



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

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www.nice.org.uk/guidance/ipg764

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.

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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 <u>assess and reduce the environmental impact of implementing NICE recommendations</u> wherever possible.

1 Recommendations

- 1.1 Endoscopic ultrasound-guided gallbladder drainage for acute cholecystitis can 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 using this procedure for gallbladder drainage.

Why the committee made these recommendations

Standard treatment for acute cholecystitis is keyhole (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 with cholecystectomy, is that cholecystitis may reoccur.

2 The condition, current treatments and procedure

The condition

- 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.
- 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 reoccurring, 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). 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 12 sources, which was discussed by the committee. The evidence included 4 systematic reviews, 1 randomised controlled trial, 3 non-randomised comparative studies, 1 registry, 1 case series and 2 case reports. 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 the gallbladder, resolution of sepsis, and symptom relief, including reduction in pain and improvement

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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.
- Two commentaries from people who have had this procedure were discussed by the committee.

Committee comments

- The committee was informed that people may need post-procedure follow up and this may involve more than 1 specialty.
- 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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Endorsing organisation

This guidance has been endorsed by <u>Healthcare Improvement Scotland</u>.