

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

Endoscopic ultrasound-guided gallbladder drainage for acute cholecystitis when surgery is not an option

Acute cholecystitis is inflammation of the gallbladder. It usually happens when a gallstone blocks the opening that drains bile from the gallbladder. Bile builds up, causing nausea, vomiting and fever. In this procedure, a flexible tube called an endoscope is passed through the mouth and into the stomach or the first part of the small intestine. Using ultrasound to identify the gallbladder, a small tube (a stent) is inserted via the endoscope through the wall of the stomach or small intestine into the gallbladder. Bile flows through the stent. The aim is to drain bile from the gallbladder.

NICE is looking at endoscopic ultrasound-guided gallbladder drainage for acute cholecystitis when surgery is not an option.

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This document contains the [draft guidance for consultation](#).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 The draft guidance may change after this consultation.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- meet again to consider the consultation comments, review the evidence and make appropriate changes to the draft guidance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: 1 March 2023

Target date for publication of guidance: June 2023

1 Draft recommendations

- 1.1 Endoscopic ultrasound-guided gallbladder drainage for acute cholecystitis may be used when surgery is not an option, if 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 For auditing the outcomes of this 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).
- 1.3 This technically challenging procedure should only be done in specialist centres by clinicians trained and experienced in the use of this procedure for gallbladder drainage.

Why the committee made these recommendations

Standard treatment for acute cholecystitis is laparoscopic or open surgery to remove the gallbladder (cholecystectomy). But for some people surgery is too risky, or they may not be able to have it because they have other conditions that make surgery unsuitable.

There is good evidence to show that this procedure is effective in treating acute cholecystitis and is an alternative when surgery is not an option. A disadvantage of this procedure, when compared to cholecystectomy, is that cholecystitis may reoccur.

2 The condition, current treatments and procedure

The condition

- 2.1 Acute cholecystitis is inflammation of the gallbladder. The most common cause of acute cholecystitis is gallstones (calculous

cholecystitis) blocking the duct that drains the gallbladder (cystic duct). This means bile cannot drain from the gallbladder, causing pain, nausea, vomiting and fever.

- 2.2 Acalculous cholecystitis is a less common, but usually more serious, cause of acute cholecystitis. It usually develops as a complication of a serious illness, infection or injury that damages the gallbladder. It can be caused by accidental damage to the gallbladder during major surgery, serious injuries or burns, sepsis, severe malnutrition, or HIV or AIDS.

Current treatments

- 2.3 Initial treatment usually involves fasting, pain relief and antibiotics if there is an infection. The gallbladder can be surgically removed (open or laparoscopic cholecystectomy) to prevent acute cholecystitis returning, and to reduce the risk of developing complications, such as gangrenous cholecystitis and peritonitis.
- 2.4 People who cannot have surgery may be able to have percutaneous cholecystostomy. This involves inserting a drainage catheter in the gallbladder through a small entry hole made in the abdominal wall. Endoscopic transpapillary gallbladder drainage is a less common alternative. It involves inserting a plastic stent through the ampulla and cystic duct into the gallbladder endoscopically.

The procedure

- 2.5 Endoscopic ultrasound-guided gallbladder drainage for acute cholecystitis is typically done under sedation or general anaesthesia using a specialist endoscope with an ultrasound probe and fluoroscopic guidance. Imaging is used before the procedure to determine its feasibility. An anastomotic tract is created into the gallbladder through either the wall of the antrum of the stomach (cholecystogastrostomy) or the wall of the duodenum (cholecystoduodenostomy) and a stent is inserted to establish

biliary drainage into the gut and relieve the gallbladder obstruction. Occasionally, the anastomotic tract may be created between the gallbladder and jejunum (cholecystojejunostomy) if the anatomy has been altered by previous surgery.

- 2.6 Different technologies are used to create the anastomotic tract and deploy the stent, and stents can be made of different materials. Single-step devices allow for single-step delivery of the stent without the need to change instruments for track dilation. Multistep devices need track dilation with a cystotome and a biliary balloon.
- 2.7 The aim is to drain bile from the gallbladder and avoid the need for emergency cholecystectomy, particularly in people for whom surgery poses a high risk.

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 3 systematic reviews, 1 randomised controlled trial, 2 non-randomised comparative studies, 1 registry, 1 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: effective drainage of gallbladder, resolution of sepsis, and symptom relief, including reduction in pain and improvement in quality of life.

- 3.3 The professional experts and the committee considered the key safety outcomes to be: pain, infection, damage to adjacent structures, bile leak and need for further intervention.
- 3.4 Two commentaries from people who have had this procedure were discussed by the committee.

Committee comments

- 3.5 The committee was informed that people may need post-procedure follow up and this may involve more than 1 speciality.
- 3.6 The committee was informed that a training programme for the procedure is provided by a company that makes a device used in this procedure.
- 3.7 The committee was informed that clinicians who wish to do this procedure need a period of training in endoscopic ultrasound-guided techniques for other procedures.

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Chair, interventional procedures advisory committee

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