



Does crural repair with biosynthetic mesh improve outcomes of revisional surgery for recurrent hiatal hernia?

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Received: 3 December 2023 / Accepted: 8 March 2024
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Abstract

Background Laparoscopic revisional surgery for recurrent hiatal hernia (HH) is technically demanding. Re-recurrences are common and esophageal hiatus mesh reinforcement might improve durability of the repair, thus minimizing the risk of re-herniation.

Purpose Assess safety and effectiveness of simple suture repair (no mesh group) vs. crural augmentation with a biosynthetic absorbable mesh (mesh group) in patients with recurrent HH.

Methods Observational retrospective study from September 2012 to December 2022. Only patients undergoing redo surgery for previous failures of hiatal hernia repair were enrolled. Surgical failure was defined as symptomatic recurrent HH with > 2 cm of gastric tissue above the diaphragmatic impression at upper gastrointestinal endoscopy and/or swallow study. Gastro-Esophageal Reflux Disease Health-Related Quality of Life (GERD-HRQL) and Short Form-36 (SF-36) questionnaires were used to assess preoperative and postoperative symptoms and quality of life.

Results One hundred four patients were included. Overall, 60 patients (57.7%) underwent mesh-reinforced cruroplasty, whereas 44 (42.3%) underwent simple suture cruroplasty. Mesh and no mesh groups had similar baseline demographics, symptoms, prevalence of esophagitis and Barrett's esophagus, and HH size. A composite crural repair was most commonly performed in the mesh group (38.3% vs. 20.5%; $p = 0.07$). In addition to cruroplasty, most patients (91%) underwent a Toupet fundoplication. The 90-day postoperative complication rate was 8.6%, and there was no mortality. Recurrent HH was diagnosed in 21 patients (20.2%) with a clinical trend toward reduced incidence in the mesh group (16.7% vs. 25%; $p = 0.06$). Compared to baseline, there was a statistically significant improvement of median GERD-HRQL score ($p < 0.01$) and all SF-36 items ($p < 0.01$).

Conclusions Laparoscopic revisional surgery for recurrent HH is safe and effective. Selective use of biosynthetic mesh may protect from early recurrence and has the potential to reduce re-herniation in the long-term.

Keywords Hiatus hernia · Recurrent hiatal hernia · Crural repair · Failed fundoplication · Biosynthetic mesh · GERD-HRQL score

Introduction

Anatomic and/or symptomatic recurrence is the Achilles' heel of hiatus hernia (HH) repair. Depending on definitions, relapse rates up to 57% have been reported [1–3]. Etiology and risk factors for recurrence are multiple and still not completely understood [4, 5]. Several techniques devised to protect or release tension on the hiatal repair (posterior fundoplication, crural mesh, falciform ligament flap, relaxing diaphragmatic incisions), to anchor the esophagogastric junction/stomach in the abdomen (posterior gastropexy, anterior gastropexy or gastrostomy), or to lengthen the esophagus (wedge resection of the gastric fundus or truncal

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vagotomy) have been applied in an attempt to reduce the risk of HH recurrence [6].

Revisional operations for recurrent HH are challenging. The current standard of care in patients with recurrent symptomatic HH is laparoscopic revisional cruroplasty and fundoplication, which is technically demanding and should be reserved to patients with refractory symptoms [7]. Despite revisional surgery is associated with increased postoperative morbidity compared to the primary operation, previous studies have reported satisfactory short-term outcomes with up to 80% symptoms resolution and improved quality of life [8, 9]. However, re-recurrences are still common and there is a lot of ongoing research to solve the dilemma of the root cause of re-herniation and to determine whether it is more important to reconstruct and reinforce the hiatus, to anchor the esophagogastric junction below the diaphragm, or to lengthen the esophagus. Reconstruction of the esophageal hiatus has been the focus of surgeons for decades [10–12]. Over the past two decades, the use of biosynthetic mesh has been proposed to improve durability of the repair while reducing the risk of visceral erosion and severe complications associated with non-absorbable meshes [13–15].

The aim of this study was to examine our 10-year experience with recurrent HH repairs comparing safety and efficacy of simple suture crural repair vs. crural augmentation with a biosynthetic absorbable mesh.

Materials and methods

This a retrospective, comparative study with data extracted from a prospectively maintained database. Patients were enrolled in two academic institutions from September 2012 to December 2022. Patients who underwent elective laparoscopic crural repair for symptomatic HH recurrence were included. The institutional review board (IRB) approved the study (HR#109-2023) and all patients signed a written informed consent.

Inclusion and exclusion criteria

Inclusion criteria (a) adult patients (≥ 18 years old), (b) symptomatic HH recurrence managed with Phasix-ST® mesh reinforced cruroplasty (mesh group) vs. simple suture cruroplasty (no mesh group) and fundoplication, (c) elective surgery, (d) patients who completed the pre- and postoperative instrumental assessment and the gastroesophageal reflux disease health-related quality of life (GERD-HRQL) and short-form 36 (SF-36) questionnaires (e) patients with a minimum 12-month follow-up. Exclusion criteria (a) previous Heller myotomy or esophagogastric resection (b) emergency repair, (c) patients with < 12-month

follow-up, (d) patients managed with mesh other than Phasix-ST®.

Data collection

Baseline demographics and patient characteristics, such as age, sex, body mass index (BMI) (kg/m^2), American Society of Anesthesiologists (ASA) physical status, comorbidities, HH size, operative data, and short-term surgical outcomes (90-day morbidity and mortality), were collected. Preoperative evaluation routinely included upper gastrointestinal endoscopy and barium swallow study. Perioperative complications were defined in accordance with the Clavien–Dindo classification [16].

Surgical technique

All revisional surgical procedures were performed laparoscopically. After taking down adhesions from previous surgery and careful dissection around the hiatus, all hernia contents and hernia sac were reduced, the distal esophagus was encircled with a Penrose drain, and traction was applied to obtain a 3–5 cm tension-free intra-abdominal segment. If present, the previous fundoplication was taken down until the angle of His was clearly identified. The posterior hiatoplasty was then performed with interrupted non-resorbable sutures (Prolene® 2.0-Ethicon) tied with extracorporeal knots. A composite dorsal–ventral repair with stitches including the apex of the left crus and the central tendon of the diaphragm was performed in selected patients with larger hiatal defect to avoid excessive angulation and narrowing of the esophagus. Care was taken to reduce the pneumoperitoneum from 13 to 6 mmHg during the hiatoplasty [17]. The decision to place or not a mesh for crural reinforcement was initially dependent on the operating surgeon preference and/or subjective assessment indicating weak crura or tissue tearing from sutures. From January 2021, the procedure was chosen according to a standardized the patient treatment algorithm [9, 10]. In case of simple suture cruroplasty (no mesh), the reconstruction of the diaphragmatic pillars was performed with interrupted non-resorbable sutures (Prolene® 2.0-Ethicon) tied with an extracorporeal knot. In case of mesh reinforced cruroplasty, after mediastinal dissection and cruroplasty with sutures, a 7×10 cm Phasix-ST® mesh made of poly-4-hydroxybutyrate (P4HB) with a hydrogel barrier on one side was shaped with ‘‘U’’ configuration and fixed over the approximated hiatus surface with at least two interrupted absorbable sutures (Fig. 1). Finally, after division of the first 2–3 short gastric vessels, a posterior fundoplication was fashioned according to the previously described critical view of safety approach [18]. To prevent postoperative nausea and vomiting, an 8 mg bolus of dexamethasone was routinely administered during the surgical

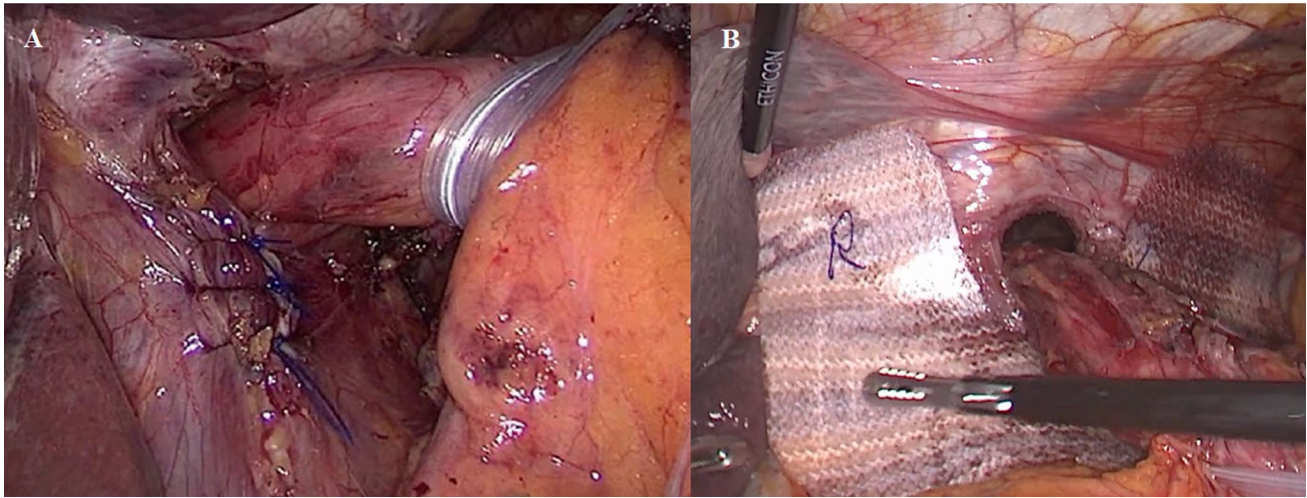


Fig. 1 **A** The hiatus is closed with interrupted non-absorbable sutures. **B** The U-shape Phasix-ST mesh is placed at the hiatus to reinforce the suture and fixed in place with absorbable braided stitches

procedure. The nasogastric tube was removed at the end of the operation. A chest film and a gastrografin swallow study were performed on postoperative day 1 to check the correct position of the esophagogastric junction. A soft diet was then allowed, and patients were discharged home with proper diet instructions.

Follow-up

Outpatient follow-up visits were scheduled at 1, 6, and 12 months after the operation, and then yearly. Endoscopic and radiological (upper gastrointestinal swallow study and computed tomography) findings were collected. Barium swallow study and/or upper gastrointestinal endoscopy were performed between 6 and 12 months after surgery and repeated every year or at any time the patient complained of symptoms. Disease-specific Gastro-Esophageal Reflux Disease Health-Related Quality of Life (GERD-HRQL) and generic Short Form-36 (SF-36) were used to assess patients' quality of life at baseline and during follow-up [19].

Outcomes and definitions

The primary aim was to compare the safety and efficacy of revisional surgery for symptomatic HH recurrence and compare data between mesh and no mesh. Secondary outcomes were short-term (90-day) surgical complications, changes in esophageal symptoms, and patient-related quality of life assessed with GERD-HRQL and SF-36. Surgical failure was defined as symptomatic recurrent HH with > 2 cm of gastric tissue above the diaphragmatic impression at upper endoscopy and/or swallow study.

Statistical analysis

Continuous data are presented as mean and standard deviation or median and IQR. Categorical variables are shown as numbers and percentages. Wilcoxon signed-rank for paired data was performed as appropriate. Two-sided *p* values were computed. Statistical significance was considered when *p* value was equal or less than 0.05. Confidence interval was set at 95% confidence level. Recurrence-free probability was estimated with the Kaplan–Meier method. The hazard function was estimated using non-parametric smoothing method. All analyses were carried out using R version 3.2.2 software [20].

Results

During the study period, 149 patients were treated for HH recurrence. One hundred four patients were included in the final analysis (Fig. 2). Overall 60 (57.7%) underwent mesh-reinforced cruroplasty whereas 44 (42.3%) underwent simple suture cruroplasty. Demographics of the patient population are shown in Table 1. Age, gender, BMI (kg/m²), ASA score, comorbidities, and smoke status were comparable between groups. Heartburn (79.8%), dysphagia (40.4%), regurgitation (28.8%), and chest pain (26.9%) were the most common typical esophageal symptoms, while 27% of patients complained atypical symptoms. Esophagitis or Barrett's esophagus was diagnosed in 35.6% and 11.5% of patients, respectively. Symptom's duration, length of PPI therapy, and daily PPI intake were also comparable. Preoperative endoscopic assessment showed a trend toward a larger HH size in the mesh group (4.1 vs. 3.4; *p*=0.07). Overall, 5 patients

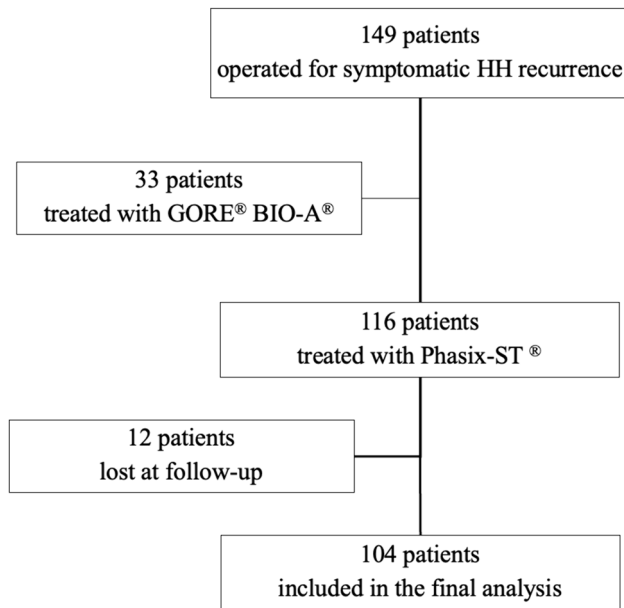


Fig. 2 Flow chart of the study population including patient recruitment, exclusion criteria, and lost at follow-up

(4.8%) had previous crural mesh repair and 91.3% had a Nissen fundoplication. The median preoperative GERD-HRQL score was 23 (range 8–44).

All operations were completed laparoscopically. The median operative time was 122 min (range 54–210) (Table 2). No intraoperative complications occurred, and intraoperative blood loss was negligible; the posterior vagal trunk was identified and preserved in 101 patients (97%), and there were no conversions to open procedures. The composite posterolateral cruroplasty was most commonly performed in patients that underwent mesh repair (38.3% vs. 20.5%; $p=0.07$). Ninety-one percent of patients underwent a Toupet fundoplication. The median postoperative hospital stay was 3 days (IQR 1–8). The 90-day postoperative complication rate was 8.6% ($n=9$). The distribution of complications according to the Clavien classification was the following: pleural effusion requiring drainage (IIIa) ($n=3$), gastroparesis requiring endoscopic dilation (IIIa) ($n=3$), hydropneumothorax and pleural empyema (grade IIIb) ($n=1$), thromboembolism (grade IV) ($n=1$), and esophageal perforation managed endoscopically (grade IV) ($n=1$). There was no mortality.

The median postoperative follow-up time was shorter ($p=0.039$) in the mesh group (55 months, IQR 6–64) compared to the no mesh group (102 months, IQR 8–128) (Table 3). Overall, recurrent HH was diagnosed in 21 patients (20.2%) and redo surgery was necessary in five patients. Despite the lack of statistical significance, there was a clinical trend toward reduced hernia recurrence in patients who underwent mesh repair (16.7% vs. 25%;

$p=0.06$) (Fig. 3). Specifically, the recurrence-free probability for mesh vs. no mesh repair at 24 months was 0.96 (95% CI 0.87–0.98) vs. 0.93 (95% CI 0.76–0.97), 0.84 (95% CI 0.67–0.91) vs. 0.75 (95% CI 0.68–0.86) at 36 months, and 0.81 (95% CI 0.65–0.89) vs. 0.69 (95% CI 0.62–0.79) at 48 months, respectively. The timeline analysis showed a comparable median time of HH recurrence between mesh (20 mos, IQR 8–32) and no mesh (24 months; IQR 6–36) patients ($p=0.24$). At the last follow-up, 80% of the patients were off PPI, with 20% taking daily or occasional PPI for residual symptoms. The median GERD-HRQL was significantly improved compared to baseline in mesh ($p=0.012$) and no mesh patients ($p=0.023$). All SF-36 items (Supplementary Table 1) were significantly improved ($p<0.001$) compared to baseline.

Discussion

The present study demonstrates the safety and the efficacy of laparoscopic repair of recurrent HH with either simple suture or mesh reinforced cruroplasty over a median follow-up > 5 years. Also, there was a clinical trend toward reduced HH re-herniation in patients who received biosynthetic mesh (Phasix-ST®) augmentation.

Reoperations for recurrent HH are technically challenging and associated with higher postoperative morbidity and conversions to open surgery [21, 22]. Multiple factors are potentially associated with the difficulties encountered during these revisional procedures, such as distorted anatomy, dense adhesions, tissue scarring, and progressive deterioration of esophagogastric physiology. In our series, none of the patients required conversion to open procedure and intraoperative complications were negligible. Furthermore, the postoperative complication rate was lower (8.6%) compared to previous studies reporting up to 29% complication rates [23, 24]. Notably, we performed a composite crural repair in both patient groups, and the Toupet fundoplication was our preferred surgical technique to minimize the risk of postoperative dysphagia and gas bloat syndrome [25].

Laparoscopic repair with mesh-reinforced cruroplasty has become an increasingly common surgical approach in patients with primary HH [26, 27]. Recent systematic reviews and meta-analyses show conflicting results in terms of recurrence prevention due to heterogeneity [28]. Furthermore, the safety and the efficacy of mesh augmentation in the setting of redo surgery for HH recurrence are even more indeterminate because evidence is scarce. Complications related to non-absorbable mesh, including esophageal strictures, abscess or fistula formation, and full-thickness erosions related to the process of mesh scarring, have been extensively reported after both primary repair and redo

Table 1 Demographic and preoperative characteristics of the patient population

	Mesh group (<i>n</i> =60)	No Mesh group (<i>n</i> =44)	<i>p</i> value
Sex, female, <i>n</i> (%)	38 (63.3)	26 (59.1)	0.19
Age, yrs, median (IQR)	58 (51–68)	53 (45–65)	0.09
BMI, median (IQR)	25.6 (23.3–27.1)	25.1 (22.4–27.9)	0.79
ASA score > 2 <i>n</i> (%)	10 (16.7)	7 (15.9)	0.65
Active smoker, <i>n</i> (%)	7 (11.7)	5 (11.3)	0.72
Comorbidities, <i>n</i> (%)			
CAD	9 (15)	6 (13.6)	0.28
COPD	8 (13.3)	6 (13.6)	0.91
Hypertension	17 (28.3)	11 (25)	0.37
Diabetes	5 (8.3)	4 (9.1)	0.17
Kyphoscoliosis	11 (18.3)	10 (22.7)	0.53
Anxious-depressive syndrome	13 (21.6)	11 (25)	0.08
Symptoms, <i>n</i> (%)			
Heartburn	48 (80)	35 (79.5)	0.48
Dysphagia	25 (41.7)	17 (38.6)	0.33
Regurgitation	18 (30)	12 (27.3)	0.16
Thoracic pain	16 (26.7)	12 (27.2)	0.51
Dyspnea	8 (13.3)	5 (11.4)	0.74
Anemia/previous blood transfusion	3 (5)	2 (4.5)	0.37
Symptom duration, mos, median (IQR)	26.5 (12–96)	35 (24–84)	0.29
PPI therapy, <i>n</i> (%)	46 (76.7)	32 (72.7)	0.49
PPI therapy duration, mos, median (IQR)	72 (24–120)	70 (48–108)	0.39
Hiatus hernia, cm, median (IQR)	4.1 (2–6)	3.4 (2–5)	0.07
GERD–HRQL score, median (IQR)	23 (8–41)	21 (6–40)	0.81
Esophagitis (grade A–D), <i>n</i> (%)	22 (36.7)	15 (34.1)	0.29
Barrett esophagus, <i>n</i> (%)	7 (11.7)	5 (11.4)	0.36
Previous operation, <i>n</i> (%)			
<i>n</i> = 1	49 (81.7)	39 (88.6)	0.17
<i>n</i> = 2	11 (18.3)	5 (10.4)	
With mesh	4 (6.7)	1 (2.3)	0.37
Previous fundoplication, <i>n</i> (%)			
Nissen	55 (91.7)	40 (91)	0.89
Toupet	5 (8.3)	4 (9)	
Time from previous surgery, mos, median (IQR)	39 (13–68)	46 (8–81)	0.65

Values are expressed as median (interquartile range—IQR) or numbers (%)

BMI Body Mass Index, *ASA* American Society of Anesthesiologists classification, *CAD* coronary artery disease, *COPD* chronic obstructive pulmonary disease, *PPI* proton pump inhibitors, *mos* months

surgery [29]. In our patient population, no mesh-related complications occurred and none of the patient's required reoperation for related complications. This may be attributable to a combination of both P4HB and Sepra Technology (ST) coating of the Phasix-ST® mesh. This barrier of sodium hyaluronate and carboxymethylcellulose applied to one side of the mesh seems important to minimize the risk of visceral adhesions [30, 31].

The overall hernia re-recurrence rate in this study was 20.2%. This is comparable to previous studies reporting data from redo surgery after failed primary HH repair [32–35]. Also, a recent meta-analysis reported a weighted pooled

proportion of recurrence across the studies of 10.7% (95% CI 7.7–14.1%) [36]. In our experience, only five patients required further surgical revision whereas the majority remained asymptomatic on PPI medications. There was a clinical trend toward reduced recurrence with mesh-reinforced cruroplasty compared to simple suture cruroplasty (16.7% vs. 25%). The lack of statistical significance may be due to the limited sample size in our study. The majority of recurrences were diagnosed after 20 months from the operation, indicating that the estimated time of absorption of the Phasix-ST mesh should provide enough time for hiatus reinforcement and protection from early failures [37–40].

Table 2 Intraoperative variables according to the mesh vs. no mesh buttressing

	Mesh group (n=60)	No Mesh group (n=44)	p value
Hiatoplasty, n (%)			
Posterior	37 (61.7)	35 (79.5)	0.07
Composite	23 (38.3)	9 (20.5)	
Numbers of hiatoplasty stitches, median (IQR)			
Posterior	3 (3–4)	3 (2–4)	0.16
Left lateral	1 (1–2)	2 (2–3)	0.25
Fundoplication, n (%)			
Toupet (CVS)	56 (93.3)	39 (88.6)	0.24
Nissen	1 (1.7)	3 (6.8)	0.21
Lortat-Jacob	1 (1.7)	1 (2.3)	0.32
Dor	2 (3.3)	1 (2.3)	0.54
Falciform ligament flap, n (%)	2 (3.3)	7 (15.9)	0.03
Wedged Collis gastroplasty, n (%)	2 (3.3)	2 (4.5)	0.32
OT, min, median (IQR)	202 (142–287)	189 (128–298)	0.19
90-day morbidity, n (%)	5 (8.3)	4 (9.1)	0.91

Values are expressed as median (IQR—interquartile range) or numbers (%)

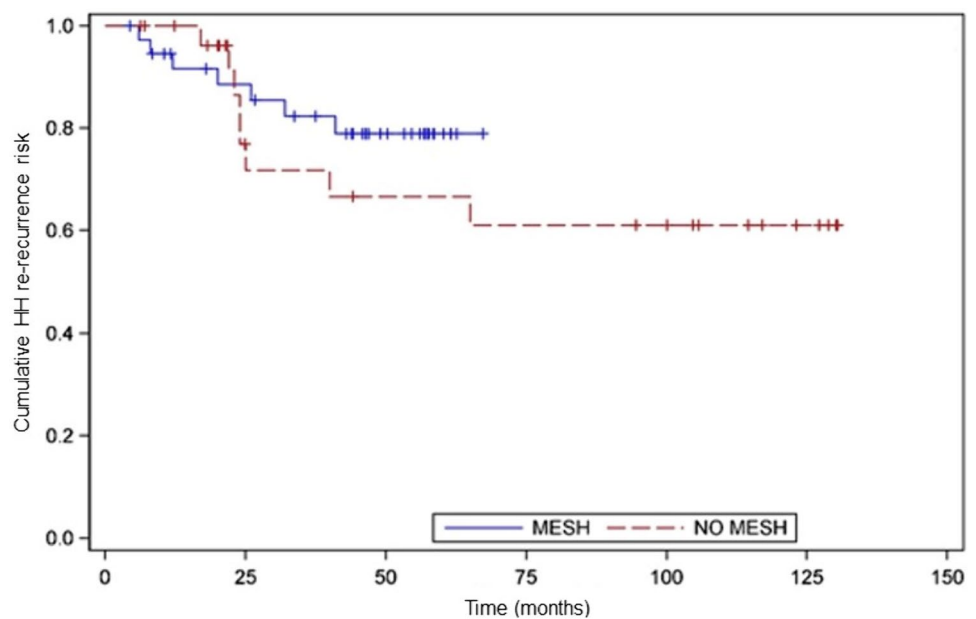
CVS critical view of safety, OT operative time, min minutes

Table 3 Follow-up variables according to the mesh vs. no mesh buttressing

	Mesh group (n=60)	No Mesh group (n=44)	p value
Follow-up, mos, median (IQR)	55 (6–64)	102 (18–128)	0.02
PPI off, n (%)	49 (81.7)	34 (77.3)	0.21
GERD-HRQL score, median (IQR)	7 (3–13)	8 (4–15)	0.51
Recurrent HH, n (%)	10 (16.7)	11 (25)	0.06
Redo surgery for HH re-recurrence, n (%)	2 (3.3)	3 (8.8)	0.08

Values are expressed as median (IQR—interquartile range) or numbers (%)

PPI proton pump inhibitors therapy, mos months, HH hiatus hernia

Fig. 3 Kaplan–Meier survival curve in patients treated with mesh (blue line) and no mesh (red line). X axis shows time expressed in months. Y axis shows the cumulative risk for HH re-recurrence

Although cruroplasty with mesh may have a role in reducing postoperative re-recurrences after failed primary HH repair, confirmation on large and well-conducted observational studies or randomized trials is warranted [41].

Patient-reported outcomes including symptoms control and quality of life parameters are important indicators of success. Quality of life in patients with recurrent HH may be severely disrupted to the point of affecting everyday activities, social functioning, and mental health [42–44]. We found a noteworthy improvement (> 50% from baseline) in GERD-HRQL scores in both patient groups compared to baseline. Similarly, the generic SF-36 questionnaires showed an improvement in both physical and mental component summaries with improvement of physical limitations (physical functioning and role-physical), suffered pain (bodily pain), self-health perception (general health), sense of vigor (vitality), ability to participate in social activities (social functioning), and level of depression (mental health). These data are in line with a recent systematic review [45].

We acknowledge some limitations related to the retrospective design of this study. Despite the homogeneous patient population, allocation bias should be considered while interpreting our results. Further, the limited number of included patients and recurrences did not allow a robust multivariate regression analysis to assess potential risk factors for recurrence. Therefore, this preliminary comparative analysis of efficacy of Phasix-ST® mesh reinforcement versus simple repair should be interpreted cautiously and mandates future research.

Conclusions

Laparoscopic revisional surgery for recurrent HH is safe and effective, and is associated with substantial quality of life improvement. Selective use of biosynthetic mesh may protect from early recurrence and may be beneficial to reduce re-herniation in the very long-term follow-up.

Supplementary Information The online version contains supplementary material available at <https://doi.org/10.1007/s10029-024-03023-x>.

Acknowledgements This work was supported by AIRES (Associazione Italiana Ricerca ESofago)

Funding Open access funding provided by Università degli Studi di Milano within the CRUI-CARE Agreement. No financial support was necessary for this study.

Data availability Not applicable.

Declarations

Conflict of interest No conflict of interest to be declared by the authors.

Ethical approval All procedures performed in this study involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Human and animal rights No animal was used for this study.

Informed consent Informed written consent was obtained from all patients before surgery.

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