



Endoscopic ablation for an anal fistula

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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 <u>Yellow Card Scheme</u>.

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 <u>assess and reduce the environmental impact of implementing NICE recommendations</u> wherever possible.

1 Recommendations

1.1 Current evidence on endoscopic ablation for an anal fistula raises no major safety concerns and the 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. Find out what standard.arrangements.mean on the NICE interventional procedures guidance page.

2 The condition, current treatments and procedure

The condition

- 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

Treatment of an anal fistula commonly involves surgery. The type of 2.3 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 (in line with NICE's interventional procedures guidance on 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 Seven commentaries from patients who had experience of this procedure were received, which were discussed by the committee.

Committee comments

- 3.5 The committee noted that the procedure needs specialised instrumentation and appropriate training.
- 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 reducing the inflammatory burden within a complex fistula tract system, rather than definitive treatment.

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Endorsing organisation

This guidance has been endorsed by <u>Healthcare Improvement Scotland</u>.