

**NATIONAL INSTITUTE FOR HEALTH AND CARE
EXCELLENCE**

Interventional procedures consultation document

**Percutaneous insertion of a cystic duct
stent after cholecystostomy for acute
calculous cholecystitis**

Acute calculous cholecystitis happens when a gallstone blocks an opening (the cystic duct) that drains fluid (bile) from the gallbladder. Bile builds up in the gallbladder causing pain, nausea, vomiting and fever. In this procedure, a stent is inserted into or across the cystic duct, through the catheter that was inserted into the gallbladder through the skin (percutaneous cholecystostomy) to relieve the acute cholecystitis. The aim is to allow bile to flow through the tube, bypassing the blockage and preventing further obstruction.

NICE is looking at percutaneous insertion of a cystic duct stent after cholecystostomy for acute calculous cholecystitis.

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This document contains the [draft guidance for consultation](#).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 The draft guidance may change after this consultation.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- meet again to consider the consultation comments, review the evidence and make appropriate changes to the draft guidance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: 2 November 2021

Target date for publication of guidance: March 2022

1 Draft recommendations

- 1.1 Evidence on the safety and efficacy of percutaneous insertion of a cystic duct stent after cholecystostomy for acute calculous cholecystitis is inadequate in quality and quantity. But because patients would otherwise need permanent external drainage, the procedure can be considered for this condition, as long as special arrangements for clinical governance, consent, and audit or research are in place. Find out [what special arrangements mean on the NICE interventional procedures guidance page](#).
- 1.2 Clinicians wanting to do percutaneous insertion of a cystic duct stent after cholecystostomy for acute calculous cholecystitis 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 Patient selection should be done by a multidisciplinary team.
- 1.5 This procedure should only be done in specialist centres by clinicians with specific training and experience in this procedure.
- 1.6 Further research should report details of patient selection, the procedure undertaken, the type of stent used and whether the patient is later able to have definitive surgery.

2 The condition, current treatments and procedure

The condition

- 2.1 Acute calculous cholecystitis is inflammation of the gallbladder caused by a gallstone or biliary sludge that blocks the cystic duct. The blockage in the cystic duct causes bile to build up in the gallbladder, increasing the pressure inside it and causing it to become inflamed. Symptoms include pain, fever, nausea and vomiting.

Current treatments

- 2.2 Treatments include intravenous fluids, medicines (analgesics and antibiotics), endoscopic or percutaneous biliary drainage, and surgery (laparoscopic or open cholecystectomy). [NICE's guideline on gallstone disease](#) recommends offering early laparoscopic cholecystectomy (to be carried out within 1 week of diagnosis) to patients with acute cholecystitis.

The procedure

- 2.3 This procedure places a stent via a cholecystostomy tract into the cystic duct to provide antegrade gallbladder drainage and prevent

further obstructive episodes of cholecystitis. This procedure is suitable for patients who otherwise need long-term external drainage.

- 2.4 Before the procedure, a percutaneous cholecystostomy and drainage is done to resolve the acute episode. This procedure is usually done using conscious sedation. The cholecystostomy drain is used for cholangiography to confirm cystic duct obstruction. Under fluoroscopic guidance, a guidewire and catheter are passed through the cholecystostomy tract, through the cystic duct and into the duodenum. A stent is then inserted and placed in or across the cystic duct.
- 2.5 After the procedure, an external gallbladder drain is usually left in situ for a few days to ensure that there is good antegrade drainage of bile into the duodenum. The external drain can then be removed after a satisfactory cholangiogram.

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 4 sources, which was discussed by the committee. The evidence included 2 case series and 2 case reports. It is presented in [the summary of key evidence section in the interventional procedures overview](#).
- 3.2 The professional experts and the committee considered the key efficacy outcomes to be: effective biliary drainage, symptom relief, and removal of the need for external drainage.

- 3.3 The professional experts and the committee considered the key safety outcomes to be: pain, bleeding, damage to biliary tree, biliary sepsis and blockage.
- 3.4 Patient commentary was sought but none was received.

Committee comments

- 3.5 Most of the evidence considered was for patients with acute calculous cholecystitis who needed persistent external drainage and were unable to have biliary surgery. However, this procedure has also been used in patients with malignant biliary obstruction.
- 3.6 The committee was informed that an external biliary drainage for 4 weeks to 6 weeks is typically needed before using this procedure.
- 3.7 Some of the patients treated with this procedure were later able to have definitive surgery.

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Chair, interventional procedures advisory committee

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