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A meta-analysis of randomized controlled trials of fixation versus nonfixation of mesh in laparoscopic total extraperitoneal inguinal hernia repair

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Abstract
Background Mesh fixation during laparoscopic total extraperitoneal (TEP) inguinal hernia repair is still controversial. Although many surgeons considered it necessary to fix the mesh, some published studies supported elimination of mesh fixation. Therefore, a meta-analysis based on randomized controlled trials (RCTs) was conducted to compare the effectiveness and safety of fixation versus nonfixation of mesh in TEP.
Methods RCTs were identified from PubMed, Embase, the Cochrane Library, SCI, and the Chinese Biomedical Literature Database (CBM). Two reviewers assessed the quality of the studies and extracted data independently. The methodological quality was evaluated according to the Cochrane Handbook 5.0.2. Statistical analysis was conducted using the Cochrane software RevMan 5.0.21.
Results Six RCTs involving 772 patients were included. The nonfixation group had advantages in length of hospital stay [MD =−0.37, 95% CI (−0.57, −0.17), $p = 0.0003$], operative time [MD = −4.19, 95% CI (−7.77, −0.61), $p = 0.02$], and costs. However, there was no statistically significant difference in hernia recurrence [OR = 2.01, 95% CI (0.37, 11.03), $p = 0.42$], time to return to normal activities [MD = −0.13, 95% CI (−0.45, 0.19), $p = 0.43$], seroma [OR = 1.25, 95% CI (0.30, 5.18), $p = 0.75$], and postoperative pain on postoperative day 1 [MD = −0.21, 95% CI (−0.52, 0.10), $p = 0.18$] and day 7 [MD = −0.11, 95% CI (−0.42, 0.20), $p = 0.47$].
Conclusions Without increasing the risk of early hernia recurrence, the nonfixation of mesh in TEP appears to be a safe alternative that is associated with less costs, shorter operative time, and hospital stay for the selected patients. Further adequately powered RCTs are required to clarify whether mesh fixation is necessary for the patients with different types of hernias and larger hernia defects.

Keywords Inguinal hernia · Total extraperitoneal repair · Mesh fixation · Meta-analysis

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Inguinal hernia is a common and widespread disease from which millions of people suffer. Repair of inguinal hernia is one of the most frequently performed operations in general surgery [1]. According to reports, about 39,000 hernia repairs are performed in Australia annually, 80,000 in the UK, 800,000 in the US, and 100,000 in France [1–4].

Total extraperitoneal (TEP) repair and transabdominal preperitoneal (TAPP) repair are the principal techniques used in laparoscopic hernia repair [5, 6]. Avoiding entering the peritoneal cavity and peritoneal closure, TEP has some advantages over transabdominal preperitoneal (TAPP)

repair with respect to postoperative pain, the rate of port-site hernias, and rate of and visceral injuries. However, TEP is more difficult technically and requires a longer learning curve [7–10].

As the technique of TEP has evolved, one debatable issue—whether the mesh should be fixed—is still controversial. Conventionally, to prevent the recurrence, surgeons use staples or tacks to fix the mesh and thus strengthen the posterior wall of the inguinal canal [11–14]. However, fixation is associated with nerve injury and chronic postoperative pain and increases the cost of hernia repair [15–17]. Thus, some surgeons are encouraged to perform TEP without fixation and have indicated that nonfixation of mesh is preferable according to the comparable clinical outcomes and lower costs compared with mesh fixation [16, 18–26].

Because of a lack of high-quality evidence produced by evidence-based medicine, this meta-analysis was undertaken to determine if mesh fixation is necessary.

Materials and methods

Criteria for considering studies for this review

Types of studies

All published and unpublished RCTs comparing mesh fixation versus mesh nonfixation in TEP were included without language restriction.

Types of participants

All participants over 18 years of age who required surgery for repair of inguinal hernia with a clinical diagnosis of inguinal hernia. Patients with a high anesthetic risk, previous lower abdominal surgeries, an underlying coagulopathy, and mental disorders were excluded.

Types of interventions

(1) Mesh was fixed in TEP. (2) Mesh was not fixed in TEP.

Types of outcome measures

Primary outcomes: hernia recurrence and postoperative pain. Secondary outcomes: length of hospital stay (days), time to return to normal activities (days), operative time (minutes), seroma, and costs.

Literature search

We conducted a systematic literature search to identify RCTs in the PubMed, Embase, SCI databases, the Cochrane Central Register of Controlled Trials (CENTRAL), and the Chinese Biomedical Literature Database (CBM) without language restriction. Since the first TEP-related report was published in 1992 [9], searches were limited from January 1992 to January 2010. The search strategies used the following major terms: "hernia, inguinal (MeSH)"; "inguinal OR groin"; "hernia"; "hernioplasty"; "herniorrhaphy"; "TEP"; "extraperitoneal". Moreover, Google scholar and reference lists of all the included studies were searched for additional reports. Contact with the authors was initiated by e-mail or telephone if any information was not available.

Risk of bias assessment

The risk of bias of the included RCTs was assessed according to the Cochrane Handbook 5.0.2 by two reviewers independently [27] and was judged using the following criteria: sequence generation; allocation sequence concealment; blinding of participants, personnel, and outcome assessors; incomplete outcome data; free of selective reporting; and free of other bias [28]. Each entry was definitively judged by an answer (Yes/No/Unclear): "Yes" indicates low risk of bias, "No" indicates high risk of bias, and "Unclear" indicates unclear or unknown risk of bias [27]. Disagreements were resolved by referring to the third reviewer until consensus was reached. If any information was unavailable, contact with the authors was initiated via e-mail or telephone.

Statistical analysis

The meta-analysis was conducted using the Cochrane software RevMan 5.0.21 [27]. The risk ratio (RR) or odds ratio (OR) with 95% confidence interval (95% CI) for dichotomous variables, and the mean difference (MD) or standardized mean difference (SMD) with 95% CI for continuous variables were calculated using the fixed-effect model or random-effect model [29]. Heterogeneity between studies was assessed by the χ^2 test with $p < 0.10$ used to indicate statistical significance. I^2 also was calculated to measure the quantity of heterogeneity, with $I^2 > 50\%$ indicating significant heterogeneity [30]. The meta-analysis was conducted using the fixed-effect model if there was no statistically significant heterogeneity ($p \geq 0.10$, $I^2 \leq 50\%$); Otherwise, the possible reasons were explored or the random-effect model was used for the significant heterogeneity ($p < 0.10$, $I^2 > 50\%$).

Subgroup analyses were performed for postoperative pain on different days and operative time for bilateral and unilateral groups. Subgroup analysis for hernias with defects >4 cm was not done because of unavailable data. Sensitivity analysis was carried out by omitting poor-

quality studies that have a high risk of bias. Intention-to-treat analysis was not performed because of insufficient information about loss to follow-up in treatment and control groups. The funnel plot was not used due to the limited number of RCTs.

Results

Description of studies

The flowchart of literature screening is presented in Fig. 1. According to the established search strategy used, a total of 513 potentially relevant literature items were identified in the databases. Of the 513 items searched, 68 duplicate studies were excluded by EndNote software. After screening the titles and abstracts of the remaining 445 studies, 433 irrelevant studies were excluded, leaving 12 studies for further assessment. After the full-text review of the 12 studies, we excluded 6 of them. Therefore, six trials [19, 22–26] that fulfilled the inclusion criteria were included.

Characteristics of included studies

Table 1 gives the characteristics of the included studies. Trials were performed in five countries: Australia, China, US ($n = 2$), India, and Spain. A total of 992 hernia repairs were performed on 772 patients (unilateral hernia, $n = 552$; bilateral hernia, $n = 220$) and the follow-up period ranged from 8 to 36 months. Both groups were well matched at baseline from the information in all of the trials.

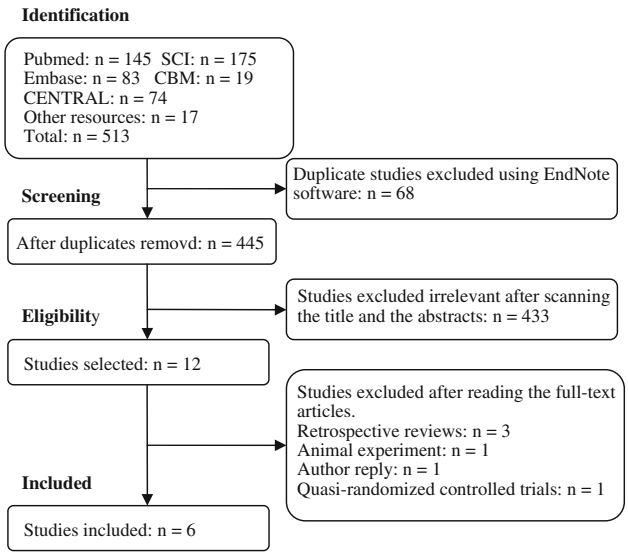

Fig. 1 The flowchart of literature screening

Risk of bias in included studies

The risk of bias in the included trials is summarized in Table 2. All trials were randomized, four [19, 22, 24, 26] of which were randomized by computer-generated numbers, one [25] by random number tables, and one [23] by sealed envelope technique. Allocation concealment was reported in detail in three trials [23, 24, 26]. Blinding was reported in only two trials: one trial [24] was single-blinded (blind to patients and nurses) and the other [26] was double-blinded (blind to surgeons and patients). Li et al. [25] reported that no one was lost to follow-up, another two studies [23, 26] reported missing data or patients lost to follow-up (the number was about the same for both groups), and the others did not report relevant information so the risk of incomplete outcome data bias was unknown.

Effects of interventions

Hernia recurrence

Hernia recurrence was measured in all of the included trials [19, 22–26]. A total of four recurrences out of 992 TEP repairs were reported: one in the fixation group in Taylor et al. [26] and 3 in the nonfixation group in Moreno-Egea et al. [22]. The fixed-effect model was used to perform meta-analysis because there was no statistical heterogeneity ($I^2 = 48\%$, $p = 0.17$, $p > 0.1$). Overall, no statistical difference between the two groups was found for hernia recurrence [OR = 2.01, 95% CI (0.37, 11.03), $p = 0.42$] (Fig. 2).

Postoperative pain

Postoperative pain was reported in five trials [22–26]. However, data were evaluated using three different measurement scales: visual analog scale (VAS) [22, 23, 25], post-herniorrhaphy pain scale [26], and the Likert scale [24]. Quantitative synthesis was not allowed, so the meta-analysis was performed for patients whose pain was evaluated by VAS. The result showed no difference on the postoperative day 1 [MD = −0.21, 95% CI (−0.52, 0.10), $p = 0.18$] and postoperative day 7 [MD = −0.11, 95% CI (−0.42, 0.20), $p = 0.47$] (Fig. 3).

Taylor et al. [26] found significantly decreased chronic pain at 6 months in the nonfixation group using the post-herniorrhaphy pain scale. Koch et al. [24] suggested that patients in the fixation group had higher levels of pain at 1, 4, and 12 months, but none of the comparisons was statistically significant with the Likert scale.

Table 1 Characteristics of included studies

Study	Country	Number of patients (total/unilateral/bilateral)		Age (years)		Follow-up period	Characteristics of hernia (nonfixation/fixation)	Characteristics of mesh	Fixation material	Outcome measures[a]
		Nonfixation	Fixation	Nonfixation	Fixation					
Ferzli et al. 1999 [19]	USA	49/48/1	43/36/7	53 (mean)	55 (mean)	8 m (mean)	Indirect (33/23), Direct (16/20),	Polypropylene Size: 6 × 6 in.^{2}	Staple	①④⑤⑥⑦
Moreno-Egea et al. 2004 [22]	Spain	85/59/26	85/52/33	56.9 ± 16.3	53.8 ± 15.6	36 ± 12 m	Indirect (53/62), Direct (32/23), Mixed (2/3), Femoral (1/0), Recurrent (3/0)	Parietex polyester Size: Unknown	Staple	①②⑤⑦
Parshad et al. 2005 [23]	India	25/21/4	25/16/9	47.16 ± 16.4	46.4 ± 15.2	23.98 ± 9.9 m/27.5 ± 8.6 m (nonfixation/fixation)	Unknown	Polypropylene Size: 11 × 15 to 13 × 15 cm^2	Staple	①②③④⑥
Koch et al. 2006 [24]	USA	20/13/7	20/14/6	54.6 ± 16.1	56.3 ± 11.5	6–30 m, 19 m (median)	Indirect (12/10), Direct (12/3), Recurrent (21/16)	Polypropylene Size: Unknown	Tack	①②③⑤
Li et al. 2007 [25]	China	30/27/3	30/26/4	58 ± 15	61 ± 15	12–24 m, 16 m (median)	Unknown	Polypropylene Size: 10 × 15 cm^2	Autosuture or staple	①②③④⑤⑥⑦
Taylor et al. 2008 [26]	Australia	180/120/60	180/120/60	59.6 (mean)	59.3 (mean)	6–13 m, 8.2 m (mean)	Indirect (52%/53%), Direct (25%/24%), Mixed (9%/9%), Femoral (4%/4%), Recurrent (10%/10%)	Polypropylene Size: 10 × 15 cm^2	Tack	①②⑤⑦

m month

[a] ① = hernia recurrence; ② = postoperative pain; ③ = length of hospital stay (days); ④ = time to return to normal activities (days); ⑤ = operating time (minutes); ⑥ = seroma; ⑦ = costs

Table 2 Risk of bias in included studies

Study	Adequate sequence generation	Allocation concealment	Blinding	Incomplete outcome data	Free of selective reporting	Free of other bias
Ferzli et al. 1999 [19]	Yes (computer)	Unclear	Unclear	Unclear	Unclear	Unclear
Moreno-Egea et al. 2004 [22]	Yes (computer)	Unclear	Unclear	Unclear	Unclear	Unclear
Parshad et al. 2005 [23]	Yes (envelopes)	Yes	Unclear	Yes	Unclear	Unclear
Koch et al. 2006 [24]	Yes (computer)	Yes[a]	Yes (single blind)	Unclear	Unclear	Unclear
Li et al. 2007 [25]	Yes (random number tables)	Unclear	Unclear	Yes	Unclear	Unclear
Taylor et al. 2008 [26]	Yes (computer)	Yes	Yes (double blind)	Yes	Unclear	Unclear

[a] Information was gotten from the author by e-mail

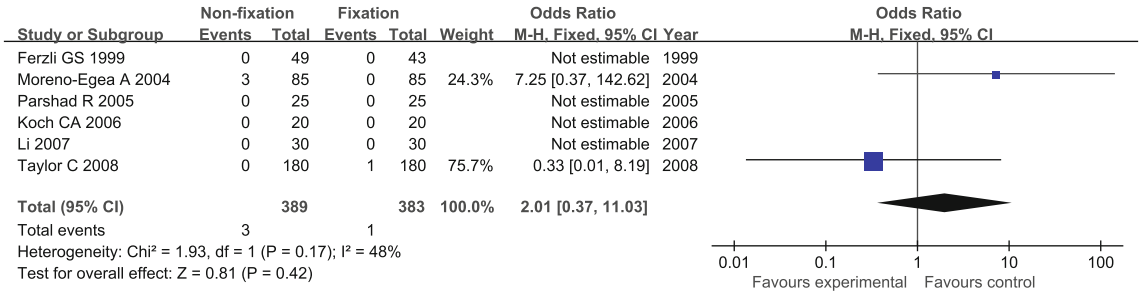

Fig. 2 Hernia recurrence

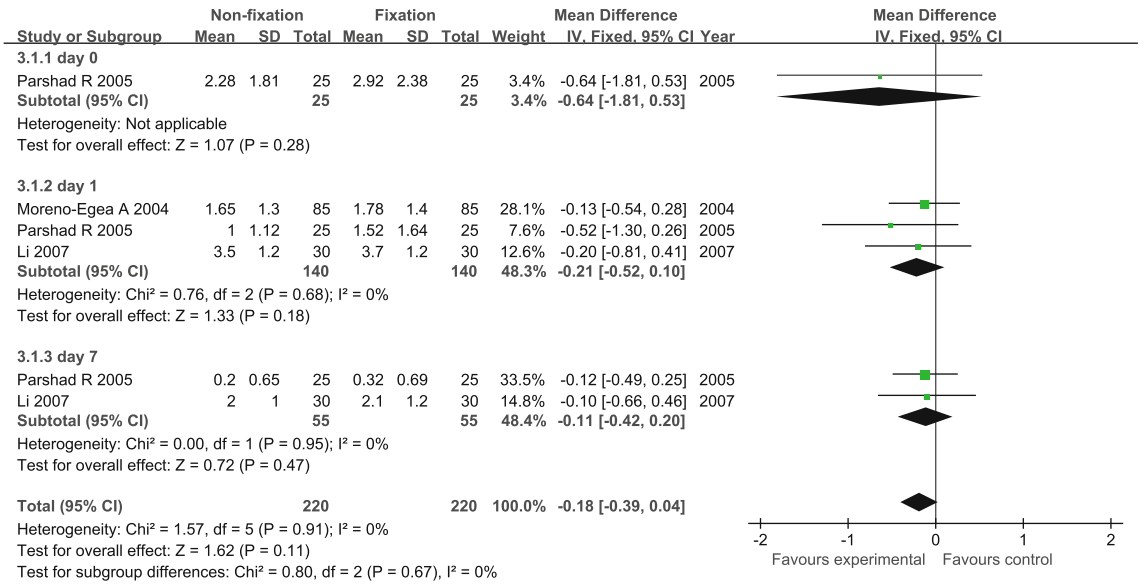

Fig. 3 Subgroup analysis of postoperative pain

Length of hospital stay (days)

Three of the six trials gave the length of hospital stay [23–25]. There was no statistical heterogeneity ($I^2 = 0\%$, $p = 0.73$, $p > 0.1$). The meta-analysis showed that length of hospital stay in the fixation group was significantly longer [MD = −0.37, 95% CI (−0.57,−0.17), $p = 0.0003$] (Fig. 4).

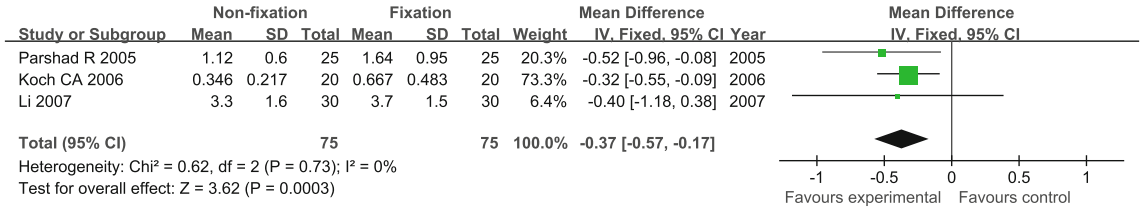

Fig. 4 Length of hospital stay (days)

Time to return to normal activities (days)

Three trials [19, 23, 25] investigated the time necessary to return to normal activities. The fixed-effect model was used to perform meta-analysis because there was no significant heterogeneity between trials ($I^2 = 0\%$, $p = 0.50$, $p > 0.1$). Although the amount of data for the nonfixation group was equal to or less than that for the fixation group, the result of meta-analysis showed that there was no significant difference between the two groups [MD = −0.13, 95% CI (−0.45, 0.19), $p = 0.43$] (Fig. 5).

Operative time (min)

The operative time was summarized in five trials [19, 22, 24–26]. In three trials [22, 24, 25] it was given as mean and standard deviation and in the other two [19, 26] the average time was given. Only one trial [22] performed a subgroup analysis for unilateral and bilateral hernia. Three trials [22, 24, 25] that gave mean and standard deviation were used for meta-analysis. No statistical heterogeneity was found between the three trials ($I^2 = 0\%$, $p = 0.69$, $p > 0.1$). The overall effect showed that the operative time for the nonfixation group was significantly shorter than that for the fixation group [MD = −4.19, 95% CI (−7.77, −0.61), $p = 0.02$]. A subgroup analysis based on one trial [22] gave a similar result in the unilateral group ($p = 0.04$, $p < 0.05$) (Fig. 6).

Seroma

Three trials [19, 23, 25] could be included for meta-analysis for seroma. Overall, there was no significant heterogeneity between trials ($I^2 = 0\%$, $p = 0.48$, $p > 0.1$) and no significant difference between groups [OR = 1.25, 95% CI (0.30, 5.18), $p = 0.75$] (Fig. 7).

Costs

The economic evaluation was conducted in four trials [19, 22, 25, 26]. A meta-analysis of costs was not performed because of the different social systems of the countries in which the trials were conducted. However, most of the trials reported that hernia repair with nonfixation of mesh cost less. Li et al. [25] and Moreno-Egea et al. [22] showed that mesh fixation increased the costs and showed a statistical difference. Taylor et al. [26] and Ferzli et al. [19] calculated only the costs but did not state whether there was a significant difference. Taylor et al. [26] and Ferzli et al. [19] showed that the nonfixation group had decreased costs by approximately 375 AUD and $120 per patient, respectively.

Sensitivity analysis

A sensitivity analysis was conducted by omitting two poor-quality studies (Ferzli et al. [19] and Moreno-Egea et al. [22] which have only one "Yes" in Table 2). The results gave similar estimates for recurrence. Sensitivity analyses for other outcomes were not conducted because of unavailable data.

Discussion

Summary of evidence

This meta-analysis was based on six RCTs that included 992 hernia repairs in 772 patients and compared fixation

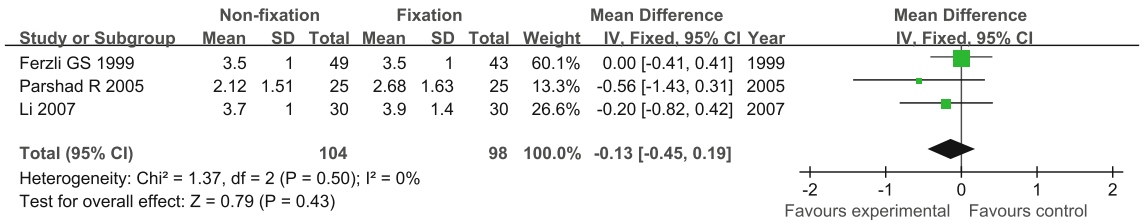

Fig. 5 Time to return to normal activities (days)

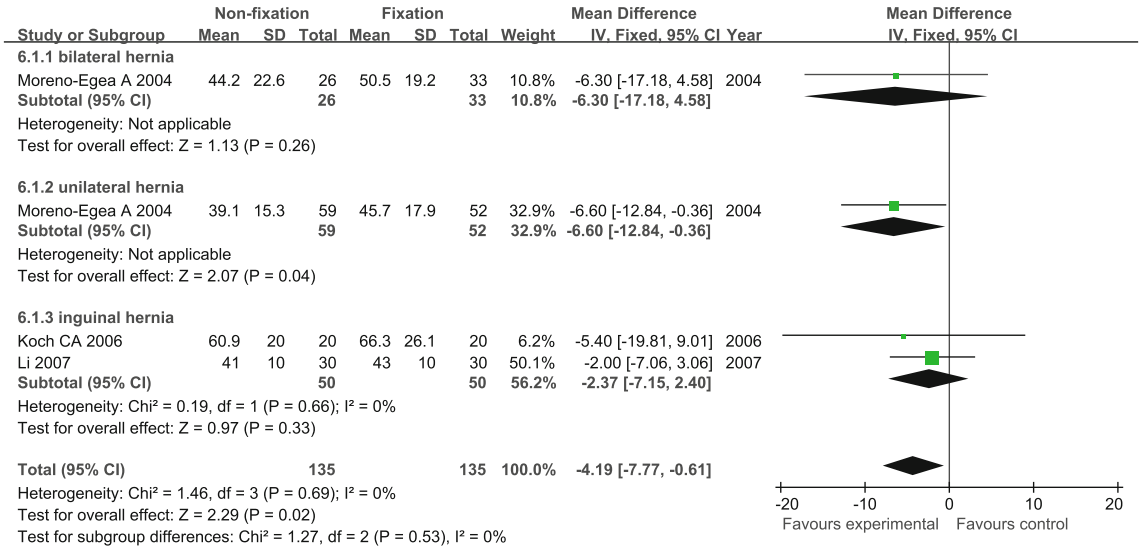

Fig. 6 Operative time (min)

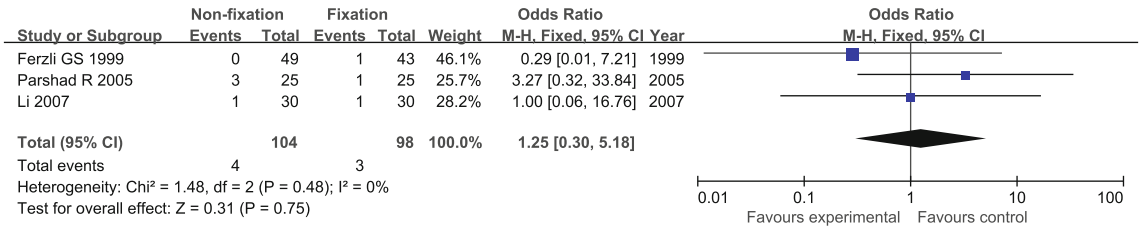

Fig. 7 Seroma

with nonfixation of mesh in TEP. All patients in both groups were reported to be well-matched for age, sex, and type of hernia. Randomization was performed in all trials. Allocation concealment was not reported in three trials, which might lead to unclear risk of selection bias. Blinding was reported in only two trials, which might cause a high risk of performance bias or detection bias. The risk of incomplete outcome data should be considered because three trials did not report the patients lost to follow-up. Although a comprehensive literature search was conducted, some published and unpublished trials might have been missed, which would lead to nonpublication bias.

It is demonstrated that hernia recurrence occurred mostly within 2 years postoperatively [31]. The duration of follow-up in the trials ranged from 8 to 36 months, which perhaps raises concerns about late recurrence. The meta-analysis showed that nonfixation of mesh in TEP would not cause increased hernia recurrence ($p = 0.42$); this corroborated earlier non-RCTs [20, 21, 32–35] in which a total of six recurrences were reported in 3409 hernia repairs without fixation. A large RCT that compared stapled and nonstapled mesh in TAPP also confirmed this conclusion at a median follow-up of 16 months (0-263 nonstapled and 3–273 stapled; $p = 0.09$) [36]. Without mesh fixation, the major concern to surgeons is a hernia recurrence arising from moving or folding of the mesh. However, previous studies have indicated that mesh stabilization might be underappreciated [26]. Li et al. [25] confirmed by type-B ultrasound that there was no significant difference in mesh shrinkage at 1, 6, and 12 months postoperatively. Choy et al. [37] and Irving et al. [38] demonstrated by relaparoscopy and postoperative X-rays, respectively, that nonfixation of mesh did not lead to mesh migration. Furthermore, a study pointed out that recurrence was most likely caused by something other than fixation, such as incomplete dissection or the mesh size was too small [23]. Other factors such as the number of patients lost to follow-up, characteristics of the hernia, indications for surgery, and especially the surgeon's expertise might influence hernia recurrence as well [22, 31, 39]. Nevertheless, data on the surgeon's expertise is available in only one trial (Moreno-Egea et al. [22], more than 3 years and 60 cases), and it is suggested that surgeons should accomplish 50–100 procedures to become experienced, with the first 30–50 being the most pivotal [10].

Whether larger defects (i.e., >4 cm) need mesh fixation is still debatable. Subgroup analyses for patients with different defects were not allowed due to insufficient data.

However, it has been confirmed in Taylor et al. [26] (74% defects <2 cm), Li et al. [25] (defects <4 cm), and Koch et al. [24] (defects <3 cm) that hernia recurrence would not increase. A case–control study trial suggested that there was no need to fix the mesh in patients with defects <4 cm, but evaluation should be done when the defect is >4 cm [34]. Another issue is what size mesh should be used in TEP without mesh fixation. Inadequate mesh size also might cause recurrence when mesh fixation is eliminated [11, 13, 34]. It has proven safe to use 10 × 15-cm^2 polypropylene mesh [25, 26] and 11 × 15- to 13 × 15-cm^2 polypropylene mesh [23]. A porcine model study indicated that it was essential to overlap the defects by 3 cm or more to reduce the risk of recurrence [40].

Theoretically, avoiding tacks or staplers was thought to contribute to a decrease in the risk of nerve injury and reduce pain. Furthermore, postoperative pain is also related to vascular injury, spermatic cord injury, hematoma compression, and spermatic cord compression [41, 42]. The meta-analysis showed no significant difference in patients whose pain was evaluated with VAS on the postoperative days 1 and 7. Taylor et al. [26] found significantly decreased chronic pain postoperatively in the nonfixation group (at 6 months using the post-herniorrhaphy pain scale), but Koch et al. [24] did not (at 1, 4, and 12 months using the Likert scale). As the different time points chosen for pain do not seem clinically relevant, it is difficult to perform meta-analyses to demonstrate whether the difference is significant. Moreover, blinding to patients and surgeons could prevent the risk of detection bias when assessing postoperative pain. However, postoperative pain was reported in only two trials in this meta-analysis.

The hospital stay was significantly longer in the fixation group. Koch et al. [24] found that it is correlated with significantly increased urinary retention caused by greater use of narcotic analgesia postoperatively. The guidelines [10] have stated that day surgery for inguinal hernia repair is safe and effective. Nevertheless, patients were admitted for 3 days in Li et al. [25]. Length of hospital stay may be determined by the health-care financing system of the country and the degree of acceptability of day care among patients and surgeons of different countries.

Surprisingly, although all trials, except one [22], reported that there was no significant difference in operative time, the overall effect of meta-analysis found a significantly shorter operative time for the nonfixation group. This might depend on the type of fixation and the proficiency of the surgeon.

A descriptive analysis of the costs was performed in this study. Li et al. [25] and Moreno-Egea et al. [22] suggested that patients in the nonfixation group saved a significant amount of money compared with those in the fixation group. Taylor et al. [26] and Ferzli et al. [19] reported that the fixation group's procedure was more costly, but they did not state whether there was a significant difference. As hernia repair is a common operation, the increased costs from using staples or tacks have been a major deterrent to extending the benefits of TEP procedures in the general, especially for the patients from the lower socioeconomic level.

Limitations and implications for RCTs and meta-analysis

In review, some limitations should be considered and some improvements should be made for further studies. (1) For outcome measures such as postoperative pain and secondary outcomes, although six studies were included, the limited number of trials eligible for meta-analysis influenced the outcome parameters. (2) This review is limited by the methodological quality of the included RCTs. Some information is insufficient to permit defined judgment. Although every attempt was made to contact the authors of the included trials via e-mail or telephone, only two authors (Farley et al. [24] and Li et al. [25]) responded. Therefore, it is recommended that additional RCTs be performed and reported according to the CONSORT Statement which offers a standard way to improve the quality of research. (3) Currently, there are few data to compare the efficacy of nonfixation with fixation of mesh in patients with different defect sizes and various types of hernias. Therefore, additional RCTs should be conducted in these specific subgroups. (4) Few trials reported the learning curves of the surgeons, hence, the TEP operation should be completed by experienced surgeons who should be trained before trials in order to ensure that the baseline is well-matched. (5) Further studies should present sufficient information about the number of cases and the reasons for patients being lost to follow-up in each group. This would help the readers analyze whether the dropout rate affects the results and conduct a further intention-to-treat (ITT) analysis.

Conclusion

From the current evidence, the nonfixation of the mesh in TEP appears to be a safe alternative for the selected inguinal hernia patients. It will not increase the risk of early hernia recurrence and seems to have advantages with respect to costs, hospital stay, and operative time. No evidence indicates that eliminating the fixation of mesh in TEP is hazardous to the patient. Further high-quality, long-follow-up RCTs are needed to clarify the necessity of mesh fixation for the patients with various types of hernias and larger hernia defects.

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