A systematic review of stapled haemorrhoidectomy

Authors' objectives
To compare the safety and efficacy of circular stapled haemorrhoidectomy against conventional haemorrhoidectomy.

Searching
MEDLINE, Current Contents, EMBASE, HealthSTAR, the Cochrane Library (Issue 2, 2001) and the National Research Register were searched from inception to June 2001; ClinicalTrials.gov (2001) and the NCCHTA database (June 2001) were also searched. The search terms were reported and no language restrictions were applied. However, foreign language papers were excluded if the findings supported those of well-designed English language studies. Additional studies were identified by checking the references of retrieved articles, by handsearching conference proceedings from specialist societies, and by searching the Internet. Unpublished clinical trials were excluded from the review. One RCT published after the time period allotted for retrieving literature was also excluded.

Study selection
Study designs of evaluations included in the review
Randomised controlled trials (RCTs) were eligible for inclusion.

Specific interventions included in the review
Trials comparing circular stapled haemorrhoidectomy with the conventional haemorrhoidal techniques of excision-ligation, diathermy (with or without ligation) and closed haemorrhoidectomy were eligible for inclusion. Studies evaluating linear stapling were excluded. The included studies compared haemorrhoidectomy using a circular stapler with either a modified Milligan-Morgan technique or open diathermy.

Participants included in the review
Patients with all levels of haemorrhoids undergoing a haemorrhoidectomy were included.

Outcomes assessed in the review
Studies reporting on at least one of the following were eligible for inclusion: post-operative pain or analgesic requirement; adverse effects or safety (e.g. bleeding, wound discharge, altered bowel habits, urinary retentions, stenosis, sphincter damage and prolapse); period of recovery and wound healing; or an efficacy evaluation assessing readmission and re-operation rates, anal resting and squeeze volumes, return to normal bowel function and the reduction of residual skin tags.

An extensive range of safety and efficacy outcomes were measured; these included pain, bleeding, readmission rates and post-operative complications. The outcomes were measured by structured questionnaire, patient self-assessment, clinical examination, histopathological assessment, observer assessment, rectoanal manometry, defecography, endoanal ultrasound and anaoscopy.

How were decisions on the relevance of primary studies made?
Two reviewers assessed the studies and reached a consensus regarding inclusion.

Assessment of study quality
The authors assessed validity using the following criteria: blinding of the patients and outcome assessors, randomisation procedures, method of allocation concealment and the duration of follow-up. The authors did not state how the validity assessment was performed.

Data extraction
Two reviewers independently extracted the data. The extracted data included intervention details, pre-, intra- and post-operative assessment methods, operator details or skills, study design, study population, inclusion and exclusion criteria, and the duration of follow-up.

**Methods of synthesis**

How were the studies combined?
The following were calculated with 95% confidence intervals (CIs): relative risks (RR) for outcomes relating to safety or adverse effects, occurrence of skin tags and readmission rates; weighted mean differences (WMDs) for operating times, length of hospital stay and pain levels; standardised mean differences (SMDs) for the resumption of usual activities. When the studies were statistically homogeneous, the results were combined using a fixed-effect model. When statistical heterogeneity was present, a random-effects model was used.

How were differences between studies investigated?
The chi-squared test was used to test for heterogeneity, with a P-value of less than 0.1 indicating significant heterogeneity.

**Results of the review**

Seven RCTs (n=591) were included in the review.

All 7 RCTs were assessed as level II in the hierarchy of evidence, where evidence was considered to be from a properly designed RCT. The authors reported that the patients were blinded to the treatment in all 7 RCTs, and that randomisation was conducted using either sealed envelopes (6 RCTs) or a table of random numbers (1 RCT). However, only one study used an adequate method of allocation concealment.

Safety.

Bleeding at 2 weeks was significantly greater in patients with conventional haemorrhoidectomy than in those with stapled haemorrhoidectomy (2 RCTs; RR 0.55, 95% CI: 0.37, 0.82, P=0.003). However, there was no significant difference in bleeding at 6 weeks (2 RCTs; RR 0.55, 95% CI: 0.05, 6.71) or at 2 to 3 months (2 RCTs; RR 0.52, 95% CI: 0.10, 2.80). There was also no significant difference in haemorrhage requiring sutures (2 RCTs; RR 1.33, 95% CI: 0.50, 3.57) or transfusion (3 RCTs; RR 0.24, 95% CI: 0.04, 1.40).

There was no significant difference between patients with stapled haemorrhoidectomy and those with conventional haemorrhoidectomy in terms of urinary retention (3 RCTs; RR 0.59, 95% CI: 0.28, 1.24), anal stenosis at 2 to 6 weeks (2 RCTs; RR 1.07, 95% CI: 0.36, 3.17), anal stenosis at late follow-up (2 RCTs; RR 0.45, 95% CI: 0.14, 1.46), thrombosis of external haemorrhoids (2 RCTs; RR 0.56, 95% CI: 0.19, 1.61), or internal sphincter damage at 6 weeks (2 RCTs; RR 0.70, 95% CI: 0.21, 2.37).

Efficacy.

Hospital stay was significantly shorter (4 RCTs; WMD 0.89, 95% CI: 1.42, -0.36, P<0.001), and resumption of usual activities was significantly quicker (4 RCTs; SMD 4.52, 95% CI: 8.93, -0.11, P=0.04), in patients with stapled haemorrhoidectomy than in those with conventional haemorrhoidectomy.

There was no significant difference between patients with stapled haemorrhoidectomy and those with conventional haemorrhoidectomy in terms of operating time (3 RCTs; WMD 9.89, 95% CI: 23.43, 3.64), readmission rate (2 RCTs; RR 0.15, 95% CI: 0.02, 1.17), visual analogue scale pain scores (2 RCTs; WMD 2.83, 95% CI: 7.43, 1.68), wound discharge at 2 weeks (2 RCTs; RR 0.57, 95% CI: 0.27, 1.19), or skin tags at 2 to 3 months (3 RCTs; RR 3.06, 95% CI: 0.85, 11.04).

**Cost information**
The authors reported that the cost of a stapler was approximately $600, compared with the cost of $25 for sutures with an open haemorrhoidectomy.
Authors' conclusions
Stapled haemorrhoidectomy appears to be a safe alternative for the treatment of haemorrhoids. However, the benefits of a shorter operating time and convalescence may only be noted after surgeons have gained experience in the use of the technique.

CRD commentary
The review question and inclusion criteria were clear. The authors searched extensively for published and unpublished studies. However, foreign language papers with findings that supported those of English language studies were excluded from the review, as were unpublished clinical trials. An RCT published after the allotted time period for literature retrieval was also excluded. These factors may have led to the introduction of publication and language bias, which were not assessed. The review was methodologically sound: two reviewers independently assessed the studies for inclusion and extracted the data, and the validity of the included RCTs was assessed. All the meta-analyses were undertaken on the results of two to four studies, with some of these displaying statistically significant heterogeneity. The authors' conservative conclusions and their recommendations for further research seem appropriate given the small number of generally low-powered RCTs available.

Implications of the review for practice and research
Practice: The authors recommended that surgeons should undergo appropriate training and supervised instructions, and should conduct an audit of their results with this technique. In addition, the Colorectal Surgical Society of Australia should develop guidelines for training on this procedure.

Research: The authors highlighted the need for larger RCTs, with standardised outcome measures, particularly for pain and bleeding outcomes. Further research is needed to ascertain the cost, feasibility as a day-case procedure, and the long-term outcomes of stapled haemorrhoidectomy.

Bibliographic details

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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.