

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.

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.

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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.

Patient-centred care

This guideline offers best practice advice on the care of adults with gallstone disease.

Patients and healthcare professionals have rights and responsibilities as set out in the [NHS Constitution for England](#) – all NICE guidance is written to reflect these. Treatment and care should take into account individual needs and preferences. Patients should have the opportunity to make informed decisions about their care and treatment, in partnership with their healthcare professionals. Healthcare professionals should follow the [Department of Health's advice on consent](#). If someone does not have capacity to make decisions, healthcare professionals should follow the [code of practice that accompanies the Mental Capacity Act](#) and the supplementary [code of practice on deprivation of liberty safeguards](#).

NICE has produced guidance on the components of good patient experience in adult NHS services. All healthcare professionals should follow the recommendations in NICE's guidance on [patient experience in adult NHS services](#).

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

The following guidance is based on the best available evidence. The [full guideline](#) gives details of the methods and the evidence used to develop the guidance.

The wording used in the recommendations in this guideline (for example, words such as 'offer' and 'consider') denotes the certainty with which the recommendation is made (the strength of the recommendation). See [About this guideline](#) for details.

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.

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.

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.

3 Other information

3.1 Scope and how this guideline was developed

NICE guidelines are developed in accordance with a [scope](#) that defines what the guideline will and will not cover.

How this guideline was developed

NICE commissioned the Internal Clinical Guidelines team to develop this guideline. The team established a Guideline Development Group (see [section 4](#)), which reviewed the evidence and developed the recommendations.

The methods and processes for developing NICE clinical guidelines are described in [The guidelines manual](#).

3.2 Related NICE guidance

Details are correct at the time of publication of the guideline (October 2014). Further information is available on the [NICE website](#).

Published

General

- [Patient experience in adult NHS services](#) (2012) NICE guidance CG138

Condition-specific

- [Dyspepsia and gastro-oesophageal reflux disease](#) (2014) NICE guideline CG184
- [Single-incision laparoscopic cholecystectomy](#) (2010) NICE interventional procedure guidance 346
- [Surgical site infection](#) (2008) NICE guideline CG74

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About this guideline

NICE clinical guidelines are recommendations about the treatment and care of people with specific diseases and conditions.

NICE guidelines are developed in accordance with a [scope](#) that defines what the guideline will and will not cover.

This guideline was developed by the NICE Internal Clinical Guidelines Programme. The Internal Clinical Guidelines Programme worked with a Guideline Development Group, comprising healthcare professionals (including consultants, GPs and nurses), patients and carers, and technical staff, which reviewed the evidence and drafted the recommendations. The recommendations were finalised after public consultation.

The methods and processes for developing NICE clinical guidelines are described in [The guidelines manual](#).

NICE produces guidance, standards and information on commissioning and providing high-quality healthcare, social care, and public health services. We have agreements to provide certain NICE services to Wales, Scotland and Northern Ireland. Decisions on how NICE guidance and other products apply in those countries are made by ministers in the Welsh government, Scottish government, and Northern Ireland Executive. NICE guidance or other products may include references to organisations or people responsible for commissioning or providing care that may be relevant only to England.

Strength of recommendations

Some recommendations can be made with more certainty than others. The Guideline Development Group makes a recommendation based on the trade-off between the benefits and harms of an intervention, taking into account the quality of the underpinning evidence. For some interventions, the Guideline Development Group is confident that, given the information it has looked at, most patients would choose the intervention. The wording used in the recommendations in this guideline denotes the certainty with which the recommendation is made (the strength of the recommendation).

For all recommendations, NICE expects that there is discussion with the patient about the risks and benefits of the interventions, and their values and preferences. This discussion aims to help them to

reach a fully informed decision (see also [Patient-centred care](#)).

Interventions that must (or must not) be used

We usually use 'must' or 'must not' only if there is a legal duty to apply the recommendation. Occasionally we use 'must' (or 'must not') if the consequences of not following the recommendation could be extremely serious or potentially life threatening.

Interventions that should (or should not) be used – a 'strong' recommendation

We use 'offer' (and similar words such as 'refer' or 'advise') when we are confident that, for the vast majority of patients, an intervention will do more good than harm, and be cost effective. We use similar forms of words (for example, 'Do not offer...') when we are confident that an intervention will not be of benefit for most patients.

Interventions that could be used

We use 'consider' when we are confident that an intervention will do more good than harm for most patients, and be cost effective, but other options may be similarly cost effective. The choice of intervention, and whether or not to have the intervention at all, is more likely to depend on the patient's values and preferences than for a strong recommendation, and so the healthcare professional should spend more time considering and discussing the options with the patient.

Recommendation wording in guideline updates

NICE began using this approach to denote the strength of recommendations in guidelines that started development after publication of the 2009 version of [The guidelines manual](#) (January 2009).

Other versions of this guideline

The full guideline, [Gallstone disease](#), contains details of the methods and evidence used to develop the guideline. It is published by the Internal Clinical Guidelines Programme.

The recommendations from this guideline have been incorporated into a [NICE Pathway](#).

We have produced [information for the public](#) about this guideline.

Implementation

[Implementation tools and resources](#) to help you put the guideline into practice are also available.

Your responsibility

This guidance represents the view of NICE, which was arrived at after careful consideration of the evidence available. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. However, 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, and informed by the summaries of product characteristics of any drugs.

Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their 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.

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Accreditation

