

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

Radially emitting laser fibre treatment of 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, a fibre containing a laser is put into the fistula. Laser energy is emitted all around the fibre (radially) and the fibre is then gradually withdrawn. The aim is that the laser energy will destroy and seal off the fistula.

The National Institute for Health and Care Excellence (NICE) is looking at radially emitting laser fibre treatment of 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, or if publishing the comments would be unlawful or otherwise inappropriate.

Closing date for comments: 20 December 2018

Target date for publication of guidance: March 2019

1 Draft recommendations

- 1.1 Current evidence on the safety and efficacy of radially emitting laser fibre treatment of an anal fistula is limited in quantity and quality. There are no major safety concerns. Therefore, this procedure should only be used with [special arrangements](#) for clinical governance, consent, and audit or research.
- 1.2 Clinicians wishing to do radially emitting laser fibre treatment of an anal fistula should:
- Inform the clinical governance leads in their NHS trusts.
 - Ensure that patients understand the procedure's safety and efficacy, as well as any uncertainties about these. Provide them with clear written information to support [shared decision-making](#). In addition, the use of NICE's [information for the public](#) [URL to be added at publication] is recommended.

- Audit and review clinical outcomes of all patients having radially emitting laser fibre treatment of an anal fistula. NICE has identified relevant audit criteria and is developing an audit tool (which is for use at local discretion), which will be available when the guidance is published.
- 1.3 The procedure should only be done by clinicians experienced in cannulating fistulas, and who are trained in the use of lasers.
- 1.4 Further research should report details of patient selection, including fistula size, recurrence rates in the medium and long term, and quality-of-life outcomes.

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 in the anal area, and leakage of blood or pus. It usually results from previous anal abscesses (cryptoglandular), and can be associated with other conditions such as inflammatory bowel disease and cancer.
- 2.2 Anal fistulas can be classified according to their relationship with the external sphincter. Intersphincteric fistulas are the most common type and cross only the internal sphincter. Trans-sphincteric fistulas pass through the internal and external sphincter.

Current treatments

- 2.3 Treatment of anal fistulas commonly involves surgery. The type of surgery depends on the location and complexity of the fistula. For intersphincteric and low trans-sphincteric anal fistulas, the most common treatment is a fistulotomy or laying open of the fistula

track. For deeper fistulas that involve more muscle, and for recurrent fistulas, a seton (a piece of suture material or rubber sling) may be used, either alone or with fistulotomy. Setons can be loose (designed to drain the sepsis but not for cure), or snug or tight (designed to cut through the muscles in a slow controlled fashion). Fistulas that cross the external sphincter at a high level are sometimes treated with a mucosal advancement flap or other procedures to close the internal opening. Another less commonly used option for treating anal fistulas is to fill the track with either a plug or paste. For example, 1 type of filler is fibrin glue (a solution of fibrinogen and thrombin).

The procedure

2.4 Radially emitting laser fibre treatment of an anal fistula can be done with the patient under regional or general anaesthesia. With the patient in lithotomy position, the external and internal openings of the fistula tract are identified. The fistula is then catheterised using a probe and cleaned by irrigation. Under ultrasound guidance, a radial-emitting laser fibre is advanced from the external to internal orifice, activated and gradually withdrawn at about 1 mm/second. The aim is to cause destruction and sealing of the fistula tract, allowing primary closure. The procedure may be used with techniques that close the internal orifice of the tract such as an advancement 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 7 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: fistula closure, resolution of symptoms, quality of life and recurrence.
- 3.3 The specialist advisers and the committee considered the key safety outcomes to be: incontinence, abscess, pain, anismus, bleeding and urinary retention.

Committee comments

- 3.4 The committee was informed that it can be difficult to assess whether the fistula is closed without using imaging.
- 3.5 The committee was informed that this procedure is likely to be less effective in wider fistula tracts.

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