NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

Laser 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 small fibre is put through the endoscope, which emits laser light onto the stone to break it up (lithotripsy). Small pieces are removed, but small sand-like pieces may be retained and will be gradually passed through the body. This procedure usually takes 30 to 60 minutes. The aim is to break up bile duct stones that cannot be treated using conventional techniques.

NICE is looking at laser 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This document contains the draft guidance for consultation.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 The draft guidance may change after this consultation.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- meet again to consider the consultation comments, review the evidence and make appropriate changes to the draft guidance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: 12 February 2021

Target date for publication of guidance: May 2021

1 Draft recommendations

1.1 Evidence on the efficacy of laser lithotripsy for difficult-to-treat bile duct stones is adequate. However, evidence on its safety, especially the risk of biliary stricture formation in the long term, 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 laser 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, and by clinicians with specific training in bile duct stone visualisation and the safe use of laser therapy.

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 Laser lithotripsy aims to fragment bile duct stones that cannot be treated using conventional endoscopic 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. A laser fibre is introduced gently through the endoscope. Once the tip of the fibre is in direct contact with the stone, a laser is focused on its surface to create a plasma bubble. This oscillates and induces cavitation with compressive waves to fragment the stone. 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 removed by conventional methods (such as a basket or balloon catheter). The endoscope is then removed. Any small sand-like

pieces may be retained and will be gradually passed through the body. The procedure usually takes 30 to 60 minutes.

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, 4 randomised controlled trials and 4 non-randomised comparative studies. 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 encourages the establishment of a registry for this procedure.

NICE interventional procedures consultation document, January 2021

Tom Clutton-Brock

Chair, interventional procedures advisory committee

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