

**NATIONAL INSTITUTE FOR CLINICAL EXCELLENCE**

**Proposed Health Technology Appraisal**

**Stapled haemorrhoidectomy for the treatment of haemorrhoids**

**Draft scope**

**Draft remit / appraisal question:**

To appraise the clinical and cost effectiveness of: stapled haemorrhoidectomy

**Background:**

Haemorrhoidal tissues are part of the normal anatomy of the distal rectum and anal canal. The disease state of haemorrhoids (also known as piles) occurs when the tissue prolapses into the anal canal as a result of laxity of the surrounding connective tissue and engorgement of blood vessels.

Haemorrhoids are found in association with increased intra-abdominal pressure (for example, resulting from prolonged constipation, straining during defecation and pregnancy).

Haemorrhoids are believed to be very common and can affect people of any age or gender. Precise incidence and prevalence figures according to grade are not available, but it is likely there will be more people with first or second-degree haemorrhoids than those with third or fourth degree haemorrhoids.

Haemorrhoids can be internal or external. Internal haemorrhoids are vascular cushions originating from the subepithelial plexus of the anal canal above the dentate line. External haemorrhoids are aggregations of congested external perianal vascular plexus covered by perianal skin.

Symptoms vary according to severity of the haemorrhoid, but include bleeding, mucous discharge, itching and pain. Haemorrhoids also lead to difficulty cleaning the perianal area after a bowel motion.

## Classification of internal haemorrhoids

Classification	Characteristics	Treatment
First degree	Small, bleed at defecation but no prolapse	Attention to bowel habit and avoidance of straining on defecation
Second degree	Bleed and prolapse from anus at defecation but reduce spontaneously	Elastic band ligation, injection sclerotherapy
Third degree	Bleed, mucous discharge, prolapse but can be manually reduced	Haemorrhoidectomy ? Haemorrhoidectomy
Fourth degree	Bleed, mucous discharge, prolapse that cannot be manually reduced	Haemorrhoidectomy

Management of first and second-degree internal haemorrhoids generally involves attention to bowel habits (by dietary modification) and an avoidance of straining. Stool softeners and laxatives are used to prevent worsening of the condition. Non-surgical interventions include injection sclerotherapy, rubber band ligation and infrared coagulation. However, given that prolapse has occurred, there is some interest in using the stapled technique for second degree haemorrhoids.

For third and fourth degree internal haemorrhoids the optimum treatment is considered to be surgical haemorrhoidectomy. This procedure has traditionally involved the excision of haemorrhoidal cushions, with or without closure of the resulting wound. The traditionally used surgical technique is the Milligan-Morgan haemorrhoidectomy (excision-ligation), although a number of other techniques are available (diathermy-, laser-haemorrhoidal dissection and submucosal haemorrhoidectomy). The Ferguson technique is a modification of the Milligan-Morgan technique whereby the incisions are totally or partially closed with absorbable running suture.

Between 1998 and 1999 in England and Wales, nearly 27,000 haemorrhoidectomies were performed.

### The technology:

Stapled haemorrhoidectomy for prolapsing haemorrhoids is a novel technique. The stapling technique does not involve an incision into the anoderm and is reported to avoid a painful cutaneous wound whilst reducing the prolapsed haemorrhoids into the anal canal. Stapled haemorrhoidectomy is only considered to be appropriate for the treatment of internal haemorrhoids.

It is estimated that approximately 1500 procedures of stapled haemorrhoidectomy were performed in the UK between August 1998 and 2002.

<b>Intervention(s)</b>	Stapled haemorrhoidectomy
<b>Population(s)</b>	People with second, third or fourth degree internal haemorrhoids.
<b>Current standard comparators</b>	Milligan-Morgan/Ferguson haemorrhoidectomy
<b>Outcomes</b>	<p>Outcomes to be considered include:</p> <ul style="list-style-type: none"> <li>• recurrent prolapse</li> <li>• wound healing time</li> <li>• time to normal bowel function</li> <li>• peri- and post-operative complications of surgery</li> <li>• health-related quality of life including pain</li> </ul>
<b>Economic analysis</b>	<p>Economic evaluations should consider:</p> <ul style="list-style-type: none"> <li>• the time period over which recurrences of haemorrhoid prolapse may occur</li> <li>• the impact of performing haemorrhoidectomy in inpatient or day-case settings.</li> </ul> <p>The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life-year.</p> <p>Costs will be considered from a NHS and Personal Social Services Perspective.</p>
<b>Other considerations</b>	The Institute seeks the views of the consultees on the appropriateness of assessing the clinical and cost-effectiveness of stapled haemorrhoidectomy for second degree internal haemorrhoids.
<b>Related NICE recommendations</b>	The NICE guidance IPG34 (December 2003) states that the current evidence on the safety and efficacy of circular stapled haemorrhoidectomy appears adequate to support the procedure for the treatment of internal haemorrhoids.