

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

Interventional procedures 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.

1 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 procedures 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 5 sources, which was discussed by the committee. The evidence included 3 case series (including 1 abstract reporting safety events) 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.
- 3.8 The committee noted that there are different stents made of different materials and they might be used for different indications.

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Endorsing organisation

This guidance has been endorsed by [Healthcare Improvement Scotland](#).