Original Article

Does a stoma reduce the risk of anastomotic leak and need for re-operation following low anterior resection for rectal cancer: systematic review and meta-analysis of randomized controlled trials

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Background: There is a relatively high risk of anastomotic leak in low anterior resection (LAR), associated with significant morbidity and mortality. This systematic review and meta-analysis aims to compare diverting stoma *vs.* no stoma for LAR in terms of leak rates, reoperations, mortality rates and complication rates.

Methods: We systematically performed electronic searches of databases Ovid Medline, PubMed, CCTR, CDSR, ACP Journal Club and DARE from inception to present. Only randomized controlled trials comparing LAR for rectal cancer with versus without stoma diversion were included for analysis. Main outcomes were anastomotic leak, reoperation rate and mortality. Secondary outcomes included other operative and stoma-related complications.

Results: Eight randomized controlled trials were included in the study for qualitative and quantitative analyses. A significantly longer operative duration for patients with stoma diversion was seen (WMD 19.50 min; 95% CI: 7.38, 31.63; I^2=0%, P=0.002). The pooled rate for anastomotic leak was significantly lower for those with stoma diversion (6.3% *vs.* 18.3%; RR 0.36; 95% CI: 0.24, 0.54; I^2=0%; P<0.00001). There was lower reoperation rate for patients with stoma diversion compared to no stoma (5.9% *vs.* 16.7%; RR 0.40; 95% CI: 0.26, 0.60; I^2=0%; P<0.00001). No significant difference was found in terms of leak-related mortality between stoma *vs.* no-stoma cohorts (0.47% *vs.* 1.0%; P=0.51).

Conclusions: The present meta-analysis suggests a diverting or defunctioning stoma following LAR for rectal cancers can reduce anastomotic leak and reoperation rates, without increased risk of mortality or other complications.

Keywords: Anastomotic leak; low anterior resection (LAR); colorectal; stoma diversion; meta-analysis

Submitted Oct 22, 2018. Accepted for publication Oct 23, 2018.
doi: 10.21037/jgo.2018.11.07
View this article at: http://dx.doi.org/10.21037/jgo.2018.11.07

Introduction

Low anterior resection (LAR) with colorectal or coloanal anastomosis for mid to distal rectal cancer less than 10 cm from the anal verge is associated with a higher risk of anastomotic leak compared to high anterior resection and restorative colonic procedures (1). LAR is associated with higher rates of morbidity and mortality including re-operations, wound infection, conversion to permanent stoma, stenosis and recurrence (1-3). Until recently, there has not been a predictor of anastomotic leak post LAR, but there is now a model based on mass nationwide data that calculates the risk of anastomotic leakage post LAR (4). In general, the Cochrane review in 2011 reported the rate of anastomotic leak following LAR to be 8.8% (38/431) without mechanical bowel preparation (MBP) and 10.4% (43/415) with bowel preparation (5).

Proximal faecal diversion via a loop ileostomy or colostomy is a common strategy used to reduce the risk of anastomotic leak post LAR. The evidence of benefit, however, has been unclear with the initial randomized controlled trials (RCTs) comparing LAR with and without stoma failing to demonstrate any significant benefit. Graffner *et al.* reported no differences in anastomotic leak rates between 50 patients randomized into the two groups (6). Pakkastie *et al.* conducted an RCT which demonstrated a trend towards lower leak rate in the stoma group, but the level of significance was not achieved (7). Other studies have reported conflicting results with regards to leak rate, mortality and morbidity (8,9). There is not consensus in the literature regarding routine use of diverting stoma following LAR.

The majority of existing meta-analyses has been significantly limited by the inclusion of studies retrospective and observational in nature (10-12). Those which attempted subgroup analysis for RCTs had small cohort sample sizes for the randomized data, and were not adequately powered to detect differences in complication rates.

To address current limitations in the literature, we have performed an updated meta-analysis including only prospective RCTs with the aim of comparing outcomes following LAR in terms of leak rates, reoperations, mortality rates and complication rates based on defunctioning stoma status.

Methods

Search strategy

Given that this study does not involve humans, animals and uses only previously published and publically available data, ethics approval was waived. The present study was performed according to PRISMA guidelines (13,14). Electronic searches were performed using Ovid Medline, PubMed, Cochrane Central Register of Controlled Trials (CCTR), Cochrane Database of Systematic Reviews (CDSR), ACP Journal Club and Database of Abstracts of Review of Effectiveness (DARE) from their dates of inception to 9th October 2017. To achieve maximum sensitivity of the search strategy and identify all studies, we combined the terms: "stoma", "ileostomy", "diversion", "defunctioning", "low anterior resection", "rectal cancer", "rectal malignancy", as either keywords or MeSH terms. The reference lists of all retrieved articles were reviewed for further identification of potentially relevant studies. All identified articles were systematically assessed using the inclusion and exclusion criteria.

Selection criteria

Eligible RCTs for the present systematic review and meta-analysis included those in which patients were randomized to either LAR with a diversion/defunctioning stoma versus no diversion/defunctioning. Stoma could be in the form of ileostomy or colostomy. When institutions published duplicate studies with accumulating numbers of patients or increased lengths of follow-up, only either the most recent or most complete reports were included for quantitative assessment. All publications were limited to those involving human subjects and in the English language. Case reports, conference presentations, editorials and expert opinions were excluded. Review articles were omitted because of potential publication bias and duplication of results.

Data extraction and critical appraisal

All data were extracted from article texts, tables and figures. Two investigators independently reviewed each retrieved article. Discrepancies between the two reviewers were resolved by discussion and consensus. Assessment of risk of bias for each selected study was performed according to the most updated Cochrane statement. Discrepancies between the two reviewers were resolved by discussion and consensus. The final results were reviewed by the senior investigator.

Statistical analysis

The relative risk (RR) and weighted mean difference

(WMD) were used as a summary statistic. In the present study, both fixed- and random-effect models were tested. In the fixed-effects model, it was assumed that treatment effect in each study was the same, whereas in a random-effects model, it was assumed that there were variations between studies. χ^2 tests were used to study heterogeneity between trials. I^2 statistic was used to estimate the percentage of total variation across studies, owing to heterogeneity rather than chance, with values greater than 50% considered as substantial heterogeneity. I^2 can be calculated as: $I^2 = 100\% \times (Q - df)/Q$, with Q defined as Cochrane's heterogeneity statistics and df defined as degree of freedom. In the present meta-analysis, the results using the random-effects model were presented to take into account the possible clinical diversity and methodological variation between studies. All P values were 2-sided. All statistical analysis was conducted with Review Manager Version 5.3.2 (Cochrane Collaboration, Software Update, Oxford, United Kingdom).

Results

Search strategy and appraisal

From systematic electronic database searches, a total of 362 references were identified (*Figure S1*). After exclusion of duplicate references, 354 potentially relevant articles were retrieved. After detailed evaluation of these articles, 18 articles remained for further full-text assessment. After application of selection criteria, 8 RCTs (6,7,15-20) were selected for analysis. The study characteristics of these trials are summarized in *Table 1*. Pimentel *et al.* was only published as abstract form but was included in analysis as the abstract reported leak rate and reoperation rates. In total, this systematic review included 892 LAR procedures for rectal cancers, comprising 460 cases with diversion stomas and 432 without temporary diversion stomas. The 8 RCTs were also assessed qualitatively using tools recommended by the Cochrane Collaboration for the risk of bias. A graph and summary of selection bias, performance bias, detection bias, attrition bias, reporting bias and other bias identified is shown in *Figure S2*. All included studies had high risk of bias for blinding of personnel and outcome assessors.

Operative characteristics

For all study populations, patients underwent a LAR procedure for rectal cancer, with tumor resection and safe stapled anastomosis with complete anastomotic rings and negative air leak test. There was a trend towards less operative blood loss for patients with no stoma diversion compared to those with stoma diversion (WMD 87.67 mL, 95% CI: –9.40, 184.75; P=0.08) (*Figure S3*) however this did not reach statistical significance. There was a significantly longer operative duration for patients with stoma diversion (WMD 19.50 min; 95% CI: 7.38, 31.63; I^2=0%, P=0.002, *Figure S4*). No significance difference in hospital stay was noted between the groups (WMD 1.79; 95% CI: –4.79, 8.37; I^2=94%; P=0.59; *Figure S5*).

Clinical anastomotic leak

All included studies reported anastomotic leak rates. The pooled rate was significantly lower for those with stoma diversion (6.3% *vs.* 18.3%; RR 0.36; 95% CI: 0.24, 0.54; I^2=0%; P<0.00001) (*Figure 1*) with no significant heterogeneity noted.

Reoperation for leak

Reoperation rate for leak was reported by all included trials. Pooled analysis demonstrated significantly lower reoperation rate for patients with stoma diversion compared to no stoma (5.9% *vs.* 16.7%; RR 0.40; 95% CI: 0.26, 0.60; I^2=0%; P<0.00001) (*Figure 2*), with no significant heterogeneity noted.

Perioperative mortality rate

There was no significant difference found in terms of leak-related mortality between stoma *vs.* no-stoma cohorts (0.47% *vs.* 1.0%; RR 0.59; 95% CI: 0.12, 2.89; I^2=0%; P=0.51) (*Figure 3*). No significant heterogeneity was noted.

Other complications

Other complications are summarized in *Figure 4*. No difference is found between stoma *vs.* no-stoma approaches in terms of wound sepsis (14.1% *vs.* 12.1%, P=0.34), postoperative bleed (1.5% *vs.* 0.4%, P=0.35), small bowel obstruction (8.2% *vs.* 2.1%, P=0.19), peritonitis (0.4% *vs.* 1.3%, P=0.47), pulmonary infection (10.9% *vs.* 11.2%, P=0.48), urinary tract infection (9.4% *vs.* 12.9%, P=0.88), or permanent stoma rates (7.9% *vs.* 11.0%, P=0.41).

Discussion

The evidence of benefit for performing defunctioning stoma

Table 1 Characteristics of included studies in the present systematic review

First author	Year	Total No. of pts	N (stoma)	N (no stoma)	Type of operation	Confirmation of leak	Inclusion criteria	Randomization and allocation	Blinding
Graffner	1983	50	25	25	LAR	Clinical exam, gastrografin enema, proctorectoscopy at 3-month, double-contrast radiography at 1 year	Anastomosis below peritoneal reflection	Sealed envelope	Not possible
Pakkastie	1997	38	19	19	LAR	Clinical exam, radiologic (rectal contrast, CT)	Anastomosis below peritoneal reflection	Sealed envelope	Not possible
Pimentel	2003	36	18	18	LAR	Not reported	Anastomosis ≤4 cm from anal verge	Sealed envelope	Not possible
Matthiessen	2007	234	116	118	LAR	Clinical (digital palpation, inspection of drain), endoscopic or radiologic (rectal contrast study, CT) diagnoses	Anastomosis ≤7 cm anal verge	Sealed envelope	Not possible
Chude	2008	256	136	120	LAR	Clinical exam, radiologic (rectal contrast, CT)	Operable rectal cancer ≤5 cm from anal verge	Sealed envelope	Not possible
Ulrich	2009	34	18	16	LAR	Septic profile, CT scan with rectal filling ± laparotomy	Operable rectal cancers low (4–9 cm) or middle (8–12 cm) from anal verge	Sealed envelope	Not possible
Thoker	2014	78	34	44	LAR	Septic profile, US abdomen/pelvis, CT with oral contrast	Operable rectal cancer 4–12 cm from anal verge	"Systemic" random sampling	Not possible
Mrak	2016	166	94	72	LAR	Clinical diagnoses, confirmed with gastrografin enema ± CT scan ± sigmoidoscopy	Distal border tumors <16 cm from anal verge on rigid rectoscopy	Internet-based randomization	Not possible

LAR, low anterior resection; n, number.

following LAR has been unclear. Various observational studies, systematic reviews and meta-analyses and lower quality studies have reported a wide range of results. Meta-analyses on this topic so far have been of limited sample size or based on lower quality evidence than RCTs. In order to synthesize the highest quality evidence, we performed a meta-analysis of only RCTs comparing stoma diversion versus no diversion for LAR for rectal cancers. Our pooled analysis of 8 RCTs, with more included randomized studies compared to prior meta-analyses (10,11), demonstrated a significant reduction in clinically relevant anastomotic leak rates and re-operation rates in patients with stoma diversion, without significant differences in perioperative mortality or other complications. As such, our findings support the creation of a defunctioning stoma following LAR for mid and low rectal cancers.

The pooled results of the present analysis are consistent with reported outcomes of several prior studies. Matthiessen *et al.* (15) conducted a study involving 234 LAR patients from 21 hospitals in Sweden, who were randomized to 116 cases with stoma and 118 cases without diverting stoma. The authors reported that the odds of having symptomatic

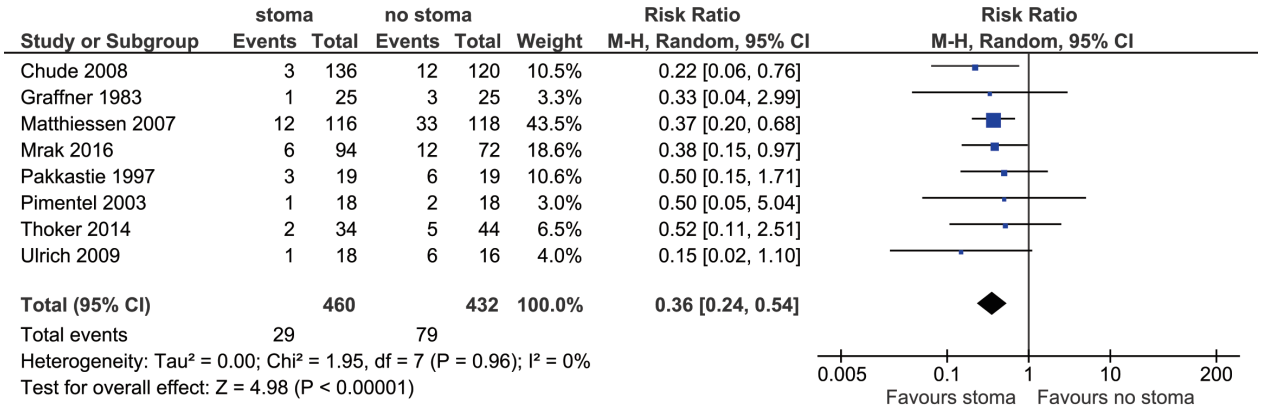

Figure 1 Forest plot of anastomotic leak rate in low anterior resection patients with stoma diversion versus without stoma.

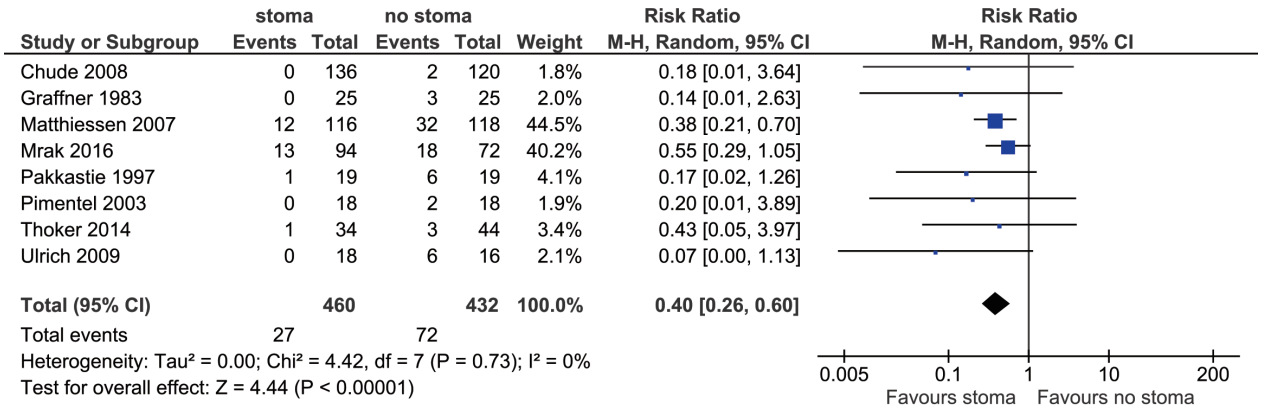

Figure 2 Forest plot of reoperation rate in low anterior resection patients with stoma diversion versus without stoma.

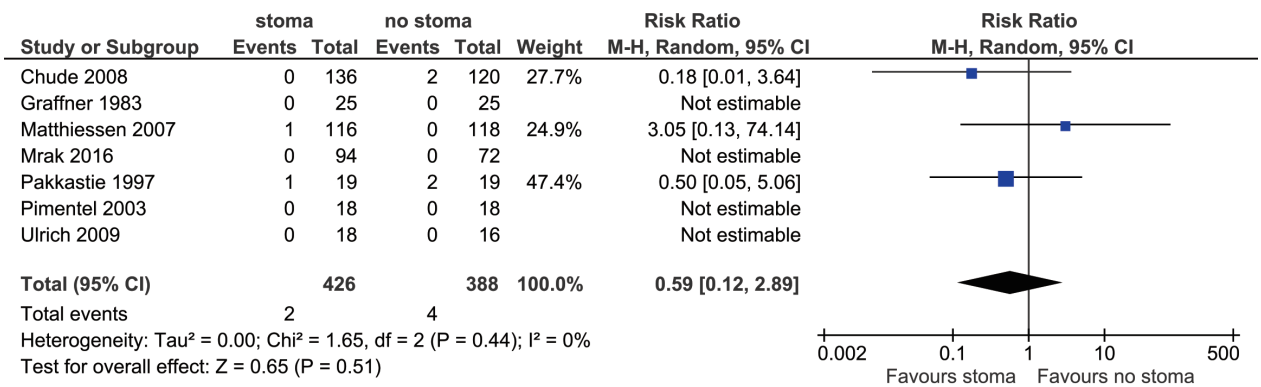

Figure 3 Forest plot of perioperative mortality rate in low anterior resection patients with stoma diversion versus without stoma.

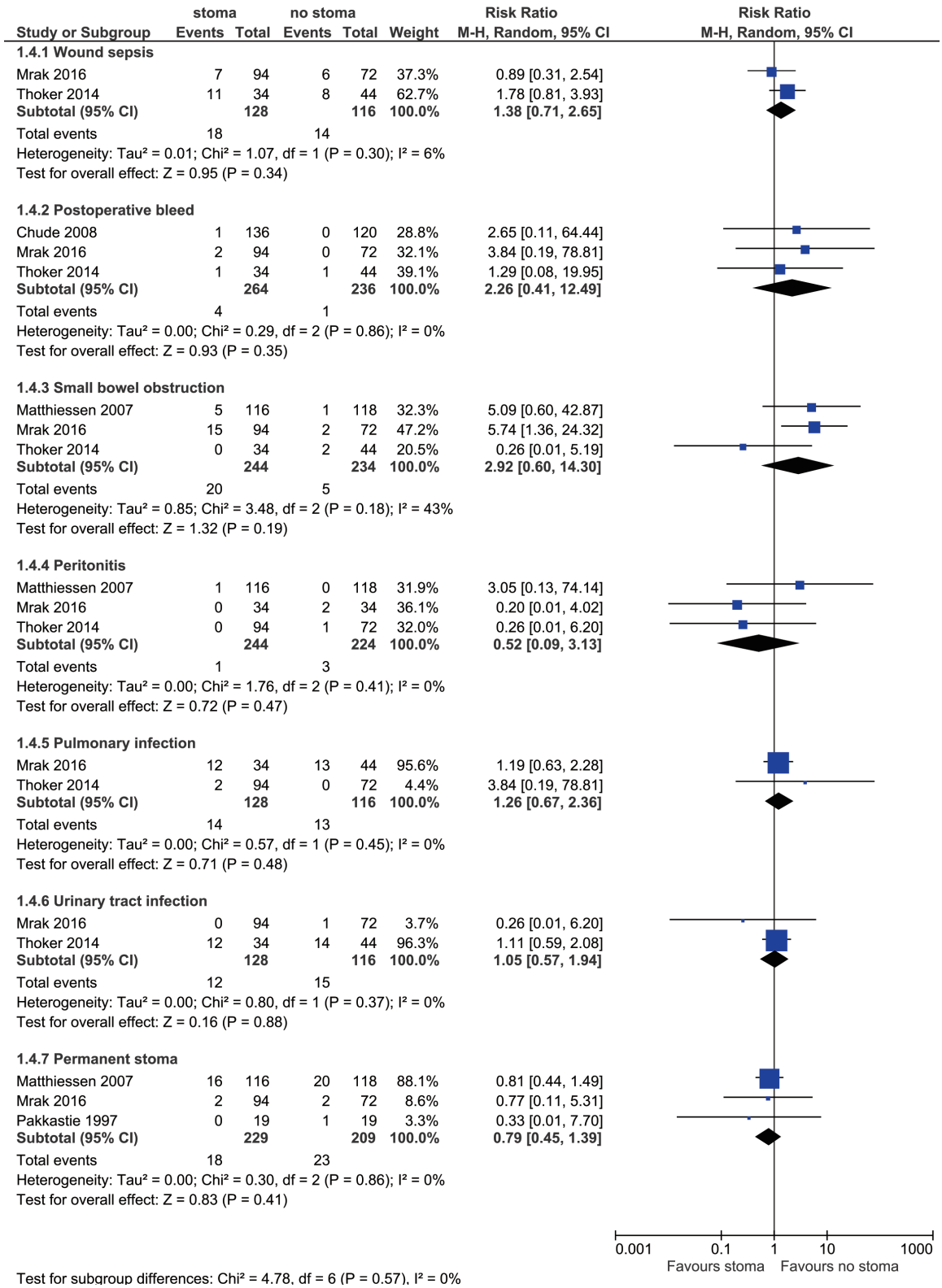

Figure 4 Forest plot of wound sepsis, postoperative bleed, small bowel obstruction, peritonitis, pulmonary infection, urinary tract infection, and conversion to permanent stoma rates in low anterior resection patients with stoma diversion versus without stoma diversion.

leakage following LAR was 3.4 times higher without ileostomy compared to those with diverting ileostomy. They also reported urgent abdominal reoperation rate of 8.6% in patients with stoma compared to 25.4% in patients without stoma.

A five-year follow-up report of this randomized study also demonstrated that anorectal function at long-term follow-up was not affected by the use of a diverting ileostomy approach (21). In another RCT, Mrak *et al.* randomized 166 patients with LAR with J-pouch reconstruction and demonstrated significant higher leakage rates and reoperation rates for patients without stoma (19).

Multivariate analysis demonstrated that male gender and absence of stoma were significant independent predictors of anastomotic leakage. Overall, the results of the present meta-analysis and prior published literature support the use of a defunctioning stoma following LAR to lower rates of anastomotic leak and reoperation rates.

Our results should not be applied blindly to clinical practice, given that quality-of-life outcome measures were not included for analysis. A temporary stoma can have significant impact on a patient's physical and psychological well-being, as assessed using the 36-item Short-Form Health Survey (SF-36) (22). Tsunoda *et al.* (23) conducted a prospective longitudinal study in 22 patients with rectal cancer who underwent a LAR with loop ileostomy. The authors found significant reduction in European Organization for Research and Treatment of Cancer QLQ-CR38 and QLQ-C30 scores after the LAR procedure compared to baseline preoperative levels, indicating reductions in physical and role functioning. These scores markedly improved following ileostomy closure.

Given the considerable quality-of-life implications, the decision to proceed with a stoma should be a highly individualised one which take into account both the negative impact on role and function and balanced with the benefits of leak risk reduction. A risk model of anastomotic leak following LAR (4) would be useful to weigh up the risk of anastomotic leak with the morbidity and quality of life implications associated with a stoma.

The strengths of the present meta-analysis include the exclusion of all retrospective evidence from the current analysis. Retrospective observational studies are susceptible to an inherent selection bias, in particularly favouring surgery without stoma. This is likely due to surgeons creating stomas in patients who they believe are likely to develop anastomotic leak complication, leading to the selection bias. Indeed there is evidence to demonstrate risk factors for leak complications including male gender, anastomotic height, obesity, steroid use, malnutrition, steroid use and prior irradiation (1,24-31). Thus in retrospective studies surgeons may more often elect to perform a stoma diverting approach in such populations. To minimize the effects of such bias, the present meta-analysis pooled data from only prospectively designed RCT data, with minimal heterogeneity detected between RCTs for the outcomes reported.

The present study is constrained by several limitations. There has been a lack of reported long-term outcomes following stoma diversion or no diversion techniques for LAR, and as such, the long-term morbidity associated with a defunctioning stoma is unclear. Some endpoints could not be pooled for analysis due to lack of reporting in the included studies, such as stoma retraction, obstruction, excoriation, prolapse rates, readmission rates, and stoma-related complications such as peristomal ulcerations/abscess, parastomal hernias, and high output leading to kidney injury. Our meta-analysis also did not address quality-of-life endpoints. Certainly, the creation of a stoma regardless of its temporary or permanent status, would reduce quality of life of patients in this population, particularly if stoma complications were to occur.

Conclusions

The findings of this present meta-analysis of level one RCT evidence demonstrates that a defunctioning stoma following LAR for rectal cancer reduces the risk of anastomotic leak and re-operation rates, without a significant increase in the risk of mortality or serious short-term morbidity.

Acknowledgements

None.

Footnote

Conflicts of Interest: The authors have no conflicts of interest to declare.

Ethical Statement: Given that this study does not involve humans, animals and uses only previously published and publically available data, ethics approval was waived.

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Cite this article as: Phan K, Oh L, Ctercteko G, Pathma-Nathan N, El Khoury T, Azam H, Wright D, Toh JW. Does a stoma reduce the risk of anastomotic leak and need for re-operation following low anterior resection for rectal cancer: systematic review and meta-analysis of randomized controlled trials. J Gastrointest Oncol 2019;10(2):179-187. doi: 10.21037/jgo.2018.11.07

Supplementary

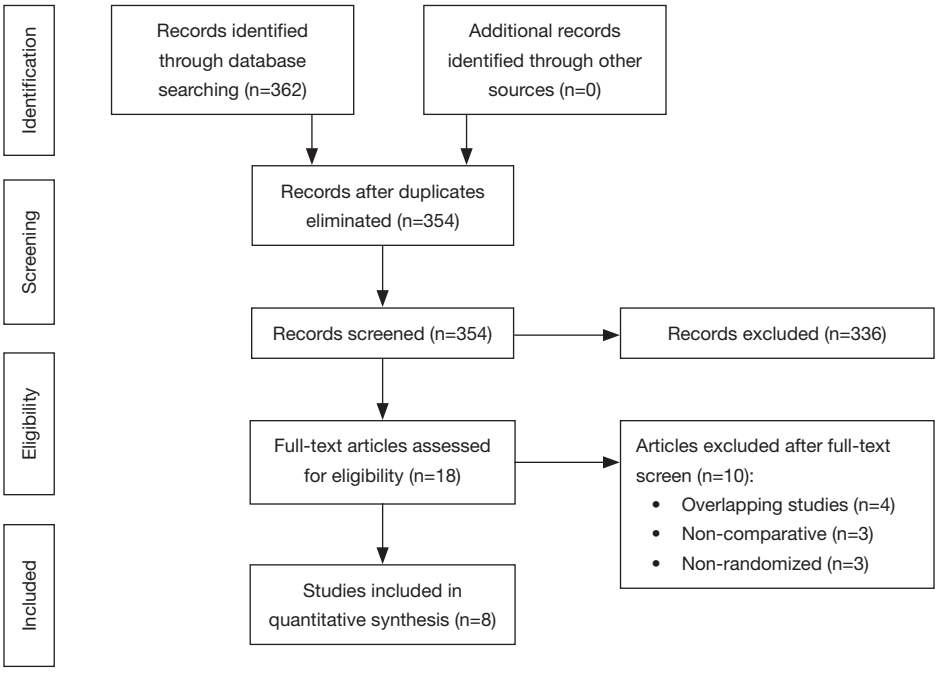

Figure S1 PRISMA flow chart for search sequence of the present systematic review and meta-analysis.

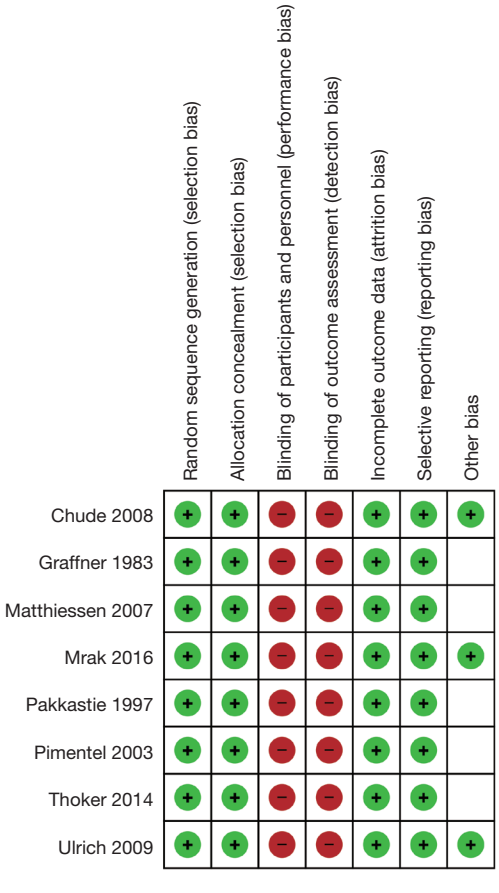

Figure S2 Risk of bias assessed for randomized trials using the Cochrane risk of bias tool.

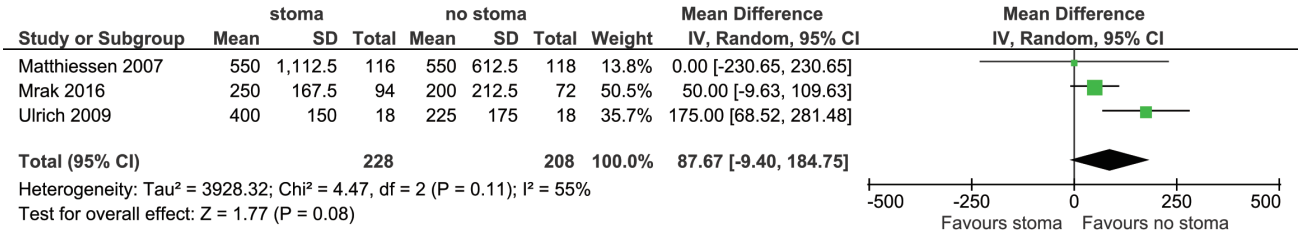

Figure S3 Forest plot of intraoperative blood loss (mL) in low anterior resection patients with stoma diversion versus without stoma diversion.

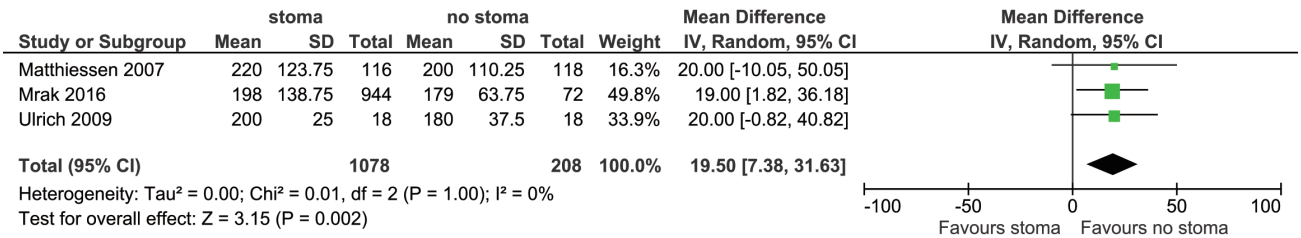

Figure S4 Forest plot of operative duration (minutes) in low anterior resection patients with stoma diversion versus without stoma diversion.

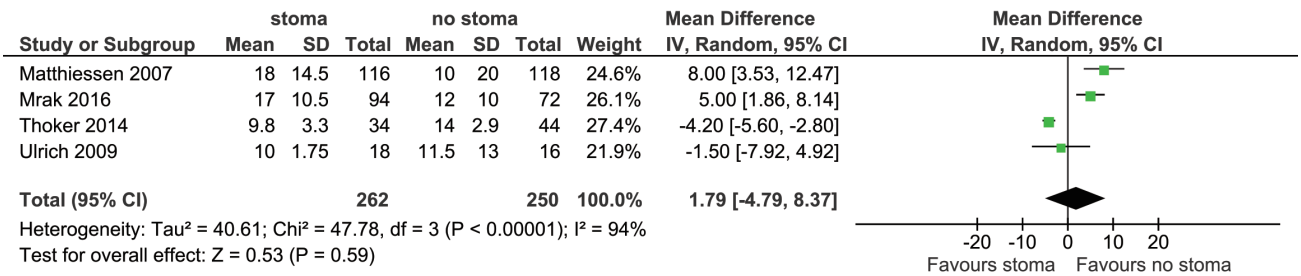

Figure S5 Forest plot of hospital stay (days) in low anterior resection patients with stoma diversion versus without stoma diversion.