Transvenous obliteration for gastric varices

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www.nice.org.uk/guidance/ipg751

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 <u>Yellow Card Scheme</u>.

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 <u>assess and reduce the environmental</u> <u>impact of implementing NICE recommendations</u> wherever possible.

1 Recommendations

- 1.1 Evidence on the safety and efficacy of transvenous obliteration of gastric varices is adequate in the short term but limited in the long term. Therefore, this procedure should only be used with special arrangements for clinical governance, consent, and audit or research. Find out <u>what special arrangements mean on the NICE interventional procedures guidance page</u>.
- 1.2 Clinicians wanting to do transvenous obliteration of gastric varices should:
 - Inform the clinical governance leads in their healthcare organisation.
 - Give people (and their families and carers as appropriate) clear written information to support <u>shared decision making</u>, including <u>NICE's information for</u> <u>the public</u>.
 - Ensure that people (and their families and carers as appropriate) understand the procedure's safety and efficacy, and any uncertainties about these. This should include the risk of:
 - balloon rupture and embolisation of sclerosant or device during the procedure
 - an increase in portal vein pressure in the long term, which may exacerbate ascites and oesophageal varices.
 - Audit and review clinical outcomes of everyone having the procedure. The main efficacy and safety outcomes identified in this guidance can be entered into <u>NICE's interventional procedure outcomes audit tool</u> (for use at local discretion).

- Enter details about everyone having transvenous obliteration of gastric varices onto suitable registry databases where available and review local clinical outcomes.
- Discuss the outcomes of the procedure during their annual appraisal to reflect, learn and improve.
- 1.3 Healthcare organisations should:
 - Ensure systems are in place that support clinicians to collect and report data on outcomes and safety for everyone having this procedure.
 - Regularly review data on outcomes and safety for this procedure.
- 1.4 Patient selection should be discussed with a specialist centre that offers all of the standard treatments for portal hypertension and bleeding gastric varices, and that is experienced in managing acute and chronic liver disease.
- 1.5 The procedure should only be done by clinicians with training in and experience of the procedure.

2 The condition, current treatments and procedure

The condition

2.1 Varices are dilated veins. Gastric varices form in around 20% of people with portal hypertension. Portal hypertension can happen in cirrhosis or in people without cirrhosis who develop thrombosis of the splanchnic circulation, such as portal vein thrombosis. Gastric varices are prone to bleeding, and this is associated with high mortality and poor prognosis.

Current treatments

2.2 Treatments for gastric varices include non-selective beta-blockers, balloon tamponade, band ligation, endoscopic cyanoacrylate or thrombin injection, transjugular intrahepatic portosystemic shunt and transvenous obliteration.

The procedure

- 2.3 Cross-sectional imaging is done to identify and confirm the target shunt (gastrorenal shunt is usually present). Percutaneous venous access of the femoral or jugular vein is done using standard angiographic technique. An occlusion balloon catheter is inserted and navigated into the target shunt under fluoroscopic guidance. The balloon is inflated to block the shunt and venography is then done to define the variceal anatomy and type of varices. Sclerosant is slowly injected into the varices to fill the full extent of the varices, with the embolisation end point being minimal filling of the afferent vein or portal vasculature. The injection of sclerosant can be done with or without using a microcatheter for more selective injection. The occlusion balloon catheter is left in situ until satisfactory embolisation of the varices is achieved. This procedure is called balloon-occluded retrograde transvenous obliteration (BRTO). The aim is to obliterate the varices and manage acutely bleeding gastric varices or those at high risk of bleeding.
- 2.4 Modified techniques, such as balloon-occluded antegrade transvenous obliteration (BATO, a collective term for portal venous access routes to the varices), vascular plug-assisted retrograde transvenous obliteration (PARTO) and coil-assisted retrograde transvenous obliteration (CARTO), follow a similar procedure to BRTO. However, for PARTO and CARTO, shunt occlusion is achieved by vascular plugging or coiling. These 2 techniques can reduce procedure time and eliminate the risk of balloon rupture.

3 Committee considerations

The evidence

3.1 NICE did a rapid review of the published literature on the efficacy and safety of this procedure. This comprised a comprehensive literature

search and detailed review of the evidence from 11 sources, which was discussed by the committee. The evidence included 4 systematic reviews and meta-analyses, 1 randomised controlled trial, 1 cohort study and 5 case series. It is presented in the <u>summary of key evidence section</u> in the interventional procedures overview. Other relevant literature is in the appendix of the overview.

- 3.2 The professional experts and the committee considered the key efficacy outcomes to be: reduction in bleeding, survival and quality of life.
- 3.3 The professional experts and the committee considered the key safety outcomes to be: bleeding, embolisation of sclerosant or device, encephalopathy and worsening of portal hypertension.
- 3.4 Patient commentary was sought but none was received.

Committee comments

- 3.5 This procedure may be done with transjugular intrahepatic portosystemic shunt insertion.
- 3.6 There are several different approaches to doing this procedure.

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Endorsing organisation

This guidance has been endorsed by <u>Healthcare Improvement Scotland</u>.

Accreditation

