



Endoscopic ultrasound-guided biliary drainage for biliary obstruction

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

1 Recommendations

- 1.1 Evidence on the safety and efficacy of endoscopic ultrasound-guided biliary drainage (EUS-BD) for biliary obstruction caused by distal malignant disease is adequate to support using this procedure. This is provided that standard arrangements are in place for clinical governance, consent and audit. Find out what standard arrangements mean on the NICE interventional procedures guidance page.
- 1.2 Evidence on the safety and efficacy of EUS-BD for biliary obstruction caused by malignant hilar or benign disease is inadequate in quality and quantity. So, this procedure should be used only in research. Find out what only in research means on the NICE interventional procedures guidance page.
- 1.3 Further research should report details of patient selection, where the obstruction is, and whether this procedure has been done after failed endoscopic retrograde cholangiopancreatography.
- 1.4 Patient selection should be done by a multidisciplinary team or, in an emergency, only after agreement with an experienced hepatobiliary team.
- 1.5 This procedure should only be done in specialised centres by a clinician with specific training and experience in the procedure.

2 The condition, current treatments and

procedure

The condition

2.1 Biliary obstruction involves blockage of any duct that carries bile from the liver to the gallbladder or from the gallbladder to the small intestine. It may have benign or malignant causes, and can lead to symptoms including jaundice, nausea and abdominal pain, itching, pale stools and dark urine.

Current treatments

2.2 Current standard management of biliary obstruction usually includes stenting using endoscopic retrograde cholangiopancreatography (ERCP) or percutaneous transhepatic biliary drainage (PTBD). For malignant obstruction, treatment may also include chemotherapy, biological therapy, photodynamic therapy and radiofrequency ablation.

The procedure

- 2.3 Endoscopic ultrasound-guided biliary drainage (EUS-BD) is an alternative procedure when ERCP is not possible; ERCP fails in a small proportion of people because of the nature of the obstruction or their anatomy (which may be altered because of disease progression or previous surgery). EUS-BD is also a minimally invasive alternative to PTBD, which is conventionally offered when ERCP has failed. The aim of the procedure is to reduce biliary obstruction and allow the biliary tract to drain.
- 2.4 EUS-BD may be done under conscious sedation or general anaesthesia. It involves inserting an echoendoscope through the mouth and oesophagus into the stomach or duodenum. Using ultrasound guidance, the biliary tract is punctured with a needle. A contrast agent may be injected to enhance imaging.
- A guidewire is then passed into the biliary tract at the site of the puncture, which is dilated to create a fistula. Finally, a metal or plastic

- stent is deployed into the biliary tract to allow biliary drainage into the stomach or small intestine. Stent delivery systems may also be used to do EUS-BD without needle puncture, dilation or insertion of a guidewire.
- EUS-BD can be done using several different techniques and stents can be deployed through multiple access routes. The 2 most common techniques, endoscopic ultrasound-guided choledochoduodenostomy (EUS-CDS) and endoscopic ultrasound-guided hepaticogastrostomy (EUS-HGS), both use a transluminal approach. In EUS-CDS, the extrahepatic bile duct is punctured, and the stent is deployed via the duodenal bulb. In EUS-HGS, the left hepatic duct is punctured, and the stent is deployed via the stent is deployed.
- 2.7 Stents may also be deployed using a transpapillary approach in which the guidewire is passed into the duodenum. In endoscopic ultrasound-guided antegrade stenting (EUS-AGS), the stent is placed across the biliary obstruction. In the endoscopic ultrasound-guided rendezvous technique (EUS-RV), the echoendoscope is swapped with an ERCP duodenoscope after placement of the guidewire, and a conventional ERCP is done before stent placement. The choice of technique depends on the cause of the biliary obstruction and the anatomy of the person having the procedure.

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 10 sources, which was discussed by the committee. The evidence included 1 systematic review and meta-analysis, 2 randomised controlled trials, 1 non-randomised comparative study, 5 case series and 1 case report. 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: relief of biliary obstruction, reduction in bilirubin levels, reintervention rates, stent patency and improvement in quality of life.
- 3.3 The professional experts and the committee considered the key safety outcomes to be: bleeding, infection (including peritonitis), bile leak and stent migration.
- 3.4 Patient commentary was sought but none was received.

Committee comments

- 3.5 The committee noted that there is more than 1 available device for this procedure.
- The committee was informed that this is a complex procedure that requires significant training in endoscopic ultrasound.
- 3.7 The committee noted that this procedure is most often used after a failed endoscopic retrograde cholangiopancreatography (ERCP).
- The committee was informed that this procedure usually involves stent placement via the duodenum.
- The committee noted that most of the evidence for this procedure was from people with malignant disease.
- The committee was informed that the decision to do ERCP or endoscopic ultrasound-guided biliary drainage may be made at the time of the procedure.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.

Accreditation

