

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

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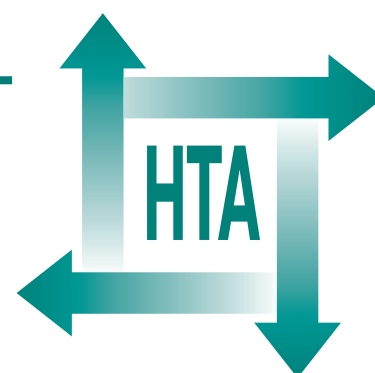
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## *Executive summary*

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## Executive summary

### Background

Haemorrhoids are inflammation or prolapse of the vascular tissues of the anal canal. They affect people of any age and gender; they most commonly occur between the ages of 45 and 65 years. Symptoms include rectal bleeding, pain, irritation and mucous discharge. Treatments include conservative management, non-excisional interventions and surgical haemorrhoidectomy. Haemorrhoidectomy is typically used when conservative management or non-excisional interventions fail. Approximately 8000 haemorrhoidectomies were performed in England in 2004/05. A range of techniques is used, including Milligan–Morgan, Ferguson, Parks, Fansler–Arnold and Fansler–Anderson; Milligan–Morgan is most commonly used in the UK. In 1998, Longo introduced a procedure called stapled haemorrhoidopexy (SH), which involves stapling haemorrhoids into their original position and excising excess haemorrhoidal tissue.

### Objective

The objective of this review was to determine the safety, clinical effectiveness and cost-effectiveness of circular SH for the treatment of haemorrhoids.

### Methods

A systematic review of the clinical and cost-effectiveness literature was conducted. Twenty-six electronic databases and Internet resources were searched from inception to July 2006, including MEDLINE, MEDLINE In Process, EMBASE, BIOSIS, CENTRAL, CINAHL and the HTA Database. Randomised controlled trials (RCTs) with 20 or more participants; comparing SH with any conventional haemorrhoidectomy (CH) technique; in people of any age with prolapsing haemorrhoids, for whom surgery is considered a relevant option, were used to evaluate clinical effectiveness. The main outcomes were pain, bleeding, prolapse and reintervention rate. Pooled odd ratios (ORs) or mean differences with 95% confidence intervals (CIs) were calculated using a random-effects model if there was no statistically

significant heterogeneity between more than three studies; where there were three or fewer studies included in the analysis, a fixed-effects model was used. An economic model of the surgical treatment of haemorrhoids was developed.

### Results

The searches identified 653 references, of which 147 full papers were retrieved and screened for relevance. The clinical effectiveness review included 27 RCTs ( $n = 2279$ ; 1137 SH; 1142 CH). All had some methodological flaws; only two reported recruiting patients with second, third and fourth degree haemorrhoids, and 37% reported using an appropriate method of randomisation and/or allocation concealment.

In the early postoperative period 95% of trials reported less pain following SH; by day 21 the pain reported following SH and CH was minimal, with little difference between the two techniques. Significantly fewer patients had unhealed wounds at 6 weeks following SH (OR 0.08, 95% CI 0.03 to 0.19,  $p < 0.001$ ). Residual prolapse was more common after SH (OR 3.38, 95% CI 1.00 to 11.47,  $p = 0.05$ , nine RCTs, results of a sensitivity analysis). There was no difference between SH and CH in the incidence of bleeding or postoperative complications. SH resulted in shorter operating times, hospital stay, time to first bowel movement and time to normal activity.

In the short term (between 6 weeks and a year) prolapse was more common after SH (OR 4.68, 95% CI 1.11 to 19.71,  $p = 0.04$ , six RCTs). There was no difference in the number of patients complaining of pain between SH and CH. Significantly fewer wounds remained unhealed at 6 weeks after SH (OR 0.08, 95% CI 0.03 to 0.19,  $p < 0.001$ , nine RCTs).

In the long term (over a year) there was a significantly higher rate of prolapse after SH (OR 4.34, 95% CI 1.67 to 11.28,  $p = 0.003$ , 12 RCTs). There was no difference in the number of patients experiencing pain, or the incidence of bleeding, between SH and CH.

There was no difference in the total number of reinterventions, or reinterventions for pain, bleeding or complications, between SH and CH. Significantly more reinterventions were undertaken after SH for prolapse at 12 months or longer (OR 6.78, 95% CI 2.00 to 23.00,  $p = 0.002$ , six RCTs).

Overall, there was no statistically significant difference in the rate of complications between SH and CH.

In the economic assessment it was found that, on average, CH dominated SH. However, CH and SH had very similar costs and quality-adjusted life-years (QALYs). On average, the difference in costs between the procedures was £19 and the difference in QALY was  $-0.001$ , favouring CH, over 3 years.

In terms of costs, the additional cost of the staple gun was largely offset by savings in operating time and hospital stay. In terms of QALYs, the superior quality of life due to lower pain levels in the early postoperative period with SH were offset by the higher rate of symptoms over the follow-up period, compared with CH. The results are very sensitive to modelling assumptions, particularly the valuation of utility in the early postoperative period.

The probabilistic sensitivity analysis showed that, at a threshold incremental cost-effectiveness ratio of £20,000–30,000 per QALY, SH had a 45% probability of being cost-effective.

### Limitations and uncertainties

No large, high-quality RCTs conducted in a representative population were located. There were limited data relating to recurrence and reintervention rates in the long term. There is currently no evidence relating to the efficacy of the PPH03 staple gun (Endo Ethicon-Surgery) or the Autosuture staple gun with the STRAM kit adaptor (Tyco Healthcare). Insufficient data were available for subgroups of patients (with different degrees of presurgery haemorrhoids, undergoing surgery as a day-case procedure, and co-morbid conditions) to assess the impact of these factors on outcomes. The main limitation of the economic study is the lack of directly observed utility data in the early postoperative period.

### Conclusions

SH was associated with less pain in the immediate postoperative period, but a higher rate of residual prolapse, prolapse in the longer term and reintervention for prolapse. There was no clear

difference in the rate or type of complications associated with the two techniques. The absolute and relative rates of recurrence and reintervention for SH and CH are still uncertain.

CH and SH had very similar costs and QALYs, the cost of the staple gun being offset by savings in hospital stay. Should the price of the gun change, the conclusions of the economic analysis may change.

Some training may be required in the use of the staple gun; this is not expected to have major resource implications for the NHS. Given the currently available clinical evidence and the results of the economic analysis, the decision as to whether SH or CH is conducted could primarily be based on the priorities and preferences of the patient and surgeon.

### Recommendations for research

The following areas are recommended for further research.

- An adequately powered, good-quality RCT is required, comparing SH with CH, recruiting patients with second, third and fourth degree haemorrhoids, and having a minimum follow-up period of 5 years to ensure an adequate evaluation of the reintervention rate.
- The effectiveness of SH in patients with fourth degree haemorrhoids and patients with co-morbid conditions should be evaluated.
- All treatments for haemorrhoids (conservative, non-surgical and surgical) need to be reviewed, investigating and comparing reintervention rates.
- Research is needed into utilities up to 6 months postoperatively.
- The trade-offs of patients for short-term pain versus long-term outcomes should be assessed through a discrete choice experiment.
- The ability of SH to reduce hospital stays, by shortening inpatient admissions or increasing the proportion of day cases, should be explored in a real practice setting.

### Publication

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# NIHR Health Technology Assessment Programme

The Health Technology Assessment (HTA) Programme, part of the National Institute for Health Research (NIHR), was set up in 1993. It produces high-quality research information on the effectiveness, costs and broader impact of health technologies for those who use, manage and provide care in the NHS. 'Health technologies' are broadly defined as all interventions used to promote health, prevent and treat disease, and improve rehabilitation and long-term care.

The research findings from the HTA Programme directly influence decision-making bodies such as the National Institute for Health and Clinical Excellence (NICE) and the National Screening Committee (NSC). HTA findings also help to improve the quality of clinical practice in the NHS indirectly in that they form a key component of the 'National Knowledge Service'.

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Reviews in *Health Technology Assessment* are termed 'systematic' when the account of the search, appraisal and synthesis methods (to minimise biases and random errors) would, in theory, permit the replication of the review by others.

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