Comparison of outcomes after restorative proctocolectomy with or without defunctioning ileostomy


CRD summary
This review concluded that functional outcomes with restorative proctocolectomy were similar to those with proximal diversion, but anastomotic leak was more common. Most of the included studies had methodological limitations and many were small in size, impacting on the reliability of the results of the review. However, the review was generally well-conducted and the authors’ conclusions were suitably cautious.

Authors' objectives
To evaluate postoperative adverse events and functional outcomes of patients undergoing restorative proctocolectomy (RPC) with or without proximal diversion.

Searching
MEDLINE, EMBASE and Cochrane databases were searched without language restrictions from 1978 until July 2005. References of retrieved articles were reviewed. Search terms were reported.

Study selection
Studies that compared RPC with and without covering ileostomy were eligible for inclusion. Studies were required to report on at least one of the predefined outcome measures and to clearly document the technique as “with covering ileostomy” or “without covering ileostomy”. Studies were excluded if it was not possible to calculate data or there was considerable overlap between authors, centres or patient cohorts. Outcomes included operative outcomes, short-term adverse events, re-operation, long-term adverse events and functional outcomes. Outcome definitions were reported in the text. Men accounted for approximately 51 per cent of patients. Median follow up ranged from 2.2 to 20 months. Mean age at surgery ranged from 10.4 to 39 years.

Assessment of study quality
The quality of each study was assessed using a modified version of the Newcastle-Ottawa, specifically three domains; patient selection; comparability of the two study groups; and assessment of outcome scale. These criteria were used to assign a score between 0 and 12. Studies achieving a score of 6 or more were considered to be of higher quality. The authors did not state how the validity assessment was performed.

Data extraction
Numbers of events in each group were used to derive odds ratios (OR) and 95% confidence intervals (CI) for dichotomous outcomes. Continuous variables were reported as means or medians (range). Three reviewers independently extracted data from each study.

Methods of synthesis
For dichotomous outcomes, the pooled OR and corresponding 95% CIs were calculated using the Mantel-Haenszel random-effects model; 0.5 was added when event rates were 0. For continuous outcomes, weighted mean differences (WMD) were calculated. Heterogeneity was reported as p values. Sensitivity analyses were conducted by comparing studies of high quality, studies with 100 patients or more and studies published since 1995. Publication bias was assessed using funnel plots.

Results of the review
Seventeen studies were included in the review (n=1,486; 721 diverting ileostomy and 765 without proximal diversion). Of these, one study scored 10, three studies each achieved scores of 7, 6, 5, 4, and 3, and one study scored 2 (out of a possible 12) for study quality.

There were no significant differences between groups for operative details (operative time, length of stay), re-operation
(second laparotomy, other operation) or functional outcomes (frequency of defecation, soiling, anal incontinence, antidiarrhoeal medication use). Anastomotic leak was significantly more common in patients without stoma at the time of surgery (11 trials; OR 2.37 (95% CI: 1.39, 4.04) p=0.002). However, other short-term adverse events (pouch-related sepsis, perianal sepsis) showed no significant differences between groups. Failure of the ileal pouch (11 trials; OR 0.30 (95% CI: 0.12, 0.74) p=0.009) and a stricture developed at the pouch-anal anastomosis (five trials; OR 0.31 (95% CI: 0.10, 0.98) p=0.045) were significantly more common in patients with stoma. Other long term adverse events showed no differences between groups.

Sensitivity analyses showed that anastomotic leak remained significant in patients without stoma when only high-quality studies were included. Although the outcomes for sepsis were not significant when all studies were included, they were significantly greater in patients with stoma in studies published since 1995 (four trials; OR 1.80 (95% CI: 1.03, 3.17) p=0.04), in studies with more than 100 patients (six trials; OR 1.72 (95% CI: 1.07, 2.77) p=0.03) and in higher quality trials (six trials; OR 1.90 (95% CI: 1.13, 3.20) p=0.02).

The assessment of publication bias was not reported.

**Authors’ conclusions**
Restorative proctocolectomy without a diverting ileostomy resulted in functional outcomes similar to those with proximal diversion, but it was associated with an increased risk of anastomotic leak. Diverting ileostomy should be omitted in carefully selected patients only.

**CRD commentary**
This review addressed a clear question in terms of inclusion criteria and outcomes of interest. Relevant medical databases were searched without language restrictions and search terms were reported, but there did not appear to be any efforts to identify unpublished studies. Although publication bias was assessed the results were not reported. Steps were taken to minimise bias and errors in searching for relevant trials, but methods used to make decisions about the relevance of primary studies and to undertake quality assessments were not reported. Studies were combined by meta-analysis and differences between studies were investigated using sensitivity analysis. Only seven of the included studies were considered to be high quality, many had small sample sizes and there was matching at baseline to varying degrees (primarily on age and gender), so the limitations of the included studies may have impacted on the reliability of the results. The authors’ cautious conclusions appeared to be justified given the evidence presented.

**Implications of the review for practice and research**
Research: the authors did not state any implications for research.

Practice: the authors stated that diverting ileostomy should be omitted in carefully selected patients only.

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