Asian Journal of Surgery (2019) 42, 53–60

Available online at www.sciencedirect.com

ScienceDirect

journal homepage: www.e-asianjournalsurgery.com

REVIEW ARTICLE

'Mesh hiatal hernioplasty' versus 'suture cruroplasty' in laparoscopic para-oesophageal hernia surgery; a systematic review and meta-analysis

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Received 26 March 2018; received in revised form 27 April 2018; accepted 1 May 2018
Available online 7 June 2018

KEYWORDS
Paraoesophageal;
Hiatus hernia;
Laparoscopy;
Mesh

Summary In laparoscopic 'paraoesophageal hernia' (POH) repair, non-absorbable suture materials have been used to close the crural defects. More recently, various types of prosthetic mesh have been utilized to repair the defect. We conducted a systematic review with meta-analysis of the recent and up to-date studies incorporating 942 POH repairs. We examined the rates of recurrence, reoperation, and complication rates alongside operative time of these two techniques in the management POH. Randomized controlled trials (RCT) and observational studies comparing mesh hiatal hernioplasty versus Suture cruroplasty for Paraoesophageal hernia were selected by searching Medline, Embase, and Cochrane Central database published between January 1995 and December 2016. Predefined inclusion and exclusion criteria were applied to select the studies. The outcome variables analysed are recurrence of hiatal hernia, reoperation, operative time and complications. Nine studies (RCTs = 4 and Observational studies = 5) were analysed totalling 942 patients (Mesh = 517, Suture cruroplasty = 425). The pooled effect size for recurrence favoured mesh repair over suture cruroplasty (OR 0.48, 95% CI 0.32, 0.73, $P < 0.05$). But the operation time is significantly less in suture cruroplasty (SMD 15.40, 95% CI 7.92, 22.88, $P < 0.0001$). Comparable effect sizes were noted for both groups which included reoperation (OR 0.35, 95%CI 0.09, 1.31, $P = 0.12$) and

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https://doi.org/10.1016/j.asjsur.2018.05.001

complication rates (OR 1.30, 95%CI 0.74, 2.29, P = 0.36). Our systematic review and meta-analysis demonstrates that mesh hiatoplasty and suture cruroplasty produce comparable results with regards to reoperation rate and complications following the repair of paraoesophageal hernias (POH). Moreover, the study showed significant reduction of recurrence following mesh hiatoplasty.

1. Introduction

Hiatus hernia (HH) is the term used to describe a condition where an organ, typically part of the stomach, protrudes into the lower mediastinum through a widening or weakness in the oesophageal hiatus of the diaphragm. HH's can be classified as Types 1—4 dependent on their anatomical features. Type 1 hiatus hernias are also known as sliding hernia and Type 4 hernias are associated with herniation of the stomach alongside an associated abdominal organ e.g. spleen.[1]

Paraoesophageal hiatal hernias (POH) account for 5—10% of all hiatal hernias and typically occur in elderly patients with multiple comorbidities.[2] A "Giant" POH has been defined as all type 3 and 4 hernias, but most limit this term to those POHs having greater than 50% of the stomach in the chest.[3] They can cause obstructive symptoms due to gastric volvulus. A giant POH can present acutely with Borchardt's triad: severe epigastric pain, retching and Inability to pass an nasogastric tube, and requires urgent surgical intervention.[4]

Laparoscopic cruroplasty for giant POH's utilizing non-absorbable sutures to perform a cruroplasty has been demonstrated to be safe in experienced with good symptom relief[5] with recurrence rates of 12% and 42%.[6] In order to improve the recurrence, hiatoplasty using synthetic mesh was introduced, moreover mesh use remains controversial due to reports of complications, most notably oesophageal erosion[7] Biological mesh has been proposed as an alternative however comes at a higher cost with conflicting results on efficacy. There remains uncertainty regarding the preferred technique for laparoscopic repair of the large hiatus hernia with several studies reporting conflicting outcomes.[8—13]

The aim of this study was to systematically retrieve, appraise the existing literature (1995—2016) on 'Laparoscopic POH' repair methods of 'mesh hiatal hernioplasty' and 'suture cruroplasty' emphasising on recurrence, operative time, reoperation rate and complications. The authors have strived to provide an up to date assessment of these two techniques on safety and efficacy.

2. Methods

2.1. Search strategy

A systematic literature search of MEDLINE (January 1995 to December 2016) and EMBASE (January 1995 to December 2016) databases was carried out using Ovid (Wolters Kluwer) interface. Further, Google scholar search engine and Cochrane Library (1995—2016) databases were also checked for Cochrane and other systematic reviews. Search terms and the medical subject headings (MeSH) were used in combination with Boolean operators AND or OR. The electronic search was supplemented by a hand-search of published abstracts from the European Association for Endoscopic Surgery, the Surgical Research Society, the Society of Academic and Research Surgery, the Association of Surgeons of Great Britain and Ireland, the Association of Upper Gastrointestinal Surgeons and the Society of American Gastrointestinal and Endoscopic Surgeons. Reference lists of all relevant studies were reviewed.

2.2. Selection of studies

The first selection was carried out by independently evaluating the search results against inclusion and exclusion criteria. A table based on PICO and inclusion/exclusion criteria was developed to aid study selection.[14] Original authors were contacted to retrieve the missing data. Abstracts of citations identified by the search were scrutinized to determine eligibility for inclusion in this meta-analysis. Studies were included based on the following inclusion criteria: randomised controlled trial, observational studies and adult patients. Exclusion criteria included studies on children, non-English study and emergency surgery. When an article did not meet the inclusion criteria, it was rejected based on title/abstract review and duplicate publications were excluded.

2.3. Outcomes

Primary outcomes included recurrence, requirement for reoperation, operative time and complications. Recurrence is defined as postoperative wrap migration or demonstration of a hiatus hernia more than 2 cm at endoscopy or Barium swallow. Reoperations included both return to theatre for postoperative complications and symptom recurrence within 1 year of initial surgery.

2.4. Assessment of methodical quality

Studies were assessed for external validity and applicability. Internal validity of the included studies was assessed according to the criteria recommended by the Cochrane Back Review Group.[15]

Randomised controlled trials were assessed using Jadad scoring system.[16] The Newcastle-Ottawa Scale (NOS)[17] was used to assess the observational studies. The NOS assessed three broad areas: selection bias, attrition bias, detection bias using a star system, with a maximum of nine stars.[7]

Studies were also classified according to the Cochrane grading (A to D) for concealment of allocation. Studies with adequate allocation concealment were classified as A, studies with unclear allocation concealment as B, studies with inadequate allocation concealment as C, and observational studies as D: criteria not used the methodological quality will not be used as a criterion for inclusion. In order to assess the effect of the low quality studies, we performed a sensitivity analysis, in which we either included or excluded those assessed as 'C' from meta-analysis.[18]

There were two major difficulties with assessing the validity of studies. The first was inadequate reporting. All attempts were made to contact authors for missing data. The second limitation, was limited empirical evidence of the relationship between parameters thought to measure validity and actual study outcomes.[18]

2.5. Statistical analysis

Data was pooled using the Cochrane Revman software.[18] Odds ratios (ORs) were used for dichotomous outcomes and standardized mean differences (SMDs) for continuous outcome measures to run the meta-analysis. To pool continuous data, mean and standard deviation of each study was required. However, some of the published clinical trials did not report the mean and standard deviation, but rather reported the size of the trial, the median and interquartile range. The effect is considered to be statistically significant if the P-value is < 0.05.

3. Results

A search of the 3 databases MEDLINE, Embase and Cochrane yielded a total number of 182 abstracts. A separate search of the Cochrane database found 8 studies. Based on the exclusion criteria and removal of duplications 157 studies were included after 1st selection. All articles were subsequently selected on title, abstract, and full text. Nine publications meeting the inclusion criteria were identified. Identification, screening, eligibility, and inclusion details are shown in PRISMA flow diagram (Fig. 1).

A total of 942 patients were included in the 9 studies with 517 patients in the mesh group and 425 patients in the suture cruroplasty group. The patients sex was only reported in 4 studies which included 172 men (51%) and 162 women (49%). None of the studies reported subclassification of age groups.

Four of the included studies were randomized controlled trials, with a mean Jadad score of 2.5. Five observational studies were included in this review with a median Ottawa Newcastle score of 5 stars. No further potentially relevant unpublished studies were identified through a citation search of previously published reviews. Study features are described in Table 1 and characteristics of surgery are described in Table 2.

The definition of Paraoesophageal or large hiatal hernia varied between studies dependent on pre-operative investigations or intraoperative findings. Granderath et al[19] and Ringley et al[20] used the definition of hernia size >5 cm, the value of > 8 cm was utilised by Frantzides et al[21] and Gouvas et al.[22] Grubnik et al[23] used the definition of hiatal defect surface area >10 cm^2 whilst Watson et al stated that $>50\%$ of the stomach in the thorax was required to meet the definition.

3.1. Results of meta-analysis

The pooled effect size of recurrent hiatal hernia in the meta-analysis favours mesh repair and it is significantly less compared to suture cruroplasty (OR 0.48, 95% CI 0.32, 0.73, $P < 0.05$) (Fig. 2).

Reoperation figures in this meta-analysis favours less risk of revisional surgery after mesh repair compared with suture cruroplasty, but it is not statically significant (OR 0.35, 95% CI 0.09, 1.31 $P = 0.12$). The reoperation itself causes a higher risk of morbidity and mortality due to the complex subsequent procedure, longer duration of operation, lengthy postoperative stay, and higher cost to patients and insurers (Fig. 3).

The pooled effect size showed significant reduction in operation time in suture group (SMD 15.4, 95% CI 7.92,22.8, $P < 0.0001$) (Fig. 4) The operating time was reported by all four the RCTs and three observational studies. However, due to lack of availability of standard deviation in Granderath et al,[19] Ringley et al[20] and Asti et al,[13] their data were excluded for analysis.

As far as the complication rate of suture cruroplasty versus prosthetic hiatal herniorrhaphy is concerned, the present analysis showed no difference in the incidence of postoperative complications between the 2 groups (OR 1.3, 95% CI 0.74 2.29, $P = 0.36$) (Fig. 5).

4. Discussion

4.1. Methodological quality

Overall the quality of RCTs demonstrated poor methodological quality based on Jadad score with an average score of 1.7 (out of 5), with a range of 1−3. Only 1 study reported on withdrawals and drop-outs.[24] Two studies described an appropriate method of randomization[19,24] whereas only 1 of the trials reported on the single blinding of the patients.[24] The methodological quality of observational studies was relatively better with mean level of 5.4 out of 9 stars.

4.2. Types of mesh

The ideal material for mesh cruroplasty should provide enough strength to provide reinforcement of the hiatus and reduce risk of recurrent herniation whilst avoiding visceral erosions and postoperative dysphagia. Using a synthetic mesh at the oesophageal hiatus differs when compared to that of inguinal or ventral hernia repairs due to the dynamic nature of the hiatal defect. The continual diaphragmatic

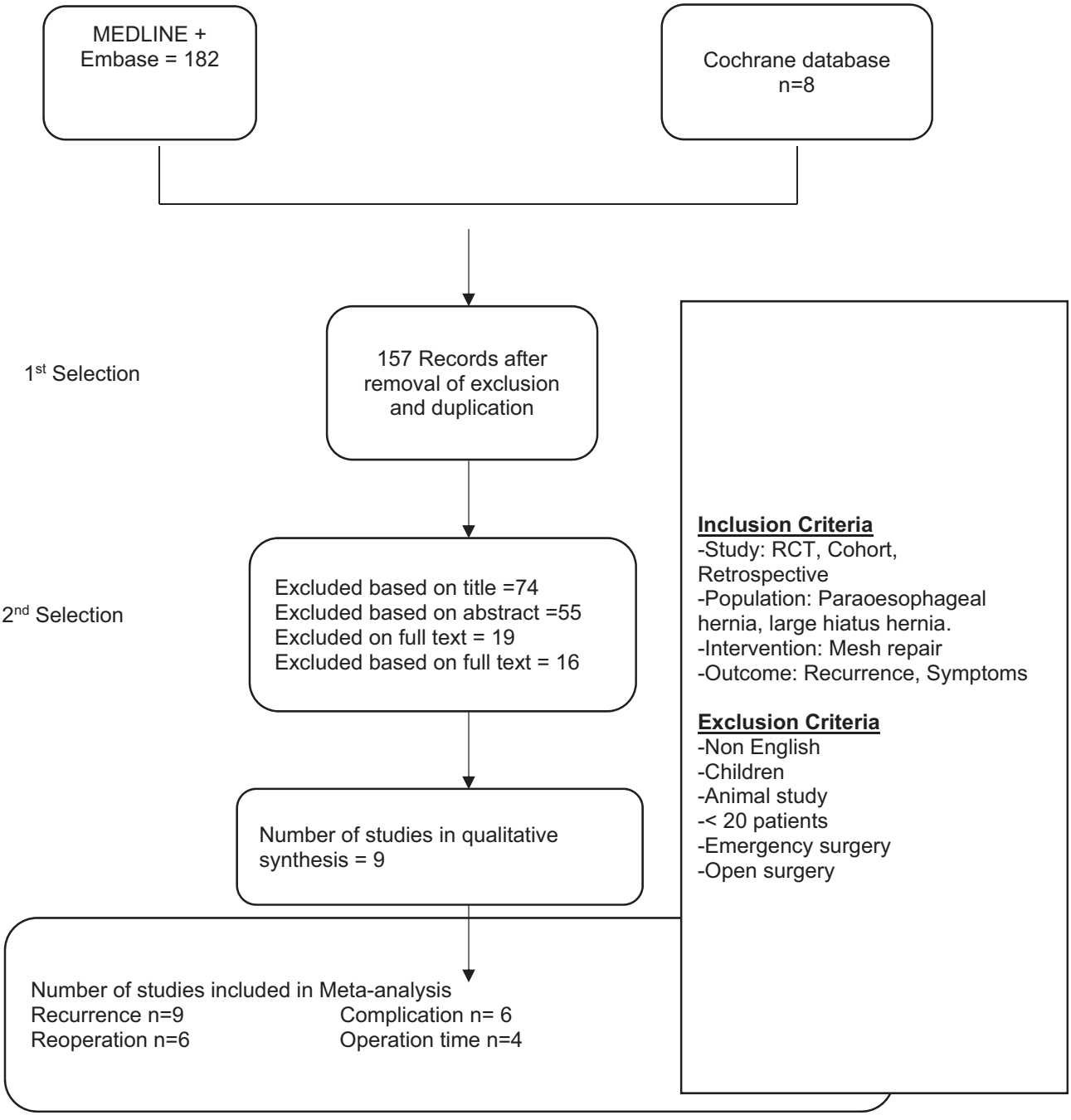

Figure 1 Prisma flow diagram for selection of papers.

motion results in ongoing friction of the mesh at the oesophageal and stomach interface. This has resulted in mesh erosion into the oesophagus and migration into the stomach.[20]

A variety of non-absorbable and absorbable meshes were utilised in the included studies. PTFE was the first mesh documented in the literature and used by Frantzides et al[21] and Gouvas et al.[22] There was no mesh related complications reported in PTFE group.[21] Polypropylene was used in three studies.[10,19,22] Partially absorbable mesh (Poliglecaprone-25/Polypropylene compositae) was used in one study.[23]

Other options include an absorbable (biodegradable) material that provides the scaffolding for significant ingrowth of tissue for persistent reinforcement. Ringley et al[20] used Human acellular dermal matrix (ACDM) patch for reinforcement of the hiatal closure during laparoscopic hiatal hernia repair. Oelschlager et al[25] used porcine small intestinal submucosa (Surgis; COOK Surgical) for repair of large paraoesophageal hernia in laparoscopic approach. The authors reported good symptomatic relief with this product. The layered nature of this material makes it more difficult to suture to the hiatus during laparoscopic

Table 1 Description of studies.

Study name	Study design	Number of patients (Mesh/Suture)	Sex (M/F)	Follow up	Hernia Definition
Frantzides et al 2002[21]	Prospective RCT	72 (36/36)	NA	3.3 ± 1.7 years	>8 cm
Granderath et al 2005[19]	Multicentre RCT	100 (50/50)	62/38	12 Months	≤5 cm = 37 >5 cm = 53
Ringley et al 2006[20]	Prospective Case control	44 (22/22)		12 Months	≥5 cm
Muller Stich et al 2006[10]	Retrospective	56 (16/40)	1:2	Mesh 20 (10–60) Suture 67 (9–117)	
Oelschlager et al 2011[25]	Multicentre RCT	108 (57/51)	50/58		
Gouvas et al 2011[22]	Prospective Case Control	68 (20/48)		1 year	>8 cm
Grubnik et al 2013[23]	Observational	284 (192/92)		28.6 Months (Mean) (10–48)	Defect > 10 cm^2
Watson et al 2015[24]	Multicentre RCT	126 (83/43)	60/66	58 Months (40–78) (Median)	>50% of stomach in the thorax
Asti et al 2016[13]	Observational Cohort	84 (41/43)	20/64	Median 24 (IQR 29) Months	>5 cm defect

Table 2 Description of surgery.

Study name	Mesh Type	Details of mesh repair	Details of Suture repair	Additional Procedure
Frantzides et al 2002[21]	PTFE (Nonabsorbable)	Keyhole shape Fixed with Stapler	Posterior cruroplasty	Nissen Fundoplication
Granderath et al 2005[19]	Polypropylene (Non-absorbable)	Mesh fixed with stitches	Posterior cruroplasty	Nissen
Ringley et al 2006[20]	HACD	Posterior U shaped anchored with silk suture	2-4 Silk Posterior cruroplasty	Nissen
Muller Stich et al 2006[10]	Polypropylene/Vicryl, Polypropylene	Butterfly shaped. Fixed with stapler.	3-4 Ethibond Posterior cruroplasty	Toupet = 46, Nissen = 6, Dorr = 4
Oelschlager et al 2011[25]	Surgisis (Absorbable)	U shape Mesh fixed with stitches	Posterior cruroplasty	Nissen
Gouvas et al 2011[22]	Polypropylene or PTFE-Polypropylene Duo Mesh	Keyhole or U shape on lay	Posterior cruroplasty	Toupet, Nissen
Grubnik et al 2013[23]	Poliglecaprone-25/Poly propylene compositae	Sandwich technique	Posterior cruroplasty	Nissen
Watson et al 2015[24]	Surgisis (Absorbable) TiMesh (Nonabsorbable)	Mesh fixed with stitches/ tacker	Posterior cruroplasty	Fundoplication —Not specified
Asti et al 2016[13]	GoreBio A (Absorbable Biosynthetic)	U shape on lay anchored with suture	Posterior cruroplasty	Toupet = 67 Nissen = 17

HACD (Human Acellular Cadaveric Dermis) Absorbable.
SIS (Small Intestinal Submucosa) Surgisis® Absorbable.

cruroplasty and may reduce the initial tensile strength before tissue in-growth.

4.3. Configuration of mesh

Various shapes of mesh were used in the included studies (Table 2). Bio mesh and polypropylene were used in most studies. In most individual studies, the mesh was positioned posterior to the oesophagus. The method used to fix the mesh to the diaphragm was stapler or sutures. The mesh was reinforced as on lay on the primarily sutured hiatus in eight studies and sandwich technique is used in Grubnik et al.[23]

4.4. Recurrence

Early results of laparoscopic antireflux surgery reported a substantial recurrence rate of 42%[6] with suture cruroplasty, and 9% recurrence with mesh.[26] Several authors started experimenting with the use of mesh to improve the operative results in terms of reducing recurrence and wrap migration.

This Meta-analysis shows significant reduction in recurrence of hiatus hernia after mesh repair compared to suture (non-mesh) repair (OR 0.48, 95% CI 0.32, 0.73, $P < 0.05$) (Fig. 2). Seven out of nine studies showed reduced recurrence rate in mesh group however the findings were not

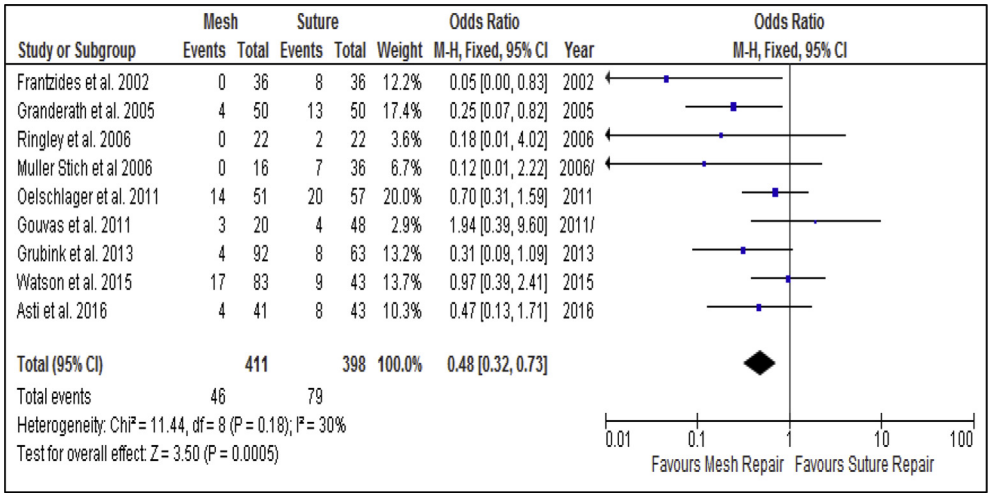

Figure 2 Forrest plot for hernia recurrence.

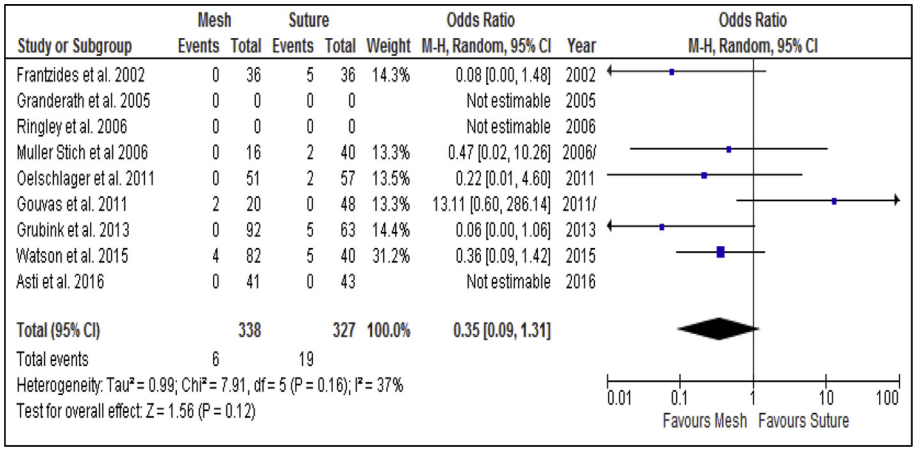

Figure 3 Forrest plot for reoperation.

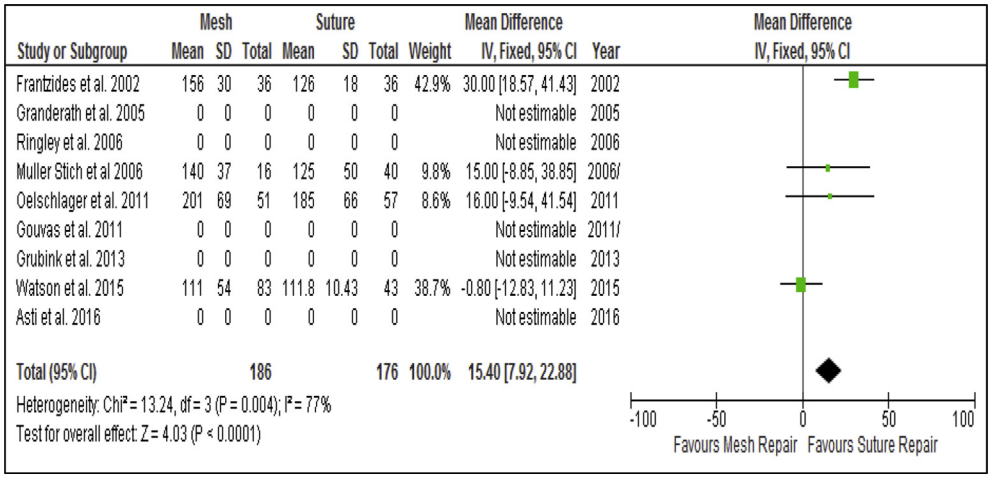

Figure 4 Forrest plot for operation time.

significant. Granderath et al[19] demonstrated a statistically significant reduction in recurrence with mesh, however another study reported higher recurrence rates in the mesh group compared to suture cruroplasty (not significant).[22] This review did not demonstrate differences in outcomes between configuration and types of mesh.

Large hiatal size, retention of the hernia sac, weak muscle fibres of the crura, inadequate mobilization of the

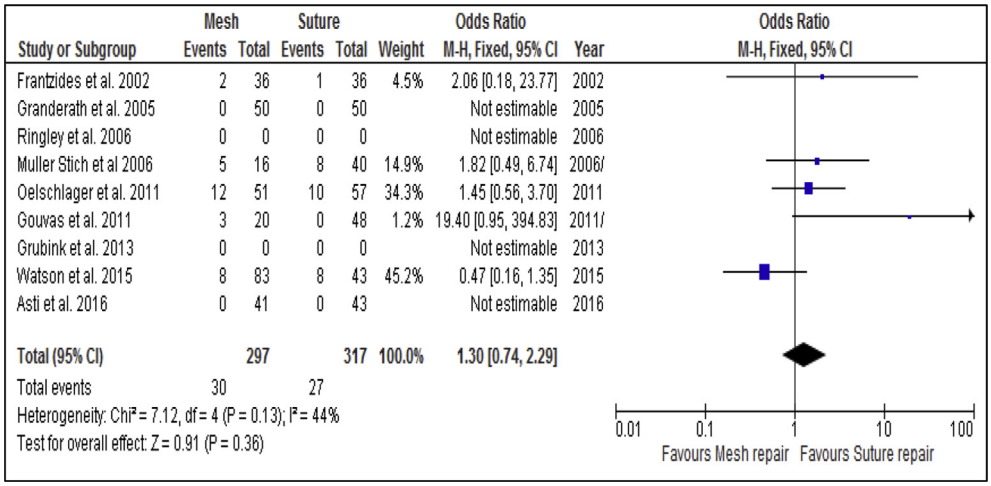

Figure 5 Forrest plot for complications.

oesophagus, tension on the crural repair, and exertion of inappropriate tension to the diaphragm at the immediate postoperative period are other possible causes predisposing to recurrence in this study. Low recurrence rates and better functional outcomes in patients with suture cruroplasty are attributed to the meticulous dissection, excision of the hernial sac and the complete mobilization of the oesophagus in this study.[22]

As none of the RCTs except for the one by Oelschlager et al[25] have provided long term follow-up data to date, the true recurrent rate of hiatal hernia between the 2 groups may diverge with passage of time especially in the nonabsorbable prosthetic group. Only long-term longitudinal studies will clarify this issue.

4.5. Reoperation

The pooled effect size in our meta-analysis did not demonstrate any difference in the hiatal reoperation between suture cruroplasty and prosthetic hiatal herniorhaphy (OR 0.35, 95%CI 0.09, 1.31, P = 0.12) (Fig. 3). Further, long term follow-up studies are essential to comment the true reoperation rate as mentioned in recurrence.

4.6. Operation time

The operating time was reported by all the RCTs[19,21,24,25] and three observational studies.[10,13,20] Due to lack of availability of standard deviation, three studies were excluded from analysis.[13,19,20] Only one study showed significantly longer operating time for the prosthetic hiatal herniorrhaphy group compared with the suture cruroplasty.[21] The other 3 studies did not show significant difference in mean operating times for the 2 groups.[10,24,25]

The pooled effect size showed significant reduction in operative time in suture cruroplasty compared to mesh group (SMD 15.4, 95% CI 7.92, 22.88, P < 0.0001) (Fig. 4). Longer operating time in the earlier trials may in part reflect an initial learning curve for laparoscopic prosthetic hiatal herniorrhaphy.

4.7. Complication rate

The present analysis showed no difference in the incidence of postoperative complications between the 2 groups (Fig. 5). Due to a lack of long term data for 3 out of 4 RCTs, accurate assessment of this variable could not be determined. When the long-term results of the published RCTs become available the true incidence of mesh related complications will become apparent.

4.8. Limitation of this review

There are several limitations in this review. Firstly, only English literature was reviewed. Secondly only one author was involved in the search and selection of studies.[14] Thirdly, there was no uniformity in the studies regarding prosthetic meshes used i.e., absorbable, nonabsorbable, material and configuration for repair, this is a potential limitation. Fourthly, definition of what constitutes a large hiatal hernia varies between different studies. Finally, follow up was short term in all studies apart from two[13,25]

5. Conclusions and recommendations

On the basis of this meta-analysis and its limitations, we believe that prosthetic hiatal herniorrhaphy and suture cruroplasty produces comparable results in terms of safety for repair of large hiatal hernias. Recurrence rates are reduced when mesh is used and according to data available with no increased risk of complications. In turn we report a reduced operative time with suture cruroplasty in comparison to the use of mesh. In the future, a number of issues need to be addressed to determine the clinical outcomes, safety, and effectiveness of these 2 methods for elective surgical treatment of large hiatal hernias. These include (i) standardized definition of large hiatal hernia; (ii) standardized techniques of suture and prosthetic repair; (iii) type of prosthesis used—biologic versus nonabsorbable; (iv) standardized method of securing the mesh such as use of sutures, tacks, or biologic glues; (v) standardized classification of recurrent hiatal hernia post repair; (vi)

standardized method of detecting recurrence e.g., gastroscopy, barium swallow or CT scan and lastly (vii) long term postoperative data collection of at least 5 years to detect the true incidence of hiatal hernia recurrence, reoperation and mesh migration or erosion between suture cruroplasty and prosthetic hiatal herniorrhaphy.

In this meta-analysis and systematic review, authors conclude that the laparoscopic mesh hiatoplasty is associated with reduced risk of recurrence. Both methods effect comparable results with regards to reoperation rate and complications except for decreased operative time for suture cruroplasty. However further studies needed to confirm long term safety, and efficacy of specific types of mesh prior to implementing it routinely.

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