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# Quality of life of the patients with gastroesophageal reflux disease in Serbia

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Gastroesophageal reflux disease (ERD) was often considered as a minor public health problem and its potential severity was not fully recognized by the general public, patients, the health care system, and in some cases health care providers. Data about GERD related HRQoL in eastern European population are scare. The aim of the study

was to evaluate the burden of GERD on patients treated in Serbian primary health care. The study included 1091 patients with diagnosed GERD, treated in Serbian primary health care. All patients completed Serbian version of generic self-administered Center for Disease Control and Prevention questionnaire, CDC-HRQoL-4.In our study, 463 (42%) GERD patients self-rated their current health status as fair or poor, 584 (53%) had poor physical health one or more days during the past 30 days, 460 (42%) had poor mental health one or more days for the same time period. Due to disease symptoms 492 (46%) GERD patients felt depressed one or more days during the past 30 days, 581 (54%) felt tired or sleepy during the same time period. In addition, GERD patients had lower scores regarding number of healthy and unhealthy days. The obtained results had demonstrated that in large proportion, GERD impaired patient everyday lives. A better understanding of the relationships between GERD and impaired HRQoL may allow the physicians in primary health care to manage these patients more effectively in the future.

Key words: GERD, quality of life, CDC-HRQoL-4

### INTRODUCTION

Gastroesophageal reflux disease (GERD), represented common non-communicable disease in the Western population. Indeed, an estimated 44% of USA adult population has heartburn at least once per month, 14% at least once per week, and 7% daily<sup>1</sup>. GERD was often considered as a minor public health problem and its potential severity was not fully recognized by the general public, patients, the health care system, and in some cases health care providers<sup>2</sup>.

Despite current misbelieves, the results of the studies conducted in the Western countries proved that patients with GERD had significantly impaired Health Related Quality of Life (HRQoL) compared to general population<sup>3,4</sup>. Even reflux symptoms rated as mild were related with clinically meaningful reduction of well-being<sup>5</sup>. Often unrecognized, sleeping problems had a significant impact on workplace productivity for those with GERD<sup>6</sup>. In the recent studies, a strong correlation between GERD symptoms and impaired emotional status was demonstrated<sup>7</sup>.

Furthermore, in the some domains of HRQoL, GERD carried out similar or higher burden than that observed in patients with conditions such as diabetes, hypertension or coronary heart disease<sup>3</sup>.

Data about GERD related HRQoL in eastern European population are scare. The aim of the study was to evaluate the burden of GERD on patients treated in Serbian primary health care, because a multifaceted approach is needed to ensure that persons suffering from GERD were optimally treated, patient outcomes maximized and proper resource allocations were realized.

#### **METHODS**

The current sample was derived from ongoing large cross-sectional survey conducted during 2011, regarding HRQoL of patients with chronic non-transmittable diseases from urban and rural areas of Serbia, treated in the primary health care. Sampling was based on one stage random selection of clusters of patients at level of general practitioners (GPs). The study included 1091 patients with diagnosed GERD, treated in Serbian primary health care. All patients completed Serbian version of generic self-administered Center for Disease Control and Prevention questionnaire, CDC-HRQOL-4, with addition of patient diagnosis evaluated by attending general practitioners, according to  $10^{th}$  revision of International Classification of Diseases (ICD-10). Descriptive statistics, including mean  $\pm$  S.D. and frequency and percentage were calculated. All statistical analysis was performed using SPSS (version 20).

#### RESULTS

The study group consisted of 1091 patients with GERD (548 males, 543 females).

Mean age was 50.0 years, with almost equal number of male and female patients. Among the patients, 16% had primary education level, 39% had upper secondary education level and 45% had tertiary education level.

In our study, 463 (42%) GERD patients self-rated their current health status as fair or poor. Average duration of poor physical health was 6,4 days, and the median was 5. Poor mental health had duration of 5.3 days. Number of GERD patients who described their physical status as a poor was 584 (53%). There were 460 (42%) GERD patients with poor mental health. Overall 399 (37%) of patients had physical or mental symptoms who kept them from doing usual activities, as shown in Table 2.

As shown in Table 3, significantly impaired activities of daily living, including personal care needs, social activities, routine needs were noted in GERD patients. Overall, 343 (31%) GERD patients had limited activities due to illness. Regarding personal care needs, 54 (5%) GERD patients were enabled in performing personal care needs. Regarding routine needs, 87 (8%) GERD patients needed help with everyday activities.

As shown in Table 4 Limited usual activities due to pain had 525 (47%) patients with GERD symptoms in average duration of 5 days. During one or more days 492 (46%) GERD patients had some of many symptoms of poor mental health as well as 581 (54%) GERD patients felt tired or sleepy during the same time period. Average duration of fatigue and sleepiness was 6.8 days. During past 30 days, at the time when questionnaire was completed 207(19%) GERD patients haven't a single day when they felt healthy and full of energy.

As shown in Table 5 GERD patients for a period of 14 days or more, had a significant percentage in physically or mentally unhealthy days, also activity limitation days as well as days with fatigue and sleepiness. In our study, number of GERD patients with 14 or more physically unhealthy days was 161 (15%) and number of mentally unhealthy days was 126 (12%). Number of GERD patients with 14 or more day with activity limitation due to poor physical or mental health 104 (9%) and activity limitation due to pain was 99(9%). During the 14 or more days, 113 (10%) GERD patients were with sadness and depression and 127 (12%) GERD patients were with fatigue and sleepiness. And finally, only 141 (13%) of GERD patients were well-being.

TABLE 1

# SOCIO-DEMOGRAPHIC CHARACTERISTICS OF THE GERD PATIENTS

Patients characteristics	GERD (n=1091)
Gender (no and %)	
Male	548 (50%)
Female	543 (50%)
Mean age (s.d)	50.0+/-14.4
Years range	(18-91)
Education (no and %)	
Elementary school	169 (16%)
High school	428 (39%)
College	220 (20%)
University	273 (25%)

#### DISCUSSION

Recent years the term "GERD iceberg" had been introduced in the clinical practice to provide better perception of GERD patients distribution among the physicians<sup>8</sup>. Thus, majority of patients with GERD should be diagnosed and treated in the primacy care setting. Indeed, empirical treatment is well documented and widely accepted method of treatment of the patients with typical GERD symptoms. However, diagnosis and treatment of the GERD patients in the primary care setting implicate necessity of problem understanding. Unfortunately, according to our data, as much as 36.9% of PGPs in Serbia still considered GERD as a minor health problem, and thus significantly underestimated the problem.

The "GERD iceberg" concept underscored the need for public education and awareness about GERD among physicians, but the empowerment of the patients too in respect to express symptoms, worry and impairment of overall wellbeing<sup>8</sup>.

Thus, the results of our survey represented how GERD patients perceived their disease, disregarding current diagnose and treatment protocols.

The study group consisted of 1091 patients with diagnosed GERD treated in Serbian primary health care. All patients completed Serbian version of generic self-administered CDC-HRQoL-4 questionnaire. This questionnaire has already demonstrated to be valid and reliable in several patients groups<sup>9-11</sup>. Mean age of the patients was 50.0 years, 16% of GERD patients had primary education level, 39% had upper secondary education level and 45% had tertiary education level, Table 1. The most of GERD

# TABLE 2

SELF-PERCEIVED HEALTH STATUS OF GERD PATIENTS

Number and %		
,		
112 (10%)		
185 (17%)		
321 (29%)		
336 (31%)		
127 (12%)		
8 (0.8%)		
2 (0.2%)		
was your phisical		
584 (53%)		
313 (29%)		
191 (14%)		
42 (4%)		
s)		
6.4+/-7.4%)		
5 (0-30)		
was your mental		
460 (42%)		
403 (37%)		
176 (16%)		
51 (5%)		
)		
5.3+/-7.3%)		
2 (0-30)		
For how many days during the last 30 days, your phisical and mental health kept you from doing usual activities, suc as self-care, work or recreaation?		
399 (37%)		
485 (45%)		
157 (14%)		
47 (4%)		
Limited usual activities (in days)		
4.2+/-6.7		

patients were in working age in which significantly impaired HRQoL leads to lowered work productivity. These results correlated with the results obtained by other au-

0 (0-30)

Median (ranges)

# TABLE 3

GERD	PATIENT	LIMITA	TION	DAYS
OLIND	1 / 1 1 1 1 1 1 1			DILLO

Limitations in usual day activities of GERD patients (n= 1091)	of Number and %	
Are you limited in any activities because of any impairment of health problem?		
Yes	343 (31%)	
No	611 (56%)	
Don't know/Not sure	96 (9%)	
I don't want to answer	42 (4%)	
Limitations in patients usual day activities (in days)		
Mean +/-s.d	419+/-1062	
Median (ranges)	60 (1-10800)	

Because of any impairment or health problem, do you need help of other persons with your personal care needs such as eating, bathing, dressing, or getting around the house?

Yes	54 (5%)

No	878 (80%)
Don't know/Not sure	116 (11%)
I don't want to answer	43 (4%)

Because of any impairment or health problem, do you need help of other persons with your routine needs, such as every day household shores, doing necessary business, shopping, or getting

around for other purposes?	
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Yes	87 (8%)
No	844 (77%)
Don't know/Not sure	115 (11%)
I don't want to answer	42 (4%)

thors<sup>12</sup>. The reflux symptoms often worsened current health status<sup>13</sup>. Indeed, in our study, 463 (42%) GERD patients self-rated their current health status as fair or poor, Table 2.

The results of the survey conducted in Canada had demonstrated that 43% of GERD patients seek medical consultation due to worsened health status<sup>14</sup>.

The recent studies demonstrated impaired physical health of GERD patients<sup>15</sup>. Furthermore, in our study, 584 (53%) patients reported physical unhealthy days. The mean value of days with poor physical health was 6.4 during the past 30 days, Table 2. Lee et al obtained similar results, 60% of GERD patients had poor physical health<sup>13</sup>.

TABLE 4

GERD PATIENTS SYMPTOMS

During the past 30 days, for about how many days did pain make it hard for you to do your usual activities, such as self-care, work or recreation?

One or more days	525 (47%)
None	314 (29%)
dont' know/Not sure	171 (16%)
I don't want to answer	76 (7%)
Limited usual activities due to pain (i	n days)
Mean +/-sd	5.0+/-6.3
Median (ranges)	3 (0-30

How thinking about your mental health, which includes stress, depression, and problems with emotions, for how many days during the past 30 daye was your mental health not good?

One or more days	492 (46%)	
None	298 (27%)	
dont' know/Not sure	221 (20%)	
I don't want to answer	79 (7%)	
Poor mental health (in days)		

Mean +/-sd	5,7+/-7.6
Median (ranges)	3 (0-30)

For how many days during the past 30 days you felt tired or sleepy?

581 (54%)
201 (18%)
221 (20%)
84 (8%)

Fatique and sleepiness (in days)

Mean +/-sd	6,8+/-7,5
Median (ranges)	5 (0-30)

For how many days during the past 30 days you felt very healthy and full of energy?

One or more days	584 (54%)
None	207 (19%)
dont' know/Not sure	216 (20%)
I don't want to answer	80 (7%)
Mean +/-sd	7,1+/-7,6
Median (ranges)	5 (0-30)

GERD reduced patients mental health in the same proportion as other chronic non-transmittable diseases . In our study, 460 (42%) patients had mentally unhealthy days with mean value of 5.3 days during the past 30 days, Table 2. Similar results were obtained from large survey conducted in Canada<sup>14</sup>.

In our survey, pain prevented 525 (47%) patients in performing usual day activities with mean value of 5.0 days during the past 30 days, Table 4. Lee et al obtained slightly different results, 66.18% of GERD patients were enabled in performing every day activities due to bodily pain. In their study, the GERD population consisted of elderly patients (>65 years of age) with GERD complications, compared to our study in which mean age of the patients was 50.0 years, and our patients were without disease complications<sup>13</sup>. Lee et al also had demonstrated that GERD complications further reduced already impaired HRQoL in GERD patients.

GERD had represented chronic condition, which in large proportion reduced patients emotional well-being'. In our study, due to reflux symptoms, 492 (46%) patients felt sad, dispirited and depressed with mean value of 5.7 days during the past 30 days, Table 4. Pacini et al had demonstrated that reflux symptoms significantly impaired patients emotional status<sup>7</sup>. Often unrecognized, sleeping problems represented major burden for patients suffering from chronic diseases including GERD<sup>6</sup>. In our study, large number 581 (54%) of patients felt fatigued and sleepy, with mean values of 6.8 days during the past 30 days, Table 4. The results obtained from other authors had demonstrated that patients with GERD had more than twice the likelihood of experiencing sleep difficulties, which included difficulty initiating sleep and maintaining sleep, which resulted in the loss of work productivity and increased impairment of daily activities<sup>6,12</sup>

Analyzing the number of healthy and unhealthy days, obtained results demonstrated that large proportion of GERD sufferers had impaired HRQoL in key domains of CDC-HRQoL-4 questionnaire, Table 5.

The results obtained from our survey had demonstrated that GERD indeed, significantly impaired HRQoL. These results were similar to the results published by other authors, although they used different patient-reported outcome (PRO) instruments<sup>15,17</sup>.

#### CONCLUSION

This study had addressed the complex relationships between GERD and patients HRQoL. The obtained results had demonstrated that in large proportion, GERD impaired patient everyday lives. However, worldwide, GERD was still underestimated health problem by patients and substantial number of PGPs.

A better understanding of the relationships between GERD and impaired HRQoL may allow the physicians in primary health care to manage these patients more effectively in the future.

# TABLE 5

# ≥14 UNHEALTHY DAYS DURING THE PAST 30 DAYS

Number of unhealthty days for the past 30 days		
GERD (n+1091)	Number and %	
$\geq$ 14 physically unhealthy days	161 (15%)	
$\geq$ 14 mentally unhealthy days	126 (12%)	
$\geq$ 14 activity limitation days due to poor physical or mental health	104 (9%)	
$\geq$ 14 activity limitation days due to pain	99 (9%)	
$\geq$ 14 days with sadness, depression	113 (10%)	
$\geq$ 14 days with fatique and sleepiness	127 (12%)	
≥14 days of well-being	141 (13%)	

# REZIME

Gastroezofagealna refluksna bolest (GERB) je često smatrana za manji zdravstveni problem, pa potencijalna ozbiljnost nije bila u potpunosti prepoznata od strane javnosti, pacijenata, sistema zdravstvene zaštite, a u nekim slučajevima i pružaoca zdravstvenih usluga. U raspoloživoj medicinskoj literaturi nema mnogo podataka o kvalitetu života pacijenata sa GERB koji žive u istočnoj Evropi. Cilj ovog istraživanja je procena kvaliteta života pacijenata sa GERB koji su lečeni u primarnoj zdravstvenoj zaštiti u Republici Srbiji.

Istraživanje je obuhvatilo 1091 pacijenta sa GERB, koji su lečeni u srpskim ustanovama primarne zdravstvene zaštite. Svi pacijenti su samostalno popunili srpsku verziju generičkog upitnika Centra za kontrolu i pre venciju bolesti,CDC-HRQoL4.

U našem istraživanju, 463 (42%) pacijenata sa GERB su samostalno ocenili svoje trenutno zdravstveno stanje kao zadovoljavajuće ili loše, 584 (53%) su fizičko zdravlje ocenili kao loše tokom jednog ili više dana u proteklih 30 dana, dok je 460 (42%) mentalno zdravlje ocenilo loše tokom jednog ili više dana u istom periodu. Usled simptoma bolesti, 492 (46%) pacijenata sa GERB se osećalo depresivno tokom jednog ili više dana u proteklih 30 dana, dok se 581 (54%) osećao umorno ili pospano u istom periodu. Pored toga, pacijenti sa GERB su imali niže rezultate u pogledu broja dana kada su bili zdravi i bolesni.

Dobijeni rezultati su pokazali da GERB i kod nas u velikom procentu narušava kvalitet svakodnevnog života pacijenata. Bolje razumevanje odnosa između GERB i narušenog kvaliteta života može omogućiti lekarima da u budućnosti efikasnije leče ovakve pacijente.

# Ključne reči: GERB, kvalitet života, CDC-HRQoL-4

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