World J Surg (2018) 42:3171–3178
https://doi.org/10.1007/s00268-018-4603-0

SCIENTIFIC REVIEW

Early Closure of Defunctioning Loop Ileostomy: Is It Beneficial for the Patient? A Meta-analysis

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Published online: 27 March 2018

Abstract

Objective To perform a meta-analysis to answer the question, whether early closure (EC) of defunctioning loop ileostomy may be beneficial for patient as compared with late closure (LC) without exceeding the risk of surgical-related morbidity.

Design Medline and the Cochrane Trials Register were searched for trials published up to November 2016 comparing EC (defined as ≤14 days from the index operation in which the ileostomy was performed) versus LC for stoma closure after rectal surgery. Meta-analysis was performed using Review Manager 5.0. Inclusion criteria

Main outcome measures Overall morbidity rate, anastomotic leakage rate, and wound infection rate within 90 days after elective surgery.

Results Six studies were included and analyzed, yielding 570 patients (252 in EC group and 318 in LC). Meta-analysis showed no significant difference in the overall morbidity rate between the EC and LC groups (OR 0.63; 95% CI, 0.22–1.78; $P = 0.38$). Despite a significant higher wound infection rate of stoma site (OR 3.83; 95% CI 2.14–6.86; $P < 0.00001$), meta-analysis showed no significant difference in the anastomotic leakage rate between the EC and LC groups (OR 0.63; 95% CI 0.22–1.78; $P = 0.38$). Moreover, both stoma-related complications (OR 0.46; 95% CI 0.24–0.86; $P = 0.02$) and small bowel obstruction rates (OR 0.11; 95% CI 0.06–0.20; $P < 0.00001$) were significantly lower in the EC group than in the LC group, respectively.

Limitations Heterogeneity of the studies

Conclusion This meta-analysis suggests that EC of a defunctioning loop ileostomy is effective and safe in careful selected patients without increasing overall postoperative complications. This promising strategy should be proposed in patients in order to reduce stoma-related complications.

Introduction

Fecal diversion using a defunctioning loop ileostomy is usually performed as a means to protect low extraperitoneal colorectal anastomosis "after partial mesorectal excision or total mesorectal excision" or colo-anal anastomosis [1–3], and to alleviate the consequences of anastomotic leakage, such as reoperation [4–7]. Defunctioning loop ileostomy is usually preferred to colostomy by most surgeons because it is easy to construct and close, and provides excellent deviation of the fecal matter without

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creating a risk of injury to the pericolic vascular arcade. While most patients will keep their stoma for at least 3 months, ileostomy-related complications (i.e., dermatitis, parastomal infection, electrolyte imbalance, dehydration from high stoma output, renal insufficiency, stenosis, retraction, necrosis, prolapse, stricture, or readmission) will occur in approximately half of the patients [8–11]. Thus, it still remains a major psychological handicap (in relation to altered body schema, odor, and uncontrolled emissions) and causes significant physical stress, leading to an adverse effect on the quality of life [12]. Furthermore, the scheduled stoma closure may be also delayed by the need to wait for the completion of postoperative adjuvant therapy [13].

While the feasibility of early stoma closure (EC) (within 2 weeks of the index operation) has been reported by several pilot studies [14–16] with promising results, this is not common practice. The available literature is scarce and unclear about the optimal timing for reversal of defunctioning loop ileostomy. One prospective randomized multicenter trial with 186 carefully selected patients demonstrated that early stoma closure on day 8 was safe, with no reported increase in the perioperative complication rate [17]. Despite the higher rate of wound complications (including the stoma site), EC was associated with lower ileostomy-related complications and small bowel obstruction rates. In a systematic review of the literature [18], no conclusion was drawn because of heterogeneity between the published studies. Since then, three additional studies [19–21] have provided evidence of the feasibility of EC of defunctioning loop ileostomy.

Given this information, we decided to perform a meta-analysis to answer the question of whether EC of defunctioning loop ileostomy may be beneficial for patients in minimizing stoma-related complications without excessive risk of surgery-related morbidity (i.e., overall morbidity and anastomotic leakage).

Materials and methods

Search strategy

We performed a systematic review of the literature published up to November 2016 by searching abstracts in Medline, the Cochrane database, and the Cochrane Clinical Trials Registry. The medical subject headings (MeSH) and keywords searched for individually and in combination were as follows: “ileostomy,” “surgical stoma,” “defunctioning stoma,” “early,” “reversal,” “closure,” and “close.” Bibliographies cited in an identified article were also searched manually to retrieve other suitable studies. We also screened the references of the relevant studies to check for potentially relevant articles.

Inclusion and exclusion criteria

Criteria for eligibility included in this meta-analysis were: (1) studies that compared EC (defined as ≤14 days from the index operation in which the ileostomy was performed) versus late stoma closure (LC) (defined as at least 8 weeks after rectal surgery); (2) studies that reported at least one of the outcome measures (i.e., death and postoperative complications such as re-intervention, small bowel obstruction/ileus, anastomotic leak, global wound infection, and stoma-related complications). These items are defined below. Types of studies included were randomized controlled trials (RCTs), case-matched studies, and comparative prospective studies.

Exclusion criteria included: (1) studies that involved pediatric patients (<18 years of age); (2) studies that included defunctioning colostomies or other types of small bowel stomas; (3) non-English papers; and (4) animal or laboratory studies. Risk of bias was analyzed across outcomes (incomplete outcome data), across studies, and across interpretation (reasons to doubt results).

Data extraction and review

Critical appraisal and data extraction were conducted independently by two reviewers (BM, AV), and discrepancies were resolved by consensus intervention of a third investigator (AA).

The following individual data were independently extracted for each included study using standardized extraction forms: general data (study design, year, sample size); characteristics of patients (age, gender, indication for the index operation); main features of the intervention (indication for ileostomy, timing of ileostomy closure, surgical technique of the anastomosis); and clinical outcomes.

The primary outcome was overall postoperative morbidity, defined as any complication occurring during the hospital stay or within 30 or 90 days after stoma closure. Secondary outcomes included death during the hospital stay or within 30 or 90 days after stoma closure, re-intervention during the hospital stay or within 30 or 90 days after stoma closure, stoma-related complications during the hospital stay or within 30 or 90 days after stoma closure, and specific surgical complications such as small bowel obstruction and/or ileus, anastomotic leak (i.e., pelvic colorectal leak and leak at the site of stoma closure), and wound infection.

Stoma-related complications were defined as the presence of any complications occurring between the index operation and stoma closure (i.e., dermatitis, parastomal infection, electrolyte imbalance, dehydration from high stoma output, renal insufficiency, stenosis, retraction,

necrosis, prolapse, stricture, or readmission). The quality of the studies was checked using the PRISMA statement and JADAD Scale [22, 23].

Statistical analysis

All statistical analyses were performed using Review Manager 5.0 software (Cochrane Collaboration, Oxford, UK). A fixed model was used if there was no evidence of heterogeneity; otherwise, a random-effects model was used. Heterogeneity was assessed using the I^2 statistic, with values >50% considered to indicate significant heterogeneity. Odds ratios (ORs) were calculated for each trial from the number of evaluable patients, and 95% confidence intervals (CIs) were calculated to confirm the effect-size estimation and test criteria. The Mantel–Haenszel OR was calculated for dichotomous variables (or Peto OR when necessary). The P value for the overall effect was calculated using the Z test, with significance set at $P < 0.05$. Sensitivity analysis and estimation of publication bias were also performed.

Results

Population characteristics

Details of the initial search results and refined inclusion are presented in the flowchart (Fig. 1). Sixty-eight full-text articles were reviewed, and 20 appropriate studies were potentially assessed to be included in the meta-analysis. Of these, 14 were excluded because they had a cohort of <10 patients [24, 25], the early ileostomy closure group was >14 days from index operation [26–29], there were insufficient details from which to extract or calculate the necessary data from the published results [15, 30, 31], and because they included reversal of jejunostomy or colostomy in the ileostomy cohort [14, 16, 32, 33]. The remaining six studies were analyzed, yielding 570 patients in two retrospective case series [19, 34] (one of which was a case-matched study [19]), one prospective case series [35], and three RCTs [17, 20, 21]. The JADAD Scale was >3 for the RCTs, and the PRISMA checklist was completed for the other studies.

All anastomoses were investigated radiologically before ileostomy closure to ensure anastomotic integrity. Patients noted as having anastomotic complications before closure did not have their ileostomy reversed early. Patients were also excluded from EC if the recovery from their index operation was complicated by one or more of the following: sepsis or active infection, organ failure, poor postoperative recovery or condition, and prolonged postoperative ileus.

Results of meta-analysis

Overall morbidity rate

Five of the six studies reported overall postoperative morbidity rates. The overall morbidity rate was 26.2% (55/210) in the EC group and 30.4% (78/257) in the LC group. Meta-analysis showed no significant difference in the overall morbidity rate between the EC and LC groups (OR 0.98; 95% CI 0.63–1.53; $P = 0.95$) (Fig. 2).

Anastomotic leakage rate

Two of the six studies reported postoperative anastomotic leakage rates. The anastomotic leakage rate was 4.0% (6/150) in the EC group and 6.1% (9/148) in the LC group. Meta-analysis showed no significant difference in the anastomotic leakage rate between the EC and LC groups (OR 0.63; 95% CI 0.22–1.78; $P = 0.38$) (Fig. 3). There was no statistical difference between the two groups regarding site of anastomotic leakage.

Reoperation rate

All studies reported postoperative reoperation rates. The reoperation rate was 5.6% (14/252) in the EC group and 5.0% (16/318) in the LC group. Meta-analysis showed no significant difference in the reoperation rate between the EC and LC groups (OR 1.06; 95% CI 0.50–2.26; $P = 0.88$) (Figure 4).

Small bowel obstruction rate

All studies reported small bowel obstruction rates. The small bowel obstruction rate was 5.6% (14/252) in the EC group and 12.3% (39/318) in the LC group. Meta-analysis showed that the rate of small bowel obstruction was significantly lower in the EC group than in the LC group (OR 0.46; 95% CI 0.24–0.86; $P = 0.02$) (Figure 5).

Overall wound infection rate

All studies reported wound infection rates. The wound infection rate was 15.5% (39/252) in the EC group and 5.3% (17/318) in the LC group. Meta-analysis showed that the rate of wound infection rate was significantly lower in the LC group than in the EC group (OR 3.83; 95% CI 2.14–6.86; $P < 0.00001$) (Figure 6).

Stoma-related complication rate

Five of the six studies reported stoma-related complication rates. The stoma-related complication rate was 8.5% (20/

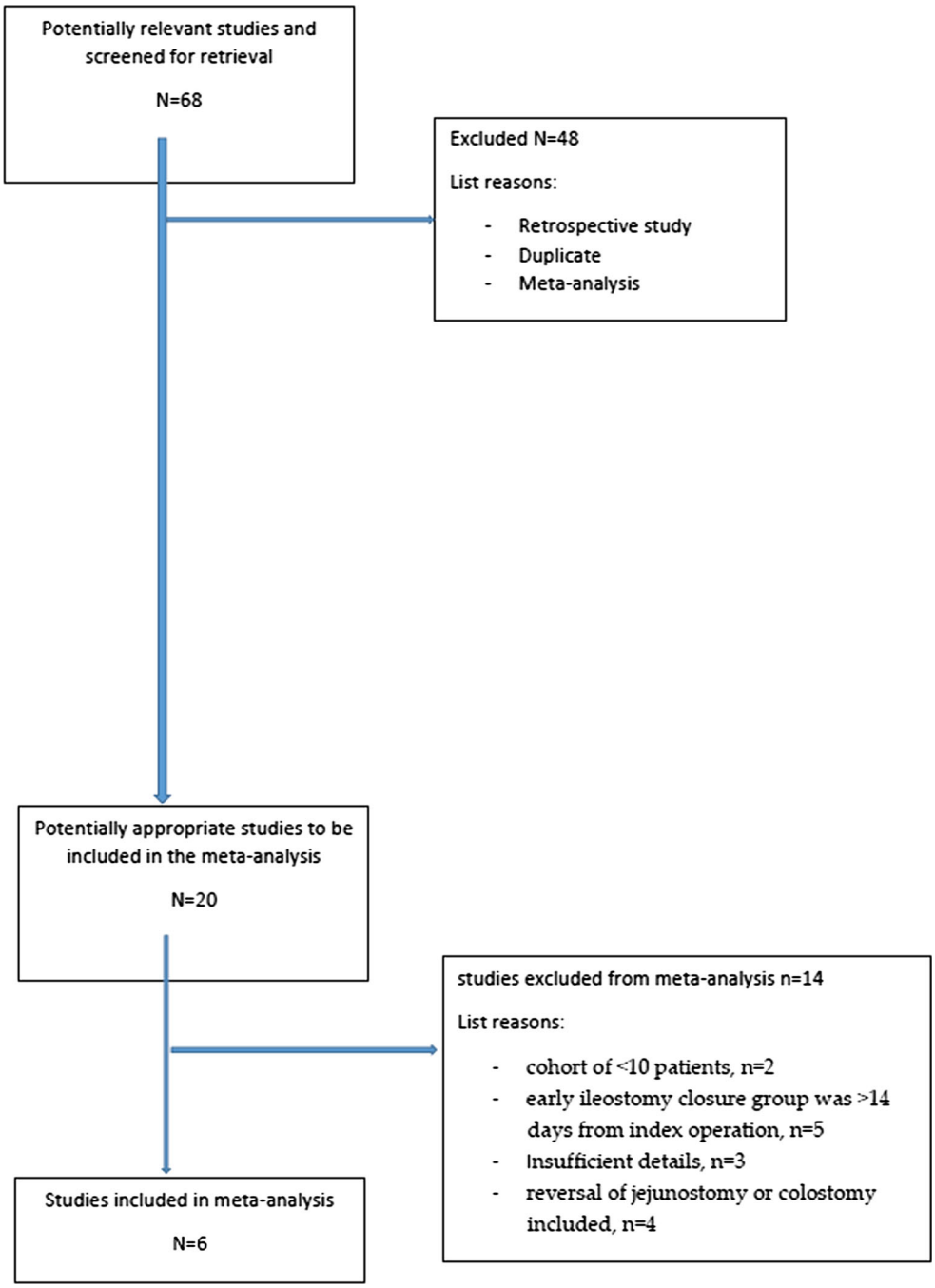

Fig. 1 Flowchart of the meta-analysis

236) in the EC group and 32.1% (99/308) in the LC group. Meta-analysis showed that the stoma-related complication rate was significantly lower in the EC group than in the LC group (OR 0.11; 95% CI 0.06–0.20; $P < 0.00001$) (Figure 7).

No deaths were reported by any of the six studies included.

Sensitivity analysis and publication bias

Sensitivity analysis and estimation of publication bias were performed with the aim of determining the significance of results. For small bowel obstruction rate, the combined OR was calculated using both a fixed-effects and a random-effects model, and the results were compared. Because statistically significant data are published more frequently than nonsignificant data, our results may be influenced by publication bias.

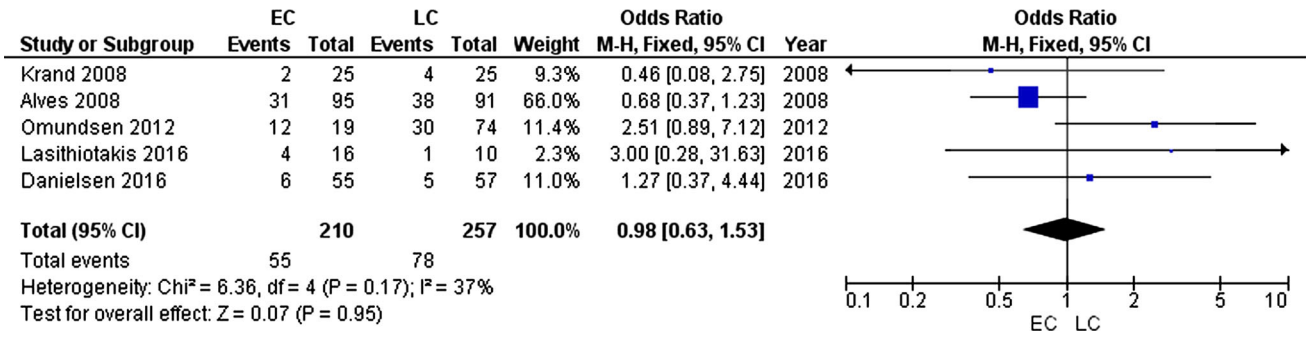

Fig. 2 Overall morbidity rate

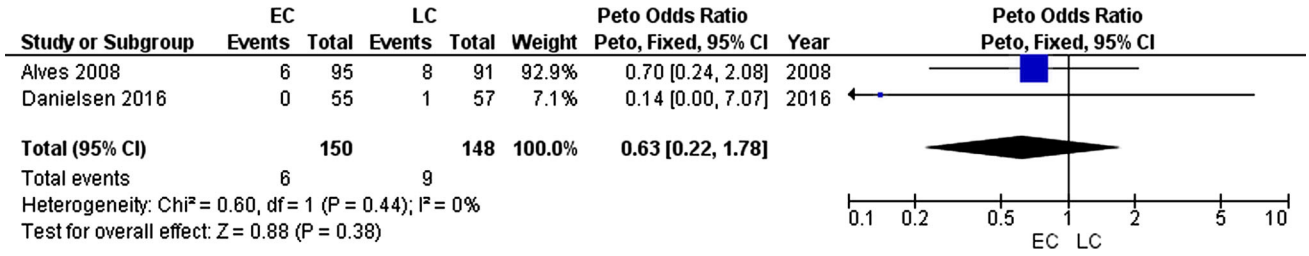

Fig. 3 Anastomotic leakage rate

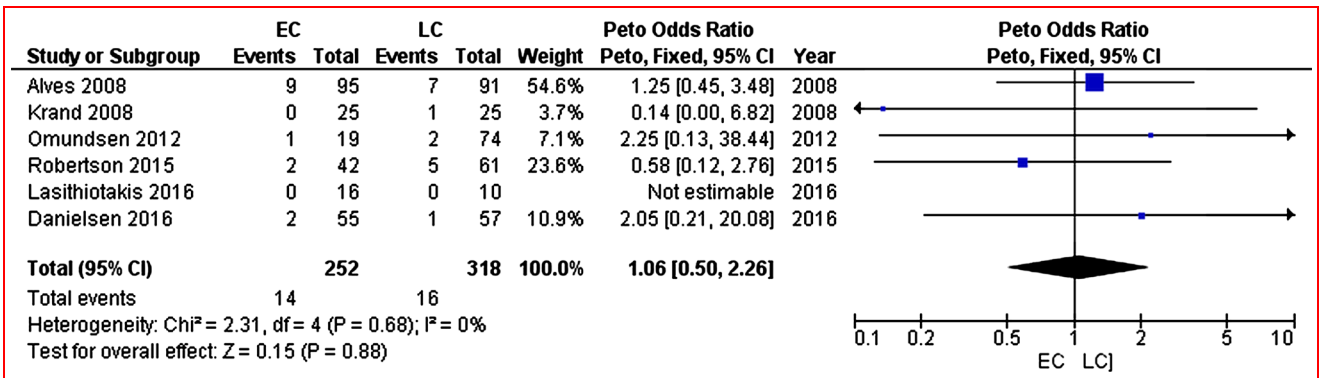

Fig. 4 Reoperation rate

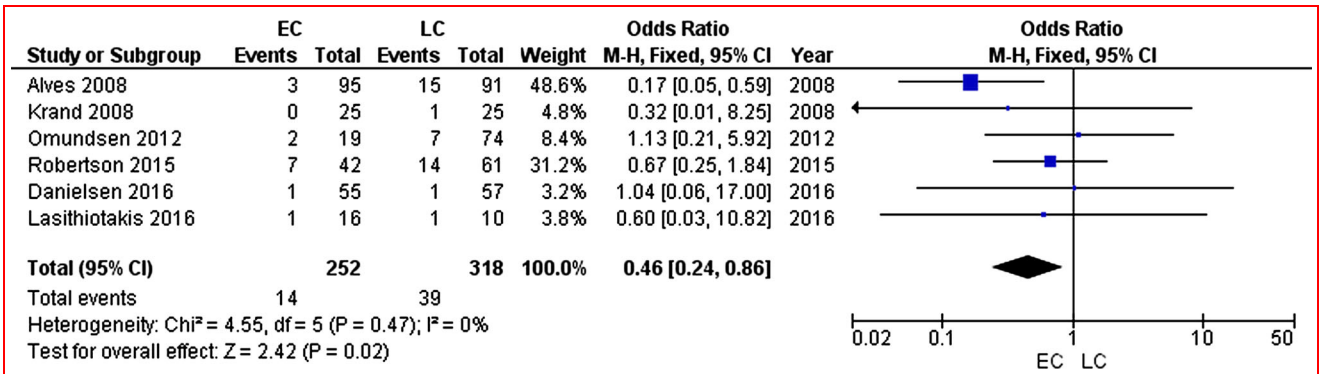

Fig. 5 Small bowel obstruction rate

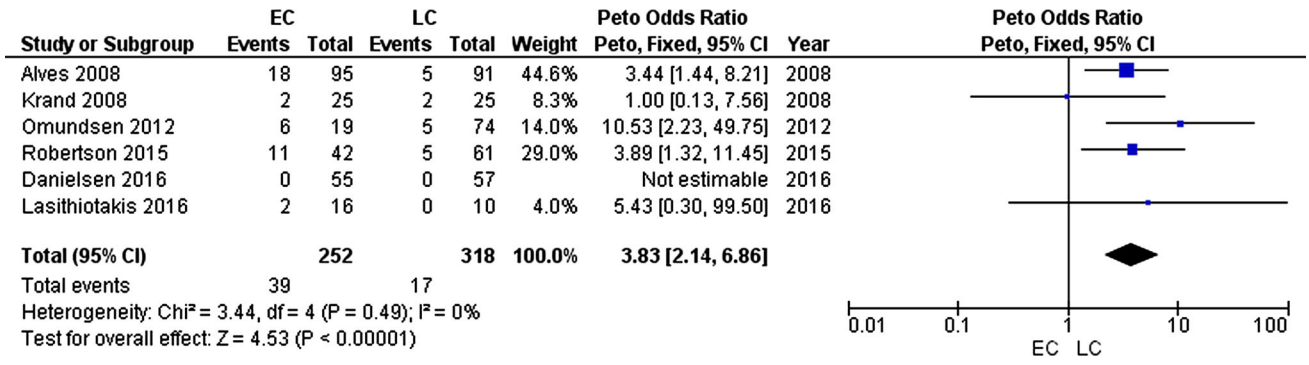

Fig. 6 Wound abscess rate

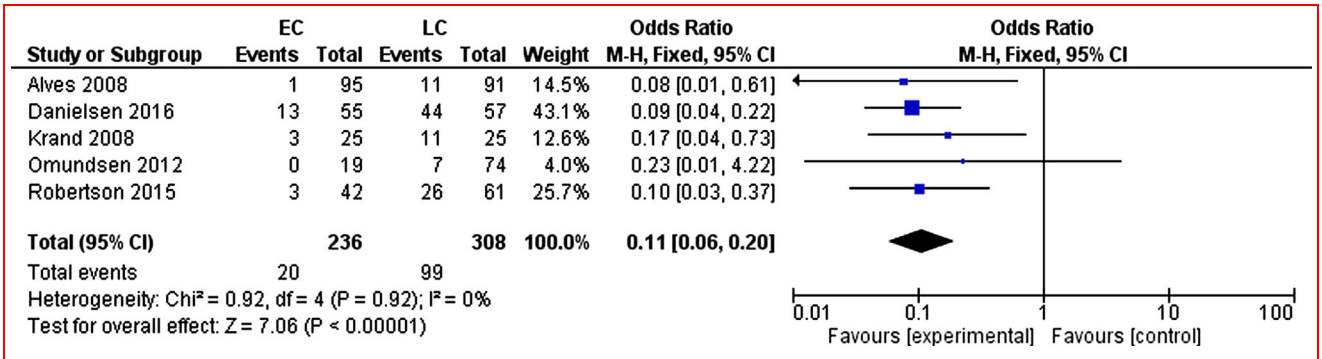

Fig. 7 Stoma-related complication rate

Discussion

The results of this meta-analysis provide evidence of the feasibility, efficacy, and safety of EC of a defunctioning loop ileostomy in carefully selected patients. This promising strategy resulted in no postoperative mortality and led to similar overall postoperative morbidity in comparison with LC. Although the wound abscess rate was significantly increased, EC reduced significantly both stoma-related complications and small bowel obstruction rates.

A defunctioning loop ileostomy is usually created to limit potentially life-threatening consequences of anastomotic leakage [1, 2]. However, three-fourths of patients undergoing rectal surgery with low colorectal anastomoses will recover without anastomotic complications [18]. Ideally, fecal diversion would only be performed in those patients who potentially develop anastomotic complications. However, the identification of patients who stand to benefit from fecal diversion cannot be accurately predicted preoperatively [36].

It is unknown how often defunctioning loop ileostomy is reversed after 8–12 weeks in routine clinical practice, while several pilot studies [14–16] have reported the feasibility of EC with promising results. The rationale behind this is to allow recovery after primary surgery, adequate healing of pelvic anastomoses, and both resolution of inflammation and reduction of adhesions around the stoma, in order to decrease the operative difficulty associated with ileostomy closure. However, operative times during early stoma closure are similar to [17] or shorter than [19–21, 35] those during LC, indicating no additional technical difficulties.

As previously described, EC significantly reduced stoma-related complication rates. This is particularly relevant because these complications can occur in approximately half of the patients, leading to an increased readmission rate [9, 10], delayed adjuvant treatment, impaired quality of life, and high economic costs [10, 11].

However, post-closure wound infections were significantly higher after EC. Therefore, to improve patient outcomes clinicians should take action to reduce wound infection [37]. According to a recent meta-analysis of RCTs, purse-string closure leads to significantly fewer surgical site infections and achieves better cosmetic outcomes following stoma reversal in comparison with conventional primary closure [38]. Thus, wounds may take longer to heal using this approach. Although the optimal

skin closure method remains controversial, purse-string closure should be used following early stoma closure [39, 40].

This promising strategy allows the surgeon to perform stoma closure during the same admission as the index operation. EC avoids the need for community stoma nursing, ongoing stoma appliances, and subsequent readmission to treat stoma-related complications or undertake ileostomy reversal. Early stoma closure can introduce cost savings by reducing the use of stoma appliances, bags, and skin protection creams, in addition to less need for home nursing and fewer hospital readmissions [19, 20, 35].

However, careful selection of the patients (i.e., both uneventful postoperative recovery and integrity of pelvic anastomoses) remains crucial to maintaining low overall postoperative morbidity, which is the aim of early stoma reversal [41]. In the literature, approximately one-third of patients were deemed inappropriate for early reversal [17, 20] (i.e., asymptomatic anastomotic leakage, small bowel obstruction, and medical complications contraindicating a new elective surgery). Selection rates in the recent randomized study reached two-thirds of the patients [21]. In this regard, imaging plays a pivotal role because a false-negative radiologic result may lead to inadequate early ileostomy closure, thereby increasing the risk of anastomotic septic complications. Standard retrograde (via the anus) or antegrade (via the distal limb of the ileostomy) fluoroscopic contrast enema examinations have been considered as standard methods to assess anastomosis integrity [42]. However, Alves et al. [17] have reported a 7.5% false-negative radiologic result rate leading to re-intervention in two-thirds of these patients. Gouya et al. [43] have recently reported that computed tomography (CT) antegrade colonography is more accurate than antegrade fluoroscopy for evaluation of both low anastomosis and surrounding space patency. Using CT with water-soluble contrast, Danielsen et al. [21] reported no false-negative radiologic results.

Up to now, it has been recommended to begin adjuvant chemotherapy up to 8 weeks from the date of surgery for colorectal cancer [44]. However, defunctioning loop ileostomy has a major impact on compliance with the adjuvant treatment. For this reason, some patients insist on stoma closure before the beginning or at the end of adjuvant chemotherapy cycles, while other patients sometimes stop therapy prematurely. However, some surgeons and oncologists are reluctant to acquiesce because stoma closure is associated with a postoperative morbidity rate of 17% [41], which may affect the administration of adjuvant chemotherapy. Tulchinsky et al. [13] reported recently that EC before the start of adjuvant chemotherapy appears to be reserved for patients with a lower pathologic stage. In the future, EC should be proposed for these carefully selected patients, who should meet the inclusion criteria of (1) absence of anastomotic leakage detected by CT and (2) uneventful postoperative outcomes.

A number of limitations to our study must be considered. We have included three RCTs, two retrospective studies, and one prospective study. We conducted sensitivity analyses and subgroup analyses including the level of study (randomized clinical and non-randomized trial), which helped to address the potential issue of clinical heterogeneity as far as possible. The proportion of rectal cancer was not uniform, varying from 35 to 100%. Furthermore, the method used to assess pelvic anastomosis integrity is also a concern. A final limitation concerns the fact that relatively few patients underwent preoperative radiotherapy [21], and we were thus unable to separate irradiated patients from non-irradiated patients and perform a subgroup analysis.

In conclusion, this meta-analysis suggests that EC (within 14 days) is feasible. However, additional studies are needed to accurately define which individuals stand to benefit from EC among carefully selected patients without increasing the overall postoperative morbidity. EC was also found to significantly decrease both stoma-related complications and small bowel obstruction rates. Further studies are needed to assess this strategy with regard to completeness of adjuvant chemotherapy.

Acknowledgments We thank Hugh McGonigle, from Edanz Group (www.edanzediting.com/ac), for editing a draft of this manuscript.

Author contribution Conception and design: BM, AA. Acquisition of data: BM, JL, AV. Analysis and interpretation of data: BM, AA. Drafting the article: BM, AA. Final approval: JL, AA.

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