good	843 (58.2)	
fair, poor	605 (41.8)	
Unhealthy days in past 30 days		
overall		11.8 ± 10.6
physically		7.2 ± 7.3
mentally		6.3 ± 7.5
activity limitation		5.1 ± 7.1
≥ 14 unhealthy days in part 30 days		
overall	430 (29.7)	
physically	220 (15.2)	
mentally	186 (12.8)	
activity limitation	155 (10.7)	
Days with good health in past 30 days		11.8 ± 9.5
≥ 14 healthy days in past 30 days	406 (28.0)	

n – number of patients; $\bar{x}$ – arithmetic mean; SD – standard deviation.

Table 2
Symptoms present in past 30 days reported by patients with functional dyspepsia

Symptoms	Patients n (%)	Days with symptoms ($\bar{x} \pm$ SD)
Pain		
≥ 14 days limited by pain	146 (10.1)	5.3 ± 6.4
pain limitation days		
Depression		
≥ 14 days feeling depression	137 (9.5)	5.8 ± 7.2
days with depression		
Anxiety		
≥ 14 days feeling anxiety	203 (14.0)	7.3 ± 7.7
days with anxiety		
Poor sleep		
≥ 14 days with poor sleep	241 (16.6)	8.4 ± 7.7
days with poor sleep		

n – number of patients; $\bar{x}$ – arithmetic mean; SD – standard deviation.

Table 3
Factors influencing quality of life in patients with functional dyspepsia

Dependent variables	Independent variables [OR (95% CI)]		
	Sex (female)	Age	Education
Fair or poor self-rated health	1.31 (1.04, 1.64)	3.49 (2.77, 4.41)	0.36 (0.29, 0.46)
≥ 14 physically unhealthy days	1.2 (0.9, 1.61)	2.0 (1.47, 2.73)	0.47 (0.34, 0.66)
≥ 14 mentally unhealthy days	1.16 (0.85, 1.58)	1.47 (1.07, 2.03)	0.6 (0.43, 0.84)
≥ 14 unhealthy days	1.43 (1.13, 1.81)	1.52 (1.2, 1.92)	0.51 (0.4, 0.65)
≥ 14 activity limitation days	1.31 (0.93, 1.85)	1.99 (1.38, 2.87)	0.34 (0.22, 0.51)
≥ 14 pain limitation days	1.39 (0.98, 1.98)	1.75 (1.21, 2.53)	0.46 (0.31, 0.69)
≥ 14 days feeling depressed	1.67 (1.16, 2.42)	1.7 (1.17, 2.48)	0.49 (0.33, 0.73)
≥ 14 days feeling anxious	1.53 (1.12, 2.08)	1.31 (0.96, 1.78)	0.52 (0.37, 0.72)
≥ 14 days with poor sleeping	1.18 (0.89, 1.57)	1.3 (0.97, 1.72)	0.58 (0.43, 0.78)
≥ 14 days feeling healthy	0.93 (0.73, 1.18)	0.32 (0.25, 0.41)	1.39 (1.09, 1.77)

OR – odds ratio; CI – confidence interval.

0.66) had a higher prevalence of ≥ 14 physically unhealthy days, regardless of gender. Furthermore, similar results were obtained for mentally unhealthy days. The patients aged over 50 years (OR = 1.47; 95%, CI = 1.07–2.03) and with lower education levels (OR = 0.6; 95% CI = 0.43–0.84) had ≥ 14 mentally unhealthy days regardless of gender.

Female gender (OR = 1.43; 95% CI = 1.13–1.81), aged over 50 years (OR = 1.52; 95% CI = 1.2–1.92) and lower education levels (OR = 0.51; 95% CI = 0.4–0.65) were signi-

ficant predictors for ≥ 14 unhealthy days. For ≥ 14 limitation days, age (OR = 1.99; 95% CI = 1.38–2.87) and lower education levels (OR = 0.34; 95% CI = 0.22–0.51) were significant predictors, regardless of gender. The age of over 50 years and lower education levels were also significant predictors for ≥ 14 pain limitation days.

Female gender (OR = 1.67; 95% CI = 1.16–2.42), older age (OR = 1.7; 95% CI = 1.17–2.48) and lower education levels (OR = 0.49; 95% CI = 0.33–0.73) were predictors for ≥

14 days with depression. Furthermore, female gender (OR = 1.53; 95% CI = 1.12–2.08) and lower education levels (OR = 0.52;95% CI = 0.37–0.72), regardless of age were predictors for ≥ 14 days with anxiousness.

Regarding healthy days, participants aged under 50 years (OR = 0.32; 95% CI = 0.25–0.41) with higher education levels (OR = 1.39; 95% CI = 1.09–1.77) had ≥ 14 healthy days over the past 30 days.

Discussion

FD can be perceived from the perspective of the patient, as well as from the perspective of the physician. FD represents an important health issue due to the facts that it occurs with a high prevalence in general population, causes a significant impairment of HRQoL and demands the excessive use of resources. This study analyzes an influence of FD on HRQoL from the perspective of patients.

HRQoL can be observed using both overall well-being and disease-specific instruments. In this study, we utilized the overall health condition by the Serbian version of the self-administered questionnaire CDC-HRQoL-4. We have already used this questionnaire for the evaluation of patients with gastroesophageal reflux disease (GERD) [11].

HRQoL refers to the consequences of the disease on the everyday activity of patients and their perception of the disease itself. Some studies have shown that the impairment of HRQoL is more severe in patients with FD than in patients with structural abnormalities [12], while other have not found any difference between FD and organic dyspepsia [13].

Etiology of FD is still unknown, although several studies have concluded that multiple factors are involved and that various mental disorders could play a significant role [14]. The diagnosis of FD is based on clinical symptoms and negative findings on upper endoscopy for structural diseases.

It was detected in the study that 5.5% of patients were not under any treatment, while 11.2% of the patients were on self-administered OTC medication. In addition, 33.5% patients used medications prescribed by a primary care practitioner, while 49.8% of patients were treated with medications prescribed by a specialist working in secondary and tertiary health care settings. According to the National Institute for Health and Care Excellence (NICE) guidelines for FD, proton pump inhibitors PPIs are the first-line therapy for FD [15].

In our study, 10.1% of patients were limited by pain for ≥ 14 days over the last 30 days. Tack et al. [16] found that 34% of patients with FD experienced hypersensitivity to gastric distention associated with symptoms of postprandial pain [16]. Mones et al. [8] reported low scores regarding all domains in patients with FD. Even if achieving improvement by decreasing physical pain with therapy (16%), the final score was still lower compared to that in general population.

It was detected that 15.2% of patients had ≥ 14 physically unhealthy days, while 12.8% had ≥ 14 mentally unhealthy days; female gender, older age and lower education levels were predictors in both, which correlates with the findings of other studies. In the study by Talley et al. [7] the mean physical, as well as the mean mental composite scores, were significantly lower when compared with age and sex adjusted to the U.S. national norms.

Our study showed that 14% of the patients had anxiety and 9.5% depression problems; female gender, older age and lower education levels were found to be strong predictors of anxiety in FD patients. These results are in accordance with results from other studies. Huang et al. [17] study results show that anxiety and depression are more severe in FD patients, and that female gender, older age and lower education levels are all risk factors for both anxiety and depression. A Swedish population-based study determined a positive correlation between anxiety and FD but failed to prove a correlation between depression and FD [18].

Based on the multiple logistic regression model, our study demonstrated that physically and mentally unhealthy days, activity limitation days, depression, anxiousness, and poor sleep were associated with female gender, older age and lower education levels, thus leading to the conclusion that all of these factors are predictors of FD. As detected in our study, higher education levels and earlier lifetime period enable a better understanding of one's own disease in both genders, primarily resulting in higher medication compliance. In addition, persons with higher education levels have better financial possibilities as well as a better understanding of the necessity for diet and lifestyle changes that are important in the treatment of FD which in turn leads to a lower impairment of HRQoL. Furthermore, patients aged over 50 years usually have a number of comorbidities which could overlap with or potentiate FD symptoms.

In this study, 41.8% of the patients described their health status as fair or poor, even though majority used medications.

The limitation of our study was the inability to determine patient compliance with medication and the comparison of efficacy among different treatment strategies. Also, overlapping with eventual comorbidities and their impact on FD symptoms were not determined. Further studies should take this into consideration in order to achieve a better assessment of HRQoL in FD patients.

Conclusion

From patients' perspective, FD has a significant impact on HRQoL. In this study, 41.8% of the patients described their health status as fair or poor, and FD significantly affects all aspects of life, both mental and physical. The recognition of that impact is probably the most important step towards appropriate treatment and decrease of HRQoL impairment in patients with FD.

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