## Comparative study between laparoscopic mesh hiatal hernioplasty versus suture cruroplasty for the repair of large hiatal hernias

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## Background

Some patients with large hiatal hernias who undergo laparoscopic hiatal cruroplasty show recurrence of hernia and/or symptoms. We are studying the outcome of laparoscopic mesh hiatal hernioplasty versus suture cruroplasty for the repair of large hiatal hernias more than 4 cm.

### Patients and methods

This is a prospective, randomized, comparative study that was conducted at the General Surgery Department of Ain Shams University Hospitals during the period from February 2019 to February 2021. The study included 20 patients with large hiatal hernia defect more than 4 cm in whom laparoscopic hiatal hernia repair was indicated. The aim of the study was to compare between feasibility, safety, and efficacy of laparoscopic mesh hiatal hernioplasty and laparoscopic hiatal hernia suture cruroplasty.

#### Results

Laparoscopic mesh hiatal hernioplasty for large hiatal hernia more than 4 cm has higher operative time  $(94 \pm 15.6 \text{ min} \text{ with } P=0.0001)$  and more intraoperative bleeding  $(130 \pm 66.8 \text{ ml} \text{ with } P=0,002)$  than laparoscopic hiatal hernia cruroplasty  $(63 \pm 8.2 \text{ min} \text{ and } 64 \pm 23.2 \text{ ml})$ . But has a better outcome regarding quality of life (at 12 months  $1.8 \pm 0.9 \text{ vs}$ .  $2.3 \pm 0.5 \text{ with } a P=0.24)$  incidence of symptoms recurrence (at 12 months, 20 vs. 30% with a P=0.605) and hernial recurrence (at 12 months 10 vs. 30% with a P=0.264).

#### Conclusion

Laparoscopic mesh hiatal hernioplasty results in improvement of symptoms, quality of life, and decrease in hernia recurrence, but evidence supporting routine use of mesh cruroplasty is low. The mesh should be used according to surgeon preference until additional studies of long-term follow-up are available.

#### Keywords:

crura repair, gastroesophageal reflux disease-health-related quality of life questionnaire, hiatal hernia, mesh placement

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## Introduction

Hiatus hernia (HH) is the term used to describe a condition where an organ, typically part of the stomach, protrudes into the lower mediastinum through a widening or weakness in the esophageal hiatus of the diaphragm. HHs can be classified as types 1–4 depending on their anatomical features [1].

Symptoms can arise from obstruction, reflux, or bleeding. Obstruction at the gastroesophageal (GEJ) or at the level of the pylorus can occur from intermittent twisting of the stomach along its long axis while herniating into the chest. Obstruction of the GEJ will cause dysphagia and regurgitation, while gastric outlet obstruction produces nausea, vomiting, and epigastric/ chest pain [2]. Controversy exists about the best technique for the repair of HH, and how to minimize the risk of hernia recurrence [Guidelines for Surgical Treatment of gastroesophageal reflux disease (GERD), 1998]. But the tenets of repair shared by most high-volume surgeons include complete mediastinal sac reduction, mobilization of at least 2–3 cm of tension-free intraabdominal esophagus, and tensionfree hiatal closure [3].

HH repair using sutures-only technique was initially used for laparoscopic repair. Subsequent studies have reported high rates of radiological recurrence of hernias,

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and this provided impetus to the use of mesh for hiatal repair, especially during the repair of large HH, even though most of the identified postoperative hernias were small and asymptomatic. Currently, the use of mesh remains controversial, with the main indication for meshaugmented hiatal repair being a large paraesophageal hernia (PEH). However, some surgeons also advocate the routine use of mesh repair for smaller sliding HHs [4].

On the other hand, the disadvantages of mesh augmentation include the risk of serious complications related to the use of prosthetic material, such as esophageal erosion and stenosis, mesh migration, local fibrosis, and dysphagia [5].

The aim of the study: to evaluate the outcome of laparoscopic mesh hiatal hernioplasty versus suture cruroplasty for the repair of large HH more than 4 cm.

## Patients and methods

This is a prospective, randomized comparative study that was conducted on 20 patients presenting to Ain Shams University Hospitals in whom laparoscopic HH repair was indicated for the management of large HH defect more than 4cm causing refractory GERD and was operated upon starting from February 2019 to February 2021 with a minimum follow-up of 1 year duration. This research was performed at the Department of General Surgery, Ain Shams University Hospitals. Ethical Committee approval and written, informed consent were obtained from all participants.

Patients were divided into two equal groups, 10 patients each, who were chosen randomly by choosing a sealed envelope method. Group A underwent laparoscopic mesh hiatal hernioplasty and group B underwent laparoscopic HH suture cruroplasty.

#### Inclusion criteria

Patients over 18 years of age and under 60 years, with symptomatic large HH (defect >4 cm) refractory to GERD symptoms despite medical treatment, identified clinically and radiologically.

## **Exclusion criteria**

Patients with recurrent HH after previous surgical repair or patients with previous major upper abdominal surgery and patients presented with any previous antireflux procedure.

#### **Preoperative assessment**

Clinical assessment

- (1) General examination.
- (2) Detailed medical, surgical, and family history.

(3) GERD health-related quality of life (HRQOL) score (Fig. 1).

## Investigations

- (1) Routine laboratory investigations.
- (2) Upper gastrointestinal endoscopy: for the diagnosis of presence of any type of HH using Loss Angeles classification and Hill grade evaluation of GEJ and assessment of reflux disease.
- (3) Esophageal manometry: for the evaluation of esophageal motility and lower esophageal sphincter pressure.

#### Operative technique

A five-port technique was used for all cases. The abdomen is entered using the Veress needle technique at the palmar's point ad exploration of the whole abdominal cavity is done. Identification and dissection of the sac as shown in Fig. 2 starts by dissection through the transparent caudal portion of the gastro-hepatic ligament (Pars flaccida) using the LigaSure device; dissection of the hernia sac begins 2 cm behind the right crus on the mediastinal reflection, as shown in Fig. 3 leaving a small portion of the sac adherent to the crus in order to avoid exposure of uncovered muscle fibers. The dissection continues toward the left crus exposing the anterior surface of the esophagus, identifying the anterior trunk of the vagus nerve (which should be preserved). The short gastric vessels are identified and divided to allow enough mobilization in order to allow a floppy fundoplication.

A tape is passed around the esophagus and clipped anteriorly and is used for traction on the esophagus to allow further posterior dissection, providing enough length of the abdominal esophagus (around 4-5 cm) completely free of tension.

# Closure of the hiatus (cruroplasty for both group A and group B) $% \left( {{\mathbf{F}}_{\mathbf{A}}} \right)$

Closure of the diaphragmatic crus as shown in Fig. 4 with a posterior approach behind the esophagus was performed using two to three nonabsorbable interrupted Ethibond 2/0 sutures. Frequently, anterior closure of the pillars may also be required with additional stitches depending on the hiatus's diameter in order to avoid angulation of the distal esophagus at the hiatal passage.

## Mesh placement (hernioplasty for group A only)

After closure of the crura by Ethibond sutures an onlay 5 cm nonabsorbable U-shaped mesh (Ventralight) is placed as shown in Fig. 5 around the esophagus and the posterior defect. Then the mesh was fixed by tuckers circumferentially around the crura and over the muscle not over the central tendon of the diaphragm itself in order to avoid pericardial or cardiac injury.

• Scale: No symptoms = 0; Symptoms noticeable, but not bothersome = 1; Symptoms noticeable and bothersome, but not every day = $2$ ; Symptoms bothersome every day = 3. Symptoms affect daily activities = 4. Symptoms are incapacitating mable to do daily activities = $5$	nptoms noticeable and bothersome, but not every day = $2$ ; notoms are incanacitating numble to do daily activities = $5$
• Questions	inverse and more than the second second and a second
1. How bad is your heartburn?	0 1 2 3 4 5
2. Heartburn when lying down?	0 1 2 3 4 5
3. Heartburn when standing up?	0 1 2 3 4 5
4. Heartburn after meals?	0 1 2 3 4 5
5. Does heartburn change your diet?	0 1 2 3 4 5
6. Does heartburn wake you from sleep?	0 1 2 3 4 5
7. Do you have difficulty swallowing?	0 1 2 3 4 5
8. Do you have pain with swallowing?	0 1 2 3 4 5
9. Do you have bloating or gassy feelings?	0 1 2 3 4 5
10. If you take medication, does this affect your daily life?	0 1 2 3 4 5
How satisfied are you with your present condition? Satisfied Neutral Dissatisfied	_ Dissatisfied
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Journal compilation $\textcircled{O}$ 2007 The International Society for Diseases of the Esophagus	agus
HRQOL patient satisfaction score. HRQOL, health-related quality of life.	

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Figure 1

Figure 2

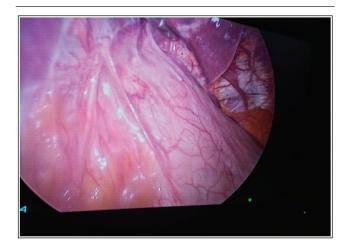
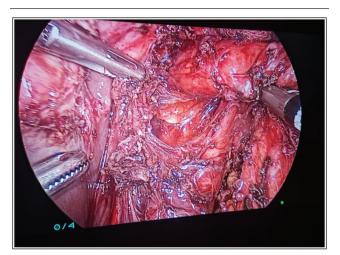


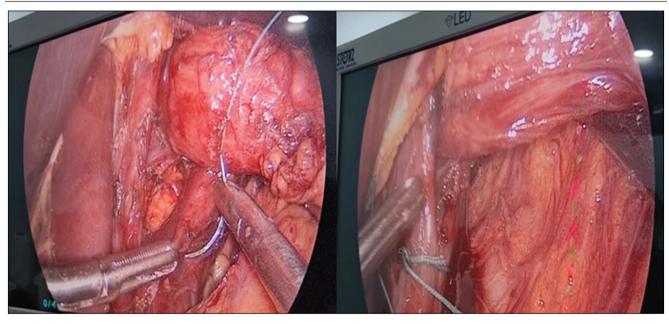
Figure 3



Hiatal defect after dissection of the sac.

Large hiatal hernia.





Closure of crus by sutures.

#### **Fundoplication**

A calibrated Nissen fundoplication over a 36 F bougie was performed with nonabsorbable Ethibond 2/0 sutures and the distal esophagus was wrapped.

## Postoperative care and follow-up

#### Immediate postoperative follow-up

The patients were kept in the hospital for 1–3 days. A naso- gastric tube was kept in situ for 24h and then removed. Patients are allowed to start oral fluids after their bowel sound became audible, and then they are allowed a soft diet on the third or fourth postoperative day and for about 2 weeks, and then started on regular oral diet.

An intraabdominal drain is used in most of the cases and mostly removed after 24 h. The patients were put on proton pump inhibitors for 2 weeks postoperatively mainly to avoid stress ulcers. Analgesics were used according to the need, and usually stopped on the third or the fourth postoperative day.

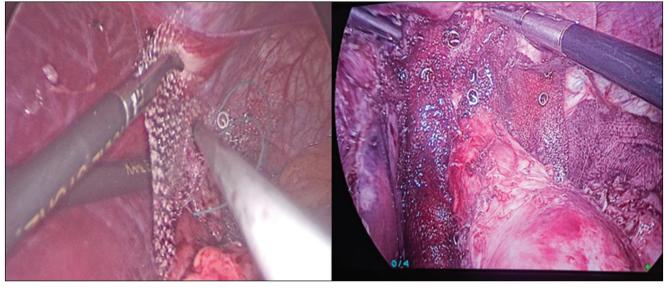
## Short-term follow-up (3-6 months)

- (1) Symptomatic improvement assessment by the HRQOL score system.
- (2) Barium meal.
- (3) Esophageal manometry.

## Medium-term follow-up (6-12 months)

- (1) Symptomatic improvement assessment by the HRQOL score system.
- (2) Upper gastrointestinal endoscopy.

#### Figure 5



Fixing mesh by tuckers circumferentially around the esophagus.

Table 1	Preoperative	demographics and	baseline quality of life
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		Groups [ <i>n</i> (%)]				
		А	l	-		
	Count	Column	Count	Column	-	
Age (mean/SD)	45.0	8.0	47.1	11.4	0.48*	
Preoperative QOL (mean/SD)	4.9	0.3	5.0	0.0	0.73*	
Sex						
Male	4	40.0	4	40.0	1.0**	
Female	6	60.0	6	60.0		

QOL, quality of life.

\*Mann–Whitney U test.

\*\* $\chi^2$  test.

### Statistical analysis

Statistical analysis was done using IBM SPSS statistics for windows, Version 23.0 (IBM Corp., Armonk, NY, USA); numeric variables were presented in mean and SD. Means were compared using the Mann–Whitney U test after normality testing. Categorical variables were presented in frequency and percentage and it was compared using the  $\chi^2$  test. Any P value less than 0.05 was considered significant.

## **Results**

In our study there were 20 patients, with a mean age of  $46.1 \pm 9.6$  years, ranging from 34 to 60 years. We had 12 (60%) female patients and eight (40%) male patients (Table 1). Regarding preoperative QOL, group A (with mesh insertion) had a mean of  $4.9 \pm 0.3$  versus  $5.0 \pm 0.0$  in group B (with suture-only repair).

During the operation, group B had a significantly shorter operative time of  $63 \pm 15.6$  min when compared with group A  $94 \pm 15.6$  min with a *P* value of 0.0001.

Table 2 Operative time and intraoperative bleeding between groups

	Groups			P value	
	А		В		_
	Mean	SD	Mean	SD	
Operative time (mean/SD)	94.0	15.6	63.0	8.2	0.0001*
Intraoperative bleeding (mean/SD)	130	66.8	64	23.2	0.002*

\*Mann–Whitney U test.

Intraoperative bleeding (Table 2) increased among group A  $130\pm66.8$  ml versus  $64\pm23.2$  ml in group B with *P* values of 0.73. One patient in group A developed intraoperative bleeding of about 300 ml from short gastric vessels and was managed intraoperatively by compression, clipping, and application of a surgical.

One patient in group A had capnothorax from  $CO_2$  leakage into the mediastinum with  $CO_2$  retention and was managed by deinsufflation for about 10 min allowing hyperventilation to a lower  $CO_2$  level and surgery was completed safely.

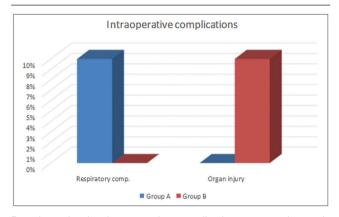
One patient (Table 3) in group B had plural injury during dissection of the sac, resulting in pneumothorax that was managed by plural repair by stitches and a chest tube was inserted into the plural cavity and was removed safely on the second postoperative day (Fig. 6).

Two patients had surgical site infection in group B at one of the laparoscopic port sites but there was no port site infection in group A. Culture was taken from the infection site and broad-spectrum antibiotics was given with daily dressing and the infection was resolved after 3 days postoperatively.

Table 3 Intraoperative organ injury and respiratory complications

	Group A [ <i>n</i> (%)]	Group B [ <i>n</i> (%)]	P value
Respiratory compl	ications		
No	9 (90.0)	10 (100.0)	0.30**
Yes	1 (10.0)	0	
Organ injury			
No	10 (100.0)	9 (90.0)	0.30**
Yes	0	1 (10.0)	
**χ² test.			

Figure 6



Bar chart showing intraoperative complications among the study groups.

Table 4 Incidence of postoperative complications between groups

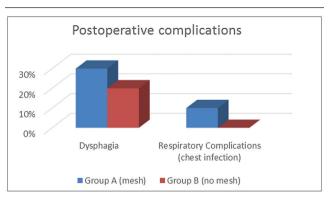
		P value			
	1	4		_	
	Count	Column	Count	Column	
Dysphagia					
No	7	70.0	8	80.0	0.60**
Yes	3	30.0	2	20.0	
Respiratory	complicati	ions (chest	infection)		
No	9	90.0	10	100.0	0.30**
Yes	1	10.0	0	0.0	
** $\chi^2$ test.					

Postoperative chest infection was reported in one patient in group A (10 vs. 0% in group B) with no significant difference with a P value of 0.30. Chest infection was manifested by an increase in temperature of 38.5, tachycardia 100 b/m with productive cough. Chest radiograph was done and showed mild form of bronchopneumonia. The patient was treated by broadspectrum antibiotics and discharged home safely on the fifth postoperative day on oral antibiotics.

## Regular follow-up at 2 weeks and 3 months

Three patients in group A and two patients in group B developed mild to moderate form of dysphagia, as shown in Table 4 (30% group A vs. 20% in group B) with a P value of 0.60 between groups. All were managed medically by prokinetics, antiemetics, and PPIs. All had successful medical treatment except one

#### Figure 7



Bar chart showing the incidence of postoperative complications.

#### Table 5 Hospital stays between groups

		P value			
	A		В		_
	Mean	SD	Mean	SD	
Hospital stays (mean/SD)	2.8	1.0	2.7	0.8	0.97*
*Mann–Whitney U test.					

#### Table 6 Quality of life between groups

		P value			
	A			В	-
	Count	Column	Count	Column	-
6-month QOL (mean/SD)	2.1	0.3	2.3	0.5	0.48*
12-month QOL (mean/SD)	1.8	0.9	2.3	0.5	0.24*
QOL, quality of life.					

\*Mann-Whitney U test.

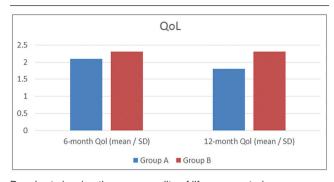
patient in group B had persistence of symptoms for more than 3 months and underwent upper OGD and was managed by pneumatic balloon dilatation of EGJ to 20 mm (Fig. 7).

There was no difference in length of hospital stay between study groups as shown in Table 5; group A had a mean hospital stay of  $2.8 \pm 1$  day versus  $2.7 \pm 0.8$  days in group B with a *P* value of 0.97.

Assessment of QOL using the HRQOL reporting system at 6 and 12 months of surgery was not significantly different between both groups as shown in Table 6  $(2.1\pm0.3 \text{ in group A vs}, 2.3\pm0.5 \text{ in group B})$  with a *P* value of 0.48 (at 6 months) (1.8\pm0.9 in group A vs, 2.3\pm0.5 in group B) with a *P* value of 0.24. (at 12 months) (Fig. 8).

Recurrence of symptoms at 6 and 12 months was evaluated by the GERD HRQOL scoring system and esophogeal manometry. At 6 months recurrence of symptoms was reported in one patient in group A versus two patients in group B with a P value of 0.30 as shown in Table 7. At 12 months recurrence of symptoms was reported in two patients in group A versus three patients in group B with a P value of 0.26 (Fig. 9).

Figure 8

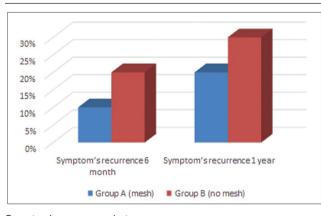


Bar chart showing the mean quality of life among study groups.

Table 7 Incidence of symptom recurrence between groups

		Groups [ <i>n</i> (%)]				
		А		В		
_	Count	Column	Count	Column	-	
6-month symptom	n recurrence	e				
No	9	90.0	8	80.0	0.531**	
Yes	1	10.0	2	20.0		
12-month sympto	m recurrenc	e				
No	8	80.0	7	70.0	0.605**	
Yes	2	20.0	3	30.0		
** $\chi^2$ test.						

Figure 9



Symptom's recurrence between groups.

Hernial recurrence was evaluated at 6 months by Barium meal, esophogeal manometry, and at 12 months by upper GIT endoscopy as shown in Table 8. At 6 months no hernia recurrence was detected in group A versus one patient in group B; at 12 months one patient with recurrence was detected in group A versus three patients in group B (Fig. 10).

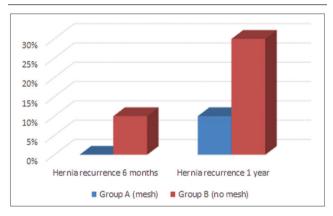
## Discussion

The aim of the current study was to evaluate the outcome of laparoscopic mesh hiatal hernioplasty (group A) versus suture cruroplasty (group B) for the repair of large HHs.

Table 8 Incidence of hernia recurrence between groups

		Groups [ <i>n</i> (%)]				
		А		В		
	Count	Column	Count	Column		
6-month herni	a recurrence	9				
No	10	100.0	9	90.0	0.53**	
Yes	0	0.0	1	10.0		
12-month herr	nia recurrenc	ce				
No	9	90.0	7	70.0	0.264**	
Yes	1	10.0	3	30.0		
** $\chi^2$ test.						

Figure 10



Bar chart showing comparison of recurrence between groups.

Watson *et al.* [6] reported that there were insignificant difference between sutures versus absorbable mesh versus nonabsorbable mesh as regards operative time and intraoperative bleeding.

In the present study, group B patients had a significantly shorter operative time  $(63 \pm 15.6 \text{ min})$  when compared with group A ( $94 \pm 15.6 \text{ min}$ ), with a *P* value of 0.0001. Intraoperative bleeding was significantly higher among group A patients  $130 \pm 66.8 \text{ ml}$  versus  $64 \pm 23.2 \text{ ml}$  in group B with a *P* value of 0.73.

Asti and colleagues conducted a study to evaluate outcomes of patients undergoing laparoscopic repair of large HHs, comparing mesh-augmented repair versus standard crura repair. In agreement with the present study findings, it was detected that there were insignificant difference between the two groups regarding the major intraoperative complications (pneumothorax, atrial fibrillation, and acute urinary retention) or mortality [7].

In our study, intraoperative organ injury and respiratory complications were insignificant in both study groups. Of group A patients 10% showed respiratory complications (chest infection) and 10% of group B patients showed organ injury (pleural injury). Among the present study population, 30% of group A and 20% of group B developed mild to moderate form of postoperative dysphagia, with a *P* value of 0.60 between groups. The incidence of postoperative complications was statistically insignificant in both groups.

In concordance with the present study results Watson and colleagues conducted a multicenter prospective double-blinded randomized controlled trial of three methods of repair: sutures versus absorbable mesh versus nonabsorbable mesh. The difference between the groups regarding the clinical outcomes (heartburn, bloating, odynophagia, nausea) was nonsignificant [6].

Similarly, Wang and colleagues conducted a study to compare PEH repairs using Gentrix mesh with primary suture repairs. There was no difference between the groups in the frequency of short-term postoperative complications (defined as any complications within 30 days post-PEHR) [8].

Granderath and colleagues published another RCT analyzing 100 patients undergoing laparoscopic Nissen fundoplication along with either simple suture cruroplasty or nonabsorbable polypropylene mesh placement for closure of hiatal defects either 5 cm or less or more than 5 cm at 12 months' follow-up. Against this study findings, a higher postoperative dysphagia rate was observed in the prosthetic group at 6 weeks and 3 months, which seems to have disappeared at 1 year follow-up [9].

The length of hospital stay among group A patients in this study was  $2.8 \pm 1$  days, while in group B patients it was  $2.7 \pm 0.8$  days. The difference was statistically insignificant.

The Asti *et al.* [7] study finding agreed with this, where insignificant difference was found considering the median hospital stay of the patients undergoing laparoscopic repair of large HHs, either with or without resorbable mesh augmentation.

Assessment of QOL using the HRQOL reporting system at 6 and 12 months of surgery showed insignificant difference between both groups (at 6 month the mean HRQOL score was  $2.1 \pm 0.3$  in group A vs.  $2.3 \pm 0.5$  in group B) (*P*=0.48) (at 12 months the mean HRQOL score was  $1.8 \pm 0.9$  in group A versus  $2.3 \pm 0.5$  in group B, *P*=0.24).

Also, Asti and colleagues reported that no statistically significant difference in postoperative GERD-HRQL scores which was noted between the patients who underwent laparoscopic repair of large HHs, either with or without resorbable mesh augmentation; however, the magnitude of odds ratio (OR) was slightly in favor of the mesh group. The 5-year recurrence-free probability was similar in both groups, but an earlier failure rate was noted in the nonmesh group at 12 months (P=0.299) [7].

In concordance with the present study, Koetje *et al.* [10] reported that SF-36-measured QOL improved significantly after the repair of large HH at up to 2 years follow-up, and there were no differences in outcome for the repair with mesh versus sutures-only repair.

Similarly, Wang and colleagues reported that there was no statistically significant difference in SF-36 mean scores between patients who underwent PEH repairs using the Gentrix mesh versus primary suture repairs, with similar median scores reported for each domain [8].

Also, Oelschlager *et al.* [11] detected that there was no statistically significant difference in relevant symptoms or QOL between patients undergoing primary diaphragm repair (PR) and small intestinal submucosa primary repair buttressed with a biologic prosthesis (small intestinal submucosa).

However, Ilyashenko *et al.* [12] reported a significant difference in QOL between mesh and no-mesh groups (*P*<0.0001).

Recurrence of symptoms at 6 and 12 months was evaluated by the GERD HRQOL scoring system, barium meal, and esophogeal manometry. No statistically significant differences were found between the two groups regarding the recurrence rate at 6 and 12 months. At 6 months, no hernia recurrence was detected in group A versus one patient in group B; at 12 months one patient with recurrence was detected in group A versus three patients in group B. The difference was statistically insignificant.

In agreement with the current study findings, Watson and colleagues detected that a recurrent hernia (any size) was identified in 23.1% after suture repair, 30.8% after absorbable mesh, and 12.8% after nonabsorbable mesh. The difference was insignificant (P=0.161) [7].

Similarly, in the Oelschlager and colleagues study it has been detected that on long-term follow-up (median 58 months) study, only two patients required surgery in the suture cruroplasty group whereas not in the biologic prosthetic group.

Also, Memon and colleagues compared 186 suture cruroplasty patients and 220 patients with prosthetic

hiatal herniorrhaphy based on four RCTs. As a result, while the rate of resurgery was lower in the prosthetic hiatal herniorrhaphy group (OR=3.73, 95% CI=1.18, 11.82, P=0.03), there was no difference in the recurrence of HH or wrap migration (OR=2.01, 95% CI=0.92, 4.39, P=0.07). The outcomes of the two procedures for LHH were almost equivalent [13].

Also, Antoniou and colleagues compared suture repair and biologic mesh repair among 295 patients in six articles. The results revealed that the short-term recurrence rate was 16.6 versus 3.5% (OR=3.74, 95% CI=1.55–8.98, *P*=0.003). Although this indicates the short-term usefulness of biologic mesh, the data were insufficient to indicate the long-term outcomes [14].

Tam and colleagues the postoperative recurrence of suture cruroplasty was 24% (91/382), while that of mesh cruroplasty was 13% (46/354). Although the rate of resurgery was 6 versus 3.7%, this rate was significantly higher in suture cruroplasty among cases in which the postoperative course could be evaluated (73 vs. 53%). They concluded that the quality of evidence supporting the routine use of mesh cruroplasty is low, and the use of mesh should be left to the discretion of the surgeon until the evaluation of symptomatic outcomes and long-term recurrence is clarified [15].

## Conclusion

On the basis of our study, laparoscopic mesh hiatal hernioplasty results in improvement of symptoms, QOL, and decrease in hernia recurrence, but evidence supporting routine use of mesh cruroplasty is low. The mesh should be used according to surgeon preference until additional studies of long-term follow-up are available.

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## **Conflicts of interest**

No conflict of interest to disclose.

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