

Systematic Review

Fascial Defect Closure During Ventral Hernia Repair: A Systematic Review of Randomized Controlled Trials

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Abstract

Background

During minimally invasive ventral hernia repair (VHR) it is unknown if a fascial defect closure, as opposed to a bridged repair (current care), is beneficial for patients. We sought to systematically review the published literature on the role of fascial defect closure during minimally invasive VHR.

Methods

PubMed, Embase, Scopus, Cochrane, and Clinicaltrials.gov were reviewed for randomized controlled trials (RCTs) that compared fascial defect closure with bridged repair. The primary outcome was major complications defined as deep/organ-space surgical site infections (SSIs), reoperations, hernia recurrences, or deaths. Secondary outcomes included SSI, seroma, eventration, hernia recurrence, post-operative pain, and quality of life (QOL). Pooled risk ratios with 95% confidence intervals were obtained through random effect meta-analyses.

Results

Of 579 screened articles, 6 publications of 5 RCTs were included. No significant difference in major complications (10.6% vs 10.4%, RR=1.05, 95% CI=0.51-2.14, $P=.90$) or recurrences (9.0% vs 10.6%, RR=0.92, 95% CI=0.32-2.61, $P=.87$) were found between groups. Fascial defect closure decreased the risk of seromas (22.9% vs 34.2%, RR=0.60, 95% CI=0.37-0.97, $P=.04$) and may decrease the risk of eventrations (6.7% vs 9.0%, RR=0.74, 95% CI=0.37-1.50, $P=.41$) at the expense of potentially increasing the risk of SSI (3.2% vs 1.4%, RR=1.89, 95% CI=0.60-5.93; $P=.28$). Reporting of pain and QOL scores was inconsistent.

Conclusion

While most individual RCTs demonstrated benefit with fascial defect closure during minimally invasive VHR, our meta-analysis of fascial defect closure demonstrated only a statistically significant difference in seromas compared to bridged repair. Large, multi-center RCTs are needed.

Keywords

fascial closure; bridged hernia repair; operative surgical procedures; ventral hernia; surgical wound infection; intraoperative complications; randomized controlled trial; systematic review

Introduction

Minimally invasive ventral hernia repair (VHR), such as laparoscopic or robotic VHR, has been shown to decrease surgical site infection (SSI) with no impact on hernia recurrence.¹⁻⁵ During minimally invasive surgery, mesh is typically placed intraperitoneal (intraperitoneal only

mesh, IPOM). In bridged repair, the defect is not closed and mesh is placed IPOM to span the defect. This has been how minimally invasive VHR has been taught to be performed since the first laparoscopic VHR was performed by Dr LeBlanc in 1991. With fascial defect closure, the hernia defect is closed using a per-

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cutaneous or minimally invasive technique and then the mesh is placed IPOM. Despite this, less than half of all ventral hernias are repaired using a minimally invasive approach. Surgeons might consider performing one approach as opposed to another related to hernia defect size, anticipated complexity of adhesions, surgeon experience, operative duration, and upfront/overall healthcare costs. Another reason may be related to post-operative complications, such as seromas, eventration/bulging, and poor function.^{6,7} For decades, laparoscopic VHR has been taught as a bridged repair where the defect was repaired by an intraperitoneal mesh spanning the defect. Some surgeons have argued that closing the fascial defect prior to mesh placement could restore patient function and decrease post-operative seromas and eventration.⁸ In theory, closing the defect could eliminate the “dead space” and provide a more robust closure which would reduce the risk of seromas and mesh eventration through the defect. Until recently, data has been limited to case series and multi-center database studies revealing conflicting results.⁹ Our aim was to systematically review the published literature on the role of fascial defect closure as opposed to bridged repair during minimally invasive VHR.

Methods

Protocol and Registration

A systematic review was conducted following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement.¹⁰ The protocol can be found on the PROSPERO International Perspective Register of Systematic Reviews, under registration number 190320 on June 4, 2020.

Search Methods

We performed a systematic review literature search using PubMed, Embase, Scopus, Cochrane Central Register of Controlled Trials, and Clinicaltrials.gov, focusing on all publications through August 10, 2022. The search algorithm employed was: "closure" AND "hernia" AND ("randomized controlled trial" OR "RCT") and adapted to the different databases. There were no limits or filters, such as study language or study design, used for the search. We eliminated duplicate copies, and 3 authors (TA, OAO, and NHD) screened titles, abstracts, and entire articles independently to identify

any eligible studies. Any discrepancies were discussed and resolved with the senior author (MKL). The selected abstracts or articles were double-checked for extra citations missed by the search parameter.

Study Selection and Data Extraction

Randomized controlled trials (RCTs) evaluating patients undergoing minimally invasive VHR with fascial defect closure as opposed to bridged repair were included. The exclusion criteria were the inability to access the complete article and articles with study designs other than RCTs. From each article, we extracted the following variables: author, year of publication, number of patients randomized, follow-up duration and percentage, baseline demographic characteristics, hernia characteristics, surgeon experience, operative technique, clinical outcomes, and patient-centered outcomes. The primary outcome was major complications at 1-2 years post-operative. Major complication was defined as a composite of deep/organ-space surgical site infection (SSI), reoperation, recurrence, or death. We chose this outcome because it accounts for all serious complications following VHR, balances the risks and benefits of common hernia interventions, and has been previously used and validated in hernia research.¹¹ Secondary outcomes included: SSI, seroma, eventration/bulging, hernia recurrence, operating room times, pain scores, and quality of life (QOL). Definitions for these terms were extracted from each paper and presented. Prior to pooling data, we assessed the outcome measure, intervention, and clinical heterogeneity.

Three authors (TA, OAO, and NHD) independently extracted data from the included studies. Any inconsistencies related to the extraction of data were resolved with the senior author (MKL).

Methodological Appraisal

In order to assess for risk of bias in RCTs, we utilized the Cochrane Collaboration's tool to appraise the quality of evidence of the included studies. The tool assesses various domains, such as (1) generating random sequencing, (2) concealing allocation sequence, (3) participant and staff blinding, (4) outcome assessment blinding, (5) outcome data completeness, and (6) selective reporting. Each domain was classi-

fied by three investigators (TA, OAO, and NHD) as either low, unclear, or high risk of bias.

Data Synthesis and Statistical Analysis

When more than one RCT with a low risk of bias were available from the studies included in quantitative synthesis, meta-analyses were performed independently for the primary outcome and each secondary outcome. To determine the appropriateness of data combination across the studies, clinical heterogeneity in patients, interventions, and outcome measures were evaluated.^{12,13} We assessed the statistical heterogeneity of the studies included using I². During analysis, when the I² value was greater than 50%, it was considered to have significant heterogeneity. The random-effect model was reported in the case of large clinical or statistical heterogeneity results; otherwise, we used the Mantel-Haenszel approach to perform fixed-effect models.^{14,15} To allow computation, studies with no observed case in 1 arm, we added a constant continuity adjustment of 0.5 to all the cells of a 2x2 table.¹⁶ We conducted subgroup analysis excluding the 1 study that performed hybrid repair (Ahonen-Siirtola et al¹⁸) and 1 study that performed a peritoneal flap (Ali

et al¹⁹) to test whether the pooled effect sizes found differed significantly from each other. We expressed the pooled effect size of all outcomes as risk ratios with 95% confidence intervals. Funnel plots were performed to assess for potential publication bias. We performed all analyses using the software, Review Manager (RevMan, Version 5.4), the Cochrane Collaboration (2020), and StataCorp (Stata Statistical Software: Release 17, College Station, TX: StataCorp LLC).

Results Systematic Review and Study Characteristics

A total of 1211 studies were reviewed, of which 1210 were identified from our database search, and 1 additional study was identified through reference review. After deduplication, 580 titles were screened and 560 were found to be titles unrelated to the topic of interest. Subsequently, 20 abstracts were reviewed, of which 14 were excluded for reasons including non-randomized controlled studies, conference abstracts, publication of protocols, and 1 commentary article. Six full-text articles from 5 RCTs were included in the final analysis (**Figure 1**). The assessment of

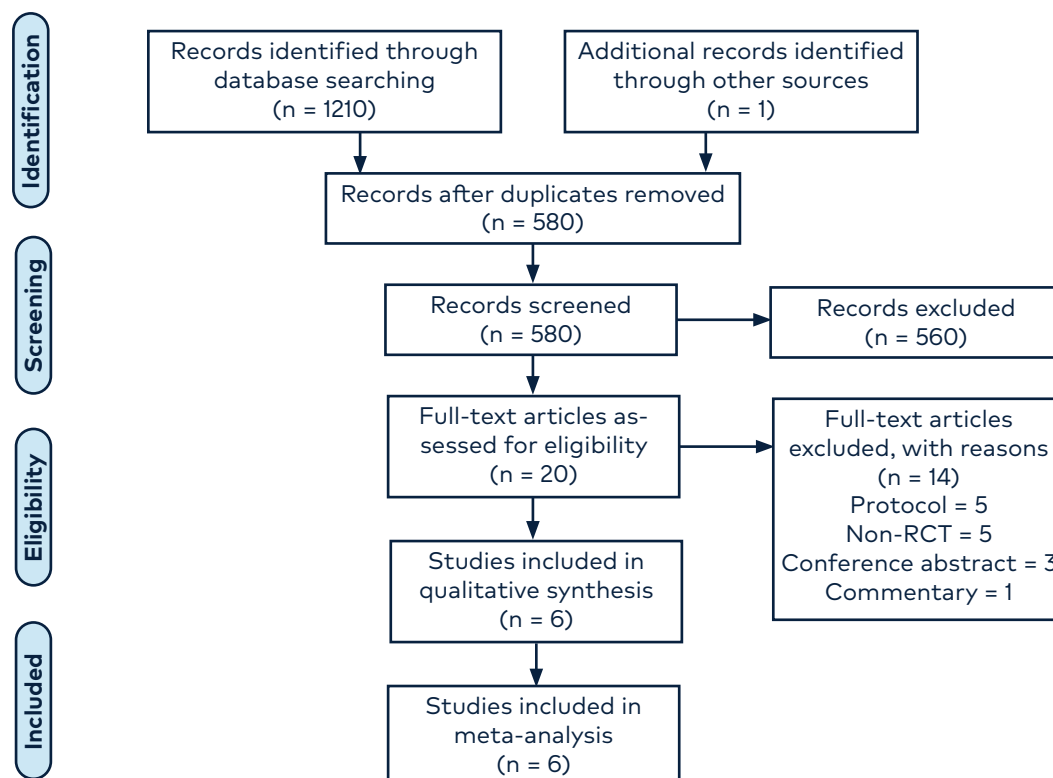


Figure 1. A PRISMA flow diagram shows the selection of the included studies.

the risk of bias in the included studies is shown in **Figure 2**.

Of the publications included, there were 5 original RCTs of which 4 had a follow-up of 1-2 years, all of which were included in the quantitative synthesis of the primary outcome.¹⁸⁻²² One additional publication reported short-term outcomes only of an included RCT.²³ In total, 543 patients were randomized, and 402 (74.0%) patients completed follow up at 1-2 years and were included in the analysis of the primary outcome. Patients were similar in mean age and gender distribution. Most patients were overweight or obese. Almost half of the patients (244, 44.2%) had a ventral incisional hernia while the remainder had either a primary ventral hernia or an undesignated paraumbilical hernia. Most hernias were small or medium in size as classified by the European Hernia Society Ventral Hernia classification (**Table 1**).²⁴

There were differences in hernia size inclusion criteria, but all studies largely excluded defects of less than 2 cm in width and evaluated seromas, eventration, and hernia recurrence by clinical examination. All of the studies assessed pain using a visual analog scale (VAS), while QOL was assessed in 3 studies using 3 different tools (SF-36, modified activities assessment scale, and Carolinas comfort score) (**Table 2**).²⁵⁻²⁷ In 4 studies, the cases were performed by experienced surgeons, while 1 did not report the participating surgeons' experience. Fascial defects were closed with different methods using a variety of sutures. In 4 studies, the defects were closed exclusively using minimally invasive techniques. However, in 1 study, a hybrid approach was performed. Similarly, different meshes were used, but all studies reported at least 5 cm of overlap. Mesh was fixated with different materials, but all 4 studies utilized a double crown technique (**Table 3**).

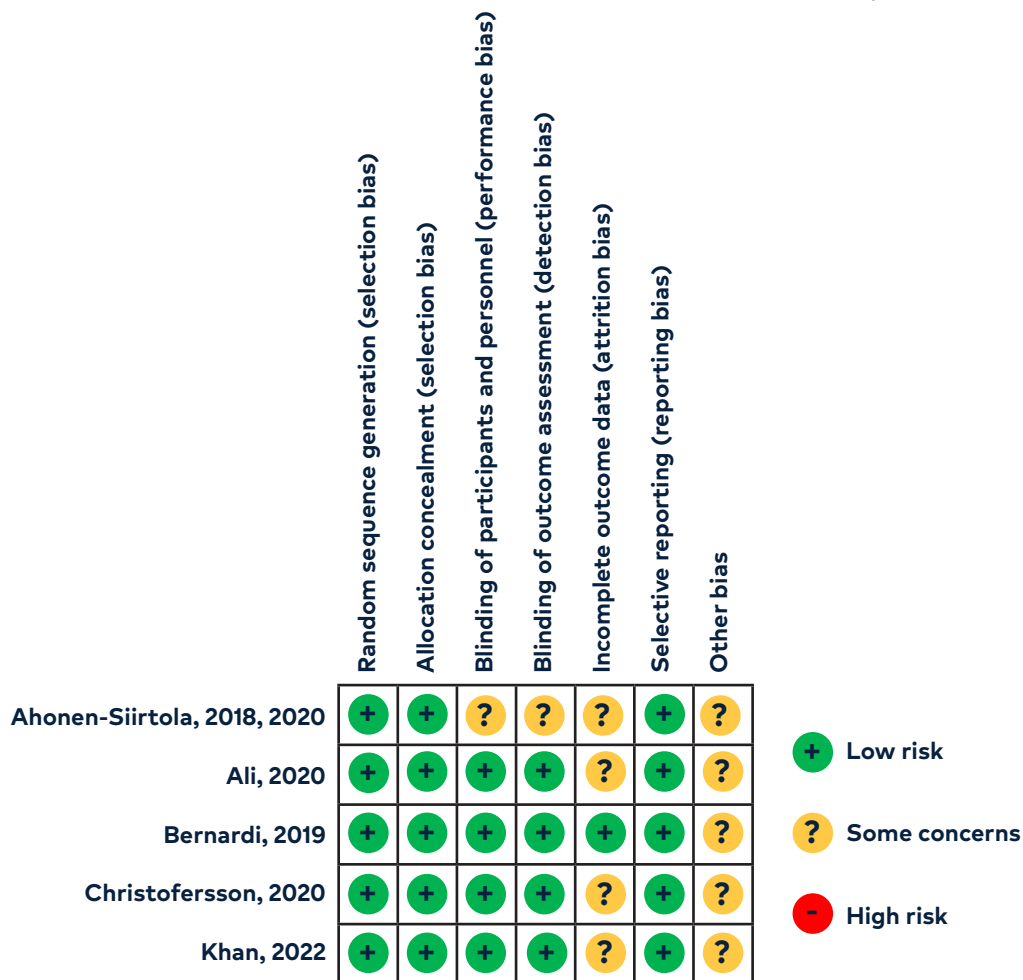


Figure 2. A chart shows an assessment of the risk of bias of the studies included in the systematic review of primary fascial closure during laparoscopic VHR.

Outcomes are reported in **Table 4**. Major complications were 10.6% versus 10.4% when pooled among the 4 studies with 1-2 year follow up. In 4 of 5 studies, fascial defect closure required more operative time than standard bridged repair (overall 76 vs 68 minutes). Seromas were more common with bridge repair (23% vs 34%). While 4 studies found fascial defect closure had a lower incidence of seromas, 1 study had the opposite finding (more seromas with fascial defect closure). Overall, there were fewer eventrations (7% vs 9%) but more SSIs (3% vs 1%) with fascial defect closure. Most of the SSIs were in 1 study that performed a hybrid repair where they suffered a mesh infection, a missed enterotomy resulting in death, and 2 additional major SSIs. There was no significant difference in recurrence rates at 1-2 years post-operative (9% vs 11%).

Only 1 study obtained baseline VAS scores (**Table 5**). The 4 studies that reported post-operative VAS scores but did not obtain baseline data, reported that patients undergoing minimally invasive VHR with fascial defect closure had more early post-operative pain but found similar pain scores between groups at 1-year post-operative. Only 1 study provided baseline and follow-up pain data and performed the optimal statistical analysis of these data (ANCOVA, Friedman's ANOVA, or regression adjusting for baseline scores). This study reported no difference in 1-month or 2-year pain scores; however, it also reported that all patients had VAS scores of 0 preoperatively.²¹ Zero VAS scores were unexpected as most patients seeking VHR have symptoms, such as pain.

Only 2 studies obtained baseline QOL scores (**Table 5**). Two of the 3 studies demonstrated no differences in QOL scores between groups after minimally invasive VHR while one did demonstrate greater improvement in QOL with fascial defect closure. None of the studies provided baseline and follow-up pain data or performed statistical analysis of this data that account for the complex relationship of baseline or follow-up scores (ANCOVA, Friedman's ANOVA, or regression adjusting for baseline patient-centered outcome).

Three studies had additional concerning findings. One study where a hybrid repair was performed had more severe complications,

including 7 organ injuries (6 enterotomies and 1 bladder injury), 1 missed enterotomy resulting in death, 1 mesh infection requiring explanation, 5 reoperations, and 14 conversions to open.^{18,23} This was the only study that did not report their surgeons as experts in minimally invasive VHR. In comparison, the other 4 studies combined reported no organ injuries, no missed enterotomies, 1 mesh infection, no missed bowel injuries, 3 reoperations, and no conversions to open. Another study used an ultralightweight polypropylene mesh that has now been withdrawn from the market due to poor clinical outcomes.^{28,29} This study reported high recurrence rates of 14% fascial versus 32% bridge repair with largely a repair of primary ventral hernias (eg, umbilical hernias or small hernias with no prior surgery). In comparison, the other studies, in which incisional hernias were largely or exclusively repaired, reported a cumulative recurrence rate of 7% fascial versus 5% bridge repair. Finally, 1 study reported completely inverse results from 4 other studies showing that fascial defect closure requires less operative time than bridged repair (61 vs 63 minutes) as well as outcomes contrary to all 3 other studies (more seromas with fascial defect closure, 16% vs 0%).¹⁹ In comparison, the other studies cumulatively reported operative times of 77 versus 69 minutes and seromas 26% fascial versus 41% bridge repair. Typically, a minimally invasive VHR with fascial defect closure is the same surgery as bridged repair, except there is 1 additional step, closing the fascial defect. In this study, the peritoneal bridge repair was actually an incision of the peritoneum and a suturing of it laparoscopically as a sac reduction.¹⁹

Meta-Analysis

Based upon the previously described concerns with 3 of the 5 studies, meta-analysis for clinical utility is not advised. Therefore, meta-analysis was performed to provide estimates to design higher-quality, large, multi-center RCTs.

Meta-analysis of the primary outcome revealed no significant difference in major complications for fascial defect and bridge repair, respectively (10.6% vs 10.4%, RR = 1.05, 95% CI = 0.51 to 2.14, $P = .900$). On secondary outcomes, there was a decrease in the risk of seromas (22.9% vs 34.2%, RR = 0.60, 95% CI = 0.37 to 0.97, $P = .04$), but a funnel plot demonstrated 1 major outlier,

Table 1. Study and Patients' Baseline Characteristics

Author, Year	Country	Intervention (Primary fascial closure)									Control (Bridged)								
		n	Age ^a	Sex, Female	BMI ^b	ASA 1-2	Smoking	Prior surgery	Size, Area ^c	Size, Width ^c	n	Age ^a	Sex, Female	BMI ^b	ASA 1-2	Smoking	Prior Surgery	Size, Area ^c	Size, Width ^c
Ahonen-Siirtola, 2018, 2020 ^{18,23}	Finland	90	60	54 (61%)	29	56 (62%)	11 (12%)	90 (100%)	11	-	94	57	54 (59%)	30	58 (62%)	17 (18%)	94 (100%)	13	-
Bernardi, 2019 ²¹	USA	64	50	41 (64%)	30	41 (64%)	3 (5%)	51 (80%)	16	4	65	49	41 (63%)	31	45 (69%)	6 (9%)	45 (69%)	20	5
Christofersson, 2020 ²⁰	Denmark	40	54	18 (45%)	24	38 (95%)	9 (23%)	5 (12%)	-	3	40	55	11 (28%)	27	37 (93%)	2 (5%)	6 (15%)	-	3
Ali, 2020 ¹⁹	Sweden	25	58	12 (48%)	29	22 (88%)	-	16 (64%)	-	5	25	56	9 (36%)	30	22 (88%)	-	18 (72%)	-	5
Khan, 2022 ^{22*}	Pakistan	50	44	28 (56%)	33	50 (100%)	-	-	-	-	50	44	37 (74%)	33	50 (100%)	-	-	-	-

Abbreviations: BMI = Body mass index, ASA = American Society of Anesthesiologists classification

^aAge was measured in years.

^bBMI was measured in kg/m².

^cArea and width were measured in centimeters.

*Data provided privately by author and average age and BMI not split by 2 groups.

Table 2. Methodological Details of Included Studies

Author, Year	Inclusion hernia width	FU duration	FU %	Seroma	SSI	Eventration	Recurrence	QOL	Pain	Other
Ahonen-Siirtola, 2018, 2020 ^{18,23}	2-7 cm	30 days 1 year	93% 89%	Clinical exam and ultrasound at 30 days	Not defined	Patient self-report Clinical exam at 1 year	Clinical exam and CT scan at 1 year	SF-36 at: Baseline, 1 month and 1 year	VAS at: 1-3 days, 1 month and 1 year No baseline	Cosmesis
Bernardi, 2019 ²¹	3-12 cm	30 days 2 years	95% 95%	Clinical exam at 30 days	CDC	Clinical exam at 2 years	Clinical exam or on demand CT at 2 years	mAAS at: Baseline, 1 month and 2 years	VAS at: Baseline, 1 month, and 2 years	Chronic pain Cosmesis
Christofersson, 2020 ²⁰	2-6 cm	30 days 2 years	98% 91%	Clinical exam at 30 days	Not defined	CT scan at 2 years	Clinical exam or reoperation at 2 years	CCS at: 30 days and 2 years No baseline	VAS at: Baseline, 1-3 days, and 30 days	Cosmesis (VRS, NRS)
Ali, 2020 ¹⁹	3-10 cm	90 days 1 year	96% 96%	1-, 3-, 6-months: Not defined 12-months: CT scan	Not defined	Not recorded	Not defined	Not recorded	VAS at: 1 week, 1 month, 6 months, and 1 year No baseline	-
Khan, 2022 ²²	Not defined	2 weeks -	100% -	Clinical exam and ultrasound	Not defined	Not recorded	Not defined	Not recorded	No baseline VAS at 2 weeks	-

Abbreviations: FU = Follow up, SSI = surgical site infection, QOL = Quality of life, CT = computed tomography, VAS = visual analog scale, SF-36 = 36 item short form survey, CDC = Centers for Disease Control and Prevention, mAAS = modified activities assessment scale survey, CCS = Carolinas comfort scale, VRS = verbal rating scale, NRS = numerical rating scale

Table 3. Operative Details of Included Studies

Author, Year	Surgeon experience	Closure technique	Closure suture	Mesh type	Overlap	Mesh fixation material	Mesh fixation technique
Ahonen-Siirtola, 2018, 2020 ^{18,23}	Not reported	Hybrid Running	0-slowly absorbable suture	Coated polyester mesh	5 cm overlap Overlap 3x width	Absorbable/Non-absorbable sutures Absorbable U-tacks	4 cardinal sutures Double crown
Bernardi, 2019 ²¹	Experienced surgeons (>50 LVHR/year)	Transcutaneous	0-slowly absorbable suture	Coated polyester mesh	5 cm overlap	Slowly absorbable sutures Permanent spiral tacks	4 cardinal sutures Double crown
Christofersson, 2020 ²⁰	Experienced surgeons (>30 LVHR with fascial closure)	Laparoscopic knot-pusher	2-0 nonabsorbable suture	Coated light-weight polypropylene mesh	5 cm overlap	Permanent spiral tacks	Double crown
Ali, 2020 ¹⁹	Experienced single surgeon	Not described	2-0 slowly absorbable suture	Not described	5 cm overlap	Absorbable arrow tacks	Double crown
Khan, 2022 ²²	Senior professor of surgery	Not described	#1 polypropylene	Polypropylene mesh	5 cm overlap	2-0 polypropylene	2-0 polypropylene

Abbreviation: LVHR = laparoscopic ventral hernia repair

Table 4. Clinical Outcomes of Included Studies

Author, Year	Intervention (Primary fascial closure)								Control (Bridged)							
	Major complications	Seroma	SSI	Eventration	Recurrence	Organ injury	Converted	OR time	Major complications	Seroma	SSI	Eventration	Recurrence	Organ injury	Converted	OR time
Ahonen-Siirtola, 2018, 2020 ^{18,23}	2 major SSI 4 reoperation 5 recurrences 1 early death	27 (31%)	4 (4%)	4 (5%)	5 (6%)	2 (2%)	3 (3%)	84	1 major SSI 1 reoperation 6 recurrences	46 (49%)	3 (3%)	6 (7%)	8 (9%)	5 (5%)	11 (11%)	81
Bernardi, 2019 ²¹	1 reoperation 6 recurrences	7 (11%)	1 (2%)	7 (11%)	6 (10%)	0 (0%)	0 (0%)	88	1 reoperation 2 recurrences 1 late death	12 (19%)	0 (0%)	9 (15%)	2 (3%)	0 (0%)	0 (0%)	75
Christofersson, 2020 ²⁰	1 entero-mesh fistula 1 reoperation 5 recurrences	14 (35%)	1 (3%)	1 (3%)	5 (14%)	0 (0%)	0 (0%)	47	1 reoperation 12 recurrences	22 (58%)	0 (0%)	2 (5%)	12 (32%)	0 (0%)	0 (0%)	32
Ali, 2020 ¹⁹	1 early death	4 (16%)	1 (4%)	-	0 (0%)	0 (0%)	0 (0%)	61	-	0 (0%)	0 (0%)	-	0 (0%)	0 (0%)	0 (0%)	63
Khan, 2022 ^{22*}	0 at 2 weeks	1 (2%)	-	-	-	-	-	57	-	-	-	-	-	-	-	57

Abbreviations: OR = operating room (minutes), SSI = surgical site infection

*Data provided privately by author and mean OR time not split by 2 groups.

Table 5. Patient Centered Outcomes

Author, Year	QOL								Pain (VAS)								
	Survey	Baseline		1 month		1-2 years		Conclusions	Baseline		First week		1 month		1-2 years		Conclusions
		I	C	I	C	I	C		I	C	I	C	I	C			
Ahonen-Siirtola, 2018, 2020 ^{18,23}	SF-36	66	63	58	57	68	68	No differences at 1 month or 1 year	-	-	Day 1: 5.2	Day 1: 4.3	2.2	2.2	1.4	1.5	More pain in first week No difference at 1 month or 1 years
Bernardi, 2019 ²¹	mAAS	36	43	-	-	78	72	Improved change in QOL with PFC at 2 years	6.4	5.5	-	-	-	-	3.4	2.5	No difference at 2 years
Christofersson, 2020 ²⁰	CCS	-	-	4	6	0	0	No difference at 2 years	-	-	Day 1: 7.3	Day 1: 6.9	2	2	-	-	No difference at first week, 1 month, or 2 years
Ali, 2020 ¹⁹	-	-	-	-	-	-	-	-	-	-	Day 7: 6	Day 7: 3	1	0	0	0	More pain in first week and 3 months No difference at 1 year
Khan, 2022 ²²	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	Pain in some patients at 2 weeks, settled by symptomatic treatment

Abbreviations: QOL = quality of life, VAS = visual analog scale, I = intervention (primary fascial closure), C = control (bridged repair), SF-36 = 36 item short form survey, mAAS = modified activities assessment scale survey, PFC = primary fascial closure, CCS = Carolinas comfort scale

the study that reported more seromas with fascial defect closure. In addition, there was an increased risk of SSI (3.2% vs 1.4%, RR = 1.89, 95% CI = 0.60 to 5.93; $P = .280$) and decreased risk of eventration with fascial defect closure (6.7% vs 9.0%, RR = 0.74, 95% CI = 0.37 to 1.50, $P = .410$), while there was no evidence of a difference with hernia recurrence (9.0% vs 10.6%, RR = 0.92, 95% CI = 0.32 to 2.61, $P = .870$). On average, there was an increase in operating room times of 5 minutes with fascial defect closure (Mean difference = 4.86 min, 95% CI = -1.75 to 11.46; $P = .150$). Subgroup analysis between the use of primary fascial closure versus a bridged repair excluding hybrid repair and peritoneal bridged repair was performed as well. We found no difference in the results with the exclusion of these 2 studies. Forest plots and funnel plots for results of meta-analyses are provided in the supplement section (**Supplemental Figures 1-11**).

A meta-analysis of QOL could not be performed as all 3 studies reporting QOL used different tools and only 2 reported baseline information. Similarly, a meta-analysis of pain scores could not be performed as only 1 study reported baseline scores.

Discussion

In this comprehensive systematic review and meta-analysis of RCTs comparing fascial defect closure with bridged minimally invasive VHR, no clear evidence of a difference in major complications was found between groups. Fascial defect closure may be associated with a decrease in the risk of seromas. Although statistical significance was not achieved, there were percentage differences of decreased eventrations at a cost of increased risk of SSI with fascial defect closure. No difference was found in hernia recurrence rates between groups, yet, considering that recurrences may appear many years after the index VHR and that the RCTs included in this meta-analysis only assessed outcomes 2 years or less, long-term follow-up of existing or future trials on fascial defect closure should be assessed.

Similar to previous observational studies on the effect of fascial defect closure, the results of the included RCTs were found to be mixed. Two large database studies showed no benefit with

fascial defect closure when compared with bridged repair; however, multiple other case series showed not only improved patient-centered outcomes but improved clinical outcomes by decreasing seromas, recurrence, eventration, and bulging.^{9,30} In our study, 3 out of 5 RCTs included demonstrated benefit with fascial defect closure but all in different outcome measures. Because of this, the meta-analysis showed no clear evidence of benefits on clinical outcomes except for seroma formation.

Symptoms associated with ventral hernias, such as pain, decreased function, and QOL, are among the main determinants for patients seeking repair, therein the importance of assessing the impact of interventions like fascial defect closure on patient-centered outcomes. Unfortunately, there is significant inconsistency in the reporting and statistical analysis utilized to analyze these types of outcome measures in literature, and the RCTs found through our search were not an exception.³¹ These outcomes should be ideally measured at baseline, prior to randomization of patients to an intervention or a control group, and are subsequently measured at follow-up(s). Statistical analysis of these outcomes with paired baseline and follow-up measurements can be conducted in various ways. A comparison of follow-up scores would lead to “at the end of the trial” differences between groups; however, this approach ignores potential differences in baseline scores, which could account for the differences found at the end of the observation period. Alternatively, comparison of the change in scores, estimated by subtracting the follow-up score from the baseline score, leads to differences in reduction or increase in the outcome of interest between groups. Yet, this approach ignores the principle of regression to the mean and incorrectly assumes that the magnitude of change in scores is equivalent across the scale.³² A preferred approach is to perform an analysis of covariance (ANCOVA) or its equivalent, a linear regression.³³ Through this method, the effects on the outcome follow-up scores are modeled for baseline score and randomization group as predictors. As opposed to a follow-up score analysis, which underestimates the treatment effect in the event that baseline scores are worse in the intervention group, and a change score analysis, which overestimates the treatment effect, the strength of ANCOVA is

that it provides an answer accounting for both baseline scores and change in scores. ANCOVA provides more precision to detect a true difference in treatment effect when compared to other methods.^{34,35} In addition to QOL being assessed through different scales, the way that pain scores and QOL information are reported prohibits performing an aggregate data meta-analysis of included RCTs. An individual participant data meta-analysis might allow the pooling of patient-centered outcomes to determine if fascial defect closure improves long term functional status.³⁶

Some limitations of this meta-analysis need to be acknowledged. First, due to the heterogeneity and quality of reported evidence regarding patient centered outcomes in existing RCTs, we were unable to perform meta-analysis of these outcomes. Moreover, substantial limitations and heterogeneity among the studies make it inadvisable to use results of the meta-analysis for informing clinical patient care. Rather, the results should be used for estimates of future trials. Authors investigating this intervention should come to consensus on standardized reporting of surgical techniques, surgeon experience, and clinical and patient centered outcome measures. Finally, the total number of studies and patients on this topic is limited. Future large multicenter studies are needed to validate these findings; until then, the current evidence is inadequate to make a strong recommendation.

Conclusion

In conclusion, while most individual RCTs demonstrate benefit with fascial defect closure during minimally invasive VHR, our meta-analysis of fascial defect closure demonstrated only statistically significant benefit in decreased seromas and no other outcomes. While fascial defect closure has sound physiologic rationale, the current evidence is inadequate to make a strong recommendation. More high-quality, well-designed, multi-center trials with standardization of technique and improved reporting and analysis of clinical and patient-centered outcomes are needed.

Conflicts of Interest

The authors declare they have no conflicts of interest.

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Dr Ali and Ms Anwoju are employees of HCA Healthcare Graduate Medical Education, an organization affiliated with the journal's publisher.

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