NICE guidance

Insertion of a collagen plug to close an abdominal wall enterocutaneous fistula

Interventional procedures guidance
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www.nice.org.uk/guidance/ipg507

1 Recommendations

1.1 Current evidence on the safety and efficacy of insertion of a collagen plug to close an abdominal wall enterocutaneous fistula 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 insert a collagen plug to close an abdominal wall enterocutaneous fistula should take the following actions.

- Inform the clinical governance leads in their NHS trust.
- Ensure that patients understand the uncertainty about the procedure's safety and efficacy and provide them with clear written information. In addition, the use of NICE's information for the public is recommended.

- Audit and review clinical outcomes of all patients having insertion of a collagen plug to close an abdominal wall enterocutaneous fistula (see section 7.1).

1.3 NICE encourages further research into insertion of a collagen plug to close an abdominal wall enterocutaneous fistula. Research should ideally take the form of prospective studies that compare the course of the enterocutaneous fistula (its natural history) with and without use of the procedure. Reports should record the conditions underlying all fistulas that are treated, their location, whether they are high or low output, and details of previous treatments. NICE may update the guidance on publication of further evidence.

2 Indications and current treatments

2.1 An enterocutaneous fistula is an abnormal opening between the small or large bowel and the skin of the abdomen, which allows the contents of the bowel to leak. A fistula can arise from any part of the bowel (duodenum, jejunum, ileum, colon or rectum). The most common predisposing conditions are inflammatory bowel disease and a history of bowel surgery or trauma.

2.2 Management options include total parenteral nutrition and measures to prevent intestinal contents from passing through the bowel, so decreasing fistula output and encouraging healing. Surgical options include primary repair with resection of the fistula track, with or without bowel diversion (creating a stoma).

3 The procedure

3.1 A variety of techniques have been described for insertion of a collagen plug to close an enterocutaneous fistula, most being carried out with the patient under sedation. The fistula track is visualised using fluoroscopy and may need dilatation to allow passage of the plug. The track is then debrided to improve incorporation of the plug. A guide wire is inserted from the skin surface through the track into the bowel lumen and a delivery sheath is put in place. Once the delivery sheath is in position, the collagen plug is passed through the track, under fluoroscopic

guidance. The delivery sheath is then taken out. The collagen plug is secured in place with absorbable sutures and a Molnar disc (a disc which lies against the skin at the external opening of the fistula, to help keep the device in place). A radiopaque flange (footplate) attached to the internal end of the plug creates a seal to help stop enteric fluids from entering the fistula track, and allows visualisation of the plug during placement. The collagen plug fills the fistula track and acts as a scaffold for tissue growth, allowing the fistula to become filled with tissue and to heal. The patient is usually kept in hospital for a few days of strict bed rest, to prevent displacement of the plug and to encourage its incorporation.

3.2 Various plugs are available for this procedure.

4 Efficacy

This section describes efficacy 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 interventional procedure overview.

4.1 In a case series of 6 patients, 100% (6/6) of fistulas had closed at 2 weeks but the fistula recurred in 33% (2/6) of patients. In both patients, the fistulas recurred at 9 months. The first patient died from postoperative complications after additional surgical repairs (no further details provided). For the second patient, after a short period of drainage, the procedure was repeated without any further recurrence at 6-month follow-up. In a case series of 5 patients, 40% (2/5) of fistulas closed after a few days. Of those that did not close, 67% (2/3) were closed by further treatment (timing not reported) without any further recurrence at 18-month median follow-up (range 8 to 29 months). In a second case series of 5 patients, 80% (4/5) of fistulas had closed by 80-day mean follow-up (range 30 to 120 days). In the remaining patient 2 separate procedures were done, 1 week apart, but the fistula did not close.

4.2 The specialist advisers stated that the key efficacy outcomes are permanent fistula closure and avoiding the need for surgical repair.

5 Safety

This section describes 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 interventional procedure overview.

5.1 Death was reported in 1 patient, 1 month after the procedure, from coccidioidomycosis with multiple other chest and abdominal abscesses in a case series of 5 patients. In a case series of 6 patients, death was reported in 1 patient, 9 months after the procedure, as a result of postoperative complications after additional surgical repairs when the fistula reopened (no further details provided).

5.2 Device migration was reported in 2 patients from the case series of 6 patients. One patient presented with a recurrent pelvic abscess 7 weeks after the procedure. A colonic fistula and a small pericolic abscess, which contained the silicone footplate of the device, were identified. The colonic fistula was the recurrence of a separate defect previously closed with fibrin glue. The footplate was removed percutaneously and the abscess and fistula closed after 6 weeks of catheter drainage. In the other patient, a CT scan at 4 months showed that the silicone footplate had migrated out of the bowel lumen, causing a pre-sacral fluid collection. The footplate was removed percutaneously and a catheter left in for drainage. The fistula recurred 9 months after the enterocutaneous fistula plug placement and the patient died from the postoperative complications following the additional surgical repairs (death reported in section 4).

5.3 One patient was admitted to hospital 2 days after the procedure because of pyrexia in a case series of 2 patients. No cause was found and no further details were given. This patient had a further admission for small bowel obstruction that resolved within 2 days of nasogastric suction (timing not reported).

5.4 The specialist advisers reported an anecdotal adverse event of severe pain during the procedure requiring conversion to general anaesthetic. They stated that theoretical adverse events could include allergic reaction, increase in diameter or output of the fistula, peritonitis and

bowel contents leaking into the abdominal cavity, bowel injury, vascular injury and bleeding.

6 Committee comments

6.1 The Committee noted that the number of patients in the published studies was very small. However, it was advised that enterocutaneous fistulas can have a serious effect on quality of life and that the options available for patients are limited, especially if conservative management has failed or if surgery is unsuitable for them. Because of this and its judgement that serious safety problems are unlikely as a result of the procedure, the Committee considered it appropriate to recommend special arrangements with high quality data collection.

7 Further information

7.1 For related NICE guidance, see the NICE website.

This guidance requires that clinicians undertaking the procedure make special arrangements for audit.

Information for patients

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

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.

Accreditation