Research Square

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Laparoscopic Hiatus Hernia Repair with BIO-A® mesh is Safe and Effective for Patients Suffering Severe Gastro-Esophageal Reflux Disease After Sleeve Gastrectomy – A Single Surgeon Experience

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Abstract

Introduction: There is a complex relationship between gastroesophageal reflux disease (GORD), hiatus hernia, obesity, and metabolic bariatric surgery. We report the outcomes of laparoscopichiatus hernia repair (HHR) with BIO-A® mesh in the management of GORD post LSG in patients who developed a hiatus hernia with migration of the proximal gastric sleeve.

Methods: A retrospective review of 50 patients who previously underwent LSG andrevisional surgery (HHR, n=25; RYGB, n=25) between 2011 and 2022. The modifiedDeMeester scoring system was used to assess the severity of the patient's GORD symptoms pre-HHR/pre-RYGB and 6 months post-op.

Results: Twenty-fivepatients underwent HHR with BIO-A® mesh following a previous LSG. The severity of GORD six months post-HHR was significantly lower(0.96 ± 0.84 vs. 2.60 ± 0.50, p= <0.0001). After HHR, 3/25 (12%) patients had ongoing GORD symptoms that were not medically controlled and underwent conversion to RYGB. In contrast, 25 patients underwent direct conversion to RYGB following a previous LSG. The severity of GORD at6 months post-RYBG was significantly lower (0.40 ± 0.50 vs. 2.36 ± 0.64, p= <0.0001). At six months, there was no significant difference in GORD symptoms when HHR was compared with RYGB (3.32 ± 1.6 vs 3.76 ± 1.54, p=0.4296).

Conclusion: In appropriately selected patients, HHR with BIO-A® meshappears safe and effective in managing persistent GORDfollowing LSG, with the added benefit of having a lower risk for serious complications and long-term sequelae associated with RYGB.

Key Points

- HHR and RYGB both improved reflux symptoms after sleeve gastrectomy.
- No significant difference in short-term treatment effect between procedures.
- HHR had fewer complications and avoids long-term RYGB sequelae.

Introduction

Laparoscopic sleeve gastrectomy (LSG) is the most common bariatric surgical procedure. [1] While it is effective at reducing weight- and obesity-related morbidity, there is an increased risk of postoperative GORD, both in patients with preexisting GORD and those who develop de novo GORD. [2, 3] Some studies have reported a > 50% incidence of GORD within 10 years post-surgery. [4] The exact mechanism is not known, but it is likely to be multifactorial, including that the altered anatomy increases the risk for the development of hiatal hernia. [3] Fundoplication is not possible after LSG, [5] so the surgical approach for treating intractable GORD generally involves conversion to RYGB. [3] Although several studies have been published regarding concomitant laparoscopic sleeve gastrectomy and hiatus hernia repair, [6–11] there are limited data on the outcomes of HHR as the sole surgical strategy for GORD after LSG. [4, 13–

14] Our hypothesis was that in selected patients with GORD symptoms after LSG, repairing a hiatal hernia without additional conversion to RYGB is a safe and effective treatment strategy.

Methods

Participants

A retrospective review of our database of patients who underwent revisional surgery between January 2011 and May 2022 for medically intractable GORD following LSG was performed. The inclusion criteria were patients aged 18 years or over who had previously undergone LSG, who had intolerable GORD symptoms despite optimal medical care with proton pump inhibitors (PPIs) and who subsequently underwent HHR and/or RYGB. Exclusion criteria included prior bariatric procedures other than LSG (e.g., gastric band). Ethical approval was gained from the health service and waved the need for informed consent.

Patients were evaluated preoperatively with endoscopy, CT fizzogram or manometry as clinically indicated. In keeping with established practices, the criteria for reoperative management were troublesome symptoms despite maximum medical therapy, inability to tolerate medical therapy or patient preference.

Patients with a hiatus hernia greater than 2 cm in length were counselled on revisional options, including HHR or conversion to RYGB. Factors that influence the decision of HHR over RYGB were – smoking, history of gastrointestinal ulcers or patient choice.

Outcomes and follow-up

Patients were followed up in the clinic at 1 month, 3 months and 6 months post-surgery. The primary outcome was the severity of GORD symptoms 6 months after the antireflux procedure. The modified DeMeester score was used to quantify the severity of GORD (Table 1). It includes three symptom domains – dysphagia, heartburn and regurgitation – scored from 0 to 3. [11] The scores were recorded retrospectively from the surgeon's patient database. The secondary outcome was to compare the treatment effect in the HHR group with that in the RYGB group.

Table 1
Modified DeMeester scoring system

Symptoms	Score	Description
Dysphagia	0	None
	1	Occasional transient episodes
	2	Requires liquids to clear
	3	Impaction requiring medical attention
Heartburn	0	None
	1	Occasional brief episodes
	2	Frequent episodes requiring medical treatment
	3	Interference with daily activities
Regurgitation	0	None
	1	Occasional episodes
	2	Predicable by posture
	3	Interference with daily activities

Surgical approach

Laparoscopic Hiatus Hernia Repair post LSG

HHR was performed via a five-incision technique: three working ports, one camera port, and one for the Nathanson Liver Retraction System. After the sleeve was reduced into the abdomen and normal anatomy was restored, anterior and posterior cruroplasty were performed with 2/0 Novofil™ interrupted over a 32F bougie. An anterior 180-degree phrenoesophageal stitch was then placed using continuous 4/0 Prolene™ to secure the oesophagus to the crura (Fig. 1A). The repair was reinforced with BIO-A® mesh, which was cut into two semicircles to allow 360-degree coverage. The mesh was positioned approximately 5 mm away from the oesophagus and secured with 3/0 PDS™ sutures and Tisseel® fibrin sealant. (Fig. 1B)

Laparoscopic Roux-en-Y Gastric Bypass

RYGB was performed via seven ports: a 12 mm optical entry port in the LUQ, two 15 mm ports on the right of the midline, a 12 mm port below the LUQ port, two 5 mm ports on the left and a 5 mm epigastric incision for the Nathanson liver retractor. The greater omentum was divided, and the lesser sac was opened to allow inspection of the posterior stomach and division of adhesions. The small bowel was transected 100 cm distal to the ligament of Treitz using an EndoGIA™ tan 60 mm stapler. A 100 cm

alimentary limb was measured, and a stapled side-to-side anti-peristaltic jejunojejunostomy was formed with the same stapler. The enterotomy was closed in one layer with continuous 3/0 PDS. The mesenteric defect was closed using a continuous 2/0 Novofil™.

A 3 cm gastric pouch was fashioned over a 32 Fr bougie along the lesser curve, beginning just proximal to the incisura, using EndoGIA black staplers and Seamguard on the most superior staple firing. A hand-sewn end-to-side gastrojejunostomy was constructed via continuous 3/0 PDS sutures in two layers. An air-leak test was performed routinely.

Peterson's defect was closed via a continuous 2/0 Ethibond™ suture. The greater omentum was restored to its anatomical position, and three interrupted 3/0 PDS sutures secured it to the alimentary limb to prevent early torsion.

Statistical analysis

Baseline characteristics are expressed as whole numbers and frequency distributions for categorical variables. Continuous data were summarised as medians with interquartile ranges (IQRs). The Mann–Whitney U test, Wilcoxon signed-rank test and Fisher's exact test were used where appropriate. Statistical significance was defined as $p < 0.05$. Analyses were performed using STATA 17.

Results

Patient demographics

A total of 50 patients met the inclusion criteria, with 25 undergoing HHR alone and 25 undergoing RYGB (Table 2). A similar proportion of patients in both groups were female (19 (76%) who underwent HHR alone compared with 21 (84%) in the RYGB group (p= 0.725)). The median age in the HHR group was 51 years (IQR 45-58 years), which was similar to that in the RYGB cohort 49 years (IQR 43-46 years), p=0.528. The median time since LSG was 48 months in the HHR cohort and 55 months in the RYGB cohort (p=0.831). Prior to undergoing LSG, the group that subsequently underwent HHR had a lower BMI than did the group that subsequently underwent RYGB (38.4 vs. 44.1, p=0.0005). Both groups achieved a similar median weight loss from their LSG (25% vs. 21%), which translated to a significantly lower median BMI at the time of the second surgery (anti-reflux procedure) in the HHR group (30.3 kg/m^2 vs. 35.5 kg/m^2, p=0.0002).

Table 2: Baseline characteristics

	HHR n=25	RYGB n=25	P value
Age (years)			
Median (IQR)	51.0 (45-58)	49.0 (43-56)	0.528+
Gender, *n* (%)			0.725^
Female	19 (76%)	21 (84%)	
Male	6 (24%)	5 (20%)	
Prior GORD, *n* (%)	16 (64%)	11 (44%)	0.256^
Prior PPI use, *n* (%)	10 (40%)	5 (20%)	0.217^
Prior HH, *n* (%)	16 (64%)	7 (28%)	0.022^
Months since LSG, median (IQR)	48.0 (42.0-77.0)	55.0 (42.0-73.0)	0.831+
BMI, kg/m^2			
Pre-SG, median (IQR)	38.4 (36.6-42.5)	44.1 (41.5-57.4)	0.0005+
Post-SG median (IQR)	30.3 (26.6-33.6)	35.5 (32.5-43.1)	0.0002+
BMI Reduction, median (IQR),	9.7 (2.9-17.6)	9.4 (25.3- 67.7)	
p value	*<0.001**	*<0.001**	0.756+

HHR - Hiatus Hernia Repair; RYGB - Roux-en-Y Gastric Bypass; IQR - Interquartile Range. GORD – Gastroesophageal Reflux Disease, PPI – Proton Pump Inhibitor, HH – Hiatus Hernia, BMI – Body Mass Index, SG – Sleeve Gastrectomy.

*Both the HHR and RYGB groups had a statistically significant reduction in BMI (p<0.0001; Wilcoxon signed-rank test).

+Mann–Whitney U test for difference in BMI per HHR and RYGB, test statistic (z) = 0.3105, P=0.7562

^Fisher's exact test for sex, GORD, prior PPI; no significant difference

In the HHR group, 16/25 (64%) patients who developed clinically significant GORD post LSG had a hiatus hernia at their primary LSG. The only baseline characteristic to have a statistically significant difference was the presence of a prior hiatus hernia, where 16 patients (64%) who had a HHR as their second procedure had a previous HH repaired at the time of LSG, compared with 7 (28%) patients who subsequently underwent RYGB (p=0.022). There was also a statistically significant median BMI reduction in both the HHR and RYGB groups between their LSG and their secondary surgical procedures (38.40 kg/m^2 vs. 30.3 kg/m^2, p<0.0001) and (44.1 kg/m^2 vs. 35.5 kg/m^2, p<0.0001), respectively (Table 2). The

median time between LSG development and GORD in the HHR group was 38 months (6-56), whereas it was 49 months (33-67) in the RYGB group. At the time of HHR/RYGB, both groups had similar symptom burdens (HHR - 0.96 ± 0.84 vs. 4.0 ± 1.44, p<0.001) (RYGB - 0.44 ± 0.50 vs. 4.16 ± 1.52, p<0.0001).

Surgical outcomes

The median time between the LSG and anti-reflux procedure was 48 ± 35 months in the HHR group and 51 ± 35 months in the RYGB group. In the hiatus hernia repair group, the median length of stay was 2 days (2-3) compared with 4 days (4-5) in the RYGB group. The early clinical outcomes are shown in Table 3. While there were no cases of reoperation or 90-day mortality in either group, there were some complications. In the HHR group, two patients were readmitted within 30 days for nausea and abdominal pain, which resolved with supportive management. In the RYGB group, only one patient was readmitted within 30 days, with PR bleeding secondary to hemorrhoids.

Table 3: Early clinical outcomes

	HHR n=25 (%)	RYGB n=25 (%)
LOS, Median days (IQR)	2 (2-3)	4 (4-5)
30-day readmission	2 (0.08%)	1 (0.04%)
Reoperation	0	0
90-day mortality	0	0
Complications		
Nausea	1 (0.04%)	-
Abdominal pain	1 (0.04%)	-
Hematochezia	-	1 (0.04%)

HHR - Hiatus Hernia Repair; RYGB -Roux-en-Y Gastric Bypass; LOS - length of stay; IQR - interquartile range.

At the intermediate follow-up, there were statistically significant reductions in the modified DeMeester score in both the HHR (4.00 ± 1.44 vs. 0.97 ± 0.84, p<0.001) and RYGB groups (4.16 ± 1.44 vs. 0.40 ± 0.58, p<0.001). However, there was no statistically significant difference in the treatment effect between the HHR and RYGB groups (3.32 ± 1.60 vs. 3.76 ± 1.58, p=0.427) (Table 4).

Table 4: Intermediate clinical outcomes

	HHR	RYGB	P value
DeMeester Score, mean ± SD (range)			
Pre-SG	0.96 ± 0.84 (0-2)	0.44 ± 0.51 (0-1)	0.025[+]
Post-SG	4.00 ± 1,44 (2-6)	4.16 ± 1.52 (2-7)	0.729
6 months post-anti reflux surgery	0.68 ± 1.25 (0-6)	0.5 ± 0.58 (0-2)	0.522
DeMeester Score Reduction[*]	3.32 ± 1.60 (0-6)[*]	3.76 ± 1.54 (2.7)[*]	0.427

HHR - Hiatus Hernia Repair; RYGB - Roux-en-Y Gastric Bypass; SD - standard deviation; SG - sleeve gastrectomy.

[+]Only a statistically significant difference in the DeMeester score was detected between the HHR and RYGB groups before SG according to the Mann—Whitney U test.

[*] Both the HHR and RYGB groups showed a statistically significant reduction at 6 months, P value <0.0001 according to the Wilcoxon signed-rank test.

The individual components of the DeMeester score were compared across the three time points of the study. In both the HHR and RYGB groups, neither group had symptoms suggestive of GORD (0.96 ± 0.84 vs. 0.44 ± 0.51, p<0.025); therefore, LSG was suitable as their primary surgery. There was a statistically significant reduction in both heartburn and regurgitation after HHR (2.60 ± 0.50 vs. 0.60 ± 0.77, p<0.001) (1.40 ± 1.12 vs. 0.10 ± 0.60, p<0.001). Additionally, both heartburn and regurgitation were compared before LSG and after HHR. There was no statistically significant difference in heartburn (1.00 ± 0.84 vs. 0.60 ± 0.77, p=0.102) or regurgitation (1.00 ± 0.84 vs. 0.60 ± 0.77, p=0.655). However, it is important to note that following HHR, the cohort's scores returned to pre-sleeve gastrectomy levels.

Overall, 22 (88%) patients in the HHR cohort had a clinically meaningful reduction in their modified DeMeester score, whereas 3 patients (12%) had no improvement. (Figure 2). Two of the three patients whose DeMeester scores remained unchanged, two, demonstrated clinical improvement in GORD symptoms and were able to reduce their PPI requirements. The remaining patient who had no improvement in the clinical or modified DeMeester score achieved conversion to RYGB. Unfortunately, this patient's procedure was complicated by an anastomotic bleeding.

In the RYGB cohort, 24 (96%) patients had a clinically meaningful reduction in their modified DeMeester score. The remaining patient did not have any change in their modified DeMeester score or PPI dose. There were two late complications in the RYGB patient group: one patient had an anastomotic ulcer successfully treated with medical therapy, and one patient developed abdominal pain with suspected intussusception requiring (negative) laparoscopy.

Discussion

The relationship between LSG and GORD has been well documented in the literature, with some studies reporting that up to 57% of patients experience GORD symptoms post LSG. [4, 12] Although some of these patients have GORD symptoms preoperatively, a significant proportion develop de novo GORD (up to 30–40%). [12, 15] For this reason, some surgeons view GORD as a contraindication to LSG. Another consequence of LSG is the development of a hiatus hernia, which is a risk factor for GORD. Multiple mechanisms have been suggested for the development of GORD and hiatus hernia following sleeve gastrectomy, such as altered anatomy, increased gastric pressure and an increased gastroesophageal pressure gradient. [3] As a result, there has been much debate in the literature regarding the most appropriate surgical procedure in patients with medically refractory GORD post LSG.

Our findings demonstrate that HHR alone and traditional RYGB are effective in managing GORD post LSG in the medium term. While both surgical procedures are safe, there were more complications in the RYGB group. In this nonrandomized, single-surgeon series, the HHR approach also proved to be noninferior to RYGB. This confirms that in appropriately selected patients, HHR alone could be considered a first-line surgical approach in patients who have intractable GORD and a proven hiatus hernia post LSG. This simple approach would address a major contributor to the GORD symptom profile while otherwise maintaining normal gastrointestinal anatomy. HHR also has the added benefit of avoiding early and late complications of RYGB, such as anastomotic bleeding, perforation or stricture, marginal ulcers, internal hernias, intussusception, nutritional deficiencies and dumping syndrome. [16–18]

We acknowledge that our study has several limitations. Our numbers are relatively small, although we are not aware of any other studies comparing HHR and RYGB in patients with intractable GORD after LSG. Additionally, this is the largest cohort currently published looking at the surgical technique of BIO-A® mesh hiatus hernia repair following LSG for medically refractory GORD. Patients were not randomized to a treatment group, and as such, there are some clear sources of selection bias. However, this reflects usual clinical practice, where an experienced clinician can help a patient decide between valid options with differing risk and benefit profiles. Third, owing to the limitations of private practice, the follow-up period was only six months, so we were unable to comment on longer-term outcomes. Furthermore, late complications such as hiatal hernia recurrence, dumping, vitamin deficiencies or stomal ulcers may have also been missed because of the short-term follow-up, and this should be considered when the results are interpreted.

Conclusion

This study demonstrated that BIO-A® mesh for hiatus hernia repair alone is a safe and effective medium-term treatment for select patients with intractable GORD and a hiatus hernia following LSG. While both HHR and RYGB significantly reduce GORD symptoms, HHR alone has a lower risk of serious complications and avoids the long-term sequelae of RYGB. Therefore, further studies are warranted to evaluate this approach.

Declarations

Blinded Statements

Conflict of Interest

The authors declare no conflicts of interest.

Ethical Approval

All procedures were conducted in accordance with institutional and national research ethics standards and the 1964 Helsinki declaration and its later amendments. For this type of retrospective study, formal consent was not required.

Informed Consent

This article does not contain any studies with human participants requiring individual informed consent.

Data Availability

Data supporting the findings of this study are available from the corresponding author upon reasonable request.

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Figures

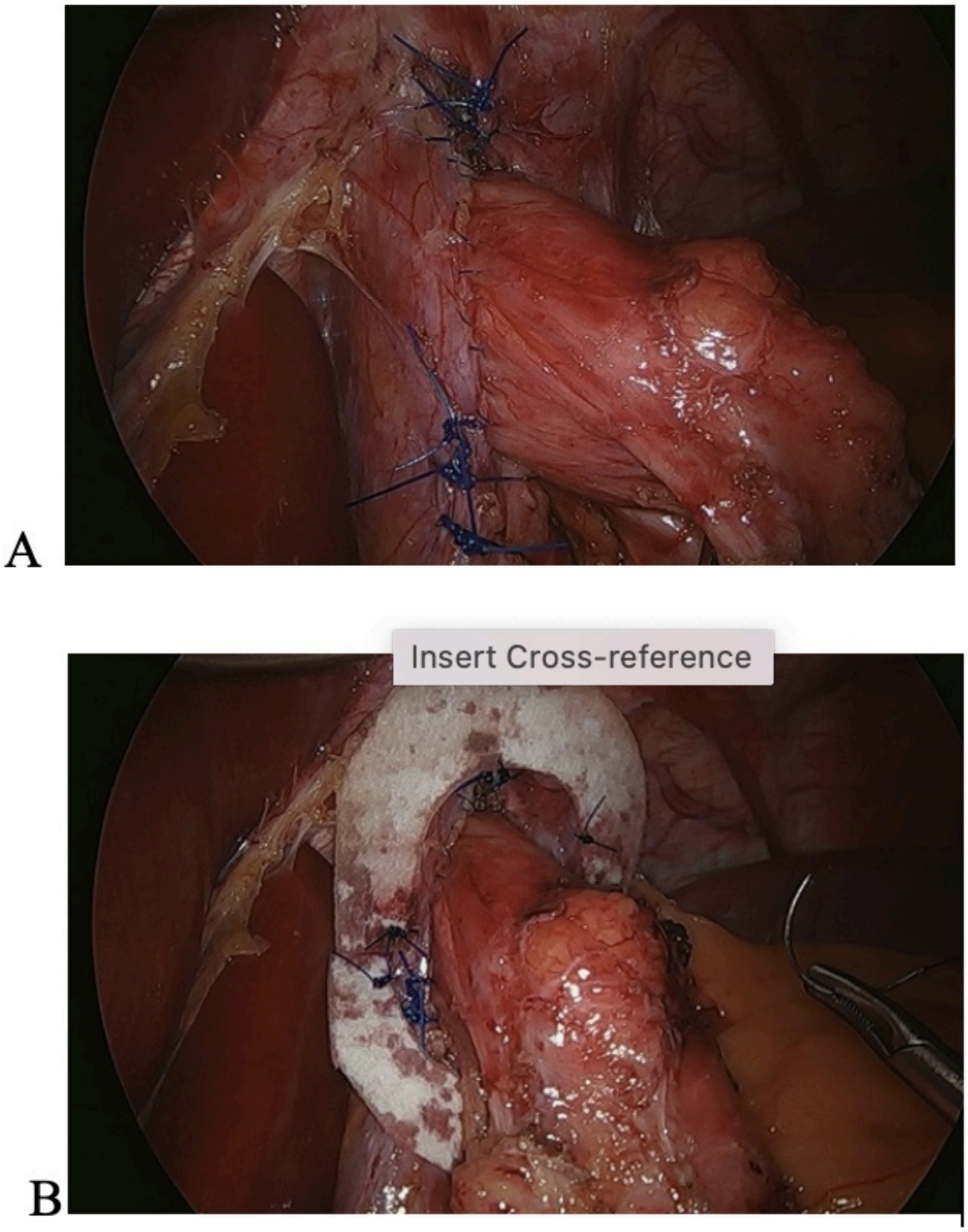


Figure 1

Clinical photographs of laparoscopic hiatus hernia repair. A – Anterior and posterior hiatus hernia repair with 180-degree phrenoesophagealcontinuous suture. B – 360-degree BIO-A® mesh reinforcement forhiatus hernia repair.

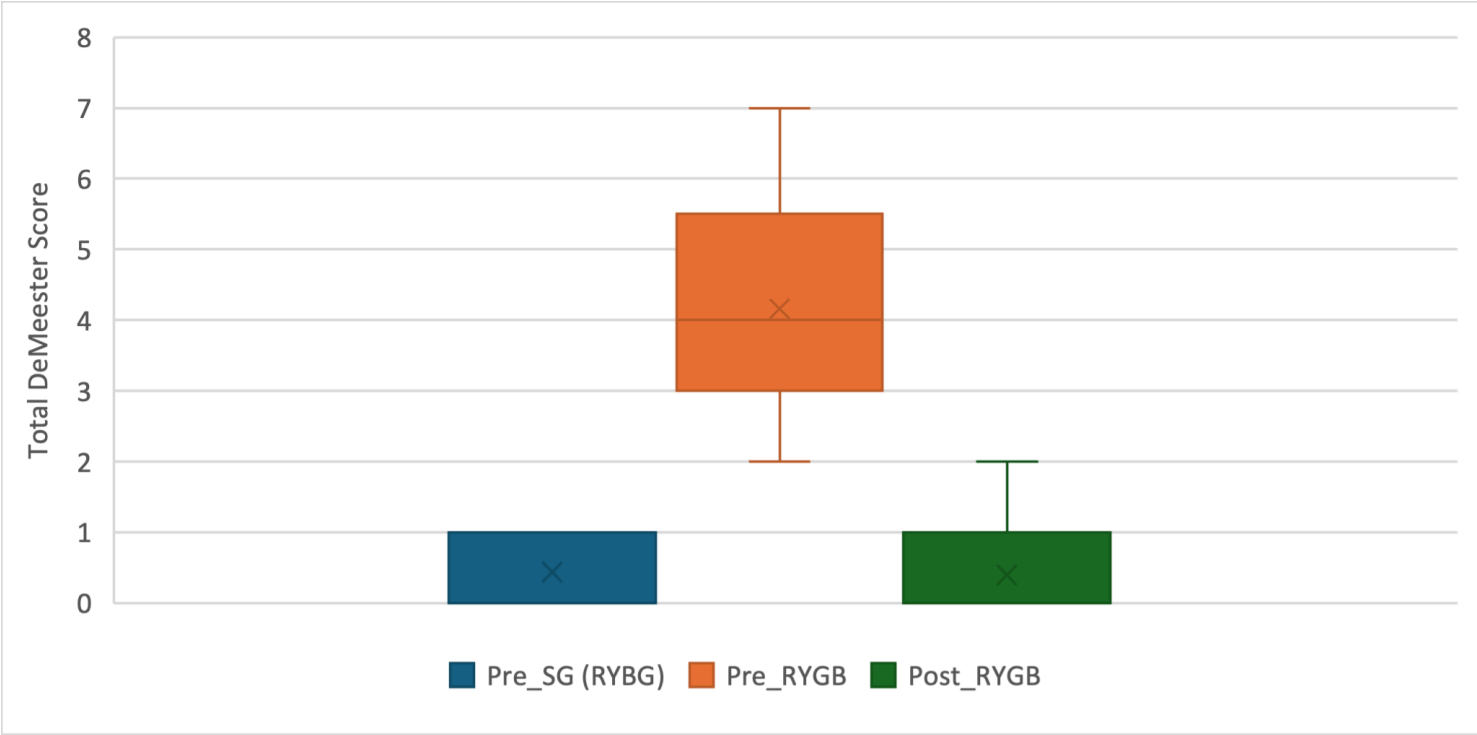


Figure 2

Box plot of the total DeMeester score at three time points: pre-sleevegastrectomy, pre-hiatushernia repair and post-hiatushernia repair. Heavy line = median score, box= interquartile range.

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- GraphicalAbstractHHRvsRYGB.pptx