A Prospective, Randomized Trial of Laparoscopic Polytetrafluoroethylene (PTFE) Patch Repair vs Simple Cruroplasty for Large Hiatal Hernia

Hypothesis: Large hiatal hernias are prone to disruption, resulting in reherniation, when repaired with simple cruroplasty. The use of mesh may decrease the rate of reherniation in the laparoscopic repair of large hiatal hernias.

Design: Prospective, randomized controlled trial.

Setting: University-affiliated private hospital.

Patients: Seventy-two individuals undergoing laparoscopic Nissen fundoplication with a hernia defect greater or equal to 8 cm in diameter.

Intervention: Nissen fundoplication with posterior cruroplasty (n=36) vs Nissen fundoplication with posterior cruroplasty and onlay of polytetrafluoroethylene (PTFE) mesh (n=36).

Main Outcome Measures: Recurrences, complications, hospital stay, operative time, and cost.

Results: Patients in both groups had similar hospital stays, but the PTFE group had a longer operative time. The cost of the repair was $960±$70 more in the group with the prosthesis. Complications were minor and similar in both groups. There were 8 hernia recurrences (22%) in the primary repair group and none in the PTFE group (P<.006).

Conclusion: The use of prosthetic reinforcement of cruroplasty in large hiatal hernias may prevent hernia recurrences.

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The laparoscopic technique has revolutionized the approach to hiatal hernia repair and the treatment of gastroesophageal reflux disease. Traditionally, an enlarged hiatus is closed with interrupted large-gauge sutures. This method is prone to disruption and reherniation. One investigation of 87 reoperations for gastroesophageal reflux disease demonstrated that 72% of patients experienced failure of their antireflux procedure because of the breakdown of the hiatal hernia repair.

A recent study has suggested that the laparoscopic approach may be inferior to the open approach for large hiatal hernia. The recurrence rate for open simple cruroplasty in their study, however, was still 15%. Others have demonstrated a similar high recurrence rate (10%-50%) even in the open approach. The diaphragmatic repair may be more susceptible to disruption because of repetitive stresses of coughing, straining, sneezing, and laughing. Prostheses have been used effectively in other fascial defects such as inguinal hernias and ventral hernias. Previous preliminary reports by our group have described the use of polytetrafluoroethylene (PTFE) for large hiatal hernia repair. No investigation with a significant sample size, however, has compared this repair with simple cruroplasty alone. Thus, a prospective randomized study was undertaken to compare the use of PTFE only with simple cruroplasty in minimally invasive hiatal herniorrhaphy.

RESULTS

A total of 628 fundoplications were performed in the period between January 1, 1991, and December 31, 2000. In this patient population, 331 underwent a hiatal hernia repair. Seventy-two patients (11% of all patients receiving fundoplications, or 21% of patients with hiatal hernias) with a hiatal defect of 8 cm or more were enrolled in this trial (Figure).

There was no significant difference in the mean age between the 2 groups (Table). There were no conversions in either group. The operative time was about 30 minutes longer in the PTFE group (Table). The increased operative time along with the cost of the PTFE resulted in an increase in hospital charges of $960±$70 in the PTFE group compared with the simple cruroplasty group.

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PATIENTS AND METHODS

The study was approved by our institutional review boards, and informed consent was obtained from all subjects. All patients with hiatal hernias (types I to IV) were considered for the study. Presence of a hiatal hernia was determined by video esophagogram and esophagogastroduodenoscopy. Patients with dysphagia, odynophagia, or dysmotility on the esophagogram underwent manometry. Any patient with a hiatal defect of 8 cm or larger was enrolled in the study. The 8-cm defect cutoff was chosen empirically.

Preoperative antibiotics were given with the induction of anesthesia. Our technique of laparoscopic hiatal hernia repair has been described in detail previously. Briefly, the hernia contents and the sac are reduced. The lower 4 to 5 cm of esophagus is mobilized into the abdomen. A cruroplasty is performed with interrupted 2-0 nonabsorbable sutures; each suture incorporates large (>1 cm) bites of both crural muscle and fascia.

In the PTFE group, interrupted 2-0 nonabsorbable crural sutures were placed and tightened up to the point to provide a nontension approximation. For the onlay repair, an oval sheet (13×10×0.1 cm) of fenestrated PTFE (DualMesh Gore-Tex; W. L. Gore & Associates, Inc, Phoenix, Ariz) was used. A radial slot with a 3-cm defect in the center of the oval ("keyhole") was cut into the PTFE. The mesh was secured to the diaphragm and the crura with a straight hernia stapler (Ethicon-EndoSurgery, Cincinnati, Ohio). The 2 leaves of the keyhole were then stapled to each other.

All patients received a 3-stitch (3 cm long), 360° Nissen fundoplication performed over a 60F esophageal bougie. The most cephalad stitch of the fundoplication incorporated either the anterior arch of the right crus (simple cruroplasty group) or the posterior and the anterior arch of the right crus (PTFE group).

All patients were seen postoperatively at 1 week, 2 weeks, 1 month, 3 months, and then yearly. At 3 months, an esophagogastroduodenoscopy and esophagogram were performed in all patients; a repeated esophagogram was done thereafter every 6 months. Any complaint of chest pain or pyrosis was evaluated with a barium contrast study and a clinic visit.

Operative time, hospitalization, complications, conversions, and recurrences were recorded. Two-tailed Fisher exact test and 2-tailed unpaired t tests were performed with GraphPad InStat Version 1.12a software (GraphPad Software, Inc, San Diego, Calif) as appropriate. Significance was defined as P<.05.

Only complications that prolonged hospitalization and/or resulted in patient distress were recorded. Thus, atelectasis and urinary retention, which did not delay discharge, were not considered complications. Also, minor abdominal wall hematomas and subcutaneous emphysema were not recorded as complications. Subcutaneous emphysema is often seen in patients after laparoscopic repair of large hiatal hernia. There were a total of 3 minor complications. The 2 complications in the PTFE group included 1 case of pneumonia and 1 of urinary retention that delayed discharge. Both patients did well after appropri-
Although more expensive and slightly longer, the technique with an onlay PTFE patch for large hiatal hernia results in a lower rate of recurrence. It has been well known that, for appropriate healing, tissues must be held together in a tension-free manner. Inappropriate tension predicts failure of tissue approximation. When performing anastomosis and abdominal wall herniorrhaphy, most surgeons try to follow this principle universally. By the same logic, tension-free hiatal hernia repairs should be performed. If there is excess tension on the hiatal hernia repair, the use of a mesh as a buttress helps decrease the tension on the repair. Also, the onlay patch buttresses the cruroplasty against the frequent mechanical perturbations that the diaphragm undergoes.

Recurrence rates after simple cruroplasty for large hiatal hernias were unacceptable in the present study, as in other investigations. In a recent review of more than 10,000 laparoscopic fundoplications, early reherniation has been cited as a frequent complication.

In the present study, we have described the first, to our knowledge, randomized controlled trial of prosthetic use in minimally invasive hiatal herniorrhaphy. Other techniques of tension-free repairs with mesh have been described. One study used polypropylene mesh, gas- troscopy, and gastrostomy for the management of paraesophageal hernias. Another report described the use of multifilamented polyester mesh to laparoscopically repair large hiatal hernias. Again, although others have described the use of mesh to close large hiatal defects in a limited number of patients, no true comparison with simple cruroplasty has been performed.

Huntington described a technique that used a relaxing incision to allow a tension-free closure of the crura. A polypropylene mesh was used to close the defect from the relaxing incision. While this technique does provide closure of the crura, we have 2 major concerns. First, the added time and risk in creating a relaxing incision seem unnecessary. Second, the use of polypropylene mesh, even if placed away from the esophagus, should be avoided because of the reported risks. Others have demonstrated that erosion and stricture of the esophagus may be caused by polypropylene mesh in both the laparoscopic and open approaches. Complications associated with the use of polypropylene have been described as mesh extrusion, bowel erosion, fistulation to gastrointestinal organs, and wound sepsis. These complications arise from the fact that polypropylene mesh creates substantial visceral adhesions to adjacent organs. Because of the aforementioned pitfalls, some authors discourage the use of prosthetic materials at the hiatus.

Our preference is a material that provides little potential for adhesion formation and fistulation, such as PTFE. Investigations have demonstrated decreased visceral adhesion formation as well as normal diaphragmatic motion on fluoroscopy with the use of PTFE. Repair of congenital diaphragmatic hernias with PTFE yielded excellent long-term results. Others have used PTFE, although they believed that intracorporeal suturing is necessary for securing the mesh. As described, we believe that the laparoscopic hernia stapling device is sufficient for anchoring the mesh on the diaphragm and crura.

Others have described the use of pledgeted sutures for large hiatal hernias. Although pledgeted sutures were not studied during this investigation, they do not provide a true tension-free repair. In fact, a high recurrence rate (42%) has been reported even when pledgeted sutures were used in the presence of increased tension during simple cruroplasty. There is an assumption that pledges are less likely than PTFE to cause complications such as erosion. However, at least one case of erosion from a Teflon pledge from a fundoplication has been reported.

Because of the proved risk of recurrence without reinforcement in large hiatal hernias, the use of mesh is recommended. The PTFE mesh provides a buttress when tissue is under tension and especially when tissue is subjected to stress from coughing, straining, retching, or obesity. This investigation demonstrates that the use of mesh reinforcement in laparoscopic hiatal hernia repair, as opposed to simple cruroplasty, eliminates recurrent herniation.

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REFERENCES

Philip E. Donahue, MD, Chicago, Ill: I want to begin by complimenting the authors for an innovative scientific study. It is the largest prospective randomized paper of its type ever performed, and it will be widely quoted for many years in the surgery of hiatal hernia. There are several issues that require discussion and confirmation before this presentation will be seen in its proper context. The first one is about these large type I hernia hernias and the short esophagus. How do you explain the apparent absence of shortening of the esophagus? North of the border about 23% of patients with gastroesophageal reflux and hiatus hernia have shortened esophagus, and yet just south of the border (I'm not sure what latitude Milwaukee is), the shortened esophagus is much less frequent. Have previous reports underestimated the incidence of short esophagus? Has widespread use of H2 blocker or proton pump inhibition eliminated transmural shortening or transmural effects of reflux and consequent shortening?

I wonder, as a corollary to my first question, how many of your patients with less than 8-cm hiatus hernias developed recurrences. The total absence of recurrence in the 8-cm group treated with mesh is really amazing, and it is a startling conclusion that will lead all programs to change their recommendations regarding mesh repair with large hernias.

The next question is about mesh repair. How about the more traditional things such as excision of the sac, complete reduction of the herniated viscus beneath the diaphragm, and careful suture approximation of the wrap with the fundoplication? If the mesh of mesh in all of the patients will help most of us avoid a 22% recurrence rate with large hiatus hernia, mesh use must become a routine. I recognize the weakness of many American studies that don't have long-term follow-up, but our lack of unified systems and various patient factors will prevent better longitudinal studies for some time.

In conclusion, I believe this is a compelling study. The authors deserve special recognition for an outstanding project, and I thank the Program Committee for the honor of beginning this discussion of the paper and accompanying manuscript.