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Laparoscopic management of large hiatal hernia: mesh method with the use of ProGrip mesh versus standard crural repair

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Abstract

Background Primary repair of large hiatal hernia is associated with a high recurrence rate. The use of mesh can lead to a reduce of recurrence rate. Despite this reduction, the type of mesh used and the placement technique are controversial. In our study, we used a new type of non-absorbable, self-fixating mesh to reinforce the cruroplasty. The aim of the present study was to compare the long-term results of laparoscopic treatment of large hiatal hernia with mesh reinforcement versus simple crura repair.

Methods This study was performed on 98 gastroesophageal reflux disease patients who underwent Nissen fundoplication with mesh-augmented crura repair and fundoplication with standard crura repair. We used non-absorbable laparoscopic self-fixating mesh by ProGrip™. All patients were separated into the mesh group ($n=50$) and non-mesh group ($n=48$). The groups were evaluated according to the following criteria: dysphagia, patients' symptomatic outcome judgment according to The Gastroesophageal Reflux Disease-Health Related Quality of Life (GERD-HRQL) questionnaire and patients' satisfaction, hiatal hernia recurrence according to upper endoscopy and a barium contrast swallow study. Follow-up was completed in 95 (97%) patients with a mean follow-up duration of 54 months (range 12–62 months).

Results Mean operative time was not significantly different ($p=0.30302$). During the 48 months of follow-up, one recurrence occurred in the mesh group and eight recurrences appeared in the non-mesh group ($p=0.027$). Patient satisfaction was significantly higher in the mesh group ($p=0.004$). The mesh group had a more significant improvement in GERD-HRQL score ($p<0.0001$) compared to the non-mesh group.

Conclusion In conclusion, this study confirms that laparoscopic repair of large hiatal hernias is effective and durable over a long period of time. Reinforcement of crura repair with ProGrip™ mesh is safe and can prevent anatomical recurrences.

Keyword Reinforcement of the crura · Self-fixating mesh · Nissen fundoplication · Dysphagia

Most patients with large hiatal hernia have the following concomitant symptoms: dyspnea, aspiration, recurrent anemia, and an increased risk of mechanical complications, such as gastric volvulus, which may cause mortality and serious morbidity [1, 2].

Laparoscopic cruroplasty with total or partial fundoplication is currently the standard of care for patients with large hiatal hernias, but it is often associated with high anatomical recurrence rate [3]. To reduce the recurrence rate in recent years there has been an increased use of prosthetic mesh to reinforce the esophageal hiatus. The crural musculature is a dynamic structure that can be affected by breathing, coughing, and vomiting after cruroplasty. The hiatal hernia (HH) repair can generate additional lateral tension [4]. Increase lateral tension of the crural musculature is associated with a high recurrence, especially after simple suture repair [5]. Reinforcement of the crura with prosthetic mesh can possibly reduce recurrence after laparoscopic cruroplasty [6–8]. One of the most common prosthetic materials is non-absorbable synthetic mesh. This mesh has been confirmed to reduce the recurrence rate [7], but is associated with esophageal scarring, stricture, erosion, and perforation [9]. Management of these complications is difficult

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and may require esophagectomy or gastrectomy [10]. Some surgeons are beginning to use absorbable biologic mesh try to avoid these serious complications. The advantages of biologic meshes for reducing recurrences have been shown but unfortunately these advantages diminish during long-term follow-up [11–13]. A survey of SAGES members has revealed a recurrence rate as high as 44% when using biological mesh [14].

A serious technical problem is the fixation of the mesh to the crura. The use of tackers may result in serious complications. A simple suture to fix the mesh can lead to dislocation of the mesh and erosion of the esophagus. To avoid dislocation problems, the majority of surgeons use large pieces of the mesh with the keyhole for the esophagus in the center of mesh. Such mesh with the keyhole can lead to serious complications in some cases [11].

To prevent such complications, we used small pieces of non-absorbable meshes to reinforce the cruroplasty. In this case, we begin to use a new type of non-absorbable self-fixating mesh, ProGrip™, that allowed us to perform the laparoscopic procedure more easily.

Methods

We only included patients with type III hiatal hernia larger than 10 cm^2 (10–20 cm^2). Hiatal surface areas (HSAs) were screened for the study. Patients with previously failed hernia repairs and those undergoing emergency procedures were excluded.

All patients underwent a standard preoperative work-up including medical history, GERD-HRQL questionnaire, physical examination, blood test analysis, EKG, Chest-X ray, barium swallow study, upper gastrointestinal endoscopy, and 24-pH monitoring. CT-scans of the chest and abdomen were performed in selected patients.

Clinical evaluation was performed at 3, 6, 12, 24, and 48 months, after operation. The GERD-HRQL questionnaire, a validated disease-specific assessment tool was administered 3, 6, 12, 24, and 48 months after discharge. A barium swallow study was routinely performed 3 months after surgery and then yearly. The upper gastrointestinal endoscopy was performed 6–12 months after surgery or at any time the patient complained of symptoms. Every patient repeated the upper gastrointestinal endoscopy every year. 24-pH monitoring was performed 6, 12, 24, and 48 months after operation. Patients were separated into the mesh group (mesh-augmented crura repair plus fundoplication) and non-mesh group (standard crura repair plus fundoplication). Informed consent for randomization to use mesh or non-use mesh was obtained. Randomization was performed with the use of a computer-generated randomization schedule.

The primary outcome was hiatal hernia recurrence, defined using endoscopy and barium swallow study. Secondary outcomes included safety, efficacy, and long-term quality of life. Study protocol was approved by the Internal Review Board.

Surgical technique

The procedures were performed by two experienced surgeons trained in upper gastrointestinal surgery. Four trocars were used for the laparoscopic approach. The first step of the operation consisted of—bringing down the herniated stomach, excision of the hernia sac, and mobilization of 5–7 cm of intra abdomen esophagus. Care was taken to preserve both vagal nerves. Posterior cruroplasty was routinely performed using interrupted non-absorbable sutures. For measurement of the hiatal defect, the method proposed by Dr. Frank Alexander Granderath [15] was used. First, the length of the crura is measured in centimeters beginning at the crural commissure up to the edge where the pars flaccida begin (radius R). Then the circuit between both crural edges is measured [16]. The HSAs were calculated with the formula: $\text{HSAs} = B \times R/2$. The patients who had HSAs of 10–20 cm^2 were included in this study. In the mesh group, ProGrip™ mesh with a "U" configuration was implanted on the hiatus. Typically, we cut pieces of ProGrip™ mesh into a U-shaped configuration, but the size of the mesh was chosen individually depending on the anatomical situation (Fig. 1).

We do not use sutures for fixation of the ProGrip™ mesh. The surgeons can identify good fixation of the mesh to the crural after pressure on it for 1–2 min. In some patients with a large hernia anterior cruroplasty was performed. In these patients, pieces of ProGrip™ mesh sized 4–6 cm were used for reinforcements of sutures.

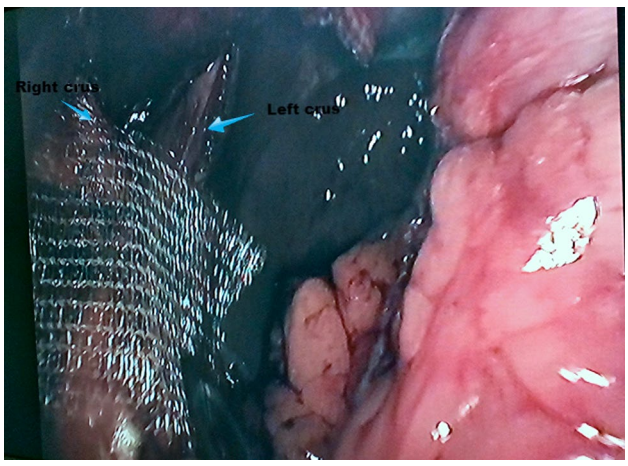

Fig. 1 Mesh group: reinforcement of crura repair with ProGrip™ mesh

Following fat pad excision and division of short gastric vessels, a tension-free total (Nissen) fundoplication was performed in all patients.

Statistical analysis

The following tests were used: the Chi-square test or Fisher's exact test as appropriate for nominal data, and Mann–Whitney *U* test for comparison of unrelated parametric data. A *p* value of <0.05 was considered statistically significant.

Results

Out of 460 patients 98 (21.3%) who were operated on between January 2011 and January 2014 met the inclusion criteria for the study and were therefore separated into the mesh group ($n=50$) and non-mesh group ($n=48$). The two groups were comparable in terms of demographic and preoperative clinical characteristics (Table 1).

All the operations were completed laparoscopically. The medium operative time was 96 ± 12 min in mesh group and 92 ± 15 in non-mesh group ($p=0.30302$). The fixing of the self-locking mesh ProGrip™ takes only 5–10 min. In seven patients from the mesh group, anterior cruroplasty was used with mesh reinforcement. In the non-mesh group, anterior cruroplasty was performed in five patients. There were no major intraoperative complications or mortality. Overall, the postoperative morbidity rate was 3% and consisted of pneumothorax ($n=2$), and atrial fibrillation ($n=1$) without significant differences between the two groups. There were no differences in the median hospital stay between groups (Table 2).

Follow-up was completed in 95 (97%) patients with a mean duration of 54 months (range 12–62 months). The barium swallow study after 3-month follow-up did not show any recurrence. After 6 months all identified recurrence was in the non-mesh group (2%).

There were 11 recurrences detected by endoscopic and barium swallow-examination during the follow-up: 1 in the mesh group and 10 in the standard repair group ($p=0.0034$) (Table 3). The mean size of recurrent hernia was 2.5 cm in mesh group and 4.0 ± 0.7 cm in non-mesh group. Of these 11 patients, only five were symptomatic, and two of them were operated on again. Reoperation rate was (2%). No mesh-related complications were detected by endoscopy.

Three patients: one from the mesh group and two from the non-mesh group, complained of dysphagia, which was due to a tight wrap. Only one patient needed endoscopic dilation of the wrap.

After 6 months there was no significant difference between the two groups with regard to patient satisfaction (Table 4). All patients who scored their symptoms as "bad" or "fair" had improvement of their GERD symptoms but developed new-onset dysphagia, especially after swallowing solids too quickly, resulting in discomfort. After 48 months we detected more recurrences in the non-mesh group. Anatomical recurrence was detected only in one patient from the mesh group and in eight patients from the non-mesh group ($p=0.027$). Patient satisfaction was significantly higher in the mesh group compared with the simple suture group (Table 4). Patient satisfaction was mostly connected with recurrence. Patients with recurrent hernias complained about other symptoms and had a low satisfaction rate.

Table 1 Demographic and preoperative clinical characteristics of the patient

	Mesh group	Non-mesh group	*p* Value
Patients number	50	48	
Gender (male/female)	19/31	13/35	0.824[d]
Age, (year)	62.8 ± 10.2	63.2 ± 12.5	0.63122*
COPD[a], *n* (%)	9 (18%)	7 (14.8%)	0.786
Diabetes, *n* (%)	6 (12%)	3 (12.5%)	0.486
Hypertension, *n* (%)	22 (44%)	16 (33.3%)	0.306
Median symptom (DM)[b]	76.4 ± 16.2	71.8 ± 15.8	0.1936
Median PPI therapy (DM)	50.8 ± 12.4	46.2 ± 10.8	0.07346*
PBTT[c], *n* (%)	17 (34%)	14 (29.2%)	0.667
Reflux symptoms, *n* (%)	39 (78%)	34 (70.8%)	0.490
Barrett's esophagus, *n* (%)	5 (10%)	4 (8.3%)	0.999
Chest pain, *n* (%)	28 (56%)	21 (43.8%)	0.235
Dyspnea, *n* (%)	20 (40%)	15 (31.8%)	0.405
Arrhythmia, *n* (%)	11 (22%)	8 (16.7%)	0.612
Mean GERD-HRQL score	16.4 ± 7.2	14.1 ± 5.6	0.20766*
Hernia size (cm^2)	15.2 ± 3.8	13.8 ± 3.2	0.03078*

Mean ± standard deviation, SD

*Mann–Whitney *U* test

[a]Chronic obstructive pulmonary disease

[b]During months

[c]Previous blood transfusion therapy

[d]Fisher's exact test (1-Tail *p* value)

Table 2 Early postoperative outcomes

	Mesh group	Non-mesh group	*p* value
Patients number	50	48	
Median operative time, min	96 ± 12	92 ± 15	0.30302
Postoperative morbidity, *n* (%)	2 (4%)	1 (2%)	0.886
Median hospital stay, days	4.2 ± 1.2	4.1 ± 1.3	0.59612

GERD-HRQL scores were significantly reduced and then returned to normal values in both groups (Table 5), whereas the results of the mesh group were better than the non-mesh group: 3.8 ± 1.2 versus 5.9 ± 1.1 ($p < 0.0001$), respectively.

There were no statistically significant differences regarding the postoperative DeMeester scores between the two groups (Table 5).

Discussion

Laparoscopic repair of hiatal hernia is the best method of treatment for patients with symptom of large hiatal hernia [17]. Failure to close of hiatal crura during laparoscopic anti-reflux surgery has proven to be the most common cause of persistent recurrence symptoms after surgery [18]. A recent meta-analysis showed the recurrence rate was 25.5% in the patients with large hernias [16]. Our study showed the same recurrence rate when we used suturing of the crura. A number of authors have made use of prosthetic material for crural reinforcement [4–10, 19–21], decreasing the recurrences after laparoscopic operation.

Table 3 Follow-up of the patients and recurrence rate

Period	Mesh group patients, number	Recurrence *n*/%	Non-mesh group patients, number	Recurrence *n*/%	*p* Value
3 months	50	0/0	48	0/0	1.000
6 months	50	0/0	48	1/2.1	0.490
12 months	50	0/0	48	3/6.3	0.114
24 months	46	1/2.2	42	6/14.3	0.042
36 months	38	1/2.6	37	7/18.9	0.025
48 months	34	1/2.9	35	8/22.9	0.027
60 months	27	1/3.7	24	8/33.3	0.016
Entire study period	50	1/2	48	10/20.8	0.0034

Table 4 Clinical outcome following laparoscopic anti-reflux surgery

	6-month follow-up			48-month follow-up		
	Mesh group	Non-mesh group	*p* Value	Mesh group	Non-mesh group	*p* Value
Patient number	50	48		34	35	
Hiatal hernia recurrence *n* (%)	0 (0%)	0 (0%)		1 (2.94%)	8 (22.85%)	0.027
Patient satisfaction *n* (%)						
Excellent/good	46 (92%)	44 (91.8%)	0.122	26 (76.4%)	19 (54.3%)	0.004
Fare	3 (6%)	2 (4.1%)		5 (14.7%)	6 (17.1%)	
Bad	1 (2%)	2 (4.1%)		3 (8.9%)	10 (28.6%)	
Postoperative dysphagia *n* (%)						
None/mild	45 (90%)	41 (85.4%)	0.092	27 (79.4%)	18 (51.4%)	0.004
Moderate	4 (8%)	5 (10.4%)		5 (14.7%)	11 (31.4%)	
Severe	1 (2%)	2 (4.2%)		2 (5.9%)	6 (17.2%)	

Table 5 Long-term results of anti-reflux surgery

	Before operation			48 months after surgery		
	Mesh group	Non-mesh group	*p* Value	Mesh group	Non-mesh group	*p* Value
Patient number	50	48		34	35	
Mean GERD-HRQL score	17.5 ± 5.2	16.3 ± 4.5	0.26272	3.8 ± 1.2	5.9 ± 1.1	< 0.0001
Mean DeMeester score	64.2 ± 12	70 ± 15	0.03	15.6 ± 8.2	19.4 ± 9.6	0.09692

However, no consensus exists about the use of mesh for cruroplasty reinforcement. It has been proven that a mesh repair of the crura effectively reduces the rate of postoperative hernia recurrences and intrathoracic wrap migration over long-term follow-up [7–9]. Many publications are focused on mesh-related complications such as erosion or migration of the mesh into the esophagus or stomach, the development of fibrotic strictures or adhesion in the hiatal area [10, 18, 19]. Most surgeons favor using mesh selectively [20, 22].

Reinforcement of the hiatus with mesh has been introduced in surgical practice to decrease the incidence of anatomical recurrence after standard repair of sliding and paraesophageal hiatal hernia [14, 23].

However, because of diversity in the materials, configuration and methods of fixation of the mesh, patient selection, and heterogeneous reporting of objective results, no evidence exists yet to recommend either for or against this procedure. A standard indication of prosthetic mesh for hiatal closure according to the size of the hiatal defeat is still poorly defined. The SAGES guideline committee recommends mesh crural reinforcements for a large HSA because a large hiatal defect has a higher chance of recurrence [24]. However, what are the objective features of large hernias? According to Wang et al. [25], a hiatal defect of 3 cm in length is an indication for mesh implantation. We used the formula of Granderath et al. [15, 26] for the calculation of hernia defect. For objective data, we proposed to define hernias with HSA less than 10 cm^2—small, hernias with an HSA 10 to 20 cm^2—as large, and hernias with an HSA greater than 20 cm^2—as huge [27]. In all cases, large and huge hernias are considered as an indication for mesh use. In the present study, we used mesh only in the patients with large hiatal hernia with HSAs 10–20 cm^2.

Some surgeons believe that biological meshes are the best materials for laparoscopic hernia repair [25]. Oelschlager et al. [11] reported a lower recurrence rate in the biologic mesh group at 6 months (24% in primary repair and 9% in mesh—reinforced groups). However, there was no significant difference in hernia recurrence between groups at the median follow-up period of 58 months (59% for primary versus 54% for mesh repair). The increasing rate of recurrence with time might be associated with strength and biodegradability of biomaterials. During the process of degradation, the mechanical properties of the biomaterial weaken.

Polypropylene mesh cruroplasty is the most popular method of crural closure [8, 28]. Large pieces of polypropylene mesh around the esophagus can lead to mesh erosion or migration, as well as to severe mesh adhesions or the development of fibrotic strictures leading to stenosis of the distal esophagus [4, 29]. Granderath et al. [15, 26] proposed the use of small pieces, 1×3 cm, of polypropylene mesh for reinforcement of crura repair. In the present study, we also used small pieces of ProGrip™ mesh with sizes of 4–6 cm. After suturing of the crura, ProGrip™ mesh with a "U" configuration was applied on posterior hiatoplasty. The main advantages of ProGrip™ mesh are that this kind of mesh is self-fixating. It takes only 5–10 min to properly fixate this kind of mesh to the crura. When we use polypropylene or other types of non-absorbable mesh, fixation of the mesh can be a problem. Incorrect mesh fixation can be the reason for mesh erosion or mesh migration inside the esophagus. American surgeons have used biological meshes for reinforcement of hiatal closure [30]. They used 8–10 sutures for the fixation of the mesh. To perform this type of fixation with many sutures can take a lot of time. The operative time was 214–244 min [30]. In our experience, the fixation of ProGrip™ mesh was very quick, and operative time was only 96 ± 12 min. Decreasing operative time is a great advantage because most of our patients were old with many serious clinical problems. The ProGrip™ mesh in our study has no contact with the esophagus : it only has contact with the wrap. Because of these observations, we did not see any mesh-related complications.

The most common causes of dysphagia are paraesophageal mesh-related fibrosis and intraluminal erosion [12]. In our experience, in order to avoid mesh-related complications, we use U-shaped mesh to leave an uncovered area on the anterior esophagus. We usually covered the hiatus posterior to the esophagus and avoided contact between mesh and esophagus. In our opinion, when surgeons use big pieces of mesh with the keyhole and mesh circularly surrounds the esophagus, there is greater probability of erosions and dysphagia due to contraction of the mesh over time. According to study by Rodrigo Gonzalez et al. [31], all mesh prostheses underwent contraction between 5 and 65% of their original size. Mesh that underwent the most contraction needed additional fixation points.

Our study shows the use of self-fixating ProGrip™ mesh for cruroplasty reinforcement. Our findings demonstrated that mesh repair is closely associated with symptomatic improvement and patient satisfaction in both short- and long-term follow-up, which is related to lower radiological recurrence rates following mesh repair.

Short-term follow-up showed the same rate of dysphagia in both groups. Patient satisfaction was very high: excellent/good results were found in 92% of the patients of the mesh group and in 91.8%—from the non-mesh group. However, long-term follow-up showed much better results in mesh group: excellent/good results in 92% in mesh group versus 54.3% in non-mesh group ($p = 0.004$).

These differences can be explained by recurrences of hiatal hernia. After 48 months, the recurrence rate in the non-mesh group was 22.9% versus 2.9% in the mesh group ($p = 0.027$). However, correlation between reappearance of GERD-related symptoms and HH recurrence was found.

Some patients with objective evidence of HH recurrence had no GERD-related symptoms. Surgeons from the Netherlands [32] showed that radiologic recurrences, symptomatic recurrences, reoperation rates, and patient satisfaction are equal after laparoscopic hiatal hernia repair with or without non-absorbable mesh reinforcement. In our study, satisfaction and quality of life was better in the mesh group. In our opinion, the reason for this was the large size of type III hiatal hernia in our patients and the high recurrence rate in the non-mesh group.

Subjective data such as symptom resolution, patient satisfaction, well-being, and quality of life are at least as important [33] as objective data. According to the opinions of some researcher's subjective clinical outcomes, evaluation of patient QoL and postoperative satisfaction are more important than functional data [18]. After 48 months, the mean GERD-HRQL score was better in mesh group than the non-mesh group: 3.8 ± 1.2 versus 5.9 ± 1.1 ($p < 0.001$), respectively.

We, like the majority of experts, believe that the indication to use mesh is strongly influenced by the size of the hiatal defect and the quality of the crura [16]. The advantages of the ProGrip™ mesh are easy fixation, short operation time, and absence of serious complications such as an erosion and stenosis of the esophagus. In the future, we hope to conduct a randomized trial comparing ProGrip™ mesh to standard synthetic mesh and biological mesh. It will be very interesting to use a new type of ProGrip™ mesh that is covered with a fast-resorbing collagen film on the non-sticky side.

Compliance with ethical standards

Disclosures V. V. Ilyashenko, Viktor V. Grubnyk, and V. V. Grubnik have no conflict of interest or financial ties to disclose.

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