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Urinary Bladder Matrix Reinforcement for Laparoscopic Hiatal Hernia Repair

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ABSTRACT

Background and Objectives: Synthetic mesh reinforcement during laparoscopic hiatal hernia repair (LHHR) reduces recurrence. Biologically derived mesh is also associated with reduced recurrence. Urinary bladder matrix (UBM), a biologically derived extracellular matrix mesh, has shown clinical success. We wanted to determine the safety and efficacy of LHHR with porcine UBM reinforcement.

Methods: This retrospective, single-surgeon study reviewed clinical data on patients who underwent LHHR from August 2009 through May 2014, with diaphragmatic reinforcement with porcine UBM mesh. Primary outcomes were (1) recurrence—a >2-cm defect above the diaphragm at 3 months; (2) intra- and postoperative complications; (3) pre- and postoperative esophageal reflux (GERD) or dysphagia; and (4) cessation of proton pump inhibitor (PPI).

Results: Sixty-two patients who had LHHR with UBM mesh were studied (mean age, 62 years, 53 women, mean body mass index 32.7 kg/m^2) Before surgery 98% had GERD, 19% had dysphagia, and 98% were on PPI. Postoperative UGIS was performed on 66% 3 months after surgery, and 19% had a recurrence of >2 cm; 56% remained on PPI, and 16% ($P < .001$) remained symptomatic. Dysphagia improved in 75% ($P = .05$). No intraoperative complications were recorded. One postoperative mortality occurred secondary to an unrelated cardiac event.

Conclusions: UBM mesh was effective and safe for LHHR. In addition to reducing the rate of recurrence compared to unreinforced primary repair, the properties of UBM, including site-specific constructive tissue remodeling, may add benefits over other biologic products. This study represents an evaluation of UBM mesh in a large cohort of patients who underwent LHHR.

Key Words: Laparoscopic hiatal hernia repair, Gastroesophageal reflux disease (GERD), Mesh, Paraesophageal hernia, Recurrence.

INTRODUCTION

Laparoscopic repair of large paraesophageal hiatal hernia has been humbled by the known and well-documented high long-term recurrence rate. Prosthetic reinforcement has often been used in an attempt to reduce recurrence rates.[1] Studies have shown that synthetic mesh lowers recurrence rates and symptoms of gastroesophageal reflux disease (GERD), but, in turn, can lead to long-term dysphagia.[1–5] These studies also emphasize the need to identify modalities to reduce recurrence rates when repairing large or paraesophageal hiatal hernias. The most common modalities used for reinforcement during hiatal hernia repair include commercially available resorbable synthetic mesh and dermal-based biologic products.

A novel biologically derived product consisting of the epithelial basement membrane and lamina propria of the porcine urinary bladder (termed urinary bladder matrix [UBM])[6] has been used for tissue reinforcement with success in a variety of body systems in both animal studies and clinical experience. The product provides mechanical support, whereas the host response to the product appears to involve a unique cellular infiltration response that results in site-appropriate tissue deposition, and the product itself is eventually fully resorbed by the body.

To date, we know of no large series reporting of the use of UBM in laparoscopic hiatal hernia repair. Given our

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experience in a large cohort of patients, a retrospective study was undertaken to evaluate the safety and efficacy of using UBM in laparoscopic hiatal hernia repair.

METHODS

An Internal Review Board–approved retrospective review of charts was completed at a single university-affiliated hospital. All patients between August 2009 and May 2014 who underwent laparoscopic hiatal hernia repair (LHHR) with UBM were included in the review. All procedures had been completed by a single surgeon, fellowship trained in minimally invasive surgery. In all operative repairs, each patient had undergone laparoscopic reduction of the hiatal hernia, mobilization (lengthening) of the esophagus, and primary repair of the hiatus via approximation of the posterior diaphragmatic crura over a 50-French bougie with permanent suture, followed by an onlay of diaphragmatic tissue reinforcement using UBM (MatriStem Surgical Matrix PSMX, ACell, Inc., Columbia, Maryland, USA). All hernia defects greater than 4 cm were repaired with mesh. UBM was used in every case, unless the patient refused, in which case synthetic mesh was used. The UBM mesh was crafted into a circular keyhole configuration with a 3.5-cm round esophageal opening. After circumferential placement around the esophagus, the mesh graft was then secured with a B-shaped 4.8 mm tacker (Covidien Endo Universal Auto Suture; Medtronic, Minneapolis, Minnesota, USA). Finally, a 3-stitch Nissen fundoplication was performed over a 50-French bougie, unless a concomitant bariatric procedure was performed, in which case there was no fundoplication. Patients were admitted for 23-h observation after surgery and underwent water-soluble UGI contrast evaluation on postoperative day 1 with subsequent dietary advancement. Postoperative nausea and vomiting were part of the preoperative assessment. Those patients who were experiencing nausea and vomiting were given 40 mg of aprepitant 2 hours before surgery. Intravenous promethazine (12.5 mg every 6 h) was used in all patients, as needed, after surgery to control nausea and vomiting.

Data collected included, age, sex, pre- and postoperative GERD, dysphagia, and use of proton pump inhibitor (PPI) or H2-blocker. Preoperative manometry, contrast upper gastrointestinal series (UGIS), endoscopy, intra- and postoperative complications, and estimated blood loss (EBL) were also recorded. Patients were observed for a minimum of 3 months after surgery, at which point they underwent a second postoperative UGIS. After the 3-month follow-up, patients were seen as needed, and no further routine follow-up was undertaken. The primary outcome was recurrence of hiatal hernia, which we defined as a recurrent herniation with >2 cm of stomach above the diaphragm noted on UGIS at 3 months. Statistical analysis was performed with the Chi-square test, with differences reaching $P < .05$ defined as significant.

RESULTS

In total, 62 patients underwent LHHR with UBM. The mean age was 62 (range, 32–83) years, with a female-to-male ratio of 53:9. The average body mass index was 32.7 kg/m^2. A total of 17 of 62 (27%) patients had a concomitant bariatric procedure performed at the time of repair, with 11 patients undergoing laparoscopic Roux-en-Y gastric bypass, 5 undergoing laparoscopic sleeve gastrectomy, and 1 undergoing a revision of the gastrojejunostomy anastomosis. The bariatric patients had only a crural repair and did not have a concomitant antireflux procedure. All 45 remaining patients had concomitant Nissen fundoplication. Three had a history of prior hiatal hernia repair. In those patients, the wrap was reduced to the abdomen and redone, and a crural repair was performed and reinforced with UBM. Before surgery, 61 of 62 (98%) patients had GERD, 12 of 62 (19%) had dysphagia, and 61 of 62 (98%) were taking a PPI or H2-blocker. No intraoperative complications were noted. EBL was, on average, 24 mL per case. One patient died of cardiopulmonary arrest on postsurgical day 1 of a cause unrelated to the mesh placement at the time of surgery. Because of difficulty advancing diet during the immediate postoperative period, 3 patients required postoperative endoscopic balloon dilation for dysphagia which was successful in all 3 patients, and no reoperative intervention was necessary.

A radiographic recurrence rate of 22% (9/41) was identified. Only patients who met the guidelines for 3-month postoperative UGIS were included in this calculation (patients undergoing weight loss surgery were excluded), and the remaining 21 patients either did not meet the criteria or were lost to follow-up. Of those patients with radiographic recurrence, only one (2.4%) became symptomatic and required revision 22 months after initial operative intervention. In addition, because of weight gain, one patient underwent laparoscopic Roux-en-Y gastric bypass.

Of the 12 patients with preoperative dysphagia, 8 (67%) improved after surgery. Of the remaining 4 patients with preoperative dysphagia, 3 were unchanged after surgery, and the fourth patient died in the immediate postoperative period of an unrelated cause. A total of 10 patients had

GERD after surgery that required PPI use, a significant reduction from 61 patients before surgery. Of the 10 patients who had continued postoperative GERD, 3 of 10 reported dramatic symptom improvement after surgery, defined as only intermittent use of PPI therapy.

DISCUSSION

Recurrence after hiatal hernia repair has been a challenging problem. The value of using mesh reinforcement has been debated.[7] Synthetic products have a host of known complications when used in hiatal hernia repair, the most troublesome of which is erosion into the esophagus.

In this retrospective review of the use of UBM in hiatal hernia repair reinforcement, the product was successfully used without adverse technical outcomes at the 3-month follow-up. Patients experienced a lower recurrence rate and a reduced incidence of GERD and dysphagia. The limited duration of follow-up evaluation at 3 months is acknowledged; however, we felt it was important to provide this review now because the novel biologic material shows promise in reinforcement of the crural repair during Nissen fundoplication without some of the side effects of synthetic material.

These results are not predictive of long-term recurrence rates, but recently, several small case reports and series have been published describing the use of UBM for reinforcement of hiatal hernia repair with a minimum of a 24-month follow-up. A small case series by Sasse et al[8] showed that use of UBM reinforcement for laparoscopic repair of hiatal hernias was successful ,with limited postoperative complications and no reported recurrence over a range of 24–56 months.[8] These results suggest that UBM plays a role in improving hiatal hernia tissue repair, possibly decreasing recurrence rates.

A collection of extracellular molecules secreted by cells, the extracellular matrix (ECM) provides structural and biochemical support to the surrounding cells. These molecules can be purified from harvested organs and tissues in an effort to aid in tissue engineering and repair. When the matrix is introduced into an organism, an influx of immune cells occurs that is referred to as the host response. In the case of UBM, studies have shown[9] that the host response to this particular type of nondermal ECM is more of a constructive remodeling response and less of a scarring response, as evidenced by both histologic studies and cellular studies comparing macrophage infiltration patterns. In one such study by Badylak and Gilbert,[10] esophageal reconstruction was undertaken in canine models, with UBM used in combination with autologous tissue. The results showed that tissue taken postmortem from the esophageal reconstruction site showed near normal histomorphologic structure and biomechanical properties.[10] It is thought that the response to UBM is dominated by the adaptive immune system, with Th2 lymphocytes and M2 macrophages, as opposed to the proinflammatory immune response typical of synthetic or dermal mesh.[11,12]

The use of biologic mesh reinforcement in LHHR has been shown to reduce short-term recurrence. UBM appears to be a safe and feasible option in LHHR. Our study revealed no intraoperative events and limited postoperative complications, with 3 patients experiencing dysphagia requiring dilation. The immediacy of this complication suggests that it is of a technical nature, as opposed to being the result of the host response to the product; this probability is also evident in the absence of recurrence of dysphagia in the patients on further follow-up. Our 22% recurrence rate is also similar to that in prior studies, when short-term outcomes are compared.[13] This statistic is most likely attributable to technique, as the most cephalad stitch on the wrap was secured high on the right crus of the diaphragm. These small radiographic recurrences were not shown to be clinically significant.

The major weakness in our study lies in its retrospective design. Further study of long-term outcomes, including recurrence rates, using ECM/UBM in LHHR is needed. In summary, UBM is an effective tool in reinforcing the diaphragm. The body's response to UBM may make it an ideal choice for diaphragmatic reinforcement of hiatal hernia repairs in an attempt to decrease complication rates.

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