Serial transverse enteroplasty procedure (STEP) for bowel lengthening in parenteral nutrition dependent children (September 2007)

In this procedure, an endoscopic stapler is passed through the mesentery and used to staple and dissect the bowel simultaneously (perpendicular to its long axis) on alternate sides leaving a zig-zag appearance. This decreases the width of the bowel and increases its length, so optimising the surface area for absorption. Data were available on the use of the STEP procedure in 53 children. These case series did not highlight any major safety concerns and reported efficacy outcomes which compared favourably with those of other (more complex) surgical procedures. However, due to the small patient numbers, NICE recommended special attention to consent and also submission of all patients to an international register based in the US.

Clinical Guidelines

None.

Other Guidance

Between July and September 2007, NICE published further guidance of relevance to surgery (listed below) which could not be summarised here. Please refer to the NICE website (<www.nice.org.uk>) for details.

Interventional Procedures guidance

- Corneal implants for ketatoconus
- Corneal implants for the correction of refractive error
- Insertion of extra-urethral (non-circumferential) retropubic adjustable compression device for stress urinary incontinence in men
- Laparoscopic cerclage for prevention of recurrent pregnancy loss due to cervical incompetence.

Technology appraisals

- Haemorrhoid – stapled haemorrhoidopexy (please also see the article below for more information).

NICE technology appraisal on stapled haemorrhoidopexy for the treatment of haemorrhoids

Helen Tucker, Elisabeth George, David Barnett, Carole Longson

This article outlines the recommendations, the clinical and cost-effectiveness evidence and the Appraisal Committee's considerations for the recently published NICE technology appraisal on stapled haemorrhoidopexy for the treatment of haemorrhoids.¹

Estimates of the proportion of the UK population affected by haemorrhoids range from 4.4–24.5%. In 2004–2005, approximately 23,000 procedures listed as 'main operations on haemorrhoids' were performed in England and Wales.

Haemorrhoids are classified as 'first-degree' if they bleed but do not prolapse; second-degree haemorrhoids prolapse during bowel movements, and reduce spontaneously; third-degree haemorrhoids prolapse on straining and require manual reduction; fourth-degree haemorrhoids prolapse and cannot be manually reduced. Surgery is the usual treatment for third and fourth degree haemorrhoids that have not responded to non-surgical interventions and for full circumferential second degree haemorrhoids.

The most commonly conducted surgical techniques are the Milligan–Morgan or Ferguson haemorrhoidectomy. The Milligan–Morgan procedure involves dissection of the haemorrhoid and ligation of the vascular pedicle with the wounds being left open to heal naturally. Healing is frequently delayed, which may result in discomfort and prolonged postoperative morbidity. The Ferguson procedure is a modified version of the Milligan–Morgan technique, in which the wound is closed with a continuous suture to promote healing. Another, less frequently used procedure is the Parks submucosal haemorrhoidectomy, which uses intra-anal incisions directly over each haemorrhoid, with the underlying haemorrhoidal tissue excised.

Stapled haemorrhoidopexy is a technique that reduces the prolapse of haemorrhoidal tissue by excising a band of the prolapsed anal mucosal membrane above the dentate line, using a specially designed circular stapling device. This interrupts the blood supply to the haemorrhoids and reduces the potential for available rectal mucosa to prolapse. Stapled

haemorrhoidopexy has been carried out in the UK for the last 2–3 years.

Clinical effectiveness evidence

Twenty-seven randomised controlled trials (RCTs) were included as part of a systematic review.² Twenty-one studies were evaluations of stapled haemorrhoidopexy using the HCSS33 device (Ethicon-Endo-Surgery; Johnson & Johnson, High Wycombe, UK) and information on the type of stapling device used was unavailable for six studies. The Milligan–Morgan procedure was used as comparator in 20 studies, the Ferguson procedure in six studies and the Parks procedure in one study. No evidence was identified for the Autosuture device.

Clinical benefits

Short- and medium-term postoperative pain (up to 15 days) was lower after stapled haemorrhoidopexy compared with conventional haemorrhoidectomy in 22 out of 23 studies. The number of patients with unhealed wounds was statistically significantly lower after stapled haemorrhoidopexy compared with conventional haemorrhoidectomy up to 6 weeks and over 6–12 weeks post-operatively (meta-analyses, 9 RCTs, and 4 RCTs, respectively). The mean length of hospital stay and the time to resume normal activity/return to work were shorter after stapled haemorrhoidopexy compared with conventional haemorrhoidectomy (14 out of 16 RCTs, and 19 out of 20 RCTs, respectively).

Recurrence

Meta-analyses revealed that the odds of re-intervention, either for prolapse (between 3–46 months) or for bleeding (between 12–46 months) were statistically significantly higher after stapled haemorrhoidopexy than after conventional haemorrhoidectomy. The odds of any non-excisional further intervention were also greater after stapled haemorrhoidopexy at 12–18 months, but this finding was not statistically significant. The odds of intervention for skin tag removal were smaller after stapled haemorrhoidopexy, but this finding was not statistically significant (2 RCTs). A statistically significantly higher odds of recurrent prolapse after stapled compared with conventional haemorrhoidectomy was found at different time points in two RCTs. However, a meta-analysis of studies, which assessed rates of prolapse between stapled and conventional haemorrhoidectomy at 12 months only, did not identify a statistically significant difference between stapled and conventional haemorrhoidectomy (7 RCTs).

Complications

A statistically significantly lower level of postoperative bleeding was found after stapled haemorrhoidopexy

compared with conventional haemorrhoidectomy at 14 days postoperatively (2 RCTs). A higher incidence of bleeding 6–8 weeks after stapled haemorrhoidopexy was seen, but this finding was not statistically significant (6 RCTs). No statistically significant differences in the incidence of a range of other postoperative complications at different time points were identified between the two procedures.

Cost-effectiveness evidence

No published economic evaluations were identified. The manufacturer of the HCSS33 device submitted a cost-utility analysis, which resulted in an incremental cost of £191 and 0.009 incremental quality adjusted life years (QALYs) for stapled haemorrhoidopexy compared with the Milligan–Morgan haemorrhoidectomy, with an incremental cost-effectiveness ratio (ICER) of £22,416 per QALY. An independent academic group also provided a cost-utility analysis, which conversely resulted in an incremental cost of £19 and 0.001 fewer QALYs for stapled haemorrhoidopexy compared with conventional haemorrhoidectomy (Milligan–Morgan or Ferguson technique). Therefore, stapled haemorrhoidopexy was dominated by conventional haemorrhoidectomy in this model (*i.e.* stapled haemorrhoidopexy was more costly and less effective).

However, the ICERs in both models presented were extremely sensitive to the assumptions used, with very small differences in the benefits resulting in large differences in the ICERs. Because there were no RCTs that recorded utility (quality of life) in the crucial early postoperative period, utility weights were estimated indirectly by both the manufacturer and the independent academic group. The utility gain estimated from using stapled haemorrhoidopexy was smaller in the independent academic group's model than in the manufacturer's model. Additionally, when the price of the device was set to the 2006 price of £420 rather than the 'estimated' 2007 price of £437, the total cost difference between haemorrhoidopexy and the conventional approach in the independent academic group's model was only reduced to approximately £2.

Appraisal Committee's decision

The Appraisal Committee was persuaded by the clinical and patient experts that less postoperative pain, shorter wound healing time, less time in hospital and earlier time to return to normal activities are of great importance to people when making decisions about treatment options. Also, it was thought that a potentially increased need for re-intervention with stapled haemorrhoidopexy at a later date was less important to patients than the expectation of significant postoperative pain with the conventional haemorrhoidectomy. Additionally, the Appraisal Committee accepted

that re-intervention for prolapse did not pose a greater risk after haemorrhoidopexy than re-intervention after conventional haemorrhoidectomy.

The Appraisal Committee noted that the cost-effectiveness results were greatly influenced by the estimates of quality of life changes (the utility values) used in the economic model. Because there were no published utility estimates for pain and overall benefits of stapled haemorrhoidopexy, the precise differences in health-related quality of life between people undergoing stapled haemorrhoidopexy compared with conventional surgery remained uncertain. However, it was concluded that a clear quality of life benefit in favour of stapled haemorrhoidopexy is likely to exist, particularly in the early postoperative period; therefore, the utility estimates used in the manufacturer's model were plausible. The Committee also noted that no account had been taken in the economic models of the likely costs of managing postoperative pain in primary care after discharge and that including these costs would favour the use of stapled haemorrhoidopexy.

The Appraisal Committee concluded that stapled haemorrhoidopexy was an appropriate treatment option in people with third-degree haemorrhoids, and also in people with fourth-degree haemorrhoids for whom residual external prolapse or skin tags would not be a concern. Although RCT evidence for the use of stapled haemorrhoidopexy for people with second-degree haemorrhoids was limited, the Appraisal Committee also agreed that for people with second-degree haemorrhoids with full circumferential mucosal prolapse where banding either would not be possible (because of the number of bands required) or would be

considered likely to be less effective, stapled haemorrhoidopexy would also be an appropriate treatment option.

The Appraisal Committee noted that the RCT evidence almost exclusively involved interventions using the PPH01 model of the HCSS33 stapling device. Clinical experts explained that there was no major difference between the PPH01 and the newer PPH03 device. It, therefore, concluded that the results of the RCTs would be applicable to the PPH03 device. However, the Committee concluded that the evidence could not be generalised to the other available stapling device, the Autosuture stapler with STRAM kit adapter (Tyco Healthcare, Gosport, UK); therefore, no recommendations could be made for the Autosuture stapler. The Committee also heard that devices other than the HCSS33 devices were rarely used in UK clinical practice.

Recommendations for surgical practice

On the basis of the available evidence, NICE has recommended that stapled haemorrhoidopexy should be an option when considering surgical treatment of prolapsed internal haemorrhoids. Only circular staplers specifically developed for haemorrhoidopexy should be used.

References

1. NICE. Technology appraisal number 128: Stapled haemorrhoidopexy for the treatment of haemorrhoids, September 2007, <<http://guidance.nice.org.uk/TA128>>.
2. Baba-Akbari A, Burch J, Epstein D *et al.* Stapled haemorrhoidectomy (haemorrhoidopexy) for the treatment of haemorrhoids, February 2007 <<http://guidance.nice.org.uk/page.aspx?o=426522>>.