Hernia (2022) 26:1473–1481
https://doi.org/10.1007/s10029-021-02533-2

REVIEW

Fascial defect closure versus bridged repair in laparoscopic ventral hernia mesh repair: a systematic review and meta-analysis of randomized controlled trials

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Received: 30 August 2021 / Accepted: 26 October 2021 / Published online: 8 November 2021

Abstract

Purpose Several studies have examined effectiveness of primary fascial defect closure (FDC) versus bridged repair (no-FDC) during laparoscopic ventral hernia mesh repair (LVHMR). The purpose of this study was to systematically review and meta-analyse randomized controlled trials (RCTs) which compared safety and effectiveness of two techniques.

Methods Systematic literature searches (EMBASE, MEDLINE, PubMed, and CINAHL) were conducted according to the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) guidelines using predefined terms. RCTs comparing FDC and no-FDC in LVHMR were identified and retrieved. Primary outcomes were risk of recurrence and risk of major complications analyzed as a single composite outcome. Secondary outcomes were risks of seroma formation, clinical or radiologically confirmed eventration, incidence of readmission to hospital, postoperative changes in quality of life (QoL), and postoperative pain. Random effects modeling to summarize statistics were performed. The risk of bias was assessed using Cohrane's Risk of Bias tool 2.

Results Three RCTs that enrolled total of 259 patients were included. There was clinical heterogeneity present between studies related to patients' characteristics, hernia characteristics, and operative techniques. There was no difference found in primary outcomes, risks of seroma formation, eventration, and chronic pain. There is conflicting evidence on how both techniques affect postoperative QoL or early postoperative pain.

Conclusions Both techniques were detected to have equal safety profile and do not differ in risk of recurrence, seroma formation, risks of clinical or radiological eventration. Giving uncertainty and clinical equipoise, another RCT examining FDC vs no-FDC laparoscopic mesh repair separately for primary and secondary hernias using narrow inclusion criteria for hernia size on well-defined population would be ethical and pragmatic.

Prospero registration CRD42021274581.

Keywords Laparoscopic ventral hernia mesh repair · Fascial defect closure

Introduction

Laparoscopic ventral hernia mesh repair (LVHMR) is a well-established technique worldwide to treat both primary and incisional abdominal wall hernias [1]. There are several variations of LVHMR. One of the variations is concerned about approach to the fascial defect. European Hernia Society and Americas Hernia Society guidelines as well as International Endohernia Society guidelines suggest adopting fascial defect closure (FDC) approach [2–4]. This recommendation is based on two systematic reviews of observational studies that showed that FDC reduces recurrence and seroma formation rates as compared to no-FDC (also known as bridged repair) technique [5, 6]. However, since publication of these

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reviews, several new high-quality prospective studies have been reported comparing FDC and no-FDC in LVHMR. The objective of our study was to perform an updated systematic review and comprehensive meta-analysis based on published randomized controlled trials (RCTs) comparing safety profile, risk of recurrence, other important secondary outcome measures such as risk of seroma formation, clinical or radiological eventration, acute and chronic pain and quality of life following FDC or non-FDC repairs.

Methods

Search strategy

The study was prospectively registered with PROSPERO (CRD42021274581) and conducted according to the Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA) guidelines [7].

The search terms were devised to cover technical aspects of laparoscopic ventral hernia repair with regards to FDC. This was performed using the following text words (including their synonyms/variants) and Medical Subject Headings (MESH terms): laparoscopy, ventral hernia repair, incisional hernia repair, umbilical hernia repair, primary fascial closure, and no-closure mesh repair. The search terms were combined using the Boolean AND/OR operators.

PubMed, Medline, Embase, and CINAHL were comprehensively searched. ClinicalTrials.gov was also explored for any registered trials. The initial database searches encompassed studies published in English from the inception date of each database to 21st of August 2021. To ensure that all relevant studies were identified, no restrictions were placed on the date of publication or regional state. Two reviewers identified relevant articles comparing FDC and no-FDC in patients undergoing LVHMR. Reference lists of all retrieved articles were manually searched to identify additional studies. Complete search algorithms for each database are available in Appendix 1.

Inclusion criteria

Studies published in English that fulfilled the following criteria were included: (1) studies that compared primary FDC with mesh and bridged mesh repair (no-FDC) in laparoscopic ventral hernia surgery, (2) randomized controlled studies, and (3) full-text manuscripts.

Exclusion criteria

Studies were excluded from analysis: (1) studies in which it was not possible to extract data from the published results, (2) the studies contained re-published data, (3) non-randomized studies, (4) studies published in other language than English, and (5) publications that are editorials, comments, letters, review articles, conference abstracts, retractions, and case reports.

Outcome measures

Primary outcomes for this study were recurrence and major complications. This study combined all complications which could be classified as grade II or above as per Clavien–Dindo classification [8, 9] into a single composite outcome. Cases of death during follow-up period which were not judged to be directly related to primary surgery were taken note of, but not included in the meta-analysis.

Secondary outcomes studied were acute and chronic postoperative pain, seroma formation, clinical or radiologically confirmed eventration (bulging), readmission to hospital, and postoperative changes in quality of life (QoL).

Study selection

Two authors (YT and CSW) implemented the search strategy independently. Both reviewed the abstracts identified by the search to exclude those that did not meet the inclusion criteria. Differences of opinion were resolved by consensus with the senior author (AK).

Data extraction

Data from each study reporting the outcomes of interest were extracted by two independent reviewers (VT, ID). The extracted data included the following: the basic characteristics of the study, including authors, year, and sample size; the basic patient characteristics and comparative outcomes. Disagreement was resolved by discussion to reach a consensus; if an agreement between the two reviewers could not be reached, a third person (AK) was involved.

Risk of bias assessment

All studies were independently assessed by two investigators for quality and validity using the Cochrane Risk of Bias Tool 2 Algorithm with the effect of principal interest being assignment to intervention at baseline [10]. Full-text manuscripts and trial protocols were assessed where available. Disagreements in the quality assessment were resolved by consensus.

Statistical analysis

All statistical analyses were performed using Revman software, version 5.3 (Cochrane Collaboration, The Nordic Cochrane Centre, Copenhagen). Meta-analysis was

performed for primary outcomes as well as for two secondary outcomes (seroma formation, clinically or radiologically confirmed eventration). Random-effects models to analyze data were used. Risk difference (RD) was calculated for dichotomous outcomes. A 95% confidence interval (CI) was recorded. Statistical heterogeneity was assessed using the I2 test statistic [11].

Results

Description of study selection

The predefined search strategy captured 315 potentially relevant publications. In total, 56 duplicate studies were removed. After titles and abstracts screening, additional 252 studies were excluded. After full-text screening, additional four studies were excluded. The full texts of the remaining three studies were reviewed and subsequently confirmed to be eligible to be entered into the review and meta-analysis. The PRISMA flow diagram of this process is shown in Fig. 1.

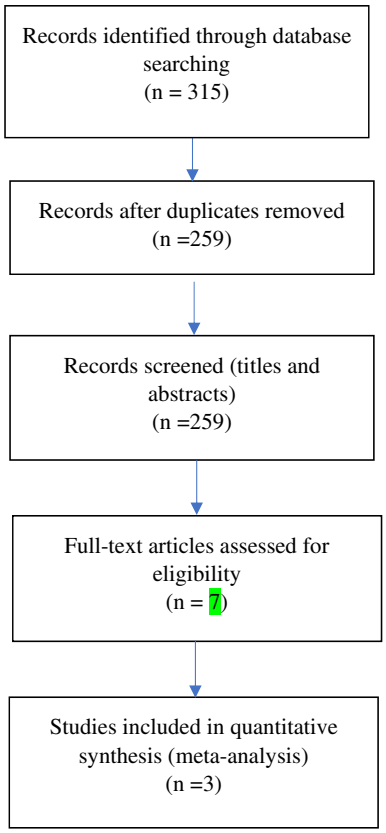

Fig. 1 PRISMA flowchart of the literature search

Study characteristics

The 3 RCT studies enrolled 259 participants. All studies included patients who underwent LVHMR repair with FDC or no-FDC. Overall, 129 and 130 patients were allocated and received intervention in the FDC group and no-FDC group, respectively. Short-term outcome data were available for meta-analysis for 251 patients, while long-term (12 months to 24 months) follow-up data were available for lower number of patients.

The main characteristics of studies are provided in Tables 1 and 2.

Risk of bias

Assessment of quality was based on journal articles, published protocols and trial protocols registered in clinicaltrials.gov. Included studies were found to have low risk of bias. The risk of bias summary data is provided in Table 3.

Primary outcomes

Recurrence

Recurrence rates in selected studies ranged from 0 to 23% [1, 12, 13]. The study of Christoffersen et al. which had the highest rate of recurrence found significantly lower number of events in no-closure group [12]. Pooled analysis of included studies based on 244 patients did not demonstrate difference in the risk of recurrence (Risk difference RD −0.01 [95 Confidence Interval CI −0.13, 0.10] $p=0.81$) (Fig. 2). Heterogeneity was 72% (Table 4).

Major complications

Complications that fell within Clavien–Dindo grade II or above were two cases of surgical site infection requiring antibiotics and one case of re-operation due to severe pain [1, 12, 13]. There were two cases of death reported during follow-up, although these were not directly related to primary surgery [1, 13]. These cases were not accounted for in the meta-analysis. No difference between two techniques was found when RD of major complications as a composite outcome was calculated (RD 0.01 [−0.02, 0.04], $p=0.58$) (Fig. 3; Table 4).

Secondary outcomes

Postoperative pain

Acute pain (day 1–day 30)

Two studies reported on pain in 30-day postoperative period [1, 12]. The study of Christoffersen et al. showed that there was no significant difference between the groups

Table 1 Patient characteristics

Study	Country	Recruitment years	Number of centers	Number of patients allocated to and received intervention			Age (FDC:no-FDC)	BMI (FDC:no-FDC)	Primary:secondary hernia	Hernia defect size
				Total (M:F)	FDC	No-FDC				
Ali et al.	Sweden	2017–2018	Single center, one surgeon	50 (29:21)	25	25	58* (45–67):56 (46–62)	29* (28–32):30 (28–35)	16:34	3–10 cm: < 4 cm—4 ≥ 4–6 cm—34 ≥ 6–10 cm—12
Christoffersen et al.	Denmark	2013–2016	5 centers	80 (51:29)	40	40	54* (30–75):55 (30–77)	24* (15–64):27 (17–38)	69:11	2.5 cm* 1.5–5.5 cm
Bernardi et al.	USA	2015–2017	4 centers	129 (47:82)	64	65	50.1:49.1**	30:30.6**	28:100	3–10 cm

M:F male:female, *FDC* fascial defect closure, *BMI* body mass index, * median value, interquartile range; ** mean value

Table 2 Main characteristics of operative technique and perioperative management

Studies	Preoperative antibiotics	Operative techniques and mesh variables	Technique of defect closure	Postoperative management	Maximum follow-up
Ali et al.	+, details n.r.	IPOM, no further details	Closure with 2/0 knotless polydioxanone	Abdominal elastic binder continuously 14 days after surgery, and only during the day for 14 days thereafter	12 months
Christoffersen et al.	1500 mg cefuroxime intravenously preoperatively	PhysiomeshTM (Ethicon) with at least a 5-cm overlap, double crown-fixed with non-absorbable tacks (ProtackTM; Covidien) with approximately 2 cm between each tack	Intracorporeal sutures: non-absorbable interrupted 2–0 ethibond 0.5-1 cm from fascial edges with 0.5-1 cm between stitches	Abdominal elastic binder continuously for 7 days after surgery	2 years
Bernardi et al.	+, details n.r.	Mesh secured with four 0-polydioxanone positioning sutures and tacked with a double crown of permanent tacks	Percutaneous technique—0-polydioxanone sutures every 1 cm	n.r.	2 years

+ −given, details not provided, *IPOM* intraperitoneal onlay mesh, *n.r.* not recorded

Table 3 Risk of bias summary

Study	Domain 1 Randomization process	Domain 2 Deviation from intended intervention	Domain 3 Missing outcome data	Domain 4 Measurement of the outcome	Domain 5 Selection of recorded results	Overall
Ali et al.	Low	Low	Low	Low	Low	Low
Christoffersen et al.	Low	Low	Low	Low	Low	Low
Bernardi et al.	Low	Low	Low	Low	Low	Low

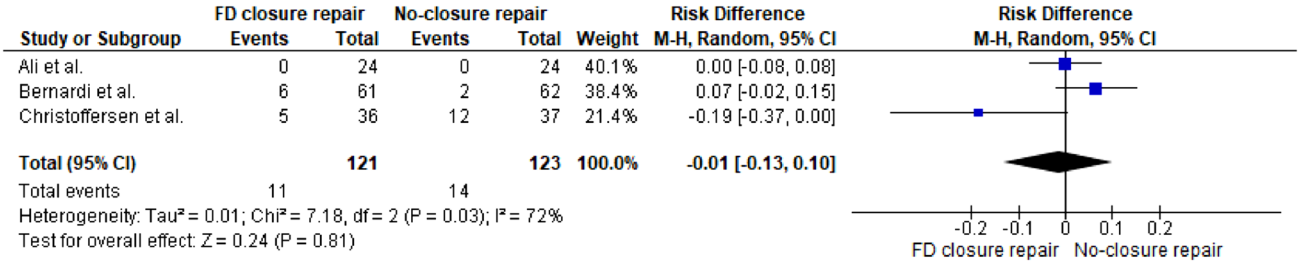

Fig. 2 Risk of recurrence

Table 4 Summary of primary outcomes

Study	Recurrence	Major complications		
		SSI requiring intervention or antibiotics (FDC:non-FDC)	Early reoperation for complication (FDC:non-FDC)	Other complication (Clavien–Dindo II or above)
Ali et al.	0:0	0:0	0:0	One patient died from cardiovascular co-morbidities
Christoffersen et al.	5:12	1:0	0:1	n.r.
Bernardi et al.	6:2	1:0	0:0	One patient died from complications of HIV/AIDS

SSI surgical site infection, *n.r.* not recorded

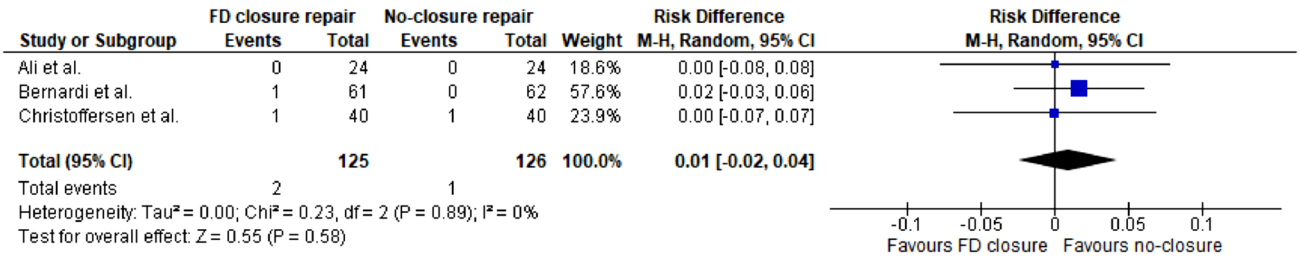

Fig. 3 Risk of major complications

at day 1 for pain on activity assessed by Visual Analogue Scales (VAS) ($P = 0{\cdot}906$) and Verbal Rating Scale (VRS) ($P = 0{\cdot}205$) as well as at 30 days (VAS ($P = 0{\cdot}986$); VRS ($P = 0{\cdot}142$)) [12]. In addition, there was no difference in need of rescue opioids between the two study groups ($p = 0{\cdot}350$). In contrast, the study of Ali et al. showed that there was significant difference between groups at day 7 for acute pain by VAS ($p < 0{\cdot}001$) and at 1 month by VAS ($p = 0{\cdot}045$) favoring no-FDC in both cases [1] (Table 5).

Chronic pain (6 months–24 months)

Three patients reported moderate or severe chronic pain on the VRS at 2-year follow-up (2 in the no-closure and 1 in the closure group) in the study of Christoffersen et al. [12]. There was no significant difference between groups in

Table 5 Summary of secondary outcome, QoL—quality of life

Studies	FDC:no-FDC							
	Duration of surgery (min)	Seroma	Readmission	Reoperation for recurrence	Pain acute	Pain chronic	Clinical or radiological eventration	QoL
Ali et al.	61 (56–70):63 (53–72)*	4:0	n.r.	0:0	Day 7 VAS: 6 (6–7):3 (3–4)* ($P<0{\cdot}001$) Day 30 VAS: 1 (0–2):0 (0–1)* ($P=0{\cdot}045$)	6 month 0:0	n.r.	n.r.
Christoffersen et al.	47 (25–89):34 (20–69)*	14:22	1:1	8	Day 1 pain on activity VAS: 73 (11–99):69 (9–100)* ($P=0{\cdot}906$) Day 30 pain on activity VAS: 2 (0–32):2 (0–39)* ($P=0{\cdot}986$)	Pain on activity 24 months VRS 1:2 *($P=0{\cdot}272$)	1:2	CCS score 0(0–12):0 (0–70)* ($P=0{\cdot}583$)
Bernardi et al.	88.3 (39.4):75.4 (38.4)**	7:12	4:3	1:1	n.r.	24 months pain at follow-up VAS 3.4 (3.1):2.5 (2.0)** ($P=0{\cdot}249$)	7:9	mAAS 77.5 (26.1):72.4 (26.6)** Change comparing to preoperative values 41.3 (31.5):29.7 (28.7)** ($P=0{\cdot}047$)

n.r. not recorded, *median value, interquartile range; **mean value, standard deviation, *VAS* visual analogue scales, *VRS* verbal rating scale, *mAAS* modified activity assessment scale, *CCS* Carolinas Comfort Scale

chronic pain using VAS score at 6 months ($p=0.052$), and no pain was reported at 12 months in either group in the study of Ali et al. [1]. There was no significant difference in the severity of pain in the study of Bernardi et al. in the follow-up time to 2 years after randomization [13] (Table 5).

Quality of life (QoL) and satisfaction rates

Long-term (12–24 months) quality of life outcomes were assessed by two studies. The study of Bernardi et al. examined QoL changes as a primary outcome and had a median follow-up of 24 months (range 9–42). Modified Activity Assessment Scale (mAAS), a validated hernia-specific QoL survey, was used [14–16]. The data were available for 107 patients. Both groups experienced an increase in their QoL scores after repair; however, those who underwent FDC had on average a 12-point higher improvement in their QoL scores (41.3 ± 31.5 vs 29.7 ± 28.7, $P=0.047$) (Table 5). There was 2.1X reported factor change in the FDC group as compared to 1.7X factor change in the no-FDC group.

The study of Christoffersen et al. used CCS, Carolinas Comfort Scale [17], to assess quality of life at 2-year follow-up [12]. This was available for 73 patients. There was no difference found in the CCS ($p=0.528$) between two groups. Neither one of two techniques was associated with better satisfaction score on VRS scale ($p=0{\cdot}955$) (Table 5).

Seroma formation

Seroma formation was reported by all three studies with rates ranging from 8 to 45%. There was no significant difference in the risk of seroma formation between groups (RD of −0.03 [−0.24, 0.18] $p=0.77$). The heterogeneity in the studies was at 80% (Fig. 4; Table 5).

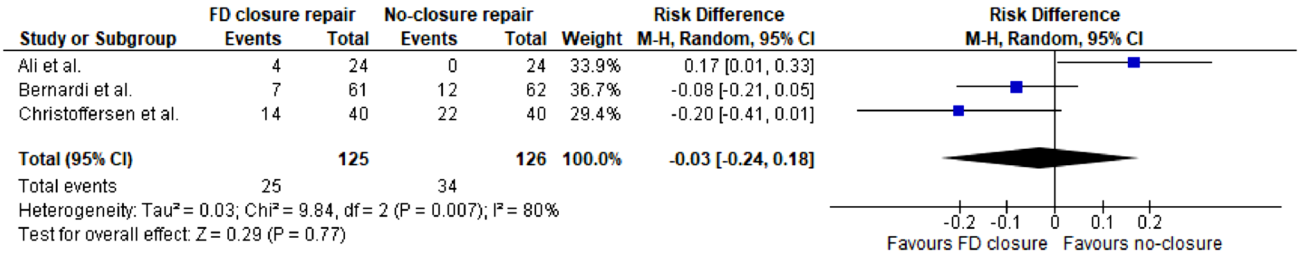

Fig. 4 Risk of seroma formation

Clinical or radiologically confirmed eventration

The rate of clinical eventration in the study of Bernardi et al. [13] was reported to be 13% (16 cases). The study of Christoffersen et al. reported on radiological signs of eventration and demonstrated the rate of 4.1% [12]. There was no significant difference between two groups when meta-analysis was performed (Fig. 5).

Incidence of readmission to hospital

Two studies reported incidence of re-admission to hospital [12, 13]. While it was confirmed that reason for two readmissions in the study of Christoffersen et al. [12] was pain, there was no explanation provided for seven cases of readmission in the study of Bernardi et al. [13] (Table 5).

Assessment of reporting biases

According to the Cochrane guidelines, we were unable to assess the reporting biases because there were fewer than 10 trials included in the analysis.

Discussion

Our systematic review and meta-analysis is the first study that compared FDC and non-FDC LVHMR using high-quality data. Our study included RCTs only as it is agreed that a meta-analysis of RCTs offers the highest level of evidence and thus allows for the highest grade of recommendation [18]. All included studies were judged to have low risk of bias and methodology design was compliant with Palermo consensus group statement recommendations on measuring and reporting outcomes in studies analyzing abdominal wall repair techniques (Palermo CG statement) [18]. Primary and secondary outcomes in our study were selected based on Palermo CG statement [18].

Our study confirmed that both techniques have equal safety profile, and no difference was detected in risk of recurrence. There was no difference detected in secondary outcomes such as risk of clinical or radiological eventration, risk of seroma formation. Findings of our study are contrary to findings of previous meta-analysis which was based on data of lower quality (observational studies) and showed better outcomes in seroma rates [5, 6]. In addition, the meta-analysis of Tandon et al. reported less adverse hernia outcomes (composite outcome consisting of all terms of recurrence, pseudo-recurrence, mesh eventration, tissue eventration, clinical eventration or bulging) in FDC group.

With regards to postoperative pain, in our review, we found that there is conflicting evidence on whether one technique is superior to another when it comes to severity of early (up to 30 days) postoperative pain. However, all studies in our review confirmed no difference in postoperative pain at a longer follow-up (6 months and onwards).

It is difficult to draw conclusion on whether one technique is superior to another with regards to postoperative QoL. One study included in our review assessed this as a primary outcome and identified better results in FDC

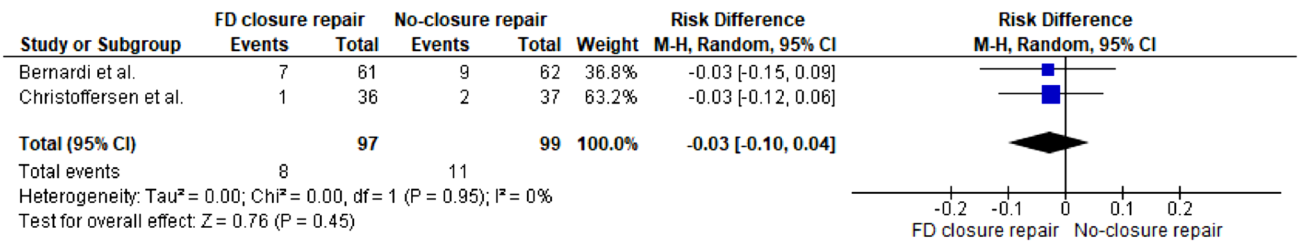

Fig. 5 Risk of clinical or radiological eventration

group [13], while another study which assessed QoL as a secondary outcome using different scale did not find any difference [12].

Our study has some limitations. The main limitation of the study was clinical heterogeneity related to patients' characteristics, hernia characteristics, and operative techniques. In the study of Bernardi et al., there were more patients with ASA equal or above III as well as with higher BMI as compared to two other studies [1, 13]. In the study of Bernardi et al. and Ali et al., there were more patients included with secondary hernia while in the study of Christoffersen most of enrolled patients had primary hernia [1, 12, 13]. There was some heterogeneity in measurement of outcomes with regards to timing and methodology. The time point at which incidence of recurrence was recorded as well as diagnostic criteria differed between the studies. While Christoffersen et al. analyzed recurrence 2 years after surgery [12], in the study of Ali et al., this outcome was recorded at 1-year time point [1]. In the study of Christoffersen, screening for recurrence was performed using clinical investigation and if this was inconclusive, computer tomography (CT) with oral contrast was performed during Valsalva maneuver [12]. In the study of Ali, recurrence was detected using CT [16]. In the study of Bernardi et al., recurrence was evaluated at 1–2 years with clinical assessment and CT imaging was utilized selectively [13]. Similarly, the time point of assessment and diagnostic criteria for seroma and eventration differed between the studies [1, 12, 13]. Differences in outcome measurement could have introduced bias to results of meta-analysis. Due to loss to follow-up in all three studies, there was decreased sample size for such outcomes as recurrence and eventration, 244 and 196 participants, respectively, hence decreased power of the result.

Our study has not resolved uncertainty with regards to whether one technique is superior to another in QoL outcomes. This is because there was heterogeneity in the QoL tools used for reporting outcome. Currently, there is no dominant widely accepted QoL tool to measure outcomes in abdominal wall hernia surgery [19].

Giving this uncertainty and clinical equipoise, another RCT examining FDC vs no-FDC laparoscopic mesh repair separately for primary and secondary hernias using well-defined narrow inclusion criteria for hernia size on a large but well-defined population would be ethical and pragmatic.

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s10029-021-02533-2.

Funding There was no funding.

Availability of data and material Data available on reasonable request.

Declaration

Conflict of interest YT, CSW, ID, VT, AK, and VP have no conflicts of interest or financial ties to disclose. DP received consulting fees from Johnson and Johnson and payment or honoraria for educational events from Johnson and Johnson, Medtronic, Novo Nordisk. These benefits were not related to this manuscript.

Ethical approval Not applicable.

Human and animal rights Not applicable.

Informed consent Not applicable.

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