

# **Gallstone disease**

## **NICE guideline**

**Draft for consultation, June 2014**

If you wish to comment on this version of the guideline, please be aware that all the supporting information and evidence is contained in the full version.

## Contents

Introduction .....	3
Patient-centred care.....	3
Strength of recommendations .....	4
Key priorities for implementation.....	5
1 Recommendations .....	6
1.1 Diagnosing gallstone disease .....	6
1.2 Managing gallbladder stones .....	7
1.3 Managing common bile duct stones.....	8
1.4 Patient, family member and carer information .....	8
2 Research recommendations.....	8
3 Other information.....	10
4 The Guideline Development Group, Internal Clinical Guidelines team and NICE project team.....	12

## 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 [Patient experience in adult NHS services](#).

## **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.

## **Key priorities for implementation**

The following recommendations have been identified as priorities for implementation. The full list of recommendations is in [section 1](#).

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

- **[1.3.3]**

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

- **[1.3.5]**

- 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. **[1.4.2]**
- 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.. **[1.4.3]**

# 1 Recommendations

The following guidance is based on the best available evidence. The [full guideline](#) [\[hyperlink to be added for final publication\]](#) gives details of the methods and the evidence used to develop the guidance.

## Terms used in this guideline

<b>Asymptomatic gallstones/ common bile duct stones</b>	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.
<b>Gallbladder empyema</b>	Build-up of pus in the gallbladder, as a result of a blocked cystic duct.
<b>Laparoscopic cholecystectomy</b>	Removal of the gallbladder through 'keyhole' surgery.
<b>Percutaneous cholecystostomy</b>	A procedure to drain pus and fluid from an infected gallbladder.
<b>Symptomatic gallstones/ common bile duct stones</b>	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 which 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 more appropriate.

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 not appropriate 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 and/ 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 planned, 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 gallstone(s) 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 gallstone(s) 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 gallstone(s) 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 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 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 at least 4 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 consultation on the guideline (June 2014). Further information is available on [the NICE website](#).

#### **Published**

##### ***General***

- [Patient experience in adult NHS services](#). NICE clinical guidance 138 (2012).

##### ***Condition-specific***

- [Single-incision laparoscopic cholecystectomy](#). NICE interventional procedure guidance 346 (2010).
- [Surgical site infection](#). NICE clinical guideline 74 (2008).
- [Dyspepsia](#). NICE clinical guideline 17 (2004).

#### **Under development**

NICE is [developing](#) the following guidance:

- Dyspepsia and gastro-oesophageal reflux disease. Partial update of NICE clinical guideline 17. Publication date to be confirmed.

## **4 The Guideline Development Group, Internal Clinical Guidelines team and NICE project team**

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