Meta-analysis of defunctioning stomas in low anterior resection for rectal cancer

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CRD summary
The review concluded that a defunctioning stoma decreased clinical anastomotic leak and reoperation rates in low anterior resection stoma for low rectal tumours. This conclusion reflects the results for both randomised and non-randomised evidence and appears likely to be reliable.

Authors' objectives
To compare the safety of low anterior resection with and without a defunctioning stoma for low rectal tumours.

Searching
MEDLINE, EMBASE, CINAHL and the Cochrane Library were searched between 1966 and April 2008. Search terms were reported. References of identified articles were also checked. Only studies published in English were eligible for inclusion, but both full publications and abstracts were included.

Study selection
Randomised controlled trials (RCTs) and non-randomised controlled studies which compared low anterior resection with a defunctioning stoma to low anterior resection without a stoma, in patients with low rectal tumours, were eligible for inclusion. Studies were required to report outcome data on anastomotic leak rate or sequelae of leakage, such as surgical intervention for leak and mortality, in each group. Other outcomes were morbidity and mortality related to stoma closure. Studies which included both high and low resections were included only if data were reported separately for these groups. Studies of laparoscopic or hand-assisted resections were also included.

Patients in included studies were undergoing low anterior resection for rectal cancer and had had completed resection of the tumour and completed safe stapled anastomosis, determined by complete anastomotic rings and a negative air leak test. Limited patient details were reported. Slightly different definitions of low anterior resection were employed in the studies. Radiologically demonstrated leaks without clinical symptoms were not included in analyses.

Two reviewers independently assessed the studies for inclusion; disagreements were resolved through discussion.

Assessment of study quality
RCTs were assessed for validity by two independent reviewers using the Cochrane criteria; disagreements were resolved through discussion. It did not appear that non-randomised studies were assessed for validity.

Data extraction
Data were extracted to permit the calculation of relative risks (RR) with 95% confidence intervals (CI). Authors were contacted for additional information where necessary. If data were unavailable, they were regarded as missing and no assumptions were made on the basis of such data.

Two reviewers independently extracted the data; disagreements were resolved through discussion.

Methods of synthesis
RCTs and non-randomised studies were combined in separate meta-analyses, using a fixed-effect model where significant statistical heterogeneity was not detected, and a random-effects model in other cases. The $X^2$ and $I^2$ statistics were used to assess heterogeneity.

Results of the review
Twenty-five studies (n=11,429 patients) were included in the review; four were RCTs (n=358 patients) and 21 were non-randomised studies (n=11,071 patients). All RCTs used an intention-to-treat analysis and made an attempt at allocation concealment. Blinding was not possible due to the nature of the intervention.
**Meta-analysis of RCTs:** The pooled analysis showed a statistically significantly lower rate of clinical anastomotic leak in groups with a stoma (RR 0.39, 95% CI 0.23 to 0.66; four RCTs) and also a statistically significantly lower rate of reoperation for leak (RR 0.29, 95% CI 0.16 to 0.53; four RCTs). There was no statistically significant difference between the groups in mortality related to leak. There was no evidence of statistically significant heterogeneity between the trials for any outcome.

**Meta-analysis of non-randomised studies:** As with the RCTs, pooled analyses showed a statistically significantly lower rate of clinical anastomotic leak in groups with a stoma (RR 0.74, 95% CI 0.67 to 0.83; 21 studies) and also a statistically significantly lower rate of reoperation for leak (RR 0.28, 95% CI 0.23 to 0.35; 15 studies). These studies also showed a statistically significant lower rate of mortality in patients without a stoma (RR 0.42, 95% CI: 0.28 to 0.61; 19 studies). Statistically significant heterogeneity was detected only for the risk of leak ($I^2 = 75\%$).

**Morbidity and mortality after routine closure of defunctioning stoma** (10 studies including four RCTs): Routine stoma closure was associated with morbidity rates ranging from 0 to 19.9% and mortality rates ranging from 0 to 1.4%.

**Authors’ conclusions**
A defunctioning stoma decreased clinical anastomotic leak and reoperation rates. It is recommended after low anterior resection for rectal cancer.

**CRD commentary**
The review question and the inclusion criteria were clear. The authors searched several relevant databases. However, the lack of a systematic search for unpublished studies and the restriction of the review to studies reported in English may have increased the chances that relevant studies were not included, and that publication and/or language biases were present. Rigorous methodology was used at all stages of the review process. An appropriate assessment of the validity of the RCTs was conducted, but it appeared that the non-randomised studies were not assessed for validity. The decision to use meta-analyses for the RCTs and non-randomised studies was appropriate; statistical heterogeneity was assessed and found to be low in all except one of these analyses.

The authors’ conclusion and their recommendations for practice clearly reflect the results of the review of both types of studies and appear likely to be reliable.

**Implications of the review for practice and research**
- **Practice:** The authors stated that a defunctioning stoma is recommended after low anterior resection for rectal cancer.

- **Research:** The authors did not state any recommendations for further research.

**Funding**
Not stated.

**Bibliographic details**

**PubMedID**
19358171

**DOI**
10.1002/bjs.6594

**Original Paper URL**
http://onlinelibrary.wiley.com/journal/122310616/abstract
Indexing Status
Subject indexing assigned by NLM

MeSH
Anastomosis, Surgical /mortality; Humans; Randomized Controlled Trials as Topic; Rectal Neoplasms /mortality /physiopathology /surgery; Reoperation; Surgical Stomas /physiology; Surgical Wound Dehiscence /surgery; Treatment Outcome

AccessionNumber
12009105330

Date bibliographic record published
16/09/2009

Date abstract record published
24/02/2010

Record Status
This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.