

## NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

### Interventional procedures consultation document

# Electrohydraulic lithotripsy for difficult-to-treat bile duct stones

The flow of bile out of the liver and the gallbladder can become blocked by stones in the bile ducts. In this procedure, which is done under general anaesthesia, an endoscope is passed into the bile ducts (usually through the mouth, stomach and the small intestine). A special probe is passed through the endoscope and sends an electric current into liquid surrounding the stone. This creates very small pressure-waves (electrohydraulic) that break up the stone (lithotripsy).

NICE is looking at electrohydraulic lithotripsy for difficult-to-treat bile duct stones.

NICE's interventional procedures advisory committee met to consider the evidence and the opinions of professional experts, who are consultants 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This document contains the [draft guidance for consultation](#).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 The draft guidance may change after this consultation.**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- meet again to consider the consultation comments, review the evidence and make appropriate changes to the draft guidance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: 17 December 2020

Target date for publication of guidance: April 2021

## 1 Draft recommendations

- 1.1 Evidence on the efficacy of electrohydraulic lithotripsy for difficult-to-treat bile duct stones is adequate. However, evidence on its safety is limited in quantity. This procedure is also associated with the well-recognised complications of endoscopic retrograde cholangiopancreatography. 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 wishing to do electrohydraulic lithotripsy for difficult-to-treat bile duct stones should:
- Inform the clinical governance leads in their healthcare organisation.
  - Give patients (and their families and carers as appropriate) clear written information to support [shared decision making](#), including [NICE's information for the public](#).

- Ensure that patients (and their families and carers as appropriate) understand the procedure's safety and efficacy, and any uncertainties about these.
- Audit and review clinical outcomes of all patients having the procedure. The main efficacy and safety outcomes identified in this guidance can be entered into [NICE's interventional procedure outcomes audit tool](#) (for use at local discretion).
- 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 every patient having this procedure.
- Regularly review data on outcomes and safety for this procedure.

1.4 The procedure should only be done in specialised centres with experience of managing difficult-to-treat bile duct stones.

1.5 Patient selection should be done by a multidisciplinary team including a hepatobiliary surgeon and clinicians with expertise in endoscopic retrograde cholangiopancreatography.

## **2 The condition, current treatments and procedure**

### **The condition**

2.1 Bile duct stones which form from cholesterol or bile pigments can block the bile ducts. Difficult-to-treat bile duct stones are defined by their diameter (above 15 mm), number, unusual shape (such as barrel-shaped), location (intrahepatic or cystic duct), stone impaction, narrowing of the bile duct distal to the stone, or the

anatomy of the common bile duct (sigmoid-shaped, short distal length or acute distal angulation of less than 135 degrees).

## Current treatments

- 2.2 Diagnosis and management of bile duct stones is described in [NICE's clinical guideline on gallstone disease](#). Treatments for bile duct stones include bile duct clearance and laparoscopic cholecystectomy. Conventional stone extraction involves endoscopic retrograde cholangiopancreatography and extraction from the bile ducts using balloon and basket catheters following a sphincterotomy. For difficult-to-treat bile duct stones, treatment options include temporary stenting to allow biliary drainage if the stones cannot be removed or stone fragmentation (lithotripsy).

## The procedure

- 2.3 Electrohydraulic lithotripsy (EHL) aims to fragment bile duct stones that cannot be treated using conventional stone removal techniques.
- 2.4 This procedure is usually done using general anaesthesia and direct visualisation of the stones using an endoscope inserted into the biliary tract. An EHL probe is inserted through the endoscope and the tip of the probe is positioned near the stone. Liquid is then injected around the stone and high-voltage energy from the probe used to generate shock waves which break the stone into smaller pieces. The procedure is usually done with the endoscope passed orally and through the stomach into the duodenum. However, a percutaneous approach is also possible.
- 2.5 When the stone fragmentation is complete, the fragments are flushed out or removed by standard techniques (such as a basket or balloon catheter). The endoscope is then removed. This procedure usually takes about 60 minutes to complete.

### 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 8 sources, which was discussed by the committee. The evidence included 1 systematic review, 2 randomised controlled trials, 4 non-randomised comparative studies and 1 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: stone removal, reduction in symptoms and relief of biliary obstruction.
- 3.3 The professional experts and the committee considered the key safety outcomes to be: cholangitis, bile duct damage including perforation and stricture, pancreatitis, bleeding and the need for surgery.
- 3.4 Patient commentary was sought but none was received.

#### Committee comments

- 3.5 The committee was informed that the technique is evolving.
- 3.6 The committee noted that stone removal can be done as a single procedure using this technique, avoiding the need for several procedures as in some other techniques.
- 3.7 The committee was informed that in a small number of patients an endoscopic retrograde approach is not possible and the procedure is done through a percutaneous approach, which is a more invasive procedure with a greater risk of complications.

- 3.8 The committee encourages the establishment of a registry for this procedure.

Tom Clutton-Brock

Chair, interventional procedures advisory committee

November 2020

ISBN: