Could Mesh Placement Solve the Problem of High Radiological and Symptomatic Recurrence in Patients with a Large Sliding Hiatal Hernia? A Prospective Comparative Study

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Introduction: Large sliding Hiatal Hernia (HH) is associated with an exceedingly high incidence of recurrence after surgery. An ongoing controversy exists while managing it regarding the best surgical technique. We aimed to compare laparoscopic mesh hernioplasty to laparoscopic suture crurorraphy for a large HH in terms of the disease-specific Gastroesophageal Reflux Disease-Health Related Quality of Life (GERD-HRQL) score, HH recurrence, and postoperative complications.

Patients and methods: This prospective study was conducted between December 2019 to August 2023 on patients diagnosed with a large sliding HH and refractory GERD undergoing either laparoscopic suture crurorraphy (Group A) or laparoscopic mesh hernioplasty using the Symbotex™ composite mesh (Group B). Patients were assessed for GERD-HRQL score, postoperative complications, recurrence of symptoms, or hernia.

Results: Throughout the study period, 34 patients with refractory GERD and large HH were included. Both techniques were comparable with no statistically significant difference in the operative time (78.7 ±18.9 min vs 81.1 ± 17.4, p=0.54), hospital stay (2.8 ± 0.6 days vs 2.6 ± 0.9, p=0.42), and postoperative complications (5 vs 6, p=1). Mesh placement was associated with a statistically significant lower rate of recurrence (P=0.042). GERD HRQL score was significantly lower in the mesh hernioplasty group at 6 months (p=0.042), 12 months (p=0.036) and 18 months (p=00.023).

Conclusion: Mesh placement significantly reduced the recurrence of a large HH and was associated with more improvement in the GERD HRQL score.

Key words: Gastroesophageal reflux disease, laparoscopic Toupet fundoplication, large hiatal hernia, suture crurorraphy, Symbotex mesh.

Introduction

HH is a common disorder with a prevalence of 20% according to a population-based study done in Sweden,[1] which rises to 51% in those with a body mass index (BMI) greater than 35kg/m2.[2]

Large sliding HH is defined radiologically by the herniation of greater than 30% of the stomach in the posterior mediastinum in an upper GIT contrast series,[3] and is defined endoscopically by the presence of 6 cm or more of the stomach above the diaphragm.[4] This is confirmed laparoscopically by an intercrural distance exceeding 5 cm, and/or a hiatal surface area (HSA) of more than 10 cm.[3] HSA is calculated by an equation proposed by Dr Frank Granderath in 2007.5 Using these definitions, only 5–10% of all HH are considered large HH.[4]

Tension-free suture crurorraphy in those patients is challenging especially if the crura are thin and atrophic and is associated with an exceedingly high incidence of recurrence. Given its success in repairing other types of hernia, mesh placement is a salvage step to prevent recurrence. The polypropylene mesh was initially used, however; the lack of evidence of its value in the management of large HH along with the wide range of mesh-related complications has led to a backstep in the routine application of mesh in large HH.[3,6]

The biomeshes were then used with no mesh-related sequelae. However, mid-term studies showed disappointing results with a recurrence rate of 54% after biomesh (Surgisis mesh®) application and 59% with the suture crurorraphy technique.[7,8]

Double-face meshes were then tried as a last-resort option with good outcomes. Symbotex composite mesh™ combines reinforced strength, significant tissue ingrowth due to its polyester-based parietal side and gentle non-erosive adherence due to its bioabsorbable collagen film on the visceral side.

A meticulous literature review unravelled marked technical heterogeneity in the form of the use of different mesh types, sizes, shapes, and fixation techniques in different randomized trials studying this issue. All these variables in addition to different follow-up periods make the comparison between them almost impossible with the resultant absence of any consensus or guidelines in this context.6 Therefore, we aimed to unveil the outcomes of large HH repair comparing laparoscopic mesh hernioplasty and laparoscopic suture crurorraphy in terms of GERD-HRQL score, recurrence, and intra and postoperative complications.

Patients and methods

Upon approval of the institutional review board, this prospective study was conducted at Ain Shams

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University Hospitals, Cairo, Egypt, on all patients suffered from a large sliding HH and refractory GERD undergoing either suture crurorraphy or laparoscopic mesh hernioplasty between December 2019 to August 2023. Large HH is defined by the herniation of more than one-third of the stomach into the chest in a barium study, which is confirmed endoscopically by the presence of greater than six cm of the stomach above the diaphragm. Patients with emergent and recurrent HH were excluded. Informed consent was obtained from all patients.

Preoperative assessment

Patients were assessed clinically with detailed history and examination. They had to complete a standardized preoperative GERD HRQL assessment form. We used the GERD-HRQL score,[9,10] to trace and identify the resolution, improvement, or relapse of GERD symptoms. All patients had preoperative laboratory investigations, upper GI endoscopy, upper GIT contrast study, and esophageal manometry.

Surgical technique

Both procedures were done under general anesthesia with the patient placed in the French position with a 20° reverse Trendelenburg position. The dissection started from left to right, starting with the gastric greater curvature by sealing the short gastric vessels via LigaSure™ (Medtronic Parkway, Minneapolis, USA). Meticulous dissection of the left crus from the esophagus was done with greater care to identify the left pleura. Then we turned to dissect the anterior aspect of the hiatus separating the sac carefully from the mediastinal structures and the right pleura as illustrated in **(Figs. 1a-d).**

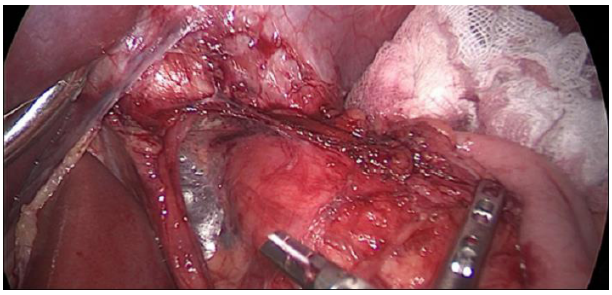

Fig 1a: Dissection of HH.

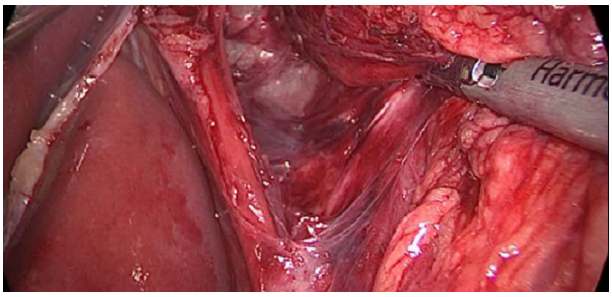

Fig 1b: Dissection of HH.

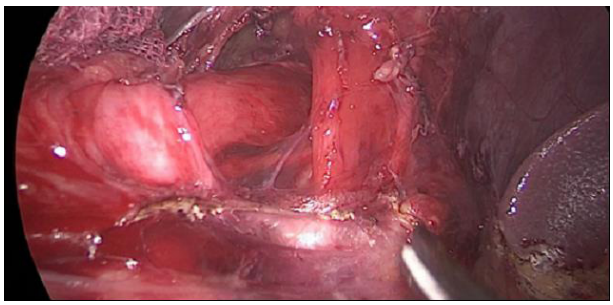

Fig 1c: Dissection of HH.

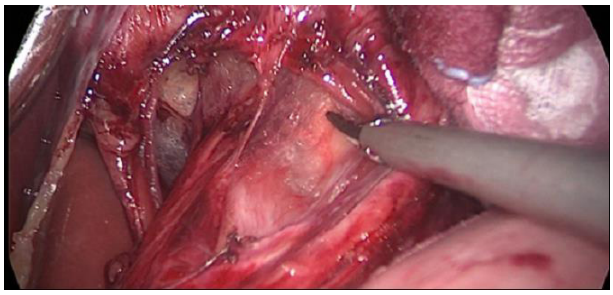

Fig 1d: Dissection of HH.

Dissection of the retroesophageal area was the last step. It was crucial to accurately identify the direction and the plane of dissection keeping it towards the lateral aspect of the left crus. This was because the widely separated crura in large hernias could lead to a hazardous intrahiatal dissection with the resultant iatrogenic left pleural injury. Achieving a 3-4 cm length of the intrabdominal esophagus was a must. This measurement was obtained while the bougie was outside the esophagus because it pushed the esophagus downward. In two patients, a short easophagus was encountered, therefore; Collis procedure was done.

Here, the two crura were approximated using 2-4 interrupted stitches of Ethibond 2-0 (Ethicon, Spreitenbach, Switzerland) starting from down **(Figs. 2a,b).** The descending aorta injured while taking the lowermost stitch, so it must be taken cautiously. It was of utmost importance to keep a good distance between the esophagus and the uppermost stitch that admitted the tip of a 5 mm grasper easily. Checking of bougie movement by anaesthesia was done.

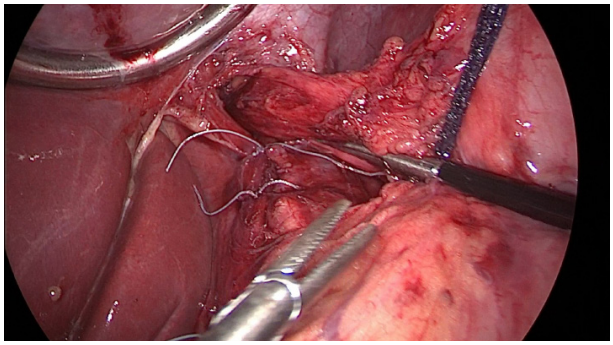

Fig 2a: laparoscopic suture crurorraphy.

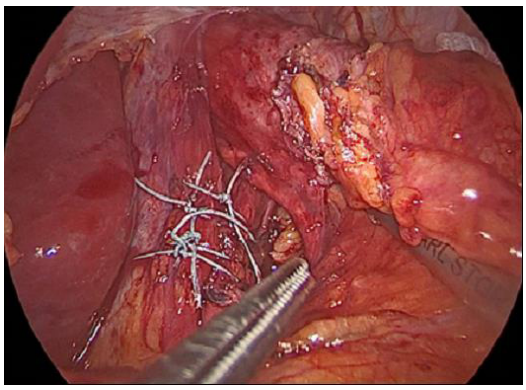

Fig 2b: Laparoscopic suture crurorraphy.

For those whose crura were very thin and could not be approximated without tension, a Symbotex™ composite mesh (Covidien, Mansfield, Massachusetts, USA) was centralized over the hiatal defect in a keyhole pattern. Orientation of this mesh was requisited to avoid erosion and recurrence. The green mark (on its polyester side) had to be towards the diaphragm and centralized over the defect, and then the central green mark was cut and removed tailoring the mesh as a keyhole pattern. It was fixed by Absorbatack™ (Medtronic, Parkway, Minneapolis) circumferentially while avoiding fixation to the central tendon to avoid pericardial injury as shown in **(Fig. 3a,3b).** Laparoscopic Toupet fundoplication was then done for all cases **(Fig. 4).** The patients who had suture crurorraphy were allocated to group (A) whereas those who had mesh hernioplasty were allocated to group (B).

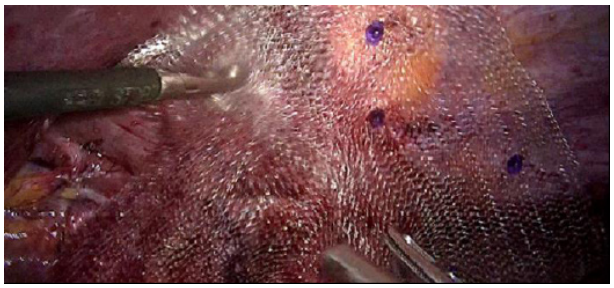

Fig 3a: Laparoscopic mesh hernioplasty.

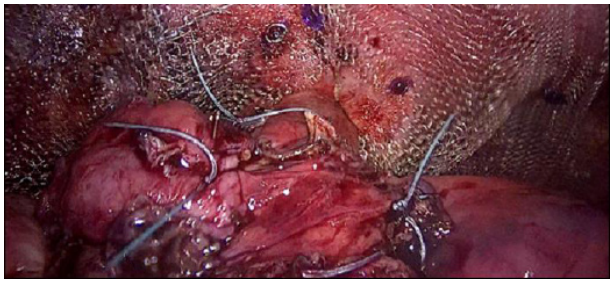

Fig 3b: Laparoscopic mesh hernioplasty.

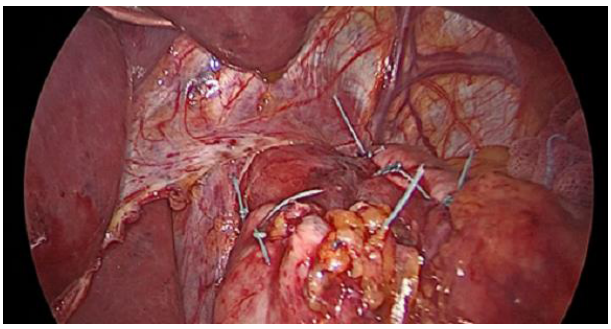

Fig 4: Laparoscopic Toupet fundoplication.

Postoperative period

All patients were asked to abide by regular follow-up at 6, 12, and 18 months. At each visit, they had to fill out the GERD HRQL questionnaire and have a barium study. The improvement or worsening of symptoms was assessed via the GERD HRQL score which is a ten-item standardized score. Each item is scored between zero and five. Any score below ten was considered normal. The HH recurrence was defined based on the recurrence of symptoms (Reincrease of the GERD HRQL score) associated with radiological and/or endoscopic evidence of recurrence (Aiolfi). The results along with the intra and postoperative complications were recorded and statistically verified to check for their relevance.

Statistical analysis

We used the standard descriptive statistics to analyze the data. The numeric data were presented in median and IQR and were compared via the independent t-test whereas the categorical variables were presented in frequency and percentage and were compared using the Chi-square test or Fischer exact test as appropriate. In addition, the Mann–Whitney U test was performed to compare unrelated parametric data.

The statistical analyses were done using the Statistical Package for the Social Sciences, software package for Windows version 29.0.1 (SPSS Inc., Chicago, Illinois, USA). The P-value is considered significant if it is less than 0.05, and highly significant if it is less than 0.01.

Results

Throughout the study period from December 2019 to August 2023, 39 patients with refractory GERD and a large sliding HH were included. Five patients were excluded due to an incomplete follow-up period. Hence, 34 patients were enrolled in this study and were subdivided into group A (Suture crurorraphy) and group B (Mesh hernioplasty). The baseline characteristics of included patients are illustrated in **(Table 1)** and showed that there is no statistically significant difference between both groups regarding these data.

We compared both techniques regarding operative time, hospital stay, and postoperative complications. Both procedures were comparable with no statistically significant difference between both groups in the operative time (78.7 ±18.9 min vs 81.1 ± 17.4, p=0.54), hospital stay (2.8 ± 0.6 days vs 2.6 ± 0.9, p=0.42), and postoperative complications (5 vs 6, p=1), **(Table 2).**

There were two cases of recurrence in the suture group and only one case in the mesh group (P=0.042) **(Figs. 5a,b).** All were asymptomatic and diagnosed by the routine 18-month barium study except one in the suture crurorraphy group. This patient with symptomatic recurrence was diagnosed clinically at 12 months and confirmed endoscopically. She was 37 years old and was reoperated with mesh fixation with a smooth uneventful postoperative period.

Improvement of the QOL after refractory GERD due to a large HH was assessed. GERD HRQL score was significantly lower in the mesh hernioplasty group at 6 months (P=0.042), 12 months (P=0.036) and 18 months (P=00.023) **(Table 3).**

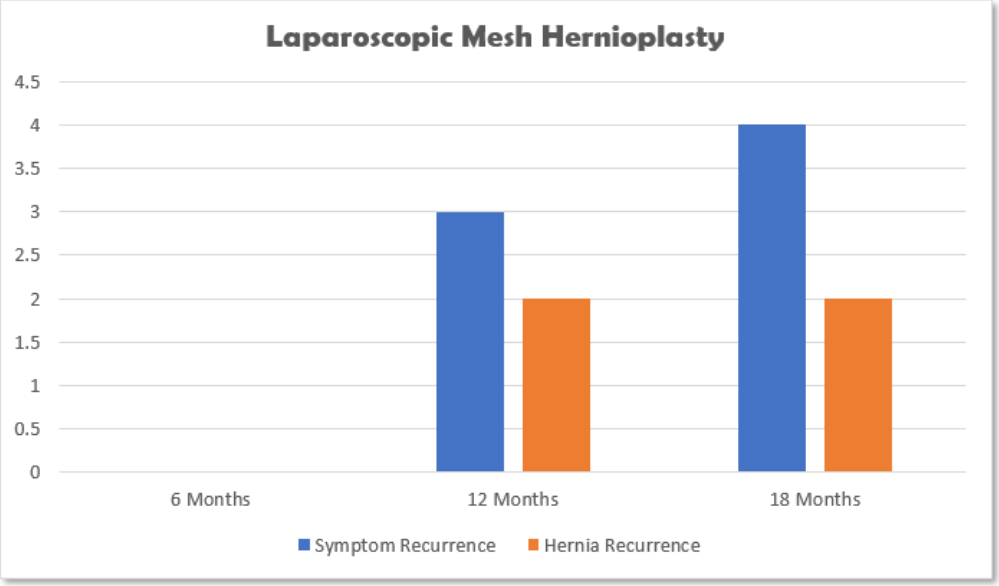

Fig 5A: Comparison between both procedures regarding hernia and symptom recurrence.

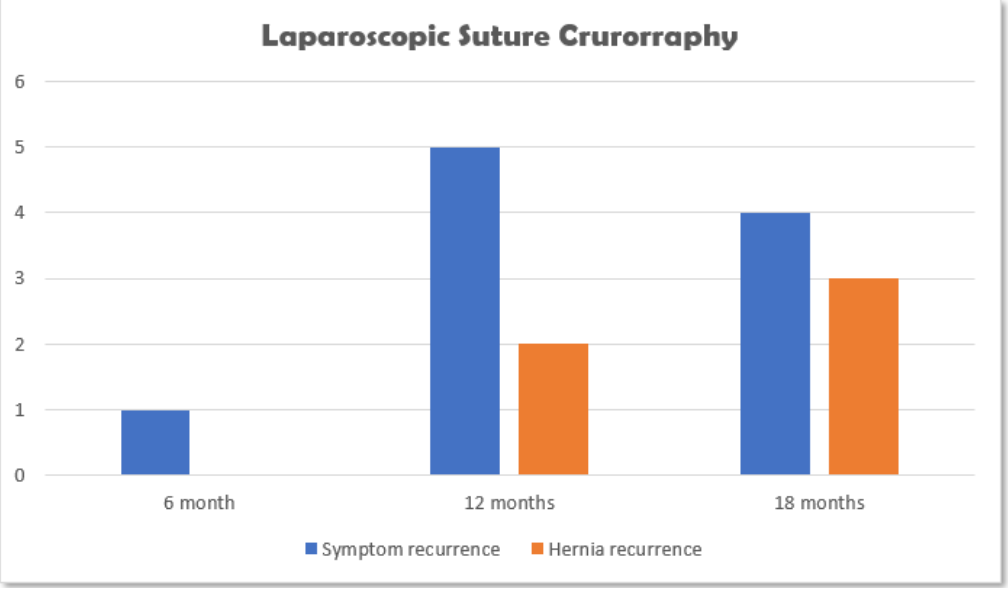

Fig 5B: Comparison between both procedures regarding hernia and symptom recurrence.

Table 1: The baseline data of included patients

Variables	Group (A) Suture crurorraphy (n=19)	Group (B) Mesh hernioplasty (n=15)	P-value
Age (mean±SD)	30.5±8.6	29.9±9.1	0.56*
Gender			
Male	8	6	0.14#
Female	11	9	
GERD-HRQL (mean±SD)	17.1±2.3	16.4±2.9	0.77*

*Via the Mann-Whitney U test.

Via the Fisher's exact test.

Table 2: The postoperative complications in both procedures

Variable	Group (A) Suture crurorraphy	Group (B) Mesh hernioplasty	P-Value
Post-operative complications	4	5	0.73
Surgical site infection	1	2	
Dysphagia	1	1	
pneumothorax	2	1	

Table 3: The mean difference in GERD HRQL score between both techniques

GERD HRQL (mean±SD)	Group (A) Suture crurorraphy	Group (B) Mesh hernioplasty	P-Value
6m	3.8 ± 0.7	3.4 ±0.6	0.042
12m	3.2 ± 0.5	2.8 ±0.3	0.036
18m	3.1 ± 0.4	2.6 ±0.5	0.023

Discussion

Since it was first introduced by Dallemagne in 1991,[11] Laparoscopic HH repair is gaining more popularity and now is considered the gold standard treatment of GERD with or without HH.[3,12] Four years later, Dr Edelman,[13] in Florida published the first experience of mesh used in the laparoscopic repair of paraesophageal hernia.

In the laparoscopic HH repair, there is a consensus regarding three steps, a complete hernial sac reduction, attaining at least 2-3 cm of the intraabdominal esophagus, and tension-free repair of the defect.[14,15] The ideal mesh should be malleable considering the dynamic nature of the hiatus, biocompatible,[16] provide adequate strength to the hiatal defect, and at the same time not erode the esophagus or cause late dysphagia.[6-8] Therefore, until now, there is no ideal mesh to be applied for large HH. All surgical meshes could be subdivided into synthetic, biosynthetic, or biological mesh.

The synthesis of the first polypropylene mesh in 1957 along with the concept of tension-free repair was the dawn of a new era in hernia surgery that led to a marked decrease in the incidence of recurrence of inguinal, femoral and incisional hernia.[17,18] It was confirmed that the polypropylene mesh leads to fistula formation when it comes in direct contact with abdominal viscera. Despite this fact, some tried to apply it in large HH repair. This has led to catastrophic complications such as mesh erosion and/or esophageal stenosis which led the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) in 2013 to advise against its use.[19] PTFE was first used by Frantzides et al,[20] with no mesh-related sequelae.

The biosynthetic meshes used either polypropylene, polyester or PTFE as a base to gain strength and prevent recurrence, with the addition of another layer that acts as a barrier to prevent erosion. The added layers included polyglactin 910 (VYPRO I; Ethicon, Spreitenbach, Switzerland), poliglecaprone, hyaluronate, atomic titanium dioxide surface coating (TiO2Mesh™) (BioCer, Entwicklungs, Germany),[16] omega 3 fatty acids, Light-weight titanium (TiMesh™) (Medizintechnik, Nuremberg, Germany),[21] and bioabsorbable collagen film (Symbotex™).

Biodegradable (Allogenic and xenogenic) meshes were innovated and presented to the surgical community as an alternative to synthetic non-absorbable mesh with no risk of erosion. The biological mesh has the advantage of resisting bacterial colonization. They include Human acellular

dermal matrix (ACDM),[22] porcine small intestinal submucosa (Surgisis, Cook Surgical, Indianapolis),[7,8] bovine pericardium, Cross-Linked collagen mesh, and poly-4-hydroxybutyrate (P4HB) (Phasix ST™) (BD, Allschwil, Switzerland).[23]

Oeschlager and his colleagues in a landmark study using a Surgisis mesh® reported that it significantly decreased the recurrence rate from 24 to 9% at 6 months.[7] Surprisingly, these initial results are not durable with a 59% recurrence at 5 years (in comparison to 54% for suture crurorraphy).[8] A survey of the SAGES reported a 44% recurrence rate with the biological meshes.[24] They stated that the difficulty in determining the long-term results of mesh fixation is due to the limited number of high-quality long-term follow-up published randomized controlled trials (RCT) using different types of meshes, and different techniques.

Three years later, and in support of these results, a Dutch team published a systematic review and meta-analysis of 26 studies that compared 924 patients with mesh repair versus 340 patients with suture crurorraphy. Authors found heterogeneity regarding the types of mesh used as well as the short duration of follow-up. They reported a recurrence rate of 14.6% after mesh placement in comparison to 26.3% after suture crurorrahphy.[25]

In August 2013, Symbotex™ was approved by the Food and Drug Administration (FDA) to be used in hernia surgery. Seven months later, it was introduced to the surgical community for the first time during the 16th annual meeting of the American Hernia Society. Indeed, Symbotex™ provides sufficient strength to prevent recurrence via its polyester content while at the same time causing no erosion due to its bioabsorbable collagen film. To our best knowledge, only a few case series studying Symbotex™ mesh for HH. In 2022, a Japanese team published a case study of a 39-year-old female with a type III HH who had a repair with Symbotex™ mesh and was followed for one year without recurrence.[26]

Recurrence of HH could be attributed to a large hiatal defect, incomplete hernial sac excision, weak or split crura, tension repair,[3,6] incomplete esophageal mobilization,[15] and undoubtedly linked to the presence of a short esophagus.[4] A short esophagus is defined as the need for further esophageal lengthening despite complete sac excision and intrathoracic esophageal dissection. Therefore, it is considered an important cause of recurrence irrespective of the technique used for repair.[4] Another pertinent factor is the U-shaped technique for mesh fixation because it leaves the naturally weak area at the anterior hiatal aspect unaugmented.[6,27]

In this trial, there were three cases of recurrence (8.8%) (Two in the suture group (10.5%) and one in the mesh group (6.6%). Two of them were asymptomatic and accidentally discovered by a routine contrast study. One patient in group A had symptomatic recurrence for which she was reoperated with mesh fixation with no further recurrence during the follow-up period.

This is in line with the previously published studies which showed a recurrence rate of 11.2-42% after suture crurorraphy in comparison to 2-9% in the mesh group.[28,29] Along the same lines, many studies continued to show the importance of mesh in reducing recurrence with a rate down to 5.8%.[20,30,31] Sathasivam et al,[15] from James Cook University, UK showed in a meta-analysis of 942 PEH repair patients that mesh significantly decreased the recurrence when compared to suture repair with no difference in the postoperative complication. However, they did not report any difference in the outcomes related to the types of mesh used. These results are in accordance with the outcomes concluded by two other meta-analyses,[14,32] which showed a significant (50-56%) reduction in the recurrence rate of mesh compared to suture crurorraphy.

Morino et al 4 in their study on 65 Patients with a large HH compared suture crurorraphy, mesh hernioplasty and Collis-Nissen gastroplasty (For short esophagus cases only). Recurrence was detected in 30% of cases (70% of them occurred during the first year). The mesh placement significantly decreases the recurrence rate. Similar to the previous observations, Muller-stitch et al,[33] recommended placing a mesh routinely in their study on 56 PEH. They had seven cases of radiological recurrence (All in the suture group).

Supporting this asseveration, Ilyashenko et al,[29] in their four-year study using the ProGrip™ self-gripping mesh found that there is no significant difference in the short-term outcomes of the mesh group and the suture crurorraphy groups in terms of GERD HRQL score and HH recurrence. However, at the four-year follow-up, the mesh showed a much lower recurrence rate of 2.9% (In comparison to 22.9% in the suture group). Additionally, the mesh group had a significantly lower GERD HRQL score than the suture group.

On the contrary, other studies,[34-38] failed to find any statistical difference between mesh and suture crurorraphy both in the short-term and medium-term follow-up. These results could be further supported by a retrospective trial,[39] using Gore Dual Mesh (GORE, Flagstaff, AZ) with a 4.3-year follow-up period. Additionally, a recent multicenter RCT of 126 patients with a large HH were allocated to 3 groups. Forty-three patients had suture crurorraphy, 41 had an absorbable mesh, and 42 had a non-absorbable mesh. After 5 years of follow-up, no

difference between the three groups in recurrence of HH or clinical outcomes, but the absorbable mesh was associated with chest pain, bloating symptoms, and diarrhea.[40]

As mentioned earlier, the patient's QOL and improvement of symptoms are a cornerstone to assess the success of any intervention for HH. Therefore, the most important symptoms were gathered as symptom scores such as the GERD HRQL scale 9,10 and the Gastrointestinal Quality of Life Index and Satisfaction scale.[41] Given its target to treat a functional disorder, laparoscopic HH repair outcomes are to some extent subjective. GERD HRQL score is a validated score suggested by Velanovich in 1996.[9] It can unveil the subjective changes by comparing the preoperative and the postoperative symptoms. By using this score questionnaire, Soricelli et al[12] speculated that sutures plus on-lay mesh are the best surgical technique by comparing it with mesh alone and suture crurorraphy.

Oelschlager et al[8] concluded that both Surgisis™ biosynthetic mesh and suture cruroplasty techniques markedly improve the symptoms at five years follow-up period with no statistically significant difference between both techniques regarding symptomatic improvement. Others,[30,42] showed that mesh placement leads to worsening of the preoperative symptoms.

Surprisingly, only 50-57% of radiologically recurrent cases were symptomatic.[33,43-45] Hietaniemi et al[46] concluded that radiological recurrence did not correlate to patients' QOL in their trial of 165 patients with a radiological recurrence rate reaching up to 29.3%.

Regarding other complications, two patients (One in each group) developed early dysphagia mostly due to edema that improved on conservative measures. Ilyashenko 29 described three cases in their series, one of them needed endoscopic wrap dilation.

Regarding the operating time, there was no statistically significant difference between both groups (78.7±18.9 min vs 81.1±17.4, p=0.54). In this context, some studies showed that mesh enforcement statistically prolongs operative time.[20] However, others considered this prolongation to be non-significant.[8,33]

A step in the right way to standardize the decision, an Italian study of 50 patients was published in 2022 by Aiolfi et al.[23] They suggested a patient-tailored algorithm (PTA) for the management of HH which includes: HH type, HH recurrence, Hiatus diastasis and degree of pillars tropism (Hypoplastic or normal). They recommended suture crurorraphy only if PTA is less than five and mesh hiatoplasty if PTA is greater than five. The limitations of the study include its short follow-up period and relatively small number of patients.

Conclusion

In this study and after a follow-up period of 18 months, laparoscopic mesh hernioplasty and suture crurorraphy were comparable regarding operative time, hospital stay, and postoperative complications. However, mesh hernioplasty significantly reduced recurrence and improved the GERD-HRQL score compared to suture crurorraphy.

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