

Evaluation of gastroesophageal reflux after standardized gastric sleeve with the *Gastroesophageal Reflux Disease Questionnaire* (GerdQ)

Evaluación del reflujo gastroesofágico después de manga gástrica estandarizada con el Gastroesophageal Reflux Disease Questionnaire (GerdQ)

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Abstract

Objective: To evaluate the appearance of gastroesophageal reflux in our population after sleeve gastrectomy as management for obesity, with the Gastroesophageal Reflux Disease Questionnaire (GerdQ). **Method:** Retrospective study of patients undergoing sleeve gastrectomy during 2016 and 2017, having ruled out gastroesophageal reflux (GER) with pre-surgical upper digestive endoscopy, and post-operative evaluation with the GerdQ scale. **Results:** 129 patients were included in the study, average age was 45 years, gender of greater male appearance was 77.5%, the most frequent comorbidities were hypothyroidism 25.6% and hypertension 23.3%. 12.4% had a score greater than or equal to 8, 14 were women and 2 men, there was no statistically significant relationship with the preoperative mass index. **Conclusions:** Standardizing the gastric sleeve technique in the bariatric surgery services, taking into account the technical factors associated with post-operative GERD de novo, decreases its appearance as evaluated by the GerdQ scale.

Keywords: Sleeve gastrectomy. Gastroesophageal reflux. Morbid obesity.

Resumen

Objetivo: Evaluar la aparición de reflujo gastroesofágico (RGE) posterior a gastrectomía en manga como manejo para la obesidad, con el Gastroesophageal Reflux Disease Questionnaire (GerdQ). **Método:** Estudio retrospectivo de pacientes llevados a gastrectomía en manga durante 2016 y 2017, habiendo descartado RGE con endoscopia digestiva alta prequirúrgica, y evaluación posoperatoria con la escala GerdQ. **Resultados:** Se incluyeron en el estudio 129 pacientes, con un promedio de edad de 45 años, el 77.5% de sexo masculino y como comorbilidad más frecuente hipotiroidismo (25.6%) e hipertensión arterial (23.3%). El 12.4% tenían un puntaje ≥ 8 , 14 eran mujeres y 2 hombres, y no hubo relación estadísticamente significativa con el índice de masa corporal preoperatorio. **Conclusiones:** Estandarizar la técnica de manga gástrica en los servicios de cirugía bariátrica, teniendo en cuenta los factores técnicos asociados a RGE posoperatorio de novo, disminuye la aparición de RGE según lo evaluado por la escala GerdQ.

Palabras clave: Manga gástrica. Reflujo gastroesofágico. Obesidad mórbida.

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Introduction

The gastric *sleeve* is one of the most frequent current therapeutic procedures to treat obesity, which has become a health issue in the entire world, due to the increase in incidence and relationship with other type of comorbidity^{1,2}.

One of the main chronic complications associated with this procedure is *de novo* postoperative gastroesophageal reflux (GER) and the implications of their appearance, which range from esophagitis to Barrett's esophagus and esophageal cancer¹⁻³.

Several theories have been formulated, including the physiological structural changes of the stomach by converting into a high pressure tube, in addition to complications related to the surgical technique, which has the closest relationship with gastroesophageal reflux disease (GERD)^{4,5}.

Therefore, we attempted to evaluate the *de novo* postoperative presence of GER using the *Gastroesophageal Reflux Disease Questionnaire* (GerdQ), internationally validated⁶⁻⁸, and to compare it with medical literature.

Method

Design

We conducted a retrospective evaluation study of GER in patients who undergo laparoscopic gastric sleeve surgery in our center in Bogotá, Colombia, between January 2016 and June 2017.

We considered performing the GerdQ over the phone with patients, after explaining the purpose of the study in the first place, and then sending the same information to them over e-mail.

The questionnaire was conducted by someone other than the surgeons who had performed the procedure and were conducting follow ups, in order to avoid biases in the answers.

A week after the patients agreed to participate in the project, they received a new called, authorized by them, where the questionnaire was applied.

The postoperative questionnaire evaluated the following variables: date of performance, date of surgery, age, gender, presurgical and postsurgical height, presurgical and postsurgical weight, presurgical and postsurgical Body Mass Index (BMI), comorbidity (type 2 diabetes *mellitus*, arterial hypertension, obstructive sleep apnea (OSA), arthropathy, dyslipidemia,

asthma, hypothyroidism, others), and the GER questionnaire with its six questions and total score.

The GerdQ questionnaire asks patients to answer with the number of days with symptoms and use of reflux medication not prescribed by a doctor. It has a minimum score of 0 and a maximum score of 18. Patients with ≥ 8 points have 80% of possibilities of having GER, and this was the cut-off point in our study to establish the presence of GERD^{7,9}.

Permission for the preliminary project was requested from the Medical Ethics Committee of Universidad del Bosque, together with the informed consent. The protocol was implemented in compliance with the provisions of the Declaration of Helsinki and good clinical practices guidelines.

Patient preparation

All patients, prior to the procedure, were in the pre-surgical bariatric surgery program for a year, evaluated by a nutritionist who provided recommendations for lifestyle changes, an endocrinologist, psychologist, and psychiatrist.

In the evaluation by the surgeon, GER symptoms were investigated, and GERD was ruled out with upper endoscopy.

Patients and their families were informed of the risks of this surgery, the potential need for additional trochars, conversion, and mortality.

Laparoscopic gastric sleeve

The surgical procedure was performed with a five port technique. The greater curvature was dried using an ultrasonic bipolar type HARMONIC® (Ethicon Endosurgery US, LLC) and the gastric sleeve was created by using the ECHELON™ (Johnson and Johnson, New Brunswick, NJ, USA) stapler, controlling the hemostasis of the suture line with titanium endoclips, with an endoluminal spark plug of 32 Fr to calibrating the size of the sleeve and performing the leak test with intraoperative methylene blue.

A high quality standard surgical technique is performed with the purpose of respecting the angle of His, without drying or altering the frenoesophageal membrane or the lower esophageal sphincter, respecting the gastric antrum, calibrating the gastric sleeve with a 32 Fr and performing a hiatoplasty while identifying a concomitant hiatal hernia.

When the surgery was completed a Jackson Pratt drain was placed on the suture line. The intervention takes an average of 45 minutes using a pneumoperitoneum with carbon dioxide at a pressure of 15 mmHg with full muscle relaxation by the anesthesiology service, and an average bleeding of 10 ml. During the subsequent dissection of the stomach, the portal or mesenteric vessels were not visualized or manipulated at any time.

Statistical analysis

Since this was a retrospective observational cohort, a descriptive analysis of data and quantitative variables was performed using Office Excel 2011, creating tables and figures, in the same way as with the qualitative variables. The statistics software IBM SPSS version 23 was used to evaluate the statistical evaluation with the chi-square test between the variables selected and those included in this study.

Results

There was a total of 174 patients, but 43 could not be reached over the phone five times and two of them declined participation in this study.

This study included 129 patients, and 100 (77.5%) were women. The average age was 45 years (Standard Deviation [DE]: 9.8; range: 26-66).

In regard to the comorbidity of patients, the most frequent was hypothyroidism reported in 33 (25.6%), followed by arterial hypertension in 30 (23.3%), arthropathy in 30 (23.3%), OSAS in 22 (17.1%) and type 2 diabetes *mellitus* in 5 (3.9%) (Table 1).

According to the score of the GerdQ questionnaire, out of 129 patients, only 16 (12.4%) scored ≥ 8 points (Table 1); the average score was 5.72 (SD: 1.69). The *de novo* symptoms appeared in an average of 15.9 months.

When performing the analysis of anthropometric measurements of the patients, the average weight before surgery was 113 kg (SD: 17.4; range: 99-126) and the average BMO was 42 kg/m² (SD: 4.8; range 39.3-45.9). After the surgical procedure, the average weight was 78.7 kg (SD: 12.9; range 68-86) and the average BMI was 29.73 kg/m² (SD: 3.98; range: 26.56-32.36) (Table 2).

In the presurgical BMI ranges, the majority was at (40-45 kg/m² 50 patients, 39%) corresponding to level III obesity, followed by 35-40 kg/m² (43 patients, 33%), 45-50 kg/m² (29 patients, 23%) and > 50 kg/m² (6 patients, 5%).

Table 1. Patient characteristics

Characteristic	Value
Age (years)	
Mean	45.3
SD	9.8
Minimum	26
Maximum	66
Gender n (%)	
Female	100 (77.5)
Male	29 (22.5)
Comorbidity, n (%)	
Hypothyroidism	33 (25.6)
Arterial hypertension	30 (23.3)
Arthropathy	30 (23.3)
OSA	22 (17.1)
Dyslipidemia	13 (10.1)
Diabetes <i>mellitus</i>	5 (3.9)
Asthma	3 (2.3)
GerdQ	
Total score, average (SD)	5.72 (1.69)
Score ≥ 8 , n (%)	16 (12.4)

SD: Standard Deviation; OSAS: obstructive sleep apnea syndrome.

Regarding the postsurgical BMI ranges, the majority of patients was between 25-30 kg/m² (54 patients, 42%), which is considered overweight, followed by 20-25 kg/m² (14 patients, 11%) and 40-45 kg/m² (2 patients, 1.6%) (Table 3).

The average presurgical weight of patients with GER was 102.9 kg (SD: 13.4) and in patients without GER it was 114.4 kg, which is a statistically significant difference. The presurgical BMI was 40.1 kg (SD: 3.9) in patients with GER and 43 kg (SD: 4.8) in patients without GER, which also represents a statistically significant difference. The postsurgical BMI in patients with GER was 28.2 kg (SD: 2.8), and in patients without GER it was 30 kg (SD: 4.1), which does not represent a statistically significant difference (Table 4).

The majority of patients did not have GER, as stated previously. The majority of those who had GER were females (14 patients, 87.5%). When reviewing the relationship between GER and the main concomitant conditions, it was found that no positive association was present between patients with GER and those without, except patients with OSA, who showed a statistically significant association; however, these values have no clinical relevance because there was no patient with GER with this comorbidity (Table 5).

Regarding the gender of patients with postoperative *de novo* GER, 14 were women and 2 were men. In total, 4 patients had a hiatal hernia, but none developed GER (Table 6).

Table 2. Presurgical and postsurgical anthropometric measurements

Anthropometric measurements	Presurgical			Postsurgical		
	Average	SD	Range	Average	SD	Range
Weight (kg)	113	17.4	99-126	78.7	12.9	68-86
Height (m)	1.62	0.08	1.57-1.67	1.62	0.08	1.57-1.67
BMI (kg/m ²)	42.6	4.8	39.3-45.9	29.7	3.98	26.56-32.36

BMI: body mass index.

Table 3. Presurgical and postsurgical body mass index, by ranges

BMI (kg/m ²)	Presurgical (n)	Postsurgical (n)
20-25	0	14
25-30	0	54
30-35	1	49
35-40	43	10
40-45	50	2
45-50	29	0
> 50	6	0

BMI: body mass index.

Table 4. Comparison of anthropometric variables in relation to gastroesophageal reflux

Variables	Gastroesophageal reflux		p
	Yes (n = 16)	No (n = 113)	
Presurgical weight (kg), average (SD)	102.9 (13.4)	114.4 (17.4)	0.010
presurgical BMI (kg/m ²), average (SD)	40.1 (3.9)	43 (4.8)	0.03
Postsurgical weight (kg), average (SD)	72.6 (10.4)	79.6 (13)	0.03
Postsurgical BMI (kg/m ²), average (SD)	28.2(2.8)	30 (4.1)	0.1

SD: standard deviation; BMI: body mass index.

Discussion

Morbid obesity is increasing all over the world and it represent a serious public health issue. A surgical approach has been considered in certain type of patients, which has shown changes in medium and long term morbidity^{1,2,4}.

Risk factors for the appearance of GERD in patients with gastric bypass include alterations in the surgical

Table 5. Relationship between comorbidities with gastroesophageal reflux.

Comorbidity	GER presence			p
	Yes n (%)	No n (%)	Total n (%)	
Hypothyroidism	6 (18.2)	27 (81.8)	33 (100)	0.242
Arterial hypertension	2 (6.6)	28 (93.4)	30 (100)	0.241
Arthropathy	4 (13.3)	26 (86.7)	30 (100)	1
OSA	0 (0.0)	22 (100.0)	22 (100)	0.041
Dyslipidemia	2 (15.4)	11 (84.6)	13 (100)	1
Diabetes	1 (20.0)	4 (80.0)	5 (100)	0.534
Asthma	1 (33.3)	2 (66.6)	3 (100)	0.365

GER: gastroesophageal reflux; OSAS: obstructive sleep apnea syndrome.

Note: table data calculated by means of Fisher statistical technique.

Table 6. Gastroesophageal reflux and hiatal hernia

Variable	De novo GER	
	Yes	No
Gender (n)		
Female	14	86
Male	2	27
Hiatal hernia (n)	0	4

GER: gastroesophageal reflux

technique, such as the angle of His or the freno-esophageal membrane, decrease in the pressure of the lower esophageal sphincter by resection of some of its oblique muscle membranes, increase in intragastric pressure when reducing stomach volume added to the presence of an intact pylorus, altering the gastric emptying when the antrum is dried⁵.

Protection factors for the presence of GER associated with surgery have been described, such as reduction of acid production by resection of fundus, systematic repair of hiatal hernias at the time of the gastric sleeve surgery, decrease of intraabdominal

pressure by weight loss, increase of gastric emptying, and reduction of stomach volume, which is reflected in the results of our study with a decrease in postoperative *de novo* GER incidence².

The definitive diagnosis of GER is established according to four criteria: symptoms, endoscopic findings, digestive tract x-rays, and esophageal physiology studies, such as high-resolution manometry and esophageal pH-metry^{6-8,10}. However, all these studies are costly, and for this reason quality scales have been designed, such as the GerdQ questionnaire validated by Jonasson, et al.⁷ in 2009, in King College in London, in the DIAMOND study.

Furthermore, the GerdQ was validated by Pérez-Alonso, et al.¹¹ in 2009, in Sevilla, Spain, and it has been shown that it can decrease the use of digestive tract endoscopy and optimize the use of resources, as shown by our study, and it adjusts to our population. This was done with the purpose of identifying the incidence of postoperative *de novo* GER at a low cost, and in this way, validating our high-quality standardized surgical technique for a gastric bypass.

In a randomized clinical trial with 128 patients, conducted by Biter, et al.¹² in 2017, in Rotterdam, Netherlands, the average scored in the scale was 6.63 after 12 months, higher than ours (5.72), which shows that these patients were more symptomatic than ours using a high-quality standardized surgical technique.

Our study shows the decrease in postoperative GER, almost by 50% compared to the global series, such as those reported by Himpens, et al.¹³ in Brussels, Belgium, with 41 patients, followed up after 6 years, with 21% of postoperative *de novo* GER incidence compared to our study, with 12%, and a sustained average loss of excess weight of 50% after six years.

A systematic review that included 8092 patients and 33 studies, conducted by Oor, et al.¹⁴, showed an incidence of postoperative *de novo* GER of 20% in 24 of them. In another study conducted in Córdoba, Argentina, Viscido, et al.¹⁰ measured the lower esophageal sphincter pressure and calculated the DeMeester score based on high-resolution manometry in 109 patients with gastric sleeve with morbid obesity, who presented an incidence of postoperative GER of 36%.

It is worth noting, in our study, that patients with lower postsurgical BMI had a higher incidence of GER; however, these results were not statistically significant ($p = 0.1$). Furthermore, in another study conducted in 2011, in Florida, United States of America, by Howard, et al.¹⁵, with 28 patients, most of them women, as in our study, there was a 22% of GER appearance measured by questionnaires.

Another important factor to avoid the appearance of *de novo* GER is conducting a hiatoplasty in patients with a hiatal hernia identified during surgery, as described by Soricelli, et al.¹⁶ in Italy, in a study with 378 patients, in which 22.9% of patients that had a gastric sleeve without hiatoplasty developed *de novo* GER. However, in the latest studies, hiatoplasty has been controversial. Samakar, et al.¹⁷, in a study conducted in the United States of America and published in 2016, with 58 patients with gastric bypass and hiatoplasty, found that 15% developed *de novo* GER.

Santonicola, et al.¹⁸, in Italy, in a study published in 2014, with 180 patients divided in two groups, one with gastric bypass and hiatoplasty, and another one with gastric bypass and no hiatoplasty, reported a higher frequency of GER symptoms in patients with hiatoplasty. Compared to our study, there was a total of four patients with hiatal hernia (between 3 and 5 cm), which was an incidental finding during surgery, and none of them developed GER, but the sample is small to consider if the hiatoplasty is a protection factor for the development of GER. It is necessary to conduct more studies in order to establish if gastric bypass concomitant with hiatoplasty is a protection factor for the development of GER, as there is great controversy today.

This study was conducted with 129 patients, which represents a significant number, since, by compared to the rest of series, the majority of them have less patients, and this makes out results reliable and they confirm that using a standardized technique for a gastric bypass significantly reduces the incidence of postoperative *de novo* GER. However, the GER in our study was measured with the GerdQ, validated to make a diagnosis equivalent to one made by a gastroenterologist, but this can be a limitation, as the patients did not receive the reference method in order to confirm the diagnosis^{7,9}.

Conclusions

Using a standardized surgical technique for a gastric bypass decreases the development of postsurgical *de novo* GER evaluated by the GerdQ questionnaire, which is cost effective because patients do not undergo invasive testing. Patients with positive scores must receive complementary studies in order to confirm the diagnosis.

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Conflicts of interest

The authors declare not to have any conflicts of interest.

Ethical disclosures

Protection of People and Animals. The authors state that no experiments have been conducted in humans or animals for this research.

Data Confidentiality. The authors state that the protocols of their work center regarding the publication of patient data have been followed.

Right to privacy and informed consent. The authors declare that no patient data appears in this article.

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