NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

Endoscopic ultrasound-guided biliary drainage for biliary obstruction

Bile is a fluid that helps digest fats. It is produced by the liver and stored in the gall bladder. 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 is usually caused by tumours or gallstones. This can cause jaundice, nausea and stomach pain.

In this procedure, a thin flexible tube called an endoscope, with an ultrasound probe at the tip, is passed through the mouth and into the stomach or small intestine. The blockage is located using sound waves. The blocked bile duct is then punctured with a needle, and a small tube called a stent is inserted to allow the bile to drain into the gut.

NICE is looking at endoscopic ultrasound-guided biliary drainage for biliary obstruction.

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This document contains the draft guidance for consultation. 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 The draft guidance may change after this consultation.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- meet again to consider the consultation comments, review the evidence and make appropriate changes to the draft guidance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 resolution process before the final guidance is agreed.

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: 4 January 2023

Target date for publication of guidance: April 2023

1 Draft recommendations

1.1 Evidence on the safety and efficacy of endoscopic ultrasound-guided biliary drainage 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 endoscopic ultrasound-guided biliary drainage 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, as well as 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 around 5 to 10% 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.

2.5 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 guidewire.

2.6 EUS-BD can be done using several different techniques and stents can be deployed via multiple access routes. The 2 most common techniques, endoscopic ultrasound-guided choledoduodenostomy (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 stomach.

2.7 Stents may also be deployed using a transpapillary approach in which the guidewire is passed into the duodenum. In an endoscopic ultrasound-guided antegrade approach (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 is dependent on the cause of biliary obstruction and the patient anatomy.

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 9 sources, which was discussed by the committee. The evidence included 1 systematic review and meta-analysis, 1 randomised controlled trial, 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.

3.6 The committee was informed that this is a complex procedure which 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).

3.8 The committee was informed that most cases of this procedure involve stent placement via the duodenum.

3.9 The committee noted that most of the evidence for this procedure was from people with malignant disease.

3.10 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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Chair, interventional procedures advisory committee
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