NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

Transvenous obliteration for gastric varices

Varices are enlarged veins that can develop in the stomach (gastric) when a person has liver disease. They can burst, causing uncontrollable bleeding. In this procedure, a tube with a tiny balloon on the end is inserted into a vein (transvenous) in the thigh or neck and passed into the enlarged vein. The balloon is inflated to stop blood flowing into the vein. The vein is then blocked (obliterated) using one of several techniques. The aim is to reduce the risk of bleeding.

NICE is looking at transvenous obliteration for gastric varices.

NICE's interventional procedures advisory committee met to consider the evidence and the opinions of professional experts with knowledge of the procedure.

This document contains the <u>draft guidance for consultation</u>. Your views are welcome, particularly:

- comments on the draft recommendations
- information about factual inaccuracies
- additional relevant evidence, with references if possible.

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

This is not NICE's final guidance on this procedure. The draft guidance may change after this consultation.

After consultation ends, the committee will:

- meet again to consider the consultation comments, review the evidence and make appropriate changes to the draft guidance
- prepare a second draft, which will go through a <u>resolution process</u> before the final guidance is agreed.

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Please note that we reserve the right to summarise and edit comments received during consultation or not to publish them at all if, in the reasonable opinion of NICE, there are a lot of comments or if publishing the comments would be unlawful or otherwise inappropriate.

Closing date for comments: 23 September 2022

Target date for publication of guidance: November 2022

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1 Draft 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 what.special.arrangements.mean on the NICE interventional procedures guidance page.
- 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 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 risks 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</u> <u>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.

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

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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 using standard angiographic technique is done. 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 (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

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10 sources, which was discussed by the committee. The evidence included 3 systematic reviews and meta-analyses, 1 randomised controlled trial, 1 cohort study, and 5 case series. It is presented in the summary of key evidence section 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, 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, worsening of portal hypertension.
- 3.4 Patient commentary was sought but none was received.

Committee comments

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

Tom Clutton-Brock
Chair, interventional procedures advisory committee
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