

# The Burden of Gastroesophageal Reflux Disease on Patients' Daily Lives: A Cross-Sectional Study Conducted in a Primary Care Setting in Serbia

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## SUMMARY

**Introduction** Recent data from the studies conducted in the Western countries have proved that patients with gastroesophageal reflux disease have significantly impaired health-related quality of life compared to general population.

**Objective** The study is aimed at evaluating the burden of reflux symptoms on patients' health-related quality of life.

**Methods** The study involved 1,593 patients with diagnosed gastroesophageal reflux disease. The Serbian version of a generic self-administered Centers for Disease Control and Prevention questionnaire was used. Statistical analyses included descriptive statistics, Pearson chi-square test and a multiple regression model.

**Results** Among all participants, 43.9% reported fair or poor health. Mean value of unhealthy days during the past 30 days was 10.4 days, physically unhealthy days 6.4 days, mentally unhealthy days 5.3 days and activity limitation days 4.3 days. Furthermore, 24.8% participants reported having  $\geq 14$  unhealthy days, 14.9% had  $\geq 14$  physically unhealthy days, 11.8% reported  $\geq 14$  mentally unhealthy days, and 9.4% had  $\geq 14$  activity limitation days.

**Conclusion** This study addressed complex relationships between reflux symptoms and patients' impaired everyday lives.

**Keywords:** gastroesophageal reflux disease; burden; health-related quality of life

## INTRODUCTION

The population based studies have revealed that gastroesophageal reflux disease (GERD) represents a common chronic disease with a prevalence of 10–20% in Western Europe and North America [1]. Recent data from studies conducted in the Western countries have proved that patients with GERD have a significantly impaired health-related quality of life (HRQoL) compared to the general population [2, 3].

Even in cases with mild reflux symptoms, a clinically meaningful reduction of well-being was demonstrated [4]. The burden associated with GERD encompassed a meaningful reduction of physical activity, psychological well-being, daily functioning, as well as reduced vitality and disturbed sleep [5, 6, 7]. The burden of reflux symptoms also included reduced work productivity [8]. A study conducted in Germany estimated the loss of gross domestic product of €688 million per year due to GERD related work inability [9]. In some domains of HRQoL, GERD brings with it similar or higher burden than that observed in patients with diabetes, hypertension or angina pectoris [2, 10].

Data about GERD related HRQoL in Eastern European countries have been scarce. GERD

was often considered a minor public health problem compared to other chronic non-transmittable diseases and its potential severity was not fully recognized by the general public, patients, the healthcare system, and in some cases healthcare providers [11].

## OBJECTIVE

The study was aimed at evaluating the burden of GERD on HRQoL in patients living in urban and rural areas, treated in Serbian primary healthcare settings.

## METHODS

The current sample was derived from a large cross-sectional survey conducted in Serbian primary healthcare during January–December 2011 period, regarding HRQoL patients with chronic non-transmittable diseases from urban and rural areas.

Using the Montreal definition of GERD for population-based studies, GERD was diagnosed by primary care physicians (PCPs), and general internists based upon the presence of

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mild symptoms of heartburn and/or regurgitation occurring at least two days per week, or moderate/severe symptoms of heartburn and/or regurgitation occurring at least one day per week [12].

These criteria ensured that only patients suffering from chronic reflux disease could be eligible for study participation. The disease classification was also done by PCPs and general internists according to the International Classification of Diseases, Tenth Revision (ICD-10). The exclusion criteria included other significant upper gastrointestinal disorders, including complications of the reflux disease in which upper flexible endoscopy was mandatory. A written informed consent was obtained from all participants before the study enrolment. The participants completed the questionnaire in the office of their PCPs.

In the current survey, the Serbian version of the generic self-administered Centers for Disease Control and Prevention questionnaire (CDC-HRQOL-4) was used. The CDC-HRQOL-4 questionnaire was developed as a survey to assess patients' subjective sense of well-being. The questions despite their brevity had reasonably good criterion validity as predictors of mortality and global disability [13, 14, 15]. In this respect, this questionnaire has advantages over other HRQoL instruments which have been described as difficult to interpret and had limited practical value [16, 17].

### Data collection and statistical analysis

The descriptive statistics, including numbers and percentages of categorical variables or mean and standard deviation of numerical data, were used to characterize the study sample. Univariate association between sociodemographic characteristics and self-rated healthy and unhealthy days ( $\geq 14$ ) during the previous 30 days were evaluated using the Pearson chi-square test. Multivariate analyses were performed using multiple logistic regression with self-rated health and  $\geq 14$  unhealthy days during the previous 30 days as dependent variables, and sociodemographic variables as independent variables. The level of significance was set at  $\alpha=0.05$ . All statistical analyses were performed using SPSS 20.

### RESULTS

The response rate of participants was 93.4%, and 1,593 patients with GERD were suitable for analysis. Overall, this survey included 810 males and 783 females, all Caucasians; 1,427 (89.6%) participants were economically active population. All participants were distributed into two groups based on the International Standard Classification of Education. Among all participants, 55.2% had a lower education level, which included no education or primary education level, 44.8% had a higher education level, which included secondary education, tertiary and post-tertiary education levels. Among all GERD participants, 43.9% reported fair or poor health. During the previous 30 days,

10.4 was the mean value of the number of unhealthy days, 6.4 was the mean value of physically unhealthy days, 5.3 of mentally unhealthy days, and 4.3 of activity limitation days. Furthermore, 24.8% participants reported having  $\geq 14$  unhealthy days, 14.9% had  $\geq 14$  physically unhealthy days, 11.6% reported  $\geq 14$  mentally unhealthy days, and 9.4% had  $\geq 14$  activity limitation days (Table 1).

Overall, the participants with GERD reported significantly increased physically unhealthy days, mentally unhealthy days and activity limitation days compared to the general population.

Impaired HRQoL of GERD participants was particularly evident when analyzing the duration of symptoms for the past 30 days (Table 2). The mean value of pain limitation days was 5.1 days. The participants with GERD experienced an average 5.9 days with depression, 6.8 days with anxiety, 7.2 days with poor sleep and 12.7 days of good health, during the previous 30 days. Overall, 8.9% of the participants had  $\geq 14$  pain limitation days, 10.4% felt depressed  $\geq 14$  days, 11.4% felt anxious  $\geq 14$  days and 12.9% had difficulty sleeping  $\geq 14$  days, as opposed to 29.6% who felt healthy  $\geq 14$  days during the previous 30 days.

As shown in Table 3, 3.33% GERD participants were without prescribed therapy, 7.78% self-administered over-

**Table 1.** Self-rated health and number of unhealthy days of the study group

Characteristics		Number
Self-rated health	Excellent, very good, good	878 (55.1%)
	Fair, poor	700 (43.9%)
Number of unhealthy days	$\geq 14$ unhealthy days	395 (24.8%)
	Unhealthy days (mean $\pm$ SD)	10.4 $\pm$ 10.6
	$\geq 14$ physically unhealthy days	237 (14.9%)
	Physically unhealthy days (mean $\pm$ SD)	6.4 $\pm$ 7.4
	$\geq 14$ mentally unhealthy days	185 (11.6%)
	Mentally unhealthy days (mean $\pm$ SD)	5.3 $\pm$ 7.3
	$\geq 14$ activity limitation days	149 (9.4%)
Activity limitation days (mean $\pm$ SD)	4.3 $\pm$ 6.7	

**Table 2.** Duration of symptoms during the previous 30 days

Symptoms	Number
$\geq 14$ days limited by pain	141 (8.9%)
Pain limitation days (mean $\pm$ SD)	5.1 $\pm$ 6.4
$\geq 14$ days felt depressed	165 (10.4%)
Days with depression (mean $\pm$ SD)	5.9 $\pm$ 7.7
$\geq 14$ days felt anxious	181 (11.4%)
Days with anxiety (mean $\pm$ SD)	6.8 $\pm$ 7.5
$\geq 14$ days had difficulty with sleep	206 (12.9%)
Days with poor sleep (mean $\pm$ SD)	7.2 $\pm$ 7.6
$\geq 14$ days felt healthy	471 (29.6%)
Days with good health (mean $\pm$ SD)	12.7 $\pm$ 10

**Table 3.** Therapy administration

Therapy administration	Number
No	53 (3.33%)
Yes, self-administered OTC drugs	124 (7.78%)
Yes, PPIs prescribed by PCPs	441 (27.7%)
Yes, PPIs prescribed by a specialist	974 (61.14%)
In total	1,593 (100%)

**Table 4.** Odds ratio (OR) from multiple logistic regression model

OR (95% CI)		Independent variables		
		Sex	Age	Education
Dependent variables	Fair or poor self-rated health	1.19 (0.97–1.49)	2.53 (2.04–3.14)	0.39 (0.31–0.48)
	≥14 physically unhealthy days	1.28 (0.97–1.70)	1.48 (1.10–1.98)	0.46 (0.33–0.62)
	≥ 14 mentally unhealthy days	1.65 (1.21–2.26)	1.03 (0.79–1.51)	0.48 (0.34–0.67)
	≥ 14 unhealthy days	1.30 (1.03–1.63)	1.41 (1.11–1.78)	0.65 (0.51–0.83)
	≥14 activity limitation days	1.31 (0.93–1.85)	1.71 (1.19–2.47)	0.44 (0.29–0.65)
	≥14 pain limitation days	1.60 (1.12–2.28)	1.58 (1.09–2.30)	0.46 (0.31–0.69)
	≥14 days felt depressed	1.51 (1.09–2.10)	1.20 (0.86–1.68)	0.44 (0.30–0.63)
	≥14 days felt anxious	1.51 (1.10–2.07)	1.31 (0.95–1.82)	0.48 (0.34–0.68)
	≥14 days had poor sleep	1.41 (1.05–1.90)	1.01 (0.75–1.37)	0.62 (0.45–0.84)
	≥14 days felt healthy	0.95 (0.76–1.19)	0.35 (0.28–0.45)	1.52 (1.21–1.94)

the-counter (OTC) medications. In total, 88.84% were on proton pump inhibitors (PPIs) therapy prescribed either by PCPs or a specialist.

After adjustment for age, sex and education level in the multiple logistic regression model (Table 4), GERD participants over 50 years of age (odds ratio – OR=1.19; 95% confidence interval – CI=0.97–1.48) with lower education level (OR=0.39; 95%, CI=0.31–0.48), had a significantly higher prevalence of poor or fair health, without gender differences. Furthermore, GERD participants over 50 years of age (OR=1.48; 95%, CI=1.10–1.98) with lower education level (OR=0.46; 95%, CI=0.33–0.62) had a higher prevalence of physically unhealthy days ( $\geq 14$ ), without gender differences.

Regarding  $\geq 14$  mentally unhealthy days, female GERD participants (OR=1.65; 95% CI=1.21–2.26) with lower education level (OR=0.48; 95%, CI=0.34–0.67) had a higher prevalence of mental problems, without age difference. Significant predictors for  $\geq 14$  unhealthy days were gender, age and education level. Female GERD participants (OR=1.30; 95%, CI=1.03–1.63) aged over 50 years (OR=1.41; 95%, CI=1.11–1.78), and of lower education level (OR=0.65; 95%, CI=0.51–0.83) reported  $\geq 14$  unhealthy days. Furthermore, significant predictors for limited activities were age and education level, without gender differences.

For pain limitation days, sex, age and education level were significant predictors. Overall, female GERD participants (OR=1.60; 95%, CI=1.12–2.28) aged over 50 years (OR=1.58; 95%, CI=1.09–2.30) with lower education level (OR=0.46; 95%, CI=0.31–0.69) had a significantly higher prevalence of pain limitation days ( $\geq 14$ ). Analyzing healthy days, the GERD participants under 50 years of age (OR=0.35; 95%, CI=0.28–0.45) with a higher education level (OR=1.52; 95%, CI=1.21–1.91), had  $\geq 14$  healthy days during the previous 30 days.

## DISCUSSION

The current study, to the best of our knowledge, was the first population-based study regarding HRQoL in GERD patients ever conducted in Serbian primary healthcare settings. The validation of the study was achieved using adequate survey methodology and the certified generic self-

administered CDC-HRQOL-4 questionnaire. Its validity and reliability are comparable to other patients' reported outcomes instruments, including SF-36 form, which has been accepted as the "golden standard" in HRQoL measures [18].

The term "GERD iceberg" has been introduced recently in the clinical practice to provide better perception of GERD patients distribution among physicians [19].

In this survey, the analysis of therapy administration revealed that up to 3.33% of participants were without therapy. Furthermore, 7.78% of participants used self-administered over-the-counter medications. Only 27.7% of participants were treated at primary healthcare level institutions with empirical PPIs therapy, as opposed to 61.14% of patients who were treated with PPIs therapy at secondary and tertiary healthcare levels by a gastroenterologist or digestive surgeon specialist. These results were in high discrepancy with currently valid treatment protocols which stated that majority of GERD patients should be diagnosed and treated at the primary care setting [12]. Indeed, the empirical PPIs therapy has been well documented and widely accepted in the management of uncomplicated GERD. The "GERD iceberg" concept has underscored the need for public education and awareness about GERD among PCPs, as well as the empowerment of patients regarding the expression of symptoms, worry and impairment of overall wellbeing [20].

Among all the participants in this survey, 43.9% self-rated their health status as fair or poor. These results highly correlated with the fact that not a negligible number of participants were without therapy or on self-administered over-the-counter medications, although up to 88.84% of the participants were treated with therapy prescribed by PCPs. However, several explanations are possible. The proportion of treated patients was higher than that observed in other studies [11, 21]. A large proportion of treated patients could be addressed to the inclusion criteria that involved patients treated with routine clinical care. Furthermore, insufficient data were obtained regarding therapy regimes (on demand or regular visits of PCPs), and no comparison of the efficacy between different types of PPIs could be made. Moreover, the participants' medication compliance could not be evaluated. All these questions should be addressed in future studies.

The mean value of unhealthy days was 10.4 during the previous 30 days. The obtained results were in high correlation with results obtained from other studies [22, 23]. The feedback relation between reflux symptoms and impaired emotional status was also demonstrated, with mean values of days with depression and anxiety of 5.9 days and 6.8 days, respectively, during the previous 30 days. Pacini et al. [24] demonstrated the presence of reflux symptoms in a large proportion of patients with deteriorated mental health. The nocturnal reflux was shown to be associated with extra-esophageal manifestations, GERD complications and a variety of sleep disturbances [25]. In this survey, the mean value of the number of past days with poor sleep was 7.2 during 30 days. Mody et al. [5] demonstrated that patients with nighttime reflux symptoms are more likely to experience sleep difficulties.

The number of unhealthy days as predictors of disability proved that GERD impacts patients' everyday lives with a higher burden than that observed in other chronic non-transmittable diseases [26].

Ford et al. [27] demonstrated that 10.4% of coronary heart disease patients reported having  $\geq 14$  physically unhealthy days, 10.3% had  $\geq 14$  mentally unhealthy days, 6.6% had  $\geq 14$  activity limitation days compared to our results, which demonstrated that 14.9% of GERD patients reported having  $\geq 14$  physically unhealthy days, 11.6% had  $\geq 14$  mentally unhealthy days and 9.4% had  $\geq 14$  activity limitation days. Similar results were obtained comparing the impact of GERD and metabolic syndrome on patients' HRQoL. Ford et al. [28] demonstrated that 41% of participants with metabolic syndrome reported fair or poor health, 11.5% had  $\geq 14$  physically unhealthy days, 11.1% had  $\geq 14$  mentally unhealthy days, while 3.9% had  $\geq 14$  activity limitation days, as opposed to our results.

The results of this survey demonstrated that predicament of HRQoL in GERD patients in a large proportion depended on variables such as age, gender and education level. GERD patients above 50 years of age and with a lower education level, without gender differences, were more likely to express impaired health status including fair or poor health. Elderly patients in large percentage usually had one or more co-

morbidities, which were not the subject of this survey, while the lower education level usually led to a lower income status and could explain difficulties in understanding disease severity and could affect patients' therapy compliance. Similar results were obtained in all CDC-HRQoL-4 core module questions with the exception of mental health questions in which females above 50 years of age and a lower education level were more likely to manifest depression, anxiety and sleep difficulties. These differences could be attributed to a higher prevalence of mood disorders in female population while several studies addressed a complex relationship between night reflux and sleep disturbances [5, 29].

Moreover, all displayed diversities in the multiple logistic regression model could be attributed to employment and income status, marital status and cultural differences, which could not be examined in this survey. According to this hypothesis and based on our results we could conclude that GERD patients of both genders, under 50 years of age and with a high education level were presumably of better disease understanding and therapy compliance, which led to a lower impairment of HRQoL.

Limitations of the study included inability to determine which particular reflux symptom participants deemed troublesome. Other limitations also included PPIs therapy regime, therapy compliance and cultural differences. Further work is obviously needed to assess these characteristics and the severity of their impact on HRQoL of GERD patients in Serbia.

## CONCLUSION

This study has addressed the complex relationships between GERD and patients' HRQoL. The obtained results demonstrate that GERD impairs patients' everyday lives in large proportion. However, worldwide, GERD is still an underestimated health problem according to patients, as well as a substantial number of PCPs.

A better understanding of the relationships between GERD and impaired HRQoL may allow healthcare providers to manage these patients more effectively in the future.

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## Утицај гастроезофагеалне рефлуксне болести на свакодневни живот болесника: резултати студије пресека спроведене у установама примарне здравствене заштите у Србији

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### КРАТАК САДРЖАЈ

**Увод** Недавни резултати студија урађених у земљама западне Европе доказали су да је код болесника са дијагностикованом гастроезофагеалном рефлуксном болешћу (ГЕРБ) знатно нижи квалитет живота повезан са здрављем у односу на општу популацију.

**Циљ рада** Циљ истраживања је био да покаже у којој мери рефлуксне тегобе утичу на квалитет живота повезан са здрављем код болесника са дијагностикованом ГЕРБ.

**Методе рада** Истраживањем су обухваћена укупно 1.593 болесника са дијагностикованом ГЕРБ. Током истраживања анализирани су резултати добијени помоћу српске верзије општег упитника за процену квалитета живота повезаног са здрављем Центара за контролу и превенцију болести у Атланти. У обради добијених налаза коришћене су следеће статистичке методе: методе дескриптивне статистике, Пирсонов  $\chi^2$ -тест и мултипли регресиони модел.

**Резултати** Од укупног броја болесника са ГЕРБ, 43,9% је оценило своје тренутно здравствено стање као озбиљно на-

рушено или лоше. Средња вредност броја дана нарушеног здравственог стања у последњих 30 дана била је 10,4 дана, дана нарушеног физичког здравља 6,4 дана, дана нарушеног менталног здравља 5,3 дана и 4,3 дана с немогућношћу обављања свакодневних активности. Даљом анализом добијени су следећи резултати: 24,8% болесника са ГЕРБ је пријавило  $\geq 14$  дана са нарушеним здравственим стањем у протеклих 30 дана, 14,9% болесника је пријавило  $\geq 14$  дана нарушеног физичког здравља, 11,8% болесника је пријавило  $\geq 14$  дана нарушеног металног здравља и 9,4% је пријавило  $\geq 14$  дана с немогућношћу обављања свакодневних активности.

**Закључак** Резултати овог истраживања показали су сложен однос између рефлуксних тегоба и смањеног квалитета живота повезаног са здрављем у групи болесника са дијагностикованом ГЕРБ.

**Кључне речи:** гастроезофагеална рефлуксна болест; рефлуксне тегобе; квалитет живота повезан са здрављем