Is it meaningful to add mesh reinforcement to laparoscopic fundoplication for esophageal hiatal hernias?

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Abstract

**Background:** While laparoscopic fundoplication is a standard surgical procedure for patients with esophageal hiatal hernias, the postoperative recurrence of esophageal hiatal hernias is a problem for patients with giant hernias, elderly patients, or obese patients. Although there are some reports indicating that reinforcement with mesh is effective, there are differing opinions regarding the use thereof.

**Purpose:** We investigated whether mesh reinforcement is effective for laparoscopic fundoplication in patients with esophageal hiatus hernias.

**Patients and Methods:** The subjects included 280 patients who underwent laparoscopic fundoplication as the initial surgery for giant esophageal hiatal hernias, elderly patients aged 75 years or older, and obese patients with a BMI of 28 or higher, who were considered at risk of recurrent hiatal hernias based on the previous reports. Of the subject patients, 91 cases without mesh and 86 cases following the stabilization of mesh use were extracted in order to compare the postoperative course including the pathology, symptom scores, surgical outcome, and recurrence of esophageal hiatus hernias.

**Results:** The preoperative conditions indicated that the degree of esophageal hiatal hernias was high in the mesh group (p=0.0001), while the preoperative symptoms indicated that the score of heartburn was high in the non-mesh group (p=0.0287). Although the surgical results indicated that the mesh group underwent a longer operation time (p<0.0001) and a higher frequency of intraoperative complications (p=0.037), the rate of recurrence of esophageal hiatal hernia was significantly low (p=0.049), with the rate of postoperative reflux esophagitis also tending to be low (p=0.083).

**Conclusions:** Mesh reinforcement in laparoscopic fundoplication for esophageal hiatal hernias contributes to preventing the recurrence of esophageal hiatal hernias when it comes to patient options based on these criteria.

Introduction

Currently, laparoscopic fundoplication (LF) is performed worldwide as a standard surgical treatment for esophageal hiatal hernias [1]. However, the postoperative recurrence of esophageal hiatal hernias has been problematic at a constant frequency. In recent years, there has been an increasing trend in the number of surgeries for cases with giant esophageal hiatal hernias due to gibbus caused by obesity and aging, with further increases expected going forward [2]. It is considered that the recurrence of esophageal hiatal hernias following surgery in these cases is particularly common [3], with mesh reinforcement having been performed following hiatal closure in order to prevent hernia recurrence [4, 5]. However, there are reports of complications such as migration due to mesh [6] and reports that mesh is not effective in preventing recurrence [7], resulting in some controversy regarding the use of mesh at present. Therefore, the purpose of this study was to clarify whether mesh reinforcement during LF for esophageal hiatal hernias was effective in preventing hernia recurrence.
Methods

Patients

Between June 1997 and December 2021, laparoscopic Toupet fundoplication was performed as the initial surgery on 487 patients suffering from gastrointestinal symptoms such as heartburn and vomiting, with esophageal hiatal hernia confirmed by upper gastrointestinal X-ray imaging and upper gastrointestinal endoscopy. Of these, there were 280 cases of patients who were either obese patients (BMI 28 or more), elderly (aged 75 and over), or those with any giant esophageal hiatal hernia (according to the AFP classification \[11\], A factor of 2 or higher), who were considered at high risk for the recurrence of esophageal hiatal hernias based on the previous reports \[8–10\]. We extracted 91 cases from the non-mesh group from January 2000 to December 2010, when the LF technique was stable, and 86 cases from the mesh group after 2016, when the mesh reinforcement technique was stable (Fig. 1).

Methods

Patient background, pre- and postoperative symptom scores, surgical results, and postoperative course including the recurrence of esophageal hiatal hernias were compared between the two groups. The Digitrapper MK-II or MK-III was used to evaluate esophageal acid reflux until June 2008, after which Sleus, esophageal multichannel intraluminal impedance with pH monitoring (MII-pH), was used. For the evaluation of esophageal motor function, we used infusion-type conventional manometry to measure the overall length (OL), abdominal length (AL), and lower esophageal sphincter pressure (LESP) until September 2012. The data was analyzed by automatic analysis using high-resolution manometry (Mano Scan) from October 2012 and high-resolution manometry (Starlet) from July 2018. Additionally, the AFP classification \[11\] and the V factor \[12\] were also evaluated.

Recurrence of esophageal hiatal hernias was defined as A1 or higher in the AFP classification \[11\] upon upper gastrointestinal endoscopy or esophageal contrast imaging during postoperative follow-up. Recurrence of esophagitis was defined as grade A or higher esophagitis according to the Los Angeles classification \[13\] in the upper gastrointestinal endoscopy findings during postoperative follow-up. This study has been reviewed by the ethics review committee of the Jikei University School of Medicine \[30–304(9325)\].

AFP classification and V-factor

The AFP classification \[11\] was proposed by Bancewics et al. at the International Society for Diseases of the Esophagus in 1991 and is a classification method that comprehensively evaluates the patient's pathology from the perspectives of anatomy, function, and pathology. Each factor is graded into four levels from 0 to 3, with the A factor indicating the degree of esophageal hiatal hernia, defined as: A0: No esophageal hiatal hernia; A1: Sliding esophageal hiatal hernia of less than 3 cm; A2: Sliding esophageal hiatal hernia of 3 cm or more; and A3: Paraesophageal or mixed esophageal hiatal hernia. The F factor indicates the degree of acid reflux in the esophagus, with the values of holding time (%) having pH less than 4 in the esophagus defined as: F0: less than 4%; F1: 4% to less than 8%; F2: 8% to less than 20%;
and F3: 20% or more. The P factor indicates the degree of reflux esophagitis, defined as: P0: No mucosal break; P1: Los Angeles classification grade A or grade B esophagitis; P2: Los Angeles classification grade C or grade D esophagitis; and P3: having complications such as esophageal stricture or penetrating ulcer. The V factor [12] is an index of the degree of cardia laxity proposed by Ismail et al. The observation of the cardia in the eversion of the stomach during upper gastrointestinal endoscopy was defined as: V0: there is no esophageal hiatus hernia and the cardia does not dilate even with an air supply of approximately 500 ml; V1: esophageal hiatal hernia is observed but the cardia does not dilate with an air supply of approximately 500 ml; V2: no esophageal hiatal hernia is observed but the cardia dilates with an air supply of approximately 500 ml; and V3: esophageal hiatal hernia is observed and the cardia dilates with an air supply of approximately 500 ml.

**Symptom score and satisfaction score**

The symptom scores were evaluated by questionnaire survey prior to surgery and 3 months following surgery. Frequency of heartburn, regurgitation, dysphagia, vomiting, and chest pain (0: never, 1: 2–3 times a month, 2: 2–3 times a week, 3: daily, 4: every meal), and the severity (0: none, 1: mild, 2: fair, 3: severe, 4: very severe) were evaluated on a 5-point scale, with the product of each score defined as each symptom score [14]. The degree of satisfaction with surgery was similarly evaluated by a questionnaire survey into five levels: excellent, good, fair, poor, and bad [15].

**Surgical procedures**

Because the details have been previously reported [16], the description here will be limited to the main points. Under general anesthesia, the patient is placed in the open leg position and the operation is started with the head elevated and slightly rotated to the right. The abdominal esophagus is taped using a Penrose drain in order to further expose the abdominal esophagus when it is already exposed to some extent. The anterior and posterior trunks of the vagus nerve are preserved at this time. The short gastric artery is dissected to allow easy ample wrapping. After sufficiently securing the abdominal esophagus and exposing the esophageal hiatus, the esophageal hiatus is sutured. Hiatus closure is performed from the dorsal side of the esophagus and, if necessary, from the ventral side as well. After closing the hiatus, the gap between the hiatus and the esophagus is adjusted to less than 1 cm. The mesh is sutured and secured after closing the esophageal hiatus. It is trimmed and fixed in a V-shape so that the mesh does not contact the esophagus. Next, cardia formation is performed using the Toupet method, but in the case of patients with a giant esophageal hiatal hernia, many of them are elderly and are likely to have decreased esophageal body motor function. Therefore, cardia formation is limited to approximately 180 degrees loosely due to concern for the postoperative dysphagia. Finally, shoulder and anchor stitches are added to prevent the recurrence of esophageal hiatal hernia, regardless of the use of mesh, and suture fixation of the anterior gastric wall to the abdominal wall is also performed as appropriate.

**Statistical analysis:**

Continuous variables are shown as median and interquartile ranges (IQR). The Mann-Whitney’s U test for continuous variables and chi-square test for categorical variables were used in order to compare the two
groups. Additionally, the t-test was used to compare the symptom scores prior to and following surgery, along with the intraesophageal pH monitoring test results. Statistical analysis was performed using STATA 16.1 (Stata Corp., TX, USA), with a P-value of less than 0.05 defined as statistically significant.

Results

Patients’ background

Of the 177 subject patients in total, 78 were male (44%) and 99 were female, with a median age of 69 (range: 25-91). There was no difference in patient background between the two groups in terms of age, gender, BMI, or disease duration (p=0.1502, p=0.122, p=0.9235, p=0.9285, respectively) (Table 1).

Pre-operative pathophysiologic data

Although the AFP classification indicated that the mesh group had a significantly higher score in terms of the A factor (p=0.0001), there was no difference in terms of the F and P factors (p=0.2838, p=1921 respectively), as well as no difference in terms of the V factor (p=0.488) (Table 1).

Esophageal pH monitoring revealed no difference in esophageal acid reflux with or without mesh. Furthermore, regarding the study after MII-pH became available, no difference was observed between the two groups, not only in terms of acid reflux but also non-acid reflux. On the other hand, while esophageal manometry revealed no difference in LES pressure, a significant reduction in LES was observed in the mesh group (OL: p<0.0001, AL: p=0.0075) (Table 2).

Surgical outcomes and postoperative course

While the operative time was significantly longer in the mesh group (p<0.0001), intraoperative bleeding was greater in the non-mesh group (p=0.0006). Intraoperative complications were significantly higher in 14 of 76 patients (18.4%) in the mesh group, compared to 7 patients (7.7%) in the non-mesh group (p=0.037). Intraoperative complications included 3 cases of vagus nerve injury, 2 cases of diaphragmatic peduncle injury, and 1 case each of esophageal injury and mediastinal pleural injury in the non-mesh group, while in the mesh group, complications included 7 cases of vagus nerve injury, 4 cases of subcutaneous emphysema, 2 cases of mediastinal pleural injury, and 1 case of esophageal injury. On the other hand, postoperative complications occurred in 9 cases (9.9%) in the non-mesh group and 8 cases (9.3%) in the mesh group, indicating no difference in terms of the incidence of postoperative complications, with a low rate observed in both groups (Table 3). The breakdown of postoperative complications in the non-mesh group included 6 cases of prolonged dysphagia, 1 case of respiratory complications, 1 case of late-onset esophageal perforation, and 1 case of late-onset esophageal tracheal fistula, while the mesh group included 4 cases of prolonged dysphagia, 2 cases of intestinal obstruction, 1 case of late-onset esophageal perforation, and 1 case of mesh infection. Two cases of delayed esophageal perforation, one case each of esophageal tracheal fistula, intestinal obstruction, and mesh infection required reoperation.
Although there was no difference in the timing of starting meals and the length of postoperative hospital stay, the incidence of postoperative esophageal hiatal hernias was significantly lower in the mesh group at 6%, compared to 16% in the non-mesh group (p=0.049). The incidence of postoperative reflux esophagitis tended to be lower in the mesh group (p=0.083), with the administration rate of postoperative acid secretion inhibitors significantly lower in the mesh group (p<0.0001). Only 1 patient (1.2%) developed mediastinitis due to mesh infection during follow-up.

**Pre- and Post-operative symptom score and satisfaction score**

Among each symptom score for heartburn, regurgitation, dysphagia, vomiting, and chest pain, only the score for heartburn in the non-mesh group was high (p=0.0287), with no difference observed in other symptoms, according to the preoperative questionnaire survey. On the other hand, the symptom scores in the questionnaire survey at 3 months following surgery were similar between the two groups, with no significant difference in any symptoms.

The postoperative symptom scores for each symptom indicated improvement compared to prior to surgery for heartburn, regurgitation, and chest pain, regardless of whether mesh was used or not. However, although the mesh group showed improvement in the dysphagia and vomiting, there was no significant improvement in the non-mesh group (Figure 2a-e). While the surgery satisfaction score was high in both groups, with a median value of 5, it was statistically significantly higher in the non-mesh group (p=0.0295).

**Post-operative pathophysiologic data**

Although the non-mesh group scored significantly higher in the A and V factors of the AFP classification (p=0.0001, p=0.0008, respectively), there was no difference between the two groups in terms of the P and F factors (Table 4). However, in comparison with preoperative scores, postoperative scores improved for all factors regardless of the use of mesh (Tables 5 and 6).

Postoperative pH monitoring in the esophagus indicated that both the holding time for a pH below 4 and the DeMeester score were significantly higher in the non-mesh group (p=0.0002, p=0.0022, respectively) (Table 4). In comparison with preoperative results, the non-mesh group significantly improved only the holding time for pH less than 4, the longest reflux time, and the total number of refluxes, while the mesh group showed significant improvement postoperatively for all items, except for the frequency of non-acidic liquid and gas reflux (Tables 5 and 6).

**Discussion**

Esophageal hiatal hernia is a pathological condition in which the esophageal hiatus dilates and the stomach invades the mediastinum due to a constant increase in abdominal pressure caused by chronic coughing, obesity, or gibbus [17]. While most esophageal hiatal hernias are sliding hernias classified as Type 1 [18], the number of cases with more advanced esophageal hiatal hernias has been increasing in
recent years [19]. On the other hand, LF has been widely used as an effective treatment for gastroesophageal reflux disease including esophageal hiatal hernia since Dellemagne et al. first reported thereon in 1991 [20]. However, there is a problem of recurrence in patients with advanced disease [21], with postoperative hernia recurrence being problematic in patients with severe esophageal hiatal hernia, similar to the recurrence of esophagitis being common in patients with severe reflux esophagitis following this procedure. [22, 23]. Surgical technique problems aside, increased abdominal pressure is an important cause of recurrence of esophageal hiatal hernia, specifically obesity and gibbus [8, 9, 24]. Furthermore, the tissues of the esophageal hiatus, including the crus of the diaphragm, are often fragile in the elderly, with being old itself considered a risk factor for postoperative recurrence [10].

Because esophageal hiatal hernia is a benign disease, new symptoms and recurrence due to surgery should be avoided as much as possible. We began reinforcing the esophageal hiatus with a mesh during LF in 2011, taking into consideration previous reports and the pathology of recurrent cases. Specifically, if the patient was 75 years of age or older, had esophageal hiatus hernia with an AFP classification of A2 or higher, or was obese with a BMI of 28 or higher, in principle, we considered reinforcement of the esophageal hiatus with mesh. Because we were able to establish a technique using a mesh and the surgical technique has been selected according to the above criteria since 2016, along with the fact that the technique has become stable, we investigated the effectiveness of using mesh in a group of patients who met our criteria.

It has been reported that the use of mesh was effective in preventing recurrence in surgical therapy for esophageal hiatal hernias [25–27]. On the other hand, complications related to the use mesh of such as bleeding, infection, stricture, esophageal ulcers, and migration have been reported. [28, 29] There are also reports that the use of mesh was if anything not recommended because it could become serious [30]. While the SAGES guideline [31] strongly recommends the use of mesh during surgical therapy for large hiatal hernias, for the prevention of hernia recurrence in terms of short-term results, there is insufficient data on long-term results, suggesting that future investigation is expected. This study also showed that the longest follow-up period for patients using mesh was approximately 5 years, suggesting further investigation is required for long-term results.

The examination of patient background indicated that the degree of esophageal hiatal hernia was significantly higher in the mesh group, with the LES length accordingly significantly shorter in the mesh group. While the values of the esophageal manometry findings are considered only for reference, because the measuring equipment was changed during the study period, due to the long duration of the subject cases, it is a measurement item that is relatively unlikely to vary due to measuring equipment and so is considered highly credible. The heartburn score was higher in the non-mesh group for the preoperative symptoms. Because there was no difference between the two groups in terms of the F and P factors according to the preoperative AFP classification, in addition to there being no difference in terms of the pH monitoring test results, it is possible that the degree of esophageal hiatal hernia had some effect. When the hernia becomes severe and the running of the esophagus is curved or displaced, reflux symptoms are less likely to occur.
The surgical results indicated significantly longer operating time in the mesh group. This is assumed mainly due to the operating time extension for suture fixation of the mesh. We trimmed the mesh for each case and sutured approximately 10 areas to fix the mesh into an appropriate position; however, we did not use a hernia tacker to do so. The intraoperative complication rate was high in the mesh group, possibly because there were 3 cases of vagus nerve injury in the non-mesh group, but 7 cases in the mesh group. Severe esophageal hiatus hernias, including upside down stomach, also have severe esophageal displacement, making it difficult to identify the vagus nerve anterior trunk and increasing the risk of injury. The ratio of A3 was 26 out of 91 (28.6%) in the non-mesh group and 48 out of 86 (55.8%) in the mesh group. This is believed to be the reason why the intraoperative complications were significantly higher in the mesh group. Furthermore, the reason why the satisfaction score was significantly lower despite the satisfaction level being high in the mesh group, may be due to the impaired gastric emptying because of this vagus nerve injury.

The recurrent esophageal hiatal hernia cases (17 cases) indicated that the degree of preoperative esophageal hiatal hernia was higher than in the non-recurrent cases (131 cases) (median A score; non-recurrent cases vs. recurrent cases = 2 vs. 3, p = 0.0453). As shown in our previous report [21], these results support the high risk of recurrence of esophageal hiatal hernia in advanced cases. This study found that although the degree of preoperative esophageal hiatal hernia was higher in the mesh group, recurrence of esophageal hiatal hernia was statistically significantly reduced in the mesh group. We believe that the results of this study are useful in terms of the significance of the use of mesh for esophageal hiatal hernias, because the recurrence prevention effect of mesh could be expected to be even higher, even if the p-value is 0.049, when the severity of esophageal hiatal hernia is the same in the control group.

This study found that there was a tendency for postoperative reflux esophagitis to be suppressed in the mesh group (no mesh group vs. mesh group = 12.5% vs. 4.4%, p = 0.083). As shown in Tables 5 and 6, the results of intraesophageal pH monitoring tests prior to and following surgery indicated that the prevention of esophageal acid reflux was significantly more effective in the mesh group. Therefore, reinforcement of the esophageal hiatus with mesh may also affect the anti-reflux mechanism in the cardia.

However, there are some limitations in this study. First, this study was based on a retrospective manner in a relatively small number of cases. Ideally, it would be desirable to examine the results of surgery with and without the use of mesh by means of a randomized controlled trial. Second, the number of postoperative esophageal pressure measurement tests performed was small in the non-mesh group, making a statistical study unavailable. In order to obtain more detailed information on the pathology, we would like to continue accumulating cases. Finally, this study is a study that is limited to short-term results. However, we believe the report is meaningful, as it is based on establishing a firm standard for the adaptation of mesh use. We would like to report again on the long-term progress in the future.
In conclusion, mesh reinforcement during LF is significant for preventing the recurrence of esophageal hiatus hernias when it comes to patient options based on the criteria for the possible recurrence of esophageal hiatal hernias.

Declarations

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Compliance with ethical standards

Conflict of interest: The authors declare that they have no conflict of interest.

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

Author’s Contributions

Study conception and design Tsuboi, Omura, Yano

Acquisition of data Tsuboi, Omura, Yano, Hoshino, Yamamoto, Akimoto, Masuda, Sakashita, Fukushima, Takeuchi, Takahashi

Analysis and interpretation of data Tsuboi, Omura, Yano

Drafting of manuscript Tsuboi, Omura

Critical revision of manuscript Tsuboi, Omura, Eto

Acknowledgement: none

References


Tables
Tables 1 to 6 are available in the Supplementary Files section

Figures
Details of subject patients are shown. Of the 487 patients diagnosed with esophageal hiatal hernia by a barium study or endoscopy, who underwent Toupet fundoplication as the initial surgery, a total of 280 patients, either with a BMI of 28 or more, aged 75 and over, or having esophageal hiatal hernia with AFP classification of A2 or more, were extracted and identified as a high-risk group for recurrent esophageal hiatal hernia. These subject patients were roughly divided into two groups: 91 patients without mesh and 86 patients who were able to stably undergo surgery using mesh.
Figure 2

Symptom scores for heartburn, regurgitation, dysphagia, vomiting, and chest pain prior to and following surgery in each group are shown. The symptoms of heartburn, regurgitation, and chest pain improved compared to prior to surgery, regardless of whether mesh was used or not. However, no significant improvement was observed in the non-mesh group in terms of the dysphagia and vomiting, although some improvement was observed in the mesh group.

Supplementary Files

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- Table1.docx
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