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REVIEW

Quality of life following ostomy reversal with purse-string vs linear skin closure: a systematic review

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Abstract

Background The importance of the defunctioning stoma on minimizing anastomotic leak in colorectal surgery is well established. However, a defunctioning stoma can substantially impact on quality of life (QoL). Circumferential purse-string approximation (PSA) and linear skin closure (LSC) are the most commonly performed surgical technique for reversal of stoma. The aim of this review was to systemically review and meta-analyze available randomized controlled trials (RCTs) comparing PSA and LSC.

Methods An electronic systematic search using MEDLINE databases (PubMed, EMBASE, and Web of Science) of RCTs comparing PSA and LSC was performed. Eight RCTs totalling 647 patients met the inclusion criteria and were included in this meta-analysis.

Results Patient's satisfaction is significantly lower in PSA group during the first postoperative week, but it sharply improves afterwards and no difference were noted at 1 and 6 months between the two groups. Relative risk (RR) of developing a SSI is significantly lower in PSA compared to LSC group (RR 0.16 95% CI 0.09; 0.30; $p = 0.0001$), whereas incisional hernia (RR 0.53 95% CI 0.08; 3.53; $p = 0.512$), operative time (MD − 0.06 95% CI − 0.30; 0.17; $p = 0.593$), and hospital stay (MD − 0.09 (95% CI − 0.29-0.11; $p = 0.401$) remain similar.

Discussion QoL was similar in both patients groups after the first postoperative week. PSA significantly reduced SSI rate. No difference was observed in incisional hernia rate, operative time, or length of hospital stay.

Keywords Ostomy reversal · Scar cosmesis · Surgical site infection · Incisional hernia

What does this paper add to the existing literature? This review showed that patient's satisfaction is lower in PSA group during the first postoperative week, whereas there is no difference when compared at 1 and 6 months. SSI rate is lower in PSA, whereas incisional hernia rate, operative time, and length of hospital stay are similar between the two groups.

Paper is containing original research and has not been submitted/published earlier in any journal and is not being considered for publication elsewhere.

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Introduction

The importance of the defunctioning stoma on minimizing the impact of anastomotic leak in colorectal surgery is well established [1]. However, a defunctioning stoma can severely affect the quality of life (QoL) [2]. Stoma reversal is one of the commonest colorectal procedures performed worldwide; however, timing and surgical technique are still debated, due to their associated surgical complications including anastomotic leakage and surgical site infection (SSI) [3]. Timing of reversal was thought to be one of the factors that may affect the anastomotic leakage rate. However, the surgical technique is also considered to be a key factor that influences SSI rate and length of hospital stay [4].

Barnerjee first introduced the circumferential purse-string approximation (PSA) method, which appears to be a viable alternative to the classic linear skin closure (LSC). PSA facilitates direct drainage of the stoma site leaving the wound open, and therefore theoretically lowering the SSI rate [5].

However, some authors have observed that secondary intention healing may impact on cosmesis and patient satisfaction because of scar formation [6, 7]. To date, only a few studies have been published comparing these techniques [4, 8]. In recent years, several randomized controlled trials (RCTs) have been published contributing to the evidence base, especially regarding QoL and patients' satisfaction [6, 9, 10]. With this in mind, we carried out a systematic review and meta-analysis to appraise the current evidence on the surgical outcomes, QoL, and patients' satisfaction following PSA and LSC for stoma reversal.

Material and methods

Search strategy

A systematic review was carried out according to the guidelines from the preferred reporting items for systematic reviews and meta-analyses checklist (PRISMA) [11]. Institutional review board approval was not required. We conducted an electronic systematic search using MEDLINE databases (PubMed, EMBASE, and Web of Science). Last date of research was June 30, 2018. We searched for papers published in English using the following search headings: purse-string approximation, linear conventional skin closure, colostomy/ileostomy reversal, closure of ileostomy, ileostomy wound, quality of life, and scar cosmesis. All titles were initially screened and suitable abstracts were reviewed. Last, each of the eligible publication reference section was also scanned for other potential articles (Fig. 1).

Inclusion/exclusion criteria

The articles had to meet the following criteria publication and report in order to be included in the analysis: (a) randomized controlled trial study design, (b) patients undergoing PSA and LSC for colostomy/ileostomy closure, and (c) have clear research methodology.

Data extraction

The following data were retrieved from the selected publications and entered in a data extraction form by two investigators (VL, ER): author, study year, country, study design, patients, gender, age, body mass index (BMI), primary diagnosis, and comorbidities. All data were entered independently by both investigators in two separate databases and only compared at the end of the reviewing process to reduce the selection bias. Finally, a third person (MK) reviewed the database. Duplicates were erased and the discrepancies were clarified.

Study quality assessment

Two authors (ER, FC) independently assessed the methodological quality of the selected trials by using the he Cochrane risk-of-bias tool [12]. This tool evaluates the following criteria: (1) the method of randomization, (2) allocation concealment, (3) baseline comparability of study groups, and (4)

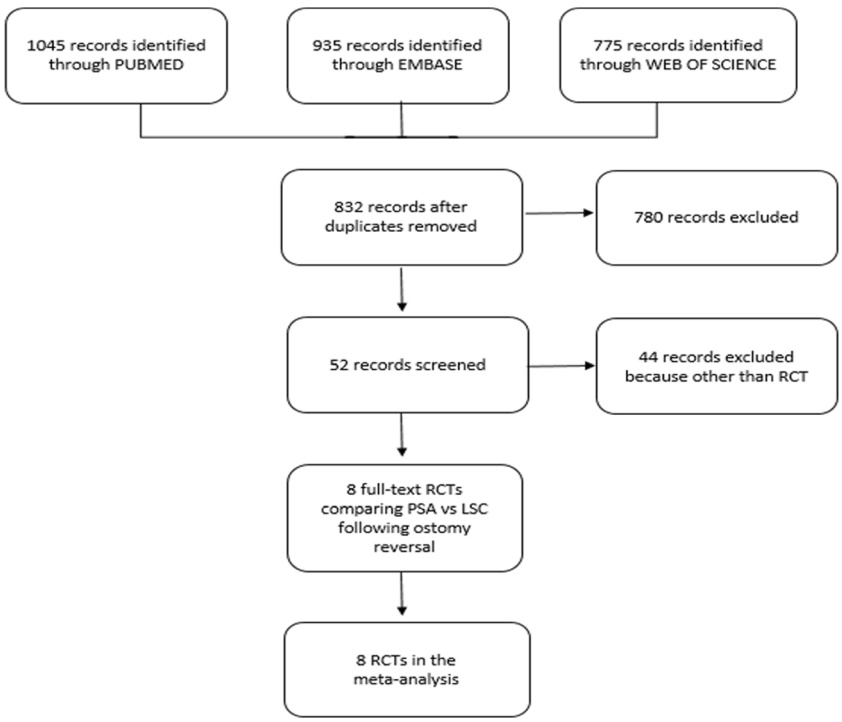

Fig. 1 Flowchart of studies retrieved from literature search

blinding and completeness of follow-up. Trials were graded as follows: A, adequate; B, unclear; and C, inadequate on each criterion. Thus, each RCT was graded as having low, moderate, or high risk of bias (Fig. 2). Disagreements were solved by discussion.

Statistical analysis

The results of the systematic review were summarized qualitatively into Frequentist meta-analysis. For pooled risk ratio, an inverse-variance-weighted random effects meta-analysis was performed by conventional methods using DerSimonian-Laird estimator for estimate between-study variance (τ^2) [13]. Continuity correction of 0.5 in studies with zero cell frequencies [14]. Heterogeneity among the studies was evaluated by I^2–index and Cochran Q test. Statistical heterogeneity was considered significant when $p < 0.10$ or I^2–index was > 50% Wald type 95% confidence interval were computed for pooled measure; otherwise, 95% confidence interval for I^2–index were calculated according Higgins and Thompson [15]. Small study and publication bias effects were assessed using visual inspection of funnel plot and by *Trim and Fill* method [16]. Egger tests were applied [17]. Prediction interval for treatment effect of a new study is calculated according to Borestein [18]. As sample size is not the same in all studies, we performed a sensitivity analysis by excluding one study each time and rerunning the analysis to verify the robustness of the overall results (leave-one-out diagnostic) [19]. *Z*-score test was performed Two-sided p value were considered statistically significant when < 0.05. All analyses and figures were carried out using R version 3.4.0 software [20].

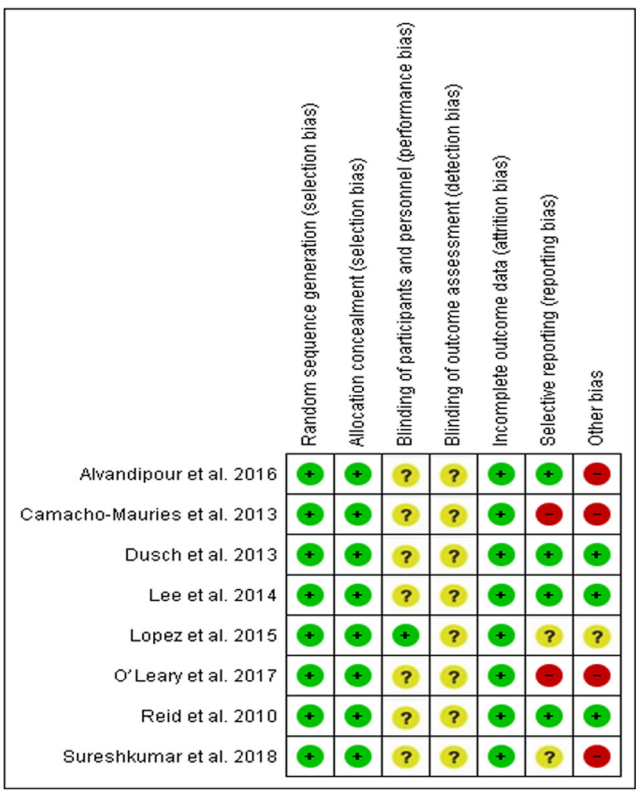

Fig. 2 Quality assessment of studies comparing PSA to LSC

Outcomes of interest

The following outcomes were used to assess and compare the PSA and LSC in patients undergoing ileostomy/colostomy closure. The primary outcomes were patient's satisfaction on scar cosmesis, QoL, SSI, (intended as any superficial or deep infection in the surgical site that occurred between day 1 and day 30 of the postoperative period), and incisional hernia. The secondary outcomes were hospital stay and operative time.

Quality of life assessment tools

The Patient and Observer Scar Assessment Scale (POSAS) was developed by Draaijers et al. to evaluate burn scars [21]. Later, the scale was proven to be reliable and valid for the subjective assessment of linear scars. The patient component of the POSAS is the only scale describing subjective symptoms such as itchiness and pain, although not considering how these interfere with patient's quality of life. The patient component of the POSAS contains seven questions: six applying to the scar-related pain, pruritus, color, thickness, relief, and pliability, and one applying to the patient's overall opinion of the scar. Each of these is scored on a scale of 1–10, with 1 representing the best scar or sensation and 10 representing the worst. The items are summed to a total score ranging from 7 to 70, with 7 representing the best cosmetic outcome with no related symptoms.

Body Image Questionnaire (BIQ) consists of eight items evaluating body image and cosmesis. The questionnaire comprises two scales: a body image scale (items 1–5) and a cosmesis scale (items 6–8). The first scale explores patients' perception of, and satisfaction with, their own body and evaluates patients' attitude towards their appearance. It consists of five items, scored on a scale of 1–4, with an overall score of 5 representing the best body image and an overall score of 20 representing the worst. The second scale consists of three questions assessing patients' satisfaction with the physical appearance of the scar [22, 23].

The Likert scale ranges from 1 to 7. Patients are asked to assess the degree of their satisfaction with the scar (1, very unsatisfied; 4, neither unsatisfied nor satisfied; 7, very satisfied) and to describe the scar's appearance (1, very repulsive; 4, neither repulsive nor beautiful; 7, very beautiful). Patients' overall opinion of the scar is graded on a scale of 1–10, with 1 being the lowest score and 10 the highest. The items are summed to a total score ranging from 3 to 24, with 24 representing the highest level of satisfaction with the scar [24].

The SF-36 version 2 (SF-36v2) is a 36-item, patient reported survey of patient health consisting of eight sections. The result of each section is reported on a 0–100 scale with each question carrying equal weight. The eight sections are vitality, physical functioning, bodily pain, general health perceptions, physical role functioning, emotional role functioning, social role functioning, and mental health. The higher the score obtained, the less disability and vice versa. The SF-36v2 is a widely accepted reliable QoL tool assessing general and specific cohorts of population on the impact of disease. It can also differentiate the health benefits produced by a variety of different treatments [25].

Cosmetic outcome was assessed by a visual analogue scale (VAS) from 0 to 10, with 0 representing the worst and 10 the best possible outcome.

Results

Literature search and study characteristics

Two thousand seven hundred and fifty-five publications were found by using the aforementioned search criteria. After removing duplicates, 832 publications were further examined. Further screening found that only eight RCTs [6, 9, 10, 26–30] met the inclusion/exclusion criteria (Fig. 1).

Patient characteristics and follow-up

Six hundred and forty-seven patients were included in this analysis. Three hundred and thirty-one patients (51.1%) were in the PSA group. There were 354 males (60.9%) Alvandipour et al. [26] did not report the gender. The median age and BMI was 53.6 years and 24.9, respectively; 7.4% patients ($n = 43/581$) were diabetic and 24.7% ($n = 57/230$ had hypertension. The majority of patients (59.8%, $n = 339$) had a primary resection and subsequent ileostomy for neoplastic indication. The mean (range) interval for stoma reversion was 115 days (51–198). Four hundred twenty-five (72.5%) patients had a reversal of an ileostomy, while 101 (27.5%) a colostomy reversal. Notably, Camacho-Mauries et al. [27] did not clarify the type of ostomy closure (Table 1).

Scar cosmesis assessment

Five studies [6, 9, 10, 27, 29] used the Likert scale, three studies the [9, 26, 28] POSAS scale, and three the [26, 27, 30] VAS questionnaire. BIQ and the F-36v2 were chosen in combination to other scar cosmesis assessment tools in two studies [9, 28]. The median compliance (range) in fully answering the questionnaires was 95.3% (61.3–100%). The follow-up was 6 months in three studies [6, 27, 28], 3 months in two studies [9, 26] and, 1 month in the remaining three studies [10, 29, 30]. The mean satisfaction score is significantly lower in PSA during the first postoperative week, but it sharply improves afterwards, with no difference identifiable at 1 or 6 months postoperatively.

Table 1 Demographic and clinical characteristics of patients undergoing ostomy reversal with PSA and LSC technique

	PSA $n = 331$	LSC $n = 316$
Median age (years)	52.8	54.4
Median BMI (kg/m^2)	24.8	25
Gender		
Male	162 (54.5%)	192 (63.6%)
Female	127 (45.5%)	110 (36.4%)
Primary diagnosis		
Malignacy	174 (59.8%)	165 (59.7%)
Benign disease	117 (40.2%)	111 (40.3%)
Type of ostomy		
Ileostomy	238 (79.3%)	187 (82.7%)
Colostomy	62 (20.7%)	39 (17.3%)

Alvandipour et al. [26] noted that POSAS score was higher at day 7 postoperatively in the LSC group ($p = 0.022$), but similar in both groups at months 1 and 3 postoperatively. Interestingly, Sureshkumar et al. [9] observed a substantial improvement in scar cosmesis in PSA group during the first postoperative month (mean POSAS score at day 7 was 65.30 and 83.40, respectively; $p = 0.012$). Likewise, in both the Sureshkumar and Lopez articles [9, 10], the Likert score showed a significantly improved patient satisfaction in PSA group during the first postoperative month ($p = 0.001$ and $p = 0.012$; respectively). However, this difference was not confirmed using SF-36v2 ($p = 0.388$) [9]. Conversely, both Lee and O'Leary did not observe any significant discrepancies in the satisfaction Likert scores between the groups postoperatively ($p = 0.15$ and $p = 0.14$; respectively) [6, 29]. Reid et al. showed similar results using the VAS scale [30]. None of the three studies [6, 27, 28] analyzing the two groups at 6 months postoperatively noted a difference in the patients' satisfaction ($p > 0.05$) (Table 2).

Meta-analysis

Surgical site infection Using the random effect model, the standardized relative risk (RR) resulting from eight studies [6, 9, 10, 26–30] was 0.16 (95% CI 0.09; 0.30; $p = 0.0001^*$). The prediction lower and upper limits are 0.08 and 0.34, respectively (Fig. 3a). There is no significant heterogeneity ($I^2 = 0.0\%$, 95% CI 0.0–28.5%; $p = 0.85$). Again, both Funnel plot (Fig. 3a) and Egger test ($p = 0.007$) did not observed any evidence of publication and small study bias. The adjusted *Trim and Fill* risk ratio is 0.19 (95% CI 0.11–0.33) is

Table. 2 Study findings and scar cosmesis assessment

Author	Year	Patients	SSI rate	Scar cosmesis assessment tool	Assessment intervals	Results	Compliance
O'Leary et al. [6]	2017	34 (PSA) 27 (LSC)	8% (PSA) 30% (LSC)	Likert scale	30 days and 6 months postoperatively	No difference between the 2 groups	88.2% 92.6%
Sureshkumar et al. [9]	2018	40 (PSA) 40 (LSC)	7.5%(PSA) 42.5% (LSC)	POSAS Likert scale F–36v2	90 days postoperatively	PSA group was more satisfied at 1 month ($p = 0.001$)	100% 100%
Lopez et al. [10]	2015	61 (PSA) 60 (LSC)	1.6% (PSA) 10% (LSC)	Likert scale	30 dayspostoperatively	PSA group was more satisfied at 1 month ($p = 0.012$).	100% 100%
Alvandipour et al. [26]	2016	34 (PSA) 32 (LSC)	2.9% (PSA) 21.8% (LSC)	POSAS VAS	1, 3, 7, 30, and 90 days postoperatively	PSA group was more satisfied at 1 and 3 months ($p = 0.043$).	100% 100%
Camacho-Mauries et al. [27]	2013	31 (PSA) 30 (LSC)	0% (PSA) 36.6% (LSC)	Likert scale VAS	6 months postoperatively	PSA group was more satisfied at 6 months ($p = 0.0001$)	100% 100%
Dusch et al. [28]	2013	43 (PSA) 41 (LSC)	0% (PSA) 24% (LSC)	POSAS BIQ	30 daysand 6 months postoperatively	No difference between the 2 groups	100% 100%
Lee et al. [29]	2016	58 (PSA) 55 (LSC)	2% (PSA) 15% (LSC)	Likert scale	7, and, 30 days postoperatively	No difference between the 2 groups	100% 100%
Reid et al. 30	2015	30(PSA) 32(LSC)	6% (PSA) 38% (LSC)	VAS	30 days postoperatively	No difference between the 2 groups	93.3% 61.3%

close to the original estimation. Sensitivity analysis shows the robustness of observed results.

Incisional hernia The standardized RR resulting from four studies [9, 10, 27, 28] was 0.53 (95% CI 0.08; 3.53; $p = 0.512$). The prediction lower and upper limits are 0.00 and 610.32, respectively (Fig. 4a). Again, there is no heterogeneity across the studies ($I^2 = 66.1\%$, 95% CI 19.0; 85.8%; $p = 0.102$). For this outcome, both Funnel plot (Fig. 4b) and Egger test ($p = 0.08$) does show evidence of publication and small study bias. The adjusted *Trim and Fill* risk ratio is 1.83 (95% CI 0.26; 13.34) is different from the original estimation. Sensitivity analysis shows the robustness of observed results.

Operative time Using the random effect model again, the standardized mean difference resulting from five studies [6, 26, 28–30] was − 0.06 (95% CI − 0.30; 0.17; $p = 0.593$). The prediction lower and upper limits are − 0.62 and 0.49, respectively (Fig. 5a). There is no significant heterogeneity ($I^2 = 24.0\%$, 95% CI 0.0; 47.2%; $p = 0.162$). Neither the Funnel

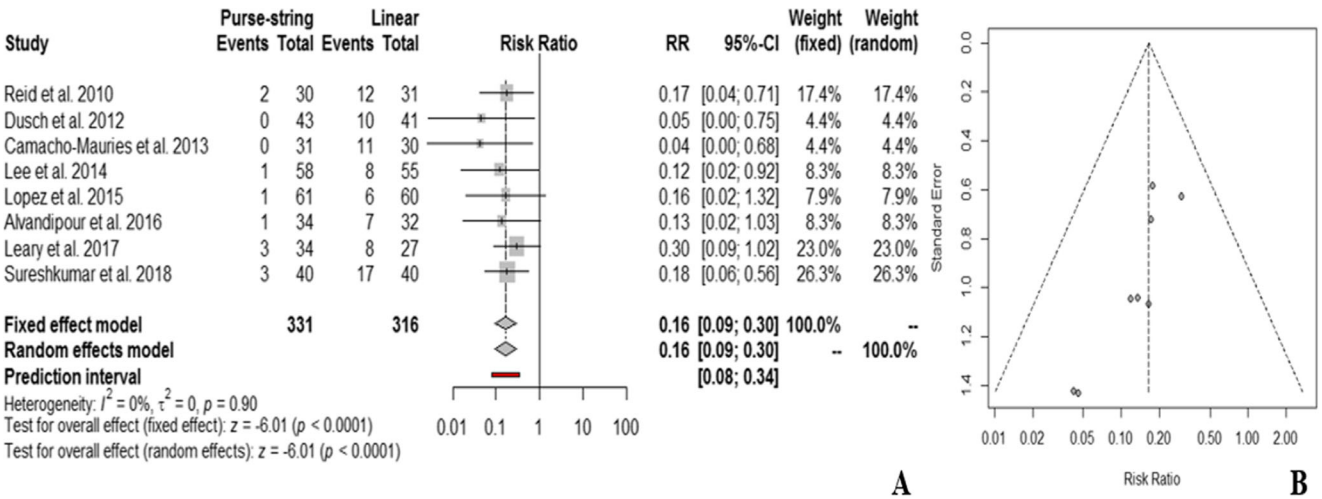

Fig. 3 **a** Forest plot for surgical site infection. **b** Funnel plot for surgical site infection

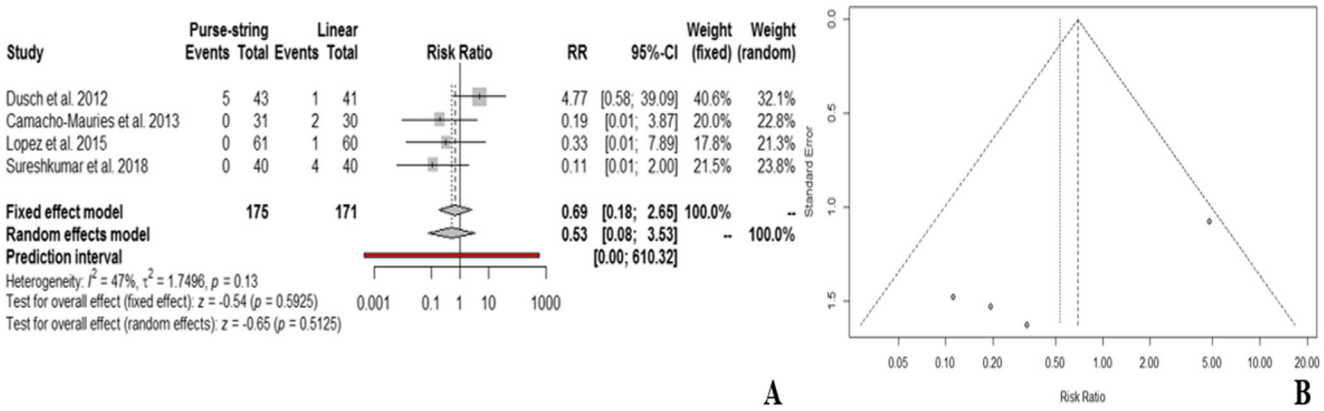

Fig. 4 **a** Forest plot for incisional hernia. **b** Funnel plot for incisional hernia

plot (Fig. 5b) or Egger test ($p = 0.252$) observe evidence of publication and small study bias. The adjusted *Trim and Fill* risk ratio is − 0.12 (95% CI − 0.36; 0.10) is close to the original estimation. Sensitivity analysis shows the robustness of observed results.

Hospital stay Using the random effect model again, the standardized mean difference resulting from five studies [6, 26, 28–30] was − 0.09 (95% CI − 0.29–0.11; $p = 0.401$). The prediction lower and upper limits are − 0.41 and 0.24, respectively (Fig. 6a). There is no heterogeneity noted ($I^2 = 0.0\%$, 95% CI 0.0–0.0%; $p = 0.999$). Again, both Funnel plot (Fig. 6b) and Egger test ($p = 0.393$) did not observe evidence of publication and small study bias. The adjusted *Trim and Fill* risk ratio is − 0.09 (95% CI − 0.28–0.12) is close to the original estimation. Sensitivity analysis shows the robustness of observed results.

Discussion

This review showed that patient's satisfaction is significantly lower in the PSA group during the first postoperative week, but sharply improves afterwards with no differences when compared with LSC at month 1 and 6 postoperatively. In addition, it supports some evidence that PSA has a lower rate of SSI, but similar differences in terms of incisional hernia rate, operative time, and hospital stay between the two groups.

SSI following ostomy closure is likely to be an underestimated complication; however, its prevalence in the literature is variable, ranging 10 to 42.5%. SSI can have a profound effect on both patients' satisfaction and health care.

PSA closure leaves a central drainage for exudative and suppurative fluid, and therefore it is understandable why the rate of SSI is considerably reduced, promoting granulating tissue that fills the central pit which may result in better cosmetic

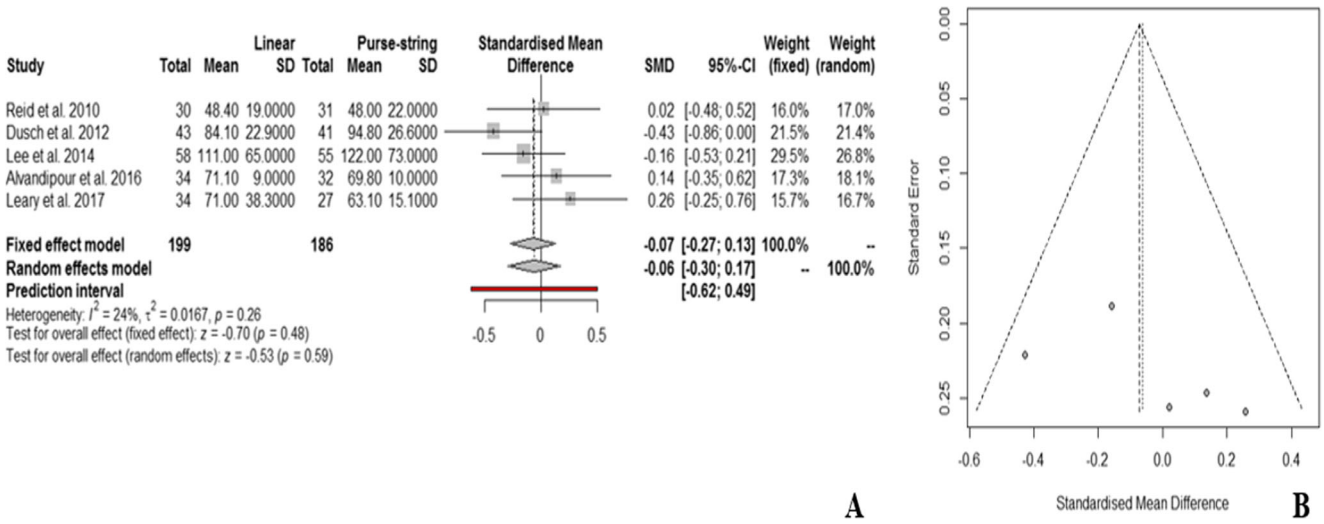

Fig. 5 **a** Forest plot for operative time. **b** Funnel plot for operative time

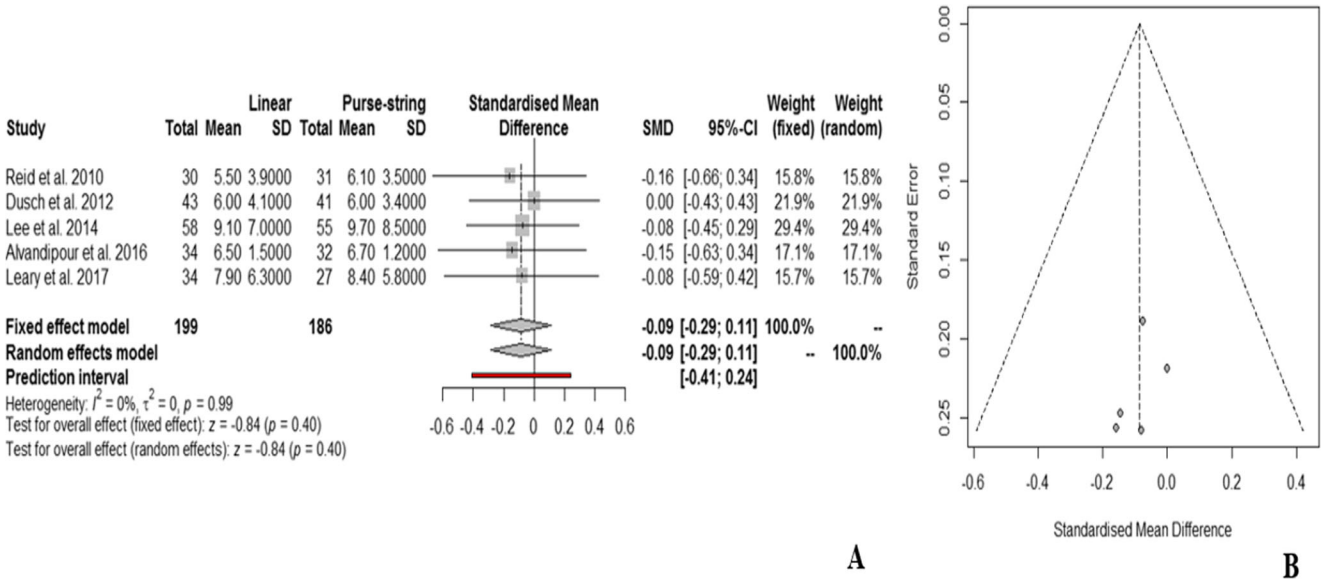

Fig. 6 **a** Forest plot for hospital stay. **b** Funnel plot for hospital stay

appearance. Historically, SSI has been the commonest surgical complication following ostomy closure. Downside of LSC method is the lack of drainage of subcutaneous fluids, which can result in abscess formation. Ultimately, infection (SSI/Abscess) are critical factors that impact wound healing and can result in poor formation [31].

Interestingly, some of the included studies observed higher satisfaction rates in the LSC cohort at week 1 following reversal. However, there is considerable lack of sub-group analysis to assess if those having SSI had worse satisfaction scores. It is conceivable that having an early SSI is associated with disapproval, due to a slow return to work or activity, as they would have to attend more outpatient dressing clinics, until the wound is fully healed. In addition, sequelae due to overuse of antibiotics or other medications are not examined. There is strong evidence that antibiotic course use in the treatment of concomitant SSI can worsen gastrointestinal symptoms [32]. Given the lower SSI rate in PSA group, it is likely that patients rarely have antibiotics administered and less potential for medication-related issues.

QoL and cosmesis are important metrics in surgery, especially when operating for benign diseases. Unfortunately, this review cannot draw conclusions from the available data on patient satisfaction, impairment to body image, or functional outcomes due to considerable heterogeneity in clinical measurements utilized. Based on this review, we conclude that a future trial combining both the POSAS and the Likert score would be needed to assess scar cosmesis and satisfaction. The POSAS provides specific information regarding the scar healing process and the scar-related symptoms, whereas the Likert score looks at the perception of the scar. Having a standardized assessment would allow future studies to steer the surgeon towards the most appropriate skin closure method in stoma reversal as well as in other surgical procedures [33].

In conclusion, the patients' satisfaction is similar in the two groups beyond the first postoperative week. We show that PSA significantly decreases the SSI rate compared to LSC, whereas incisional hernia, operative time, and hospital stay remain similar.

Compliance with ethical standards

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

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