

**NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE**

**Health Technology Appraisal**

**Stapled haemorrhoidectomy for the treatment of haemorrhoids**

**Scope**

**Remit/ appraisal objective**

To appraise the clinical and cost effectiveness of stapled haemorrhoidectomy versus conventional haemorrhoidectomy in patients for whom surgery is considered, and to provide guidance to the NHS in England and Wales.

**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 by severity	Characteristics	Treatment
First degree	Small, bleed at defecation but no prolapse	Attention to bowel habit and avoidance of straining on defaecation
Second degree	Bleed and prolapse from anus at defaecation but reduce spontaneously	Elastic band ligation, injection sclerotherapy
Third degree	Bleed, mucous discharge, prolapse but can be manually reduced	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 optimal 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 sub-mucosal 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 2002 and 2003, 23 664 procedures listed as "main operations on haemorrhoids" were performed in England and Wales.

### 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. The staples remain in-situ after the operation. Stapled haemorrhoidectomy is only considered to be appropriate for the treatment of internal haemorrhoids.

It is estimated that approximately 2100 procedures of stapled haemorrhoidectomy were performed in the UK between August 1998 and 2003.

<b>Intervention(s)</b>	Stapled haemorrhoidectomy
<b>Population(s)</b>	People with haemorrhoids for whom surgery is considered.
<b>Current standard comparators</b>	Milligan-Morgan/Ferguson haemorrhoidectomy
<b>Outcomes</b>	Outcomes to be considered include: <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>	Economic evaluations should consider: <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>	If evidence allows, the appraisal will seek to identify subgroups of individuals for whom the technology is particularly clinical and cost effective.
	If evidence allows, the appraisal will seek to identify the conditions and settings of care (e.g. as an inpatient or day case procedure, under general or local anaesthesia) in which the technology is particularly clinical and cost-effective.
<b>Related NICE recommendations</b>	Related Technology Appraisals: <ul style="list-style-type: none"> <li>• None</li> </ul> <p>Related Guidelines:</p> <ul style="list-style-type: none"> <li>• Interventional Procedures Guidance on Circular Stapled Haemorrhoidectomy (IPG034) (December 2003).</li> </ul>