Meta-analysis of colonic reservoirs versus straight coloanal anastomosis after anterior resection

CRD summary
The authors concluded that colonic J-pouch improved functional outcomes compared with straight coloanal anastomosis, without any increase in post-operative complications; coloplasty and J-pouch appeared to have similar effects, but further research is required. The pooling of studies of diverse study design and the limited quality assessment of the included studies weaken the strength of the conclusions.

Authors' objectives
To compare the effectiveness and safety of colonic J-pouch with transverse coloplasty and straight coloanal anastomosis (CAA) in patients undergoing anterior resection.

Searching
MEDLINE (via PubMed), EMBASE and the Cochrane Library were searched for studies published between 1986 and 2005. The search terms were reported and no language restrictions were applied. Related articles were tracked and reference lists were screened. Abstracts were reviewed. The reviewers were unable to obtain three potentially relevant studies.

Study selection

Comparative study designs were eligible for inclusion in the review.

Specific interventions included in the review
Studies that compared colonic J-pouch with transverse coloplasty or with straight CAA without a colonic reservoir were eligible for inclusion in the review.

Participants included in the review
Studies of patients who were undergoing low anterior resection were eligible for inclusion. Where reported, the mean age of the participants in the included studies ranged from 52 to 69 years. The participants included patients with carcinoma and mid or low rectal disease. Some studies excluded patients with inflammatory bowel disease, extensive local disease, local recurrence or distal disease; in some studies patients had received pre- or post-operative chemotherapy or radiotherapy.

Outcomes assessed in the review
Studies that assessed any of the stipulated early, functional or physiological outcomes were eligible for inclusion: The early outcomes considered were post-operative mortality within 30 days, anastomotic leak, wound infection and other adverse events, and complications including anastomotic stricture, rectovaginal fistula, perianal excoriation, small bowel obstruction, pelvic abscess, ureteric injury, and length of hospital stay and operating time. Functional outcomes, which were evaluated within 6 months of the procedure or reversal of the proximal diversion, and at 1 year and 2 or more years, included frequency of defaecation per 24 hours, faecal urgency, lack of discrimination between faeces and flatus, nocturnal seepage, incomplete evacuation and the requirement for antidiarrhoeal medication. Physiological outcomes, which were evaluated within 6 months and at 1 or more years, included resting and maximal squeeze pressure of sphincter complex, neorectal threshold volume and maximal neorectal volume. Comparable outcomes had to be reported or calculable from reported data. Compliance and quality of life were not assessed since these outcomes were reported in only a few studies.

How were decisions on the relevance of primary studies made?
Three reviewers independently selected the studies.
Assessment of study quality
The validity of randomised controlled trials (RCTs) and non-randomised controlled trials (CCTs) was assessed using the following criteria, modified from the Newcastle-Ottawa scale: patient selection, comparability of the three treatment groups, and assessment of outcomes. Studies scoring six or more stars were classified as the highest quality.

Data extraction
Three reviewers independently extracted pre-specified data. For each study, odds ratios (ORs) with 95% confidence intervals (CIs) were calculated for dichotomous data and weighted mean differences (WMDs) with 95% CIs for continuous data. Where required, standard deviations (SDs) were calculated from reported data. For outcomes with zero events in one treatment group, 0.50 was added to both treatment groups. Specified factors matched for, as well as inclusion and exclusion criteria, were also extracted for each study.

Methods of synthesis
How were the studies combined?
The studies were combined using a random-effects meta-analysis (Mantel-Haenszel). Pooled ORs and 95% CIs were calculated for dichotomous data and pooled WMDs and 95% CIs for continuous data. Studies that reported zero events in both treatment groups for the outcomes of interest were excluded. A funnel plot was used to assess publication bias.

How were differences between studies investigated?
Statistical heterogeneity was assessed using the chi-squared statistic. A sensitivity analysis was used to examine the effect on the results of a sample size more than 50 patients, publication after 1999 and highest quality.

Results of the review
Thirty-five studies (n=2,240) were included: 14 RCTs (n=789), 13 prospective CCTs (n=797) and 8 retrospective studies (n=654).

The studies scored between three and nine stars for quality. Sixteen studies (14 RCTs and 2 CCTs) were classified as the highest quality (six or more stars).

Failure to construct a J-pouch reservoir was found in 4.8% of the patients (12 out of 249 patients in 7 studies).

J-pouch versus transverse colostomy (5 studies, n=280).

There was no significant difference between J-pouch and transverse colostomy for any of the adverse post-operative events or functional outcomes.

Hospital stay and operating time were significantly shorter with J-pouch, but only one study (n=88) reported these outcomes: the WMD was -1.40 days (95% CI: -1.86, -0.94, p<0.001) for hospital stay and 33.60 minutes (95% CI: 24.55, 42.65, p<0.001) for operating time.

J-pouch versus CAA (31 studies, n=1,976).

J-pouch was associated with a reduction in anastomotic leak compared with CAA, but the reduction was not statistically significant; the OR was 0.71 (95% CI: 0.48, 1.0, p=0.069; based on 17 studies, n=1,225). No evidence of statistical heterogeneity was found. There were no statistically significant differences between J-pouch and CAA for any of the other adverse post-operative events.

J-pouch was associated with a significant reduction in the frequency of defaecation at 6 months compared with CAA (WMD -1.88, 95% CI: -3.33, -0.42, p=0.011). The reduction was less but remained statistically significant at 1 year (WMD -1.35, 95% CI: -1.92, -0.78, p<0.001) and 2 or more years (WMD -0.74, 95% CI: -1.31, -0.18, p=0.010). Significant statistical heterogeneity was found for all three meta-analyses (p<0.001 for all).
J-pouch was associated with a significant reduction in faecal urgency at 6 months compared with CAA (OR 0.27, 95% CI: 0.12, 0.60, p=0.001) and at 1 year (OR 0.21, 95% CI: 0.12, 0.37, p<0.001), but there was no significant difference between treatments at 2 or more years (based on 3 studies, n=134). Significant statistical heterogeneity was found for the meta-analysis at 6 months (p=0.022) but not for the other two meta-analyses.

A funnel plot based on post-operative anastomotic leak showed no evidence of publication bias.

The sensitivity analysis showed similar results. For faecal frequency, heterogeneity remained statistically significant for high-quality studies and for studies with more than 50 patients.

**Authors’ conclusions**

Colonic J-pouch improved functional outcomes compared with straight CAA, with no increase in post-operative complications. Coloplasty and J-pouch appeared to have similar effects, but further research is required to confirm the findings.

**CRD commentary**

The review question was defined in terms of the participants, outcomes and study design. However, eligible interventions were reported differently in various parts of the text. The lack of specified primary review outcomes amid the multiplicity of the reported outcomes gives rise to the potential for significant differences to arise by chance. Several relevant sources were searched and attempts were made to reduce language bias. No specific attempt to locate unpublished studies was reported, thus raising the possibility of publication bias. However, publication bias was assessed and no evidence for it was found. Methods were used to minimise reviewer errors and bias in the study selection and data extraction processes. Validity was assessed using a modification of a specified validity scoring system, but only the composite score was presented; this makes it difficult for the reader to judge the validity of the studies for themselves. In addition, the validity criteria seemed limited and did not include losses to follow-up.

Statistical heterogeneity was assessed but the pooling of various study designs (RCTs, CCTs and retrospective studies) is questionable; poorer quality studies tend to overestimate treatment effects. However, the authors did use a sensitivity analysis to examine the effect on the results of study quality and other factors. For some meta-analyses heterogeneity remained statistically significant, but studies assessing faecal frequency appeared to have similar directions of treatment effect. The conclusion appeared to be supported by the results presented, but, the pooling of studies with diverse study designs and the limited assessment of the quality of the included studies weaken the strength of the conclusions.

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

Practice: The authors stated that, if technically possible, J-pouch would appear to be the optimal procedure following anterior resection.

Research: The authors stated that more high-quality RCTs are required to confirm the benefits of J-pouch compared with coloplasty reconstruction.

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