

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

Collagen paste for closing 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, collagen paste is injected into the fistula. The paste fills the fistula, sealing it. The aim is to encourage healing.

The National Institute for Health and Care Excellence (NICE) is looking at collagen paste for closing 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: 30 January 2019

Target date for publication of guidance: April 2019

1 Draft recommendations

- 1.1 Current evidence on the safety and efficacy of collagen paste for closing an anal fistula is inadequate in quantity and quality. Therefore, this procedure should only be used in the [context of research](#).
- 1.2 Further research should report details of patient selection, the type of fistula treated, how the internal fistula opening was closed, and long-term outcomes including recurrence and the need for reoperation.

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 usually results from previous anal abscesses (cryptoglandular) and can be associated with other conditions such as inflammatory bowel disease and cancer. It may

cause symptoms such as pain or discomfort in the anal area, and leakage of blood or pus. 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

2.2 Treatment of anal fistulas usually 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 procedure 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 option for treating an anal fistula is to fill the track with a plug or glue.

The procedure

2.3 The use of collagen paste for closing an anal fistula is usually done with the patient under general anaesthesia and in the lithotomy position. The fistula tract is de-epithelised and granulation tissue is removed, before being cleaned with dilute hydrogen peroxide followed by saline. A guiding catheter is connected to a syringe containing the paste and the other end is inserted into the external opening of the fistula. The paste is injected into the fistula until it is visible at the internal opening, and then the guiding catheter is slowly withdrawn. The internal opening of the fistula is closed using resorbable stitches. The external opening is partially closed, using

resorbable stitches if needed, to allow any inflammatory fluid to drain out without allowing the collagen paste to escape.

- 2.4 The paste fills the exact shape of the tract, which is intended to reduce the risk of it being expelled from the body when defaecating.
- 2.5 It is a less invasive procedure than traditional surgery and the aim is to allow the fistula to heal whilst preserving sphincter function.

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 4 sources, which was discussed by the committee. The evidence included 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 fistula, prevention of recurrence and the need for further surgery, and improved quality of life.
- 3.3 The specialist advisers and the committee considered the key safety outcomes to be: bleeding and infection.

Committee comments

- 3.4 The committee was informed that the fistula tract needs to be appropriately prepared before the collagen paste is applied.
- 3.5 The committee noted that the current evidence for this procedure was mostly from the treatment of simple anal fistulas.

NICE interventional procedures consultation document, January 2019

Andrew Cook

Vice Chairman, interventional procedures advisory committee

January 2019

ISBN: