

# Laparoscopic Repair of Very Large Hiatus Hernia With Sutures Versus Absorbable Mesh Versus Nonabsorbable Mesh

## A Randomized Controlled Trial

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**Objective:** Determine whether absorbable or nonabsorbable mesh in repair of large hiatus hernias reduces the risk of recurrence, compared with suture repair.

**Background:** Repair of large hiatus hernia is associated with radiological recurrence rates of up to 30%, and to improve outcomes mesh repair has been recommended. Previous trials have shown less short-term recurrence with mesh, but adverse outcomes limit mesh use.

**Methods:** Multicentre prospective double blind randomized controlled trial of 3 methods of repair: sutures versus absorbable mesh versus nonabsorbable mesh. Primary outcome—hernia recurrence assessed by barium meal radiology and endoscopy at 6 months. Secondary outcomes—clinical symptom scores at 1, 3, 6, and 12 months.

**Results:** A total of 126 patients enrolled: 43 sutures, 41 absorbable mesh, and 42 nonabsorbable mesh. Among them, 96.0% were followed up to 12 months, with objective follow-up data in 92.9%. A recurrent hernia (any size) was identified in 23.1% after suture repair, 30.8% after absorbable mesh, and 12.8% after nonabsorbable mesh ( $P = 0.161$ ). Clinical outcomes were similar, except less heartburn at 3 and 6 months and less bloating at 12 months with nonabsorbable mesh; more heartburn at 3 months, odynophagia at 1 month, nausea at 3 and 12 months, wheezing at 6 months; and inability to belch at 12 months after absorbable mesh. The magnitudes of the clinical differences were small.

**Conclusions:** No significant differences were seen for recurrent hiatus hernia, and the clinical differences were unlikely to be clinically significant. Overall outcomes after sutured repair were similar to mesh repair.

**Keywords:** hiatus hernia, laparoscopy, mesh repair, randomized controlled trial

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Laparoscopic surgery for the treatment of patients with a very large hiatus hernia is now standard clinical practice. This prob-

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lem occurs most commonly in elderly patients, and in the early days of laparoscopic antireflux surgery it represented less than 10% of the antireflux surgery and hiatus hernia repair workload.<sup>1</sup> However, as laparoscopic techniques for repair have become more reliable, surgeons have been referred more patients with very large hiatus hernias, and in recent years the number of patients with this problem has increased greatly, now comprising approximately 50% of the laparoscopic antireflux surgery workload in our practices.<sup>1</sup> In the 1990s, the standard approach to laparoscopic repair of very large hiatus hernias entailed complete dissection of the hernia sac from the mediastinum, hiatal repair with sutures, and a fundoplication.<sup>2,3</sup> Although good clinical outcomes were reported after laparoscopic repair, and clinical success rates of approximately 90% have been described,<sup>2,3</sup> later studies, which utilized barium meal radiology follow-up, demonstrated that suture repair alone is associated with radiological recurrence rates of approximately 25% to 30%, although only 5% of these patients actually develop symptoms from the recurrent hernia.<sup>4</sup> Nevertheless, concern remains that patients with an asymptomatic recurrence could develop problems later.

Mesh repair has been suggested as a strategy to prevent hernia recurrence, as it applies the principles of groin hernia repair, that is, tension-free repair with prosthetic reinforcement, and it is technically straightforward to perform laparoscopically. Although good results have been reported from case series of mesh repair, some surgeons are concerned that the potential advantages of mesh repair might be offset by the risk of the mesh eroding into the esophageal lumen, and other complications.<sup>5</sup> Difficulties also occur when assessing the outcomes of mesh repair, as there is great variability between mesh types and configurations, and little standardization of surgical techniques.

Three randomized trial have examined the impact of mesh repair of the esophageal hiatus, 2 in the context of very large hiatus hernia.<sup>6–9</sup> In 1 study, Frantzides et al<sup>6</sup> enrolled 72 patients to undergo repair with sutures versus a piece of polytetrafluoroethylene mesh and the results at median 2.5 years follow-up showed a reduction in hernia recurrence from 22% to 0%. In another study, Oelschlager et al<sup>7</sup> reported 6-month outcomes from a multicenter trial of 108 patients who underwent repair with sutures versus an absorbable mesh, and hernia recurrence was reduced from 24% to 9% at short-term follow-up. Later follow-up, however, revealed no outcome differences.<sup>8</sup>

Currently, there remains uncertainty about the preferred technique for repair of very large hiatus hernia, with surgeons disagreeing about whether or not to use mesh, and if mesh is used, what type of mesh and what configuration is optimal. To inform this debate, we conducted a multicenter prospective double-blinded randomized trial designed to determine the effectiveness of mesh repair for very large hiatus hernia. In this study, we compared a sutured repair technique with 2 different mesh types—absorbable versus nonabsorbable, with posterior placement of mesh for hiatal repair.