NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

Endoscopic ablation for an anal fistula

An anal fistula is a narrow tunnel that forms between the end of the bowel and the skin near the anus. It may cause pain or discomfort, and leak blood or pus. In this procedure, an endoscope (a thin flexible tube with a camera on the end) is put into the fistula. An electrode is passed through the endoscope to deliver heat, which seals the inside of the fistula. Stitches are used to close the end of the fistula that is nearest to the bowel. The aim is to encourage healing.

The National Institute for Health and Care Excellence (NICE) is looking at endoscopic ablation for an anal fistula. NICE's interventional procedures advisory committee has considered the evidence and the views of specialist advisers, who are consultants with knowledge of the procedure.

The committee has made draft recommendations and we now want to hear your views. The committee particularly welcomes:

- comments on the draft recommendations
- information about factual inaccuracies
- additional relevant evidence, with references if possible.

This is not our final guidance on this procedure. The recommendations may change after this consultation.

After consultation ends:

- The committee will meet again to consider the original evidence and its draft recommendations in the light of the consultation comments.
- The committee will prepare a second draft, which will be the basis for NICE's guidance on using the procedure in the NHS.

For further details, see the Interventional Procedures Programme process guide.

Through our guidance, we are committed to promoting race and disability equality, equality between men and women, and to eliminating all forms of discrimination. One of the ways we do this is by trying to involve as wide a range of people and interest groups as possible in developing our interventional procedures guidance. In particular, we encourage people and

organisations from groups who might not normally comment on our guidance to do so.

To help us promote equality through our guidance, please consider the following question:

Are there any issues that require special attention in light of NICE's duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations between people with a characteristic protected by the equalities legislation and others?

Please note that we reserve the right to summarise and edit comments received during consultations or not to publish them at all if in the reasonable opinion of NICE, there are a lot of comments, of if publishing the comments would be unlawful or otherwise inappropriate.

Closing date for comments: 30 January 2019

Target date for publication of guidance: April 2019

1 Draft recommendations

1.1 Current evidence on endoscopic ablation for an anal fistula raises no major safety concerns. Evidence on efficacy is adequate in quality and quantity. Therefore, this procedure can be used provided that standard arrangements are in place for clinical governance, consent and audit.

2 The condition, current treatments and procedure

The condition

2.1 An anal fistula is an abnormal tract between the anal canal and the skin around the anus. It may cause symptoms such as pain or discomfort, and leak blood or pus. It usually results from previous anal abscesses (cryptoglandular), and can be associated with other

conditions including inflammatory bowel disease (such as Crohn's disease) and cancer.

2.2 Anal fistulas can be classified according to their relationship with the external sphincter. A fistula may be complex, with several openings onto the perianal skin. Intersphincteric fistulas are the most common type and cross only the internal anal sphincter. Trans-sphincteric fistulas pass through both the internal and external sphincters.

Current treatments

2.3 Treatment of an anal fistula commonly involves surgery. The type of surgery depends on the medical history, extent, location and complexity of the fistula in relation to surrounding muscles. The aim is to drain infected material and encourage healing. If the fistula does not heal completely another surgical procedure may be needed. For simple intersphincteric and low trans-sphincteric anal fistulas, the most common treatment is a fistulotomy or laying open of the fistula tract (involving muscle division that may affect continence). For high and complex (deeper) fistulas that involve more muscle, with a high risk of faecal incontinence or recurrence, surgery aims to treat the fistula and preserve sphincter-muscle function. Techniques include a 1-stage or 2-stage seton (suture material or rubber sling) either alone or in combination with fistulotomy, ligation of an intersphincteric fistula tract, creating a mucosal advancement flap, injecting glue or paste, or inserting a fistula plug.

The procedure

2.4 Endoscopic ablation of an anal fistula is a less invasive procedure than surgery. It aims to preserve sphincter muscle function and faecal continence. It may be done in combination with surgical techniques such as creating a mucosal advancement flap.

2.5 The procedure is usually done as a day case using spinal or general anaesthesia. With the patient in the lithotomy position a fistuloscope is inserted into the fistula tract from the external opening. A continuous jet of irrigation solution is used, which allows optimal visualisation of the fistula tract, the internal opening and any secondary tracts or abscess cavities. When the fistuloscope exits through the internal opening to the rectal mucosa, 2 or 3 stitches are inserted to isolate the internal opening. Under direct vision an electrode is passed through the fistuloscope and the material in the fistula tract is cauterised from the external to the internal opening. All necrotic material is removed using a fistula brush and a continuous jet of irrigation solution. The fistuloscope is removed and the internal opening closed by suturing, stapling or by creating a cutaneous mucosal flap.

3 Committee considerations

The evidence

3.1 To inform the committee, NICE did a rapid review of the published literature on the efficacy and safety of this procedure. This comprised a comprehensive literature search and detailed review of the evidence from 7 sources, which was discussed by the committee. The evidence included 3 systematic reviews and 4 case series, and is presented in table 2 of the interventional procedures overview. Other relevant literature is in the appendix of the overview.

3.2 The specialist advisers and the committee considered the key efficacy outcomes to be: ablation of the fistula, prevention of recurrence and the need for repeated surgery, and improved quality of life.

3.3 The specialist advisers and the committee considered the key safety outcomes to be: bleeding and infection.

3.4 Patient commentary was sought but none was received.

Committee comments

3.5 The committee noted that the procedure needs specialised instrumentation and appropriate training.

3.6 The committee was informed that this procedure allows the direct visualisation of the fistula tract to allow treatment planning, and that this is important for the procedure's success.

3.7 The committee was informed that for patients with inflammatory bowel disease the aim of the procedure is often visualisation of the tract and to reduce the inflammatory burden within a complex fistula tract system, rather than definitive treatment.

Andrew Cook
Vice Chairman, interventional procedures advisory committee
December 2018