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Original research

Short-term results for laparoscopic repair of large paraesophageal hiatal hernias with Gore Bio A® mesh

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HIGHLIGHTS

- The standard treatment for paraesophageal hiatal hernias remains controversial.
- Use of meshes in the hiatus has resulted in a significant reduction in recurrences.
- However, these meshes could develop potential complications.
- In order to prevent them, a new group of bioabsorbable meshes have been proposed.
- We present our short-terms results with the Gore Bio A® mesh.

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ABSTRACT

Background: The application of mesh-reinforced hiatal closure has resulted in a significant reduction in recurrence rates in comparison with primary suture repair. One of the most debated issues is the risk of complications related to the use of the prosthesis, such as esophageal erosion and postoperative dysphagia. The aim of this study is to present our short-terms results in the treatment of laparoscopic paraesophageal hiatal hernia (LPHH) with a synthetic polyglycolic acid:trimethylene carbonate mesh (Gore Bio A®).

Methods: From January 2011 to December 2012, 10 patients with large paraesophageal hiatal hernias and hiatal defect over 5 cm were included. Primary simple suture of the crura and additional reinforcement with a Gore Bio A® mesh was performed. Hiatal hernia or gastroesophageal reflux disease (GERD) symptoms recurrence, dysphagia and mesh-related complications were investigated.

Results: Of the 10 patients undergoing mesh repair, there were 7 women and 3 men with a mean age of 65.5 years. All operations were completed laparoscopically. Median postoperative stay was 3 days. After a median follow-up of 20.3 months, one patient developed a recurrent hiatal hernia (10%). There were no mesh-related complications.

Conclusions: The use of Gore Bio A® mesh for the laparoscopic repair of large paraesophageal hiatal hernias is safe and with a reasonably low recurrence rate in this short-term study. Additional long-term studies with ample numbers carried out for years will be necessary to see if this synthetic mesh is not only safe but also successful in the prevention of recurrences.

1. Introduction

Laparoscopic antireflux surgery is considered the gold standard in the treatment of gastroesophageal reflux disease (GERD) [1]. However, the standard of care for repairing large and paraesophageal hiatal hernias (LPEH) remains controversial [2,3].

The application of mesh-reinforced hiatal closure has resulted in a significant reduction in recurrence rates in comparison with primary suture repair, at least in short-term follow-up [4,5]. However, the application of meshes in the hiatus and recurrence rates are still highly debated, especially after the publication of Oelschlager et al. [6] that concluded that recurrence is not different for mesh repair versus primary repair after a long-term follow-up. Furthermore, other of the most debated issue is the risk of complications related to the use of the prosthesis, such as esophageal erosion and postoperative dysphagia [7].

Given these data on the association of mesh-related complications, and in order to prevent it, a new group of biologic and synthetic bioabsorbable meshes have been proposed [8–14].

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The aim of this study is to present our short-terms results in the treatment of laparoscopic paraesophageal hiatal hernia (LPHH) with a synthetic polyglycolic acid:trimethylene carbonate mesh (Gore Bio A®).

2. Methods

2.1. Patients

A retrospective study was performed in the Hospital General of Castellón, Spain. From January 2011 to December 2012, 10 consecutive patients with LPEH and hiatal defect over 5 cm were included.

2.2. Preoperative, postoperative and long-term clinical assessment

All the patients underwent a standard preoperative workup including physical examination, blood analysis, chest X-ray, upper gastrointestinal barium meal X-ray study, esophagogastroduodenoscopy with biopsy and CT scan.

Postoperatively, patients were placed on a clear liquid diet and discharged home on a soft diet. Follow-up was performed approximately 1, 2, 4 weeks and 3rd, 6th and 12th months, then every year after surgery. An upper gastrointestinal X-ray study and CT scan were performed at the 6th and 12th months, esophagogastroduodenoscopy, 24 h-pH monitoring and esophageal manometry in the case of symptoms. Hiatal hernia or GERD symptoms recurrence, dysphagia and mesh-related complications were investigated.

Hernia hiatal recurrence was defined as the greatest measured vertical height of stomach being at least 2 cm above the diaphragm.

2.3. Surgical technique

The first step was reduction of the herniated stomach, removal of the hernia sac and section of the phrenogastric attachment. The short gastric vessels (maximum 3) were cut only when necessary to obtain a "floppy Nissen". The gastrohepatic omentum was then divided and the esophagus was isolated. Primary cruroplasty was then performed using 3–4 interrupted nonabsorbable sutures between the right and left diaphragmatic pillars. Due to the high size of the hiatal defect (>5 cm), a 7 cm × 10 cm synthetic polyglycolic acid:trimethylene carbonate (PGA:TMC) absorbable tissue reinforcement (Gore Bio A® mesh) was onlay, and fixed on the pillars using absorbable tacks (Covidien AbsorbaTack™). In order to avoid the use of tackers, in the last 4 cases we have added a fibrin sealant (Tissucol®) to reinforce the placement of the mesh. A "floppy" Nissen fundoplication was then tailored in all the patients using 3 nonabsorbable stitches.

2.4. Gore® Bio-A® Tissue Reinforcement [15]

The Gore® Bio-A® Tissue Reinforcement is a synthetic bioabsorbable mesh composed of a porous, 3-dimensional (3D) web of polymers (polyglycolic acid/trimethylene carbonate), that is gradually absorbed by the body (over six months) while its 3D matrix is replaced by vascularized soft tissue. The mesh provides a non-permanent scaffold for tissue generation like biologics, but due to its synthetic nature, the product is consistent and uniform with handling characteristics that facilitate placement and with no risk of human or animal source contamination. It is easy to use with no operative preparation, such as soaking or stretching, and no special storage conditions are required.

3. Results

Seven patients were female and three male. The mean age was 65.5 years (range, 53–82 years) and the mean body mass index (BMI) was 31.65 kg/m^2 (range, 27.2–39.6 kg/m^2). Perioperative patient risk was assessed using the American Society of Anesthesiology (ASA) Scoring System (ASA I: 1 case, ASA II: 8 cases, ASA III: 1 case).

An overview of all complaints and the cardinal symptoms leading to laparoscopic repair of large HH are shown in Table 1.

Six cases were primary large paraesophageal hiatal hernias (60%), two cases were LPHH associated with gastric volvulus (20%), and two cases were large recurrent hiatal hernias (20%).

The mean operative time was 162 min (range, 120–240). None of the patients underwent conversion to open surgery. Intraoperative complications occurred in 3 patients (30%): 3 cases of pneumothorax during dissection of the sac. However, all these complications were intraoperatively managed without the placement of a chest tube. The mean hospital stay was 3 days (range, 2–5 days). Early postoperative mild operation-related side effects such as diarrhea, flatulence and transitory dysphagia were seen in three patients (30%). However, only one patient persists with flatulence and a certainly grade of diarrhea several months after the operation.

Complete follow-up assessment was obtained for all the patients after a median follow-up period of 20.3 months (range, 10–30 months). One patient returned with symptoms of GERD at 5 months and was found to have a recurrent HH. Thus, the HH recurrence rate was 10% (1/10). There were no mesh-related complications.

4. Discussion

Surgical treatment of LPEH is a challenging entity for surgeons, and the standard of care for its reparation remains controversial [2,3].

In 2012, Antoniou et al. [4] published results of a meta-analysis of three randomized controlled trials involving 267 patients undergoing LPHH repair. After a follow-up period ranged between 6 and 12 months, the recurrence rates after primary and mesh-reinforced hiatoplasty were 24.3% and 5.8%, respectively. In summarize, mesh-reinforced hiatal hernia repair is associated with an approximately 4-fold decreased risk of recurrence in comparison with single repair.

In the same way, there are other many non randomized and retrospective studies that report that the application of mesh-reinforced hiatal closure has resulted in a significant reduction in recurrence rates in comparison with primary suture repair [15–20].

Despite these excellent results, there have been some reports of an increasing failure rate of LPEH repair in long-term follow-up studies [6,21].

For this reason, nowadays, a great number of controversies associated with the use of meshes in the hiatus remains, including the indication for mesh placement, the type of mesh to use, the configuration of the mesh with respect to the hiatus and esophagus, and how the mesh is anchored in place [7].

Table 1
Hiatal hernia related symptoms.

	Cases % (ratio)
Reflux	60 (6/10)
Epigastric pain	50 (5/10)
Dysphagia	50 (5/10)
Vomiting	40 (4/10)
Anemia	40 (4/10)

Some authors [22–24] argue against routine mesh reinforcement, due to the risk of mesh-related complications, such as mesh migration, stenosis, esophageal erosion and postoperative dysphagia. Incidence rates of these entities vary from 0.1% to 20% in the literature, but it must be noted that the incidence is significantly lower in recent series with a large number of patients than in older and smaller ones, probably reflecting the learning curve in the mesh placement [2].

Given these data on the association of mesh-related complications, and in order to prevent it, a new group of biologic and synthetic bioabsorbable meshes have been proposed. However, published results in relation to this biomaterials reinforcement are also controversial [8–13].

In relation to the use of human acellular dermal matrix (HADM: Allo-Derm®, Lifecell Corporation, Branchburg, NJ), preliminary short-term results reported that LPEH repair with this mesh is an effective method of repair with a low perioperative morbidity, with no mesh-related complications, and with a recurrence rate of 4% [9–12].

In case of Surgisis® (derived from porcine intestinal submucosa) the results are so much contradictory. In this way, Jacobs et al. [13] published a low recurrence rate (3.3%) when posterior cruroplasty and absorbable mesh reinforcement was placed compared with a 20% recurrence rate in the group without mesh and with a long follow-up of 58 months.

In 2006, Oelschlager et al. [6] reported results of a randomized trial of LPEH repair, comparing primary diaphragm repair (PR) with primary repair buttressed with a biologic prosthesis (Surgisis®). The primary endpoint, radiologic HH recurrence, was higher with PR (24%) than with Surgisis® buttressed repair (9%) after 6 months.

However, in the same study and after a median follow-up of 58 months, there were 20 patients (59%) with recurrent HH in the PR group and 14 patients (54%) with recurrent HH in the Surgisis® group ($p = 0.7$). There was no statistically significant difference in relevant symptoms or quality of life between patients undergoing PR and Surgisis® buttressed repair. Anyway, there were no strictures, erosions, dysphagia, or other complications related to the use of Surgisis® mesh.

At this stage, no firm recommendations on the use of mesh at the esophageal hiatus can be made. If you choose a permanent mesh there is a risk of erosion, but if you choose a biologic mesh there is an increase of the recurrence rate [7].

In our experience, in a recent published paper [25] about the long-term results of LPEH repair with a Crurasoft® mesh (V-shaped mesh with porous polytetrafluorethylene (PTFE) on one side and expanded polytetrafluorethylene (e-PTFE) on the other side), that showed the experience of Ramón y Cajal Hospital in the management of these problem [26–28], a wrap migration appeared in only one patient (2%), and excepting this case, there were no other cases of clinically apparent HH recurrence. Moreover, there were no mesh-related complications.

Regarding the indication for mesh placement, in our opinion, when a correct repair of the hiatus is not achieved with three stitches, the performance of more sutures will not lead to a tension-free repair, and this hiatoplasty would be more suitable for dehiscence. In LPEH (size of hiatus >5 cm in diameter), more than three sutures are usually not enough to close the crural defect, and therefore we recommend placing a prosthetic mesh in these cases.

In our opinion it is important to perform an extended dissection of the mediastinum and an adequate mobilization of the esophagus, in order to achieve an enough length of intraabdominal esophagus. We prefer to perform a posterior closure of the hiatus. We do not personally like to perform an anterior closure of the hiatus. We think that we sometimes insist in closure the hiatus in both approaches (anterior and posterior), and in our experience, some cases of postoperative dysphagia are more related to an excessive closure of the crura rather than the proper mesh.

We have no cases of recurrence after the reparation of primary LPEH, and one case of recurrence in a patient operated for a recurrent hiatal hernia. Globally, our rate of recurrence with the use of this mesh is 10%.

This case of recurrence was a 66 years old woman with a BMI of 40 kg/m^2. The reintervention of the primary failure was so difficult, and finally we could identify the crura, but diaphragmatic pillars were completely destroyed and we could not closure them. We decided to arrange the mesh onlay and fixed it with tackers. Apparently, the anatomical closure of the hiatus was acceptable and the postoperative care was uneventfully. Patient was completely asymptomatic for 5 months, but symptoms of GERD appeared again.

As Granderath reports [29], the main challenge of laparoscopic refundoplication in patients with intrathoracic wrap migration seems to be closure of the hiatal crura. The problem of postoperative breakdown of the crura has led him to use a polypropylene mesh for reinforcement of the hiatal crura during laparoscopic refundoplication.

Although we have had only one case of recurrence, and we feel comfortable with the use of this Gore Bio A® mesh, maybe we agree with Granderath that we should use a polypropylene mesh in this case of laparoscopic refundoplication, moreover when we could not closure the hiatal crura.

There are not many papers published related to the use of this mesh, and sometimes are poster's presentations in meetings [30–32]. Anyway, our results are similar to the reported by Massullo et al. [30].

We have not observed any mesh-related complications neither with the use of tackers to fix the mesh. However, as we have described in surgical technique, we have added a fibrin sealant (Tissucol®) in the last four cases, and maybe in we have good results, we would possibly change the fixation of the mesh in order to avoid tackers.

The limitations of the study are the retrospective review of the patients, with a small number of cases, as well as the short duration of follow-up.

In **conclusions**, the use of Gore Bio A® mesh for the laparoscopic repair of large paraesophageal hiatal hernias is safe and with a reasonably low recurrence rate in this short-term study.

Additional long-term studies with ample numbers carried out for years will be necessary to see if this synthetic mesh is not only safe but also successful in the prevention of recurrences.

Ethical approval

None.

Author contribution

Dr Pablo Priego: data collections, analysis and writing.
Dr José Luis Salvador: study design.
Dr Vicente Ángel: data collections.
Dr Javier Escrig: study design, data collections and analysis.

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Conflicts of interest/disclosures

No conflicts of interest or financial ties to disclose.

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