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Predictive value of preoperative DeMeester score on conversion to Roux-en-Y gastric by-pass for gastroesophageal reflux disease after sleeve gastrectomy

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Abstract

Background: Obesity is well-known to increase the risk of GastroEsophageal Reflux Disease (GERD). Impact of Sleeve Gastrectomy (SG) on GERD is still discussed but seems to be associated with the development of de novo GERD or the exacerbation of preexisting GERD.

5 Objective: The objective of this study was to evaluate the impact of preoperative pH monitoring, using the DeMeester score (DMS), on the risk of conversion to Roux-en-Y gastric by-pass (RYGB) after SG.

Setting: University Hospital in Nantes (France)

Methods: This monocentric study reported the results of a retrospective chart review of 523
10 obese individuals treated between 2011 and 2018. All patients underwent primary bariatric surgery. Ninety five percent of them had undergone a SG. GERD diagnosis was established with preoperative DMS based on 24-hour esophageal pH monitoring.

Results: Preoperative DMS was identified in 423 patients (86%). Sixty-seven patients (14%) underwent a second bariatric procedure; among them, 36 (54%) have been converted to
15 RYGB because of GERD. There was no significant difference between preoperative DMS (16.1 +/- 22 vs 13.7 +/- 14, P= 0.37) in patients undergoing conversion for GERD and the non-converted ones. The sensitivity, specificity, positive predictive and negative predictive values of the preoperative DMS for predicting conversion to RYGB were 25%, 66%, 7% and 4% respectively. In patients who underwent a conversion for GERD, DMS (P<0.002), rates of
20 esophagitis (P=0.035) and hiatal hernia (P=0.039) significantly increased after SG.

Conclusion: Preoperative DMS alone is not predictive of the risk of conversion of SG to RYGB for GERD.

Key Words: Reflux; Sleeve gastrectomy ; 24h Ph monitoring ; conversion

Introduction:

Gastro Esophageal Reflux Disease (GERD) is a very common digestive disorder worldwide with an estimated prevalence of 18.1–27.8%. GERD is a highly prevalent condition in morbid obese patients (65%).⁽¹⁾

Sleeve gastrectomy (SG) has rapidly gained a large consensus worldwide in the bariatric community with 43.6% of procedures performed worldwide between 2013 and 2017.⁽²⁾ The impact of SG on GERD is discussed. Chronic GERD is accepted as the primary risk factor for the development of Barrett's esophagus (BE) and therefore esophageal adenocarcinoma (EAC).⁽³⁾ Systematic endoscopies are now recommended to diagnose esophagitis and BE at 5 and 10 years follow-up for SG.⁽⁴⁾ Cobey et al. reported a regression of BE 1 year after Roux-en-Y Gastric Bypass (RYGB).⁽⁵⁾ Gorodner et al. proved that RYGB was the best treatment option for obesity combined with GERD.⁽⁶⁾ Sebastianelli et al. reported a remission in 36% cases at one year of BE on esophageal biopsy after RYGB.⁽⁷⁾ To better choose between SG to RYGB, we need a tool to determine which patients will be affected by post-operative GERD. The aim of our work was to study the impact of preoperative 24-h pH monitoring using the DMS on the risk of conversion to RYGB for GERD after SG. We also studied the manometric changes at the esophageal-gastric junction before and after SG.

Material and methods:

Patients:

This retrospective study was conducted between January 2011 and December 2018 in the Department of Digestive and Endocrine Surgery at the University Hospital of Nantes. The eligibility criteria were: age > 18-years old, indication for a bariatric surgery procedure

according to the French Health Authorities (HAS) guidelines: i) obesity with a Body Mass Index (BMI) $> 35 \text{ kg/m}^2$ with secondary co-morbidities (type 2 diabetes (TD2), high blood pressure (HBP), obstructive sleep apnea syndrome (OSA), impact on locomotor system), or ii) BMI $> 40 \text{ kg/m}^2$.

55

Bariatric procedure:

All patients underwent an extensive preoperative multidisciplinary evaluation according to the National French guidelines that are similar to the recommendations of the National Institute
60 of Health. The choice of the procedure (laparoscopic adjustable gastric banding (LAGB), SG or RYGB) was determined after a comprehensive multidisciplinary discussion including the assessment of risks and benefits of the various options for each individual patient and considering their co-morbidities. At the time of the study, impact of DMS on long-term post-SG GERD was unknown. All patients had sleeve gastrectomy as surgeon preference
65 regardless of symptoms on DMS or clinical symptoms. The reason why a gastric bypass, 14 patients (36%), was initially performed was: metabolic comorbidities in 5 patients (35%), hiatal hernia > 4 centimeters in 5 patients (35%) , request of patient in 2 patients (14.5%) and 2 patients (14.5%) already had a SG elsewhere.

70 All SG were performed by laparoscopic approach. Gastrolysis was started 7 cm away from the pylorus for antral preservation. Gastrolysis was started by the gastric mobilization with vascular dissections, then the opening of lesser sac and finally the section of gastrosplenic ligament. No extensive esophageal gastric junction dissection was performed. Gastric resection was calibrated on a 39 Fr tube. Continuous oversuture was performed in stapling
75 line with non-absorbable suture. No staple line reinforcement and no gastric drainage were

performed. In case of hiatal hernia, concomitant repair was performed during SG. Sixteen percent (87/523) of the patients had simultaneous repair of hiatal hernia at the time of SG. Hiatal hernia was systematically repaired during first procedure. Hiatal hernia repair was performed by reduction of hernia and posterior suture of the diaphragmatic pillars. No mesh reinforcement has been used.

The decision to convert to RYGB was taken in case of clinical GERD symptom and/or pathological DMS after sleeve gastrectomy. When symptoms appeared after SG, systematic pH-monitoring was performed. The mean delay between first bariatric procedure and second esophageal monitoring was 2.5 +/- 1 years.

Clinical and biological measurements:

Preoperative data included demographic data (age, sex, height) and the type of planned surgery (SG, RYGB, LAGB). Preoperative and postoperative weight, BMI and percentage of excess weight loss (%EWL) were registered for each patient. EWL was expressed as percent excess BMI loss (%EBMIL) calculated as: $((\text{initial BMI} - \text{current BMI}) / (\text{initial BMI} - 25)) \times 100$. Ideal weight was calculated as weight for a BMI= 25 kg/m².

The diagnosis of T2D was established on the basis of the American Diabetes Association criteria.⁽⁸⁾ The diagnosis of chronic HBP required 2 consecutive outpatient systolic blood pressures > 140 mmHg or diastolic blood pressures > 90 mmHg, or the use of antihypertensive medication. The current recommended hypopnea definition was defined by the American Academy of Sleep Medicine. All patients in this study had a polysomnography.

24-h pH monitoring and DMS:

GERD was studied using ambulatory 24-h pH measurements 3 months before SG.⁹

No validated symptom questionnaire was used to define GERD. The clinical symptoms were: cough, pain, heartburn, regurgitation and proton pump inhibitors therapy consumption. The diagnosis was established only by the preoperative DeMeester score based on 24-hour esophageal pH monitoring and/or clinical symptoms. The results were expressed using 6 standard components. Using these parameters, the DMS, which is a global measurement of esophageal acid exposure has been calculated. A DMS > 14.72 indicated reflux. The components of 24-h esophageal pH monitoring were percentage of total time at pH < 4, percentage of upright time at pH < 4, percentage of supine time at pH < 4, number of reflux episodes, number of reflux episodes > 5 min, longest reflux episode (min).⁽¹⁰⁾ In case of conversion, this procedure has been repeated before RYGB.

In our study, GERD was defined by a DMS > 14.72 regardless of the presence of GERD clinical symptoms or/ and an association of clinical symptoms. We only used the Jamieon-DeMeester score which is normal under 14,72. During this period, 14% of the patients did not undergo evaluation because either the pre-operative assessment has been done in another institution or the results were not available. To evaluate the impact of DMS before SG on the conversion to RYGB, two sub-groups were created: no conversion group (NCG) and conversion because of GERD group (CGERD). DMS were calculated in both groups.

High Resolution Manometry (HRM)

HRM was performed with a 4.2 mm outer diameter solid-state assembly with 36 circumferential pressure sensors spaced at a 1 cm interval (approximately 3 intra-gastric sensors). Mano View software was used to perform high resolution manometry analysis.

Manometry was performed by 12 successive 5 ml water swallows. Hypotonic lower esophageal sphincter (LES) was defined by a mean residual pressure of the low esophageal sphincter < 4 mmHg. All patients had HRM within 3 months before surgery.

130 **Ethics:**

All patients were informed that their data would be used in the study and gave their consent. This study was validated by the local ethic center.

Statistical analysis:

135 Quantitative results are presented in mean and standard deviation. Welch test was used to compare variations between two groups. Sensitivity, specificity, predictive positive and negative values were calculated. For all tests, a two-sided $P < 0.05$ was considered statistically significant. All statistical analyses were performed with the use of R software®. The database was built using Microsoft Excel® (Microsoft, Redmond, Washington, United States).

140 **Results:**

Population characteristics:

Five hundred and twenty three patients were included in this retrospective study. Patients' characteristics are summarized in Table 1. The primary intervention was SG in 95%,
145 regardless of DMS score. In these patients, seven (5%) with a abnormal preoperative DMS
DMS had no clinical symptoms of GERD after intervention. Their %EWL was 30 +/- 13%
and their BMI was 37+/- 6 kg/m² at one year.

Fourteen percent of the patients (67/497) underwent a second bariatric procedure for GERD
(*n*= 36, 7.2%) or for insufficient weight loss after SG (*n*= 31, 6.5%). Among patients who
150 underwent a conversion to RYGB for GERD, 29 (80%) had no post-SG GERD clinical
symptoms. Sixty-four patients of the 67 patients (95%) have been converted to RYGB and 3
patients (insufficient weight loss) had an omega gastric bypass.

Impact of preoperative DeMeester Score on conversion:

155 There were no significant differences between the NCG and CGERD groups in terms of
preoperative BMI (*P*=0.11), esophagitis (*P*=0.52), hiatal hernia (*P*=0.9), T2D (*P*=0.6),
obstructive sleep apnea (OSA) (*P*=0.5), tobacco consumption (*P*=0.9), non alcoholic steato-
hepatitis (NASH) (*P*=0.8) and helicobacter pylori (HP) infection (*P*=0.54). . Details are in
table 2. All patients have benefited from a preoperative HRM. For patients who underwent a
160 RYGB because of GERD (*n*=36), 13 presented a lower esophageal sphincter hypotonia
before SG and 15 after the first procedure.

DMS before SG was not statistically different between patients in CGERD (16.1+/- 22)
and NCG (13.7 +/- 14) (*P*=0.37). However, mean DMS was lower than 14.72 in NCG and

165 higher in the CGERD. Diagnostic value of the 24-h pH monitoring to predict conversion because of GERD was calculated. Sensitivity, specificity, positive predictive value and negative predictive value were respectively 25, 66, 7 and 4%. There was no DMS cut-off which could improve diagnosis value.

Otherwise, DMS prior to sleeve was normal (11.4 +/- 13.58) in patients who did not undergo a conversion. Twenty-five percent (115/459) patients had a pre-SG DMS > 14.72 In these patients, 22 patients (15%) underwent a conversion to RYGB for GERD.

Patients who underwent conversion to RYGB undergo pH monitoring and DMS only before conversion 24h Ph monitoring and manometry monitoring were performed only if clinical symptom appeared after RYGB (no patient in our study).

Impact of SG on the DMS, esophagitis and hiatal hernia (in CGERD group) (table 3):

All patients in CGERD underwent a second 24-h pH monitoring and a second upper gastrointestinal endoscopy before the second procedure. The 24-h pH monitoring was performed in a mean delay of 2.5 +/- 1 year after the first bariatric procedure. The BMI at this time was 39 +/- 5,2 kg/m². Only one patient in the CGERD group had a BMI under 35kg/m². For patients in CGERD, DMS was significantly higher and esophagitis/hiatal hernia were significantly more frequent after SG than before: 16.1 +/- 22 vs 30.71 +/- 20 (P< 0.002); 22% vs 47%, (P=0.035) and 22% vs 45%, (P=0.039) respectively. For patients who underwent a conversion to RYGB because of GERD, esophagitis grade A and B were diagnosed in 11% (4/36) before SG versus 5% (2/36) after RYGB.

Post-SG Barrett esophagus was observed in 8.3% according to Prague classification. All patients were C0M0. Patients had no GERD symptoms after RYGB and no 24-h pH monitoring was performed.

Discussion:

195 The impact of SG on GERD is debated in the literature. Previous studies even reported a favorable impact of SG on GERD.⁽¹¹⁾ Braghetto et al. explained that by weight loss, reduced acid production related to resection of the acid-producing gastric fundus and accelerated gastric emptying.⁽¹²⁾ On the contrary, Sheppard et al. found that GERD symptoms were significantly increased after SG compared to a LRYGB.⁽¹³⁾ Yeung et al. observed a 19% increase rate of postoperative GERD after SG, a 23% increase rate of *de novo* reflux, a 28% increase rate of esophagitis, a 8% increase rate of BE with 4 % of all patients requiring conversion to RYGB for GERD.⁽¹⁴⁾

205 In this context, the aim of our study was, firstly, to examine the impact of preoperative pH monitoring using the DMS on the risk of conversion to RYGB for GERD. The second objectives were to evaluate the impacts of SG on GERD, esophagitis, BE and hiatal hernia prevalence.

Our results showed that the preoperative DMS was not a reliable predictive score for conversion of SG to RYGB, despite a trend for a higher preoperative DMS in converted patients. In our study, the CGERD group had a mean BMI > 35kg/m² before conversion. Only one patient had a BMI under 35kgs/m². The indication for conversion was clinical symptoms of GERD. The BMI before conversion for GERD was high: 39±5.2 kg/m². It could explain that the weight was responsible for the GERD ⁽¹²⁾

215 After RYGB, no patients had GERD symptoms. Therefore, no 24h-pH monitoring was performed after conversion.

According to Thereaux et al., SG was associated with *de novo* GERD but did not seem to exacerbate preexisting GERD: 70% of the patients (20/29) without preoperative GERD experienced *de novo* GERD as determined by 24-h pH monitoring ($P<0.001$) and in patients
220 with preoperative GERD, there was no difference for total time at $\text{pH}<4$ after SG.⁽¹⁵⁾ Melendez et al. reported that the use of preoperative 24-h pH monitoring lead to a better patient selection for either SG or RYGB. In their cohort, with preoperative 24-h pH monitoring, no patient underwent a surgical conversion or revision.⁽¹⁶⁾ However, the follow-up is only of 9.5 months and only 43 patients with severe heartburn underwent pH monitoring
225 which constitutes a bias. These authors estimated that the true DMS' threshold was 25 and not 14.72.

Usually, the presence of a hiatal hernia, erosive esophagitis, and GERD are relative contraindication for SG.⁽¹³⁾ Few patients in our center were selected for SG despite grade B
230 esophagitis because of super obesity or concomitant oral GERD treatment. Genco et al., reported that incidence of erosive esophagitis and BE in SG patients was considerably higher and was not related to preoperative GERD symptoms.⁽¹⁷⁾

In patients who, after a SG, presented with *de novo* GERD or GERD symptoms exacerbation, conversion to RYGB is a therapeutic option. Yeung et al., in a meta-analysis,
235 reported a 4% conversion rate of patients to RYGB because of severe GERD post-SG.⁽¹⁴⁾ In fact, conversion of SG to RYGB seemed to be more efficient for relieving GERD symptoms than for weight loss.⁽¹⁸⁾

Finally, in this study diagnosis of Barrett's without metaplasia was observed for patient in CG
in 8.3% but the delay of the second exam was 2.5 +/- 1 year. In a multicenter study,
Sebastianelli et al., reported an 18.8% prevalence of BE. Therefore they suggested to provide
systematic endoscopy 5 years after SG.⁽⁷⁾

Post-RYGB, 45% patients had histologic regression of BE to normal esophageal mucosa, with
no evidence of BE.⁽¹⁹⁾ RYGB is then recommended as an effective combined bariatric and
anti-reflux surgical procedure for patients with severe obesity and BE.⁽¹⁹⁾

This study had limitations especially by its retrospective nature. All patients did not have
24h_pH monitoring after SG. It was limited to patients having GERD symptoms or with
insufficient weight loss, which may underestimate the post SG GERD rate

Conclusion:

Even though preoperative DMS was higher in patients who underwent SG conversion to
RYGB because of GERD, preoperative DeMeester score alone was not a reliable predictive
score for conversion of SG to RYGB because of GERD.

Conflict of interest: none

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Table 1: Patients' characteristics

BMI: Body Mass Index, SD: Standard Deviation, T2D: Type 2 Diabetes, NASH: Non Alcoholic Steato-Hepatitis ; GERD: GastroEosophageal Reflux Disease ; LAGB: Laparoscopic Adjustable Gastric Banding; SG: Sleeve Gastrectomy; RYGB: Roux-en-Y Gastric Bypass; DMS: DeMeester Score; LES: lower esophageal sphincter

| | |
|---------------------------------|----------------|
| Patients, n | 523 |
| Age, yr mean +/- sd | 44.5 +/- 11.3 |
| Sexe, n female (%) | 420 (80%) |
| Initial BMI, kg/m2, mean +/- sd | 46.20 +/- 8.38 |
| Tobacco, n (%) | 90 (17%) |
| GERD + | 30 (33%) |
| HTA, n (%) | 160 (30%) |
| T2D, n (%) | 282 (54%) |
| OSA, n (%) | 183 (35%) |
| Dyslipidemia, n (%) | 88 (17%) |
| NASH, n (%) | 282 (54%) |
| GERD, n (%) | |
| Clinical symptoms | 57 (11) |
| DMS> 14.72 | 145 (28) |
| First procedure | |
| SG, n (%) | 497 (95) |
| RYGB, n (%) | 14 (3) |
| LAGB, n (%) | 8 (1,5) |
| LES hypotonia | 130 (24.8) |

Table 2 Patients' characteristics before sleeve gastrectomy (except 31 patients converted for insufficient weight loss only)

CGERD: converted group to RYGB for GERD (defined by clinical symptom and/or pathological DMS) after SG, NCG: non converted group, BMI: Body Mass Index, SD: Standard Deviation, T2D: Type 2 Diabetes, NASH: Non Alcoholic Steato-Hepatitis, OSA: Obstructive sleep apnea; GERD: GastroEsophageal Reflux Disease; HP : Helicobacter Pylori
 $P < 0.05$ was considered statistically significant

| | Conversion for GERD (CGERD) | No conversion (NCG) | <i>P</i>-value |
|---|--|--------------------------------|-----------------------|
| Patients, n | 36 | 430 | |
| Female, n (%) | 29 (80) | 346 (80) | 0.6 |
| BMI, mean+/- sd (kg/m²) | 47 +/- 9 | 45 +/- 8 | 0.11 |
| Esophagitis, n (%) | 8 (23) | 70 (16) | 0.52 |
| NASH, n (%) | 3 (8) | 20 (5) | 0.8 |
| Hiatal hernia, n (%) | 7 (20) | 80 (19) | 0.9 |
| TD2, n (%) | 15 (41) | 155 (36) | 0.6 |
| OSA, n (%) | 19 (51) | 194 (45) | 0.5 |
| Tobacco, n (%) | 8 (23) | 107 (25) | 0.9 |
| Hp infection, n (%) | 11 (31) | 103 (24) | 0.54 |
| LES hypotonia before SG, n (%) | 13 (36) | 117 (27.2) | 0.25 |
| LES hypotonia after SG | 15 (41) | No data | No data |

Table 3: Endoscopic and 24-h pH monitoring characteristics of patients before and after SG

BE: Barrett's Esophagus (Prague Classification); SG: Sleeve gastrectomy; DMS: DeMeester Score ; SD : Standard Deviation

$P < 0.05$ was considered statistically significant

| | Before SG | After SG (before conversion) | <i>P-value</i> |
|-----------------------------|------------------|-------------------------------------|-----------------------|
| DMS mean +/- sd | 16.09 +/- 22.35 | 30.71 +/- 20.27 | < 0.002 |
| Esophagitis, n (%) | 8 (22) | 17 (47) | 0.035 |
| BE (COMO) , n (%) | 0 | 3 (8.3) | 0.25 |
| Hiatal hernia, n (%) | 8 (22) | 16 (45) | 0.039 |