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Hiatal Hernioplasty with a Novel Composite Mesh Design: Results of a Multicenter Study after Two- Years Follow-up

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Abstract

Background: Surgical treatment of paraesophageal hiatal hernia is still controversial, particularly in aspects related to surgical technique, being the main problem the high recurrence rate, between 20% and 30%.

Methods: The aim of this study is to describe the surgical technique and results of laparoscopic repair of paraesophageal hernia using a new composite silicone/polypropylene mesh. This is a retrospective study of 61 patients who underwent laparoscopic repair of symptomatic large (6 cm or more in diameter) hiatal hernias in three public hospitals of the Valencia Community (Spain). The study analyzes postoperative mesh-related morbidity, functional outcomes and recurrence rate.

Results: There were two conversions due to technical difficulties. The mean hospital stay was 3.2 days. Mean follow-up was 26 months. A recurrence rate of 11.7% was recorded. Complications, reoperations and quality of life are analyzed.

Conclusion: This newly designed prosthetic mesh offers easy laparoscopic implantation with acceptable recurrence and complications. Additional studies are needed to determine the most appropriate material and shape to cover hiatal defects.

Keywords: Paraesophageal hernia; Hiatoplasty; Hiatal hernioplasty; Mesh; Laparoscopic repair

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Introduction

Hiatal Hernia (HH) is a common disorder characterized by enlargement of the space between the diaphragmatic crura, secondary to increased intra-abdominal. Current classification of HH defines 4 types of hiatal or Paraesophageal Hernias (PEH): Type 1: Sliding hernia; Type 2: True PEH or rolling hernia, herniation of gastric funds with gastroesophageal junction in the normal anatomic location; Type 3: Combination of types 1 and 2 a Type 4: Herniation of other intraabdominal viscera [1].

Large hiatal defects (>6 cm) may cause giant hernias that are associated with symptoms like chest pain, vomit and post-prandial dysphagia and may lead to torsion, perforation and massive bleeding [2].

Surgical treatment of paraesophageal hiatal hernia is still controversial, particularly in aspects related to surgical technique and functional outcomes [3-5]. Laparoscopic repair of paraesophageal hernia is more complex than that of GERD, although it offers similar benefits when performed by experienced surgeons, with less pain, better recovery and shorter hospital stay with no increase in morbidity [6].

The main problem with surgical treatment is still the high recurrence rate, between 20% and 30%. Although not always associated with symptoms, recurrence requires redo operations in a significant number of patients and has been attributed to excessive tension after the closure of large hiatal defects [7]. To overcome this problem, meshes were introduced to provide tensionless cover of such defects [8-10]. The meshes initially used were made of non-absorbable materials (polypropylene and PTFE) as used for inguinal hernia repair. Serious complications have been reported, particularly with polypropylene meshes, related to fibrosis thus conditioning dysphagia and even esophageal

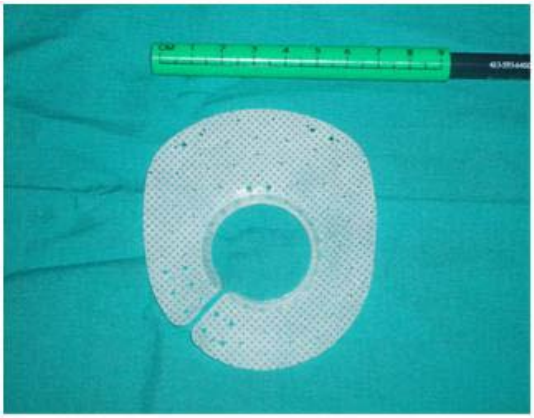

Figure 1: Aspect of the mesh.

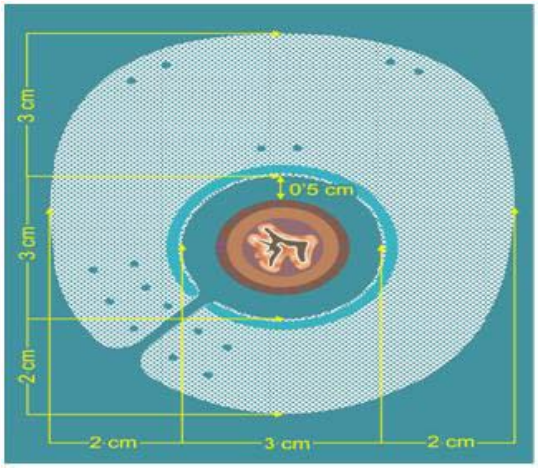

Figure 2: Schematic view of the mesh with dimensions.

erosion [11-13]. Subsequently, absorbable biological meshes have been used to avoid this situation. Mesh repairs show a decrease in recurrence when compared with primary closure in several studies [14-18].

The aim of this study is to describe the surgical technique and results of laparoscopic repair of paraesophageal hernias using a new composite silicone/polypropylene mesh. The study analyzes postoperative mesh-related morbidity, functional outcomes and recurrence rate.

Materials and Methods

Patients

This is a retrospective study of 61 patients who underwent laparoscopic repair of symptomatic paraesophageal hiatal hernias (types II, III and IV) in three public hospitals of the Valencian Community (Spain) (Dr. Peset Hospital in Valencia, Lluís Alcanyís Hospital in Xativa and Arnau de Vilanova Hospital in Valencia).

The study analyzes operative morbidity, anatomic recurrence, reoperation, mesh-related complications and quality of life by means of the Visick scale. In a subset of patients belonging to one of the participating centers the GIQLI test (Gastrointestinal Quality of Life Index) was also used [14].

Diagnostic work-up

All patients underwent clinical assessment, barium swallow and gastroscopy. CT scan was indicated in cases of complex hernias (more than one organ) or gastric volvulus. When gastroesophageal reflux disease or an esophageal motor disorder was suspected, esophageal manometry and 24 hr pH-metry were carried out.

Surgical technique

All operations were performed by experienced surgeons in laparoscopic and esophagogastric surgery.

A standardized 5-trocar laparoscopic approach was performed. The procedure begins with a thorough dissection of the esophageal hiatus, avoiding the vagus nerves and fully exposing the crura. Herniated organs are reduced in the abdomen, the hernia sac is resected and the esophagus is dissected free from its mediastinal attachments to obtain at least 3 cm of intra-abdominal esophagus. The hiatal defect is closed by approximating the diaphragmatic crura with non-absorbable sutures in the retroesophageal space. A maximum of two stitches are used to avoid kinking of the esophagus. Additional sutures can be utilized to close the pre-esophageal gap of the defect if necessary with a maximum of two.

Indications for mesh implantation: The use of a reinforcing mesh is indicated when hiatal defects 6 cm or more in largest diameter or excessive tension in the standard diaphragmatic suture is encountered. A composite mesh designed by the first author (*MicroVal-France*) is subsequently placed (Figure 1).

The mesh consists of two layers, polypropylene and silicone, for the diaphragmatic and peritoneal sides respectively, measuring 7 cm × 8 cm in size with an adjustable 3 cm central ring, opened at the right lower rim to allow passage of the esophagus. Furthermore, the ring has a silicone reinforcement to prevent erosion of the esophagus. It can be easily inserted around the esophagus due to its preformed shape. Once in place, the ring is closed with a suture including the right crus leaving a 0.5 cm gap with the esophagus to avoid excessive contact or migration of the fundus (Figure 2). An additional suture needs to be attached at the opposite side of the hiatal orifice for proper mesh fixation. Supplementary stitches or cyanoacrilate glue are used when considered necessary. After the anatomic reconstruction a short floppy 360° fundoplication is performed.

Follow-up

A clinical assessment was carried out to all patients at least three months and one year after the operation. Special attention was focused on dysphagia, pain or reflux symptoms. Recurrence was systematically monitored by performing a barium meal at one year.

Results

Sixty one patients, 46 women and 15 men were included in the study with a mean age of 66 years (range 46-84). Mean body mass index was 29.70 (range 22.9-40). The ASA risk factor was distributed as follows: 12% classified as ASA I, 65% as ASA II and 23% as ASA III. Predominant symptoms were heartburn in 53.5% of the cases, dysphagia in 42.2%, epigastric or retrosternal pain in 41.7%, vomiting in 38.4%, regurgitation in 34.5%, and anemia in 20% and respiratory symptoms in 19.5%. All patients underwent barium swallow and endoscopy, 39% had also a CT scan and 18% esophageal pH measurement and manometry. All hernias contained the stomach, two cases included greater omentum and transverse colon was contained in one. In 4 cases an incidental opening of the pleura occurred during the operation with no consequences for the

patient. The average operative time was 116 mins (range 75-240). There were two elective conversions due to intra-operative technical difficulties (3.3%). Two patients (3.3%) had to be re-operated in the first 24 hrs due to intra-abdominal hemorrhage in one case and immediate recurrence with incarceration of the stomach in the other. Oral intake was initiated during the first 24 hrs in 61% of patients. The mean hospital stay was 3.2 days (range 2-14). There was no mortality in our series.

The mean follow-up was 26 months (range 12-48). Three patients were lost to follow-up (5%). Anatomical recurrence was evidenced in 11.7% of the patients, although in half of these, the patients either did not present symptoms or referred clinical improvement after the operation. The Visick scale was tested in all cases, with a 52% of Visck I, 39.5% of Visick II and 14.5% of Visick III patients. Two patients needed esophageal dilatations due to postoperative dysphagia with good final outcome. Five patients (8%) had to be reoperated, because of severe symptomatic recurrence in three and intraluminal migration of the mesh in two. In the subset of 15 patients where quality of life was assessed by means of a GIQLI test, 10 patients had a score higher than 106 (higher than the normal population), and 5 ranked below.

Discussion

Currently there is little controversy in gastro-esophageal reflux surgery. The advantages of laparoscopic approach in terms of shorter hospital stay, postoperative morbidity and improved quality of life compared to open surgery has been documented, with no differences in postoperative results [20,21]. 360° fundoplication seems to be the option offering the lowest recurrence rate in the long-term when compared to other techniques [22-24].

Paraesophageal hernias, which include hiatal hernias type II, III and IV, are a different problem [25]. Its surgical treatment is still controversial mainly in relation to elderly patients and patients with comorbidity [26]. There is consensus in restricting surgery to symptomatic patients with dysphagia, retrosternal pain, dyspnea, dyspepsia, heartburn or anemia. Occasionally, emergency surgery is needed to deal with complications such as incarcerated volvulus, perforation, ischemia or bleeding. In the present study, all patients were symptomatic. Regarding diagnosis, essential preoperative studies are barium meal and upper endoscopy. CT can be useful in emergency situations to detect complications caused by volvulus. If a motor disorder is suspected, a ph-metry and esophageal manometry should be performed [27].

Most authors agree in the advantage of laparoscopic approach, the need for excision of the hernia sac and the restoration of the gastroesophageal junction into the abdominal cavity [28]. The association of an antire flux procedure is currently recommended over simple anatomic reduction, due to the need of extensive dissection of the hiatus, thus facilitating postoperative gastroesophageal reflux. Nevertheless some studies do not support this point [29-31].

The main issue in surgical treatment of paraesophageal hernias is the high recurrence rate as observed in all published series. Recurrence does not always imply a bad clinical outcome since many of these patients are no or mildly symptomatic [32,33]. This was also our experience. An efficient closure of the hiatal defect is the most determinant factor [34]. The use of reinforcing meshes was initiated in the late 90's with the use of polypropylene and polytetrafluoroethylene materials as in abdominal wall repairs. Severe adverse effects were reported with these materials, such as mesh migration, esophageal erosion, fibrosis and stenosis, leading to occasional esophageal and gastric resections. The placement of reinforcing meshes in the hiatus generates controversies such as true recurrence reduction, appropriate indication of the procedure -defect's size *vs.* suture tension-; appropriate mesh attachment -sutures *vs.* tacks *vs.* adhesives-; and proper esophageal protection [35]. A reduction of the recurrence rate under 15% has been reported with the use of meshes during the first years of follow-up, but a long term decrease in recurrence has not been demonstrated yet [36-38].

In the present study, the recurrence rate was 11% after a mean follow-up of 26 months. Some authors indicate the need of mesh reinforcement when hiatal defects larger than 5 cm or 6 cm or when excessive suture tension occurs [39]. It is known that nausea and vomiting in the early postoperative period favor immediate recurrence, as it occurred in one of our patients who had to be reoperated in the first 24 hrs. There were two cases of mesh erosion and subsequent migration into the gastric lumen that needed reoperation. This complication could be attributed to excessive closure of the mesh around the gastroesophageal junction. It is very important to leave enough free space (0.5 cm) around the esophagus to permit free mobility of the organ. The use of tissue adhesive combined with sutures has been useful, facilitating the initial fixation of the mesh. The use of tacks for fixation is discouraged due to the risk of injury to nearby structures such as the aorta, the pericardium or the lung.

The most innovatory aspect of this study concerns the new type of mesh used, made of composite, flexible, synthetic materials with an original shape designed to avoid contact of the polypropylene layer either with the esophagus or the peritoneal cavity. The peritoneal side of the mesh and the esophageal circumferential rim are made of silicone.

The characteristics of an ideal prosthesis for this anatomical region should include easy handeling during laparoscopy, strong and rapid tissue integration on the diaphragmatic surface, together with minimal adherence to hollow viscera, minimal shrinkage, and good transparency for secure fixation.

To cope with these principles our rationale was to use a double layer mesh. A polypropylene side in order to reduce recurrence risk, believing that polypropylene rapidly incorporates to tissue developing a scar that strengthens the muscular fibers of the hiatal crura [40] and a silicone side due to its low adhesive potential, believing that its use at the hiatus might reduce the risk of erosive complications. We preferred silicone to PTFE because of its known "mesh shrinkage" effect [41].

Silicone, the main compound used in this innovative prosthesis, is an inert substance commonly used in breast implants since 1960. The safety of the compound was approved in 2000 by FDA [42]. Since then many investigations have proved its safety in medical uses. Considering the Cumberland criteria, silicone seems to be an ideal substance to be used for repairing hernia [43].

In our literature review we have only found one study using a silicone reinforced mesh for hiatal hernia repair in humans, with good results [44].

We believe that the decrease in recurrence obtained in the present study is due to the particular shape of the mesh, with its widest side being anterior, thus reinforcing the widest and less muscular area of the hiatal defect. The mesh presented has several openings in each

branch facilitating its fixation with stitches to the crura and the diaphragm. The internal circular silicone reinforcement of this mesh allows free frictionless sliding of the esophagus, thus minimizing the risk of erosion or intraluminal prosthesis migration. To our knowledge this mesh design has not been previously described.

Our study presents the inherent constraints of a retrospective series with a still limited follow-up, particularly in relation to recurrence and quality of life, although 30% of the patients were followed for more than 4 years with a satisfactory outcome. Additional studies are needed to determine the most appropriate material and shape to cover hiatus defects.

Disclosures

Dr. Delgado F, as designer of the prosthesis, has a commercial relation with the manufacturer (Microval - France)

Drs. Aguiló J. Asencio F., Primo V. Saborit R., and Gomez-Abril S. have no conflicts of interest or financial ties to disclose.

The manufacturing company has not sponsored or influenced by any means in the free opinion of the authors.

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