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Understanding NICE guidance

Information for people who use NHS services

National Institute for Health and Clinical Excellence

Stopping enlarged veins in the oesophagus from bleeding by inserting an expandable mesh tube

NICE 'HealthTech guidance' advises the NHS on when and how new procedures can be used in clinical practice.

This leaflet is about when and how an expandable mesh tube (called a stent) can be used in the NHS to treat people with enlarged veins in the oesophagus (the tube through which food passes from the throat to the stomach) that are bleeding. It explains guidance (advice) from NICE (the National Institute for Health and Clinical Excellence).

This HealthTech guidance makes recommendations on the safety of a procedure and how well it works. An interventional procedure is a test, treatment or surgery that involves a cut or puncture of the skin, or an endoscope to look inside the body, or energy sources such as X-rays, heat or ultrasound. The guidance does not cover whether or not the NHS should fund a procedure. Decisions about funding are taken by local NHS bodies (primary care trusts and hospital trusts) after considering how well the procedure works and whether it represents value for money for the NHS.

This leaflet is written to help people who have been offered this procedure to decide whether to agree (consent) to it or not. It does not describe enlarged veins in the oesophagus or the procedure in detail – a member of your healthcare team should also give you full information and advice about these. The leaflet includes some questions you may want to ask your doctor to help you reach a decision. Some sources of further information and support are on page 7.

What has NICE said?

The evidence for this procedure is from small numbers of patients. However, the evidence shows that it is safe and works well in selected patients for whom other treatment methods have not worked to control bleeding. This procedure can be offered routinely as a treatment option for people with enlarged veins in the oesophagus that are bleeding, provided that doctors are sure that:

- the patient understands what is involved and agrees to the treatment, and
- the results of the procedure are monitored.

This procedure may not be the only possible treatment for bleeding enlarged veins in the oesophagus. Your healthcare team should talk to you about whether it is suitable for you and about any other

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The medical name for this procedure is 'stent insertion for bleeding oesophageal varices'.

The procedure is not described in detail here – please talk to your specialist for a full description.

Patients with cirrhosis of the liver (where the liver has become scarred due to continuous damage over a long period of time) may develop high blood pressure in the veins that carry blood from the digestive system to the liver. The medical term for this is portal hypertension.

This can cause veins in the oesophagus to become abnormally enlarged (these are called oesophageal varices) and bleeding may occur. Without treatment, large amounts of blood can be lost which can

lead to death. There is also a high risk of the veins bleeding again after normal treatments.

Patients with bleeding oesophageal varices often need a blood transfusion. Ways of stopping the bleeding include medication and surgery. If the bleeding doesn't stop, patients may need to have other procedures.

In this procedure, a stent is inserted into the oesophagus using a special introducer device. When in place, the stent is expanded, applying pressure to the sides of the oesophagus. The aim is to compress the varices to stop the bleeding. The stent is left in place for up to 2 weeks before being removed. The person is normally able to swallow liquids and some food with the stent in place.

Other treatments may be needed later to reduce the risk of further bleeding.

What does this mean for me?

NICE has said that this procedure is safe enough and works well enough for use in the NHS. If your doctor thinks stents are a suitable treatment option for you, he or she should still make sure you understand the benefits and risks before asking you to agree to it. You may want to ask the questions below

- 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?

You might decide to have this procedure, to have a different procedure, or not to have a procedure at all.

Summary of possible benefits and risks

Some of the benefits and risks seen in the studies considered by NICE are briefly described below. NICE looked at 6 studies on this procedure.

How well does the procedure work?

Two studies of 34 and 20 patients reported that the procedure stopped the bleeding in all patients and there was no re-bleeding within 60 days. In 1 of the studies, 14 out of 20 patients needed further treatment after the stent was removed. In the study of 34 patients, 24 patients needed further treatment.

In another study, the bleeding stopped in 7 out of 9 patients. Re-bleeding occurred in 1 patient, which was treated successfully by another surgical procedure.

In the 3 studies mentioned above, a total of 17 patients died between 42 and 60 days after the procedure. Of these, 2 died from heavy blood loss, 1 from multi-organ failure and failure to control the bleeding, and the rest were because of liver or multi-organ failure.

As well as looking at these studies, NICE also asked expert advisers for their views. These advisers are clinical specialists in this field of medicine. The advisers said that key success outcomes were control of the bleeding, reduction in the risk of re-bleeding, lack of need to use blood products, and survival.

Risks and possible problems

A study of 1 patient reported obstruction of the airways on day 6, which was cured by removing the stent.

In the studies of 34 and 20 patients, the stent had moved into the stomach in 7 out of 34 patients when they were checked at 60 days. All stents were surgically moved back to the right place within 24–48 hours.

In the other study of 20 patients, the stent had moved into the stomach in 5 patients, and these were all put back successfully.

The study of 34 patients reported that 1 patient had minor ulcers in the oesophagus within 60 days of having the procedure.

As well as looking at these studies, NICE also asked expert advisers for their views. These advisers are clinical specialists in this field of medicine. The advisers said that problems include damage to the lining of the oesophagus when the stent is removed, perforation of the oesophagus, pressure ulcers in the oesophagus, formation of abnormal connections between vessels, bleeding getting worse, failure of device removal, and pneumonia caused by breathing in foreign material. They also said that in theory there could be problems with swallowing.

More information about oesophageal varices

NHS Choices (www.nhs.uk) may be a good place to find out more. Your local patient advice and liaison service (usually known as PALS) may also be able to give you further information and support.

About NICE

NICE produces guidance (advice) for the NHS about preventing, diagnosing and treating different medical conditions. The guidance is written by independent experts including healthcare professionals and people representing patients and carers. They consider how well an interventional procedure works and how safe it is, and ask the opinions of expert advisers. HealthTech guidance applies to the whole of the NHS in England, Wales, Scotland and Northern Ireland. Staff working in the NHS are expected to follow this guidance.

To find out more about NICE, its work and how it reaches decisions, see www.nice.org.uk/aboutguidance

This leaflet is about 'stent insertion for bleeding oesophageal varices'. This leaflet and the full guidance aimed at healthcare professionals are available at www.nice.org.uk/guidance/HTG261

You can order printed copies of this leaflet from NICE publications (phone 0845 003 7783 or email publications@nice.org.uk and quote reference N2515). The NICE website has a screen reader service called Browsealoud, which allows you to listen to our guidance. Click on the Browsealoud logo on the NICE website to use this service.

We encourage voluntary organisations, NHS organisations and clinicians to use text from this booklet in their own information about this procedure.

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