Stapled haemorrhoidectomy (haemorrhoidopexy) for the treatment of haemorrhoids: a systematic review and economic evaluation


CRD summary
This well-conducted review concluded that stapled haemorrhoidopexy was associated with less pain in the immediate postoperative period, but that absolute and relative rates of recurrence and reinterventions for stapled haemorrhoidectomy and conventional haemorrhoidectomy remained unclear. The authors’ conclusions are likely to be reliable.

Authors' objectives
To determine the clinical effectiveness, safety and cost effectiveness of circular stapled haemorrhoidopexy (SH) for the treatment of haemorrhoids. This abstract focuses on clinical effectiveness and safety.

Searching
Cochrane Database of Systematic Reviews, DARE, BIOSIS Previews, Cochrane Central Register of Controlled Trials (CENTRAL), CINAHL, EMBASE, Health Technology Assessment Database, MEDLINE, Science Citation Index, ISI Proceedings, Zetoc Conferences, ClinicalTrials.gov, MetaRegister of Controlled Trials and National Research Register (NNR) were searched without language restriction up to July 2006; search terms were reported. A number of clinical guidelines and systematic review sources – Clinical Evidence (BMJ Publishing Group), Health Evidence Bulletin Wales, National Guideline Clearinghouse, National Institute for Health and Clinical Excellence (NICE), National Library for Health (NHL), Scottish Intercollegiate Guidelines Network (SIGN), Turning Research into Practice (TRIP+) – and topic-specific websites were searched. Studies in any language were included as long as a translator was available.

Study selection
Randomised controlled trials (RCTs) with more than 20 patients comparing SH with any conventional haemorrhoidectomy (CH) technique where excision is conducted using a scalpel, scissors or diathermy in people of any age with prolapsing haemorrhoids for whom surgery was considered an appropriate option were eligible for inclusion in the review. Only the use of circular staple guns suitable for SH were eligible for inclusion in the review (PPH01, PPH03 (EE-S) or Autosuture using the STRAM kit). Studies comparing SH with any non-excisonal interventions and studies using a linear stapler were excluded from the review, as were those with patients undergoing emergency procedures for thrombosed haemorrhoids. Primary outcomes of interest were pain, bleeding, prolapse and reintervention rate. A number of secondary outcomes were also reported. Outcomes were classified by time-point: peri-operative/post-operative (less than six weeks), short term (greater than six weeks and less than 12 months), 12 months and longer term (greater than 12 months).

Included interventions were mechanical suture, PPH01, and non-specified staple gun. Comparators included: Ferguson, Fransler and Anderson, Parks and Fransler-Arnold, Milligan-Morgan (M&M) alone or with diathermy, LigaSure, Hospital Leopold Bellan (HLB) and Harmonic Scalpel. Where reported, anaesthesia used included general, regional or combination. Where reported, mean age ranged from 45.15 years to 51 years. Severity of haemorrhoids ranged from grade I to IV.

Two reviewers independently selected studies for inclusion in the review and any disagreements were resolved by consensus or through consultation with a third reviewer.

Assessment of study quality
The quality of the RCTs was assessed using a modified topic-specific 12-item checklist. Validity criteria included: number randomised reported, randomisation method, allocation concealment, blinding, type and experience of surgeon, power calculation and loss to follow up. One reviewer assessed the validity of the included studies, which was checked independently by a second reviewer. Any disagreements were resolved through consensus or by discussion with a third reviewer.
Data extraction
Incidence or mean and standard deviations (SDs) were extracted for each intervention group and outcome of interest. Odds ratio (ORs) and 95% confidence intervals (CIs) were calculated for binary outcomes. Mean differences (MD) and 95% CIs were calculated for continuous outcomes. Authors were contacted where additional information was required.

One reviewer extracted data from the included studies, which was independently checked by a second reviewer; any disagreements were resolved through consensus or by discussion with a third reviewer. Non-English language studies were extracted by one reviewer along with a native speaker of that language (four non-English language papers were included in the review).

Methods of synthesis
Studies were combined in a meta-analysis using a random-effects model where no statistically significant heterogeneity was found. Summary estimates were reported as ORs or MD along with their associated 95% CIs. Where there were three or fewer studies included in the analysis, a fixed-effect model was used. Statistical heterogeneity was assessed using $\chi^2$ test and the $I^2$ statistic. Subgroup analysis by time point was performed. Sensitivity analysis was conducted to explore the impact of patient population, quality criteria and high losses to follow-up and outlying results.

Results of the review
Twenty-seven RCTs were included in the clinical effectiveness review (n=2,279; 1,137 SH and 1,142 CH). Overall, four per cent of studies were described as double-blind, four per cent reported that patients were blinded, 19 per cent reported that outcome assessors were blinded, 37 per cent reported using an appropriate method of randomisation and/or allocation concealment, 33 per cent reported a power calculation, 19 per cent did not report loss to follow-up and 7 per cent had a loss to follow-up greater than 80 per cent at the final time point. Only two studies reported recruiting patients with second, third and fourth degree haemorrhoids. Most of the trials were carried out in the UK and other European countries. Some trials were carried out in USA, Asia, India, Saudia Arabia and Mexico.

Early post-operative period
Significantly fewer patients had unhealed wounds at six weeks following SH compared with CH (OR 0.08, 95% CI: 0.03, 0.19, p<0.001, nine RCTs), although residual prolapse was more common following SH (OR 3.38, 95% CI: 1.00, 11.47, p=0.05, nine RCTs). No evidence of significant statistical heterogeneity was found. No statistically significant between-group differences in the incidence of bleeding, rate of interventions required for bleeding or post-operative complications were found. Shorter operating times, hospital stay, time to first bowel movement and time to normal activity were found with SH (when compared to CH).

Short term
Prolapse was significantly more common after treatment with SH (OR 4.68, 95% CI: 1.11, 19.71, p=0.04, six RCTs). No statistically significant between-group difference was found for the number of patients complaining of pain.

Long term (more than 12 months)
Prolapse was significantly more common after SH (OR 4.34, 95% CI: 1.67, 11.28, p=0.003, 12 RCTs) and significantly more reinterventions were performed after SH for prolapse at 12 months or longer (OR 6.78, 95% CI: 2.00, 23.00, p=0.02, six RCTs). No evidence of significant statistical heterogeneity was found. No statistically significant difference was found in the number of patients experiencing pain, the total number of reinterventions or interventions for pain, bleeding or complications between SH and CH.

Cost information
CH and SH were found to have similar costs and quality-adjusted life years (QALYs); on average, the difference in costs between the two procedures was £19 and the difference in QALY was -0.001 in favour of CH over 3 years. In terms of QALY, a superior quality of life in the early post-operative period due to reduced pain after SH was offset by a higher rate of symptoms over the follow-up period. Results were sensitive to modelling assumptions, particularly the valuation of utility in the early post-operative period. Probabilistic sensitivity analysis found that at a threshold
incremental cost-effectiveness ratio of £20,000-30,000 per QALY, SH had a 45% probability of being cost-effective.

**Authors' conclusions**
SH was associated with less pain in the immediate post-operative period, but a higher rate of residual prolapse, prolapse in the longer term and reintervention due to prolapse. There was no clear difference in terms of the rate or type of complications between the two interventions. The absolute and relative rates of recurrence and reinterventions for SH and CH remained uncertain.

**CRD commentary**
The review was supported by clear inclusion criteria. Several sources were searched without language restriction, minimising the likelihood of language or publication biases. Methods used to select studies, extract data and assess study quality were likely to minimise the possibility of reviewer error and bias. Study quality was assessed using appropriate criteria and the results reported. Appropriate methods were used to pool the results and to investigate statistical heterogeneity. In addition, the authors explored possible sources of any heterogeneity found. This was a well conducted review and the authors conclusions were likely to be reliable.

**Implications of the review for practice and research**
Practice: the authors stated that some training may be required in the use of the staple gun. Given the clinical and economic evidence, the decision of whether SH or CH is performed could be based on the priorities and preferences of the patient and surgeon.

Research. The authors' recommendations on research included: a well-conducted trial with a minimum five-year follow up period to ensure adequate evaluation of reintervention rates; evaluation of the effectiveness of SH in patients with fourth degree haemorrhoids and with patients with co-morbid conditions as well as research into utilities up to six months post-operatively; reintervention rates for all treatments for haemorrhoids should be reviewed and the trade-off for patients of short-term pain versus long-term outcomes should be assessed; and the ability of SH to reduce hospital days by shortening inpatient admissions or increasing the proportion of day cases should be explored in a real practice setting.

**Bibliographic details**

**Original Paper URL**

**Other publications of related interest**

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Subject indexing assigned by NLM

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Record Status
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.