Meta-analysis of observational studies of ileorectal versus ileal pouch-anal anastomosis for familial adenomatous polyposis


CRD summary
The review assessed ileorectal anastomosis and ileal pouch-anal anastomosis as first-line surgery for familial adenomatous polyposis. The authors concluded that both approaches had individual merits. The review pooled results from observational studies without providing enough detail about the studies to be confident that the differences in outcomes observed between the two approaches were reliable.

Authors' objectives
To compare ileorectal anastomosis (IRA) and ileal pouch-anal anastomosis (IPAA) by using meta-analysis to determine which approach is the better first-line treatment for familial adenomatous polyposis (FAP).

Searching
MEDLINE and EMBASE were searched; the search terms were reported. The authors also reported a Cochrane database search but did not elucidate the source searched. Studies published between 1991 and 2003 were sought. Additional studies were identified using the related articles function in the electronic databases.

Study selection
Study designs of evaluations included in the review
Inclusion criteria for the study design were not stated. Prospective and retrospective observational studies were included in the review. The mean or median follow-up time was at least 3 years in all but one study.

Specific interventions included in the review
Studies that compared IRA with IPAA were eligible for inclusion. IRA had to be clearly documented as ileorectal anastomosis and IPAA as ileal pouch-anal anastomosis, ileo-anal pouch or restorative proctocolectomy. Handsewn and stapled anastomoses and both W and J reservoirs for IPAA were included. Studies that compared primary IRA with secondary IPAA were excluded. Further details of the interventions in each included trial were not reported.

Participants included in the review
Studies in patients with FAP were eligible for inclusion. Studies in mixed populations of patients with FAP and patients with ulcerative colitis were excluded, as were studies of patients who had undergone IRA and subsequent conversion to IPAA. Only studies conducted in named institutions were included. Care was taken to identify duplicate publications of data to avoid including the same participants twice. Men and women were in the included studies that provided information on gender. No further details about the participants were reported.

Outcomes assessed in the review
To be included in the review, the studies had to report at least one of the outcomes of interest or data from which they could be calculated. The outcomes of interest were early post-operative adverse events, long-term adverse events, functional outcomes and quality of life. Early post-operative events included bowel obstruction, haemorrhage, intra-abdominal sepsis, anastomotic separation, wound infection, and reoperation within 30 days. Long-term adverse events included perianal irritation, anastomotic stricture, desmoid formation, cancer in the pouch or rectum, and need for further operation on the pouch or rectum. Functional outcomes included bowel frequency, night defaecation, incontinence, faecal urgency, need for incontinence pads and antidiarrhoeal medication. Quality of-life outcomes included dietary and social restriction and sexual dysfunction. Definitions of the outcomes were given in the report which also listed the actual outcomes reported in each of the included studies.

How were decisions on the relevance of primary studies made?
The authors did not state how the papers were selected for the review, or how many reviewers performed the selection.
Assessment of study quality
The quality of the included studies was assessed using a modified Newcastle-Ottawa Scale comprising patient selection, comparability between groups and outcome assessment, including the adequacy of overall follow-up. Studies achieving three or more stars were defined as high quality (the maximum possible score was not stated). The authors did not state how the validity assessment was performed.

Data extraction
Two reviewers independently extracted the data. The extracted data included the prospective or retrospective nature of the study design, and whether the study groups were matched on age, gender, follow-up and polyp density in the colon. The outcome data extracted were numbers of events and total numbers in each treatment group, group means and standard deviations. Data reported as a range were transformed to obtain the standard deviation.

Methods of synthesis
How were the studies combined?
The studies were combined using meta-analysis. The pooled odds ratio (OR) was calculated for dichotomous outcomes. The authors appeared to use the Mantel-Haenszel fixed-effect method and a random-effects method. The results reported were calculated using the random-effects method. If there were no events in one group the value 0.5 was added; if there were no events in either group the study was not included in the pooled analysis. Continuous data were pooled using the weighted mean difference (WMD). Publication bias was investigated using a funnel plot.

How were differences between studies investigated?
Heterogeneity was assessed using the chi-squared and I-squared statistics. Heterogeneity was investigated by comparing fixed-effect and random-effects analyses, funnel plots and sensitivity analysis restricted to high-quality studies, studies published from 1997 onwards, and studies with more than 20 patients in each group. A further analysis excluded one study with less than 3 years’ follow-up.

Results of the review
Twelve studies (1,002 patients) were included in the review. One study with 38 participants was prospective, while the others were retrospective.

Ten studies were considered to be high quality.

Early post-operative adverse events.
A pooled analysis of 6 studies showed a significantly lower need for reoperation within 30 days in the IRA group compared with the IPAA group (OR 2.11, 95% confidence interval, CI: 1.21, 3.70), with no significant heterogeneity between the studies. There was no significant difference between groups in bowel obstruction (reported in 10 studies), post-operative haemorrhage (3 studies), intra-abdominal sepsis (8 studies), anastomotic separation (5 studies) or wound infection (6 studies).

Long-term adverse events.
The meta-analysis showed a statistically significant difference in favour of IRA over IPAA in perianal irritation in 7 studies (OR 2.48, 95% CI: 1.36, 4.55) and in anastomotic stricture in 5 studies (OR 3.84, 95% CI: 1.46, 10.11).
Conversely, the benefit was significantly in favour of IPAA over IRA for reduction in cancer in the pouch or rectum in 5 studies (OR 0.13, 95% CI: 0.03, 0.61) and the need for further operation on the pouch or rectum in 6 studies (OR 0.10, 95% CI: 0.04, 0.23). No difference was shown in desmoid formation (reported in 6 studies).

Functional outcomes.
IRA was shown to have a significant benefit over IPAA in a pooled analysis of bowel frequency in 24 hours as reported in 8 studies (WMD 1.62, 95% CI: 1.05, 2.20), night defaecation in 4 studies (OR 6.64, 95% CI: 2.99, 14.74).
incontinence day or night in 6 studies (OR 2.71, 95% CI: 1.81, 4.07) and the need for incontinence pads day or night in 4 studies (OR 2.72, 95% CI: 1.02, 7.23). There was significant heterogeneity between studies in the meta-analysis of bowel frequency, which was no longer significant when only the 4 high-quality studies were included whilst the difference in effect remained statistically significant. In 5 studies significantly fewer patients who underwent IPAA were affected by faecal urgency compared with the IRA group (OR 0.43, 95% CI: 0.23, 0.80). No difference was shown between IRA and IPAA in the need for antidiarrhoal medication (reported in 8 studies).

Quality of life.

Social restriction was significantly lower after IRA compared with IPAA in 2 studies (OR 6.04, 95% CI: 1.53, 23.78). No difference was shown in dietary restriction in 6 studies or in male (6 studies) or female (5 studies) sexual dysfunction.

The meta-analysis results were unchanged when only studies with mean or median follow-up of 3 years or more were included. The sensitivity analysis based on study quality, size and publication date reduced heterogeneity for some outcomes. There was no evidence of publication bias in a funnel plot of antidiarrhoal medication use.

**Authors’ conclusions**

IRA and IPAA have individual merits.

**CRD commentary**

The review addressed a clear question and defined the inclusion and exclusion criteria. The search for studies was adequate. However, methods to minimise bias in the study selection process were not reported. Steps were taken to minimise errors in the extraction of data. Study quality was assessed systematically, but was not reported in enough detail to allow an independent assessment of the potential impact of bias and confounding on the results. The report did not provide reassurance that the quality assessment was adequately incorporated in the interpretation of the meta-analysis. Similarly, insufficient details about the included studies were reported to allow an independent assessment of differences between the comparison groups that might have affected the results. The authors’ conclusion might be correct but the pooled effect sizes reported need to be interpreted with caution.

**Implications of the review for practice and research**

Practice: The authors stated that given the increased risk of cancer in the retained rectum following IRA, the decision to undertake IRA as first-line surgery for FAP must be justified on the strength of post-operative morbidity and functional outcome.

Research: The authors stated that further research is needed to determine which patients with FAP are suitable for which procedure, IRA or IPAA. In addition, predictive modelling might be possible if large multicentre databases were established.

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