

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

Information for the public

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What has NICE said?

There is not much good evidence about how well inserting a collagen plug to close an abdominal wall enterocutaneous fistula works or how safe it is. It should only be used if extra care is taken to explain the risks and extra steps are put in place to record and review what happens.

What does this mean for me?

Your health professional should fully explain what is involved in having this procedure and discuss the possible benefits and risks with you. In particular, they should explain the uncertainty about the evidence on how likely it is to improve your symptoms and possible complications. You should also be told how to find more information about the procedure. You should only be asked if you want to agree to this procedure after having this discussion. Your health professional should ask you if details of your procedure can be

collected.

The condition

An enterocutaneous fistula is a small tunnel that forms between the bowel and the surface of the skin of the abdomen, creating an abnormal opening. It allows the contents of the bowel to leak out and can be difficult to treat. The most common conditions that may lead to a fistula forming are inflammatory bowel disease and surgery or trauma to the bowel.

Several treatment options are available, including surgery under general anaesthetic to close the fistula. NICE has looked at using a collagen plug to close an abdominal wall enterocutaneous fistula without the need for general anaesthetic as another treatment option.

The procedure

In this procedure a collagen plug is inserted into the fistula. The plug is made of polyurethane and animal tissue (such as pig intestine). The aim is to seal off the fistula where it joins the bowel, helping it to heal. The collagen plug fills the fistula and acts as a scaffold for tissue growth, allowing the fistula to heal.

There are a number of techniques that can be used to insert a collagen plug and most of these are done with the patient under sedation. One method uses X-rays to see where the fistula leaves the bowel. A guide wire is inserted from outside the body, along the fistula tunnel and into the bowel. The collagen plug is pulled from inside the bowel into the fistula, to plug the hole. The fistula may have been cleaned first, to help the plug go in more easily and to improve healing. A silicone footplate on the end of the plug helps to secure it inside the bowel. The plug may also be attached to a disc that lies outside the body, against the skin, helping to keep it in place. The patient is usually kept in hospital for a few days of bed rest, to prevent the plug coming out and to encourage healing.

Benefits and risks

When NICE looked at the evidence, it decided that there is not much good evidence about how well this procedure works or how safe it is. The 5 studies that NICE looked at involved a total of 19 patients.

The studies showed that the procedure closed the fistula at the first attempt in 12 out of 16 patients. The risks of insertion of a collagen plug included:

- the fistula not closing after the first attempt, or closing but then coming back several months later, needing further surgery. One person had the procedure 3 times in total, but the fistula did not close
- the silicone footplate moving out of the fistula, inside the body, and causing fluid to collect or an abscess. One person died from complications after surgery to remove a footplate that had moved into the body
- 1 person died 1 month after the procedure, from an infection and multiple abscesses.

NICE was also told about the risk of severe pain during the procedure, leading to the patient needing general anaesthesia.

If you want to know more about the studies, see the [guidance](#). Ask your health professional to explain anything you don't understand.

Questions to ask your health professional

- What does the procedure involve?
- What are the benefits I might get?
- How good are my chances of getting those benefits? Could having the procedure make me feel worse?
- Are there alternative procedures?
- What are the risks of the procedure?
- Are the risks minor or serious? How likely are they to happen?
- What care will I need after the procedure?
- What happens if something goes wrong?
- What may happen if I don't have the procedure?

About this information

NICE [interventional procedures guidance](#) advises the NHS on the safety of a procedure and how well it works.

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Accreditation

