VIEW POINT

Stapled haemorrhoidopexy for the treatment of haemorrhoids

Hémorroïdopexie par agrafage dans le traitement des hémorroïdes

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Available online 16 September 2009

Transanal stapling for the treatment of prolapsing haemorrhoids (PPH: Procedure for Prolapse and Haemorrhoids) was introduced by Antonio Longo in 1998 [1]. For probably the first time, a procedure addressed the underlying pathophysiology of haemorrhoidal disease and offered a novel surgical solution. Rather than simply excising the prolapsing haemorrhoidal tissue, as performed in the Milligan-Morgan or Ferguson haemorrhoidectomies, stapled haemorrhoidopexy (PPH) combined haemorrhoidal excision with a “pexy” procedure, restoring the haemorrhoidal cushions to their original anatomical position. In addition, there was no anodermal wound, so the much feared postoperative pain associated with conventional haemorrhoidectomy was potentially reduced with a quicker return to normal function.

Stapled haemorrhoidopexy rapidly gained popularity, particularly in Italy, the country of origin. However, other groups remained sceptical [2,3] and concerns were expressed as reports of serious complications began to emerge [4]. In 2003, the National Institute for Health and Clinical Excellence (NICE) in the United Kingdom issued its first guidance on stapled haemorrhoidopexy [5]. It concluded “the current evidence on the safety and efficacy of circular stapled haemorrhoidectomy appears to support the use of the procedure, provided the normal arrangements are in place for consent, audit, and clinical governance”.

Subsequently, a wealth of data has become available from a variety of case-series, randomised controlled trials, and systematic reviews. In 2006, the NHS R&D Health Technologies Assessment in the United Kingdom commissioned an updated assessment of stapled haemorrhoidopexy to include longer term follow-up and a cost analysis. This was undertaken independently by the Centre for Reviews and Dissemination and Centre for Health Economics at the University of York, United Kingdom, and the findings published in 2008 [6].

The York group performed a systematic review of the literature up until July 2006, comparing stapled haemorrhoidopexy with conventional excisional haemorrhoidectomy as performed with scalpel, scissors, or diathermy. A total of 27 randomised controlled trials were included in the final analysis, with 1137 stapled and 1142 conventional procedures. Stapled haemorrhoidopexy was found to be favourable to conventional haemorrhoidectomy for most short-term outcomes, including shorter operating times, reduced early postoperative pain, shortened length of hospital stay, less postoperative wound complications, and quicker return to normal activity. Due to data heterogeneity, meta-analysis was only possible for “postoperative
pains'', with a significant difference between the two techniques in favour of the stapling procedure. Unlike earlier systematic reviews [7,8], no significant difference was observed between stapled haemorrhoidopexy and conventional haemorrhoidectomy in postoperative bleeding. There was no difference between stapled haemorrhoidopexy and conventional haemorrhoidectomy in short-term or long-term complications, and importantly, there were no reports of pelvic/perineal sepsis or rectovaginal fistula.

The short-term results of the meta-analysis will be no surprise to those regularly performing stapled haemorrhoidopexy. What continues to cause controversy is the issue of recurrent prolapse. On both short-term (<12 months postoperation) and long-term (>12 months postoperation) follow-up, stapled haemorrhoidopexy was associated with an increased rate of recurrent prolapse, with odds ratios of 3.38 (95% CI: 1.00, 11.47; p = 0.05) and 4.34 (95% CI: 1.67, 11.28; p = 0.003) respectively. This was matched by an increased rate of re-intervention for prolapse in the long-term (odds ratio: 5.78; 95% CI: 2.0, 23.0; p = 0.002), although the overall rate of re-intervention for any reason was no different between the two techniques. The increase in recurrent prolapse following stapled haemorrhoidopexy may not be all attributable to a reduced efficacy of the stapling technique. It is well-recognised that patients often mistake residual anal skin tags as haemorrhoidal prolapse and the reporting of such will inevitably lead to an overestimation of the problem. However, even taking this into account, the stapling technology must also play some part in the susceptibility to recurrent prolapse. This is likely to be a problem in only a subgroup of patients, namely those with large volume grade III and IV haemorrhoidal prolapse. In such individuals, the volume of the prolapse will often exceed the capacity of the stapler ‘‘housing’’, resulting in inadequate haemorrhoidal ‘‘debulking’’ and predisposing to recurrent symptoms. This explanation is supported, at least to some extent, by the finding that when grade IV haemorrhoids were excluded in the York meta-analysis, the odds ratio for recurrent prolapse was reduced, although the difference remained significant. To address the limitations of the current stapling technology, the manufacturer is developing a modified device with an enlarged stapler ‘‘housing’’. Currently, the only alternatives for large volume haemorrhoidal prolapse, if recurrence is to be minimised, appear to be a conventional excision, accepting the increased postoperative pain, or a double-stapling technique [9,10] accepting the increased costs associated with the use of two stapling devices.

Unlike previous reviews, the York analysis included costs based on three parameters: the length of theatre time, length of hospital stay, and the device cost for the PPH-01 stapler. The increased cost of the stapler (£420, 2005/6 manufacturer’s price) was offset by a reduction the average theatre times and lengths of hospital stay, such that the mean difference in costs was £9 in favour of stapled haemorrhoidopexy. The direct hospital costs associated with the stapling procedure therefore appear to be marginal, and if one considers that community costs are likely to be greater following conventional haemorrhoidectomy, given the increased postoperative pain and the open anodermal wounds, then overall the cost of stapled haemorrhoidopexy will be favourable, provided the rates of recurrent prolapse and re-intervention are not too dissimilar.

In September 2007, NICE produced its updated guidance, based on the York group’s analysis and supplemented with advice from a clinical specialist and patient expert [11]. This guidance contained two important statements. Firstly, it was concluded that ‘‘stapled haemorrhoidopexy would be an appropriate use of NHS resources’’ and ‘‘should be recommended as a treatment option for people in whom surgical intervention is appropriate for the treatment of prolapsed internal haemorrhoids’’. The implications of this statement are that in the United Kingdom, health care providers have an obligation to fund stapled haemorrhoidopexy such that it becomes ‘‘normally available’’. The second important statement relates to patient selection and informed consent and is contained in the conclusion ‘‘patient choice [is] important in deciding between the two options for surgical intervention’’. That is, the patient should be made aware that stapled haemorrhoidopexy, although giving better short-term outcomes, and in particular less postoperative pain, may be associated with an increased risk of recurrent prolapse. As the most feared problem associated with haemorrhoidectomy, at least from the patient’s perspective, is postoperative pain and protracted recovery, it is likely that many patients will accept an increased risk of recurrence in favour of a quicker, less painful recovery.

There have been recent calls for further randomised trials to investigate the long-term outcomes of stapled haemorrhoidopexy [12]. Whether such trials are now practicable is debatable. Given the proven short-term benefits of the stapled technique, it is possible that clinicians and patients will be reluctant to randomise to open surgery. Long-term follow-up data is already beginning to emerge [13–17], and perhaps future research efforts might better be engaged in undertaking a comprehensive cost-effectiveness analysis, incorporating both hospital and community costs.

The latest evidence on stapled haemorrhoidopexy suggests that it is a technique that is finally coming of age and establishing itself as a credible alternative to conventional haemorrhoidectomy. It is probably most suited to the treatment of grade III, and perhaps circumferential grade II, haemorrhoidal prolapse. Controversy remains regarding its role in large volume and grade IV prolapse, due to increased rates of recurrence. Until this is resolved, it is unlikely that stapled haemorrhoidopexy will attain acceptance as the preferred ‘‘gold standard’’. In comparison, the fate of conventional haemorrhoidectomy appears somewhat uncertain, accepting that it will continue to have a role in specific circumstances. It is likely that ‘‘patient’s choice’’ will ultimately determine its survival or otherwise, and will be driven by how acceptable postoperative pain is in the era of modern surgical technology.

Conflict of interest

The author acts in an advisory capacity to Ethicon Endo-surgery (Europe) and participates in training programmes for Procedure for Prolapse and Haemorrhoids (PPH) and Stapled Transanal Rectal Resection (STARR) on behalf of the company.
References


