

Laparoscopic Paraesophageal Hernia Repair To Mesh or not to Mesh. Systematic Review and Meta-analysis

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Objective: This study aimed to compare outcomes after laparoscopic paraesophageal hernia repair (LPEHR) with mesh or primary repair alone.

Summary of Background Data: High recurrence rates after LPEHR have been reported. Whether the use of mesh improves outcomes remains elusive.

Methods: A systematic literature search was performed to identify randomized controlled trials (RCTs) comparing LPEHR with mesh repair versus suture repair alone. Early (≤ 6 months) and late (> 6 months) recurrence rates were used as primary endpoints to assess efficacy. Intraoperative complications, overall morbidity, and reoperation rates were used as secondary endpoints to assess safety. A meta-analysis was conducted using relative risks (RR) with 95% confidence intervals (CI) for the analyzed outcomes.

Results: Seven RCTs comparing mesh ($n = 383$) versus suture only ($n = 352$) repair were included for analysis. Patients undergoing LPEHR with mesh reinforcement had similar early (RR = 0.74, 95% CI = 0.26–2.07, $P = 0.46$) and late (RR = 0.75, 95% CI = 0.27–2.08, $P = 0.48$) recurrence rates as those with primary repair. Similar recurrence rates were also found when stratifying the analysis by the type of mesh utilized (absorbable and nonabsorbable). Intraoperative complications (RR = 1.03, 95% CI = 0.33–3.28, $P = 0.92$) and reoperation rates (RR = 0.75, 95% CI = 0.29–1.92, $P = 0.45$) were also similar in both groups. Overall morbidity, however, was higher after mesh repair with nonabsorbable mesh (RR = 1.45, 95% CI = 1.24–1.71, $P < 0.01$).
Conclusions: Patients undergoing LPEHR have similar early and late recurrence rates with either mesh reinforcement or suture only repair, regardless of the type of mesh utilized. Overall morbidity, however, seems to be higher in patients repaired with nonabsorbable mesh.

Keywords: laparoscopic paraesophageal hernia repair, laparoscopy, mesh, primary repair, recurrence

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Hiatal hernias result from a widening of the diaphragmatic esophageal hiatus and a weakening of the phrenoesophageal membrane. Type I hernias are the most common and represent the herniation of the esophagogastric junction above the diaphragm (“sliding hernias”). Types II, III, and IV are together termed paraesophageal hernias and occur when a portion of the stomach or other intra-abdominal organ herniate through the hiatus.¹ The laparoscopic paraesophageal hernia repair (LPEHR) repair has gained acceptance in the last decades due to the benefits of minimally invasive surgery.² A LPEHR mainly consists in adhesions release, sac reduction, tension-free cruroplasty, and fundoplication.³

Radiological recurrence after LPEHR ranges between 11% and 67%.^{4–8} Reinforcement of the esophageal hiatus with a mesh has

been advocated to reduce such recurrence rates.^{9–12} However, some studies have questioned the usefulness of prosthetic reinforcement,^{11,13–15} and others have even risen major concerns regarding mesh-related complications (eg, infection, migration, stenosis, erosion of the esophagus or stomach).^{16,17}

The Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) guidelines on the management of hiatal hernia recommend the use of mesh for the repair of large hernias.¹⁸ This recommendation was based on 3 randomized controlled trials (RCTs) that showed decreased recurrence rates in patients with mesh reinforcement.^{9–11} Interestingly, more recent RCTs have challenged this recommendation.^{8,13–15}

The aim of this systematic review and meta-analysis was to compare recurrence rates, intraoperative complications, overall morbidity, and reoperation rates between LPEHR with mesh reinforcement or primary repair in published RCTs to date.

METHODS

Data Sources

A systematic literature review of articles on LPEHR was performed according to the PRISMA (*Preferred Reporting Items for Systematic Reviews and Meta-Analyses*) guidelines. Electronic search in PubMed was performed using the following key terms: “hiatal hernia repair,” “paraesophageal hernia repair,” “laparoscopy,” “minimally invasive,” “mesh.” Each set of keywords was used to obtain the maximal number of articles. The search was limited to the English language.

RCTs including patients with LPEHR and published between January 1990 and October 2020 were reviewed. A total of 5632 articles were initially screened. After removing duplicates and publications that did not meet the inclusion criteria, 11 articles were reviewed by both authors based on the methodological quality of the publications. Discrepancies between the 2 reviewers were resolved by discussion and consensus. Finally, 7 articles were included for the meta-analysis (Fig. 1).

The data were carefully evaluated and extracted independently from all the eligible publications. Information retrieved from the studies included author, publication year, population size, mean follow-up, use of mesh, type of mesh, mesh size and shape, intraoperative complications, reoperation rates, overall morbidity, and recurrence rates.

Main Outcomes and Measures

Early (≤ 6 months) and late (> 6 months) recurrence rates were used as primary endpoints to assess efficacy. Intraoperative complications, overall morbidity, and reoperation rates were used as secondary endpoints to assess safety.

Recurrence was determined by barium esophagogram in all studies.^{8,9,10,12–15} Although Oelschlager et al⁸ defined recurrence as > 2 cm of stomach above the diaphragm, the other authors defined recurrence as any size of stomach above the diaphragm. Watson et al and Oelschlager et al provided some of the outcomes (ie, recurrence

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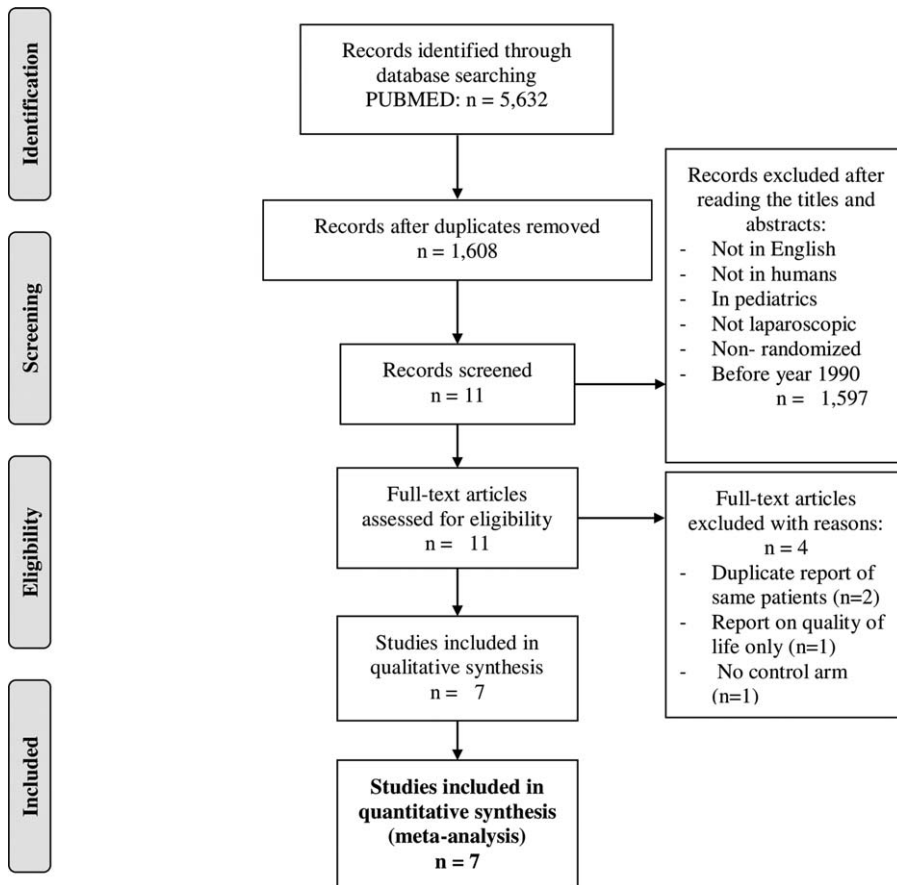


FIGURE 1. Selection process in accordance with the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-analyses).

rate at 6 months, intraoperative complications, and overall morbidity) in the short-term follow-up study.^{11,19}

Statistical Analysis

A meta-analysis was conducted using relative risks (RR) with 95% confidence intervals (CI) for the following variables: early and late recurrence, intraoperative complications, overall morbidity, and reoperation rates. The control group was defined as patients with suture only repair and the experimental group as those with mesh reinforcement.

Heterogeneity across studies was assessed with χ^2 -based Cochran Q statistics, determining its presence with a *P* value <0.05. To further quantify the amount of variability between studies, *I*² metric of inconsistency was used. *I*² values were interpreted as follows: 0% to 40%, might not be relevant; 30% to 60%, moderate heterogeneity; 50% to 90%, substantial heterogeneity; and 75% to 100%, considerable heterogeneity. A random-effect model (DerSimonian-Laird method) was used to combine the summary data. Leave-one-out sensitivity analyses were conducted to assess the influence of each study on the pooled estimate by omitting one study at a time and recalculating the combined estimates for the remaining studies. The Baujat plot was also performed to detect outliers and influence points by plotting the change of the summary effect for systematically leaving out one study at a time against the contribution of this study to the between-study heterogeneity statistic *Q*. Publication bias was assessed using funnel plots (data not shown) and rank correlation test.

All statistical analyses were performed using R software version 4.0.2.

RESULTS

A total of 735 (mesh: *n* = 383 vs suture: *n* = 352) LPEHR procedures were reported in the 7 RCTs included in the analysis. Supplementary Table 1 (Supplemental Table 1, Supplemental Digital Content 1, <http://links.lww.com/SLA/D92>) describes all the studies comprised in the meta-analysis.

Early recurrence (reported in 5/7 studies) was similar among patients with mesh reinforcement and primary repair (RR = 0.74, 95% CI = 0.26–2.07, *P* = 0.46). The heterogeneity χ^2 was 0.26 (*P* = 0.15) with an *I*² statistic of 40% (Fig. 2). When stratifying the analysis by the type of mesh (absorbable and nonabsorbable), both groups also had similar early recurrence rates: nonabsorbable mesh (RR = 0.70, 95% CI = 0.13–3.81, *P* = 0.55, χ^2 = 0.48, *P* = 0.16, *I*² = 42%) and absorbable mesh (RR = 0.75, 95% CI = 0–2380.64, *P* = 0.73, χ^2 = 0.62, *P* = 0.05, *I*² = 74%).

Late recurrence was reported in 6/7 studies. Mean follow-up in these studies was 42 (12–60) months. Patients undergoing mesh reinforcement had similar late recurrence rates as those with primary repair (RR = 0.75, 95% CI = 0.27–2.08, *P* = 0.48). The heterogeneity χ^2 was 0.27 (*p* = 0.03) with an *I*² statistic of 64% (Fig. 3). When stratifying the analysis by the type of mesh (absorbable and nonabsorbable), similar late recurrence rates were also noted: nonabsorbable mesh (RR = 0.59, 95% CI = 0.12–2.94, *P* = 0.37, *d*

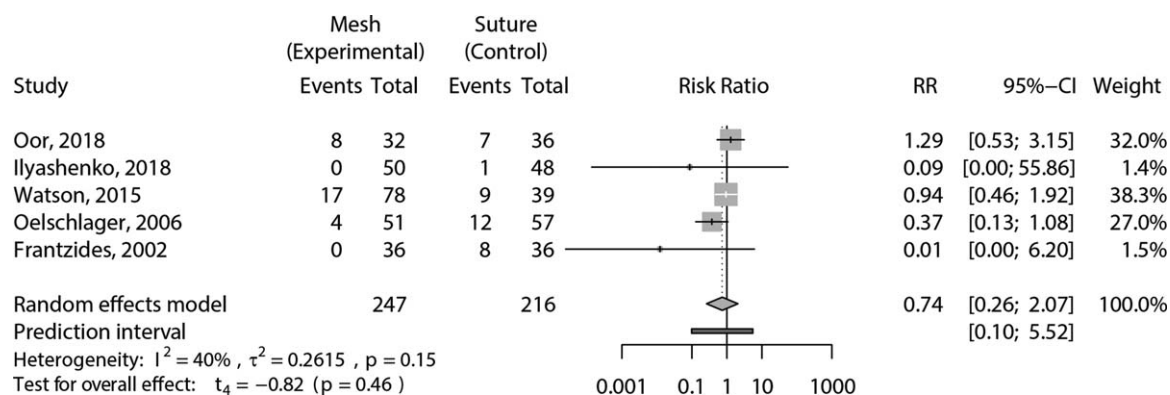


FIGURE 2. Forest plot of the risk ratio for early recurrence.

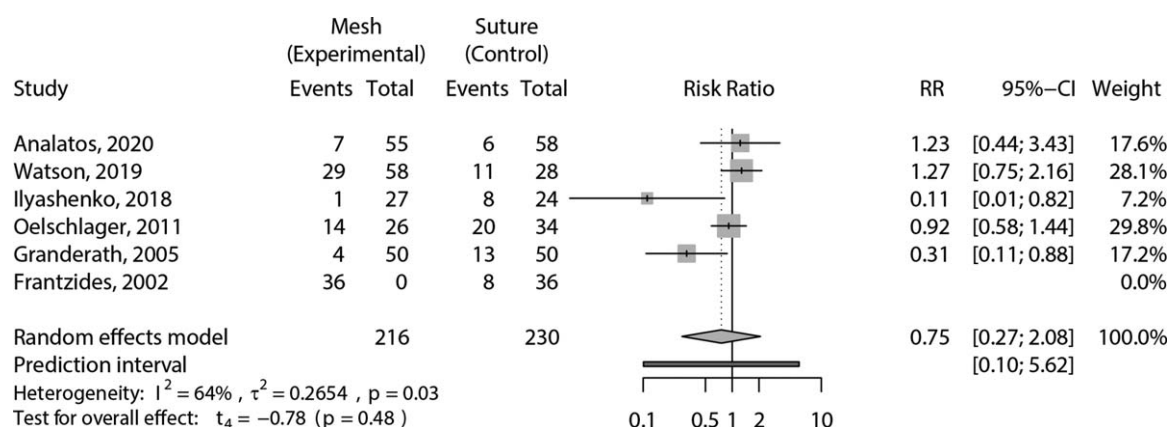


FIGURE 3. Forest plot of the risk ratio for late recurrence.

0.57, $P = 0.03$, $I^2 = 68\%$) and absorbable mesh (RR = 1.12, 95% CI = 0.06–19.57, $P = 0.71$, $\chi^2 = 0.04$, $P = 0.21$, $I^2 = 36\%$)

Intraoperative complication rates (reported in 5/7 studies) were similar in both groups (RR = 1.03, 95% CI = 0.33–3.28, $P = 0.92$), with no evidence of significant statistically heterogeneity ($\chi^2 = 0$, $P = 0.50$, $I^2 = 0\%$) (Fig. 4). Pooled analysis showed a significant increase in the overall morbidity (assessed in 6/7 studies) after mesh repair compared to primary repair (RR =

1.45, 95% CI = 1.24–1.71, $P < 0.01$). The heterogeneity χ^2 was 0 ($P = 1$) with an I^2 statistic of 0% (Fig. 5). However, when stratifying the analysis by the type of mesh (absorbable and nonabsorbable), higher morbidity was significantly related to repairs with non-absorbable mesh (RR = 1.58, 95% CI = 1.14–2.18, $P = 0.02$, $\chi^2 = 0$, $P = 0.97$, $I^2 = 0\%$) but not to those with absorbable mesh (RR = 1.32, 95% CI = 0.60–2.92, $P = 0.14$, $\chi^2 = 0$, $P = 0.86$, $I^2 = 0\%$).

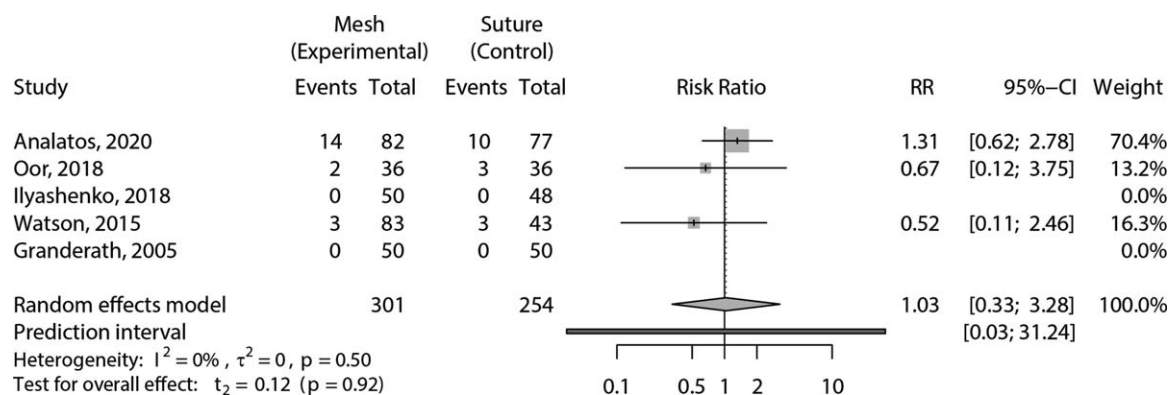
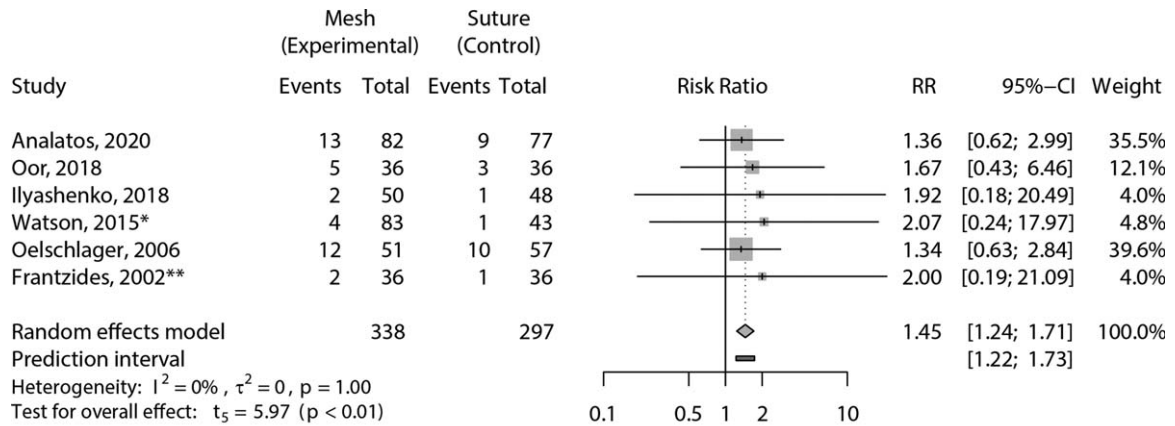


FIGURE 4. Forest plot of the risk ratio for intraoperative complications.



* Only major complications were reported.

** Only complications that prolonged hospitalization and/or resulted in patient distress were reported.

FIGURE 5. Forest plot of the risk ratio for overall morbidity.

The pooled effect size of reoperation rate (reported in 5/7 studies) did not favor any of the 2 groups (RR = 0.75, 95% CI = 0.29–1.92, $P = 0.45$), with an acceptable statistical heterogeneity ($\chi^2 = 0$, $P = 0.53$, $I^2 = 0\%$) (Fig. 6).

Leave-one-out analysis and Baujat plot (data not shown) did not show any statistically significant changes in the overall effect or in the heterogeneity after excluding outliers' studies. The shape of the funnel plots (data not shown) did not reveal any evidence of obvious asymmetry and rank correlation tests were not statistically significant, suggesting that there was no publication bias likely affecting the results.

DISCUSSION

The aim of this meta-analysis of RCTs was to determine whether the use of mesh could modify postoperative outcomes after LPEHR. We found that mesh reinforcement did not reduce early or late recurrence rates regardless of the type of mesh used. In addition, although intraoperative complication and reoperation rates were similar between groups, overall morbidity was higher after mesh repair, especially with the use of nonabsorbable mesh.

Presently, LPEHR with fundoplication has become the preferred surgical approach for patients with symptomatic paraesophageal hernia due to numerous advantages such as shorter hospital stay, lower morbidity and mortality, and lower costs for the health care

system, as compared to the conventional approach.^{20–22} Hiatal hernia recurrence, however, has always been the Achilles heel of this procedure.^{23,24} For this reason, many surgeons embraced the use of mesh to reinforce the cruroplasty in the last decade.²⁵

Previous studies have reported conflicting results regarding the usefulness of mesh in LPEHR. Although most recent meta-analyses found insufficient evidence to recommend the systematic use of mesh,²⁶ 4 previous meta-analyses showed a statistically significant decrease of recurrence rates with mesh reinforcement.^{27–30} For instance, Memon et al²⁷ reported that patients with suture only repair were 3.26 times more likely to undergo a reoperation due to recurrence. Interestingly, none of these previous meta-analyses were able to evaluate both short- and long-term recurrence rates. Oelschlager et al reported a lower recurrence rate in the biologic mesh group at 6 months (24% in primary repair group vs 9% in mesh reinforced group).¹¹ However, after 5 years of follow-up they found similar recurrence rates in both groups (59% vs 54%).⁸ Therefore, trials with short follow-up should be analyzed cautiously. In fact, by including recent RCTs with long-term follow-up, our study was able to demonstrate that patients undergoing LPEHR with mesh had similar early and late recurrence rates than those with primary repair. In addition, our pooled analysis showed that the type of mesh (absorbable and nonabsorbable) did not modify the success rates of the operation. Albeit the evidence for efficacy is limited by the different

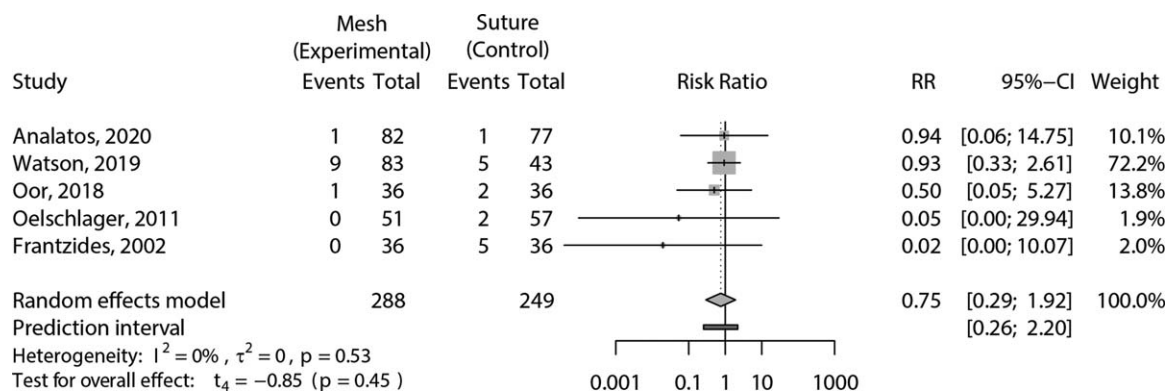


FIGURE 6. Forest plot of the risk ratio for reoperation.

definitions of recurrence considered, the diverse types of mesh used, and the different sizes of hernias fixed in the studies, our pooled data challenge the common belief that a mesh in the esophageal hiatus decreases the probabilities of recurrence.

Patients with radiological hiatal hernia recurrence after LPEHR are often asymptomatic.⁷ Therefore, symptom control and quality of life improvement might serve as better proxies of success. One of the RCTs using self-fixating mesh (ProGrip) found that patients with mesh repair had better reflux control and greater patient satisfaction.¹² Another study reported no differences in quality of life among patients with suture alone, absorbable mesh, and non-absorbable mesh over a 24-month follow-up period.³¹ Analatos et al showed that although quality-of-life scores at 3 years were comparable between mesh and suture only repair patients, a higher proportion of patients complained of dysphagia for solid food after mesh closure.¹⁴ Watson et al found that patients undergoing repair with absorbable mesh had worse control of symptoms than those with primary repair and nonabsorbable mesh.¹³ Unfortunately, only few RCTs included in this meta-analysis reported the assessment of quality of life or symptom control, and thereby we were unable to meta-analyze these outcomes.

Mesh-related complications after LPEHR have been widely reported in previous studies.^{32–37} It has been postulated that the process of scarring could cause esophageal strictures, abscess or fistula formation, and mesh erosions.^{38,39} For instance, a recent survey showed that mesh erosion and esophageal stenosis were encountered by 21% and 25% of the respondents, respectively.⁴⁰ Similar intraoperative complication and reoperation rates were found in our study among patients undergoing LPEHR with mesh or suture only repair. However, we did find a significant increase in postoperative morbidity after mesh repair. Interestingly, when stratifying the analysis by the type of mesh, we found that this higher overall morbidity was intrinsically related to the use of non-absorbable mesh. Therefore, we strongly believe that this type of prostheses should be cautiously used in the esophageal hiatus. Unfortunately, due to the relative short follow-up of some of the RCTs, the incidence of long-term complications cannot be accurately determined yet.

Several methodological design discrepancies of the RCTs included in the analysis may limit the results of our study. First, the heterogeneity in the inclusion criteria between studies (eg, hernia size). Second, different types of mesh, location of the prosthesis, and fixation methods were used. Third, recurrence was not uniformly defined in all the studies. Lastly, a moderate heterogeneity was found in the late recurrence analysis. Despite these limitations, to our knowledge, this is the first meta-analysis analyzing both short- and long-term recurrence rates discriminating the different types of mesh used in the studies.

CONCLUSIONS

Patients undergoing LPEHR with mesh reinforcement have similar early and late recurrence rates as those with suture only repair, regardless of the type of mesh utilized. Although intraoperative complication and reoperation rates are similar between groups, overall morbidity seems to be higher after mesh repair with nonabsorbable mesh.

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