






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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Summary

We investigated whether adding gastropexy to sleeve gastrectomy (SG) reduced gastroesophageal reflux disease (GERD) in patients operated for severe obesity, assessed mainly by use of anti-reflux medication (ARM) and second operations due to GERD worsening. In a prospective non-randomized study, patients undergoing SG at two Norwegian hospitals were included from 2011 to 2015 and followed for 7 years. GERD was defined by regular use of ARM, and epigastric pain and heartburn were measured by the Rome II questionnaire. Gastropexy was done by suturing the gastrocolic ligament to the staple line. Patients undergoing SG only, mainly before gastropexia was introduced in 2013, were compared to those with additional gastropexy from 2013 onwards. Of 376 included patients (75% females, mean age 42.6 years and BMI 42.9 kg/m²), 350 (93%) and 232 (62%) were available for evaluation after 1 and 7 years, respectively. Baseline characteristics in the no-gastropexy ($n = 235$) and gastropexy groups ($n = 141$) were similar. In patients without ARM use before surgery, the use increased and in those that used ARM at baseline, the proportion decreased, with no difference in the no-gastropexy and gastropexy groups. With a combined endpoint of ARM use and/or second operation for GERD, there was no difference during follow-up between the two groups. With time, adding gastropexy did not reduce symptoms of GERD significantly. In this population, adding gastropexy to SG did not reduce use of ARM and/or second operation for uncontrolled GERD, epigastric pain or heartburn during the first 7 postoperative years.

KEYWORDS

gastroesophageal reflux disease, gastropexy, Sleeve gastrectomy

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Key points

What is already known about this subject?

- De novo, or worsening of GERD are common complications after sleeve gastrectomy for severe obesity.
- Gastropexy has been proposed as a surgical procedure to prevent GERD after sleeve gastrectomy.

What this study adds?

- Adding gastropexy to sleeve gastrectomy was associated with longer operation time, but not with an increased rate of short-term complications.
- Adding gastropexy to the sleeve gastrectomy did not reduce GERD after surgery when assessed by use of anti-reflux medication, second operations for severe GERD, epigastric pain or heartburn.

1 | 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 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, e.g., by disrupting the phrenoesophageal ligament, 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. Other changes introduced by surgery, such as possible damage to the sling fibres during SG, may not be alleviated by such fixation.¹⁸

Gastropexy 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.^{19,20} 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 gastropexy, as measured by dose and duration of ARM usage.²¹ However, in another smaller double-blinded RCT from the United States, adding gastropexy did not significantly improve symptoms from GERD 1 year after surgery.²² A prospective study from one Norwegian hospital evaluating the effect of adding gastropexy to SG showed a clear reduction in use of anti-reflux medication (ARM) at 2 years compared to a historical cohort operated with SG alone.¹⁷

To expand the knowledge of how gastropexy 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 gastropexy as a routine adjunct to the SG operation. Our objective was to determine whether adding gastropexy to the SG procedure was associated with a decline in these GERD-related outcomes in a long-term follow-up study.

2 | 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](https://clinicaltrials.gov/ct2/show/study/NCT01533142)).

The study design has been described in detail previously.²³ In brief, patients were included at the community hospitals in Voss and Haugesund that serve patients from non-overlapping geographical regions.²³

Eligible patients (BMI ≥ 40 kg/m² or ≥ 35 kg/m² with obesity-related comorbidities, age 18–70 years, no alcohol or drug abuse and no active psychosis) scheduled for bariatric surgery were invited to participate.²⁴ 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, all detailed in the protocol. Five-year data were supplemented with an electronically administered survey on average 7 years after surgery, specifically also capturing symptoms related to GERD and ARM use. Hospital records were reviewed to ensure consistent recording of per-operative gastropexy and/or performance of hiatal repair, use of ARM and reoperations performed for GERD symptoms not sufficiently controlled by medication. Routine evaluation for GERD by endoscopy, esophageal manometry or pH monitoring was not done, but could be part of the evaluation of selected patients during follow up, e.g., before reoperation. Written informed consent was obtained from all patients prior to inclusion.

2.1 | 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, gastropexy was gradually added to the SG procedure at Voss hospital, steadily increasing in use with the experience of the surgical team. From January 2014, adding gastropexy to SG became standard procedure at Voss, but not at Haugesund hospital. Gastropexy 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 (illustrated by one example in Figure 1). Non-resorbable sutures were used. Hiatal repair ($n = 19$; 3 and 16 in the no-gastropexy and gastropexy groups, respectively) was performed when deemed medically indicated intraoperatively, 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

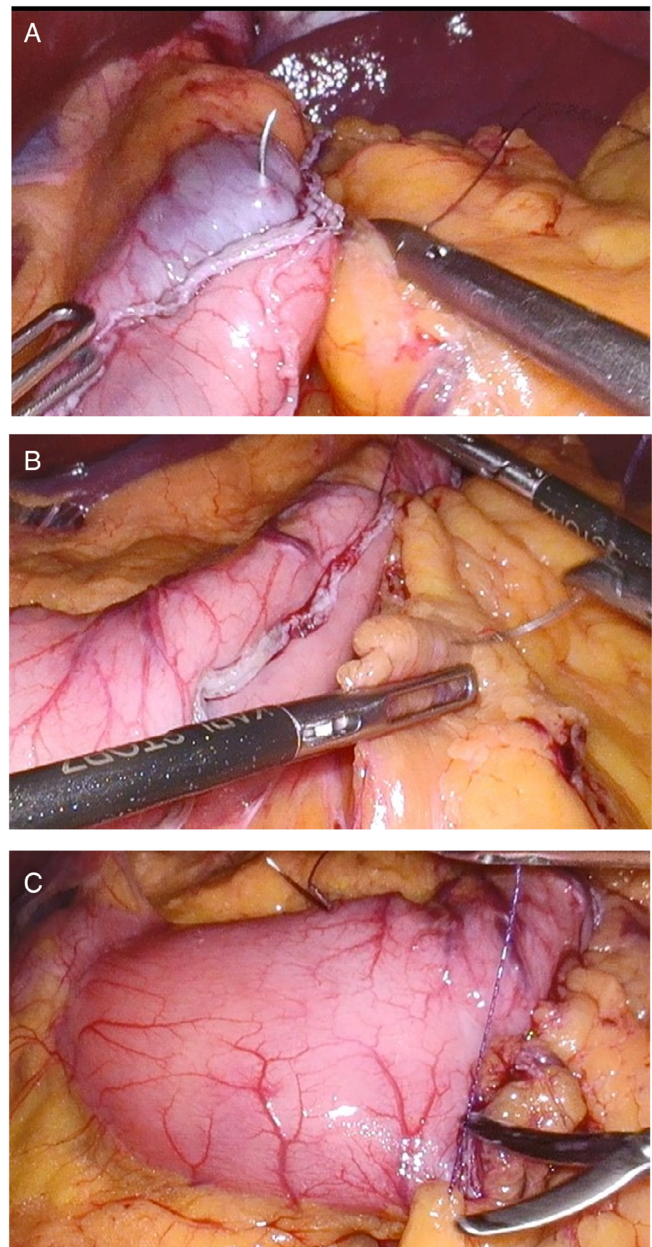


FIGURE 1 Stepwise illustration of the gastropexy surgical procedure. The gastrocolic ligament is sutured to the sleeve at the oral end of the stapler line (A), continuous suture-line with V-Loc™ to ensure inclusion of sufficient tissue of both the gastrocolic ligament and stapler-line of the sleeve (B). In this case, the suture includes the full length of the stapler-line (C).

performed by an experienced laparoscopist, allowing <10% of the procedures to be done by novice professionals under supervision.

2.2 | 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. As prespecified in the protocol, ARM use as

proton pump inhibitors with or without additional medication was recorded for each timepoint. Patients who underwent a secondary operation for GERD symptoms with or without other simultaneous indications for reoperation, such as inadequate weight loss, 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 questionnaire for functional esophageal disorders: *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?*^{25,26} Response categories were yes or no.

Weight was assessed according to international guidelines.²⁷ Baseline weight (in light clothing without shoes to the nearest 0.1 kg), height (in a standing position without shoes to the nearest 1 cm) 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 ≥ 3 b.²⁸ Length of hospital stay was counted from day of operation to discharge from hospital to home, excluding intermittent days outside of hospital care.

2.3 | 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 gastropexy (yes/no) and time from surgery as random factors. All models include interaction of time and use of gastropexy. Two-sided *p*-values are reported, and values below .05 considered significant without adjustments for multiple comparisons. Since the analysis of any benefit of gastropexy added to SG was not *a priori* defined in the protocol, no *post hoc* power calculations were done.

Data were analysed 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).

3 | 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/m²), 350 (93%) and 232 (62%) were evaluable after 1 and 7 years, respectively (Figure 2). No-gastropexy was performed before

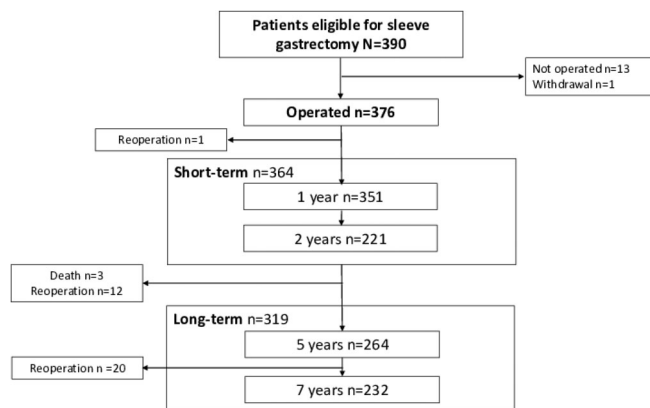


FIGURE 2 Flow-chart of included patients. Merged short- and long-term time points include patients with data available from 1 and/or 2 years or 5 and/or 7 years follow-up. n, number of patients with data registration at respective timepoint.

TABLE 1 Patient baseline characteristics according to type of surgery.

Variables	All, N = 376	No gastropexy, n = 235	Gastropexy, n = 141	<i>p</i> -value
Mean age \pm SD ^a (years)	42.6 \pm 11.5	42.4 \pm 11.6	42.9 \pm 11.3	.63
Women	282 (75%)	172 (73.2%)	110 (78.0%)	.30
Mean BMI ^b \pm SD (kg/m ²)	42.9 \pm 4.9	43.0 \pm 4.7	42.8 \pm 5.3	.68
BMI \geq 50 kg/m ²	38 (10.1%)	21 (8.9%)	17 (12.1%)	.38
GERD ^c	50/375 ^d (13.3%)	29/234 (12.4%)	21/141 (14.9%)	.49
Present smoking	91/362 (25.1%)	52/223 (23.3%)	39/139 (28.1%)	.31
Epigastric pain	21/108 (19.4%)	20/94 (21.3%)	3/14 (21.4%)	.99
Heartburn	60/106 (50.0%)	48/92 (52.2%)	5/14 (35.7%)	.24

^aStandard deviation.

^bBody mass index.

^cGastroesophageal reflux disease.

^dNumber of patients with valid data.

2013. During 2013, gastropexy was added in 31 of 150 cases. During 2014–2015, gastropexy was added in 110 of 124 procedures, the remaining 14 patients all operated at Haugesund Hospital where gastropexy was not introduced.

Baseline patient characteristics in the no-gastropexy ($n = 235$) and gastropexy ($n = 141$) groups were similar (Table 1). For an

attrition analysis, we compared patients available for follow-up at 7 years to those who were not. No significant differences at baseline in any of the groups were seen, except more patients reporting heartburn at baseline in the no-gastropexy group were lost to follow-up (Table 2, $p = .03$). Mean duration of surgery was 80 ± 32 min in the no-gastropexy group compared to 95 ± 39 min in the gastropexy

TABLE 2 Patient baseline characteristics according to type of surgery and attendance at 7 years follow-up.

Variables	No gastropexy, $n = 235$		p -value	Gastropexy, $n = 141$		p -value
	Attending 7 years $n = 135$	Not attending 7 years $n = 100$		Attending 7 years $n = 97$	Not attending 7 years $n = 44$	
Mean age \pm SD ^a (years)	42.5 \pm 12.1	42.1 \pm 10.9	.79	43.4 \pm 11.5	41.9 \pm 10.8	.47
Women	104 (75.0%)	68 (68.0%)	.12	79 (78.4%)	34 (77.3%)	.89
Mean BMI ^b \pm SD (kg/m ²)	43.0 \pm 4.4	42.9 \pm 5.0	.91	42.3 \pm 4.9	43.8 \pm 6.2	.13
BMI \geq 50 kg/m ²	11 (8.1%)	10 (10.0%)	.62	9 (9.3%)	8/44 (18.2%)	.13
GERD ^c	12/135 ^d (8.9%)	17/99 (17.2%)	.06	14/97 (14.4%)	7/44 (15.9%)	.82
Present smoking	32/131 (24.4%)	20/92 (21.7%)	.64	23/96 (24.0%)	16/43 (37.2%)	.11
Epigastric pain	11/52 (21.2%)	9/42 (21.4%)	.97	2/10 (20.0%)	1/4 (25.0%)	.84
Heartburn	21/52 (42.0%)	27/42 (64.3%)	.03	4/10 (40.0%)	1/4 (25%)	.60

^aStandard deviation.

^bBody mass index.

^cGastroesophageal reflux disease.

^dNumber of patients with valid data.

TABLE 3 Operating time, hospital stay and complications.

	All $N = 276$	No gastropexy $n = 235$	Gastropexy $n = 141$	p -value
Mean operating time \pm SD ^a (min)	87.4 \pm 36.3	79.8 \pm 32.3	95.1 \pm 38.6	<.001
Hospital stay \pm SD ^a (days)	3.1 \pm 8.5	3.4 \pm 9.9	2.7 \pm 5.5	.38
Major early complications	8 (2.1%)	6 (2.6%)	2 (1.4%)	.46
Thereof leak	4 (1.1%)	3 (1.3%)	1 (0.7%)	.60
Major late complications	40 (10.6%)	30 (12.8%)	10 (7.1%)	.08
Thereof due to GERD ^b with or without inadequate weight loss	37 (9.8%)	28 (11.9%)	9 (6.4%)	.08
Thereof due to GERD ^b alone	18 (4.8%)	13 (5.5%)	5 (3.5%)	.38

^aStandard deviation.

^bGastroesophageal reflux disease.

TABLE 4 Use of acid-reducing medication after surgery.

	Use of ARM ^a before surgery		p -values	No use of ARM before surgery		p -values
	No gastropexy $n = 29$	Gastropexy $n = 21$		No gastropexy $n = 205$	Gastropexy $n = 119$	
ARM use at 1 year	17/28 (60.7%) ^b	13/20 (65.0%)	.76	50/183 (27.3%)	33/116 (28.4%)	.83
ARM use at 2 years	17/28 (60.7%)	15/20 (75.0%)	.30	62/183 (33.9%)	34/116 (29.3%)	.41
ARM use at 5 years	14/24 (58.3%)	15/20 (75.0%)	.25	57/166 (34.3%)	43/108 (39.8%)	.36
ARM use at 7 years	16/24 (66.7%)	17/21 (81.0%)	.28	69/171 (40.4%)	49/110 (44.5%)	.49

^aAnti-reflux medication.

^bNumber of patients with valid data.

TABLE 5 Use of acid-reducing medication and/or reoperation for GERD, presence of epigastric pain or heartburn and BMI over time.

ARM ^a and/or reoperation for GERD ^b	Groups	Baseline	1 year	2 years	5 years	7 years	Mixed model with interaction
Epigastric pain	No gastropepy	14.6% (10.3–18.8)/234 ^c	31.4% (26.0–36.7)/211	36.4% (30.7–42.0)/211	39.5% (33.5–45.6)/196	46.0% (39.5–52.4)/201	P-value <.001 ^d
	Gastropepy	14.0% (8.9–19.2)/141	31.5% (24.7–38.4)/136	33.3% (26.3–40.3)/136	43.8% (35.9–51.8)/128	48.3% (40.1–56.5)/131	.88 ^e
	Odds ratio (95% CI) ^f	0.9 (0.3–2.7)	1.1 (0.4–3.4)	0.8 (0.3–2.5)	1.6 (0.5–5.1)	1.3 (0.4–4.2)	.70 ^g
Heartburn	No gastropepy	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	.01
	Gastropepy	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	.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)	.76
BMI (kg/m ²)	No gastropepy	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	.03
	Gastropepy	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	.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)	.01
Anti-reflux medication	No gastropepy	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	<.001
	Gastropepy	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	.85
	Difference (95% CI)	–0.1 (–0.8 to 0.7)	–0.4 (–1.3 to 0.4)	–0.2 (–1.2 to 0.8)	–0.7 (–1.6 to 0.3)	–1.0 (–1.9 to 0.0)	.32

^aAnti-reflux medication.^bGastroesophageal reflux disease.^cNumber of patients with valid data in the model.^dP-value for effect of time.^eP-value for gastropepy.^fConfidence interval.^gP-value for interaction for time and gastropepy.

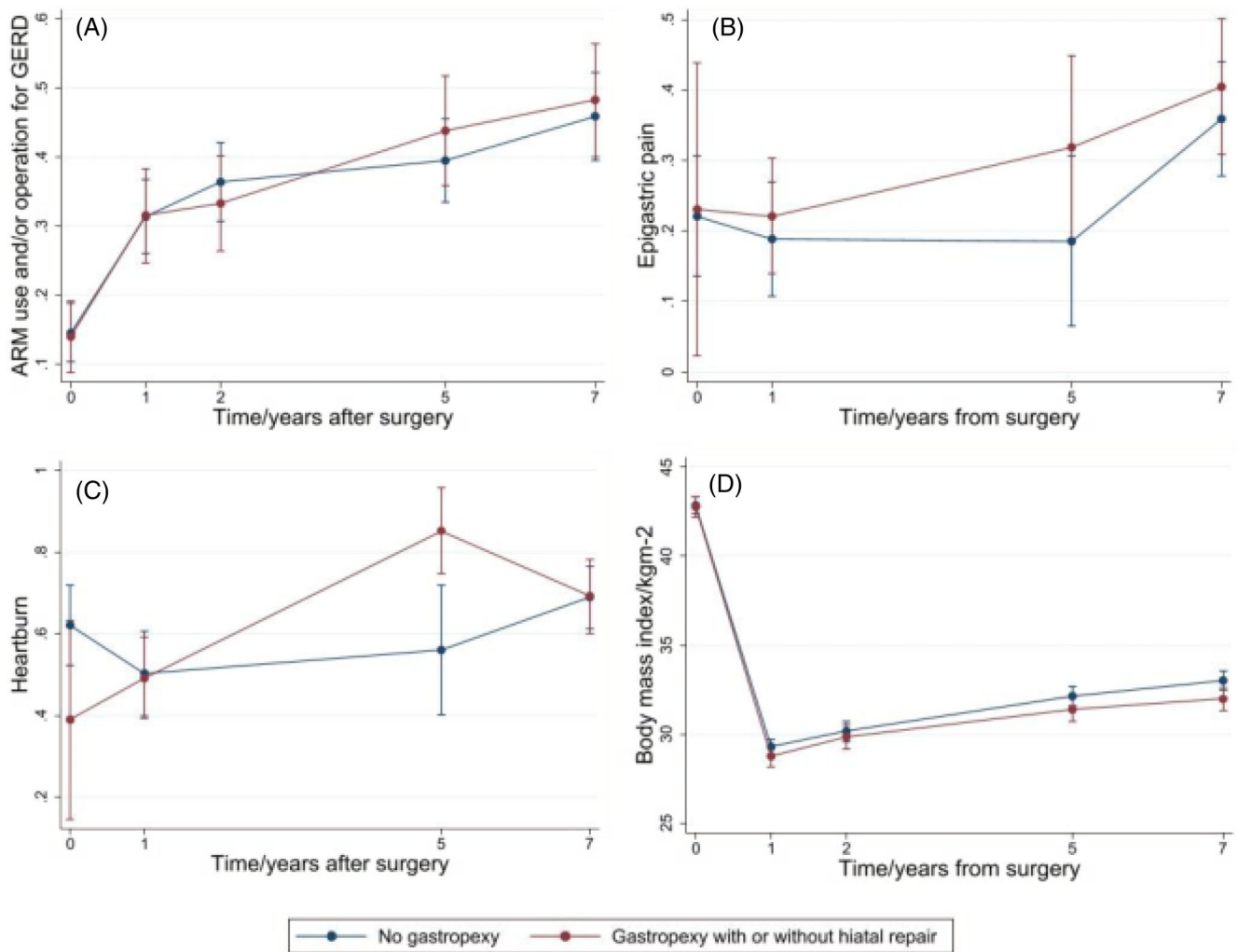


FIGURE 3 Changes from surgery to 7 years after sleeve gastrectomy in predicted probability for use of anti-reflux medication (ARM) and/or surgery for inadequately controlled gastro-esophageal reflux disease (GERD) (A), epigastric pain (B) or heartburn (C) and body mass index (D).

group. The rate of major early complications was similar in both groups (Table 3). The proportion of patients with major late complications was 12.8% in the no-gastropexy group and 7.1% in the gastropexy group ($p = .08$). Most major late complications were second operations because of GERD with or without inadequate weight loss, done in 11.9% and 6.4% of the cases in the respective groups ($p = .08$). Reoperations solely due to GERD symptoms not controlled by ARM were done in 5.5% and 3.5% of the patients in the no-gastropexy and gastropexy groups, respectively ($p = .38$).

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 ($p < .001$). 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 no-gastropexy and gastropexy groups; from 0 at baseline to 40.4% and 44.5% at 7 years after SG, respectively (Table 4). In patients who used ARM prior to surgery, the proportion decreased to 60.7% and 65% at 1 year in the

no-gastropexy and gastropexy 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 no-gastropexy and gastropexy groups at any timepoint during follow-up (Table 4).

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 5, Figure 3).

Similarly, the number of patients reporting epigastric pain increased significantly from baseline to 7 years after SG, with no difference between the no-gastropexy and gastropexy groups. Over time, BMI was similar for patients who did not undergo gastropexy as compared to those who did (Table 5, Figure 3).

Patients reporting heartburn were differently distributed between the no-gastropexy and gastropexy groups at several timepoints. At baseline, more patients reported heartburn in the no-gastropexy group than in the gastropexy group, but the difference was not statistically

significant. With time, more patients suffered from heartburn after gastropexy, and in the mixed effect model, the interaction between time and surgical technique reached significance ($p = .01$; Table 5, Figure 3).

4 | 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 gastropexy to SG in terms of preventing ARM use, second operations for GERD symptoms not adequately controlled by medication, 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 gastropexy as an adjunct to SG in patients undergoing surgery for severe obesity. Two smaller randomized trials were previously published, both with 1-year follow-up, but with conflicting conclusions.^{21,22} 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 gastropexy reported reflux symptoms in the post-operative phase (6% vs. 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 gastropexy reported to use proton pump inhibitors beyond 3 months as compared to 23% of those operated with SG only.²¹ 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.²² 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 gastropexy.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 gastropexy, the study by Afaneh et al. 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.²² Another explanation for differences in outcome may involve surgical technique, i.e., alternative ways of which the gastrocolic ligament is fixed to the gastric remnant. All three reports cited here state that the gastropexy 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 gastropexy.²³ 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.^{29,30} Furthermore, mucosal damage due to acid reflux may be asymptomatic.³⁰ Nevertheless, common reporting criteria for outcomes after bariatric surgery acknowledge use of medication and changes thereof as indicators also for GERD, and ARM use was the main outcome in one of the studies that has shown benefit of adding gastropexy to SG.^{17,27} Furthermore, 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 quality of life.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 gastropexy may not reduce rates of more objective GERD findings in our cohort of patients.

The main limitation of our study is the non-randomized design comparing patients operated on before and after the introduction of gastropexy as an adjunct to SG and the lack of objective measures of GERD. However, the large number of patients compared to other studies, the use of gastropexy as part of routine bariatric surgery, the long-term follow-up with fair retention rates add valuable information to the field.

Taken together with the available evidence, our data do not support routine use of gastropexy to prevent or ameliorate GERD after SG. The conflicting results as to the efficacy of gastropexy warrant a RCT, 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.

5 | CONCLUSION

In this prospective non-randomized cohort study, addition of gastropexy 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.

AUTHOR CONTRIBUTIONS

Designing and reviewing the research protocol: Bjørn Gunnar Nedrebø and Gunnar Mellgren. *Collecting and registering the data:* Tone Nygaard Flølo. *Extracting and analysing the data:* Tone Nygaard Flølo, Alexander Fosså and Magne Rekdal. *Conducting the literature search, screening potential eligible studies and drafting the manuscript:* Tone Nygaard Flølo and Alexander Fosså. *Interpreting the results:* Tone Nygaard Flølo, Alexander Fosså, Bjørn Gunnar Nedrebø, Gunnar Mellgren, Johan Fernø, Simon Nitter Dankel, Magne Rekdal, Jonas Ingolf Petersson Nedkvitne and Jo Erling Riise Waage. *Writing the manuscript:* Tone Nygaard Flølo and Alexander Fosså. *Revising the manuscript:* Tone Nygaard Flølo, Alexander Fosså, Bjørn Gunnar Nedrebø, Gunnar Mellgren, Johan Fernø, Simon Nitter Dankel, Magne Rekdal, Jonas Ingolf Petersson Nedkvitne and Jo Erling Riise Waage. *Final revision:* Tone Nygaard Flølo and Alexander Fosså. All authors approved the final version and agreed to be accountable for the accuracy and integrity of the work.

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CONFLICT OF INTEREST STATEMENT

The authors declare no conflicts of interest.

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