



Purse-string vs. linear skin closure at loop ileostomy reversal: a systematic review and meta-analysis

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Abstract

Background There is no level 1a evidence regarding the best technique for skin closure at loop ileostomy reversal. The aim of this study was to evaluate whether purse-string skin closure (PSC) is associated with lower surgical site infection (SSI) rates as compared to linear skin closure (LC).

Methods EMBASE, MEDLINE, Pubmed, Cochrane Library, Web of Science, and CINAHL databases were systematically searched. PSC was defined as a circumferential subcuticular suture leaving a small circular skin defect allowing for free drainage, granulation, and epithelialization. In LC, the wound edges were approximated side to side with or without drainage. The primary endpoint was SSI rate. Secondary endpoints included operating time, length of hospital stay, wound healing time, and incisional hernia rates.

Study selection Inclusion criterion was any observational or experimental study comparing PSC to LC in patients undergoing ostomy reversal.

Results Twenty studies (6 experimental and 14 observational) totaling 1812 patients (826 PSC and 986 LC) were included. SSI rates were significantly lower statistically and clinically in patients with PSC [OR (95% CI)=0.14 (0.09, 0.21); $p < 0.0001$; NNT=6] in the meta-analysis of all studies. The subgroup analysis of randomized trials [OR (95% CI)=0.10 (0.04, 0.21); $p < 0.0001$; NNT=6] as well as the analysis of randomized trials including patients with loop ileostomy only [OR (95% CI)=0.12 (0.05, 0.28); $p < 0.0001$; NNT=5] confirmed this finding.

Conclusions This meta-analysis found that PSC was associated with significantly decreased rates of SSI in patients undergoing loop ileostomy reversal.

Keywords Loop ileostomy reversal · Purse-string closure · Linear skin closure · Surgical site infection

Introduction

Diverting the gastrointestinal flow with a loop ileostomy has been shown to decrease complications from sepsis after colocolonic or colorectal anastomosis [1]. However, ileostomies are associated with complications including (but not limited to) physiologic adverse events such as dehydration

and acute renal failure [2]. Moreover, the closure of the loop ileostomy can be associated with additional short-term post-operative morbidity in 2–33% of the patients [3, 4]. Surgical site infection (SSI) is the most prominent complication after ileostomy reversal with incidence rates of 0–41% [5–7]. Techniques already described and used for wound closure at ileostomy reversal include conventional linear skin closure (LC), primary skin closure with subcutaneous vacuum drain [8], and negative pressure wound therapy [9]. Nonetheless, the optimal technique is still a subject of debate. Purse-string skin closure (PSC) was first introduced as an alternative method to decrease the rate of incisional SSI by Banerjee in 1998 [10]. In PSC, the skin is partially closed in a circular fashion placing a purse-string suture in the dermal layer. PSC allows the wound to drain in its center throughout the healing process. Since the introduction of PSC, several studies have reported decreased incisional

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SSI rates and improved cosmetic appearance with PSC as compared to LC. Two previous systematic reviews showed that PSC led to lower rates of incisional SSI compared to other types of closure methods [11, 12]. However, the studies included in these systematic reviews suffered from a low level of evidence with a high risk of bias rendering a definitive conclusion difficult. In this systematic review and meta-analysis, we reviewed the most up-to-date literature to evaluate the outcomes of PSC compared to LC following ostomy reversal.

Materials and methods

The Cochrane Handbook for Systematic Reviews of Interventions was used to perform this systematic review [13]. The study complies with Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) as well as Meta-analysis of Observational Studies in Epidemiology (MOOSE) guidelines [14, 15]. The protocol of this meta-analysis was prospectively developed and registered in the International prospective register of systematic reviews PROSPERO: CRD42017069354. The literature search, quality assessment, extraction and analysis of the data, and critical appraisal were performed by two researchers independently (GM and LH). Any methodological discrepancies were revised and corrected by the senior author. The research question was developed within the patient/problem, intervention, comparison, outcome, time, and setting (PICOTS) framework as follows:

- (P) Population: adults older than 18 years undergoing ostomy reversal.
- (I) Intervention: PSC.
- (C) Comparator intervention: LC.
- (O) Outcomes: SSI rate, operating time, length of stay, incisional hernia rate.
- (T) Time: both short- and long terms.
- (S) Setting: in- and outpatient.

Eligibility criteria, definitions, and endpoints

The inclusion criterion was any observational (case–control, retrospective or prospective cohort) or experimental study comparing PSC to LC in patients with temporary ileostomy or colostomy undergoing ostomy reversal. The exclusion criteria were non-comparative descriptive studies; studies comparing either PSC or LC to an irrelevant intervention, systematic reviews, technical notes, and correspondence papers.

PSC was defined as a circumferential subcuticular suture leaving a small circular skin defect allowing for free drainage, granulation, and epithelialization. In LC, the wound

edges were approximated side to side with or without drainage. SSI was defined according to the Center for Disease Control (CDC) National Nosocomial Infections Surveillance System [16]. Wound infection and wound sepsis were categorized as SSI. Incisional hernia was defined as either a radiological or clinical defect at the ostomy reversal site.

The primary endpoint was:

- SSI

Secondary endpoints were:

- Operating time
- Length of hospital stay
- Wound healing time
- Incisional hernia rate

Search strategy and study selection

EMBASE, MEDLINE via Ovid, Pubmed, Cochrane Library, Web of Science, and CINAHL databases were searched for the following MeSH terms: ‘purse-string’, ‘purse-string’, and ‘closure’. Existence of any ongoing relevant clinical studies was assessed by searching ClinicalTrials.gov. Records of interest were identified and screened through the title, abstract, or full-text article. The references of included articles were screened for additional publications to test the sensitivity of the search strategy.

Quality assessment and data extraction

The quality of the included studies was assessed by two independent researchers according to the Cochrane Handbook for Systematic Reviews of Interventions [13]. Extracted data from the included records were inserted into a pre-defined Microsoft Excel table and included article identifiers (author, journal, and year of publication), study design, number of patients, type of and indication for ostomy, time to ostomy reversal, follow-up, details of study interventions, and pre-defined primary and secondary endpoints.

Statistical analysis

RevMan (version 5.3; Nordic Cochrane Center, Cochrane Collaboration, Copenhagen, Denmark), Microsoft Excel (Version 2016; Microsoft Corporation, WA, USA), and CMA Software (Version 3; Biostat, NJ, USA) were used for statistical analysis. The Mantel–Haenszel method using odds ratios with 95% confidence intervals [OR (95% CI)] as an effect measure was employed to compare dichotomous variables. Continuous variables were compared using the inverse variance method with mean difference and standard error as an effect measure. In cases when the median

and range were reported to express continuous variables, Hozo's formula was utilized to estimate mean and standard deviation (SD) [17]. Statistical heterogeneity among effect estimates was evaluated using I^2 and Cochran Chi^2 , and between-study variance was evaluated using Tau^2 statistic when the I^2 was 50% or greater [18]. The random-effects model for meta-analysis was utilized in case of high heterogeneity. The findings of the meta-analysis were illustrated on forest plots. Relative risk reduction (RRR), absolute risk reduction (ARR), and number needed to treat/harm (NNT) were calculated for evaluation of clinical significance of the results [19]. Considering that above-mentioned metrics also have variability, 95% CI for NNT were calculated by taking reciprocals of the values defining the 95% CI for the ARR to demonstrate whether there was uncertainty in the NNT [20]. Publication bias was assessed through visual assessment of funnel plots, Egger's, and Begg and Mazumdar rank correlation tests. A p value < 0.05 was considered statistically significant.

Results

Literature search and study selection

The detailed search strategy is shown in Supplement 1. The PRISMA flow diagram of study selection is illustrated in Fig. 1. Systematically searched databases had 884 records. Screening of the references of eligible studies revealed seven additional records and three records were found at clinical-trials.gov. A hundred and one records were screened after excluding duplicates and irrelevant articles. Fifty-eight articles included the medical subject headings (MeSH) terms in their titles, but were not related to skin closure techniques. Hence, they were excluded. After assessment of 43 full-text articles and exclusion of reviews, descriptive studies, studies comparing either intervention of interest to an irrelevant comparator, technical notes, and correspondence articles, 21 studies were included in the qualitative synthesis. One randomized controlled trial (RCT) was not included in the quantitative synthesis due to a different study population (patients older than 12 years were included in the study) [21].

Description of included studies

Among 43 potentially eligible studies, 20 were included in the meta-analysis [22–41] totaling 1812 patients (826 PSC and 986 LC). A description of the included studies is provided in Table 1. Six studies were RCTs with 1b level of evidence [22–24, 29, 34] and 14 (12 retrospective and 2 prospective cohort studies) were observational studies with 2b level of evidence [25–28, 30–33, 35–40]. Nineteen of 20 records were full-text articles. One record was an abstract

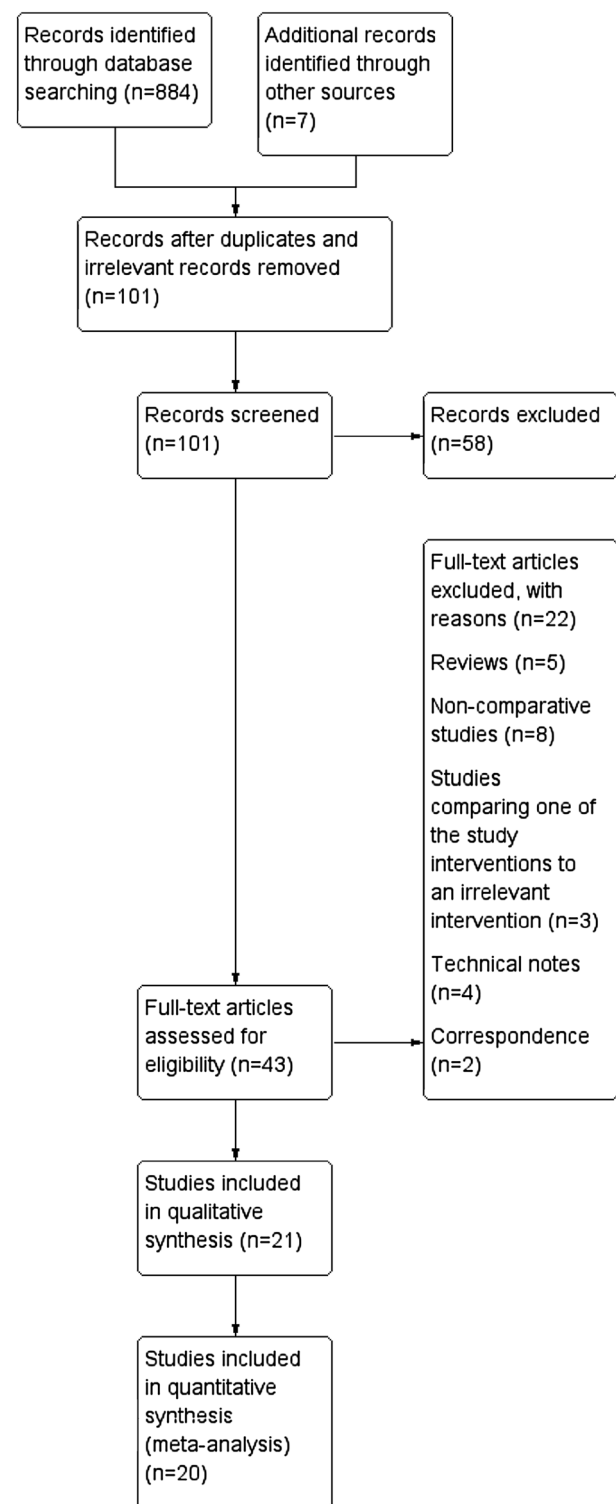


Fig. 1 PRISMA flow diagram

published in a surgical journal supplement [40]. In 18 studies, the primary endpoint was incisional SSI [22–25, 27–40]. In one observational study, the primary endpoint was incisional hernia rates [26]. In another study, multiple

Table 1 Characteristics of included studies

Author	Publication	Country	Study design	Sample size (PSC vs. LC) 826 vs. 986	Type of ostomy (I, C) and (E, L)	Indication for ostomy (B, M)	Primary endpoint	Time to stoma reversal (PSC vs. LC)	Ab Prophylaxis	Bowel preparation (Y/N)	Follow-up	NOS (S-C-O)	Oxford CEEM evidence level
Alvandipour	Ann Colo-proctol 2016	Iran	RCT (2015)	34 vs. 32	I and L	B + M	SSI	NR	NR	NR	3 Months		Ib
Camacho-Mauries	Dis Colon Rectum 2013	Mexico	RCT (2010–2011)	31 vs. 30	I + C and E + L	B + M	SSI	7.3 vs. 7.7 ^{a,c}	IV amoxicillin-clavulanate	NR	1 Year		Ib
Dusch	Colorectal Dis 2013	Germany	RCT (2009–2011)	43 vs. 41	I and L	B + M	SSI	6.6 vs. 5.3 ^{b,c}	Yes (NS)	NR	6 Months		Ib
Habbe	Int J Colorectal Dis 2014	Germany	Retrospective cohort (2009–2012)	33 vs. 81	I and L	B + M	SSI	4.7 vs. 4.0 ^{a,c}	Cefuroxime and metronidazole	Y	27 Months		2b
Juratli	Int J Colorectal Dis 2018	Germany	Retrospective cohort (2009–2012)	54 vs. 34	I and L	B + M	Incisional hernia rate	12 ^{a,c}	Cephalosporins and metronidazole	NR	24 Months		2b
Klink	Int J Surg 2013	Germany	Retrospective cohort (2005–2012)	44 vs. 96	I and L	B + M	SSI	NR	Ceftriaxone and metronidazole	NR	11 Days		2b
Lee	J Korean Soc Colo-proctol 2011	S. Korea	Retrospective cohort (2002–2010)	18 vs. 30	I and L	B + M	SSI	4.1 vs. 4 ^{a,c}	Cephalosporins (not routinely)	Y	3.7–23.3 Months		2b
Lee	Dis Colon Rectum 2014	USA Switzerland	RCT (2008–2012)	58 vs. 55	I + C and E + L	B + M	SSI	7.1 vs. 7.1 ^{b,c}	Cephalosporins or fluoroquinolone, and metronidazole	Y	1 Month		Ib

Table 1 (continued)

Author	Publication	Country	Study design	Sample size (PSC vs. LC) 826 vs. 986	Type of ostomy (I, C) and (E, L)	Indication for ostomy (B, M)	Primary endpoint	Time to stoma reversal (PSC vs. LC)	Ab Prophylaxis	Bowel preparation (Y/N)	Follow-up	NOS (S-C-O)	Oxford CEBM evidence level
Li	Dig Surg 2014	USA	Retrospective cohort (2005–2011)	18 vs. 40	I + C & E + L	B + M	SSI	15 vs. 9.3 ^{a,c}	Ertapenem Cefoxin or quinolone/ metronidazole	N	5.1–8.2 Months		2b
Marquez	World J Surg 2010	USA	Retrospective cohort (2002–2007)	17 vs. 61	I + C and E + L	B + M	SSI	NR	Cephalexin	NR	NR		2b
Milanchi	Dis Colon Rectum 2009	USA	Retrospective cohort (2005–2007)	24 vs. 25	I and L	B + M	SSI	2.4 vs. 2.6 ^{b,c}	Cephalexin	N	13.7 Months		2b
Mirbagheri	Tech Colo-proctol 2013	Australia	Retrospective cohort (2003–2011)	28 vs. 114	I + C and E + L	B + M	SSI	NR	Yes (NS)	Y (for colostomy)	NR		2b
O'Leary	Tech Colo-proctol 2017	Ireland	RCT (2013–2015)	34 vs. 27	I and L	B + M	SSI	NR	Augmentin	NR	6 Months		1b
Reid	Br J Surg 2010	Australia	RCT (2006–2007)	30 vs. 31	I and L	B + M	SSI	3.7 vs. 4.8 ^{b,c}	Cefazolin and metronidazole	NR	12 Months		1b
Suh	Int J Surg 2014	S. Korea	Retrospective cohort (2010–2011)	78 vs. 79	I and L	M	SSI	7.2 vs. 6.3 ^{b,c}	Cefotetan	N	6 Months		2b
Wada	Mol Clin Oncol 2015	Japan	Retrospective cohort (2013–2014)	26 vs. 29	I + C and NR	M	SSI	NR	Cefmetazole	Y	NR		2b

Table 1 (continued)

Author	Publication	Country	Study design	Sample size (PSC vs. LC) 826 vs. 986	Type of ostomy (I, C) and (E, L)	Indication for ostomy (B, M)	Primary endpoint	Time to stoma reversal (PSC vs. LC)	Ab Prophylaxis	Bowel preparation (Y/N)	Follow-up	NOS (S-C-O)	Oxford CEBM evidence level
Yamamoto	Am J Surg 2018	Japan	Retrospective propensity score match (2000–2014)	64 vs. 64	I and L	B + M	SSI	NR	Cefotiam	Y	NR		2b
Yoon	Ann Colo-proctol 2015	S. Korea	Prospective cohort (2010–2013)	34 vs. 14	I + C and E + L	B + M	SSI	3.3 vs. 3.2 ^{b,c}	Cephalosporins	NR	4–17 Weeks		2a
Younis	Colorectal Dis 2011	UK	Prospective and retrospective cohort (2008–2010)	50 vs. 58	I and NR	NR	SSI	NR	NR	NR	NR		2b
Zhou	Ostomy Wound Manage 2016	USA	Retrospective cohort (2009–2012)	108 vs. 45	I and L	B + M	SSI, LOS, and incisional hernia	NR	NR	NR	24–28 Months		2b

PSC purse-string skin closure, LC linear skin closure, RCT randomized controlled trial, I ileostomy, C colostomy, E end, L loop, NR not reported, B benign disease, M malignant disease, SSI surgical site infection, LOS length of hospital stay, NS not specified, Y yes, N no, NOS Newcastle–Ottawa Quality Assessment Scale for cohort studies, S selection, C comparability, O outcome, CEBM Center for Evidence-Based Medicine

^aMedian; ^bmean; ^cweeks; ^dmonths

comparisons and endpoints were reported [41]. Studies stratified by endpoints are presented in Supplement 2. Thirteen studies included patients with loop ileostomies only [22, 24–28, 32, 34–36, 38, 40, 41]. Seven studies included patients with ileostomy or colostomy [23, 29–31, 33, 37, 39]. Two of the 20 studies included patients undergoing surgery for colorectal cancer [36, 37].

Description of study populations and interventions

Patients were adults from ten countries: USA, Germany, South Korea, Australia, Japan, UK, Ireland, Mexico, Switzerland, and Iran. The breakdown of patient by country is shown in Fig. 2. The RCTs involved 446 patients (230 PSC vs. 216 LC) from 7 countries: USA, Germany, Australia, Ireland, Mexico, Switzerland, and Iran [22–24, 29, 34]. In all studies, patients with PSC were comparable to their counterparts in terms of demographics. The definition of study interventions was heterogeneous (Supplement 3). Eleven studies reported having used absorbable suture for PSC [22, 28, 29, 31, 32, 34, 36–39, 41]. In six studies, non-absorbable sutures were used [23–26, 33, 35]. Three studies did not report the type of suture used for PSC [27, 30, 40]. The diameter of the circular skin defect after PSC varied from 3 mm to 20 mm. Drains were routinely used in seven studies [24, 29, 31, 32, 36, 37, 39].

Quality assessment

The summary and graph of the risk of bias in included studies are presented in Fig. 3. Oxford Centre for Evidence-Based Medicine (CEBM) classification was utilized to assess levels of evidence provided by the included studies (Table 1). The quality of cohort studies was evaluated using the Newcastle–Ottawa score (Table 1). There was low risk of selection bias in six RCTs only [22–24, 29, 34, 35]. The risks of performance and detection biases were high in

Number of patients included by country of origin

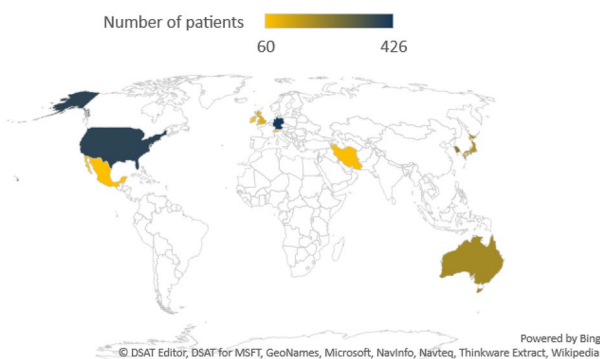


Fig. 2 Map chart of number of patients by country of origin

observational studies as well as in RCTs. Blinding surgeons to the intervention and the outcome for preventing performance and detection bias is impracticable and unethical. The risks of attrition, reporting, and other biases were low in most studies.

Meta-analysis of the data from all studies

All 20 studies regardless of the evidence level were included.

SSI rate

Surgical site infection was defined as stoma site superficial or deep incisional SSI and was reported in all included studies (826 PSC vs. 986 LC) [22–41]. The fixed effects model was utilized as among-study heterogeneity was low ($I^2 = 1\%$). SSI rate was 3.1% (26/826) in PSC vs. 20.2% (199/986) in LC. This difference was statistically and clinically significant [OR (95% CI) = 0.14 (0.09, 0.21); $p < 0.0001$] [NNT (95% CI) = 6 (5, 7)] (Fig. 4; Table 2). It was impossible to correlate the incidence of SSI with any details of intervention, such as aperture size or packing of the wound as the studies did not report such correlations.

Secondary endpoints

Operating time was reported in 13 studies (510 PSC vs. 656 LC) [22–25, 27–29, 31, 34–38]. The fixed effects model was utilized as statistical among-study heterogeneity was low ($I^2 = 14\%$). The mean difference in operating time between PSC and LC was not statistically significant [MD (95% CI) = 1.17 (–2.00, 4.34); $p = 0.47$] (Fig. 5a).

Twelve studies reported the length of hospital stay (479 PSC vs. 626 LC) [22, 24, 25, 27–29, 31, 34–38]. The random-effects model was utilized. The length of hospital stay was significantly shorter in patients with PSC as compared to those with LC [MD (95% CI) = –2.07 (–3.72, –0.42); $p = 0.01$] with high statistical among-study heterogeneity ($I^2 = 85\%$; $\text{Tau}^2 = 6.06$) (Fig. 5b).

Incisional hernia rates were reported in 7 studies (396 PSC vs. 333 LC) [23, 24, 26, 30, 36, 38, 41]. The fixed effects model was utilized as among-study heterogeneity was low ($I^2 = 30\%$). Incisional hernia rates were 10.3% (41/396) after PSC and 15.3% (51/333) after LC with no statistically significant difference [OR (95% CI) = 0.64 (0.40, 1.02); $p = 0.06$] (Fig. 5c). It was not possible to test any correlations between SSI and incisional hernia as the authors did not report such correlation.

Outcomes with no temporal relationship to skin closure technique such as anastomotic leak and ileus rates are given in Supplements 4 and 5.

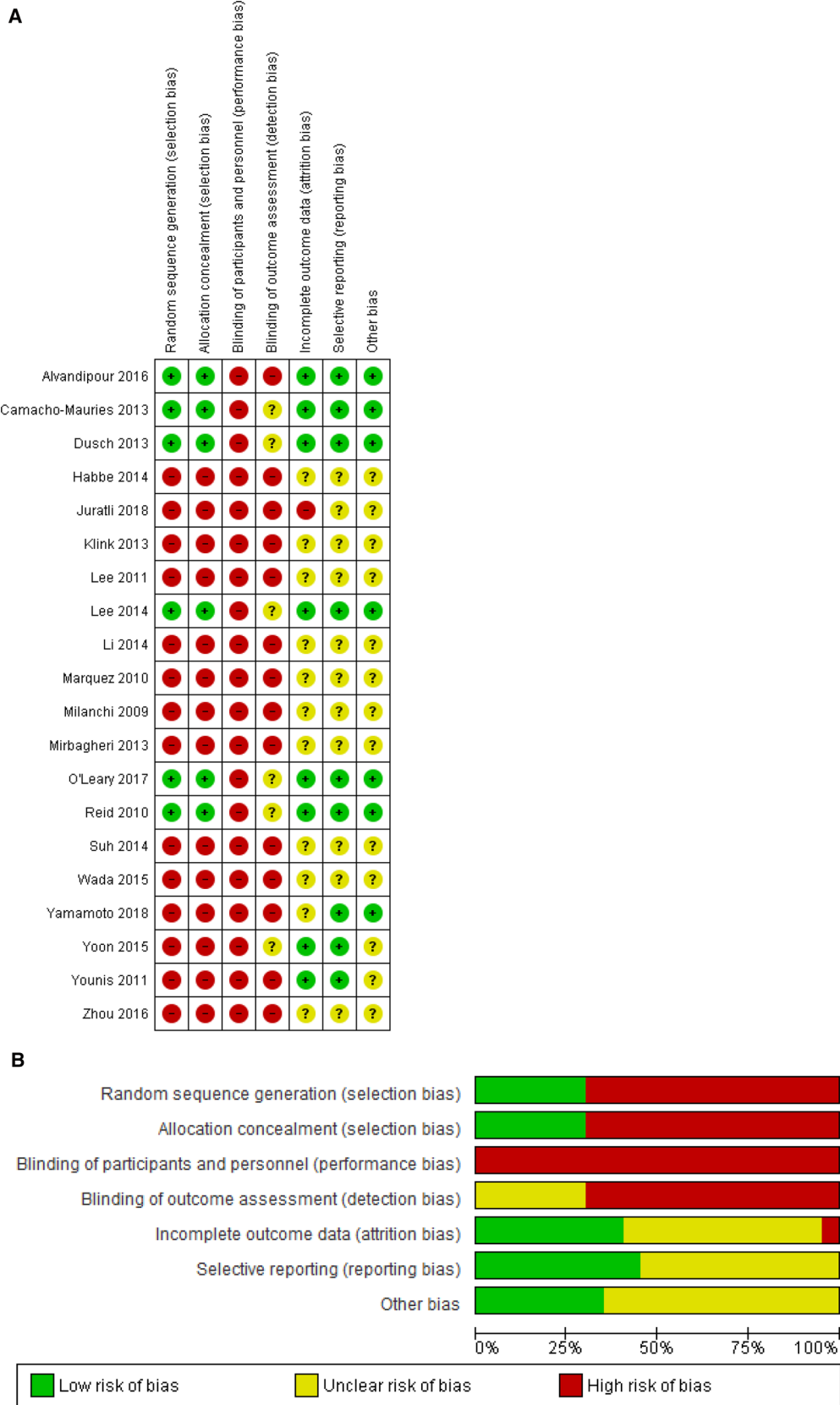


Fig. 3 a Risk of bias summary. b Risk of bias graph

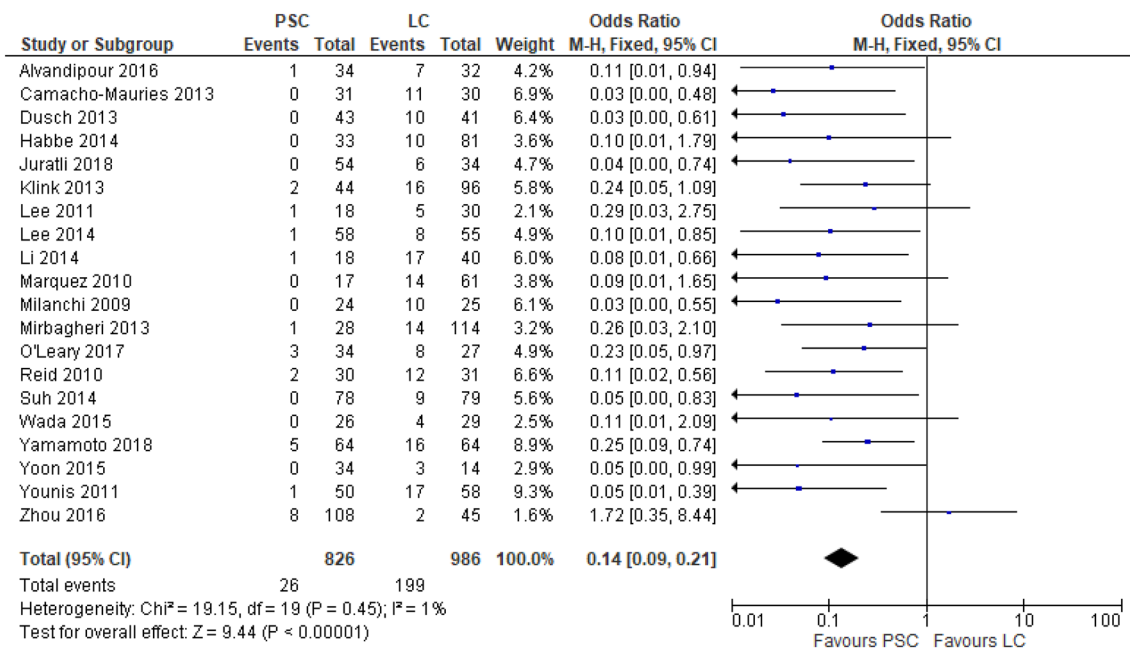


Fig. 4 Meta-analysis of experimental and observational studies: incisional SSI rate in PSC vs. LC

Table 2 Clinical significance of the statistical difference in incisional SSI rates between PSC and LC

Endpoints	RRR	ARR (95% CI)	NNT (95% CI)
All studies	5.41	0.170 (0.143, 0.198)	6 (5, 7)
RCTs	7.52	0.229 (0.166, 0.291)	6 (3.4, 6)
RCTs including ileostomy only	5.64	0.240 (0.156, 0.324)	5 (3.1, 6.4)

PSC purse-string skin closure, LC linear skin closure, SSI surgical site infection, RRR relative risk reduction, ARR absolute risk reduction, NNT numbers needed to treat, 95% CI 95% confidence interval

Subgroup meta-analysis of the data from randomized controlled trials

Six RCTs with low risk of bias and evidence level 1b were included.

SSI rate

The SSI rate was reported in all included RCTs including 230 PSC patients and 216 LC patients [22–24, 29, 34, 35]. The fixed effects model was utilized given the low statistical among-study heterogeneity ($I^2=0\%$). The SSI rate was 3% (7/230) in PSC vs. 25.9% (56/216) in LC. This difference was both statistically and clinically significant [OR (95% CI)=0.10 (0.04, 0.21); $p<0.0001$] [NNT (95% CI)=6 (3.4, 6)] (Fig. 6a) (Table 2).

Two of the six RCTs included patients with ileostomies or colostomies. Another subgroup analysis of RCTs

including patients with loop ileostomy only was performed to determine whether colostomy was a confounding factor. Four RCTs (including 141 PSC patients and 131 LC patients) reported incisional SSI rates in patients with loop ileostomy only [22, 24, 34, 35]. The fixed effects model was utilized as the heterogeneity was low ($I^2=0\%$). SSI rate was 4.3% (6/141) in PSC vs. 28.2% (37/131) in LC. This difference was both statistically and clinically significant [OR (95% CI)=0.12 (0.05, 0.28); $p<0.0001$] [NNT (95% CI)=5 (3.1, 6.4)] (Fig. 6b; Table 2).

Secondary outcomes

Operating time was reported in all RCTs (230 PSC vs. 216 LC) [22–24, 29, 34, 35]. The fixed effects model was utilized as heterogeneity was low ($I^2=16\%$). The difference in operating time between PSC and LC was not statistically significant [MD (95% CI)=0.48 (–3.28, 4.24); $p=0.80$] (Fig. 6c).

Five RCTs reported length of hospital stay (199 PSC vs. 186 LC) [22, 24, 29, 34, 35]. The fixed effects model was utilized as the statistical among-study heterogeneity was low ($I^2=0\%$). No statistical significance was found in the mean difference in length of stay between PSC and LC [MD (95% CI)=–0.26 (–0.82, 0.30); $p=0.37$] (Fig. 6d).

Three RCTs reported wound healing time (119 PSC vs. 116 LC) [23, 29, 35]. Statistical among-study heterogeneity was high ($I^2=90\%$; $\text{Tau}^2=117.5$). Hence, the random-effects model was utilized.

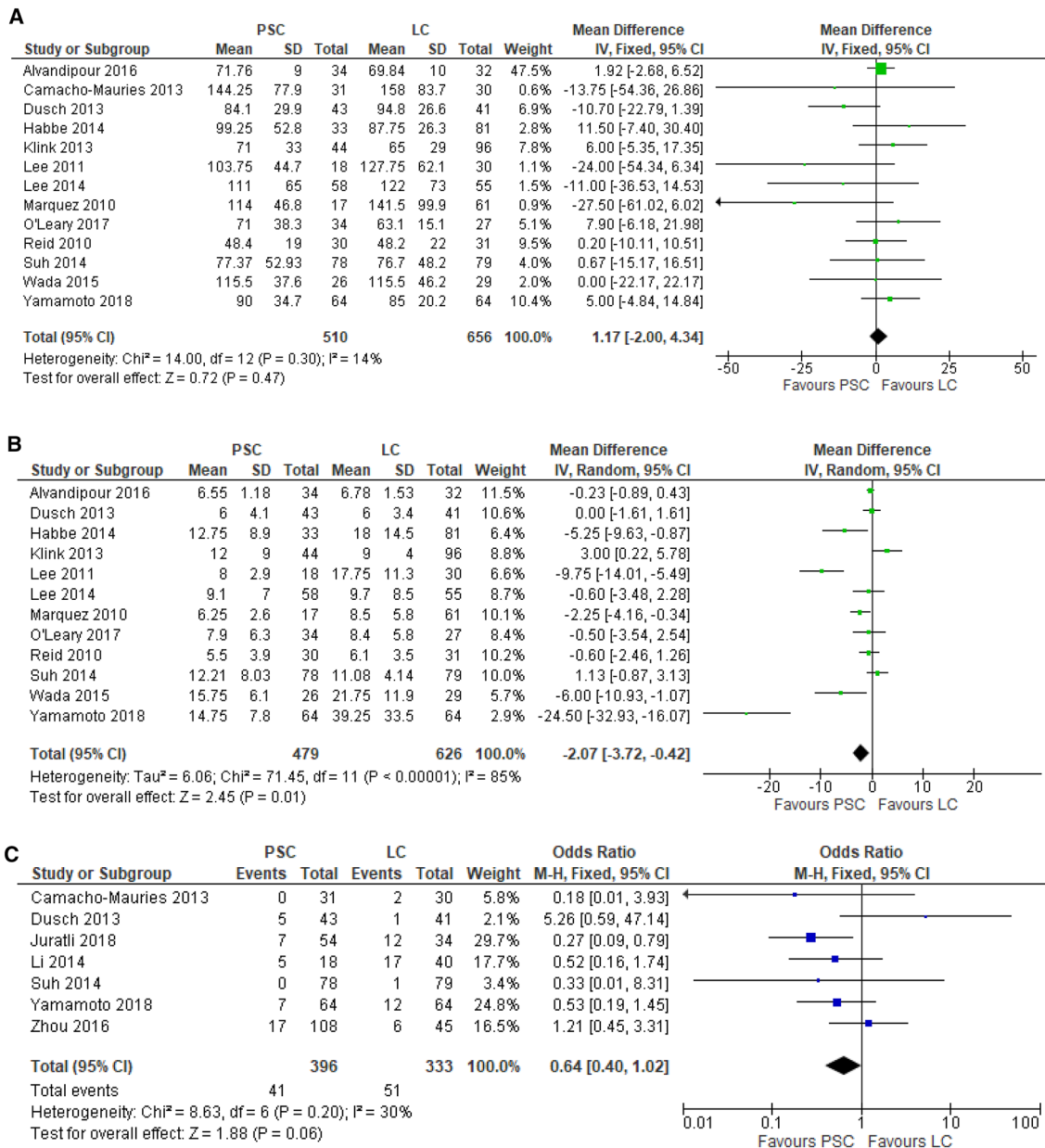


Fig. 5 Meta-analysis of experimental and observational studies: secondary outcomes in PSC vs. LC. **a** Operating time. **b** Length of hospital stay. **c** Incisional hernia rate

The mean difference in healing time between PSC and LC was not statistically significant [MD (95% CI) = -1.94 (-14.98, 11.09); *p* = 0.77] (Fig. 6e).

Clinical significance

Relative risk reduction (RRR), absolute risk reduction (ARR), and number needed to treat/harm (NNT) for primary endpoint in meta-analysis of all studies, subgroup meta-analysis of RCTs, and subgroup meta-analysis of RCTs including patients with loop ileostomy only are shown in Table 2. The

difference in the primary endpoint, namely, SSI rate, was clinically significant favoring PSC over its counterpart.

Sensitivity analysis and publication bias

A sequential exclusion of the abstract with no full text and studies with the highest risk of bias was performed for sensitivity analysis. The findings were not affected by such exclusions. Publication bias was found in the meta-analysis of the data from all studies (asymmetry in the funnel plot of precision; Egger’s *p* = 0.002; Begg and Mazumdar *p* = 0.021)

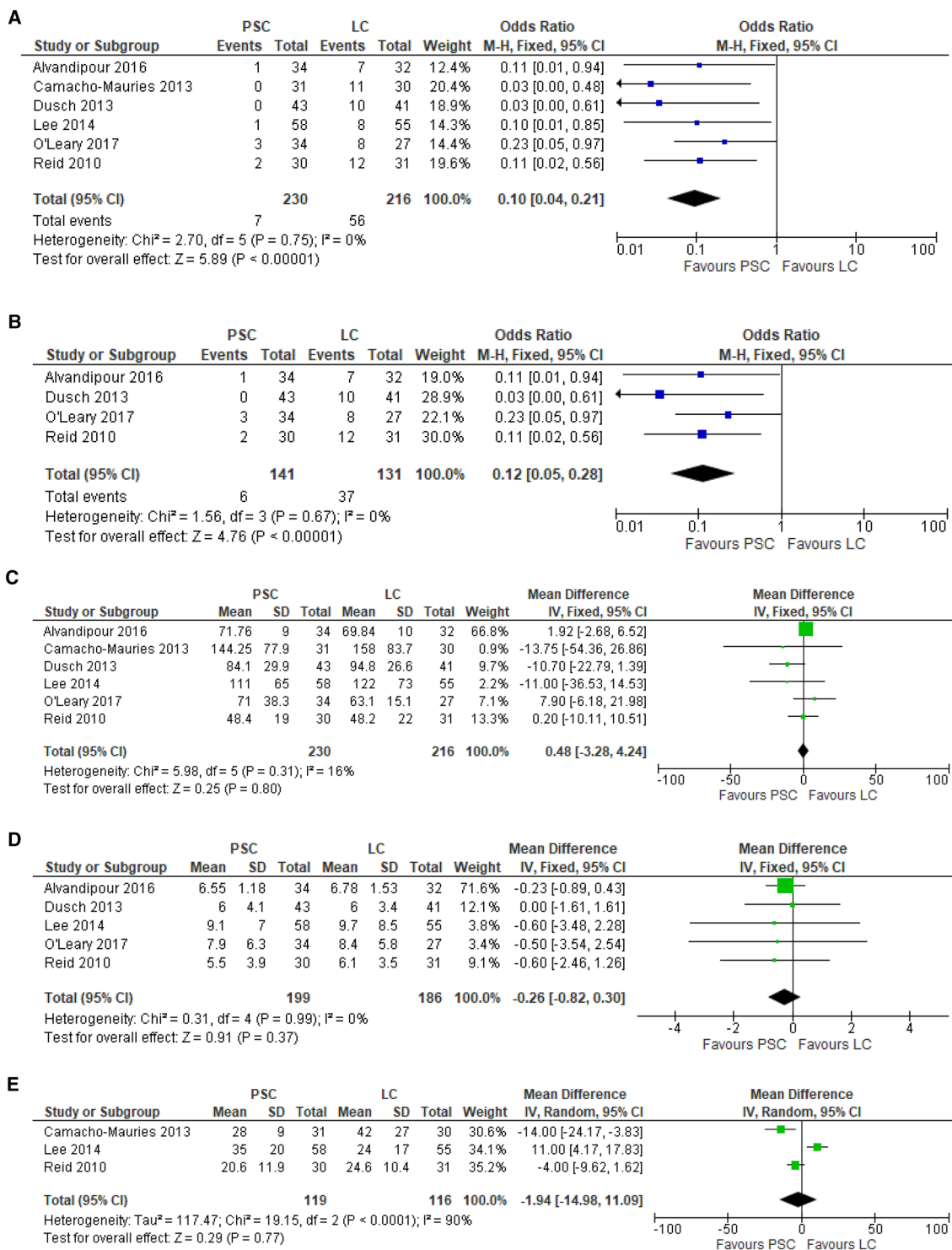


Fig. 6 Subgroup meta-analysis of experimental studies (PSC vs. LC): **a** incisional SSI rate. **b** Incisional SSI rate in patients with loop ileostomy only. **c** Operating time. **d** Length of hospital stay. **e** Healing time

(Fig. 7a) (Supplements 6 and 7) and in the subgroup meta-analysis of RCTs (asymmetry in the funnel plot of precision; Egger’s $p=0.007$; Begg and Mazumdar $p=0.024$) (Fig. 7b) (Supplements 8 and 9). No publication bias was found in

the subgroup meta-analysis of RCTs including patients with loop ileostomy only (no asymmetry in the funnel plot of precision; Egger’s $p=0.103$; Begg and Mazumdar $p=0.308$) (Fig. 7c) (Supplements 10 and 11).

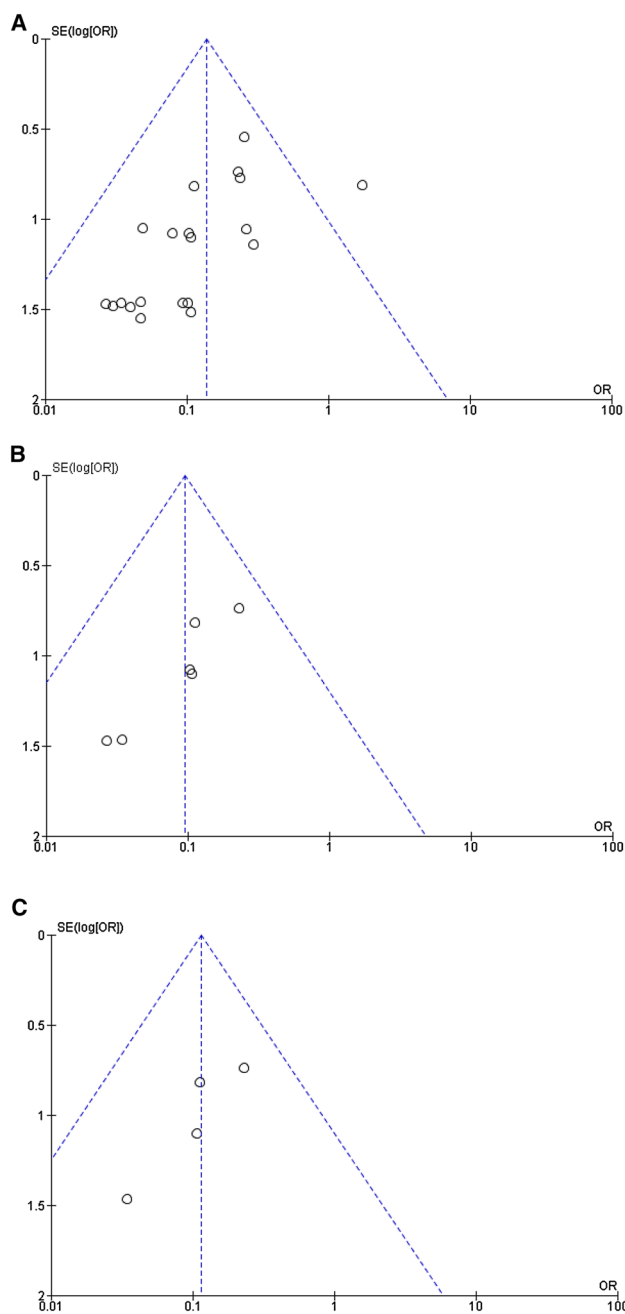


Fig. 7 Funnel plots: **a** meta-analysis of experimental and observational studies. **b** Subgroup meta-analysis of experimental studies. **c** Subgroup meta-analysis of experimental studies including patients with ileostomy only

Discussion

Interpretation of the results

The main finding of this meta-analysis was that PSC was associated with decreased SSI rates. Clinically sound conclusions can, however, be drawn only in patients undergoing loop ileostomy reversal. Due to publication bias, the impact

of skin closure techniques on SSI rates following colostomy reversal is unclear and should be studied separately. Another potential confounder was the use of biologic mesh, which has become increasingly common practice. In the studies published so far, the role of biologic meshes in the development of SSI was not addressed.

Most secondary endpoints have no temporal relationship to skin closure techniques. Operating time varies depending on a number of factors such as adhesions, mobilization, and anastomosing technique. Skin closure techniques contribute the least to operating time. The same applies to length of hospital stay, wound healing time, and incisional hernia rates. There might be a correlation between SSI and incisional hernia, even though it was impossible to establish in this meta-analysis. The timing and metrics of patient-reported outcomes (PRO) were heterogeneous and did not allow for external validity. Some studies reported Patient and Observer Scar Assessment Scale (POSAS) or Body Image Questionnaire (BIQ) scores [24], whereas others reported 10-point visual analog scales [22, 23, 35], or non-validated 4- or 5-point Likert scales [23, 29, 32, 34].

Existing evidence

The finding that PSC yielded lower SSI rates compared to the LC is consistent with the previous systematic reviews. A meta-analysis found that PSC yielded a 3% SSI rate which compared favorably to other closure techniques such as loose primary closure, secondary closure, delayed primary closure, and primary closure with drain [11]. When compared to LC, PSC yielded statistically significant lower SSI rates [OR (95% CI)=0.12 (0.02, 0.40)]. This finding is remarkably close to our result of SSI rate of 3.1% [OR (95% CI)=0.14 (0.09, 0.21); $p < 0.0001$]. Another meta-analysis showed decreased SSI rates after PSC as compared to LC [2.4% vs. 29.6%; OR (95% CI)=0.083 (0.03, 0.21); $p < 0.001$] [12]. A more recent meta-analysis of four RCTs reported significantly decreased SSI rates after PSC as compared to LC [6.79% vs. 25.67%, ARR (95% CI)=0.25 (0.15, 0.36); $p < 0.00001$, NNT=4] [42]. There was no statistically significant difference between the two groups in terms of length of stay, operative time, and wound healing time. Both aforementioned meta-analyses found improved patient cosmetic satisfaction after PSC, although among-study heterogeneity was very high. However, none of the previously published meta-analyses censored studies with colostomy, thereby introducing a confounding effect of colostomy factor.

Strengths and limitations

The strength of this meta-analysis was a scrupulous literature search of several databases, which allowed the inclusion of

more clinical studies including prospective randomized trials. The evaluation of the metrics of clinical significance made it possible to reach methodologically and clinically sound conclusions. Moreover, the subgroup analysis of all RCTs as well as RCTs including patients with loop ileostomy only strengthened the core finding deriving from the analysis of observational studies.

The main limitation of this meta-analysis was that majority of the eligible studies involved a small sample size. Seven of 20 included studies involved patients with colostomy. Despite the experimental design, all RCTs were subject to high risk for performance and detection bias. There was heterogeneity in the definition of study interventions, such as midline laparotomy, technique of anastomosing, technique of closure of the stoma site layers.

Clinical and scientific implications

The evidence provided in this meta-analysis is sufficient to favor PSC over LC as a skin closure technique following loop ileostomy reversal to reduce incisional SSI rates. However, the limitations of the existing evidence should be taken into account. The optimal type of suture for PSC and the diameter of the central skin defect are yet to be determined. The rate of incisional SSI should be considered the only outcome associated with skin closure technique.

Further studies on this subject should use a standardized technique and focus on the SSI rate. Moreover, the timing of the patient-reported outcomes should also be standardized (e.g., 30 days postoperatively), and they should be based on previously validated questionnaires avoiding self-established 4- or 5-point Likert scales. Future larger scale experimental design studies including patients with loop ileostomy only (undergoing reversal with biologic mesh) with the null hypothesis built using the findings of this meta-analysis would add to the existing evidence. Based on inequality design given an α -error of 0.05 and statistical power of 80%, the required sample size is at least 72 patients (36 patients in each arm). Such sample size was achieved in one RCT only with the statistical power of 94% at post-hoc power analysis [24]. A separate observational or experimental study including patients with colostomy only is needed. A pooled analysis of patient-level data from the included RCTs might help to determine whether incisional hernia after ostomy reversal is correlated to SSI. Moreover, such pooled analysis may make it possible to find any correlations between SSI and the details of the intervention, such as aperture size or use of packing.

Conclusions

This meta-analysis found that PSC was associated with significantly decreased rates of SSI in patients undergoing loop ileostomy reversal. Further studies are required to identify the impact of PSC on colostomy reversal as well as the role of biologic mesh in the development of adverse events.

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Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical approval This article does not contain any studies with human participants or animals performed by any of the authors.

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