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Esophageal Manometry in Patients with Gastroesophageal Reflux Disease; A Study from Saudi Arabia

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1. Abstract

1.1. Background: The burden of Gastroesophageal reflux disease is high among the Saudi population. Various defense mechanisms play a role in preventing GERD, and the usefulness of manometry in identifying them has not been studied well in Saudi Arabia.

1.2. Objective: The objective of the study was to identify risk factors for GERD. The second objective was to study the role of esophageal manometry to detect defects in defensive mechanisms of GERD at gastroesophageal junction and esophagus.

1.3. Study Design: Retrospective cohort study

1.4. Methods: The data of patients who underwent esophageal pH study and esophageal manometry from September 2015 until August 2018 at King Faisal specialist hospital and research Centre, Riyadh, Saudi Arabia were included. The length and presence of hiatus hernia, distal contractile integral, lower esophageal basal pressure, body mass index is some of the risks we studied.

1.5. Results: From 506 manometry studies, we identified 102 patients who had both esophageal manometry and PH study. From the 102 patients, GERD was confirmed in 59 patients by the pH study. From 59 patients, males were 39 (66.1%) and females were 20 (33.9%) (*p-value* 0.017). The mean age of the patients with GERD was 43.39 years, and those without GERD were 38 years (*p-value* 0.038). The mean body mass index of patients with GERD was 29.31 (standard deviation of 7.06) compared to 23.6 in patients who do not have GERD (p-value 0.0001).

Male gender, high BMI, presence of hiatus hernia, higher length of hiatus hernia, lower levels of esophageal basal pressure, and lower levels of mean lower esophageal sphincter residual pressure significantly associated with GERD by univariate analysis.

Binary logistic regression analysis showed male gender (odds ratio 3.7, 95% CI 1.3 to 10.6); low residual LES pressure (Odds ratio 1.2 95% CI 1.024 to 1.42); and high BMI (Odds ratio 1.16, 95% CI 1.06 to 1.3) associated with GERD.

1.6. Conclusion: Esophageal manometry is beneficial to identify risk factors associated with GERD. From different variables studied, risk factors for GERD were low residual lower esophageal sphincter pressure, male gender, and high BMI.

2. Background

Gastroesophageal reflux disease is a condition in which reflux of gastric material through the lower esophageal sphincter into the esophagus or oropharynx occurs and causes symptoms and or injury to the esophageal tissue [1]. The prevalence of GERD in Saudi Arabia has been reported as high. It ranged from 23.8% to 58%, and all the prevalence studies have used the Gastroesophageal Reflux Disease Questionnaire for diagnosing GERD [2-5]. Based on the definition of GERD, the global prevalence of GERD varies from country to country. It has been reported in the range starting from 2.5% to 51.2%. The global pooled prevalence of GERD based on weekly heartburn or regurgitation has been reported at 13.3% [6].

Risk factors of GERD include the presence of hiatus hernia, which leads to weakness of LES (lower esophageal sphincter) and stasis of food content in the hernia sac above the diaphragm. Another

risk factor for GERD is obesity which may increase intra-abdominal pressure and relaxes LES (lower esophageal sphincter). GERD increases with lax lower esophageal resting (LES) pressure. Abnormal transient lower esophageal sphincter relaxations (TLESRs) are another risk factor. The impaired esophageal peristalsis and impaired clearance of the esophagus is a risk for GERD [7,8]. To understand some of the pathophysiologic mechanisms of GERD, esophageal high-resolution manometry (HRM) is useful. HRM is helpful to evaluate the esophagogastric junction (EGJ), such as intactness of EGJ, LES pressure, and the presence of a hiatus hernia. HRM is also beneficial for the assessment of esophageal body motor function. It will identify the fragmented peristalsis, ineffective esophageal motility, and absent contractility. In addition, in patients with abnormal esophageal motor function, contraction reserve is assessed by doing provocative tests with HRM [8]. HRM can be utilized for identifying the location of LES and proper positioning of the pH catheter [9]. We conducted this study to find risk factors for GERD. The second objective was to study the role of esophageal manometry to detect defects in defensive mechanisms of GERD at gastroesophageal junction and esophagus.

3. Methods

3.1. Study Design: The data of patients who underwent esophageal pH study and esophageal manometry from September 2015 until August 2018 at King Faisal specialist hospital and research Centre, Riyadh, Saudi Arabia, were included.

3.2. Inclusion Criteria: Patients were included if they were above the age of 18 years who had undergone both esophageal manometry and esophageal pH study. Patients who had pH study with either a catheter 24-hour study or wireless capsule were accepted.

3.3. Exclusion Criteria: The exclusion criteria included: Patients on antisecretory medications during the last seven days before the study; altered gastrointestinal (GI) anatomy; previous gastrointestinal surgery; esophageal pH study that lasted <20 hours; esophagogastric junction outflow pathology (achalasia or esophagogastric junction outflow obstruction) on manometry.

3.4. Study Subjects and Materials: The following variables were studied from the esophageal manometry: The presence of hiatus hernia and its length. The distal contractile integral (DCI) and mean respiratory-basal pressure at the lower esophageal sphincter. In addition, the gender of the patients and body mass index (BMI) were recorded. The patients were subdivided into different groups based on their BM measurements: those with BMI <18.5, 18.5 to 24.9, 25 to 29.9, 30 to 34.9, and >35.

3.5. Esophageal Manometry: Esophageal manometry was performed by a qualified physician using SIERRA manometry device and catheter, Manoscan360 and ManoscanZ. Software: ManoView ESO version 3.0. Patients were positioned at 45 degrees. Standard calibration was performed as per manufacturer and optimal thermal compensation were done. In each study, landmark reading was performed. Followed by 10 swallows of water or saline. For the diagnosis of esophageal motility disorders, Chicago Classification of esophageal motility disorders v3.0. was used.

3.6. Hiatus Hernia: The length of the hiatus hernia was measured as the distance between the lower esophageal sphincter zone and pressure inversion point (PIP). Hiatus hernia was diagnosed if this measurement was one centimeter or more. The severity of hiatus hernia was divided into three groups: with hiatus hernia size of 1 to 2 centimeters, 2.1 to 4 centimeters, and those with >4 centimeters.

3.7. Distal Contractile Integral: Distal contractile integral was subdivided into three groups: < 450 millimeters of Mercury cm. s between 450 and 700, and those with >700 mmHg·s·cm.

3.8. Lower Esophageal Basal Pressure: Lower esophageal basal pressure (LEBP) (mean respiratory resting pressure) was grouped into the following: patients with LEBP less than 5 mm of Mercury; from 5 to 12.9 millimeter of Mercury; 13 to 28 mm of Mercury; 28.1 to 43 mm of Mercury; and those with more than 43 mm of Mercury.

3.9. pH Study and GERD Diagnosis: For pH capsule study, OMOM capsule was used, and analysis was performed using the software of pH capsule Data analyses V2.3.0 supplied by the same company. For pH catheter studies, the following catheter was used: insight g3 SANDHILL, and analysis was done using the software of bio-VIEW analysis V5.7.0.0.The patients were advised to stop taking PPIs or any other acid anti-secretory medications seven days before the pH study. But they were allowed to eat and drink and behave as normal during the pH study.

Diagnosis of gastroesophageal reflux disease (GERD) was made when the pH of the refluxate is less than 4, and total acid exposure time (AET) is more than 4% of the total study time (catheter pH study).

3.10. Ethics Statement: The trial design was accepted by the institute's research promotion committee. We conducted the study by following guidelines set by the research committee and declaration of Helsinki for medical research involving human subjects.

3.11. Statistics: Primary objective of the study was to find risk factors associated with GERD. Categorical variables were expressed as numbers and proportions, while continuous variables were expressed as means with standard deviations. The Pearson's Chi-square test was used to compare categorical variables, and t-test for comparing continuous variables. Binary logistic regression analysis was done to look for any risk factors for GERD. The data was analyzed by statistical software SPSS, Chicago, Illinois. A two-tailed P-value of < 0.05 was considered statistically significant.

4. Results

A total of 506 patients underwent manometry studies during the study period. The patients who had both esophageal manometry and pH study were 102. From this pool, in 59 cases GERD was confirmed by pH study. In the group with GERD, 39 (66.1%) were

males, and 20 (33.9%) were females (p-value 0.017). The mean age of the patients with GERD was 43.4 years, and those without GERD were 38 years (p-value 0.038). The mean body mass index of patients who had GERD was 29.31 (standard deviation of 7.1) in comparison to 23.6 in patients who did not have GERD (p-value 0.0001). Hiatus hernia was identified in 41 (69.5%) patients with GERD compared to 18 (30.5% of the patients without GERD (p-value 0.008). The mean length of pip to mid of lower esophageal sphincter and pressure inversion point was 1.68 centimeters in patients with GERD and 1.2cm in patients without GERD (p-value 0.020). Mean distal contractile integral was 1178 mmHg·s·cm in patients with GERD and 1219 mmHg·s·cm in patients without GERD (p-value 0.22). The lower esophageal basal mean pressure was 18.7 in patients with GERD and 25.4 in patients without GRE (p-value 0. 005). Mean lower esophageal sphincter residual pressure was 5.3 in GERD and 6.96 in patients without GERD (p-value 0.015). Mean distal latency in patients with GERD was 6. 5 and those without 6.6 (p-value 0.8).

The mean De-Meesters score in patients with GERD was 39.8 and 4.5 in the group without GERD (p-value 0.0001). (Table 1) shows the characteristic findings in patients with acid reflux and those without acid reflux. Binary logistic regression analysis showed male gender (odds ratio 3.7, 95% CI 1.3 to 10.6); low residual LES pressure (Odds ratio 1.2 95% CI 1.024 to 1.42); and high BMI (Odds ratio 1.16, 95% CI 1.06 to 1.3) was associated with GERD. The results of logistic regression analysis are given in (Table 2).

Table 1: Characteristic findings of 102 patients who had both esophageal pH study and manometry.

Variable	GERD (acid reflux) n=59	No acid refluxes n=43	p Value
Gender			
Male: n (%)	39 (66.1)	18 (41.9)	0.017
Female: n (%)	20 (33.9)	25 (58.1%)	
Age: mean (SD)	43.39 (13.2)	38 (12.25)	0.038
Body mass index: mean (SD)	29.31 (7.07)	23.86 (5.71)	0.0001
Hiatus hernia: n (%)	41 (69.4)	18 (41.86)	0.008
LES length: mean (SD)	1.68 (1.068)	1.2 (0.92)	0.02
Distal contractile integer: mean (SD)	1178 (911)	1219 (711)	0.804
LES Basal mean pressure (SD)	18.6 (11.9)	25.4 (11.77)	0.005
LES residual pressure (SD)	5.26 (3.5)	6.95 (3.3)	0.015
Distal latency	6.5 (1.18)	6.6 (1.4)	0.8
Acid exposure time	10.87 (5.57)	1.1 (1.08)	0.0001
DeMeester	39.85 (21.76)	4.47 (3.94)	0.0001

Table 2: Multivariate binary logistic regression analysis to predict factors associated with GERD and manometric findings in 102 patients; 59 patients had acid reflux on pH study and 43 patients were negative for acid reflux.

	ODDS RATIO	95% Confidence Interval		P VALUE
		Lower	Upper	
Age	0.986	0.947	1.028	0.512
Gender (1=male, 2=female)	0.271	0.094	0.777	0.015
Distal contractile intger (DCI)	1	0.999	1.001	0.684
LES Basal mean pressure	1.02	0.966	1.076	0.482
LES residual pressure	1.207	1.024	1.423	0.025
Distal latency	0.89	0.596	1.327	0.567
BMI	0.858	0.779	0.945	0.002
Hiatus hernia	2.118	0.456	9.841	0.338
LES length	0.935	0.439	1.99	0.861

5. Discussion

In this study, we studied the characteristic features at gastroesophageal junction and esophagus by high-resolution manometry in patients with GERD. After that we compared manometry findings in patients with GERD and those without GERD and identified risk factors for GERD. From univariate analysis, male gender, hiatus hernia, length of hiatus hernia, lower esophageal basal pressure and mean esophageal sphincter residual pressures were found significantly associated with GERD. From Multivariate analysis male gender, low residual LES pressure, and high BMI were found as significant risk factors for GERD.

Few of the important pathophysiologic mechanisms of GERD are structural mechanisms involving the EGJ causing transient lower esophageal sphincter mechanisms, hypotensive EGJ, and hiatus hernia.

In addition, at the level of esophageal body, hypomotility mechanisms from impaired clearance from fragmented peristalsis, ineffective esophageal motility or absent contractility plays additional role in the development and aggravation of GERD [8].

From our study, HRM was found useful in identifying some of the risk factors of GERD. From the univariate analysis, we were able to detect some of the important pathophysiologic mechanisms playing a role in the development of GERD at the EGJ, and they included hiatus hernia, length of hiatus hernia, lower esophageal basal pressure and mean esophageal sphincter residual pressure. Low residual LES pressure was found significant from both univariate and multivariate analysis. In this study HRM failed to detect TLESRs that is one of the important mechanisms of GERD. The reasons for HRM failing to detect TLESRs is as following. The HRM and pH catheter studies in our patients were done in fasting state and in supine position or at 45degree angle from the ground level. Most reflux and pathological TLESRs happen postprandial [10]. This might be the reason for not detecting the TLESRs in the current study from patients with GERD.

In this study, we found low LES mean respiratory basal pressure (resting pressure) is associated with GERD. A significant number of patients with GERD (37%) with GERD had lax LES in comparison to only 12% of patients with negative pH study. Lax LES was determined by having LES mean respiratory basal pressure less than low limit of normal which is less than 13 mmHg. Our observation is similar to conclusions made by other researchers [8, 9, 11].

We found that obesity is a risk factory of having GERD. All patients in our study who has BMI >35 was diagnosed with GERD. This observation is also in agreement with others [12]. DCI (distal contractile integral) evaluates the vigor of peristalsis in the distal esophagus. Weak esophageal peristalsis is associated with GERD because the esophagus is not able to clear refluxed material from the stomach. From our group of patients with GERD 10 of them had weak peristalsis. Some of the previous studies have indicated that prevalence of ineffective esophageal motility (IEM) is high in GERD, and patients with IEM and GERD may have more recumbent gastroesophageal reflux and delayed acid clearance [13].

Some of the limitations of HRM is that the study lasts only for 15-30 minutes, and it does not recognize the reflux activities happening in the extended period. During HRM, the patient is positioned most of the times in a supine position or in some centers at 45 degrees recumbent position, this may reduce intra-abdominal pressure and LES pressure. HRM is done in a fasting state and this will also affect TLESRs that often happens in the fed state.

However, in this study we tried to figure out the usefulness of HRM in identifying some of the pathophysiologic mechanisms of GERD. Once we have this knowledge, physicians can offer more individualized treatment for GERD.

In conclusion, esophageal manometry was found useful in identifying some of the risk factors associated with GERD. Low residual lower esophageal sphincter pressure, male gender and high BMI was found to be risk factors for GERD.

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