A comparison of hand-sewn versus stapled ileal pouch anal anastomosis (IPAA) following proctocolectomy: a meta-analysis of 4183 patients


CRD summary
This review reported that hand-sewn and stapled ileal pouch anal anastomosis (IPAA) following proctocolectomy had similar early post-operative outcomes. However, improved nocturnal continence and anorectal physiologic measures were found with stapled IPAA. The authors’ conclusions may not be reliable given limitations in both the data and analyses.

Authors' objectives
To determine the effect of hand-sewn versus stapled ileal pouch anal anastomosis (IPAA) on post-operative adverse events and functional outcomes following restorative proctocolectomy for inflammatory bowel disease, familial adenomatous polyposis or cancer.

Searching
MEDLINE, EMBASE and the Cochrane Library were searched from 1988 to 2004 unrestricted by language; the search terms were reported. References from articles were also checked.

Study selection
Study designs of evaluations included in the review
Comparative studies were eligible for inclusion. Prospective randomised controlled trials (RCTs), prospective non-randomised studies and retrospective comparative studies were included in the review.

Specific interventions included in the review
Studies comparing hand-sewn versus stapled IPAA were eligible for inclusion. Of the included participants, 64.5% underwent hand-sewn pouch anal anastomosis with mucosectomy and 35.5% underwent stapled pouch anastomosis without mucosectomy.

Participants included in the review
Studies of patients having undergone restorative proctocolectomy for inflammatory bowel disease, familial adenomatous polyposis or cancer were eligible for inclusion. The individual studies varied in their inclusion criteria for participants, and the participants were matched for one or more of the following characteristics: age, gender, pouch type, pre-operative diagnosis and/or follow-up.

Outcomes assessed in the review
Adverse events, functional outcomes and anorectal physiologic measures were eligible for inclusion. Adverse events included anastomotic leak, pouch failure, wound infection and post-operative mortality; functional outcomes included frequency of defecation, incontinence, stool seepage, pad usage, use of antidiarrhoeal medication, quality of life and sexual function measures; anorectal physiologic measures included resting and maximum squeeze pressure of the sphincter complex and maximum neorectal volume. Outcome definitions were reported.

How were decisions on the relevance of primary studies made?
Two reviewers independently selected papers for inclusion.

Assessment of study quality
The validity of the randomised and non-randomised studies was assessed using a modified Newcastle-Ottawa Scale; studies scoring seven or more stars were considered to be of high quality. The authors did not state how many reviewers
were involved in the validity assessment.

**Data extraction**
Two reviewers independently extracted the data according to a pre-specified protocol; agreement between the reviewers was 100%. Estimates of effect, i.e. odds ratio (OR) for dichotomous outcomes and weighted mean difference (WMD) for continuous outcomes, and their 95% confidence intervals (CIs) were extracted for each study. A value of 0.5 was added to both groups to outcomes where one group contained zero events. If both groups had zero events, or if the end points were incompatible, or if it was not possible to calculate appropriate end points from the data provided, the study was excluded from the analysis.

**Methods of synthesis**
How were the studies combined?
The studies were combined in a meta-analysis using a random-effects model. Summary estimates were presented as ORs and WMDs with 95% CIs. Funnel plots were used to explore publication bias.

How were differences between studies investigated?
The chi-squared test and the I-squared statistic were used to assess statistical heterogeneity. A sensitivity analysis was undertaken for the following subgroups: study size, year of publication, study quality, outcomes reported only on J-pouch reservoirs.

**Results of the review**
Twenty-one studies (n=4,183) were included in the review: 6 RCTs, 5 prospective non-randomised studies and 10 retrospective comparative studies.

Studies scored between three and eight stars for quality; 8 studies were considered to be of a high quality.

Effectiveness.

There was a significant effect on the incidence of nocturnal seepage (OR 2.78, 95% CI: 1.70, 4.56), incontinence to liquid stool (OR 2.32, 95% CI: 1.24, 4.34) and nocturnal pad usage (OR 4.12, 95% CI: 1.48, 11.44) in favour of stapled IPAA; significant heterogeneity was found for nocturnal seepage and incontinence. A significant reduction in anorectal resting (WMD -13.36, 95% CI: -19.03, -7.69) and maximum squeeze pressure (WMD -14.43, 95% CI: -26.86, -2.01) was also found in favour of the handsewn IPAA; significant heterogeneity was found for both analyses. The remaining outcomes showed no significant differences between the two intervention groups.

Sensitivity analyses.

The sensitivity analysis suggested that hand-sewn IPAA as compared with stapled IPAA was associated with significantly more ileal pouch failures and lower resting pressures when only high-quality studies were considered. For studies published after 1995, significant differences in favour of stapled IPAA were found for seepage during the day, seepage at night, anorectal resting pressure and squeeze pressure. When only larger studies were considered (over 50 participants), seepage during the day, resting pressure and squeeze pressure significantly favoured stapled IPAA. When only J-pouch IPAA was considered, significant differences were found in favour of stapled J-pouch compared with hand-sewn J-pouch for anorectal resting and squeeze pressure. However, with the exception of squeeze pressure for studies published after 1995, statistical heterogeneity was associated with all of the above analyses.

In relation to publication bias, the results of the funnel plots were not reported.

**Authors' conclusions**
Similar early post-operative outcomes were found for hand-sewn IPAA and stapled IPAA. However, improved nocturnal continence and anorectal physiologic measures were found with stapled IPAA. A risk of increased incidence of dysplasia in the anal transition zone may exist with stapled IPAA, but this could not be quantified in this review.
CRD commentary
The research question was supported by clear inclusion criteria in terms of the intervention, outcomes and study design. Appropriate databases were searched for relevant papers unrestricted by language. Attempts were also made to assess the possibility of publication bias, though these were not reported in the review and so it was unclear whether publication bias might have affected the findings. The methods undertaken to select papers and extract the data were likely to have minimised error or bias. The quality of the primary studies was assessed and the results reported, but it was unclear whether appropriate steps were taken to reduce the risk of error and bias in the assessment.

Statistical heterogeneity was assessed and the authors attempted to explore study differences. However, most of the studies were not of a high quality: the studies relied on short-term data and retrospective control groups; were small in size; and showed evidence of both clinical heterogeneity and significant statistical heterogeneity. Overall, given these limitations, the authors’ conclusions may not be reliable.

Implications of the review for practice and research
Practice: The authors stated that the review supports the selective use of stapled pouch-anal anastomosis.

Research: The authors stated that comparative studies with longer follow-up and larger sample sizes are needed to determine the risk of anal canal dysplasia or cancer after restorative proctocolectomy.

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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.