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ORIGINAL CONTRIBUTIONS

GERD-Related Questionnaires and Obese Population: Can They Really Reflect the Severity of the Disease and the Impact of GERD on Quality of Patients' Life?

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Abstract
Introduction There is a strong association between obesity and gastroesophageal reflux disease (GERD). GERD-related questionnaires have been developed in order to objectify symptoms. However, none of them has been tested in obese population.
Purpose The purpose of this study is to evaluate if GERD score and GERD-Health-Related Quality of Life (HRQL) can reflect severity of the disease and screen obese patients for GERD preoperatively. GERD's impact on the quality of life of obese patients is being assessed with the use of EORTC-QLQ C30.
Patients-Methods Obese patients during their preoperative evaluation were recruited regardless of the presence of GERD symptoms. A targeted GERD symptom history was obtained. Patients completed GERD score, GERD-HRQL, and EORTC-QLQ C30, and then, a 24-h multichannel intraluminal impedance pHmetry (MIIpH) was conducted.
Results Forty-seven consecutive obese patients with mean age 39.91 years and mean BMI 46.94 kg/m^2 were included in the study. GERD score and GERD-HRQL have a positive linear correlation with DeMeester score ($p=0.001$ and $p<0.001$, respectively). EORTC QLQ-C30 does not correlate with DeMeester score.
Conclusions GERD-related questionnaires could be used in obese population as preoperative screening tool for GERD. However, our results indicate that the quality of life of obese patients is not affected by the existence of GERD.

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Introduction

Gastroesophageal reflux disease (GERD) affects an important percentage of people worldwide. It is has been reported that GERD affects up to 25 % of population in Europe, reaching up to 28 % in the USA [1]. GERD incidence is high among the obese, affecting up to 40 % and in a single study even 90 % of obese population [2, 3]. Complications of GERD are development of erosive esophagitis, Barrett's esophagus, and adenocarcinoma. Indeed, studies reveal increasing incidence of GERD complications, as a result of the increasing incidence of GERD.

GERD and obesity have been related; however, not a certain mechanism explains this correlation [4]. In Greece, 22.5 % of adult population is obese [5]. As obesity has reached epidemic proportions worldwide, it is reasonable to think of the significance of timely diagnosing GERD in this population—since most obese patients already have important comorbidities. Even more important would be the diagnosis of GERD and its complications in obese patients before a bariatric procedure. This could lead surgeons to modify the bariatric procedure to one that protects against GERD. Although literature data are inconsistent, Roux-n-Y gastric bypass is thought to reduce GERD in obese patients [6].

GERD can be suspected through a targeted history about typical (heartburn, regurgitation) and atypical (pain, dysphagia, hoarseness, cough) symptoms. In many cases, though, patients neglect or misinterpret their symptoms; thus, not all of patients who report heartburn suffer from GERD. In

addition, surgeons may underestimate symptoms and their impact to patients' life. To eliminate the discrepancies and globally objectify symptoms, several GERD questionnaires have been developed, but none of them has been validated in an obese population, yet. However, GERD questionnaires could be a cost-effective way to screen obese patients for GERD preoperatively, in order to further investigate them with esophagogastroscopy, manometry, and pHmetry.

GERD score is a disease-related questionnaire that assesses six GERD symptoms (heartburn, regurgitation, epigastric or chest pain, epigastric fullness, dysphagia, and cough) [7]. For each symptom, severity (scores 0–3) and frequency (scores 0–4) are being scored. The final score varies from 0 to 72 and comes by adding the severity and frequency score of each symptom. It is designed to be administered by an external investigator rather than self-administered and has been validated in a population of patients with GERD preoperatively and 6 months postoperatively.

The Gastroesophageal Reflux Disease Health-Related Quality of Life (GERD-HRQL) questionnaire consists of ten items scored in a 6-point scale (e.g., heartburn, regurgitation burden of medication) [8]. GERD-HRQL does not evaluate extraesophageal or atypical GERD symptoms; it is self-administered and was developed for pre- and postoperative patients' assessment.

EORTC-QLQ C30 is a questionnaire consisting of 30 questions that was developed to assess the quality of life in cancer patients, but recently, it has been used to assess the quality of life in patients with chronic health impairment. EORTC-QLQ C30 has three subscales—the functional, symptom, and global subscales—which come by grouping certain questions of EORTC-QLQ C30. Zeman et al. have published a psychometric evaluation of the quality of life of patients undergoing antireflux surgery using EORTC-QLQ C30 among other questionnaires [9].

The purpose of our study is to evaluate if GERD score and GERD-HRQL can effectively screen obese patients for GERD preoperatively and if existence of GERD affects the quality of life—assessed through EORTC-QLQ C30.

Patients and Methods

For the purpose of our study, obese patients were recruited during their preoperative evaluation for bariatric surgery. Age over 18 and no previous upper gastrointestinal surgery were the inclusion criteria.

A detailed targeted history on typical and atypical or extraesophageal symptoms of GERD was obtained. All patients completed GERD score, GERD-HRQL, and EORTC-QLQ C30 questionnaire.

After completing the questionnaires, patients underwent a 24-h multichannel intraluminal impedance pHmetry (MIIpH). Patients had to fast at least 6 h prior to the study and to stop PPI or other antacid therapy for at least 10 days. A dual pH probe catheter with six impedance channels (Sandhill Scientific) was used, with the one pH sensor being placed 5 cm above the manometrically identified lower esophageal sphincter (LES) and the other in the stomach 10 cm distal of LES. Patients were instructed not to change their lifestyle or their meals (with the exception of creamy foods and chewing gum) and were asked to indicate—by pushing the appropriate button on the portable machine—their three more frequent symptoms of GERD (if any), their meals, and their body position, namely supine or upright. A diary to comment on anything that might be relevant to the study was provided. The study was conducted on an outpatient basis, and 24 h later, patients returned to remove the catheter. BioVIEW Analysis software (Sandhill Scientific) was used for data analysis. Patients were diagnosed with GERD if DeMeester score was above 14.72.

The study protocol was approved by the Ethical Committee of our institution. Informed consent was obtained from all individual participants included in the study.

Statistical analysis was performed using the Statistical Package for the Social Sciences (IBM SPSS 19). All variables were tested for normality using nonparametric one-sample Kolmogorov-Smirnov test. Chi-square or Fisher's exact tests were used to compare categorical data; Student's t test or Mann-Whitney U test was used for continuous data. p values lower than 0.05 were considered statistically significant. Pearson's test was used for bivariate correlations between normal continuous variables and Spearman's test for continuous variables that have not a normal distribution. Linear regression models were constructed to assess the effect of several factors on GERD score and GERD-HRQL.

Results

Our study population consists of 47 consecutive obese patients, of whom 35 (74.5 %) are female. Mean age is 39.91 years old (SD=9.45), and mean body mass index (BMI) is 46.94 kg/m^2 (SD=7.12) with a minimum of 36 kg/m^2 and a maximum of 63.78 kg/m^2.

No correlation was found between age, sex, or BMI and DeMeester score (p=0.560, p=0.648, and p=0.938, respectively). In addition, age, sex, and BMI have no correlation with GERD score and GERD-HRQL (p=0.395, p=0.963, and p=0.743, respectively, for GERD score; and p=0.818, p=0.860, and p=0.383, respectively, for GERD-HRQL).

GERD score (Fig. 1) and GERD-HRQL (Fig. 2) have a positive linear correlation with DeMeester score (p=0.001 and p<0.001, respectively). Patients with DeMeester score

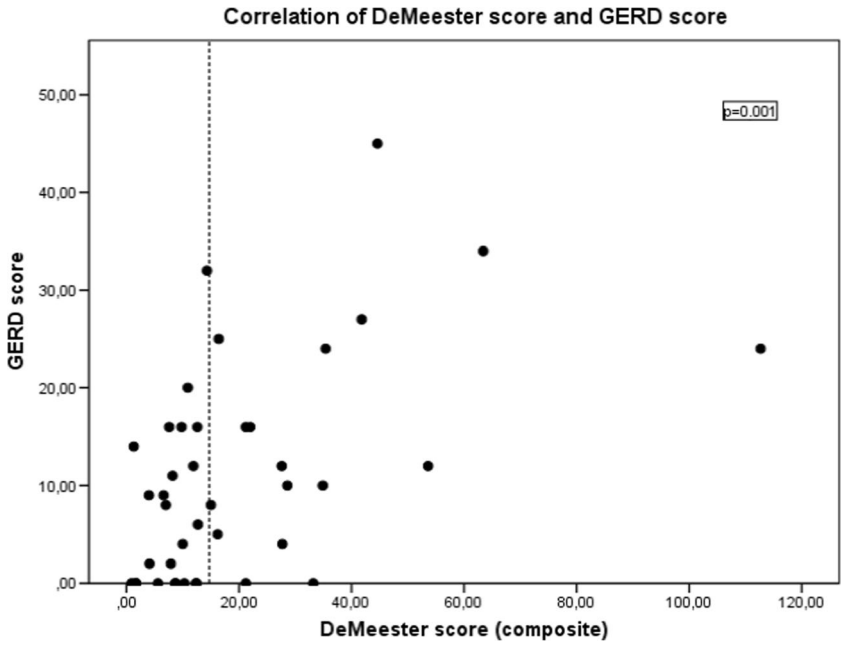

Fig. 1 The graph presents the correlation of DeMeester score and GERD score. The *dotted vertical line* is positioned at the upper limit of normal for DeMeester score (14.72)

≥14.72 have higher GERD score (12.35 vs 8.43, $p=0.019$) and GERD-HRQL (9.88 vs 4.66, $p=0.004$).

However, no correlation was found between functional, symptom, and global subscales of EORTC-QLQ C30 and DeMeester score ($p=0.794$, $p=0.554$, and $p=0.850$, respectively).

Multivariate analysis adjusted for age, sex, and BMI revealed that GERD score and GERD-HRQL are independently associated with DeMeester score having a strong positive correlation ($p=0.002$, $-B_{coef}=0.481$ and $p=0.014-B_{coef}=0.376$).

Discussion

GERD-related scores and questionnaires have been developed in order to diagnose, objectify symptoms, or assess the quality of life of patients with GERD [10]. Most of them have been used in order to follow up patients after therapeutic interventions, but they can also be used as a tool for scoring the severity of GERD.

Diagnosis of GERD is employed through invasive methods such as esophagoduodenoscopy and pHmetry. Except for

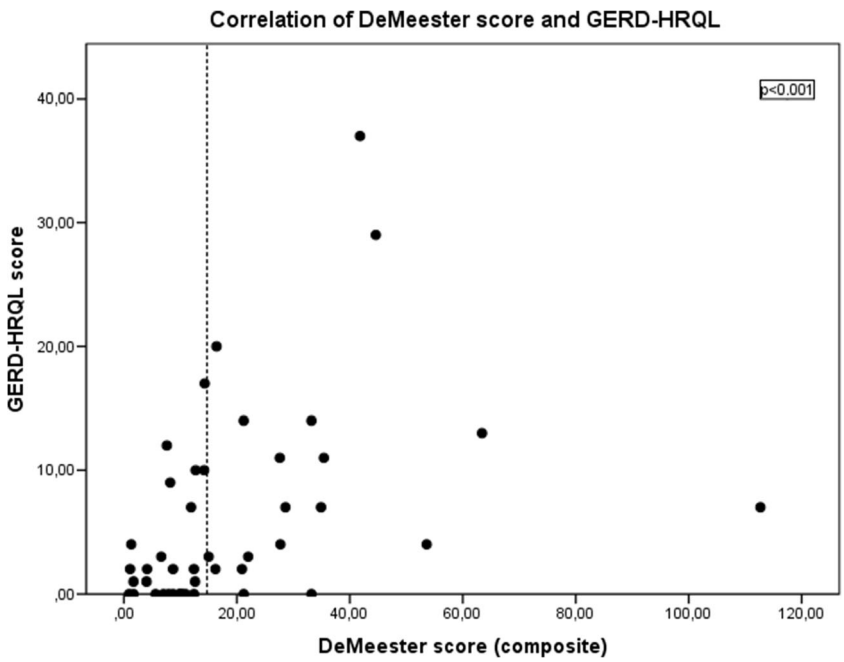

Fig. 2 The graph presents the correlation of DeMeester score and GERD-HRQL. The *dotted vertical line* is positioned at the upper limit of normal for DeMeester score (14.72)

patients' inconveniency, these methods are not widely available and have a high cost. In order to overcome these disadvantages, a symptom-based diagnosis—Montreal definition—has been proposed for the general population, especially for younger patients without alarming symptoms [11]. The usefulness of GERD-related questionnaires in the diagnosis of GERD has been evaluated by Rey et al., who concluded that Reflux Disease Questionnaire could be useful in primary care settings for diagnosis of GERD according to Montreal definition [12].

GERD has been strongly related with obesity, although the mechanism is still unclear. Mechanisms that could explain this association are decreased LES pressure, increased transient relaxations of LES, presence of hiatal hernia, increased intraabdominal pressure, and consumption of rich-in-carbohydrate foods [13]. Preoperatively, a thorough evaluation of GERD symptoms is very important in order to decide which patient needs further investigation with esophagogastroscopy, manometry, and pH study. Tolone et al. proposed to perform reflux testing with MIIpH to all obese candidates for bariatric surgery with symptoms or endoscopic evidence of GERD [3]. However, currently, the indication for further testing is still debatable and there is no consensus on preoperative work-up.

Literature data are inconsistent regarding the effect of bariatric procedures to GERD. Although losing weight or changing eating habits might help in eliminating symptoms of GERD, some bariatric operations may worsen or even produce newly presenting GERD.

Our study focuses on the use of GERD score and GERD-HRQL for preoperative evaluation of GERD in obese patients in comparison to the results of 24-h MIIpH. A limitation of our study is the small subject number. However, it consists of obese patients with a high mean BMI and to our knowledge there are no other studies correlating the results of MIIpH with GERD questionnaires.

Results of our study reveal that both questionnaires have a positive linear correlation with DeMeester score. This finding implicates that they effectively reflect the severity of GERD in obese patients and that the use of these questionnaires can screen obese patients for GERD preoperatively, in order to investigate them with further pH studies. Quality of life is not affected by the existence of GERD, thus indicating that GERD may not have a great impact on obese patients' quality of life.

Further studies with larger series are needed in order to validate cutoff points of these scores. This may lead to a new approach of the diagnosis of GERD in obese population preoperatively.

Conclusion

In conclusion, GERD score and GERD-HRQL can be used in obese population as a preoperative screening tool for GERD in order to identify patients who will further need pH testing. The quality of life of obese patients is not affected by the existence of GERD.

Conflict of Interest All authors declare no conflict of interest.

Ethical Approval All procedures performed were in accordance with the ethical standards of the institutional research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

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