Update of complications and functional outcome of the ileo-pouch anal anastomosis: overview of evidence and meta-analysis of 96 observational studies
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CRD summary
The review found that according to post-2000 studies, ileo-pouch anal anastomosis was associated with pouch failure in 4.3% of cases, pelvic sepsis in 7.5% and severe daytime faecal incontinence in 6.1%. Limitations in the review, particularly differences between the studies and failure to assess study quality, mean that these conclusions may not be reliable.

Authors' objectives
To assess the incidence of complications and evaluate functional outcomes associated with ileo-pouch anal anastomosis among adults with established ulcerative colitis or familial adenomatous polyposis.

Searching
PubMed, EMBASE and The Cochrane Library were searched to January 2010 for studies in any language. Search terms were not reported. Reference lists of included studies were checked for further studies.

Study selection
Eligible studies included at least 50 consecutively enrolled adults (over 18 years) with established ulcerative colitis or familial adenomatous polyposis, undergoing a primary open ileo-pouch anal anastomosis procedure. Procedures had to be clearly documented and performed in elective settings with or without a diverting ileostomy. The surgery could involve any number of operation stages. Studies were required to report one of the primary review outcomes of pouch failure, pelvic sepsis or severe daytime incontinence. Secondary review outcomes were other complications and functional measures (such as defecation frequency, incontinence). Outcomes were defined in the review. The reviewers excluded studies where most patients were elderly (over 65 years) and those that reported only a single outcome (such as pouchitis).

All participants in the review had ulcerative colitis or familial adenomatous polyposis and most studies included participants with either diagnosis. Mean or median participant ages ranged from 27 to 53 years. From 33% to 68.5% of participants were female (where reported). Diverting ileostomy was used in 79% (range 5% to 100%) of cases. Hand-sewn anastomosis was conducted in 40% of cases (range zero to 100%). Some studies used several different surgical techniques. Median duration of recruitment was 12 years (range four to 30). All studies were published between 2000 and 2009.

Two reviewers independently selected the studies. They resolved disagreements in discussion with a third reviewer.

Assessment of study quality
The authors did not state that they assessed validity.

Data extraction
Incidence rates with 95% confidence intervals (CIs) were extracted for each outcome in each study.

Two reviewers independently extracted these data. Primary study authors were contacted for more information where necessary.

Methods of synthesis
Data were combined using a random-effects model to calculate pooled incidence rates and 95% confidence intervals. A restricted maximum likelihood method was used to address heterogeneity between studies. Sensitivity analysis was conducted for pouch failure and restricted analysis to studies with at least five years' follow-up.

Results of the review
Fifty-three studies were included (14,966 participants) with a median sample size of 127 (range 50 to 2,491). Most studies (70%) were retrospective cohort studies. Median duration of study follow-up was 75 months (range six to 180).

Pooled incidence rates for primary outcomes were: pouch failure 4.3% (95% CI 3.5 to 5.3; 43 studies), pelvic sepsis 7.5% (95% CI 6.1 to 9.1; 46 studies) and severe daytime faecal incontinence 6.1% (95% CI 2.9 to 12.3; 13 studies). In sensitivity analysis, pouch failure rate was 4.7% in studies with at least five years' follow-up.

Pooled incidence rates for secondary outcomes were: fistula 4.5% (95% CI 3.5 to 5.7; 38 studies), stricture 10.7% (95% CI 8.2% to 13.8; 35 studies), pouchitis 26.8% (95% CI 21.0 to 33.5; 39 studies), sexual dysfunction 3.0% (95% CI 1.7 to 5.2; 13 studies), small bowel obstruction 11.4% (95% CI 9.1 to 14.1; 34 studies), mild daytime faecal incontinence 14.3% (95% CI 7.3 to 25.9; 21 studies), mild night-time incontinence 17.3% (95% CI 4.7 to 46.8; nine studies), severe night-time incontinence 7.6% (2.5 to 21.3; 10 studies), daytime faecal frequency 5.7% (95% CI 4.9 to 6.7; 26 studies), night-time frequency 1.5% (95% CI 1.0 to 2.1; 22 studies) and 24-hour frequency 5.9% (95% CI 5.0 to 6.9; 26 studies).

The review also reported how these estimates of incidence compared with the findings of a systematic review of 43 studies conducted prior to 2000 (see Other Publications of Related Interest).

**Authors' conclusions**

According to post-2000 studies, ileo-pouch anal anastomosis was associated with pouch failure in 4.3% of cases, pelvic sepsis in 7.5% and severe daytime faecal incontinence in 6.1%.

**CRD commentary**

The objectives and inclusion criteria of the review were clear in most respects. However there was no strong clinical rationale for including only post-2000 studies and the calculated incidence rates were based on a time-frame determined solely by the publication date of an earlier review. Relevant sources were searched for studies and there were no language restrictions. Search terms were not reported. It appeared that the review was limited to published studies, in which case it may have been subject to publication bias. The risk of publication bias was not assessed formally but the authors attempted to minimise the risk by restricting inclusion to larger studies.

Steps were taken to minimise the risk of reviewer bias and error in study selection and data extraction but it did not appear that study quality was assessed and no details were available on attrition rates. The design of individual studies was not reported in the table of study characteristics. It was stated that 70% of studies were retrospective cohorts but the design of other studies was not reported. All these factors made it difficult to assess the reliability of primary studies' findings.

It did not appear that studies were weighted by sample size or variability in the calculation of pooled incidence rates as rates for pouch failure in the three largest studies (each with over 2000 participants) ranged from 5.7% to 7.7% and were substantially higher than the overall pooled estimate. Statistical heterogeneity was not quantified but it was evident from the forest plots that there was very marked variation between the studies and it was questionable whether they were suitable for pooling. As the authors noted, the review was limited by reliance on retrospective observational studies and there was wide variation even within individual studies.

Limitations in the review, particularly statistical and clinical differences between the studies and failure to assess study quality, mean that the authors' conclusions may not be reliable.

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

**Practice**: The authors did not state any implications for practice.

**Research**: The authors stated that reduction of complications such as pelvic sepsis and pouch failure should be a major goal for future surgical developments.

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