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Quality of Life in the Third Trimester of Pregnancy in Patients with Gastroesophageal Reflux Disease

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Abstract

BACKGROUND/AIMS: Health-related quality of life (QoL) relating to mental, physical and social functioning in pregnant women with gastroesophageal reflux disease (GERD) may depend on several factors. The aim of this study was to investigate the impact of GERD on the QoL in the advanced stages of pregnancy.

MATERIALS AND METHODS: A total of 53 pregnant women suffering from GERD (group 1) and 54 age, body mass index (BMI) and gestational age-matched pregnant controls (group 2) were enrolled. The Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36) was completed to measure of health-related QoL, and the Gastroesophageal Reflux Disease Questionnaire was used to assess the classical symptoms of reflux disease. Socio-demographic variables including age, gravidity, parity, BMI and previous history of GERD were noted.

RESULTS: SF-36 scores were found to be significantly lower in the pregnant women with GERD in regard to the following domains: their general health ($p<0.01$), mental health ($p<0.01$), and their mental component score ($p=0.01$). Educational status and GERD symptoms before pregnancy were not found to have an impact on QoL in pregnant women with GERD.

CONCLUSION: Pregnant women with GERD seem to have a poorer QoL in many respects.

Keywords: Pregnancy, quality of life, gastroesophageal reflux disease

INTRODUCTION

Most pregnant women experience symptoms of gastroesophageal reflux disease (GERD) at some point during their pregnancy. According to the Montreal consensus, GERD can be defined as troublesome symptoms and/or complications due to reflux of the stomach contents to the esophagus.[1] The most common reasons for GERD development in pregnancy are alterations in the gastrointestinal transit time due to hormonal changes, decreased lower esophageal sphincter pressure and increased intra-abdominal pressure due to the expanding gravid uterus.[2,3] GERD in pregnancy is often new onset but some women may have had symptoms before pregnancy. The most common symptoms of GERD which are seen in pregnancy are heartburn and acid reflux, which are traditionally considered innocuous.[4] Although heartburn can happen at any time during pregnancy, the last three months deserves special attention because it presents a special challenge for the clinician.[5] Moreover, heartburn and acid reflux, which are clinical signs of GERD, significantly affects the quality of life (QoL) in pregnant women, especially in their third trimester.

The impact of GERD on QoL in certain disease conditions has been demonstrated in multiple clinical studies, but there has been little or scarce data which analyzed QoL in third trimester pregnant women with GERD.[3] Analyzing QoL in pregnant women is of great importance because it is an important indicator of the strength of health and

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wellness. In this context, several generic instruments including the Nottingham Health Profile, the Psychological General Well-Being Index, the Quality of Well-Being Scale and the 36-Item Short-Form Health Survey (SF-36) have been put forward to quantify QoL in distinct disease states, particularly in gastrointestinal system disorders.[6-8] Among these questionnaires, the SF-36 is the most widely used worldwide and it is designed to offer a concurrent measurement of both the individual's physical and mental health (MH) status. It has been particularly well-studied across a wide range of populations with specific conditions and it is considered to be an appropriate tool for describing health and QoL during pregnancy.[3]

The general belief is that health-related functional status during pregnancy changes only for the physical measures of health, and the impact of GERD on health-related QoL has not been sufficiently studied to date. The objective of this study was to investigate QoL in third trimester pregnant women with GERD. The primary hypothesis was that pregnant women in the advanced stages of pregnancy with GERD have a worse QoL than those without any of the signs or symptoms associated with GERD.

MATERIALS AND METHODS

Characteristics of the Patients

This study was a case-control study and it was conducted in accordance with the guidelines proposed by the World Medical Association of Helsinki. Ethical clearance was obtained from Çanakkale Onsekiz Mart University Faculty of Medicine Ethics Board (approval number: 2016-03, date: 17.02.2016). Written informed consent was obtained from all of the participating women.

The patients and controls included in this study were recruited from the outpatient clinic of the Department of Obstetrics and Gynecology, Çanakkale Onsekiz Mart University during a 6-month period. The study group consisted of 53 pregnant women with GERD followed up in the obstetrics and gynecology clinic of the same hospital. The control group consisted of 54 healthy pregnant women without symptoms of GERD who were admitted to the outpatient clinic for regular antenatal care.

The inclusion criteria were determined as a viable pregnancy of more than 28 weeks gestation, a lack of any systemic maternal diseases including, renal, pulmonary, gastrointestinal, or cardiovascular system disorders, an absence of any previously known psychiatric disorders, an absence of multiple pregnancies or any known obstetric complications. Pregnant women who had hormonal diseases, including diabetes mellitus or thyroid related disorders, were excluded from this study. Pregnant women who were using medications (including antidepressants, anti-psychotic or other psychiatric drugs), those who had current or past illicit drug abuse, those with past patterns of alcohol consumption, or those with cognitive impairments which could make it hard to complete the SF-36 were excluded.

Instruments

Gastroesophageal Reflux Disease Questionnaire

The Gastroesophageal Reflux Disease Questionnaire (GERDQ) (Table 1) is a unique, self-administered, patient-centered validated tool which was designed for healthcare professionals to improve and standardize symptom-based diagnosis and evaluations of treatment response in patients with GERD. It is a Likert-type (0-3) questionnaire which contains 6 questions with symptoms frequency scores to be completed by the patient. It comprises four positive predictors of GERD (heartburn and regurgitation, sleep disturbance because of these two reflux symptoms, and the need for over-the-counter medication) and two negative predictors of GERD (epigastric pain and nausea).[9] An overall GERDQ score of 0-18, and an impact score of 0-6 are used to compile a total score, which informs the clinicians' diagnosis of disruptive or inconveniencing GERD and allows for recommendations to be made to the patient. The GERDQ can be used to diagnose GERD with a diagnostic accuracy similar to that of a gastroenterologist at a cut-off value of 8 (out of 18) points with a specificity of 71.4% and a sensitivity of 64.6%.[10] A total GERDQ score of 8-10 indicates a 79% likelihood of GERD and 11-18 indicates an 89% likelihood of GERD.[11] The validation process for the GERDQ questionnaire in the Turkish general population was carried out by Mungan in 2012.[12]

Assessment of Quality of Life

In order to evaluate the QoL of women in their third-trimester, the SF-36 form was used. The SF-36 is a generic instrument developed by Ware and Sherbourne[13] which evaluates QoL for the last four weeks via eight dimensions of physical and MH including *physical functioning*, *role-physical*, *bodily pain*, *general health* (GH), *vitality*, *social functioning*, *role-emotional*, and MH. These 8 subscales are constructed from 36 items. Two additional measures, which are known as the Physical Health Component Score (PCS) and the Mental Health Component Score (MCS), can be derived as a summary. A high score achieved with this questionnaire indicates better physical and MH which are both related to QoL. The validation studies of the Turkish version of SF-36 were carried out on 100 patients with rheumatic disease by Koçyiğit et al.[14] in 1999.

Table 1. The Gastroesophageal Reflux Disease Questionnaire

	Question	Frequency score for symptom			
		0 day	1 day	2-3 days	4-7 days
1	How often did you have a burning feeling behind your breastbone (heartburn)?	0	1	2	3
2	How often did you have stomach contents (liquid or food) moving upwards to your throat or mouth (regurgitation)?	0	1	2	3
3	How often did you have a pain in the center of the upper stomach?	3	2	1	0
4	How often did you have nausea?	3	2	1	0
5	How often did you have difficulty getting a good night's sleep because of your heartburn and/or regurgitation?	0	1	2	3
6	How often did you take additional medication for your heartburn and/or regurgitation, other than what the physician told you to take?	0	1	2	3

Statistical Analysis

The Statistical Package for Social Sciences version 19 (SPSS Inc., Chicago, IL, USA) for Windows was used to analyze the data. Continuous variables were tested for normality with the Kolmogorov-Smirnov test and are presented as mean ± standard deviation (SD). Student's t-test was used to compare continuous variables. Data found to be non-normally distributed were compared using the Mann-Whitney U test. A p-value <0.005 was used to indicate statistical significance.

RESULTS

A total of 53 pregnant women with GERD (mean age: 28.0±5.4 years) and 54 pregnant women without GERD (mean age: 27.7±5.4 years) as controls were enrolled in the present study. There were no statistically differences between the ages of the study participants. The mean pre-gestational body mass index of the two groups were similar (p=0.139). The level of education did not differ between the groups (p>0.005 in all subgroups). Twenty out of the 53 pregnant women with GERD reported a history of pregestational heartburn and/or regurgitation when not pregnant. The socio-demographic data of the two groups are summarized in Table 2.

The mean SF-36 scores for each variable including their physical and mental component summaries are shown in Table 3. In general, pregnant women with GERD had lower scores on both their physical and mental dimensions and this was statistically significant for GH (p<0.01), MH (p<0.01), and MCS (p=0.01). The differences for the other SF-36 domains were not statistically significant. The pregnant controls had higher SF-36 mean scores for GH (72.7) and MH (72.0) with over 70 points (Figure 1).

The pregnant women with GERD were divided into three groups according to their educational status. The education levels of the study participants were classified as low (illiterate or primary education up to 8 years), medium (high school, 8-12 years of education) and high (university level, more than 12 years of education). According to their educational status, the SF-36 scores did not differ between the pregnant women (p>0.05) (Table 4). Twenty out of the 53 patients were reported to experience GERD symptoms before pregnancy. Experiencing GERD before pregnancy did not affect their SF-36 scores compared with those pregnant women who did not experience any GERD symptoms before pregnancy (p>0.05) (Figure 2).

According to the GERDQ scores, the pregnant women with GERD were divided into 2 groups (GERDQ scores 8-10 and GERDQ scores 11-18). The SF-36 scores were reexamined between these subgroups of GERD. No significant difference was found in all eight domains of the SF-36 between these 2 GERD patient subgroups (Figure 3).

DISCUSSION

This study was undertaken to assess the QoL in those pregnant women with or without GERD. We demonstrated that third trimester pregnant women with GERD have worse GH, MH and MCS compared with those pregnant women without GERD. However, in pregnant women with GERD, their educational status was not found to have an impact on their QoL. Additionally, those pregnant women with GERD who had experienced GERD symptoms including heartburn and acid reflux before their pregnancy demonstrated no additional health-related QoL score alterations in their third trimester of pregnancy.

Most pregnant women have symptoms of GERD, including heartburn and regurgitation, due to weakened lower esophageal sphincter and/or the growing uterus, which can put pressure on the stomach. Due to the special conditions of pregnancy, invasive investigations such as esophageal manometry and pH probes to map the gastroesophageal pH gradient are rarely applied, although both of these tests can be safely performed on pregnant women in advanced centers.[15] In general, the diagnosis of GERD in a pregnant woman can reliably be made clinically according to its typical symptoms. In this context, the GERDQ can be used to diagnose GERD with an accuracy comparable to the accuracy of a diagnosis of GERD by a gastroenterologist.

Our analysis emphasizes the importance of clinical conditions on health-related QoL in pregnant women and suggests the need for a

Table 2. Socio-demographic characteristics of study participants

	*Group 1 (n=53), (with GERD)	*Group 2 (n=54), (without GERD)	p
Age (years)	28.0±5.4	27.7±5.4	0.80
Pre-pregnancy BMI in kg/m^2	23.8±4.3	25.2±5.2	0.139
Gravida [median, (minimum-maximum)]	2 (1-6)	2 (1-7)	0.934
Parity [median, (minimum-maximum)]	1 (0-3)	1 (0-2)	0.818
Abortus [median, (minimum-maximum)]	0 (0-3)	0 (0-4)	0.366
Educational status	-	-	0.821
Low (%)	18 (33.9)	18 (33.4)	-
Medium (%)	17 (32.2)	16 (29.6)	-
High (%)	18 (33.9)	20 (37.0)	-
Smoker	-	-	0.76
No (%)	52 (98.2)	52 (96.3)	-
Yes (%)	1 (1.8)	2 (3.7)	-
Prior GERD history	-	-	0.024
No (%)	34 (64.1)	49 (90.8)	-
Yes (%)	20 (35.9)	5 (9.2)	-

BMI: Body mass index, GERD: Gastroesophageal reflux disease, *Group 1: Pregnant cases with GERD, Group 2: Pregnant controls without GERD.

comprehensive medical and social approach for pregnant women with GERD. In clinical practice, QoL assessment has a significant impact on clinically relevant outcomes in healthcare management and clinical research. Different specific and generic instruments are used to evaluate QoL in gastrointestinal disorders during pregnancy but their interrelationship is not well known. SF-36, which was developed as part of the Medical Outcomes Study,[16] is one of the most widely used standardized self-reported assessments which is sufficiently general to be used in various health and disease states including pregnancy.[3,17,18] It is a reliable generic instrument which has 8 scaled scores in which lower scores represent more disability and higher scores represent less disability and better functioning.[16,19]

Although the negative impact of GERD on the QoL of patients has been shown in multiple studies,[20-23] there is scarce data in the literature addressing the effect of GERD on QoL in the advanced stages of pregnancy. In this context, the results of the present study confirmed that GERD in pregnancy significantly impaired the mother's health-related QoL. We demonstrated that, during the third trimester, pregnant women with GERD had significantly decreased QoL in their GH, MH and MH component domains, while no significant changes were observed in the other components of the QoL domains. These alterations, especially in the mental domains, may be explained by the negative influence of the psychological stress induced by GERD. Moreover, complex interactions between biological, environmental, and hormonal factors during pregnancy may be regarded as the predisposing causes of lower QoL scores in these three domains.

One of the key findings of this research was that pregnant women even with or without GERD had mean PCS and MCS scores below 50. It is not surprising to detect a mean PCS or MCS scores below 50 in pregnant women because pregnancy is a condition in which physical activity levels significantly decline. In addition, physical incapacity is a major factor adversely affecting the perceived QoL in pregnancy.[24,25] Although we found low MCS scores in both study groups, the MCS scores of the pregnant women with GERD were statistically lower than the control group. The reason for the lower mean MCS scores in the GERD patients can be attributed to the high levels of psychological stress exacerbated by GERD.

We also revealed that levels of education were not a contributing factor to the QoL scores of the pregnant women. This might be due to the

Table 3. Results of the quality of life (short-form 36) among pregnant women with or without GERD

	*Group 1 (n=53), (with GERD)	*Group 2 (n=54), (without GERD)	p
Physical functioning	55.4±20.9	58.7±21.1	0.419
Role-physical	35.4±35.8	49.7±41.1	0.057
Bodily pain	56.6±23.0	57.2±20.6	0.884
General health	61.3±18.5	72.7±13.8	<0.01
Vitality	49.3±21.8	55.8±18.2	0.097
Social functioning	63.0±23.8	63.1±24.7	0.987
Role-emotional	46.8±32.1	50.6±34.0	0.551
Mental health	58.6±21.7	72.0±13.8	<0.01
Physical component summary	40.6±10.1	42.9±9.80	0.220
Mental component summary	42.7±9.30	46.8±6.70	0.010

GERD: Gastroesophageal reflux disease, *Group 1: Pregnant cases with GERD, Group 2: Pregnant controls without GERD.

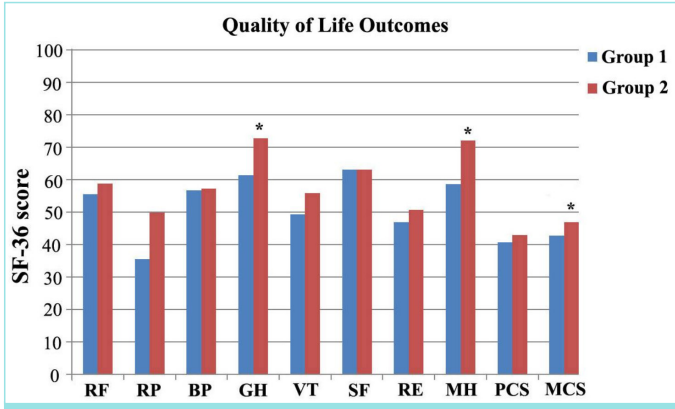

Figure 1. Short-form 36 scores of the pregnant women with GERD (group 1) and without GERD (group 2).

SF-36: Short-form 36, GERD: Gastroesophageal reflux disease, RF: Role functioning, RP: Role-physical, BP: Bodily pain, GH: General health, VT: Vitality, SF: Social functioning, RE: Role-emotional, MH: Mental health, PCS: Physical Health Component Score, MCS: Mental Health Component Score.

Table 4. Results of the quality of life (short-form 36) scores according to the level of education among the pregnant women

	Educational status								
	Low			Middle			High		
	Group 1	Group 2	p	Group 1	Group 2	p	Group 1	Group 2	p
Physical functioning	56.1±19.5	63.8±23.2	0.25	54.7±19.8	67.3±16.1	0.55	57.6±18.9	59.0±24.6	0.84
Role-physical	27.7±34.1	41.7±34.3	0.22	29.3±33.8	36.4±33.3	0.29	29.4±34.5	35.8±35.0	0.57
Bodily pain	57.0±28.6	57.3±18.9	0.96	56.2±28.0	61.4±18.0	0.53	60.4±25.5	53.6±21.6	0.38
General health	62.2±23.4	62.0±12.9	0.97	62.5±22.8	62.8±11.9	0.95	61.4±23.9	61.7±12.7	0.96
Vitality	53.5±20.8	53.7±16.1	0.97	53.9±20.3	53.1±14.9	0.90	54.9±20.6	50.5±17.3	0.48
Social functioning	63.9±27.7	71.9±15.3	0.29	63.8±26.9	73.0±16.4	0.25	66.2±26.8	67.5±18.9	0.85
Role-emotional	45.6±27.3	50.0±33.0	0.66	43.2±28.5	55.6±30.3	0.22	46.3±28.0	44.4±34.0	0.85
Mental health	60.5±20.6	58.2±19.2	0.72	61.1±20.2	60.5±18.6	0.92	61.2±21.0	56.9±18.0	0.51
Physical component summary	42.2±14.2	41.7±7.3	0.88	41.6±14.0	42.0±6.0	0.92	43.1±14.1	40.1±7.8	0.40
Mental component summary	44.0±8.6	43.3±8.0	0.79	44.1±8.3	44.4±7.9	0.89	44.4±8.7	42.3±7.8	0.44

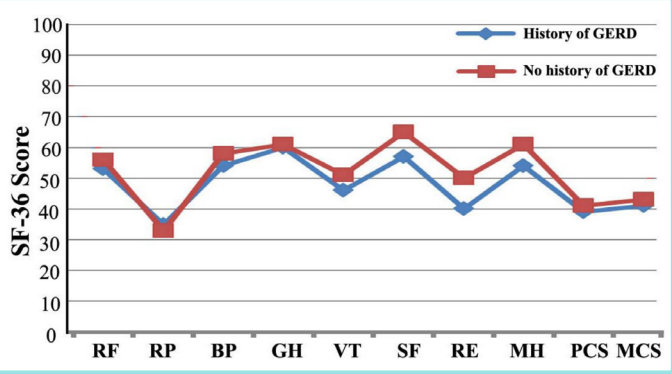

Figure 2. Results of the short-form 36 questionnaire in pregnant women with GERD according to their history of GERD prior to pregnancy.

SF-36: Short-form 36, GERD: Gastroesophageal reflux disease, RF: Role functioning, RP: Role-physical, BP: Bodily pain, GH: General health, VT: Vitality, SF: Social functioning, RE: Role-emotional, MH: Mental health, PCS: Physical Health Component Score, MCS: Mental Health Component Score.

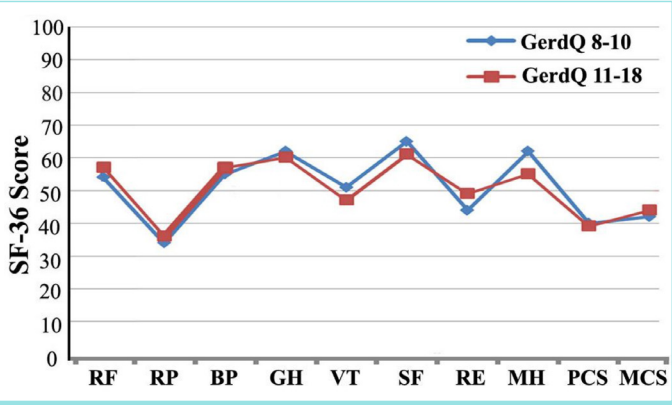

Figure 3. Comparison of the Short-form 36 (SF-36) scores of the pregnant women with GERD according to their GERDQ scores (GERDQ 8-10 vs GERDQ 11-18).

SF-36: Short-form 36, GERD: Gastroesophageal reflux disease, RF: Role functioning, RP: Role-physical, BP: Bodily pain, GH: General health, VT: Vitality, SF: Social functioning, RE: Role-emotional, MH: Mental health, PCS: Physical Health Component Score, MCS: Mental Health Component Score.

already lower QoL scores of the pregnant women, even those with GERD. Furthermore, it can be speculated that the advanced stages of pregnancy which are associated with higher perceived stress leads to restrictions on mental and physical health-related QoL, independent from the educational status of the pregnant women. Contrary to our findings, in a recent study by Barbareschi et al.[26], patients with low educational levels were reported to have worse physical and functional conditions. Similarly, Nicholson et al.[27] reported that not only educational levels but age, marital status and social support during pregnancy might affect the QoL in pregnant women.

Study Limitations

The main limitation of the present study was that the number of patients enrolled was relatively low. A larger sample is required to confirm these results. Moreover it would have been beneficial if we had assessed other factors which could affect QoL in pregnancy, including anxiety and depression.

CONCLUSION

GERD during pregnancy is associated with poor levels of QoL in terms of general and MH. This condition has to be taken into account by those clinicians involved in the care of pregnant women. Further studies are necessary in order to elucidate the factors which contribute to the poor levels of health-related QoL in pregnant women with GERD.

MAIN POINTS

- Gastroesophageal reflux disease significantly affects the quality of life of pregnant women.
- It represents a major healthcare problem due to the high prevalence of gastroesophageal reflux throughout pregnancy.
- In order to improve the quality of life of pregnant women with gastroesophageal reflux disease, a combined health management strategy is needed.

ETHICS

Ethics Committee Approval: Ethical clearance was obtained from Çanakkale Onsekiz Mart University Faculty of Medicine Ethics Board (approval number: 2016-03, date: 17.02.2016).

Informed Consent: Written informed consent was obtained from all of the participating women.

Peer-review: Externally and internally peer-reviewed.

Authorship Contributions

Concept: F.B., A.Ç.G., Design: F.B., A.Ç.G., Y.B., Supervision: F.B., M.A.Ü., Data Collection and/or Processing: A.Ç.G., Y.B., Analysis and/or Interpretation: A.Ç.G., M.A.Ü., Literature Search: Y.B., Writing: F.B., M.A.Ü., Critical Review: F.B., M.A.Ü.

DISCLOSURES

Conflict of Interest: No conflict of interest was declared by the authors.

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