

A meta-analysis comparing tacker mesh fixation with suture mesh fixation in laparoscopic incisional and ventral hernia repair

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Abstract

Objective To systematically compare the tacker mesh fixation (TMF) with the suture mesh fixation (SMF) in laparoscopic incisional and ventral hernia (LIVH) repair.

Methods Trials evaluating the TMF with the SMF in LIVH repair were analysed using the statistical tool RevMan[®]. Combined dichotomous and continuous data were expressed as odds ratio (OR) and mean difference (MD), respectively.

Results Four trials (2 randomised and 2 non-randomised) encompassing 207 patients undergoing LIVH repair with TMF versus SMF were retrieved from the standard electronic databases and analysed systematically. Ninety-nine patients underwent TMF and 108 patients underwent SMF in LIVH repair. There was no statistically significant heterogeneity ($p = 0.27$) among trials. In the fixed-effects model, LIVH repair with TMF was associated with shorter operation time (MD, -23.65 ; 95 % CI, -31.06 , -16.25 ; $z = 6.26$; $p < 0.00001$). Four- to six-week postoperative pain score was significantly lower (MD, -0.69 ; 95 % CI, -1.16 , -0.23 ; $z = 2.92$; $p < 0.004$) following TMF. Peri-operative complications ($p = 0.65$), length of hospital stay ($p = 1$) and risk of hernia recurrence (OR, 1.54; 95 % CI, 0.38, 6.27; $z = 0.61$; $p = 0.54$) following TMF and SMF were statistically not different.

Conclusion TMF in LIVH repair is associated with shorter operative time and lesser postoperative pain. TMF is comparable with SMF in terms of peri-operative complications, length of hospital stay and hernia recurrence.

Therefore, TMF may be used in LIVH repair. However, further randomised trials recruiting higher number of patients are required to validate these findings.

Keywords Ventral hernia · Incisional hernia · Laparoscopic repair · Tacker mesh fixation · Suture mesh fixation

Introduction

Primary ventral hernia (umbilical hernia, para-umbilical hernia, epigastric hernia and spigelian hernia) is a common surgical disorder which may or may not require surgical repair depending on the size and consequent symptoms. Secondary ventral hernia commonly known as an incisional hernia has a reported incidence of 3–15 % of patients undergoing laparotomy and laparoscopy [1–6]. In the USA, approximately 4–5 million laparotomies are performed annually [4], leading to at least 400,000–500,000 incisional hernias, of which approximately 200,000 repairs are performed [4, 7]. Estimated rate of incisional/ventral hernia repair is about 300,000 per annum in Europe. In terms of success rate, mortality, morbidity and recurrence rate, the superiority of laparoscopic incisional/ventral hernia (LIVH) repair as opposed to traditional open repair has been widely accepted in surgical fraternity after the publications of at least seven systematic reviews including one Cochrane review [8–14] over a span of last 9 years. Although LIVH repair has become almost a universal standard, but significant controversy still exists regarding the management of large hernial sac, postoperative seroma, mesh selection and technique of intra-abdominal mesh fixation. In addition, patients undergoing LIVH repair tend to have higher pain score in early postoperative pain than after any other

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laparoscopic abdominal procedure [15–18]. Etiology and pathogenesis of postoperative complications is being investigated extensively leading to the introduction of new generation of meshes (lightweight) and new approaches for mesh fixation.

In LIVH repair, various mesh fixation techniques have been reported including tacker mesh fixation (TMF), suture mesh fixation (SMF), combined TMF and SMF using either absorbable or non-absorbable sutures, resorbable fixation devices and fibrin glue [19–24]. TMF and SMF are two most commonly used techniques but both are associated with variable risk of postoperative complications. TMF is associated with relatively weaker fixation because tacker clips do not fix mesh with muscle and fascia and it merely penetrates through few millimeters of inner abdominal wall and peritoneum which potentially may lead to partial or complete mesh dislodgment leading to hernia recurrence [25]. Since SMF penetrates through full thickness of muscle and fascial sheath, therefore, the tensile strength of SMF has shown to be up to 2.5 times more than TMF [25]. TMF may also contribute into the hernia recurrence due to tacker-induced mesh shrinkage [20]. Other reported implications of spiral tacks include intestinal erosion, intestinal fistula formation and intra-abdominal adhesions leading to small bowel obstruction [26, 27]. SMF is also an effective mesh fixation technique but has been reported with prolonged postoperative pain, longer operative time, prolonged hospital stay and hernia recurrence through fixation holes [28–30]. The objective of this article is to systematically analyse the role of TMF with SMF in LIVH repair in terms of operation time, postoperative pain, surgical site infection, peri-operative complications, length of hospital stay and recurrence of incisional and ventral hernia.

Methods

Relevant randomised and non-randomised controlled trials (irrespective of type, language, blinding, sample size or publication status) evaluating the role of TMF with SMF during LIVH repair until July 2012 were included in this review. The Cochrane Colorectal Cancer Group (CCCG) Controlled Trial Register, the Cochrane Central Register of Controlled Trials (CENTRAL) in The Cochrane Library, Medline, Embase and Science Citation Index Expanded were searched until July 2012 using the medical subject headings (MeSH) terms “incisional hernia” and “ventral hernia.” These headings were used in combination with “laparoscopic repair,” “minimal invasive surgery,” “surgical mesh,” “mesh,” “suture fixation” and “tacker fixation.” The “related article” function was used to widen the search criteria. All abstracts, comparative studies,

non-randomised trials and citations scanned were reviewed in order to get the maximum results by comprehensive literature search. A filter for identifying relevant studies recommended by the Cochrane collaboration [31] was used to filter out irrelevant studies in Medline and Embase. The references of the included studies were searched to identify further trials. We included all types of comparative trials evaluating the role of TMF with SMF in LIVH repair. Two authors independently identified the relevant studies for inclusion: extracted data related to the outcomes and secured data on a Microsoft Excel spread sheet. Conflict about data was resolved by mutual agreement among authors. The software package RevMan 5.0.1 [32] provided by the Cochrane collaboration was used for analysis. The odds ratio (OR) with a 95 % confidence interval (CI) was calculated for binary data variables. If the standard deviation was not available in case of continuous variables, it was calculated according to the guidelines of the Cochrane collaboration [31]. This involved assumptions that both groups have the same variance, which may not be true. The random-effects model [33] and the fixed-effects model [34] were used to calculate the combined outcome in both binary and continuous variables. In cases of heterogeneity, only the results of the random-effects model were reported. Heterogeneity was explored using the χ^2 test, with significance set at $p < 0.05$, and quantified using I^2 [35] test [31]. The Mantel–Haenszel method was used for the calculation of OR under the fixed- and random-effect models [36]. In a sensitivity analysis, 0.5 was added to each cell frequency for trials in which no event occurred in either the treatment or control group, according to the method recommended by Deeks et al. [37]. The estimate of the difference between both techniques was pooled depending upon the effect weights in results determined by each trial estimate variance. A forest plot was used for the graphical display of results from the meta-analysis. The square around the estimate stood for the accuracy of the estimation (sample size) and the horizontal line represented the 95 % CI.

Results

Figure 1 depicts the literature search strategy, methodology and trial selection based on the published trials. Four trials (two randomised and 2 non-randomised) [19–22] on 207 patients undergoing LIVH repair were retrieved from the electronic databases. Ninety-nine patients of LIVH repair underwent TMF and 108 patients underwent SMF. The important features of included trials are given in Table 1. Extracted data of the reported variables used to achieve a combined outcome are given in Table 2. In all four included studies, non-absorbable tacks were used to fix

mesh. The data pertaining to different types of tacks were not reported and therefore it was not possible to generate a combined outcome depending upon type of the tacks.

Methodological quality of included studies

The methodological quality of included randomised, controlled trials was assessed by the published guidelines of Jadad et al. [38] and Chalmers et al. [39]. The methodological quality of included non-randomised trials was assessed by the published guidelines of Scottish Intercollegiate Guidelines Network (SIGN) and Rangel et al. [40, 41]. Based on the quality of included trials [19–22], the strength and the summary of evidence was further evaluated by GradePro[®] [42], a statistical tool provided by Cochrane collaboration (Fig. 2). The Mantel–Haenszel fixed-effects model was used to compute robustness and susceptibility to an outlier among these trials. The allocation concealment and blinding of investigator or assessor were not clearly reported.

Operative time

Statistically, there was no significant heterogeneity [$\chi^2 = 7.41$, $df = 3$, ($p = 0.06$); $I^2 = 59\%$] among four trials. Therefore, in the fixed-effects model (MD, -10 ; 95% CI, -19.77 , -0.23 ; $z = 6.20$; $p < 0.00001$; Fig. 3), TMF took shorter operative time as opposed to SMF.

Postoperative pain

Variable of postoperative pain was not thoroughly investigated in all included studies. Timing of postoperative pain data recording was also variable among studies. Combined outcome of 4–6 weeks postoperative pain was achieved by meta-analysis. Statistically, there was no significant heterogeneity [$\chi^2 = 0.20$, $df = 1$, ($p = 0.65$); $I^2 = 0\%$] among three [19, 20, 22] included trials. Therefore, in the fixed-effects model (MD, -0.69 ; 95% CI, -1.16 , -0.23 ; $z = 2.92$; $p < 0.004$; Fig. 4), TMF was associated with lesser postoperative pain.

Fig. 1 PRISMA flow chart showing trial selection methodology

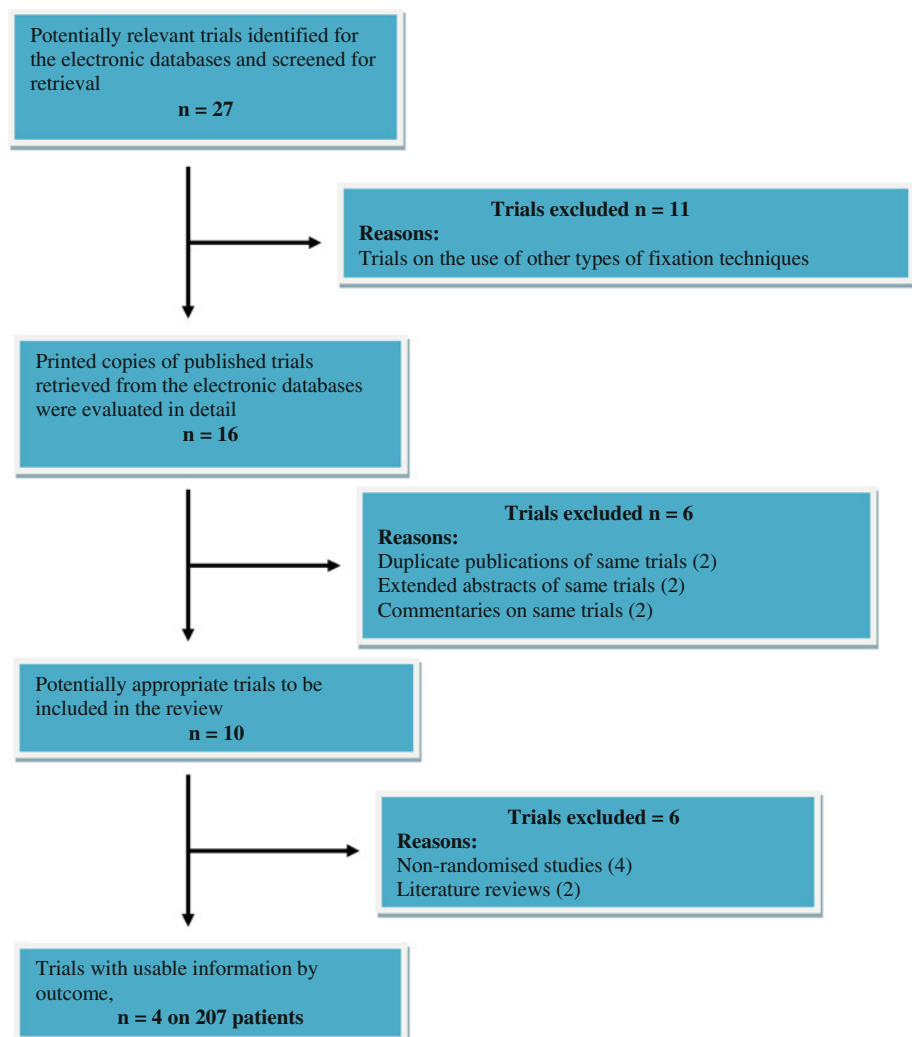


Table 1 Characteristics of included trials

Features	Bansal 2011	Beldi 2011	Greenstein 2008	Nguyen 2008
Type of trial	Randomised	Randomised	Non-randomised	Non-randomised
Country	India	Switzerland	USA	USA
Mesh used	Polypropylene mesh Barrier coated in 29 patients	Parietene composite mesh (Sofradim Production: Covidien Group Trevoux, France)	Not reported	Composix EX, Dualmesh, Dulex, Parietex
Tacker used	5-mm tackler (Protack, Autosuture, Tyco Healthcare, USA) Double crown technique was used for tackler fixation Four polypropylene stitches were used to keep mesh in place before tackler fixation	5-mm Titan tackler (Protak, Autosuture; Switzerland, CH- 8832B Wollerau)	Type of tackler used is not reported	Not reported
Fixation suture used	1/0 Polypropylene interrupted transfascial stitches approximately 2 cm apart were put circumferentially for suture mesh fixation	Prolene and ethilon size 0 (Ethicon Switzerland, Johnson & Johnson Medical, CH-8957 Spreitenbach)	Type of fixation suture used is not reported	Not reported
Hernia defect size	Mean: $9.38 \pm 6.5 \text{ cm}^2$ Range: 4–25 cm^2	Tackler: 126 cm^2 Suture: 126 cm^2	Tackler: 109 cm^2 Suture: 91 cm^2	Tackler: 81 cm^2 Suture: 106 cm^2
Body mass index kg/m^2	Tackler: 29.6 ± 5 Suture: 28.4 ± 5.3	Tackler: 28.7 Suture: 28.4	Tackler: 27.8 Suture: 30.5	Tackler: 27.4 Suture: 31.3
Follow-up	TMF: 16.3 ± 9.9 months (97 % patients) SMF: 14.2 ± 8.1 months (100 % patients)	6 months (90 % patients)	18 (6–22) months (98 % patients)	3 months (100 % patients)

Table 2 Outcome variables

Variables	Bansal 2011	Beldi 2011	Greenstein 2008	Nguyen 2008
Patients <i>n</i>				
TMF	36	20	22	21
SMF	32	20	27	29
Operative time in minutes				
TMF	52.6 ± 12.1	92 ± 66	$131 \pm 58.9^{**}$	$122 \pm 17.4^{**}$
SMF	77.5 ± 19.4	120 ± 41	$128 \pm 58.9^{**}$	$132 \pm 17.4^{**}$
4–6 weeks pain score (VAS)				
TMF	$1.3 \pm 12.7^{**}$	2.5 ± 0.8	Not reported	$1 \pm 0^{**}$
SMF	$0.6 \pm 12.7^{**}$	3.2 ± 0.7		$1 \pm 0^{**}$
Surgical site infection				
TMF	0	0	0	Not reported
SMF	0	0	0	
Complications				
TMF	2	1/18	4	4
SMF	3	5/18	1	1
Hospital stay in days				
TMF	1.15 ± 0.44	6 ± 2.5	$2.4 \pm 1.7^{**}$	$1.7 \pm 1.2^{**}$
SMF	1.19 ± 0.51	6 ± 2.1	$1.7 \pm 1.7^{**}$	$2.4 \pm 1.2^{**}$
Recurrence of hernia				
TMF	0	1/18	4	0
SMF	0	1/18	3	0

** Standard deviation was estimated from the *p* value

Tacker versus suture mesh fixation

Patient or population: patients with laparoscopic incisional and ventral hernia repair
 Settings: in both elective and emergency situations
 Intervention: Tacker versus suture mesh fixation

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk Control	Corresponding risk Tacker versus suture mesh fixation				
Operation time Mean difference Follow-up: 3-22 months		The mean operation time in the intervention groups was 18.67 lower (24.57 to 12.77 lower)		207 (4 studies)	⊕⊕⊕⊕ moderate ¹	
Pain score Mean difference Follow-up: 3-22 months		The mean pain score in the intervention groups was 0.69 lower (1.16 to 0.23 lower)		158 (3 studies)	⊕⊕⊕⊕ moderate	
Complications Odds ratio Follow-up: 3-22 months	Study population 94 per 1000	113 per 1000 (50 to 233)	OR 1.22 (0.51 to 2.92)	203 (4 studies)	⊕⊕⊕⊕ moderate	
	Moderate 65 per 1000	78 per 1000 (34 to 169)				
Hospital stay Mean difference Follow-up: 3-22 months		The mean hospital stay in the intervention groups was 0.07 higher (0.14 lower to 0.27 higher)		207 (4 studies)	⊕⊕⊕⊕ moderate	
Recurrence of hernia Odds ratio Follow-up: 3-22 months	Study population 41 per 1000	62 per 1000 (16 to 212)	OR 1.54 (0.38 to 6.27)	194 (4 studies)	⊕⊕⊕⊕ moderate	
	Moderate 28 per 1000	42 per 1000 (11 to 153)				

*The basis for the assumed risk (e.g. the median control group risk across studies) is provided in footnotes. The corresponding risk (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).

CI: Confidence interval; OR: Odds ratio;

GRADE Working Group grades of evidence
High quality: Further research is very unlikely to change our confidence in the estimate of effect.
Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very low quality: We are very uncertain about the estimate.

¹ This review is based upon two moderate quality RCTs and two non-RCTs assessed by evaluating risk of bias, inconsistency, imprecision and suspicion of publication bias

Fig. 2 Trial quality and strength of evidence

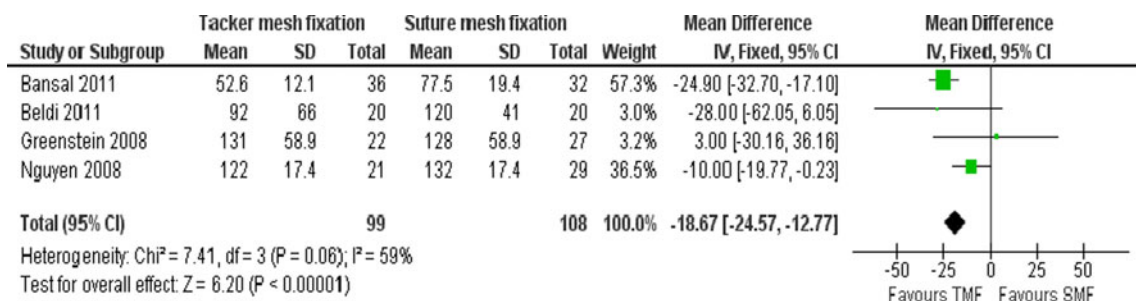


Fig. 3 Operative time

Peri-operative complications

The reported peri-operative complications in included trials were bleeding, wound infection, seroma formation, urinary

retention, urinary tract infection, lower respiratory tract infection and the development of any condition requiring medical, surgical and pharmacological treatment or delaying the discharge from the hospital. Statistically, there

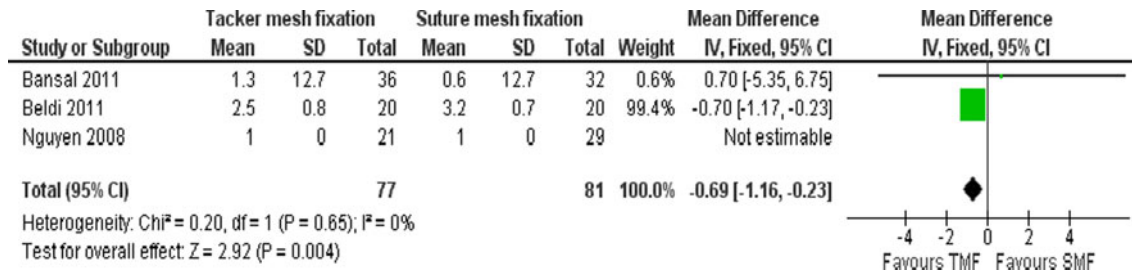


Fig. 4 4–6 weeks postoperative pain score

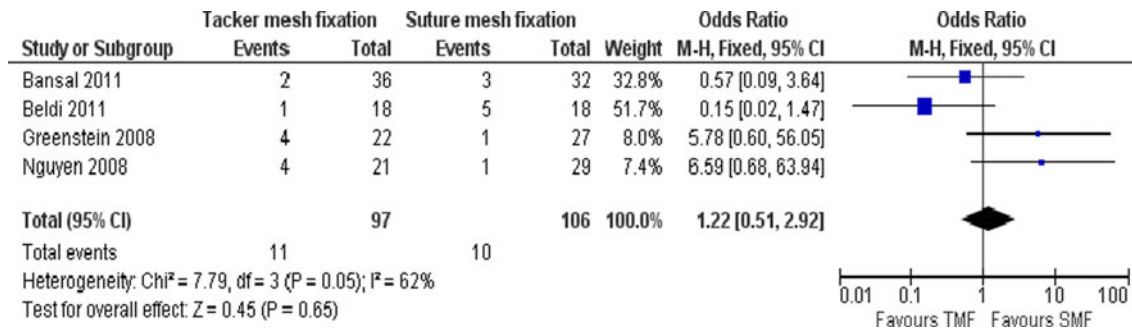


Fig. 5 Peri-operative complications

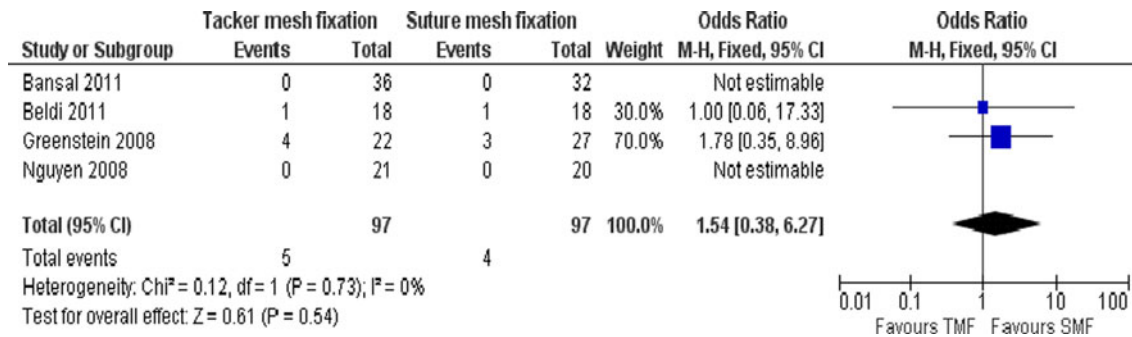


Fig. 6 Recurrence of hernia

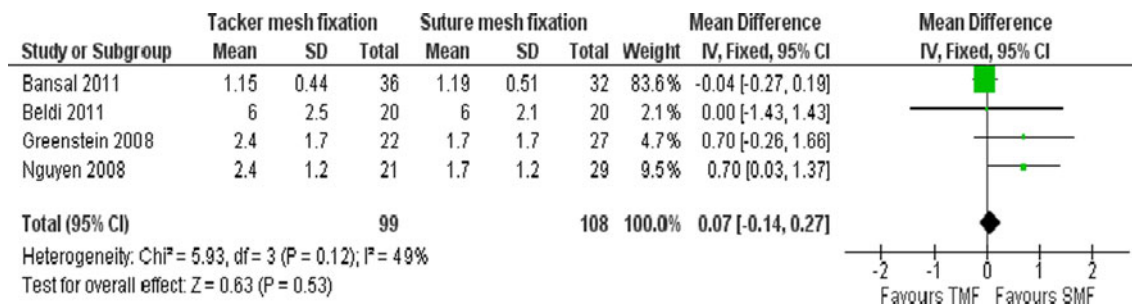


Fig. 7 Length of hospital stay

was no significant heterogeneity [$\chi^2 = 7.79$, $df = 3$, ($p = 0.05$); $I^2 = 62\%$] among four trials. Therefore, in the fixed-effects model (OR, 1.22; 95 % CI, 0.51, 2.92; $z = 0.45$; $p = 0.65$; Fig. 5), there was no statistical difference in the incidence of peri-operative complications in the use of both types of mesh fixation techniques.

Recurrence of hernia

Statistically, there was no significant heterogeneity [$\chi^2 = 0.12$, $df = 1$, ($p = 0.73$); $I^2 = 0\%$] among four trials. Therefore, in the fixed-effects model (OR, 1.54; 95 % CI, 0.38, 6.27; $z = 0.61$; $p = 0.54$; Fig. 6), the risk

of developing recurrent incisional or ventral hernia was similar following TMF and SMF during LIVH repair.

Length of hospital stay

Statistically, there was no significant heterogeneity [$\chi^2 = 5.93$, $df = 3$, ($p = 0.12$); $I^2 = 49\%$] among four trials. Therefore, in the fixed-effects model (MD, 0.07; 95% CI, -0.14, 1.37; $z = 0.63$; $p = 0.53$; Fig. 7), there was no statistical difference in the total length of hospital stay following the use of TMF and SMF.

Subgroup analysis

Subgroup analysis was performed on randomised trials and non-randomised trials separately and combined outcomes were compared. Statistically, TMF was associated with shorter operative time, lesser postoperative pain and was not different to SMF in terms of peri-operative complications, length of stay and hernia recurrence.

Other relevant variables

Authors intended to analyse data of other relevant and important variables like cost-effectiveness, mesh fixation time and surgical site infection following the use of TMF and SMF but unfortunately due to either insufficiently investigated or reported data, these calculations were virtually impossible to perform.

Discussion

Based on this review, TMF in LIVH repair is associated with shorter operative time and lesser postoperative pain which is consistent with previously published randomised, controlled trials [19, 20], non-randomised trials [21, 22] and other cohort studies [28–30]. The incidence of postoperative complications has been reported higher in SMF in two randomised [19, 20] studies but lower in two non-randomised studies [21, 22]. However, statistically this difference was not significant according to our review. TMF is comparable with SMF in terms of length of hospital stay and hernia recurrence. Therefore, TMF may be used in LIVH repair.

Authors are fully aware of the fact that combined outcome of this review is based on merely 207 patients undergoing LIVH repair in two randomised and two non-randomised trials. Both types of trials are of moderate strength and therefore, conclusions of this review may be considered weaker and biased. Although statistically there was no “significant” heterogeneity among the trials but methodologically there was significant diversity among studies. The Cochrane collaboration recommends overcoming the problem of weak power of the Chi-square test

for heterogeneity by using the significance level 0.10. The problem is inherent here, because of the small number of studies. By using this level in the statistical analysis of this review article, the principle conclusion did not change. Measuring scales for postoperative pain were not homogenous among included studies leading to potentially a less reliable conclusion. In addition, timing of postoperative pain data recording was variable among studies. The shorter duration of follow-up in included studies seems insufficient to detect any given rate of hernia recurrence. The size of hernia in recruited patients was also relatively small which may have contributed into variable readings of postoperative pain and other morbidities. The reported randomised, controlled trials were not homogenous in terms of inclusion criteria, exclusion criteria and mesh fixation protocols. For example, fixations in the TMF group were without four corner sutures in Beldi et al. [20], but four polypropylene sutures were used in the study reported by Bansal et al. [19]. This review did not explore the role of absorbable versus non-absorbable tacks or tacks versus tacks plus sutures fixation due to either insufficiently reported or investigated variables. However, TMF in conjunction with suture fixation in case of larger defects is also a viable option but further investigation is required before the routine use. It is impossible to tell surgeons to apply TMF in all ventral hernias repaired laparoscopically based on the analysed data. If a patient has a 250-cm² defect, it is unlikely tacks alone would be successful. Additionally, it is not just the size of the defect that affects recurrence rates; it is also the shape and location of the defect and the size/type of prosthetic mesh relative to the defect that is influential. Other contributing factor would be whether or not the defect was near the pubis and whether or not the mesh was anchored to Cooper’s ligaments. Another influential factor is whether the mesh was placed over the fat of the umbilical ligament and/or falciform ligaments, or whether these were dissected off the abdominal wall prior to the mesh placement. This review is not capable to answer the concerns raised by these questions. Therefore, further studies in the form of a major multicentre randomised, controlled trials recruiting higher number of patients are mandatory. High quality trials are required to validate the findings of this review as well as to explore the role of absorbable versus non-absorbable tacks in addition to other influencing factors.

Conflict of interest None to declare.

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