NICE guidance

Haemorrhoidal artery ligation

Interventional procedures guidance
Published: 19 May 2010

www.nice.org.uk/guidance/ipg342

Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

1 Guidance

1.1 Current evidence on haemorrhoidal artery ligation shows that this procedure is an efficacious alternative to conventional haemorrhoidectomy or stapled haemorrhoidopexy in the short and medium term, and that there are no major safety concerns. Therefore, this procedure may be used provided that normal arrangements are in place for clinical governance, consent and audit.

2 The procedure

2.1 Indications and current treatments

2.1.1 Haemorrhoids (piles) occur when the vascular anal cushions become enlarged. They may cause bleeding, itching or discomfort (grade 1) and, if large, may prolapse out of the rectum. Haemorrhoids that prolapse may reduce (return into the anal canal) spontaneously after defaecation (grade 2); they may need to be reduced digitally (grade 3); or they may not be reducible, remaining continually prolapsed (grade 4).

2.1.2 Grade 1 or 2 haemorrhoids may be treated by diet modification and topical applications. Interventional treatments include rubber band ligation and sclerosant injections. Treatments for grade 3 and 4 haemorrhoids include surgical excision of the haemorrhoids (haemorrhoidectomy) or stapled haemorrhoidopexy.

2.2 Outline of the procedure

2.2.1 Haemorrhoidal artery ligation reduces the blood flow to haemorrhoids, with the aim of reducing discomfort and bleeding. It also aims to achieve some shrinkage of haemorrhoids but adjunctive treatment is required for large prolapsing

haemorrhoids.

2.2.2 The procedure is usually performed with the patient under general anaesthesia, and is normally carried out after an enema. Using a proctoscope, the haemorrhoidal arteries are ligated with sutures (above the dentate line) to remove the flow of blood to the haemorrhoids. A Doppler probe may be used to help locate the haemorrhoidal arteries. For larger prolapsing haemorrhoids, an adjunctive mucosal plication procedure is done. The prolapsing mucosa is plicated up to the level of the dentate line where it is fixed by ligation of the plicating sutures (haemorrhoidopexy).

2.3 Efficacy

Sections 2.3 and 2.4 describe efficacy and safety outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the overview.

2.3.1 In a systematic review of 17 studies with a total of 1,996 patients, a subset of 6 studies with a follow-up of 1 year or more (850 patients treated by the procedure) reported bleeding, pain on defaecation, and prolapse in 10% (49 out of 507), 9% (18 out of 206) and 11% (46 out of 427) of patients respectively. A subset of 9 studies with a follow-up of less than 1 year (855 patients treated by the procedure) reported bleeding and prolapse in 6% (40 out of 638) and 8% (50 out of 638) of patients respectively. The proportion of patients with preoperative bleeding, pain and prolapse ranged from 45% to 100%, 12% to 83% and 12% to 100% respectively across the studies.

2.3.2 A randomised controlled trial (RCT) of 41 patients treated by the procedure or stapled haemorrhoidopexy reported symptom resolution in 78% (18 out of 23) and 83% (15 out of 18) of patients respectively at 6-week follow-up (p = not significant).

2.3.3 A case series of 616 patients treated by the procedure without Doppler guidance reported symptom resolution at 4-week follow-up in 96%, 98% and 96% of patients who had presented with bleeding, prolapse and pain on defaecation respectively (absolute figures not stated). In the same study, among 523 patients

with 1-year follow-up, mean patient satisfaction score was 8.2 on a 10-point visual analogue scale (VAS). A case series of 330 patients reported resolution of symptoms at a mean follow-up of 46 months in 93% (132 out of 142) of patients who presented with bleeding and 92% (110 out of 119) of patients who presented with prolapse.

2.3.4 The Specialist Advisers listed key efficacy outcomes as less postoperative pain than other treatments, resolution of haemorrhoids, and relief of symptoms such as bleeding, prolapse, swelling, pain, soreness and itching in the short and long term.

2.4 Safety

2.4.1 Postoperative haemorrhage was reported in 3 of 1,996 patients treated by the procedure in the systematic review (2 required blood transfusion and 1 developed coagulopathy, not otherwise described). Bleeding requiring readmission was reported in 4 patients in the case series of 616 patients (timing of events not stated). Immediate and delayed bleeding was reported in 4 and 3 patients respectively in the case series of 330 patients (1 case of immediate bleeding was due to laceration of a rectal polyp; 1 case of delayed bleeding required a further operation to stop the bleeding). Submucosal haematoma was reported in 1% (4 out of 330) of patients in the case series of 330 patients (not otherwise described).

2.4.2 Postoperative haemorrhoid thrombosis was reported in 18 and 5 patients in the case series of 507 and 330 patients respectively (follow-up not stated). In a case series of 100 patients, thrombosis of residual haemorrhoids was reported in 3 patients at 4-, 7- and 17-month follow-up (patients had grade 3 haemorrhoids; 2 treated by thrombectomy, 1 treated by haemorrhoidectomy).

2.4.3 Postoperative fistula formation was reported in 1 patient in the case series of 507 patients (1-year follow-up).

2.4.4 Postoperative fissure was reported in 11 and 2 patients in the case series of 507 and 330 patients respectively (not otherwise described). Acute fissure (successfully managed by conservative treatment) was reported in 3 patients at

9-, 10- and 15-day follow-up and anal fissure was reported in 2 patients at 8- and 11-month follow-up in the case series of 100 patients (not otherwise described).

2.4.5 The RCT of 41 patients treated by haemorrhoidal artery ligation or stapled haemorrhoidopexy reported postoperative pain on a VAS (higher score indicates more pain; range not defined) as 1.6 and 3.2 respectively at 7-day follow-up ($p<0.001$) and 0.2 and 1.0 respectively at 21-day follow-up ($p=0.06$).

2.4.6 The Specialist Advisers considered theoretical adverse events to include infection, rectal perforation, pelvic abscess, anal stenosis, acute and chronic pain and faecal incontinence.

3 Further information

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the overview.

Information for patients

NICE has produced information for the public on this procedure. It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

ISBN: 978-1-4731-6247-1

Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.