

Stent insertion for bleeding oesophageal varices

Interventional procedures guidance

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www.nice.org.uk/guidance/ipg392

Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the [Yellow Card Scheme](#).

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with

those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

This guidance replaces IPG265.

1 Guidance

- 1.1 Current evidence on stent insertion for bleeding oesophageal varices is from small numbers of patients, but shows no major safety concerns. There is evidence to show that this procedure is efficacious in selected patients in whom other methods of treatment have failed to control bleeding. Therefore, this procedure may be used provided that normal arrangements are in place for clinical governance, consent and audit.

2 The procedure

2.1 Indications and current treatments

- 2.1.1 Oesophageal varices are enlarged veins within the lower oesophagus and the oesophagogastric junction which develop in patients with portal hypertension, often as a result of cirrhosis. Bleeding from varices has a significant risk of death and the risk of re-bleeding is high.
- 2.1.2 The management of bleeding oesophageal varices commonly requires blood transfusion. Measures aimed at arresting the bleeding include vasoactive medication, balloon tamponade, endoscopic variceal band ligation or sclerotherapy. In patients with refractory bleeding, transjugular intrahepatic portosystemic shunts (TIPSS), and shunt or devascularisation surgery, may be required.

2.2 Outline of the procedure

- 2.2.1 The aim of this procedure is to apply pressure to the bleeding oesophageal varices to induce haemostasis.
- 2.2.2 A coated metal stent supplied on a delivery system is inserted with the aim of compressing the bleeding varices in the oesophageal wall. The stent is usually inserted with the aid of an endoscope (but can be inserted without), and appropriate positioning may be confirmed endoscopically, fluoroscopically or by chest X-ray.
- 2.2.3 The stent maintains a patent oesophageal lumen for passage of food, saliva and other fluids. It is left in position for up to 2 weeks and is then removed endoscopically.
- 2.2.4 Further procedures, such as TIPSS or surgery, may be done to reduce the risk of further bleeds.

2.3 Efficacy

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](#).

- 2.3.1 Case series of 34 and 20 patients reported that stent insertion stopped the bleeding in all patients and that no re-bleeding occurred in any patients (60-day follow-up). A case series of 10 patients reported immediate control of bleeding in 78% (7 out of 9) of patients who had successful stent insertion (stent insertion was unsuccessful in 1 patient). Re-bleeding, which was successfully treated by TIPSS, occurred in 1 patient.
- 2.3.2 Case series of 34, 20 and 10 patients treated with stent insertion reported 10, 2 and 5 deaths respectively during follow-up of between 42 and 60 days. Of the 17 deaths, 2 resulted from exsanguination, 1 was caused by multi-organ failure and failure to control the bleeding, and the remainder were as a result of hepatic or multi-organ failure.

- 2.3.3 The case series of 34 patients reported that 32% (11 out of 34) of patients required endoscopic band ligation, 24% (8 out of 34) required radiologic TIPSS insertion and 15% (5 out of 34) required laparoscopic azygoportal disconnection after stent removal (timing of events not stated).
- 2.3.4 The case series of 20 patients reported that after stent removal 25% (5 out of 20) of patients required TIPSS insertion, 25% (5 out of 20) required laparoscopic azygoportal disconnection and 20% (4 out of 20) required embolotherapy with sclerosing agents combined with coils (timing of events not stated).
- 2.3.5 The Specialist Advisers listed key efficacy outcomes as control of bleeding, reduction in risk of re-bleeding, avoidance of using blood products and survival.

2.4 Safety

- 2.4.1 A case report described acute bronchial obstruction at day 6 caused by stent-related compression of the left main bronchus (confirmed by computed tomography scan) which was relieved by stent removal.
- 2.4.2 Migration of the stent into the stomach was reported in 21% (7 out of 34) of patients during 60-day follow-up in the case series of 34 patients. All stents were successfully repositioned within 24 to 48 hours. In the case series of 20 patients, stent migration into the stomach was reported in 25% (5 out of 20) of patients: all stents were repositioned endoscopically. Three of the 5 migrations were in the first 5 patients in the series.
- 2.4.3 Slight oesophageal ulceration at the distal end of the stent was reported in 1 patient within 60-day follow-up in the case series of 34 patients.
- 2.4.4 The Specialist Advisers listed adverse events reported in the literature or from their own experience as mucosal trauma on withdrawal, oesophageal perforation, oesophageal pressure ulceration, fistula formation, worsening of bleeding, failure of removal of the device and aspiration pneumonia. They considered theoretical adverse events to include dysphagia.

3 Further information

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the [overview](#).

Information for patients

NICE has produced [information for the public on this procedure](#). 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](#).