

Closure of anal fistula using a suturable bioprosthetic plug

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NICE interventional procedure guidance 410

guidance.nice.org.uk/ipg410

NHS Evidence has accredited the process used by the NICE Interventional Procedures Programme to produce interventional procedures guidance. Accreditation is valid for 5 years from January 2010 and applies to guidance produced since January 2009 using the processes described in the 'Interventional Procedures Programme: Process guide, January 2009' and the 'Interventional Procedures Programme: Methods guide, June 2007'



Contents

1 Guidance	3
2 The procedure	4
2.1 Indications and current treatments	4
2.2 Outline of the procedure	4
2.3 Efficacy	5
2.4 Safety	6
2.5 Other comments	6
3 Further information	7
Information for patients	7
About this guidance	8

1 Guidance

This document replaces previous guidance on closure of anal fistula using a suturable bioprosthentic plug (interventional procedure guidance 221). For details see '[About this guidance](#)'.

- 1.1 Current evidence on closure of anal fistula using a suturable bioprosthentic plug raises no major safety concerns. The evidence on efficacy is inadequate in quantity and quality. Therefore this procedure should only be used with special arrangements for clinical governance, consent and audit or research.
- 1.2 Clinicians wishing to undertake closure of anal fistula using a suturable bioprosthentic plug are encouraged to enter patients into the Fistula-In-Ano Trial (FIAT) (www.hta.ac.uk/project/1998.asp or www.controlled-trials.com/ISRCTN78352529). Clinicians wishing to undertake closure of anal fistula using a suturable bioprosthentic plug outside a clinical trial should take the following actions.
 - Inform the clinical governance leads in their Trusts.
 - Ensure that patients understand the uncertainty about the procedure's efficacy and provide them with clear written information. In addition, use of NICE's information for patients ([Understanding NICE guidance](#)) is recommended.
 - Audit and review clinical outcomes of all patients having closure of anal fistula using a suturable bioprosthentic plug (see [section 3.1](#)).
- 1.3 Closure of anal fistula using a suturable bioprosthentic plug should only be carried out by surgeons with specific training in the procedure. The methods agreed for the FIAT trial provide a useful source of information on technical aspects of the procedure.
- 1.4 NICE may review the procedure upon publication of further evidence.

2 The procedure

2.1 Indications and current treatments

- 2.1.1 Anal fistula is an abnormal tract between the anal canal and the skin around the anus. Fistulae usually result from perianal abscesses and can be associated with conditions such as Crohn's disease. Intersphincteric fistulae are the most common type and cross only the internal sphincter. Trans-sphincteric fistulae pass through both the internal and external sphincters. Fistulae may be complex, with several openings onto the perianal skin.
- 2.1.2 Symptoms include pain or discomfort in the anal area, and discharge of blood or pus.
- 2.1.3 Treatment usually involves surgery and depends on the position of the fistula in relation to the sphincters. Intersphincteric fistulae are usually laid open. The laying open of trans-sphincteric fistulae involves muscle division that may impair continence (usually to a minor degree). A seton may be used to effect a slow, controlled division of the sphincter below the fistula tract. An alternative is to use an advancement flap, but early success may not be continued in the longer term.
- 2.1.4 Less invasive techniques, developed with the aim of minimising the risk of incontinence, include injection of fibrin glue.

2.2 Outline of the procedure

- 2.2.1 Closure of anal fistula using a suturable bioprosthetic plug aims to leave the sphincter muscles intact, allowing the use of subsequent treatments if required.
- 2.2.2 The procedure is usually carried out with the patient under general anaesthesia. The fistula tract is identified using a probe or by imaging techniques, and may be irrigated. A conical plug, usually made of porcine intestinal submucosa, is pulled into the tract until it blocks the internal opening, and 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.

2.2.3 More than one device is available for this procedure.

Sections 2.3 and 2.4 describe efficacy and safety outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the [overview](#).

2.3 Efficacy

2.3.1 A randomised controlled trial (RCT) of 90 patients treated by a suturable bioprosthesis plug or endorectal advancement flap reported successful fistula closure in 82% (37/45) and 64% (29/45) of patients respectively at 6-month follow-up ($p < 0.05$).

2.3.2 A non-randomised comparative study of 232 patients treated by a suturable bioprosthesis plug, fibrin glue, draining seton or advancement flap reported healing rates of 59% (16/27), 39% (9/23), 33% (28/86) and 60% (58/96) respectively at 12-week follow-up ($p < 0.05$ between the groups). A non-randomised comparative study of 245 patients treated by a suturable bioprosthesis plug, fistulotomy, staged fistulotomy, draining seton, cutting seton, fibrin glue or advancement flap reported healing rates of 32% (14/43), 87% (104/120), 50% (18/36), 5% (1/21), 69% (9/13), 80% (4/5) and 75% (3/4) of patients respectively at 3-month follow-up ($p < 0.001$ for plug versus fistulotomy).

2.3.3 The RCT of 90 patients reported significantly higher quality of life scores (Fecal Incontinence Quality of Life Scale; higher scores best) in patients treated by a suturable bioprosthesis plug compared with those treated by endorectal advancement flap at 6-month follow-up (85.9 versus 65.3, $p < 0.001$).

2.3.4 The Specialist Advisers stated that the key efficacy outcome is healing (clinically and on magnetic resonance imaging [MRI]).

2.4 Safety

- 2.4.1 In a non-randomised comparative study of 80 patients treated by a suturable bioprosthentic plug or endorectal advancement flap, 14% (5/37) of patients in the plug group were treated with antibiotics postoperatively because of pain and increased drainage.
- 2.4.2 The Specialist Advisers listed reported adverse events as new abscess formation and plug extrusion.

2.5 Other comments

- 2.5.1 The Committee noted that anal fistulae can cause distress to patients and are difficult to treat successfully. The Committee recognised the potential usefulness of suturable bioprosthentic plugs if further evidence supports their efficacy in a substantial proportion of patients.
- 2.5.2 The Committee was advised of the potential value of MRI in the diagnosis of complex fistulae and in assessing the results of treatment.

3 Further information

- 3.1 This guidance requires that clinicians undertaking the procedure make special arrangements for audit. NICE has identified relevant audit criteria and has developed an [audit tool](#) (which is for use at local discretion).
- 3.2 For related NICE guidance see www.nice.org.uk

Information for patients

NICE has produced information on this procedure for patients and carers ([Understanding NICE guidance](#)). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

About this guidance

NICE interventional procedure guidance makes recommendations on the safety and efficacy of the procedure. It does not cover whether or not the NHS should fund a procedure. Funding decisions are taken by local NHS bodies after considering the clinical effectiveness of the procedure and whether it represents value for money for the NHS. It is for healthcare professionals and people using the NHS in England, Wales, Scotland and Northern Ireland, and is endorsed by Healthcare Improvement Scotland for implementation by NHSScotland.

This guidance was developed using the NICE [interventional procedures guidance](#) process.

It updates and replaces NICE interventional procedure guidance 221.

We have produced a [summary of this guidance for patients and carers](#). Tools to help you put the guidance into practice and information about the evidence it is based on are also [available](#).

Changes after publication

May 2012: minor maintenance

Your responsibility

This guidance represents the views of NICE and was arrived at after careful consideration of the available evidence. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. This guidance does not, however, override the individual responsibility of healthcare professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to avoid unlawful discrimination and to have regard to promoting equality of opportunity. Nothing in this guidance should be interpreted in a way which would be inconsistent with compliance with those duties.

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