NICE National Institute for Health and Care Excellence

NICE guidance

Laser lithotripsy for difficult-to-treat bile duct stones

HealthTech guidance
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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 assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

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This guidance replaces IPG699.

1 Recommendations

1.1 Evidence on the efficacy of laser lithotripsy for difficult-to-treat bile duct stones is adequate. However, evidence on its long-term safety is limited in quantity. 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 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 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.

1.6 Further research should report long-term safety, including biliary stricture.

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 the section on managing common bile duct stones in NICE's guideline on gallstone disease. Treatments for bile duct stones include bile duct clearance and laparoscopic cholecystectomy. Conventional stone extraction involves endoscopic retrograde cholangiopancreatography and a sphincterotomy, then extracting the stones from the ducts using balloon and basket catheters. 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 13 sources, which was discussed by the committee. The evidence included 1 systematic review, 2 systematic reviews and meta-analyses, 5 randomised controlled trials, 4 non-randomised comparative studies and 1 case series (registry). It is presented in the summary of key evidence section in the 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 and different techniques may have different efficacy and safety profiles.

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

Update information

Minor changes since publication

January 2026: Interventional procedures guidance 699 has been migrated to HealthTech guidance 584. The recommendations and accompanying content remain unchanged.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.