

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

Bioprosthetic plug insertion for 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 plug is put into the fistula and stitched in place. The plug is made from animal tissue (bioprosthetic). The aim is to block the fistula.

The National Institute for Health and Care Excellence (NICE) is looking at bioprosthetic plug insertion for 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: 23 May 2019

Target date for publication of guidance: September 2019

1 Draft recommendations

- 1.1 Current evidence on the safety and efficacy of bioprosthetic plug insertion for anal fistula is adequate to support the use of this procedure provided that [standard arrangements](#) are in place for clinical governance, consent and audit.
- 1.2 The procedure should only be done by a surgeon experienced in managing anal fistulas.

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 anatomical 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 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 tract. 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. Other options for treating anal fistulas are to fill the tract with glue or paste.

The procedure

2.3 Bioprosthetic plug insertion for anal fistula aims to leave the sphincter muscles intact, allowing the use of subsequent treatments if needed.

2.4 The procedure is usually done using general anaesthesia. The fistula tract is identified using a probe or by imaging techniques, and it may be irrigated. A conical plug, usually made of porcine intestinal submucosa, is pulled into the tract until it blocks the internal opening. It is sutured in place at the internal opening. The external opening is not completely sealed so that drainage of the

fistula can continue. The plug acts as a scaffold into which new tissue can grow.

2.5 More than 1 device is available for this procedure.

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 9 sources, which was discussed by the committee. The evidence included 1 systematic review and meta-analysis, 4 randomised controlled trials, 3 case series and 1 unpublished NIHR Health Technology Assessment report on the fistula-in-ano trial (FIAT), 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, 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: plug extrusion, incontinence, abscess or infection, bleeding, pain and anismus.

3.4 This guidance is a review of NICE's interventional procedures guidance on [closure of anal fistula using a suturable bioprosthetic plug](#).

Committee comments

3.5 The committee was informed that the success rate of the procedure is likely to be higher for single tracts and posterior fistulas.

- 3.6 The evidence reviewed by the committee shows that bioprosthetic plug insertion for anal fistula has a similar safety and efficacy profile to standard treatments for anal fistulas.
- 3.7 The committee was informed that bioprosthetic plug insertion for anal fistula may be used in combination with other treatments.

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