Long-term impact of gastropexy on use of acid-reducing medication, second operations for gastroesophageal reflux and subjective reflux symptoms after sleeve gastrectomy

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Abstract

Background/Objectives

Gastopexy (G) has been introduced as a surgical technique to reduce gastroesophageal reflux disease (GERD) in patients undergoing sleeve gastrectomy (SG). We aimed to determine whether adding G to SG improves use of acid reducing medication (ARM), second operations for GERD, epigastric pain or heartburn after surgery.

Subjects/Methods

Patients undergoing SG at two Norwegian hospitals were included consecutively from 2011 to 2015. Data was collected prospectively up to 7 years after surgery. GERD was defined by use of ARM on a regular basis and epigastric pain and heartburn by questions derived from the Rome II classification of functional gastrointestinal disorders. G was defined as suturing the gastrocolic ligament to the staple line. Patients undergoing SG only (NG group) were compared to those with additional G (G group) by mixed effect models.

Results

Of 376 included patients (75% females, mean age 42.6 years and BMI 42.9 kg/m\(^2\)), 350 (93%) and 232 (62%) were available for evaluation after one and 7 years, respectively. Baseline patient characteristics in the NG (n=235) and G groups (n=141) were similar. In patients without ARM use before surgery, the use increased equally in the NG and G groups up to 7 years after SG. In patients that used ARM at baseline, the proportion decreased equally in the NG and G groups. With a combined endpoint of ARM use and/or second operation for GERD, there was no difference during follow-up between the NG and G groups. With time, the proportion of patients with epigastric pain did not differ between the groups, whereas heartburn was significantly more prominent in the G group.

Conclusion

In this population of patients undergoing SG, adding G was not associated with reduced use of ARM and/or second operation for uncontrolled GERD, epigastric pain, or heartburn during the first 7 postoperative years.

Introduction

Obesity is one of the major risk factors for gastroesophageal reflux disease (GERD), a condition where reflux of gastric contents causes symptoms and/or complications, and GERD is common in patients seeking bariatric surgery (1, 2). GERD outcomes after sleeve gastrectomy (SG) are significantly worse than after Roux-en-Y gastric bypass (RYGB), and de novo GERD and Barrett’s esophagus have been reported after SG. Technical modifications introduced to ameliorate GERD symptoms after SG are currently being investigated (3–6).

SG, a preferred bariatric procedure globally, has the advantages of preserving the normal continuity of the gastrointestinal tract with no anastomoses, and fewer metabolic disruptions (6). However, in randomized controlled trials (RCTs), SG is associated with a higher rate of GERD symptoms and GERD-related complications in the years following surgery compared to RYGB (7–10). For instance, in the SM-BOSS trial, the rates of GERD worsening and de novo GERD were both 32% at 5 years after SG, compared to 6% and 11% after RYGB (7). In the SLEEVEPASS trial, with 10 years follow up available, the prevalence of esophagitis was 31% after SG compared
to 7% after RYGB (8). The combined analysis of these two landmark RCTs further showed that surgical reintervention for severe GERD symptoms was performed in 16 of 228 patients after SG compared to none of 229 after RYGB. This is concerning as acid reflux into the esophagus increases the risk of complications such as Barrett’s esophagus, stenosis, and/or esophageal cancer (11, 12). The presence of GERD may also impair patients’ quality of life (QOL) and social functioning (8, 13–15).

It has been proposed that the increased incidence of GERD and related complications after SG is caused by loss of gastric fixation, leading to improper positioning of the sleeved stomach with intrathoracic migration of the gastroesophageal junction and remaining ventricle (16). Furthermore, prevention of strictures, kinks or twists of the gastric remnant is important as these may increase intragastric pressure and cause reflux (17). These possible mechanisms have motivated gastropexy or omentopexy as means to stabilize the position of the gastric remnant by suturing the gastrocolic ligament, separated from the gastric wall during the SG procedure, back onto the staple line.

G was pioneered by Lucius D Hill as a surgical treatment for hiatal hernia, but the efficacy of several modified techniques of gastric fixation to abdominal structures in alleviating GERD after SG is still unclear (18, 19). An RCT from Egypt with 200 patients undergoing SG showed a lower incidence of reflux symptoms during the first three postoperative months after the addition of G, as measured by dose and duration of ARM usage (20). However, in another smaller double-blinded RCT from the United States, adding G did not significantly improve symptoms from GERD one year after surgery (21). A prospective study from one Norwegian hospital evaluating the effect of adding G to SG showed a clear reduction in use of anti-reflux medication (ARM) at two years compared to a historical cohort operated with SG alone (17).

To expand the knowledge of how G may affect GERD-related outcomes when added to SG we prospectively recorded changes in ARM use, second operations for severe reflux symptoms not adequately controlled by ARM, and symptoms of epigastric pain and heartburn up to 7 years after SG. We compared two cohorts before and after the introduction of G as a routine adjunct to the SG operation. Our objective was to determine whether adding G to the SG procedure was associated with a decline in these GERD-related outcomes in a long-term follow-up study.

Methods

This two-center observational study is part of the project “Bariatric Surgery on The West Coast of Norway”, approved by the Regional Committee for Medical and Health Research Ethics – Western Norway (2010/3287/REK, ClinicalTrials.gov: NCT01533142).

The study design has been described in detail previously (22). In brief, patients were included at the community hospitals in Voss and Haugesund that serve patients from non-overlapping geographical regions (22).

Eligible patients (BMI ≥ 40 kg/m² or ≥ 35 kg/m² with obesity-related comorbidities, age 18 to 70 years, no alcohol or drug abuse, and no active psychosis) scheduled for bariatric surgery were invited to participate (23). The present analysis includes patients undergoing SG at either hospital. We collected demographic, clinical and biochemical data using standardized checklists 2-3 months before surgery, and at routine outpatient visits 3 months, 1, 2, and 5 years postoperatively. Five-year data was supplemented with an electronically administered
survey on average 7 years after surgery. Hospital records were reviewed to ensure consistent recording of per-
operative G and/or performance of hiatal repair, use of ARM and reoperations performed for GERD symptoms
not sufficiently controlled by medication. Written informed consent was obtained from all patients prior to
inclusion.

Surgical procedures

All patients were part of a comparative study of SG and RYGB, allocated to the preferred procedure at their
respective hospital. In a limited number of cases an individual decision as to the surgical procedure was
allowed. Pre- and postoperative care were similar at both hospitals and included prescription of a low-calorie diet
(<1000 kcal per day) 3-4 weeks prior to surgery. SG was performed laparoscopically with a gastric resection
using a 32 French tube, starting 2-5 cm proximal to the pylorus and ending at the cardia, typically 0-1 cm from
the angle of His. Due to updates on the surgical procedure during the study period, staple line reinforcement was
performed in 99 patients. From 2013, G was gradually added to the SG procedure in a proportion of patients at
Voss hospital, steadily increasing with the experience of the surgical team. From January 2014, adding G to SG
became standard procedure at Voss, but not at Haugesund hospital. G was achieved by suturing the gastrocolic
ligament (including the gastroepiploic arcade) to the staple line using either separate sutures or a continuous
suture. The length of the suture varied depending on the surgeon’s choice, varying from the area around the
incisura angularis up to the cranial end of the staple line. Non-resorbable sutures were used. Hiatal repair (n=19;
3 and 16 in the NG and G groups, respectively) was performed when deemed medically indicated intra-
operatively, and consisted of circumferential dissection of the hiatus and distal esophagus with subsequent
approximation of the anterior and posterior crura using non-resorbable sutures. All operations were performed by
an experienced laparoscopist, allowing <10% of the procedures to be done by novice professionals under
supervision.

Outcome definitions

The primary endpoints for our analysis were use of ARM or undergoing a secondary operation for GERD
symptoms not adequately controlled by medication. ARM use as proton pump inhibitors with or without
additional medication was recorded for each timepoint, either from hospital charts at follow-up visits or the
electronic survey at 7 years. Patients who underwent a secondary operation for GERD symptoms were recorded
to have reached the endpoint for all following visits, irrespective of ARM use. Patients undergoing a second
bariatric procedure for inadequate weight loss or other complications not related to GERD were excluded at the
time of operation.

Before surgery, and at 1, 5 and 7 years we obtained patient reports of epigastric pain and heartburn by the
following two questions derived from the Rome II classification: In the last 3 months, did you often have pain in
the middle of your chest? and In the last 3 months, did you often have heartburn, a burning pain or discomfort in
your chest? (24). Responses were dichotomized into yes or no.

Weight was assessed according to international guidelines (25). Baseline weight (in light clothing without shoes
to the nearest 0.1 kilogram), height (in a standing position without shoes to the nearest 1 centimeter), and BMI
were recorded at the first preoperative visit and at all follow-up visits.
Early major postoperative complications within 30 days and late major complications were classified as Clavien-Dindo ≥ 3b (26). Length of hospital stay was counted from day of operation to discharge from hospital to home, excluding intermittent days outside of hospital care.

**Statistical analysis**

Categorical and continuous variables are presented as percentages and mean values with standard deviations (SD) or 95% confidence intervals (CI). Groups of patients at defined timepoints were compared using chi-square and two sample t-tests as appropriate.

Changes over time in continuous or categorical variables were examined with linear or logistic mixed effect models as appropriate. Models included patients’ sex, age and BMI at operation, smoking habits (yes/no), per-operative use of hiatal repair, preoperative use of ARM, with use of G (yes/no) and time from surgery as random factors. All models include interaction of time and use of G. Two-sided p-values are reported, and values below 0.05 considered significant without adjustments for multiple comparisons.

Data was analyzed with IBM SPSS (Statistics for Windows, Version 27.0. IBM Corp, Armonk, NY) and Stata SE (Stata Statistical Software: Release 15, StataCorp LLC, College Station, TX).

**Results**

Of 376 SG patients operated between September 2011 and February 2015 (75% females, mean age 42.6 years, mean baseline BMI 42.9 kg/m$^2$), 350 (93%) and 232 (62%) were evaluable after 1 and 7 years, respectively (Fig. 1). No G was performed before 2013. During 2013, G was added in 31 of 150 cases. During 2014–2015, G was added in 110 of 124 procedures, the remaining 14 patients all operated at Haugesund Hospital where G was not introduced.

Baseline patient characteristics in the NG (n = 235) and G (n = 141) groups were similar (Table 1). Mean duration of surgery was 80 ± 32 minutes in the NG group compared to 95 ± 39 minutes in the G group. The rate of major early complications was similar in both groups (Table 2). The proportion of patients with major late complications was 12.8% in the NG group and 7.1% in the G group (p = 0.08). Most major late complications were o second operations because of GERD, in 11.9% and 6.4% of the cases in the respective groups (p = 0.08).
Table 1

<table>
<thead>
<tr>
<th>Variables</th>
<th>All N = 376</th>
<th>No gastropexy n = 235</th>
<th>Gastropexy n = 141</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age ± SD&lt;sup&gt;1&lt;/sup&gt; (years)</td>
<td>42.6 ± 11.5</td>
<td>42.4 ± 11.6</td>
<td>42.9 ± 11.3</td>
<td>0.63</td>
</tr>
<tr>
<td>Women</td>
<td>282 (75%)</td>
<td>172 (73.2%)</td>
<td>110 (78.0%)</td>
<td>0.30</td>
</tr>
<tr>
<td>Mean BMI² ± SD (kg/m&lt;sup&gt;2&lt;/sup&gt;)</td>
<td>42.9 ± 4.9</td>
<td>43.0 ± 4.7</td>
<td>42.8 ± 5.3</td>
<td>0.68</td>
</tr>
<tr>
<td>BMI ≥ 50 kg/m²</td>
<td>38 (10.1%)</td>
<td>21 (8.9%)</td>
<td>17 (12.1%)</td>
<td>0.38</td>
</tr>
<tr>
<td>GERD³</td>
<td>50/375&lt;sup&gt;4&lt;/sup&gt; (13.3%)</td>
<td>29/234 (12.4%)</td>
<td>21/141 (14.9%)</td>
<td>0.49</td>
</tr>
<tr>
<td>Present smoking</td>
<td>91/362 (25.1%)</td>
<td>52/223 (23.3%)</td>
<td>39/139 (28.1%)</td>
<td>0.31</td>
</tr>
<tr>
<td>Epigastric pain</td>
<td>21/108 (19.4%)</td>
<td>20/94 (21.3%)</td>
<td>3/14 (21.4%)</td>
<td>0.99</td>
</tr>
<tr>
<td>Heartburn</td>
<td>60/106 (50.0%)</td>
<td>48/92 (52.2%)</td>
<td>5/14 (35.7%)</td>
<td>0.24</td>
</tr>
</tbody>
</table>

<sup>1</sup>Standard deviation; <sup>2</sup>Body mass index; <sup>3</sup>Gastroesophageal reflux disease; <sup>4</sup>number of patients with valid data

Table 2

<table>
<thead>
<tr>
<th>Operating time, hospital stay and complications</th>
<th>All N = 276</th>
<th>No gastropexy n = 235</th>
<th>Gastropexy n = 141</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean operating time ± SD&lt;sup&gt;1&lt;/sup&gt; (minutes)</td>
<td>87.4 ± 36.3</td>
<td>79.8 ± 32.3</td>
<td>95.1 ± 38.6</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Hospital stay ± SD&lt;sup&gt;1&lt;/sup&gt; (days)</td>
<td>3.1 ± 8.5</td>
<td>3.4 ± 9.9</td>
<td>2.7 ± 5.5</td>
<td>0.38</td>
</tr>
<tr>
<td>Major early complications</td>
<td>8 (2.1%)</td>
<td>6 (2.6%)</td>
<td>2 (1.4%)</td>
<td>0.46</td>
</tr>
<tr>
<td>Thereof leak</td>
<td>4 (1.1%)</td>
<td>3 (1.3%)</td>
<td>1 (0.7%)</td>
<td>0.60</td>
</tr>
<tr>
<td>Major late complications</td>
<td>40 (10.6%)</td>
<td>30 (12.8%)</td>
<td>10 (7.1%)</td>
<td>0.08</td>
</tr>
<tr>
<td>Thereof due to GERD</td>
<td>37 (9.8%)</td>
<td>28 (11.9%)</td>
<td>9 (6.4%)</td>
<td>0.08</td>
</tr>
</tbody>
</table>

<sup>1</sup>Standard deviation

There was a significant association between ARM use and symptoms of heartburn at all timepoints after surgery. At 1 and 7 years, 44.7% and 63% of those with heartburn used ARM, respectively, compared to 12.0% and 37.2% of those without (p < 0.001). No such difference was seen between reports of epigastric pain and ARM use (data not shown).

In patients not reporting ARM use prior to surgery, the use increased significantly and at similar rates in the NG and G groups; from 0 at baseline to 45.7% and 48.8% at 7 years after SG, respectively (Table 3). In patients who used ARM prior to surgery, the proportion decreased to 60.7% and 65% at 1 year in the NG and G groups and was found to be 66.7% and 81% at 7 years. In patients who did not use ARM before surgery, rates of ARM use were
generally lower at all timepoints after surgery compared to those with pre-operative use of ARM, but again there was no difference between the G and NG groups at any timepoint during follow-up (Table 3).

Table 3
Use of acid-reducing medication after surgery

<table>
<thead>
<tr>
<th>Use of ARM(^1) before surgery</th>
<th>p-values</th>
<th>No use of ARM before surgery</th>
<th>p-values</th>
</tr>
</thead>
<tbody>
<tr>
<td>No gastropexy</td>
<td></td>
<td>No gastropexy</td>
<td></td>
</tr>
<tr>
<td>n = 29</td>
<td></td>
<td>n = 205</td>
<td></td>
</tr>
<tr>
<td>ARM use at 1 year</td>
<td>17/28(^2) (60.7%)</td>
<td>13/20 (65.0%)</td>
<td>0.76</td>
</tr>
<tr>
<td>ARM use at 2 years</td>
<td>17/28 (60.7%)</td>
<td>15/20 (75.0%)</td>
<td>0.30</td>
</tr>
<tr>
<td>ARM use at 5 years</td>
<td>14/24 (58.3%)</td>
<td>15/20 (75.0%)</td>
<td>0.25</td>
</tr>
<tr>
<td>ARM use at 7 years</td>
<td>16/24 (66.7%)</td>
<td>17/21 (81.0%)</td>
<td>0.28</td>
</tr>
</tbody>
</table>

\(^1\)Anti-reflux medication; \(^2\)Number of patients with valid data

In mixed effect analysis, there was no difference in the combined endpoint, the proportion of patients with ARM use and/or second operation for GERD symptoms not adequately controlled by medication over the study period (Table 4, Fig. 2).
Table 4

Use of acid-reducing medication and/or reoperation for GERD, presence of epigastric pain or heartburn and BMI over time

<table>
<thead>
<tr>
<th>Groups</th>
<th>Baseline</th>
<th>1 year</th>
<th>2 years</th>
<th>5 years</th>
<th>7 years</th>
<th>Mixed model with interaction</th>
</tr>
</thead>
<tbody>
<tr>
<td>ARM¹ and/or reoperation for GERD²</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No gastropexy</td>
<td>14.6% (10.3–18.8)/234⁴</td>
<td>31.4% (26.0–36.7)/211</td>
<td>36.4% (30.7–42.0)/211</td>
<td>39.5% (33.5–45.6)/196</td>
<td>46.0% (39.5–52.4)/201</td>
<td>&lt; 0.001⁵</td>
</tr>
<tr>
<td>Gastropexy</td>
<td>14.0% (8.9–19.2)/141</td>
<td>31.5% (24.7–38.4)/136</td>
<td>33.3% (26.3–40.3)/136</td>
<td>43.8% (35.9–51.8)/128</td>
<td>48.3% (40.1–56.5)/131</td>
<td>0.88⁶</td>
</tr>
<tr>
<td>Odds ratio (95% CI³)</td>
<td>0.9 (0.3–2.7)</td>
<td>1.1 (0.4–3.4)</td>
<td>0.8 (0.3–2.5)</td>
<td>1.6 (0.5–5.1)</td>
<td>1.3 (0.4–4.2)</td>
<td>0.70⁷</td>
</tr>
</tbody>
</table>

Epigastric pain

| No gastropexy | 22.1% (13.6–30.7)/94 | 18.9% (10.8–27.0)/85 | 18.6% (6.6–30.6)/39 | 35.9% (27.8–43.9)/141 | 0.01 |
| Gastropexy | 23.0% (23.2–43.8)/14 | 22.1% (14.0–30.3)/94 | 31.9% (18.9–44.9)/45 | 40.4% (30.8–50.8)/101 | 0.93 |
| Odds ratio (95% CI) | 1.1 (0.2–7.1) | 1.2 (0.2–9.6) | 2.7 (0.3–26.0) | 1.2 (0.2–8.9) | 0.76 |

Heartburn

| No gastropexy | 62.2% (52.4–71.9)/92 | 50.4% (40.0–60.7)/86 | 56.0% (40.3–71.7)/39 | 69.0% (61.4–76.6)/139 | 0.03 |
| Gastropexy | 38.9% (14.7–63.2)/14 | 49.1% (39.2–59.1)/94 | 85.3% (74.7–95.8)/44 | 69.2% (60.1–78.2)/102 | 0.10 |
| Odds ratio (95% CI) | 0.3 (0.1–1.3) | 3.5 (0.6–19.4) | 28.7 (3.7–223.9) | 3.8 (0.7–20.6) | 0.01 |

BMI (kg/m²)

| No gastropexy | 42.9 (42.4–43.3)/235 | 29.3 (28.8–29.3)/219 | 30.1 (29.6–30.7)/132 | 32.1 (31.6–32.7)/160 | 33.0 (32.5–33.6)/135 | < 0.001 |
| Gastropexy | 42.8 (42.2–43.4)/141 | 28.8 (28.2–29.3)/131 | 29.8 (29.2–30.5)/89 | 31.4 (30.7–32.0)/97 | 32.0 (31.3–32.6)/97 | 0.85 |

¹Anti-reflux medication; ²Gastroesophageal reflux disease; ³Confidence interval; ⁴Number of patients with valid data in the model; ⁵p-value for effect of time; ⁶p-value for gastropexy; ⁷p-value for interaction for time and gastropexy
Similarly, the number of patients reporting epigastric pain increased significantly from baseline to 7 years after SG, with no difference between the NG and G groups. Over time, BMI was similar for patients who did not undergo G as compared to those who did (Table 4, Fig. 2).

Patients reporting heartburn were differently distributed between the NG and G groups at several timepoints. At baseline, more patients reported heartburn in the NG group than in the G group, but the difference was not statistically significant. With time, more patients suffered from heartburn after G, and in the mixed effect model, the interaction between time and surgical technique reached significance (p = 0.01; Table 4, Fig. 2)

**Discussion**

In the present non-randomized comparison of two cohorts, both part of the same prospective study investigating effects of bariatric surgery, we found no effect of adding G to SG in terms of preventing ARM use, second operations for GERD symptoms not adequately controlled by mediation, or self-reported symptoms of epigastric pain or heartburn during 7 years of follow-up.

Our study was motivated by the limited data to support routine use of G as an adjunct to SG in patients undergoing surgery for severe obesity. Two smaller randomized trials were previously published, both with one year follow-up, but with conflicting conclusions (20, 21). In a non-blinded study of 200 patients from Egypt, addressing nausea, vomiting and reflux symptoms during 3 months after surgery, a significantly lower proportion of patients after G reported reflux symptoms in the post-operative phase (6% versus 18%), but neither the time of assessment nor the method for capturing patients’ symptoms were stated. In a retrospectively added analysis, patients were interviewed about their ARM use in the post-operative phase, and 8% of patients after G reported to use proton pump inhibitors beyond three months as compared to 23% of those operated with SG only (20). In a smaller randomized study with 60 patients from the United States, both the patient and the interviewer remained unaware of the surgical procedure up until 1 year of follow-up. The authors reported no statistically significant differences in GERD impact scale during follow-up (21). On the other hand, a recent Norwegian prospective non-randomized cohort study with a similar design to ours, found a clear reduction in the postoperative occurrence of GERD, defined by ARM use, after addition of G (17). With comparable baseline patient characteristics, sample size and outcome measures, it is notable that our study did not support this association.

There are obvious differences between the studies listed above and ours, both in terms of assessment of GERD (outcomes defined by patient symptoms or ARM use, use of standardized patient reported outcome measures or not) and timepoint of assessment. With two of the studies showing an effect of G, the study by Afaneh et al

<table>
<thead>
<tr>
<th>Groups</th>
<th>Baseline</th>
<th>1 year</th>
<th>2 years</th>
<th>5 years</th>
<th>7 years</th>
<th>Mixed model with interaction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Difference (95% CI)</td>
<td>-0.1 (-0.8-0.7)</td>
<td>-0.4 (-1.3-0.4)</td>
<td>-0.2 (-1.2-0.8)</td>
<td>-0.7 (-1.6-0.3)</td>
<td>-1.0 (-1.9-0.0)</td>
<td>0.32</td>
</tr>
</tbody>
</table>

1 Anti-reflux medication; 2 Gastroesophageal reflux disease; 3 Confidence interval; 4 Number of patients with valid data in the model; 5 p-value for effect of time; 6 p-value for gastropexy; 7 p-value for interaction for time and gastropexy
reports a low symptom burden in both arms, and was powered to detect a 50% difference in food intolerance symptoms, i.e. it was not focusing primarily on GERD. Therefore, even meaningful differences in GERD symptoms at 1 year may have been missed by this smaller study (21). Another explanation for differences in outcome may also involve surgical technique, i.e., alternative ways the gastrocolic ligament is fixed to the gastric remnant. All three reports cited here state that the G procedure involved suturing the omentum back to the staple line or greater curvature, with the length of the fixations being clearly defined. In our cohort, the proximal extension of the fixation appears to have varied depending on individual choices of the surgeon intraoperatively. If fixation of the gastric remnant to prevent torsion, kinks or intrathoracic displacement is a mechanistic determinant of success, one may assume that the length of fixation plays a role for outcome.

With 38% of patients developing de novo GERD and only 5% of those with pre-existing GERD entering remission at 7 years, patients in our prospective study have a high symptom burden of GERD and high rate of ARM use, even despite adding G (22). In a recent systematic review, it was estimated that up to 30% of patients may experience some GERD symptoms after SG, but most do not require operative therapy and can be treated successfully with medication (8). Unfortunately, we did not perform pre- and postoperative gastroscopy as a routine, and postoperative gastroscopy was only performed in a small minority of patients with severe symptoms of reflux, vomiting, or if a leak was suspected. The presence of symptoms cannot be considered a reliable indicator of higher-grade acid reflux or endoscopic mucosal changes as many of these may be asymptomatic (27). However, in the 10 year follow-up of the SLEEVEPASS study, where 73% of all patients volunteered to a second gastroscopy as part of their 10-year evaluation, the rate of objective esophagitis correlated with the worsening of reported symptoms, rate of ARM use and reduced GERD health-related QOL (8). Other late complications of GERD, such as stenosis and Barrett's esophagus, were rare both after SG and RYGB and no differences were detected. However, such a correlative analysis of patients after SG supports the notion that G may not reduce rates of more objective GERD findings in our cohort of patients.

Taken together with the available evidence, our data do not support routine use of G to prevent or ameliorate GERD after SG. The conflicting results as to the efficacy of G warrant a randomized controlled trial which ideally should include pre- and postoperative endoscopy, use of validated patient reported outcome measures and need for ARM, and with a clear and uniform surgical technique.

Conclusion

In this prospective non-randomized cohort study, addition of G to SG did not significantly reduce the use of ARM, risk of any secondary operation for GERD symptoms not adequately controlled by medication, symptoms of heartburn or epigastric pain at any point during a 7-year trajectory after surgery. Definition of the optimal surgical technique and evaluation in an RCT are warranted.

Declarations

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Author contributions

Designing and reviewing the research protocol (BGN, GM). Collecting and registering the data (TNF). Extracting and analysing the data (TNF, AF, MR). Conducting the literature search, screening potential eligible studies and drafting the manuscript (TNF, AF). Interpreting the results (TNF, AF, BGN, GM, JF, SND, MR, JIPN, JERW). Writing the manuscript (TNF, AF). Revising the manuscript (TNF, AF, BGN, GM, JF, SND, MR, JIPN, JERW). Final revision (TNF, AF). All authors approved the final version and agreed to be accountable for the accuracy and integrity of the work.

Competing interests

The authors declare no competing interests

References


Figure 1

Legend not included with this version.
Figure 2

Legend not included with this version.