NICE National Institute for Health and Care Excellence

NICE guideline

Gallstone disease: diagnosis and management

Clinical guideline
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Your responsibility

The recommendations in this guideline represent the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, professionals and practitioners are expected to take this guideline fully into account, alongside the individual needs, preferences and values of their patients or the people using their service. It is not mandatory to apply the recommendations, and the guideline does not override the responsibility to make decisions appropriate to the circumstances of the individual, in consultation with them and their families and carers or guardian.

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.

Local commissioners and providers of healthcare have a responsibility to enable the guideline to be applied when individual professionals and people using services wish to use it. They should do so in the context of local and national priorities for funding and developing services, and in light of their duties to have due regard to the need to eliminate unlawful discrimination, to advance equality of opportunity and to reduce health inequalities. Nothing in this guideline should be interpreted in a way that would be inconsistent with complying with those duties.

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.

Contents

This guideline is the basis of QS104.

Introduction

Gallstone disease occurs when hard fatty or mineral deposits (gallstones) form in the gallbladder. Approximately 15% of the adult population are thought to have gallstone disease, and most of these people experience no symptoms. For a small proportion of people with gallstone disease, the stones irritate the gallbladder or block part of the biliary system, and this can cause symptoms such as pain, infection and inflammation. If these symptoms are left untreated, gallstones can cause more serious and in some cases life-threatening conditions such as cholecystitis, cholangitis, pancreatitis and jaundice.

There is variation in how gallstone disease is managed. Some people with symptomless gallstone disease are offered treatment to prevent symptoms developing in the future, whereas others are offered a watch-and-wait approach. When people experience symptoms of gallstone disease they often need surgery to remove their gallbladder. There is uncertainty about the best way of treating gallstone disease. In addition, if surgery is appropriate there is uncertainty about whether it should be performed as soon as possible after a gallstones attack or delayed until any infection and inflammation has subsided.

This guideline addresses some of these uncertainties and provides recommendations about how gallstone disease should be identified, diagnosed and managed in adults.

Key priorities for implementation

The following recommendations have been identified as priorities for implementation. The full list of recommendations is in section 1.

- Reassure people with asymptomatic gallbladder stones found in a normal gallbladder and normal biliary tree that they do not need treatment unless they develop symptoms.
- Offer early laparoscopic cholecystectomy (to be carried out within 1 week of diagnosis) to people with acute cholecystitis.
- Reconsider laparoscopic cholecystectomy for people who have had percutaneous cholecystostomy once they are well enough for surgery.
- Clear the bile duct:
  - surgically at the time of laparoscopic cholecystectomy **or**
  - with endoscopic retrograde cholangiopancreatography (ERCP) before or at the time of laparoscopic cholecystectomy.
- If the bile duct cannot be cleared with ERCP, use biliary stenting to achieve biliary drainage only as a temporary measure until definitive endoscopic or surgical clearance.

1 Recommendations

People have the right to be involved in discussions and make informed decisions about their care, as described in making decisions about your care.

Making decisions using NICE guidelines explains how we use words to show the strength (or certainty) of our recommendations, and has information about prescribing medicines (including off-label use), professional guidelines, standards and laws (including on consent and mental capacity), and safeguarding.

1.1 Diagnosing gallstone disease

1.1.1 Offer liver function tests and ultrasound to people with suspected gallstone disease, and to people with abdominal or gastrointestinal symptoms that have been unresponsive to previous management.

1.1.2 Consider magnetic resonance cholangiopancreatography (MRCP) if ultrasound has not detected common bile duct stones but the:

- bile duct is dilated **and/or**
- liver function test results are abnormal.

1.1.3 Consider endoscopic ultrasound (EUS) if MRCP does not allow a diagnosis to be made.

1.1.4 Refer people for further investigations if conditions other than gallstone disease are suspected.

1.2 Managing gallbladder stones

1.2.1 Reassure people with asymptomatic gallbladder stones found in a normal gallbladder and normal biliary tree that they do not need treatment unless they develop symptoms.

1.2.2 Offer laparoscopic cholecystectomy to people diagnosed with symptomatic gallbladder stones.

1.2.3 Offer day-case laparoscopic cholecystectomy for people having it as an elective planned procedure, unless their circumstances or clinical condition make an inpatient stay necessary.

1.2.4 Offer early laparoscopic cholecystectomy (to be carried out within 1 week of diagnosis) to people with acute cholecystitis.

1.2.5 Offer percutaneous cholecystostomy to manage gallbladder empyema when:

- surgery is contraindicated at presentation **and**
- conservative management is unsuccessful.

1.2.6 Reconsider laparoscopic cholecystectomy for people who have had percutaneous cholecystostomy once they are well enough for surgery.

1.3 Managing common bile duct stones

1.3.1 Offer bile duct clearance and laparoscopic cholecystectomy to people with symptomatic or asymptomatic common bile duct stones.

1.3.2 Clear the bile duct:

- surgically at the time of laparoscopic cholecystectomy **or**
- with endoscopic retrograde cholangiopancreatography (ERCP) before or at the time of laparoscopic cholecystectomy.

1.3.3 If the bile duct cannot be cleared with ERCP, use biliary stenting to achieve biliary drainage only as a temporary measure until definitive endoscopic or surgical clearance.

1.3.4 Use the lowest-cost option suitable for the clinical situation when choosing between day-case and inpatient procedures for elective ERCP.

1.4 Patient, family member and carer information

1.4.1 Advise people to avoid food and drink that triggers their symptoms until they have their gallbladder or gallstones removed.

1.4.2 Advise people that they should not need to avoid food and drink that triggered their symptoms after they have their gallbladder or gallstones removed.

1.4.3 Advise people to seek further advice from their GP if eating or drinking triggers existing symptoms or causes new symptoms to develop after they have recovered from having their gallbladder or gallstones removed.

Terms used in this guideline

Asymptomatic gallstones/ asymptomatic common bile duct stones

Stones that are found incidentally, as a result of imaging investigations unrelated to gallstone disease in people who have been completely symptom free for at least 12 months before diagnosis.

Gallbladder empyema

Build-up of pus in the gallbladder, as a result of a blocked cystic duct.

Laparoscopic cholecystectomy

Removal of the gallbladder through 'keyhole' surgery.

Percutaneous cholecystostomy

A procedure to drain pus and fluid from an infected gallbladder.

Symptomatic gallstones/ symptomatic common bile duct stones

Stones found on gallbladder imaging, regardless of whether symptoms are being experienced currently or whether they occurred sometime in the 12 months before diagnosis.

2 Research recommendations

The Guideline Development Group has made the following recommendations for research, based on its review of evidence, to improve NICE guidance and patient care in the future.

2.1 Diagnosing gallstone disease

What are the long-term benefits and harms, and cost effectiveness of endoscopic ultrasound (EUS) compared with magnetic resonance cholangiopancreatography (MRCP) in adults with suspected common bile duct stones?

Why this is important

MRCP and EUS have both been found to be sufficiently accurate for diagnosing common bile duct stones, with EUS regarded as the most accurate test. MRCP is non-invasive and so carries negligible risks to the patient. However, EUS carries a small but significant risk of patient harms, including death. There is insufficient evidence available to determine whether the benefits of improved diagnosis associated with EUS outweigh its procedural risks. Therefore, research is needed to compare MRCP with EUS to evaluate the subsequent management of common bile duct stones.

2.2 Managing gallbladder stones

What are the benefits and harms, and cost effectiveness of routine intraoperative cholangiography in people with low to intermediate risk of common bile duct stones?

Why this is important

In the evidence reviewed for this guideline, there was a lack of randomised controlled trials of intraoperative cholangiography, and the evidence that was available did not support the knowledge and experience of the Guideline Development Group. Therefore, there is a need for large, high-quality trials to address clinical questions about the benefits and harms of intraoperative cholangiography.

2.3 Managing common bile duct stones

What models of service delivery enable intraoperative endoscopic retrograde cholangiopancreatography (ERCP) for bile duct clearance to be delivered within the NHS? What are the costs and benefits of different models of service delivery?

Why this is important

Evidence reviewed for this guideline identified that intraoperative ERCP is both clinically and cost effective, but it is unclear whether delivery of this intervention is feasible in the NHS because of the way current services are organised. It is also unclear whether intraoperative ERCP will remain cost effective if services are reorganised.

2.4 Timing of laparoscopic cholecystectomy

In adults with common bile duct stones, should laparoscopic cholecystectomy be performed early (within 2 weeks of bile duct clearance), or should it be delayed (until 6 weeks after bile duct clearance)?

Why this is important

There is a lack of evidence from randomised controlled trials of early compared with delayed laparoscopic cholecystectomy after bile duct clearance with ERCP. It is unclear what effect the timing of laparoscopic cholecystectomy has on clinical outcomes and resource use.

2.5 Information for patients and carers

What is the long-term effect of laparoscopic cholecystectomy on outcomes that are important to patients?

Why this is important

There is a lack of information on the long-term impact of cholecystectomy on patient outcomes. Many patients report a continuation of symptoms or the onset of new symptoms after laparoscopic cholecystectomy, and these affect quality of life. Research is needed to establish the long-term patient benefits and harms, so that appropriate

information can be provided to patients to aid decision-making and long-term management of their condition.

Finding more information and committee details

You can see everything NICE says on this topic in the NICE Pathway on gallstone disease.

To find NICE guidance on related topics, including guidance in development, see our web page on gallstone disease.

For full details of the evidence and the guideline committee's discussions, see the full guideline and appendices. You can also find information about how the guideline was developed, including details of the committee.

NICE has produced tools and resources to help you put this guideline into practice. For general help and advice on putting NICE guidelines into practice, see resources to help you put guidance into practice.

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