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SYSTEMATIC REVIEWS AND META-ANALYSIS

The influence of diverting loop ileostomy vs. colostomy on postoperative morbidity in restorative anterior resection for rectal cancer: a systematic review and meta-analysis

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Abstract

Background The aim of this systematic review and meta-analysis was to evaluate the morbidity of loop ileostomy (LI) and loop colostomy (LC) creation in restorative anterior resection for rectal cancer as well as the morbidity of their reversal.

Methods PubMed, EMBASE, MEDLINE via Ovid, and Cochrane Library were systematically searched for records published from 1980 to 2017 by three independent researchers. The primary endpoint was overall morbidity after stoma creation and reversal. Mantel-Haenszel odds ratio (OR) was used to compare categorical variables. Clinical significance was evaluated using numbers needed to treat (NNT).

Results Six studies (two randomized controlled trials and four observational studies) totaling 1063 patients (666 LI and 397 LC) were included in the meta-analysis. Overall morbidity rate after both stoma creation and closure was 15.6% in LI vs. 20.4% in LC [OR(95%CI) = 0.67 (0.29, 1.58); $p = 0.36$] [NNT(95%CI) = 21 (> 10.4 to benefit, > 2430.2 to harm)]. Morbidity rate after stoma creation was both statistically and clinically significantly lower after LI [18.2% vs. 30.6%; OR(95%CI) = 0.42 (0.25, 0.70); $p = 0.001$; NNT(95%CI) = 9 (4.7, 29.3)]. Dehydration rate was 3.1% (8/259) in LI vs. 0% (0/168) in LC. The difference was not statistically or clinically significant [OR(95%CI) = 3.00 (0.74, 12.22); $p = 0.13$; NNT (95%CI) = 33 (19.2, 101.9)]. Ileus rates after stoma closure were significantly higher in LI as compared to LC [5.2% vs. 1.7%; OR(95%CI) = 2.65 (1.13, 6.18); $p = 0.02$].

Conclusions This meta-analysis found no difference between LI and LC in overall morbidity after stoma creation and closure. Morbidity rates following the creation of LI were significantly decreased at the cost of a risk for dehydration.

Keywords Temporary fecal diversion · Morbidity rates · Loop colostomy · Rectal cancer · Ileostomy

Introduction

Temporary fecal diversion has been carried out for decades with the purpose of minimizing the clinical manifestations of anastomotic leakage following restorative surgery for resectable rectal cancer. Nonetheless, the current literature comparing anterior resection of the rectum with or without temporary stoma seems to suggest that fecal diversion does not prevent anastomotic leakage [1–4]. The question of whether diversion at surgery for rectal cancer should be accomplished by loop ileostomy (LI) or loop colostomy (LC) is still unclear. In the 1980s, two randomized controlled trials (RCTs) including left-sided resections with anastomosis for a multitude of diseases concluded in favor of LI in terms of complications related to stoma creation as well as its reversal [5, 6]. However, a decade later, another RCT including left resections for different indications warned against LI on the basis of its higher mortality [7]. The controversy grabbed the headlines again in 2001 with a retrospective study recommending LI in patients with rectal cancer due to lower morbidity rates following its creation and reversal [8]. A similar recommendation was formulated in an RCT including rectal cancer patients on the basis of the rates of parastomal hernias [9]. Though, a year later, another RCT on rectal cancer concluded that LC was to be preferred due to the high rates of postoperative ileus and obstruction following the creation of LI [10]. Moreover, LC was also recommended

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in a large multicenter prospective nonrandomized study on the basis of lower complication rates following its reversal [11]. In the last decade, a number of meta-analyses comparing LI with LC in patients undergoing left colon resections with anastomosis for different diseases endorsed LI because of its lower complication rates [12–15]. However, a recent systematic review warned against the risk of dehydration following LI in patients with preexisting compromised renal function [16]. An umbrella review of previously published systematic reviews was performed using the AMSTAR 2 quality assessment tool prior to developing the protocol for this meta-analysis. The decision to carry out this study was prompted by the fact that all previously published systematic reviews were of moderate quality only (Supplements 1 and 2). Moreover, seven out of eight such review studies had substantial heterogeneity due to the inclusion of benign and malignant diseases.

The aim of this systematic review and meta-analysis was to evaluate the morbidity of LI and LC creation in restorative anterior resection for rectal cancer as well as the morbidity of their reversal.

Materials and methods

This systematic review was performed according to the Cochrane Handbook for Systematic Reviews of Interventions [17] and follows the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) and Meta-analysis Of Observational Studies in Epidemiology (MOOSE) guidelines [18, 19]. The protocol of this systematic review was developed a priori and registered in the International prospective register of systematic reviews PROSPERO: CRD42018086630. The literature search, data retrieval, and analysis, followed by critical appraisal, were performed by three independent researchers (AC, MG, and AD); any disagreements occurring during the process were discussed and resolved by the senior authors. The research question was formulated as following:

(P) Population: adults older than 18 years old.
Intervention: temporary loop ileostomy
(C) Comparator intervention: temporary loop colostomy
(O) Outcomes: morbidity
(T) Time: following stoma creation and closure
(S) Setting: in- and outpatient

Eligibility criteria, definitions, and endpoints

Articles included in this review were all experimental and observational clinical studies comparing temporary loop ileostomy (LI) to loop colostomy (LC) performed in patients undergoing restorative rectal resections for resectable rectal cancer. Exclusion criteria were non-comparative descriptive studies; studies comparing any of the interventions of interest to an irrelevant intervention such as anterior rectal resection with no diverting ostomy.

Stoma creation was defined as index surgery, namely anterior rectal resection with either LI or LC. Stoma closure was performed after both. Surgical site infections (SSI) were defined according to the Center for Disease Control (CDC) National Nosocomial Infections Surveillance System [20]. Wound abscess and wound infection were categorized as incisional SSI. Anastomotic leak after closure was defined as either clinical or radiological.

Primary endpoint of this systematic review was overall postoperative morbidity following both stoma creation and closure. Secondary endpoints were:

1. Morbidity following stoma creation, including
   - Dehydration
   - Stoma prolapse
   - Stoma site infection
   - Parastomal hernia
2. Morbidity following stoma closure, including
   - Anastomotic leak
   - Ileus
   - Incisional SSI

Search strategy and study selection

Literature search was conducted according to recently published recommendations [21]. The Pubmed, EMBASE, Cochrane Library, and MEDLINE via Ovid databases were systematically searched using the following MeSH terms: ‘ileostomy’, ‘colostomy’, ‘rectal cancer’, ‘anterior resection’ combined with the Boolean operator ‘AND’ and all synonyms combined with the Boolean operator ‘OR’. Relevant articles were identified and the results of the search were screened through the title, abstract, and/or full text article.

Data extraction and quality assessment

The data from the included articles were collected according to predefined Microsoft Excel tables and studies were assessed for validity by three researchers independently. Collected data included author, year of publication, study design, sample size, and morbidity. Quality assessment of each individual study was performed according to Cochrane Handbook for Systematic Reviews of Interventions on the following items: selection, performance, detection, attrition, selective reporting, and other bias risks [17]. Moreover,

Newcastle Ottawa score was used to evaluate the quality of included cohort studies.

Statistical analysis

Mantel-Haenszel odds ratios with 95% confidence intervals (OR (95%CI)) were calculated for dichotomous variables. In cases when continuous variables were reported in median and interquartile range in the included studies, mean and standard deviation (SD) were estimated using Hozo's formula [22]. Statistical heterogeneity among effect estimates was assessed using Cochran Chi^2 and I^2, and between-study variance was assessed using Tau^2 statistic when the I^2 was 50% or greater [23]. Fixed-effects model of meta-analysis was utilized to analyze data with low heterogeneity. In case of high heterogeneity, random-effects model was utilized. The results of the meta-analysis were illustrated on forest plots. To assess clinical significance of the results, relative risk reduction (RRR), absolute risk reduction (ARR), and number needed to treat/harm (NNT) with 95%CI were calculated [24]. Considering that above-mentioned metrics also have variability, confidence intervals (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 [25]. Funnel plots and Egger's tests were utilized to evaluate for publication bias. A p value <0.05 was considered statistically significant. Statistical analysis was performed using RevMan (version 5.3; Nordic Cochrane Center, Cochrane Collaboration, Copenhagen, Denmark) and CMA Software (Version 3; Biostat, NJ, USA).

Results

Literature search and study selection

Details of study selection are presented in the PRISMA flowchart [Fig. 1]. Four searched databases revealed 153 records. Additional six articles were found through the references of eligible studies. Six articles were included after excluding duplicates, irrelevant articles, and articles not reporting the outcome of interest.

Description of included studies

Six studies were selected among 37 potentially eligible studies [8–11, 26, 27] totaling 1063 patients (666 LI and 397 LC). The characteristics of the included studies are provided in Table 1. Two studies were RCTs (level of evidence-1b) [9, 10], whereas the remaining four were observational studies with 2b level of evidence (1 prospective and 3 retrospective cohort studies) [8, 11, 26, 27]. All included studies were full text articles published in journals. The primary endpoint of all included studies was postoperative morbidity.

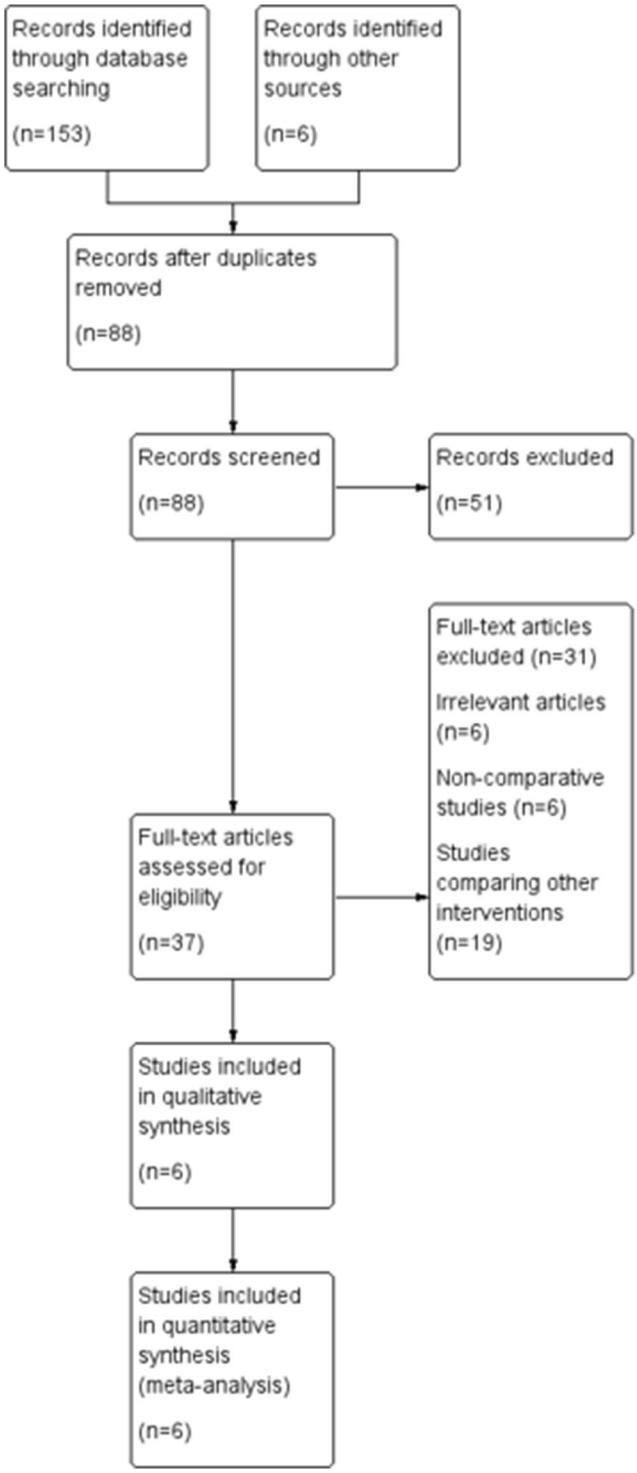

Fig. 1 PRISMA flow diagram

Quality assessment

The risk of bias summary and graph of the included studies are presented in Fig. 2. Levels of evidence according to the

Table 1 Description of included studies

Author	Publication	Design	Primary endpoint(s)	Sample size (*n*)	Number of patients with the creation of LI vs. LC	Number of patients with the closure of LI vs. LC	Tumor height from the anal verge (cm)	Preoperative chemoradiotherapy	NOS score S-C-O	Outcomes of ostomy closure were reported	Level of evidence (Oxford CEBM)
Edwards	Br J Surg 2001	Randomized controlled trial	Morbidity	70	34 vs. 36	32 vs. 31	7 (LI) vs. 6 (LC)[a]	NR	–	Yes	1b
Gastinger	Br J Surg 2005	Prospective cohort study, multicenter	Morbidity	881	407 vs. 229	407 vs. 229	7.9 (Both arms)[b]	Yes (13.5%)	4–2-3	Yes	2b
Law	Br J Surg 2002	Randomized controlled trial	Morbidity	77	39 vs. 38	35 vs. 38	6.8 (LI) vs. 6.4 (LC)[b]	NR	–	Yes	1b
Mala	Colorectal Dis 2008	Retrospective cohort study	Morbidity	72	62 vs. 10	62 vs. 10	NR	NR	4–2-3	Yes	2b
Rullier	World J Surg 2001	Retrospective cohort study	Morbidity	167	107 vs. 60	96 vs. 50	NR	NR	4–2-2	Yes	2b
Tocchi	G Chir 2002	Retrospective cohort study	Morbidity	41	17 vs. 24	NR	NR	NR	4–2-2	No	2b

[a] Median

[b] Mean

LI loop ileostomy, *LC* loop colostomy, *NOS* Newcastle Ottawa Scale, *S-C-O* Selection-Comparability-Outcome, *CEBM* Center for Evidence-Based Medicine, *NR* not reported

Oxford Centre for Evidence Based Medicine (CEBM) provided by each included study are presented in Table 1. Random sequence generation and allocation concealment to prevent selection bias was provided in two included RCTs only [9, 10]. The risk of performance and detection bias is high or unclear in all studies including RCTs. Preventing performance and detection bias by blinding surgeons to the intervention and assessment of the outcome is impracticable. Attrition, reporting, and other bias risks are low in most studies.

Meta-analysis

All six studies regardless of the evidence level and risk of bias were included in the meta-analysis.

Overall morbidity after both stoma creation and closure

Morbidity after stoma creation and closure was defined as postoperative morbidity after both index surgery, namely restorative anterior rectal resection for rectal cancer and ostomy closure. This outcome was reported in all included studies (666 LI vs. 397 LC) [8–11, 26, 27]. Statistical among-study heterogeneity was high ($I^2 = 74\%$; $\text{Tau}^2 = 0.8$); hence, random effects model was utilized. Morbidity rate was 15.6% (104/666) in LI vs. 20.4% (87/391) in LC. This difference was not statistically or clinically significant [OR (95%CI) = 0.67 (0.29, 1.58); $p = 0.36$] [NNT (95%CI) = 21 (> 10.4 to benefit, > 2430.2 to harm)] (Fig. 3a).

Overall morbidity after stoma creation

Overall morbidity after stoma creation was reported in four studies (242 LI vs. 144 LC) [8–10, 26]. Statistical among-study heterogeneity was low ($I^2 = 37\%$); hence, fixed effects model was utilized. Morbidity rate was 18.2% (44/242) in LI vs. 30.6% (44/144) in LC. The difference was both statistically and clinically significant [OR (95%CI) = 0.42 (0.25, 0.70); $p = 0.001$] [NNT (95%CI) = 9 (4.7, 29.3)] (Fig. 4a).

Dehydration after stoma creation Dehydration after stoma creation was reported in five studies (259 LI vs. 168 LC) [8–10, 26, 27]. Among-study heterogeneity was low ($I^2 = 0\%$); hence, fixed effects model was utilized. Dehydration rate was 3.1% (8/259) in LI vs. 0% (0/168) in LC. The difference was not statistically or clinically significant [OR (95%CI) = 3.00 (0.74, 12.22); $p = 0.13$] [NNT (95%CI) = 33 (19.2, 101.9)] (Fig. 4b).

Stoma prolapse Prolapse after stoma creation was reported in three studies (180 LI vs. 134 LC) [8–10]. Among-study heterogeneity was low ($I^2 = 0\%$). Fixed effects model was utilized. Stoma prolapse rates were 2.2% (4/180) in LI vs. 8.2%

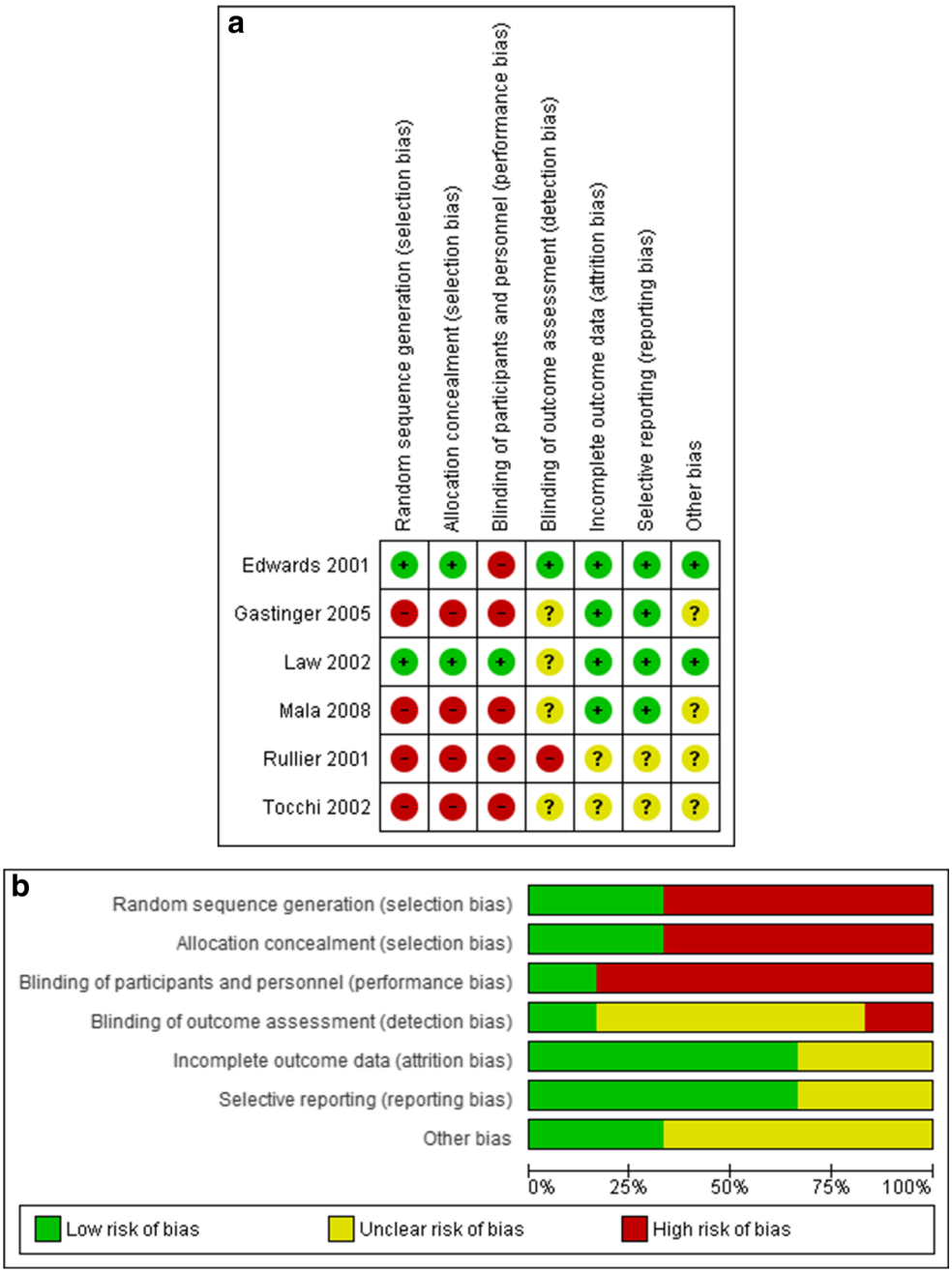

Fig. 2 **a** Risk of bias summary. **b** Risk of bias graph

(11/134) in LC. The difference was statistically significant [OR (95%CI) = 0.26 (0.09, 0.79); $p = 0.02$] (Fig. 4c).

Stoma site infection Stoma site infection rate after stoma creation was reported in three studies (158 LI vs. 120 LC) [8, 9, 27]. Among-study heterogeneity was low ($I^2 = 0\%$). Fixed effects model was utilized. Stoma site infection rates were significantly lower in LI (1.3% (2/158)) as compared to LC (6.6% (8/120)) [OR (95%CI) = 0.25 (0.06, 1.02); $p = 0.05$] (Fig. 4d).

Parastomal hernia Parastomal hernia rate after stoma creation was reported in five studies (259 LI vs. 168 LC) [8–10, 26, 27]. Among-study heterogeneity was low ($I^2 = 0\%$). Fixed effects model was utilized. Parastomal hernia rates were significantly lower in LI (1.9% (5/259)) as compared to LC (5.9% (10/168)) [OR (95%CI) = 0.31 (0.11, 0.86); $p = 0.02$] (Fig. 4e).

Overall morbidity after stoma closure

Overall morbidity after stoma closure was reported in five studies (632 LI vs. 358 LC) [8–11, 26]. Statistical among-study heterogeneity was high ($I^2 = 65\%$; $\text{Tau}^2 = 0.68$); hence, random effects model was utilized. Morbidity rate was 9.2% (58/632) in LI vs. 9.5% (34/358) in LC. The difference was not statistically and clinically significant [OR (95%CI) = 0.92 (0.37, 2.34); NNT = 313; $p = 0.87$] (Fig. 5a).

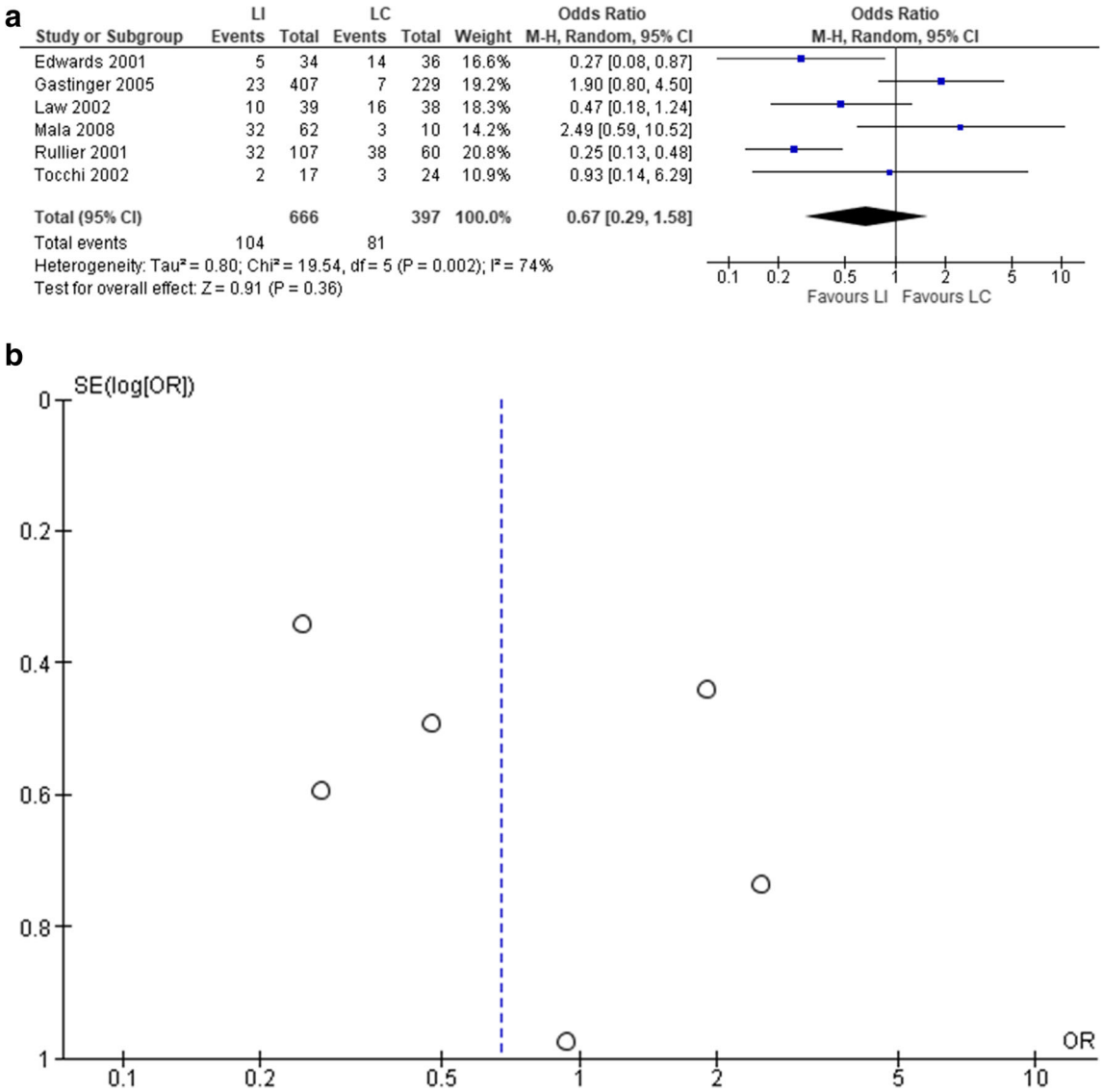

Fig. 3 Meta-analysis of morbidity following creation and closure of loop ileostomy (LI) vs. loop colostomy (LC). **a** Forest plot. **b** Funnel plot

Anastomotic leak after stoma closure Anastomotic leak rates after stoma closure were reported in three studies and defined as clinical (535 LI vs. 310 LC) [8, 9, 11]. Statistical among-study heterogeneity was high ($I^2 = 60\%$; $\text{Tau}^2 = 3.01$); hence, random effects model was utilized. Anastomotic leak rate was 2.1% (11/535) in LI vs. 1% (3/310) in LC. The difference was not statistically and clinically significant [OR (95%CI) = 1.39 (0.11, 17.52); NNT = 91; $p = 0.80$] (Fig. 5b).

Ileus after stoma closure Ileus rate after stoma closure was reported in five studies (632 LI vs. 358 LC) [8–11, 26]. Among-study heterogeneity was low ($I^2 = 0\%$). Fixed effects model was utilized. Ileus rates were significantly higher in LI (5.2% (33/632)) as compared to LC (1.7% (6/358)) [OR (95%CI) = 2.65 (1.13, 6.18); $p = 0.02$] (Fig. 5c).

Incisional SSI after stoma closure Incisional SSI rate after stoma closure was reported in four studies (225 LI vs. 129 LC) [8–10, 26]. Two studies have reported the skin defect after stoma closure to be closed primarily [8, 10], whereas others have not reported this detail. Among-study heterogeneity was low ($I^2 = 0\%$). Fixed effects model was utilized. Incisional SSI rates were significantly lower in LI (3.1% (7/225)) as compared to LC (10.8% (14/129)) [OR (95%CI) = 0.25 (0.09, 0.64); NNT = 13; $p = 0.02$] (Fig. 5d).

Sensitivity analysis and publication bias

A sensitivity analysis of the included observational studies was performed by excluding studies with the highest risk of bias. This did not affect the findings. When a sensitivity

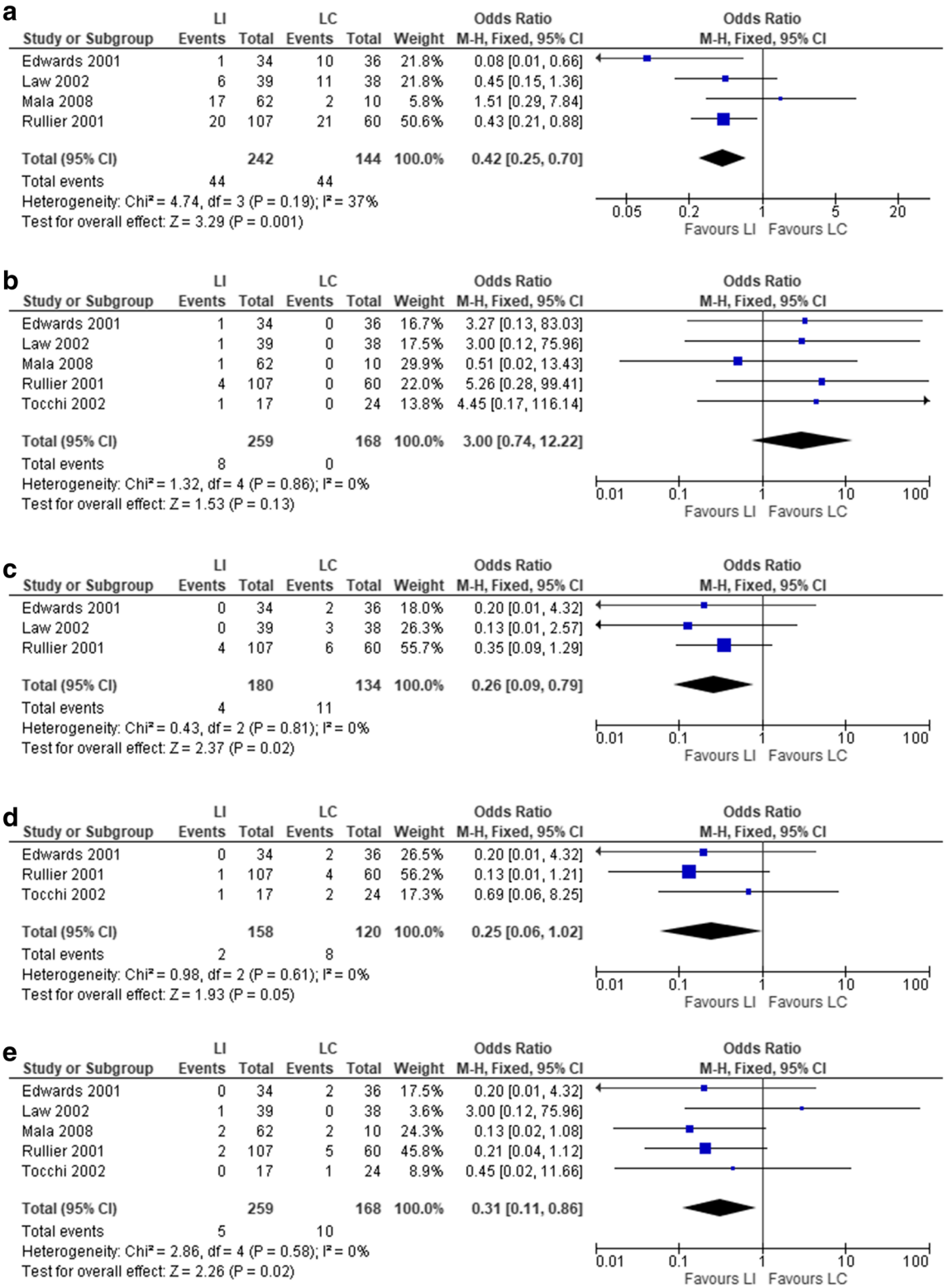

Fig. 4 Meta-analysis of morbidity following creation of loop ileostomy (LI) vs. loop colostomy (LC). **a** Overall morbidity. **b** Dehydration. **c** Stoma prolapse. **d** Stoma site infection. **e** Parastomal hernia

analysis was performed including the two RCTs only, overall morbidity rates after stoma creation and closure favored LI [20.5% (15/73) LI vs. 40.5% (30/74) LC; OR (95%CI) = 0.38 (0.18, 0.79); $p = 0.01$]. Publication bias was evaluated by visual assessment of symmetry on the funnel plot, Egger's test ($t = 0.95$; $p = 0.39$), and Begg's correlation test (Tau = 0.13; $p = 0.70$) (Fig. 3b). No publication bias was found.

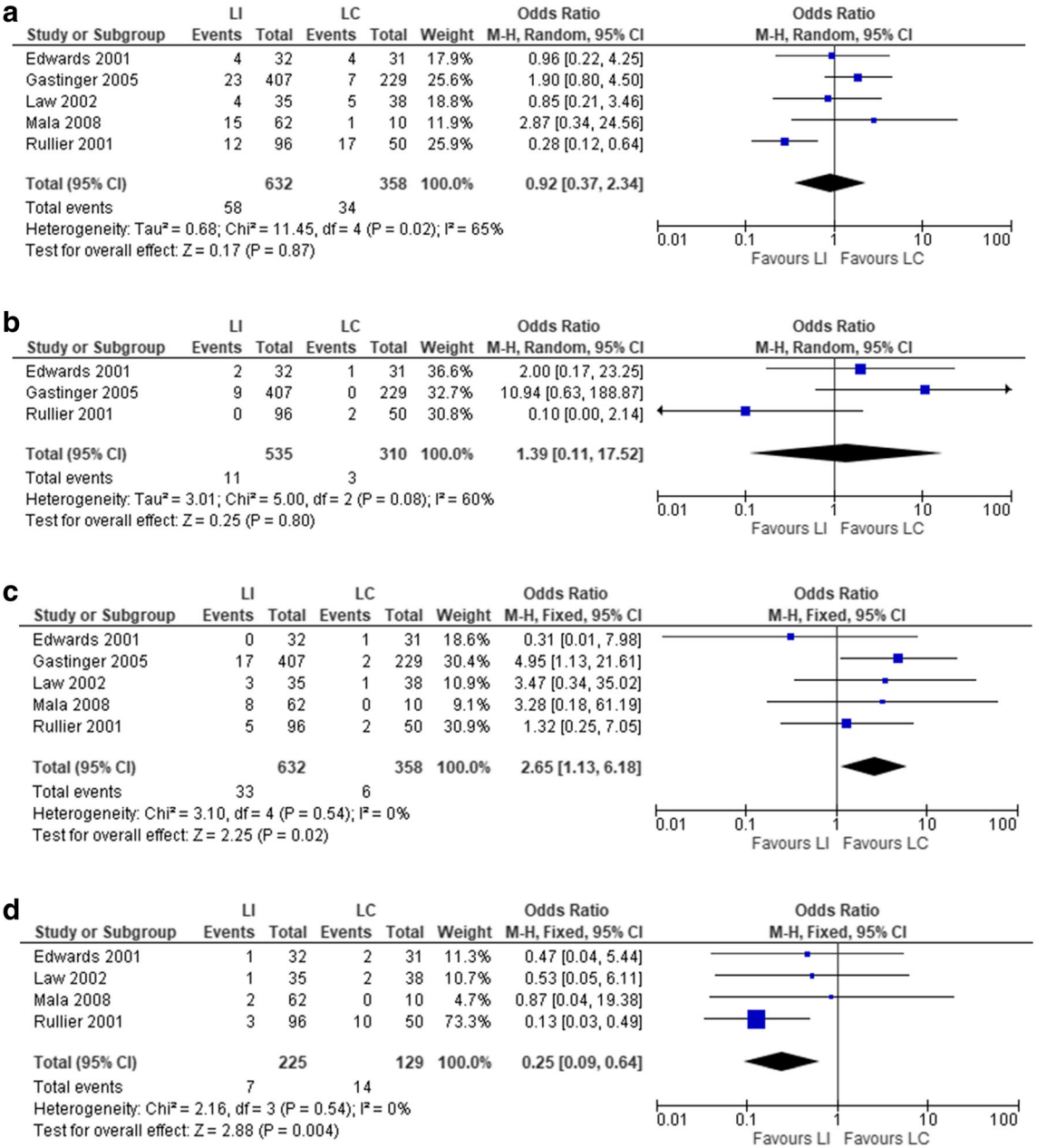

Fig. 5 Meta-analysis of morbidity following closure of loop ileostomy (LI) vs. loop colostomy (LC). **a** Overall morbidity. **b** Anastomotic leak. **c** Ileus. **d** Incisional SSI

Discussion

This meta-analysis was designed to evaluate the morbidity of LI and LC creation in restorative anterior resection for rectal cancer as well as the morbidity of their reversal. Considering the fact that primary disease (whether malignant or not), extent and technique of colorectal resection, and preoperative chemoradiotherapy may be risk factors playing key role in postoperative morbidity, in this meta-analysis, we aimed at including rectal cancer cases only to minimize confounding role of the indications for surgery.

Interpretation of the results

No robust conclusions should be drawn from the absence of statistical significance in overall morbidity rates following creation and closure of LI and LC. In fact, in addition to substantial heterogeneity among studies, the two RCTs in this meta-analysis included medical complications such as arrhythmia, deep venous thrombosis, pneumonia, pulmonary embolus, and urinary retention, which are neither mechanical nor physiologic [28]. The creation of LC was followed by significantly increased risk for mechanical complications such

as stoma prolapse, stoma site infection, and parastomal hernia. The confounding factor, which might have contributed to prolapse rates after LC, consists of whether the transverse colon segment proximal or distal to the midcolic vessels was externalized [29]. In fact, only one RCT described the location of the LC to be to the right of the middle colic vessels [10]. The finding of increased infection rates after LC is not surprising given the difference in bacterial load. The rates of parastomal hernia after ileostomy or colostomy depend on a number of factors such as preoperative marking of stoma site by enterostomal nurses, location in the abdominal wall, body habitus and surgical technique. Only three studies included in this meta-analysis reported that the stoma site was routinely marked. Only one study reported the location of LC creation to be through the rectus muscle sheath [8]. The same study also provided the details of the surgical technique reporting an increased number of digits allowed through the abdominal wall incision made for LC (two fingers in LI vs. three fingers in LC) [8]. Although there was not even a statistical trend towards an increased risk for physiologic complications after LI, no patient with LC suffered from dehydration in this meta-analysis. Moreover, it is likely that retrospective studies may have underreported the rate dehydration and acute kidney injury [11]. Although it may be difficult to prevent physiologic complications after LI, it is possible to improve their management [28].

Morbidity rates following closure of LI and LC did not differ. Interestingly, contrary to the previous reports in the literature, this meta-analysis did not find any statistically and clinically significant differences in leak rates following closure of LI and LC. Although there was a statistically increased rate of postoperative ileus following LI closure, the definition of ileus was substantially heterogeneous. In fact, 25 out of a total of 33 events in the meta-data were reported in two observational studies [11, 26], which included six cases of subileus [26]. Moreover, three studies reported this outcome as intestinal obstruction rather than ileus [8–10]. Hence, postoperative ileus included a wide range of clinical presentations from subileus to intestinal obstruction. Nonetheless, no correlation with readmissions and reinterventions due to postoperative ileus could be found. Statistically significant difference in SSI rates following closure of LI and LC was found. However, only two studies provided details of the surgical technique employed in stoma closure [8, 11].

Existing evidence

Five randomized controlled trials comparing temporary loop ileostomy to colostomy have previously been published [5–7, 9, 10]. Three of these were not included in this meta-analysis because the patients enrolled underwent restorative colorectal resections for diseases other than rectal cancer [5–7]. Similarly, a number of previously published observational studies were not included [30–35]. Several previously published meta-analyses have found significantly higher overall morbidity rates after LC creation as compared to LI, which corroborates with the findings of this meta-analysis [12, 14, 15, 36, 37]. Moreover, the statistical trend towards increased rates of physiologic complications is in line with previously published meta-analyses. None of the studies included in this meta-analysis reported details of physiologic complications following ostomy creation. One observational study reported that renal insufficiency rate was significantly higher after the creation of LI (10% vs. 1%; $p = 0.005$) [30]. The major limitation of previously published meta-analyses was the substantial heterogeneity in the indications for restorative colorectal resections with temporary loop ostomy. In order to mitigate heterogeneity and increase external validity, we included studies reporting only anterior rectal resections for resectable rectal cancer. The literature search shows only one meta-analysis comparing LI to LC in patients with resectable rectal cancer. The meta-analysis concluded that LI was superior to LC for the outcomes of stoma creation but not its closure [38].

Strengths and limitations

One of the strengths of this meta-analysis is a thorough literature search of several databases. The evaluation of the metrics of clinical significance (relative and absolute risk reduction, numbers needed to treat/harm) allowed reaching methodologically and clinically sound conclusions.

This meta-analysis has a number of limitations. The majority of the eligible studies were observational studies with high risk of bias. Two included experimental studies involved a small number of patients. In spite of the experimental design, both RCTs were subject to high risk of performance bias. There was a substantial heterogeneity in the definition of study interventions, such as stoma site location and closure technique. An overall lack of details in reporting physiologic complications of stoma creation did not allow drawing robust and clinically sound conclusions.

Conclusions

This meta-analysis including studies on rectal cancer found no difference between LI and LC in overall morbidity after stoma creation and closure. However, morbidity rates following the creation of LI were significantly decreased at the cost of a risk for dehydration. Hence, the evidence provided by this meta-analysis allows recommending LI in patients with no concurrent renal dysfunction. LC was associated with similar anastomotic leak and higher incisional SSI rates following reversal as compared to LI.

Author's contribution Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND Drafting the work or revising it critically for important intellectual content; AND Final approval of the version to be published; AND Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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Compliance with ethical standards

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

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

Informed consent Not applicable as this is a summary design study.

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