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ORIGINAL ARTICLE

The Efficacy of Laparoscopic Mesh Augmented Hiatoplasty versus Laparoscopic Fundoplication in Treatment of Gastroesophageal Reflux Disease: A Comparative Study

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ABSTRACT

Background: An integral part of laparoscopic antireflux surgery for Gastroesophageal Reflux Disease (GERD) that has not responded to medication is fundoplication or mesh enhanced hiatoplasty. Finding out how laparoscopic mesh hiatus hernia repair and Nissen fundoplication fared in GERD patients was the primary goal of this research. **Methods:** This prospective randomized clinical trial included twenty-four individuals diagnosed with hiatal hernia. Group A had a laparoscopic hiatal hernia repair (HHR) procedure without fundoplication, and group B had an HHR procedure with Nissen fundoplication (HHR - LNF). The surgical procedure's duration, results, and potential risks complications were evaluated. **Results**: Number of reflux episodes in both group decreased from preoperative mean (91.2±17.8, 104.7±18.9) to (31±14.5, 18.5±10.3), number of lasting 5 minutes reflux episodes from preoperative mean (9.2±3.7, 9.8 ± 2.1) to postoperative (2.3±1.1, 0.3±0.02) and time of PH<4 form preoperative from (242.1±50.6, 261.5±57.8) to postoperative (97.3±45.1, 42.3±24.9) and also statistically significant improvement(increased) from preoperative (8.9±9.3, 9.3 ± 2.3) receptively to postoperative (14.2±7.8, 20.5±3.9) on resting LOS pressure. A higher operative time was revealed among group B than group A (p=0.007). **Conclusion:** Despite laparoscopic Nissen fundoplication being time consuming more than mesh augmented hiatoplasty, nearly same results were found in both techniques.

Keywords: Laparoscopic Mesh Augmented Hiatoplasty, Laparoscopic Fundoplication, Gastroesophageal Reflux Disease.

INTRODUCTION

A hiatal hernia happens when a part of the stomach moves upwards into the chest cavity through the esophageal hiatus. There are two types of hiatal hernias: sliding hernias and paraesophageal hernias (PEH). The most common type of hiatus hernia, accounting for 95% of cases, is characterized by an axial detachment between the lower esophageal sphincter (LES) and the crural diaphragm (CD) [1].

Hernias can occur without any symptoms or may cause a wide range of signs and symptoms. The usual symptoms include heartburn and regurgitation, which are commonly associated with gastro-esophageal reflux disease (GERD). On the other hand, there are also less common symptoms such as vomiting and difficulty swallowing after eating, as well as coughing or shortness of breath caused by recurrent aspiration pneumonia [2].

Over the past decade, there has been a significant increase in the use of laparoscopic defect repair for treating certain conditions. This approach involves simple reduction and posterior cruroplasty or mesh

reinforcement of posterior cruroplasty, followed by a fundoplication procedure. It has been found to have lower morbidity rates compared to the traditional open approach [3].

The concept behind laparoscopic mesh-augmented hiatoplasty (LMAH) is to effectively control reflux and minimize the chances of recurrence. This is achieved by securely anchoring the cardia to a polypropylene mesh at the dorsal hiatus, which helps prevent adhesion-induced complications. The latter idea was derived from experimental findings and the experience gained from hiatal hernia surgery, which has shown that recurrences can be minimized through mesh augmentation [4].

With or without mesh, laparoscopic anti-reflux surgery (LARS) has emerged as a viable alternative to the conventional methods of treating GERD and repairing hiatal hernias since the first laparoscopic fundoplication was published in 1991 [5].

This study aimed to compare laproscopic hiatus hernia repair with mesh and Nissen fundoplication in patients with GERD.

METHODS

In this study, which took place from June to December 2023 at the General Surgery Department of the Faculty of Medicine at Zagazig University, twenty-four patients presenting with symptoms of gastroesophageal reflux disease (GERD) and a hiatus hernia were included. The study was authorized by the research ethical council of the Faculty of Medicine at Zagazig University, and all participants provided written informed permission. The study was done according to The Code of Ethics of the World Medical Association (Declaration of Helsinki) for studies involving humans. This study was carried out after the approval of the Institutional Review Board (IRB#10794/4-6-2023).

The inclusion criteria were Patients over the age of 18 who exhibit classic GERD symptoms (heartburn and/or acid regurgitation) along with endoscopically proven esophagitis of grade A or higher according to the Los Angeles classification [6], who also have a sliding hiatus hernia, and who require long-term continuous standard proton pump inhibitor (PPI) therapy, as well as a total or superficial parotidectomy surgery,

The exclusion criteria were Patients who did not meet the criteria for laparoscopic surgery, those with diseases of the central nervous system or connective tissues, those who had undergone prior gastric or esophageal surgeries, those with esophageal stricture or a shorter esophagus, those with Barrett's esophagus (rolling or mixed type), achalasia, or a malignant tumor, and those whose GERD responded well to medical treatment.

Preoperative Phase:

Patients underwent a thorough history-taking and a detailed general and local examination. Routine lab investigations, encompassing Complete blood picture, Prothrombin Time (PT), INR, Serum creatinine levels were measured using ELISA technique and Liver Function Test. Esophagitis was assessed using the Savary and Miller or Los Angeles classification, and endoscopy was used to investigate the type of hiatal hernia in patients who had undergone screening for GERD [6]. Pathological patients with symptoms who did not have endoscopic evidence of erosive esophagitis prior to surgery should have their pH levels monitored every 24 hours. The use of esophageal manometry to assess the wall motility and pressure of the lower esophageal sphincter.

Surgical technique:

Patients were fasting started only 8 hours before surgery. General anesthesia was done with endotracheal intubation. Prophylactic parentral antibiotics in the form of 3rd generation cephalosporines one hour before induction of anesthesia and continued postoperatively for two days. A nasogastric tube was inserted, removed 12 hours postoperative. All cases have been operated laparoscopically. Patients were randomized by computerized program and divided into 2 groups: Group A (n=12) patients who undergone Mesh augmented hiatus hernia repair with Nissen fundoplication.

Laparoscopic hiatal hernia repair

The patient was placed on the operating table in the “French position” with the legs abducted. After that the patient had been washed, prepped and draped. Creation of pneumoperitoneum using veruss needle which was inserted in the palmar point and insufflation of CO_2 was done until intra-abdominal pressure reaches between 12-14 mmHg. The first port was inserted inside the abdomen (10 mm umbilical or supra umbilical port for the telescope), Four other ports were inserted under direct vision (one 12mm and others 5 mm) the 1st one 12mm at Lt. paramedian, the 2nd 5 mm at Rt.paramedian, the 3rd 5mm at Lt. The fourth 5 mm at the epigastrium or right lateral for liver retraction, and the lateral for the assistant. The left lobe of the liver was retracted using the

organ retractor, which was inserted through the right lateral port. The gastric fundus was drawn downward and toward the left side using a grasping forceps that was passed through the left lateral port. Before anything else, make sure the stomach and gastroesophageal junction are in good working order by checking the width of the hiatus and looking for signs of probable cardia fixation (and, by extension, LES) within the thorax.

After the left segment of the liver was retracted, the posterior vagus nerve was located by bluntly separating the crust from the right side of the esophagus. Deconstruction of the right crus had progressed all the way to its confluence with the left crus.

Using a blue gauze thread or drain placed at the level of the gastroesophageal junction, the esophagus was drawn upward, and a window was opened under the esophagus using blunt dissection. After entering the mediastinum, the dissection should continue until the esophagus reaches the abdomen, a distance of at least 3 cm, free of strain.

To get the right view, we used gauze thread or a drain to position the esophagus higher and to the patient's left. Nonabsorbable sutures, specifically 2-0 ETHIBOND EXCEL Polyester Suture, were used to close the crural opening. Just above the two pillars' intersection was where the initial stitch was inserted. The esophagus should be left approximately 1 cm in between the topmost stitch and any further stitches that are placed 1 cm apart. An esophageal probe should be able to slip smoothly beyond the crura because it is not too tight.

Mesh augmented hiatoplasty: Dual coated PTFE mesh permanent mesh patch (Ventralight ™ BARD®) was then applied over the hiatal repair and fixed by tacks using Tacker (CapSure™ Permanent Fixation System) (Figure 1).

Laparoscopic hiatal hernia repair with Nissen fundoplication

A bougie was put into the esophagus prior to commencing the fundoplication. After removing the orogastric tube, the anesthesiologist will place a bougie down the esophagus via the esophagogastric junction. After the stomach has been passed behind the esophagus, a "shoe-shine" maneuver is used to make sure the fundic muscles have been mobilized enough and to keep the gastric fundus from being exposed to the wrap. In the Nissen fundoplication, which is a full 360-degree fundoplication, the gastric fundus is pushed beneath the esophagus and wrapped above the esophagogastric junction as the first stitch is placed. To approximate the right and left sides of the fundoplication, we employed synthetic non-absorbable stitches (2-0 ETHIBOND EXCEL Polyester Suture) at 1 cm intervals. Making a short and floppy wrap, around 2 cm in length, is the objective. Before the incision was closed, a regular nasogastric tube was inserted to replace the esophageal bougie. In order to avoid stomach distention after surgery, this remained in place for twelve hours. Following a thorough deflation of the abdomen and the removal of all trocars under direct eyesight, the skin incisions at the trocar sites were closed (Figure 2).

Follow-up assessment

At one week, one month, three months, and six months after surgery, all patients were seen in the clinic for a full evaluation of their reflux symptoms (heartburn, regurgitation, dysphagia, gas bloating, etc.).

The patients were asked to rank their symptoms from 0 (none), 1 (moderate), 2 (severe), and 3 (very severe). Dysphagia, heartburn, regurgitation, gas, and bloating were the components that made up the DeMeester symptom score. A total score of 0 indicated no symptoms and a score of 9 indicated the most severe symptoms. Furthermore, the symptomatic outcome was categorized using the modified Visick score: I for no symptoms, II for mild symptoms that did not require regular medication or medical assistance, III for significant symptoms that did require regular medication or medical assistance, and IV for symptoms that were as bad as or worse than before surgery.

STATISTICAL ANALYSIS

Statistical Package for the Social Sciences, version 29.0, was used to process, input, and analyze the data. The qualitative data is presented as numbers and percentages, while the quantitative data is presented as the mean ± SD of each group. To compare the means of two separate groups, the student "t" test is used. The quantitative variables in the two sets of non-normally distributed data were compared using the Mann Whitney test, while the qualitative variables were compared using the Chi-square test (X2). The 5% level of significance (P-value) was set as the threshold for significant results, with a significance level of less than 0. 05..

RESULTS

No statistically significance differences were found between both studied groups as regards age, sex, Body mass index, pre-operative symptoms, the Demeester score, or pre-operative esophagitis (Table 1).

Number of reflux episodes in both group decreased from preoperative mean (91.2±17.8, 104.7±18.9) to (31±14.5, 18.5±10.3), number of lasting 5 minutes reflux episodes from preoperative mean (9.2±3.7, 9.8 ± 2.1) to postoperative (2.3±1.1, 0.3±0.02) and time of PH<4 form preoperative from (242.1±50.6, 261.5±57.8) to postoperative (97.3±45.1, 42.3±24.9) and also statistically significant improvement(increased) from preoperative (8.9±9.3, 9.3 ± 2.3) receptively to postoperative (14.2±7.8, 20.5±3.9) on resting LOS pressure (Table 2).

A statistically significant higher operative time was revealed among group B than group A (129.4±17.3 vs 105.7± 15.6 minutes respectively) with p value=0.007 (Table 3). As regard pre and post-operative esophagitis among the HHR group we found more reduction among HHR NF than HHR group (Figure 3).

Although there was no statistically significant difference between the two groups, group B showed greater improvement on the modified vision score (77.8% versus 55.6%), also as regards post-operative complications, total patients Satisfaction, and Surgical success no significant differences were revealed between both groups (Table 4).

Table (1): Comparison between the two studied groups regarding socio-demographic characteristics, symptoms and Demeester

Variable	Group A	Group B	P Value
Age (years) Mean ± SD Range	 46.2 ± 10.5 (30 – 60)	 49.1 ± 9.7 (28 – 61)	0.8
BMI (Kg/m^2) Mean ± SD Range	 24.1 ± 1.9 (20.2 – 27.1)	 23.9 ± 1.8 (20.5 – 27.5)	0.9
Sex Male (11) Female (13)	 4 (33.3 %) 8 (66.7 %)	 7 (58.3 %) 5 (42.7 %)	0.3
Symptoms	Group A (%)	Group B (%)	P Value
Heart burn **Yes** **No**	 8 (66.7 %) 4 (33.3 %)	 9 (75 %) 3 (25 %)	0.5
Epigastric pain **Yes** **No**	 7 (58.3 %) 5 (41.7 %)	 8 (66.7 %) 4 (33.3 %)	0.6
Dysphagia **Yes** **No**	 5 (41.7 %) 7 (58.3 %)	 4 (33.3 %) 8 (66.7 %)	0.6
Regurgitation **Yes** **No**	 4 (33.3 %) 8 (66.7 %)	 3 (25 %) 9 (75 %)	0.5
Post prandial Chest pain **Yes** **No**	 8 (66.7 %) 4 (33.3 %)	 9 (75 %) 3 (25 %)	0.5
Cardiac or Respiratory symptoms **Yes** **No**	 5 (41.7 %) 7 (58.3%)	 8 (66.7 %) 4 (33.3 %)	0.3

Demeester # symptom score	**Group A**	**Group B**	**P_Value**
Mean ± SD Range	40.1_13.6 (26-55)	45.2 ±10.7 (34 – 56)	0.3
Esophagitis*	Group A (%)	Group B (%)	P Value
No	0	0	0.3
Grade A	5	6	0.6
Grade B	4	4	0.5
Grade C	2	1	0.5
Grade D	1	1	0.1

DMS composite score ≥ 14.72 was considered GERD, * esophagitis was classified according to Los Angeles (LA) classification

Table (2): 24-h-ph monitoring and manometry (lower esophageal sphincter pressure).

24-ph monitoring Manometry	**Group A**		**Group B**		**P_Value**
	pre	**post**	**pre**	**Post**	
No of reflux episodes Mean ± SD Range	91.2±17.8 (55-135)	31±14.5 (16-47)	104.7±18.9 (85 – 139)	18.5±10.3 (9-29)	0.1
No of lasting 5minute reflux Mean ± SD Range	9.2±3.7 (5-14)	2.3±1.1 (1-4)	9.8 ± 2.1 (7 – 15)	0.3±0.02 (0-2)	0.7
Resting LOS pressure(mmhg) Mean ± SD Range	8.9±1.4 (7-12.5)	14.2±7.8 (6.2-23)	9.3 ± 2.3 (7.5 – 132)	20.5±3.9 (10.5 – 27.6)	0.6
Time PH<4 (minutes) Mean ± SD Range	242.1±50.6 (191-288)	97.3±45.1 (52-143)	261.5±57.8 (203 – 320)	42.3±24.9 (17 – 67.4)	0.4

Table (3): Comparing operative data between the two studied group.

Operative data	**Group A**	**Group B**	**P_Value**
Operative time (minutes) Mean ± SD Range	105.7± 15.6 (96-121)	129.4±17.3 (95 – 147)	**0.007***
Post-Operative hospital stay (days) Mean ± SD Range	5.1 ±0.9 (4-7)	5.8 ± 1.5 (4 –7)	0.3
post-Operative complications			0.5
- No	12 (100 %)	10 (83.3 %)	
-Dysphagia	0 (0 %)	2 (16.6 %)	
- Pnumothorax	0 (0 %)	0 (0.0 %)	
- Mesh related complications	0 (0 %)	0 (0 %)	

Table (4): Comparing modified visick score, Long term post-operative complications, total patients Satisfaction, and Surgical success among the two studied group.

Modified visick score	**Group A (%)**	**Group B (%)**	**P_Value**
I (No symptom)	7 (58.3)	9 (75 %)	0.3
II (Mild symptom)	3 (25 %)	3 (25 %)	1
III (Significant symptom)	2 (16.6 %)	0 (0.0 %)	0.1
IV (Symptom as bad or worser)	0 (0.0 %)	0 (0.0 %)	1
Variables	Group A (%)	Group B (%)	P Value
Dysphagia	1 (8.3 %)	3 (25 %)	0.5
Abdominal distension	3 (25 %)	1 (8.3 %)	0.2
Patients Satisfaction	Group A (%)	Group B (%)	P_Value
Very satisfied	7 (58.3 %)	6 (50 %)	0.3
Satisfied	3 (25 %)	4 (33.3 %)	
Unsatisfied	2 (16.6 %)	2 (16.6 %)	
Surgical success	Group A (%)	Group B (%)	P_Value
Success	12 (100.0 %)	12 (100.0 %)	1
Recurrence	0 (0.0%)	0 (0.0 %)	1

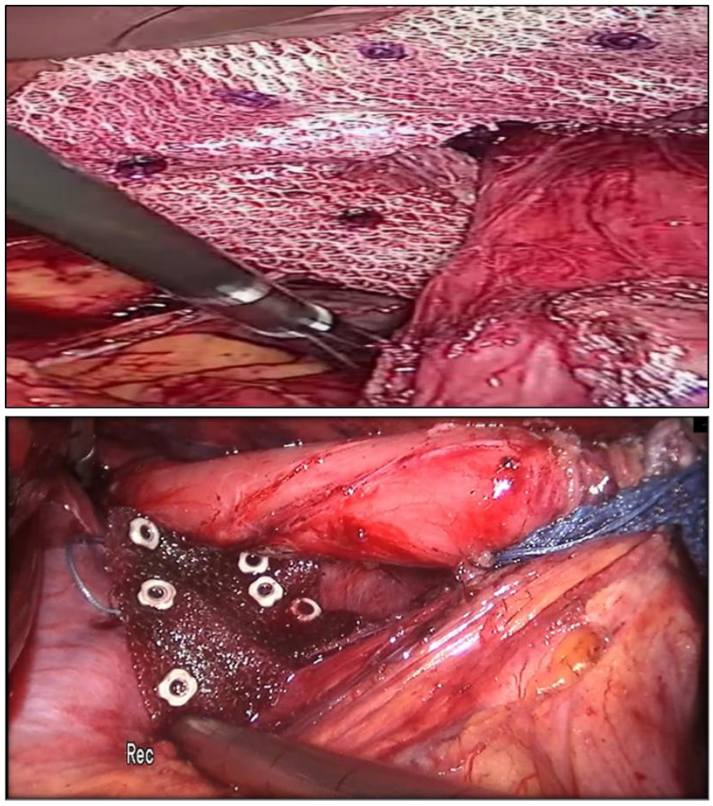

Figure 1: Mesh fixation by tacks over hiatal repair

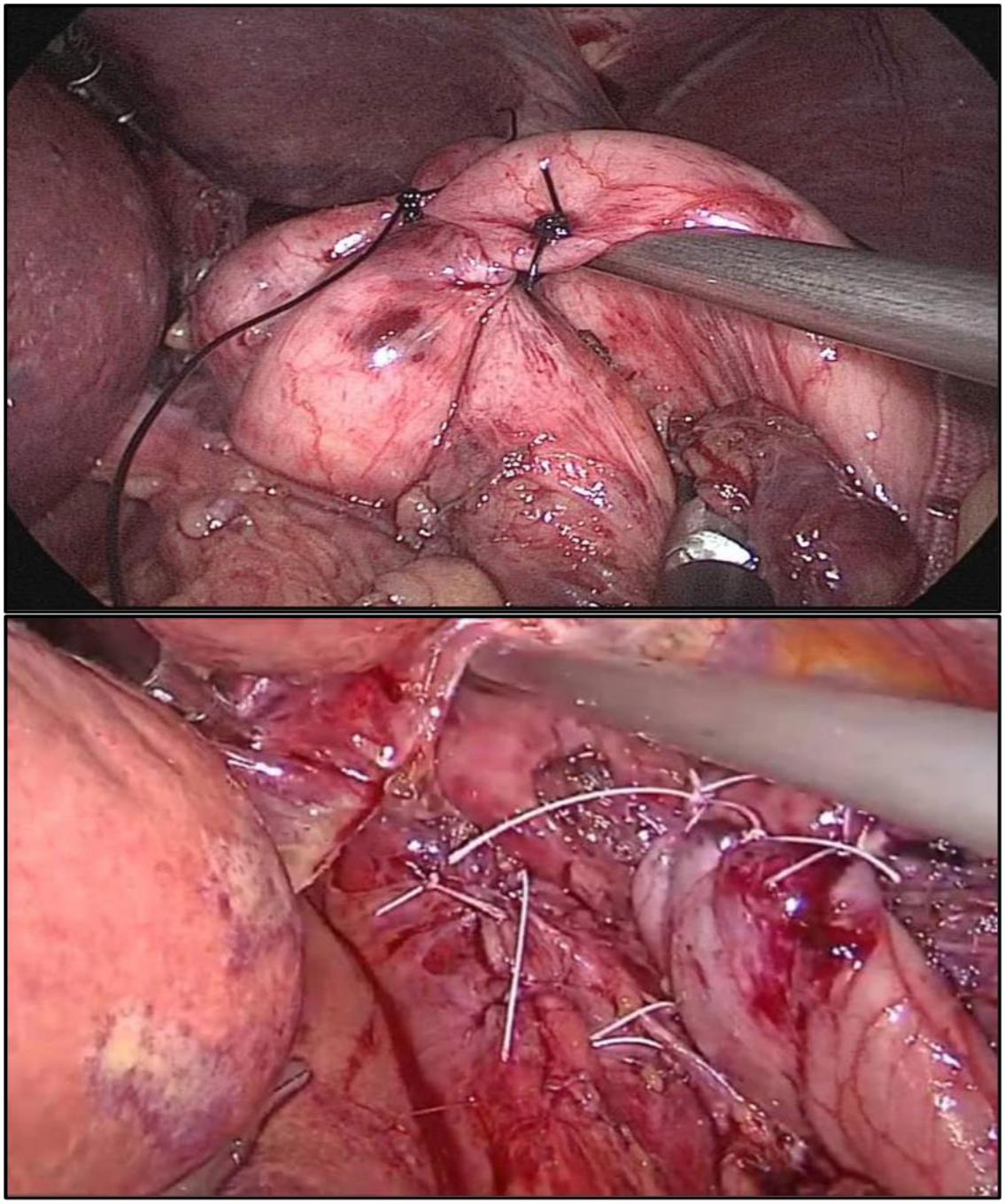

Figure 2: Final view primary crurial repair with nissen fundoplication

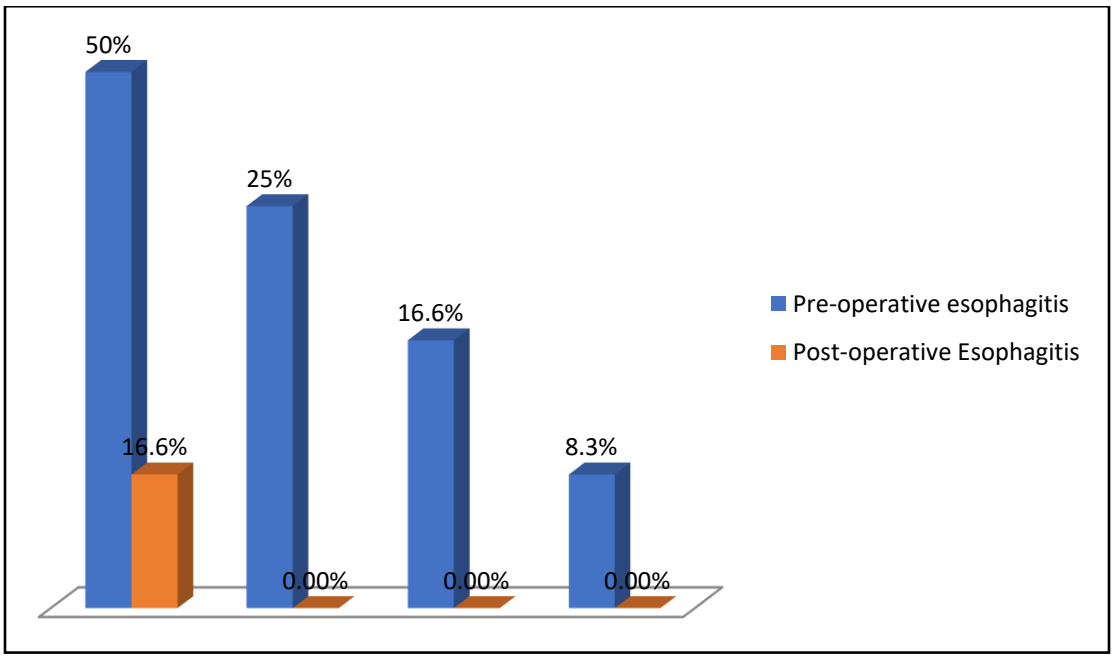

Figure (3): Bar chart for pre- and post-operative esophagitis among the HHR group shows more reduction among HHR_NF than HHR group.

DISCUSSION

In our present study, Majority of patients were females (66.7%) in group A and males (58.3%) in group B. The mean ± SD ages of group A and group B were (46.2±10.5) years and (49.1±9.7) years, respectively and there were no significant differences in BMI in both groups which was less than 30KG/M2 and 80% of cases were non-obese. In contrast to our findings both sex at risk even BMI less than 30kg/M2, Samuell et al. [7] performed research that showed a negative correlation between sliding hiatus hernia and a body mass index (BMI) more than 30 kg/m2. However, the risk appears to be higher in females and those with a BMI that indicates obesity.

The most prevalent presenting symptoms in our study were chest pain and heart burn in both groups by (66.7 %, 77.8%) and (66.7%, 77.8%) respectively and that was similar to results of Koetje et al. [8], and Gordon et al. [9]

In our study, all cases of the two groups were investigated by upper GI endoscopy, manometry and 24 PH monitoring, with non-significant differences between the studied groups regarding investigation method, these was in line with furnee et al. [10] and Watson et al. [11]

Regarding intraoperative time; between both groups, there were significant higher operative time among group B than group A. Mean time was (105, 129 min) respectively that was in line with Andolfi et al. [12]

No statistically significant differences were seen between the two groups with respect to postoperative complications, this was online with the findings of Oor et al. [13].

For 6 months follow up we found that there was statistically highly significant improvement (decreased) of Demeester score, in both groups receptively in same line with Linke et al. [6]

Our results demonstrated that there was no recurrence of hiatal hernia patients both groups, in comparison 5.3% recurrence rate in Arévalo et al. [14]

Statistical analysis revealed no difference between the two groups at 6 months with respect to postoperative long-term sequelae, such as dysphagia and abdominal distension, exactly as in the Waston et al. research [15]

In other side, late postoperative complications include dysphagia improves during the 3–6 months after surgery. Dietary modifications,

pharmacologic therapies, and esophageal dilation may be helpful [16].

Currently there have been no reported cases of mesh-related complications from the use of absorbable mesh in same line with Biondo-Simões et al. [17] and in contrast to De Moor et al. [18] reported that there were 3 of patients who presented with complications related to mesh placement at the hiatus.

In contrast to our study Pneumothorax, stomach or esophageal ripping injury, dysphagia, fullness, bloating, or flatulence are particular complications of antireflux surgery, according to this study Song. on page 19, Participants in a Swedish population-based study were all patients who had ARS performed in the years 2005–2014. Within 30 days following the initial ARS, individuals experienced a specific consequence, such as infection, hemorrhage, or esophageal perforation. Members of the Maret-Ouda group [20]

Van der Peet et al. reported persistent postoperative dysphagia that was resistant to dilatations. According to [21], a reoperation was necessary to remove the mesh from one patient who experienced a serious reaction to it after undergoing laparoscopic hiatal hernia repair using it. The other patient had mesh erosion into the esophagus; Casabella et al. [22] reported two additional patients with mesh-related problems. The mesh having intruded into the lumen necessitated repeat surgery and distal esophageal resection in both patients.

The PTFE mesh was the first mesh used in this area and has evidence to reduce recurrence rate but the problem in long term complications like dysphagia and erosions are catastrophic [23].

During our study, in terms of PH-monitoring, Demeester Symptom score, number of reflux episodes, and lower esophageal sphincter (LOS) pressure, we could not find a statistically significant difference between the two groups that were evaluated. Swanstrom proposed that patients with a big sliding hiatal hernia should not have their esophageal pH monitored before surgery because the aberrant gastroesophageal anatomy in these patients makes the monitoring inaccurate and increases the risk of false-negative results. The high incidence of postoperative gastroesophageal reflux disease induction supports the idea of routinely adding a fundoplication to these patients' preoperative workup, but also suggests that pH monitoring should be eliminated [23]. Unlike Ilyashenko et al. [24], we did not find any patients who had pleural effusion after the operation in our study. Who discovered that a pleural effusion had been absorbed in a single patient after only a week.

These findings contradict those of the study by Draaisma and colleagues, who examined the effects of GERD surgery on patients with normal GERD architecture or type I hiatal hernias. Between 4.1% and 12.5% of the patients they looked at had chronic abnormal acid exposure [25].

As a result of a mesh-related issue, one patient (3% of the total) had to have their distal esophagus removed (Coluccio et al., 2015). The patient's PTFE prosthesis migrated into the cardial lumen after undergoing surgery to correct a severe hiatal hernia. The patient needed a distal esophageal resection and mesh removal during the reoperation [26].

According to Kemppainen et al., a deadly consequence occurred. In addition to imprisonment of the stomach and acute thoracic herniation, this patient was presented with a massive paraesophageal hernia. The patient had a tension-free hiatoplasty performed laparoscopically to correct a hiatal hernia. A hernia stapler was used to secure the mesh. The patient experienced cardiac tamponade following surgery as a result of a stapler laceration to a coronary vein [27].

CONCLUSION

Despite laparoscopic Nissen fundoplication being time consuming more than mesh augmented hiatoplasty, nearly same results were found in both techniques.

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