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REVIEW

Association between surgical hernia repair techniques and the incidence of seroma: a systematic review and meta-analysis of randomized controlled trials

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Abstract

Purpose Ventral hernia repair (VHR) includes the surgical reconstruction of the abdominal wall (AW) using different surgical techniques. Although such procedures are usually devoid of complications, the formation of seroma may frequently occur. We performed a systematic review to assess the evidence from randomized controlled trials (RCTs) comparing VHR techniques and their impact on seroma formation.
Methods We included RCTs having seroma formation as primary endpoint. We included patients of both sexes (age > 18). For data synthesis we applied a random-effects model and calculated risk ratios (RR) with 95% confidence intervals (CI) using the Mantel–Haenszel method. Risk of bias (ROB) and publication bias were evaluated following Cochrane recommendations.
Results After database search and article screening, 21 records were included in this review. Ten RCTs compared onlay vs. sublay mesh placement techniques. Pooled analysis showed a significantly higher risk ratio for seroma in the onlay cohort (RR = 2.61, 95% CI 1.86–3.66, $I^2 = 0$, GRADE quality of evidence, moderate). Five RCTs compared laparoscopic intraperitoneal onlay mesh repair vs. open mesh placement. Pooled analysis showed that seroma formation did not differ significantly between groups (RR = 1.91, 95% CI 0.69–5.28, $I^2 = 66\%$, GRADE quality of evidence, poor). High ROB was found in all studies and significant publication bias was detected in both meta-analyses.
Conclusion Compared to sublay ventral hernia repair, the onlay procedure is associated with a significantly higher risk of seroma. No significant differences were observed when laparoscopic VHR was compared with the open surgical procedure. Due to the diversity of surgical techniques reported in included RCTs, it is currently not possible to draw conclusive clinical recommendations. Future studies should be standardized to provide detailed data allowing thorough evaluation of the impact of the evidence on clinical practice.

Keywords Abdominal hernia · Surgery · Reconstruction · Seroma

Introduction

The incidence of ventral hernias is steadily increasing in the Western world. Because of the increasing lifespan expectancy, the numerical growth of the population and the frequency of abdominal operations, the overall costs of ventral hernia repairs are expected to be rising [1].

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Ventral hernia repair (VHR) includes the surgical reconstruction of the abdominal wall (AW) using a variety of open or laparoscopic/robotic techniques. Although such procedures are usually devoid of major complications, the formation of seroma may frequently occur. Seroma can develop up to 10–20 days after surgery and is diagnosed by clinical inspection or by imaging techniques like ultrasound or computed tomography [2]. There are several mechanisms associated with the occurrence of seroma. Disruption of blood and lymphatic vessels following surgical incision can cause an inflammatory response whereby macrophages and mast cells become activated. Vasoactive substances (histamine, bradykinin, prostaglandin, leukotriene, nitric oxide), also secreted by these cells, mediate a local vasoconstriction, which is followed by vasodilation and by increased permeability of the vascular wall, ultimately resulting in the accumulation of serous fluid in dissected soft tissue spaces [3]. Other factors may also lead to the formation of seroma. Studies have shown that thicker surgical flaps, rich in adipose tissue, have a hypertrophic lymphatic system, prone to seroma formation [4]. In addition, previous abdominal scars may act as mechanical barriers to lymphatic drainage causing retention of extracellular fluids, thus leading to seroma. Dead space formation and shearing forces between tissue planes are also potential mechanisms for seroma formation [5]. Finally, seroma formation can be correlated with risk factors such as bleeding, smoking, obesity, recent weight loss and the mass of excised abdominal skin [4].

Although seroma formation is usually self-limiting, it can be associated with various complications such as wound dehiscence, flap necrosis and infection. The treatment of seroma requires multiple visits for aspiration, which results in a higher risk of infection, prolonged recovery, increased costs, and often requires repeated surgical treatments [6]. Among the various strategies adopted for AW repair, surgical techniques characterized by reduced occurrence of seroma may reduce the occurrence of complications, reduce hospitalization time and public health expenditures, and avoid discomfort and anxiety for patients [5].

We performed a systematic review in order to assess the available evidence from randomized controlled trials comparing in patients of both sexes a number of ventral hernia repair techniques and their impact on seroma formation following abdominal wall reconstruction. When feasible (adequate number of trials, sufficient homogeneity of techniques, endpoints and data reporting approaches), we performed a meta-analysis of the available data published so far.

Methods

The protocol for the present systematic review was registered on the PROSPERO international register (registration ID: 234670, accessible at: [7]). The review adhered to PRISMA guidelines, within the word and space limits allowed by the journal [8].

Review design and inclusion/exclusion criteria

We analyzed the results of randomized controlled trials (RCTs), comparing surgical techniques for ventral hernia repair, having seroma formation as a primary end point. We excluded non-randomized comparative studies, retrospective studies, case–control studies, case series and RCTs describing seroma as a secondary end point or as incidental finding.

We included patients of both sexes (age > 18), subjected to any surgical procedure involving abdominal wall reconstruction in the frame of ventral hernia repair procedures.

Subjects affected by inguinal hernia were excluded, as in such patients seroma has a lesser impact and is in almost all cases self-limiting.

We focused on interventions aimed at restoring the facial/myofascial layer of the abdominal wall and abdominoplasty procedures were excluded.

Outcomes

The primary outcome for this systematic review was the incidence of postoperative seroma, assessed clinically or instrumentally (ultrasound, radiology, etc.). Secondary outcomes were the total seroma volume and/or the average volume of drained seroma fluid per time unit.

Search and selection of records, data extraction

The following electronic databases were searched for records published in the English language, up to March 31st, 2021: PubMed, Embase, Cochrane Central Register of Controlled Trials (CENTRAL), Web of Science, international trial registers (http://clinicaltrials.gov, http://clinicaltrialsregister.eu). Handsearching was performed on reference lists of included studies, review articles, systematic reviews and meta-analyses.

Search strategies are presented in the online appendix (supplementary information).

Two independent researchers (LBP, FS) performed a first assessment of each record based on title and abstract screening. A second round of selection was performed by full-text reading of the screened records.

The study data relevant for this review were extracted using a standardized form. Disagreements were managed by discussion among all authors.

Assessment of bias and quality of included studies

The risk of bias (ROB) of included trials was analyzed at the study level by two independent researchers (LBP, FS) using the Cochrane Collaboration risk of bias tool [9].

To identify publication bias and in particular the impact of missing studies, we generated funnel plots and performed the Egger's regression test using the Meta-Essentials Software (Erasmus University, Rotterdam) [10].

The quality of the evidence was evaluated according to GRADE criteria and reported, together with the final findings of the meta-analysis, in a summary of findings (SOF) table [11].

Data synthesis, assessment of heterogeneity and sensitivity/subgroup analysis

For data synthesis, we applied a random-effects model to all meta-analyses. For dichotomous variables we pooled study data by calculating risk ratios (RRs) with 95% confidence intervals (CIs) using the Mantel–Haenszel method. An alpha error of 5% was defined as the threshold for statistical significance for all tests and measurements.

Forest plots were created using the Cochrane Review Manager (RevMan) 5.3 software.

Heterogeneity was assessed by visual inspection of forest plots, quantified by calculating the I^2, and rated according to the Cochrane Handbook [12]. In case of moderate to substantial heterogeneity, we planned to perform sensitivity analysis by excluding one by one (1) studies which were more likely to generate heterogeneity (e.g., effect size outliers), (2) studies in which more than one Cochrane ROB tool items were at high risk of bias, (3) or studies that might include major confounders (e.g., important differences in surgical techniques in a single arm).

Since elevated CRP and specific serum abnormalities (e.g., electrolyte imbalances, hyperglycemia) are known to be predictors of seroma formation, subgroup analysis in the presence of substantial heterogeneity was planned to be performed if a sufficient number of studies would provide such data.

Missing data

For the management of missing data, when data appeared to be missing "at random", we analyzed only the available information, and we limited our analysis to patients for whom outcome data were provided ("available case analysis"). We avoided bias-prone imputation strategies and preferred per-protocol analyses.

Results

Database search

Database search and handsearching yielded 5040 potentially relevant records. After title and abstract screening, 4979 records were excluded, and 61 articles were subjected to full-text reading. At the end of this process, 40 articles were excluded and 21 records, reporting the results of RCTs having seroma formation as primary outcome, were finally included in this systematic review. A detailed PRISMA flowchart of the entire process is shown in Fig. 1.

Risk of bias analysis

The results of individual studies and the detailed reasons by which low, high or unclear risk of bias was rated are found in in the online appendix (supplementary information, Table 1). An ROB graph is shown in Fig. 2.

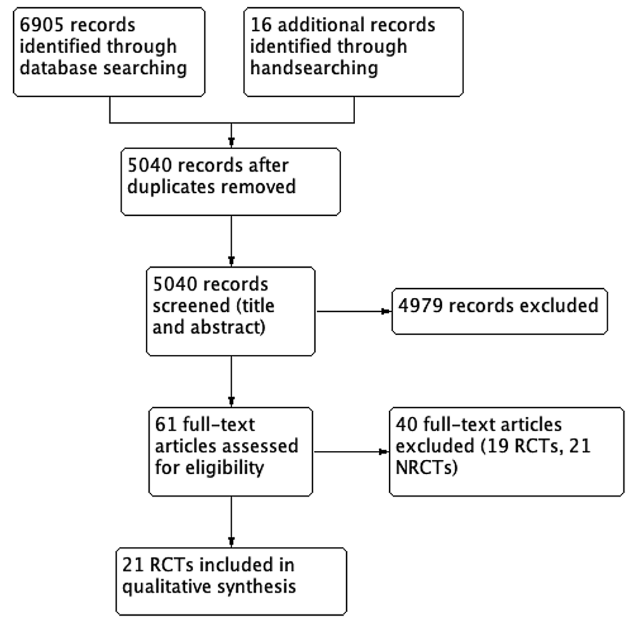

Fig. 1 PRISMA flowchart of the study selection process

Random sequence generation was evaluated to be at low ROB in 12 studies [13–24], high ROB was detected in 2 studies [25, 26] and 6 studies gave insufficient information (unclear risk of bias) [27–32]. Fifteen studies gave insufficient information for rating the risk of bias linked to allocation [14, 15, 18–20, 22, 24–28, 30–33] and 6 studies were rated at low ROB due to adequate allocation concealment [13, 16, 17, 21, 23, 29].

In the frame of a surgery trial, the ROB associated with the lack of blinding is not straightforward. Whereas lack of patient blinding may affect subjective end points such as pain or quality of life, hard end points like seroma formation or surgical site infection are less affected by lack of blinding [34]. Nevertheless, lack of blinding of physicians assessing postop complications may also affect the evaluation of trial endpoints like seroma (e.g., a very small seroma may be or may be not subjectively overlooked) [35]. Thus, lack of blinding was classified as having high risk of (involuntary and intrinsic) performance bias in most studies [13–17, 19–31, 33]. However, in one study patients could be blinded to the allocation, thus reducing the ROB to a certain extent [18].

Blinding of outcome assessors was reported in two studies (low ROB, 21, 25), high risk of bias was assessed in two studies [17, 27] and was unclear in the remaining cases [13–16, 18–20, 22–24, 26, 28–33].

Low attrition ROB was rated for nine studies [13, 16, 17, 21, 23, 24, 29, 32, 33], whereas in one study a high ROB was detected [18]. In the remaining cases, no dropouts were reported, and data were very likely analyzed as being

Table 1 Main characteristics of the 21 RCTs included in this systematic review

Study	Comparisons (number of patients randomized)	Patients with seroma (%)	Statistical significance	Evaluation method of seroma	Treatment of seroma
Abo-Ryia et al. [25]	Sublay ($n=30$) vs. onlay repair ($n=30$)	0% 17%	$P=0.044$, Fisher's exact test	Clinical detection of seroma and use of ultrasound in suspected cases	Repeated aspiration under aseptic measures was sufficient to cure the condition in all cases
Afzal et al. [28]	Sublay ($n=32$) vs. onlay repair ($n=32$)	6% 25%	$P=0.039$, statistical test used not disclosed	Not specified	Seroma developing in both groups required multiple aspirations
Ahmed et al. [26]	Sublay ($n=32$) vs. onlay repair ($n=33$)	9% 39%	$P=0.005$, Chi-square test	Seroma formation was clinically detected during the follow-up	Not disclosed
Ahonen-Siirtola et al. [13]	IPOM repair ($n=94$) vs. IPOM-plus ($n=90$)	3% 3%	$P=0.96$, Chi-square test or Fisher's exact test [not specified in article]	Clinical detection of seroma in 39.7% and detection with ultrasound in 55.4%. Seroma was defined as an anechoic fluid collection	Seromas detected in the IPOM group were significantly larger and 6 patients needed seroma puncture According to the Morales–Conde classification, only 49.2% of the seromas in the IPOM group and 48.7% of the seromas in the IPOM-plus group were graded as complications
Arroyo et al. [14]	Mesh-free ($n=100$) vs. mesh repair ($n=100$)	5% 6%	$P=1$, Fisher's exact test was performed by us (statistical analysis was not available)	Not specified	Not disclosed
Bansal et al. [29]	Suture fixation ($n=32$) vs. tacker fixation ($n=35$)	22% (1 week) 6% (1 month) 11% (1 week) 6% (1 month)	1 week: $P=0.219$, 1 month: $P=0.669$, chi-square test	Not specified	Not disclosed
Barbaros et al. [15]	Laparoscopic ($n=23$) vs. open repair ($n=23$)	17% 0%	$P<0.05$, Chi-square test	Not specified	None of the detected seromas required surgical intervention Seromas reabsorbed spontaneously over a period of 6 weeks during the follow-up
Bessa et al. [16]	Sublay ($n=40$) vs. onlay repair ($n=40$)	0% 5%	$P=0.494$, Chi-square or Fisher's exact test [not specified in article]	Clinical detection of seroma formation	Clinically evident seromas were aspirated repeatedly. If the collection was sizeable enough, a catheter drain was inserted under local anesthesia for an extra week
Carbajo et al. [30]	Laparoscopic ($n=29$) vs. open repair ($n=30$)	14% 67%	$P<0.05$, Fisher's exact test performed by us (statistical analysis was not available)	Not specified	Not disclosed
Clay et al. [21]	Full-thickness graft ($n=24$) vs. mesh repair ($n=28$)	54% 46%	$P=0.58$, chi-square test	Clinical detection of seroma formation	Not disclosed
Demetrashvili et al. [18]	Sublay ($n=77$) vs. onlay repair ($n=78$)	17% 41%	$P=0.0013$, chi-square test or Fisher's exact test [not specified in the article]	Clinical detection of seroma	Not disclosed

Table 1 (continued)

Study	Comparisons (number of patients randomized)	Patients with seroma (%)	Statistical significance	Evaluation method of seroma	Treatment of seroma
Dhaigude et al. [31]	Sublay ($n = 50$) vs. onlay repair ($n = 50$)	2% 8%	$P = 0.169$, statistical test not disclosed	Clinical and radiological detection of seroma	Not disclosed
Ibrahim et al. [22]	Sublay repair ($n = 20$) vs. onlay repair ($n = 20$)	5% 15%	$P = 0.01$, Chi-square test or Fisher's exact test [not specified in the article]	Not specified	Seromas were treated with repeated aspiration under complete aseptic conditions
Kaafarani et al. [33]	Laparoscopic ($n = 59$) vs. open repair ($n = 80$)	7% 25%	$P = 0.011$, Chi-square test or Fisher's exact test, [not specified in article]	Seroma was clinically detected. Ultrasound and computed tomography were not used	71% of the seromas reabsorbed spontaneously, while 29% required aspiration. Three patients required more than 1 aspiration. Aspiration was done when persistent or moderately severe symptoms (abdominal discomfort, skin tension, etc.) of the seroma were present
Malik et al. [19]	Laparoscopic ($n = 166$) vs. open repair ($n = 171$)	3% 10%	$P < 0.001$, Fisher's exact test	Not specified	Not disclosed
Misra et al. [23]	Laparoscopic ($n = 33$) vs. open repair ($n = 33$)	12% 3%	$P = 0.35$, Fisher's exact test performed by us (statistical analysis was not available)	Not specified	One patient in the open repair group and 3 patients in the laparoscopic repair group required one-time aspiration. One patient in the laparoscopic repair group needed an aspiration twice
Sevinc et al. [24]	Sublay ($n = 50$) vs. onlay repair ($n = 50$)	2% 14%	$P = 0.027$, Chi-square test	Seroma formation was clinically detected during the follow-up	Not disclosed
Shehryar et al. [20]	Sublay ($n = 100$) vs. onlay repair ($n = 100$)	2% 6%	$P = 0.31$, Chi-square test	Not specified	Not disclosed
Tsimoyiannis et al. [27]	Cauterization ($n = 25$) vs. no cauterization ($n = 26$) of the hernia sac	4% 27%	$P < 0.025$, Chi-square test	Seromas were clinically detected. Computed tomography was performed on the 1st and 15th postoperative days; if seroma was present, computed tomography was scheduled on the 30th postoperative day	In the group where no cauterization was performed, 2 patients had persistent symptomatic seromas that needed multiple aspirations; 2 clinical seromas and 3 subclinical seromas resolved without intervention. In the group where the sac was cauterized, 1 subclinical seroma was found, resolving in a few days without intervention
Venclauskas et al. [32]	Mesh-free ($n = 54$) vs. sublay ($n = 50$) vs. onlay repair ($n = 57$)	9% 24% 46%	Keel vs. onlay: $P = 0.001$, onlay vs. sublay: $P = 0.02$, keel vs. sublay: $P = 0.043$, Chi-square test	Seroma formation was clinically detected during follow-up	Not disclosed

Table 1 (continued)

Study	Comparisons (number of patients randomized)	Patients with seroma (%)	Statistical significance	Evaluation method of seroma	Treatment of seroma
Westphalen et al. [17]	Drainage ($n=21$) vs. no drainage ($n=21$)	19% (day 5) 48% (day 15) 52% (day 30) 29% (day 5) 57% (day15) 43% (day 30)	Day 5: $P=0.469$, Chi-square test, Day 10: $P=0.843$, Fisher's exact test Day 30: $P=0.852$, Fisher's exact test	Seroma formation was detected by ultrasound at three time points. Seroma was defined as the collection of any volume of subcutaneous fluid without debris	Not disclosed Clinical seroma was defined as a visible bulge or fluctuation without signs of infection: subclinical seroma as the absence of detectable abnormalities on physical examination, but as the presence of any volume of fluid collection on abdominal wall ultrasound

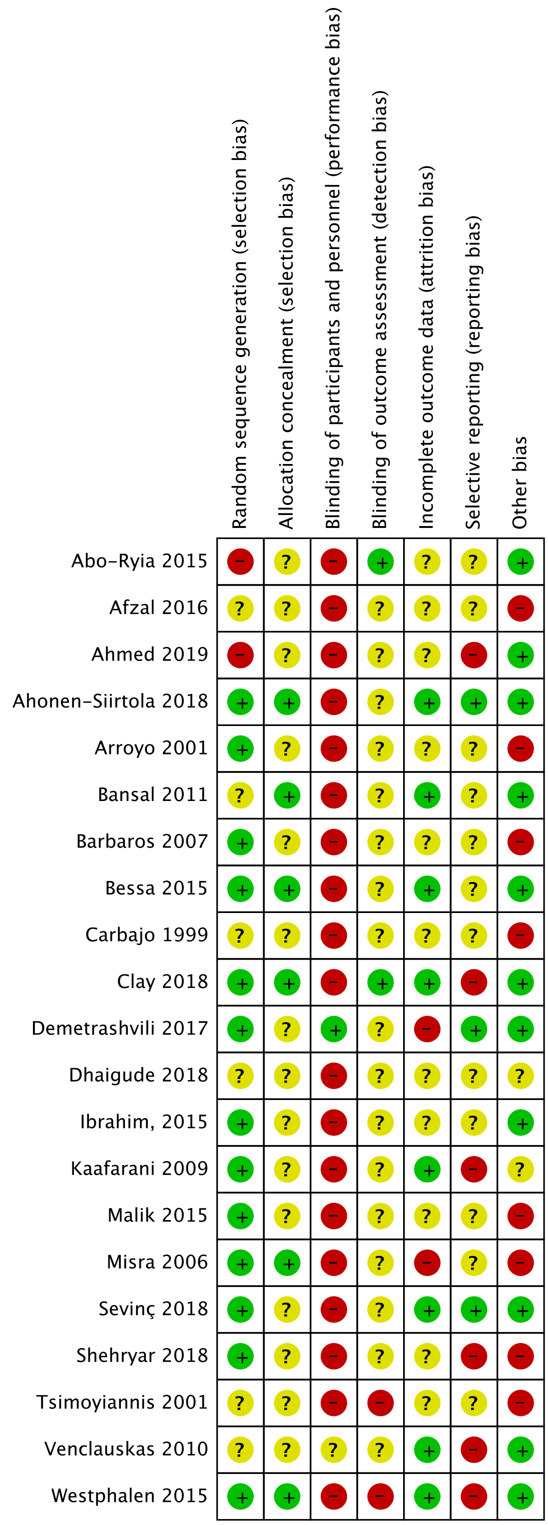

Fig. 2 Risk of bias summary of 21 RCTs included in this review

per-protocol; these cases were rated as having an unclear ROB [12, 14, 15, 19, 20, 25–28, 30, 31].

In judging the risk of bias for selective reporting, the ROB was rated as unclear in 12 studies [14–16, 19, 22, 23, 25, 27–31], low in 3 studies [13, 18, 24] and high in 6 studies [17, 20, 21, 26, 32, 33]. Concerning other sources of bias, 7 studies were rated as having high ROB [14, 15, 19, 23, 27, 28, 30].

Meta-analysis

Ten RCTs compared onlay vs. sublay mesh placement techniques and assessed the incidence of seroma in 971 patients diagnosed with ventral hernia [16, 18, 20, 22, 24–26, 28, 31, 32]. Seroma occurred in 106 out of 490 patients subjected to onlay repair and in 35 out of 481 patients subjected to sublay repair. Pooled analysis of these studies showed a significantly higher risk ratio for seroma in the onlay cohort (RR = 2.61, 95% CI 1.86–3.66, $P < 0.00001$) (Fig. 3). No heterogeneity was detected in this analysis ($I^2 = 0$).

The Abo-Ryia et al. study (60 patients) used a different sublay technique compared to the other nine studies (i.e., preperitoneal mesh placement) [22]. We performed sensitivity analysis by excluding this study to confirm the robustness of the results and the outcome of the meta-analysis remained substantially unchanged (RR = 2.56, 95% CI 1.82–3.60, Forest plot not shown).

Five RCTs compared laparoscopic intraperitoneal onlay mesh (IPOM) repair vs. open mesh placement in 654 patients diagnosed with ventral hernia [15, 19, 23, 30, 33]. Seroma occurred in 21 out of 311 patients subjected to IPOM repair and in in 58 out of 343 patients subjected to the open repair. Pooled analysis showed that seroma formation did not significantly differ between groups (RR = 1.91, 95% CI 0.69–5.28, $P = 0.21$) (Fig. 4). Substantial heterogeneity was found ($I^2 = 66\%$). Two studies [15, 23] appeared to be generating heterogeneity. The three remaining trials, showing homogeneous design, were pooled. Laparoscopic repair showed a significantly lower risk of seroma (RR = 0.26, 95% CI 0.15–0.46, Forest plot not shown), but these data should be evaluated with caution due to the small sample size.

Since the open repair arm included both onlay and sublay techniques, we performed subgroup analysis but no statistically significant differences were found (sublay, RR = 2.25, 95% CI 0.64–7.93, $P = 0.21$; onlay, RR = 0.81, 95% CI 0.03–24.81, $P = 0.90$, Forest plot not shown).

In the study by Barbaros et al., the open repair group included more incisional hernias compared to the laparoscopy arm (incisional hernias: laparoscopic, $n = 9$; open, $n = 13$; primary hernias, laparoscopic, $n = 14$; open, n = 10, $P < 0.05$) [15]. Such imbalance might have accounted for the outlying RR detectable in the forest plot. Exclusion of this outlier in the frame of a sensitivity analysis resulted in a significant RR favoring the laparoscopic technique (RR = 2.79, 95% CI 1.21–6.41, $P = 0.02$, forest plot not shown).

Secondary end points (seroma volume, drained volume from seroma) could not be pooled, as data were only available in two cases [13, 33]. In the study by Ahonen-Siirtola et al., comparing the classic laparoscopic (IPOM) approach to a hybrid (IPOM-plus) approach, the median seroma volume in the IPOM group (162 ml, interquartile range 30–388) was significantly larger than the one found in the IPOM-plus group (50 ml, interquartile range 13–145, $P = 0.025$, Mann–Whitney test) [13]. In the study by Kaafarani et al. (open vs laparoscopic hernia repair), seroma fluid was aspirated, but data for individual groups were not available [33].

Publication bias assessment

Visual inspection of the funnel plots generated for the sublay vs. onlay meta-analysis (Fig. 5) suggested the presence of asymmetry. The Egger's test confirmed the presence of

Study or Subgroup	Onlay Events	Onlay Total	Sublay Events	Sublay Total	Weight	Risk Ratio M-H, Random, 95% CI
Abo-Ryia 2015	5	30	0	30	1.4%	11.00 [0.64, 190.53]
Afzal 2016	8	32	2	32	5.3%	4.00 [0.92, 17.40]
Ahmed 2019	13	33	3	32	8.5%	4.20 [1.32, 13.37]
Bessa 2015	2	40	0	40	1.3%	5.00 [0.25, 100.97]
Demetrashvili 2017	32	78	13	77	36.1%	2.43 [1.38, 4.26]
Dhaigude 2018	4	50	1	50	2.5%	4.00 [0.46, 34.54]
Ibrahim, 2015	3	20	1	20	2.4%	3.00 [0.34, 26.45]
Sevinç 2018	7	50	1	50	2.7%	7.00 [0.89, 54.83]
Shehryar 2018	6	100	2	100	4.6%	3.00 [0.62, 14.51]
Venclauskas 2010	26	57	12	50	35.3%	1.90 [1.08, 3.36]
Total (95% CI)		**490**		**481**	**100.0%**	**2.61 [1.86, 3.66]**
Total events	106		35			

Heterogeneity: $Tau^2 = 0.00$; $Chi^2 = 4.71$, df = 9 (P = 0.86); $I^2 = 0\%$
Test for overall effect: Z = 5.57 (P < 0.00001)

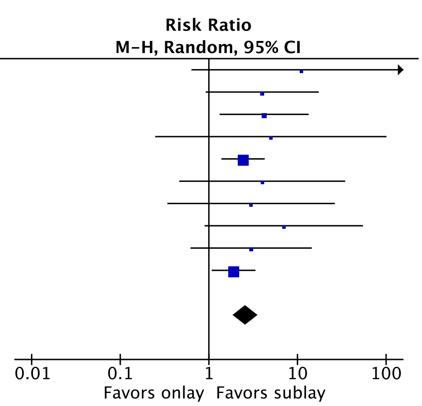

Fig. 3 Meta-analysis of RCTs investigating the incidence of seroma as a result of onlay vs. sublay mesh placement techniques. The number of subjects allocated to onlay or sublay arms, risk ratios, the 95% confidence intervals, the Z value for the overall effect, the significance of the pooled comparisons and heterogeneity data (Chi^2, I^2) are presented. Data to the right of the vertical no-effect line of forest plots represent increased risk for seroma in onlay repair patients (sublay is the favored technique). The diamond represents the overall effect size extending to the limits of the 95% confidence intervals of risk ratios

Study or Subgroup	Open Events	Open Total	Laparoscopic Events	Laparoscopic Total	Weight	Risk Ratio M-H, Random, 95% CI
Barbaros 2007	0	23	4	23	9.2%	0.11 [0.01, 1.95]
Carbajo 1999	20	30	4	29	26.2%	4.83 [1.88, 12.43]
Kaafarani 2009	20	86	4	60	25.2%	3.49 [1.26, 9.69]
Malik 2015	17	171	5	166	25.8%	3.30 [1.25, 8.74]
Misra 2006	1	33	4	33	13.6%	0.25 [0.03, 2.12]
Total (95% CI)		**343**		**311**	**100.0%**	**1.91 [0.69, 5.28]**
Total events	58		21			

Heterogeneity: Tau² = 0.80; Chi² = 11.69, df = 4 (P = 0.02); I² = 66%
Test for overall effect: Z = 1.24 (P = 0.21)

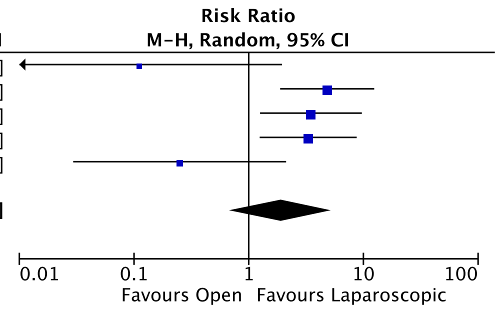

Fig. 4 Meta-analysis of RCTs investigating the incidence of seroma as a result of laparoscopic vs. open hernia repair techniques. The number of subjects allocated to laparoscopic or open repair arms, risk ratios, the 95% confidence intervals, the *Z* value for the overall effect, the significance of the pooled comparisons and heterogeneity data (Chi^2, I^2) are presented. Data to the right of the vertical no-effect line of forest plots represent increased risk for seroma in patients undergoing open repair (laparoscopic repair is the favored technique). The diamond represents the overall effect size extending to the limits of the 95% confidence intervals of risk ratios

significant bias ($P=0.003$). Due to surgical technique differences, we tested publication bias by excluding the Abo-Ryia et al. study. However, significant asymmetry was confirmed ($P=0.01$).

In the meta-analysis comparing laparoscopic (IPOM) versus open hernia repair, the funnel plot asymmetry was also found to be significant ($P=0.003$).

Quality of the evidence emerging from meta-analysis

An evaluation of the quality of the evidence generated by the meta-analyses is presented in the summary of findings table (Table 2).

The overall quality of evidence emerging from the onlay vs. sublay comparison was rated as moderate. Reasons for downgrading the quality were the presence of significant publication bias and of high ROB. Notably, although we evaluated all unblinded studies as having high risk of performance bias, we did not consider such bias as a major limitation to the GRADE assessment of the quality of the evidence.

In the meta-analysis, the effect size was large according to GRADE criteria, and this allowed one level upgrading of the quality.

Low quality of the evidence was rated for the open vs. laparoscopic pooled comparison. The inconsistency of effect due to substantial heterogeneity ($I^2=66\%$) and the presence

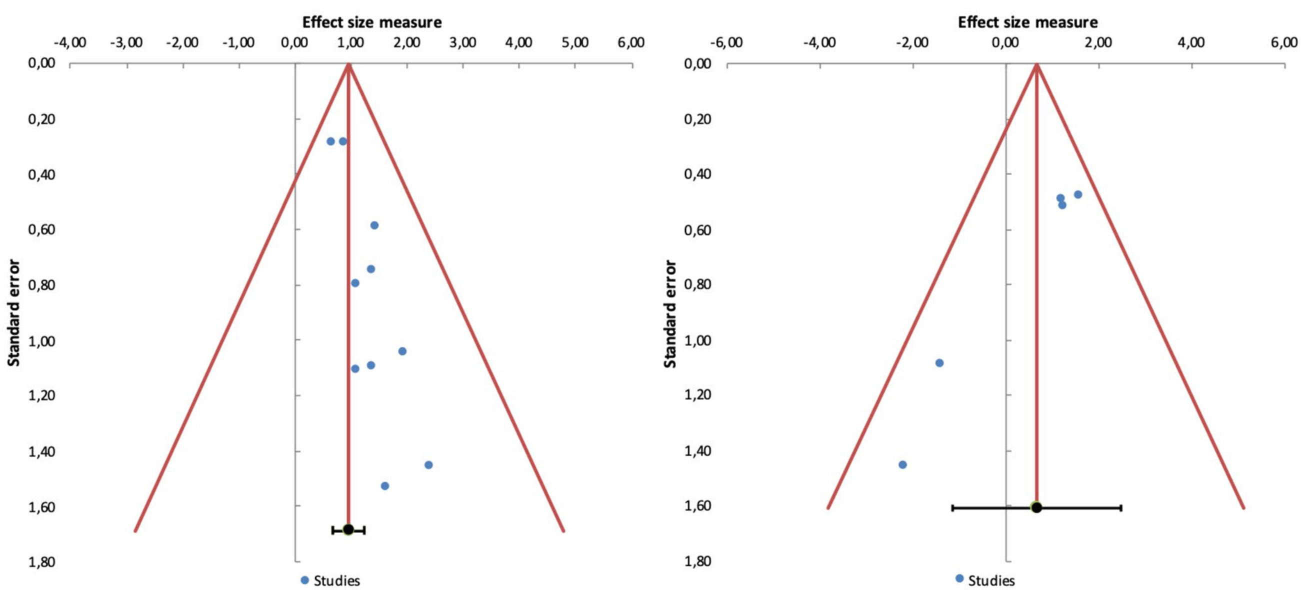

Fig. 5 Funnel plot for publication bias analysis. **A** Comparison between onlay and sublay ventral hernia repair techniques. **B** Comparison between laparoscopic intraperitoneal onlay mesh repair vs. open mesh placement. In these plots the effect sizes are expressed as the natural logarithms

Table 2 Outcomes

Onlay versus retromuscular mesh placement techniques for seroma prevention						
Patient or population: male and female ventral hernia patients Intervention: onlay mesh placement technique—comparison: retromuscular mesh placement technique						
Outcomes	Illustrative comparative risks[a] (95% CI)		Relative effect (95% CI)	No. of participants (studies)	Quality of the evidence (GRADE criteria)	Comments
	Assumed risk	Corresponding risk				
	Sublay technique	Onlay technique				
Incidence of seroma formation (all studies)	72.8 per 1000	190.0 per 1000 (135.4–266.4)	RR 2.61 (1.86–3.66)	971 (10 studies)	⊕⊕⊕⊖ moderate	Reasons for downgrading: 1. Risk of bias 2. Publication bias Reasons for upgrading: 1. Large effects
Incidence of seroma formation (Abo-Ryia study excluded)	77.6 per 1000	198.7 per 1000 (141.2–179.4)	RR 2.56 (1.82–3.60)	911 (9 studies)	⊕⊕⊕⊖ moderate	Reasons for downgrading: 1. Risk of bias 2. Publication bias Reasons for upgrading: 1. Large effects

Open versus laparoscopic hernia repair techniques for seroma prevention						
Patient or population: male and female ventral hernia patients Intervention: open mesh repair—comparison: laparoscopic (IPOM) repair						
Outcomes	Illustrative comparative risks[a] (95% CI)		Relative effect (95% CI)	No. of participants (studies)	Quality of the evidence (GRADE criteria)	Comments
	Assumed risk	Corresponding risk				
	Laparoscopic repair	Open repair				
Incidence of seroma formation	67.5 per 1000	128.9 per 1000 (46.6–356.4)	RR 1.91 (0.69–5.28)	529 (3 studies)	⊕⊕⊖⊖ low	Reasons for downgrading: 1. Consistency of effect 2. Publication bias Reasons for upgrading: none

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

CI confidence interval, *RR* risk ratio

[a]The assumed risk represented the ratio between the number of seroma cases assessed in the open repair group and the total amount of open repair interventions. 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)

of significant publication bias were the main reasons for quality downgrading.

Results of studies not included in the meta-analysis

Five RCTs [13, 14, 17, 21, 29], not included in our meta-analysis, did not report significant differences in seroma formation as a result of different comparisons (mesh repair vs. mesh-free repair, mesh fixation with suture vs. fixation with tackers, full-thickness skin graft vs. synthetic mesh, drainage vs. no drainage, IPOM vs. IPOM-plus, data not shown). The study by Tsimoyiannis et al., comparing cauterization vs. non-cauterization of the hernia sack in the frame of laparoscopic intraperitoneal repair, showed that the incidence of seroma is significantly lower when the hernia sac is cauterized (seroma after cauterization: 4%, no cauterization: 27%, $P<0.025$, Chi-square test) [27].

Discussion

Seroma formation is a relatively common occurrence after abdominal wall reconstruction. However, seroma is perceived by patients and is considered by surgeons to be a complication only in a fraction of cases. Indeed, an important factor in this respect is the distinction between significant seromas—which represent actual complications—and incidental seromas that are detected during the postoperative examination, but do not cause any discomfort to the patient and disappear spontaneously within few months [36]. Significant seromas, which cause discomfort, pain or even infection, are complications that should be prevented or remediated.

There are multiple reasons why abdominal wall surgery can cause seroma formation. During open surgery, soft tissue is dissected, and vessels are disrupted; this causes inflammation and serous fluid accumulates in the dissected space. Conversely, in laparoscopic surgery, the surgeon has to dissect to a lesser extent, thus creating less dead space for fluids to accumulate. On the other hand, in laparoscopic surgery the hernia sac is left in place and this can represent a space where serous fluid may accumulate.

Moreover, a number of other variables can influence the incidence of seroma, such as the choice between mesh vs. mesh-free repair, the mesh choice, the mesh fixation method, the choice of cauterizing or not the hernia sac, the placement of surgical drainage.

The goal of our systematic review was to investigate which surgical techniques may be characterized by a lower risk of seroma formation. Systematic search of the literature resulted in the inclusion of 21 RCTs in the present review, which provided evidence that specific techniques may decrease the postoperative formation of seroma.

Among these studies, ten focused on the comparison between onlay vs. sublay techniques. Meta-analysis of these RCTs, including 971 patients randomized to onlay vs. sublay mesh repair of ventral hernias, showed that the former is associated with a significantly higher risk of seroma complications. One strength of this meta-analysis is that the risk is high (2.61) and highly significant ($P<0.00001$), and heterogeneity is absent ($I^2=0\%$) despite the presence of possible differences in surgical skills between studies. Moreover, the surgical techniques and materials (e.g., the sublay procedure according to Rives-Stoppa, the usage of a polypropylene mesh) are homogeneous in nine out of ten studies, and exclusion of the trial by Abo-Ryia et al., using a different sublay technique [25], did not affect the main result of the meta-analysis.

In a similar meta-analysis of sublay vs. onlay mesh repair by Timmermans et al. [37], no significant differences in seroma formation were reported (odds ratio = 1.06, 95% CI 38–2.95, $I^2=48\%$, $P=0.89$). A comparison with our results is not possible, since in the Timmermans review only incisional hernias were included. Moreover, in that meta-analysis five studies were pooled, of which four were retrospective analyses and only one was an RCT. Despite their non-significant results, Timmermans and coworkers admit that although onlay may be easier and quicker to perform, the dissection of the suprafascial space would promote seroma formation. This view is supported by Köckerling, who stated that the higher incidence of seroma may be caused by the more extensive dissection in the abdominal wall, achieved to expose the anterior rectus sheath and the anterior abdominal wall fascia for mesh placement in the onlay position [38].

A recent meta-analysis by Ibrahim et al. included six studies, of which three were not RCTs, focusing on the sole incisional hernias [39]. This analysis also found that seroma occurs less frequently with the sublay technique. A direct comparison with our results is not feasible, due to the substantial differences between analyses.

These results suggest that the sublay technique may perform better than onlay mesh placement concerning seroma formation. Likely, sublay may perform better because the mesh is placed in a well-vascularized space underneath the rectus muscle. This can minimize the seroma rate in contrast to onlay mesh placement [25]. Moreover, in sublay repair, tissue integration is bi-directional, as it occurs through the in-growth of load-bearing tissue at both interfaces of the mesh [40].

Seroma formation may occur more frequently after onlay repair, since extensive skin flaps need to be created. Importantly, these flaps are devascularized, the subcutaneous tissue is dissected and a dead space, prone to accumulate fluids, is created. Several strategies may be implemented to prevent seroma formation when an onlay technique is adopted. Suction drainage, fasciocutaneous quilting with progressive tension sutures, the application of fibrin sealants, the choice of non-biological mesh, hypertonic saline irrigation, and negative pressure wound therapy are notable for their seroma preventing capacity [41–43]. Among those techniques, suction drainage was applied to all onlay arms of all trials included in our meta-analysis, whereas none of the other techniques (with the exception of hypertonic saline irrigation in the Abo-Ryia 2015 trial) was apparently adopted. Therefore, it is unknown whether the implementation of these techniques during onlay repair might reduce the gap between onlay and sublay repair with respect to seroma formation, thus potentially modifying the outcome of a meta-analysis focusing on seroma. This represents a limitation to our conclusions.

The sublay technique has additional advantages besides the lower rate of seroma formation. Holihan et al. [44] showed that sublay repair performed better than onlay repair in terms of hernia recurrence (odds ratio = 0.74, 95% CI 0.01–0.39) and prevention of surgical site infection (sublay, 23.8% probability, onlay, 12.6%). Accordingly, the 2020 Guidelines for treatment of umbilical and epigastric hernias [45] stated that sublay mesh placement is associated with the lowest risk of surgical site infection and/or recurrence. Nevertheless, the onlay technique may be advantageously when used in specific cases such as small and lateral incisional hernias, without major differences in terms of complications [46].

Five RCTs compared open mesh repair with IPOM [15, 19, 23, 30, 33]. The relative risk for seroma was not significantly different between the two groups and substantial heterogeneity was found ($I^2 = 66\%$). Among the included studies, three out of five showed significant superiority of the laparoscopic approach. In a Cochrane review by Sauerland et al., seroma formation after laparoscopic vs. open ventral hernia repair was investigated [47], and no significant differences were found (RR = 1.42, 95% CI 0.60–3.40). Also in that case, the comparison showed substantial heterogeneity ($I^2 = 69\%$). The fact that the results of this and our meta-analyses are not significant can be due to the differences in how seroma is formed in open and laparoscopic repair. In laparoscopic surgery, the hernia sac is left in place and, if the sac is not cauterized, the space between the mesh and the hernia sac can fill with serous fluid. Conversely, in open surgery the sac is removed, and the defect is closed. However, open repair can also cause the formation of seromas because large flaps and big dissections are created when an onlay repair is performed. Another reason can be the variability in classification and definition of seromas between different studies. In fact, only part of the seromas are actually a complication, and that most of the seromas that occur after surgery will resolve spontaneously. In conclusion, further research with seroma as primary end point may provide more evidence about the most favorable surgical technique to prevent seroma formation. Accordingly, the 2019 updated guidelines for laparoscopic treatment of ventral and incisional abdominal wall hernias of the International Endohernia Society (IEHS) stated that most publications showed no significant differences between laparoscopic and open approaches in terms of seroma formation, and that further studies may provide more solid lines of evidence in the future [48]. It should also be considered that both open and laparoscopic surgery using intraperitoneal mesh position may be characterized by higher rates of intraoperative or postoperative complications such as bleeding or organ injuries, as well as mesh adhesion, fistulation, or mesh migration [49, 50]. These complications, together with seroma formation and surgical site infection should be taken into careful consideration and the appropriate technique can be chosen and tailored to each specific case and presentation.

Finally, we deem important to evidence that our meta-analyses present the following limitations: (1) the intrinsic bias of most surgical trials, linked to the non-blinded design, (2) the risk of publication bias, (3) the lack of information concerning the method of evaluation of seromas, their clinical significance (viz., significant vs. incidental) and their treatment in some studies, (4) the different characteristics of hernias diagnosed in the included studies (umbilical/paraumbilical/epigastric, primary or incisional, hernia size). Concerning the latter limitation, it is to be hoped that new large and adequately powered studies may allow to perform subgroup analyses based on specific subtypes of hernia.

The diversity of hernia repair techniques reported in the RCTs included in this review does not allow to draw conclusive clinical recommendations. Future trials focusing on seroma occurring in hernia repair should be better standardized, so granular data can be extrapolated from such trials, and future meta-analysis may provide more conclusive evidence that can impact in the clinical practice.

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