NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

SCOPE

1 Guideline title

Cholelithiasis and cholecystitis: diagnosis and management of cholelithiasis and cholecystitis.

1.1 Short title

Cholelithiasis and cholecystitis.

2 The remit

The Department of Health has asked NICE to produce a guideline on the diagnosis and management of cholelithiasis and cholecystitis.

3 Clinical need for the guideline

3.1 Epidemiology

a) Cholelithiasis ('gallstones') is the presence of discrete, hard fatty or mineral deposits ('calculus') in the gallbladder. Approximately 15% of the UK adult population are thought to have the condition.

b) 80% of people with cholelithiasis are asymptomatic meaning they experience no symptoms or have non-specific symptoms such as pain in their abdomen, stomach, back or shoulder which may be misattributed to other conditions such as dyspepsia or general back ache. For the majority of cases, asymptomatic cholelithiasis is detected incidentally through imaging such as ultrasound or MRI as part of investigations for other conditions.

c) For around 20% of people with cholelithiasis, the condition is symptomatic causing the following complications:

- Biliary colic
- Cholecystitis
- Cholangitis
- Obstructive jaundice
- Pancreatitis.

d) These complications can be extremely painful, and in some cases life-threatening and will often require emergency treatment.

e) Cholecystitis is inflammation of the gallbladder. In 90% of cases cholecystitis is caused by cholelithiasis . For the remaining 10% of cases, cholecystitis develops as a result of serious illness or injury that causes damage to the gallbladder and is associated with more serious morbidity and higher mortality rates than cholecystitis caused by cholelithiasis.

f) Known risk factors for cholelithiasis include:

- Women, particularly those taking oral contraception, having high dose oestrogen therapy, or those who have been pregnant
- Increasing age
- Family history of gallstones
- Obesity
- Recent weight loss (e.g. after weight loss surgery)
- Digestive disorders such as Crohn's disease or irritable bowel syndrome
- Cirrhosis
- Taking the antibiotic ceftriaxone.

3.2 Current practice

a) For asymptomatic cholelithiasis, a watch and wait approach is usually taken. For symptomatic cholelithiasis a conservative approach is taken for conditions such as biliary colic that may spontaneously resolve. For these patients, analgesics are used to manage the painful episode. For patients with complications that

are unlikely to resolve without additional intervention (such as cholecystitis, or recurrent biliary colic), a more radical approach is taken. For these patients, cholecystectomy (surgical removal of the gallbladder) is performed. Approximately 50,000 cholecystectomies are performed each year in the UK, about one third of which are for cholecystitis. This is one of the most common surgical procedures performed in the UK.

b) There are differences in the timing of cholecystectomy with some procedures being carried out within 7 days of the onset of symptoms (acute cholecystectomy), and some procedures being carried out at least 6 weeks after symptoms have settled (delayed cholecystectomy). It is widely perceived that delayed cholecystectomy is safer than acute cholecystectomy as the risk of complications such as infections is thought to be lower. However, acute cholecystectomy may have important benefits compared to delayed procedures, such as potential to avoid readmission and shorter length of stay, and may also be as safe and feasible as delayed cholecystectomy.

c) There are uncertainties about whether some people with asymptomatic gallstones should be offered prophylactic cholecystectomy to prevent future complications.

d) There are uncertainties about the optimal management of people with cholecystitis for whom surgery is not appropriate.

e) Guidance is therefore needed to improve the way that cholelithiasis and cholecystitis are diagnosed and managed so that treatments are equitable, cost effective and improve quality of life for people with the condition.

4 The guideline

The guideline development process is described in detail on the NICE website (see section 6, ‘Further information’).

This scope defines what the guideline will (and will not) examine, and what the guideline developers will consider. The scope is based on the referral from the Department of Health.

The areas that will be addressed by the guideline are described in the following sections.

4.1 Population

4.1.1 Groups that will be covered

a) Adults with signs and symptoms of or diagnosed with cholelithiasis.

b) Adults with signs and symptoms of or diagnosed with cholecystitis.

4.1.2 Groups that will not be covered

a) Children and young people, as cholelithiasis and cholecystitis in this group are rare and have a different aetiology to the adult condition.

b) Adults without signs and symptoms or a diagnosis of cholelithiasis or cholecystitis.

4.2 Healthcare setting

a) All settings in which NHS care is received.

4.3 Clinical management

4.3.1 Key clinical issues that will be covered

a) Procedures for diagnosing symptomatic and asymptomatic cholelithiasis.

b) Procedures for diagnosing cholecystitis.

c) Relative effectiveness of different types of interventions for the management of symptomatic and asymptomatic cholelithiasis, and cholecystitis:

- Surgical interventions such as cholecystectomy
- Radiological/gastroenterological interventions such as endoscopic retrograde cholangiopancreatography (ERCP), endoscopic drainage, and lithotripsy.
- Pharmacological interventions such as analgesics and ursodeoxycholic acid.
- Prophylactic antibiotic use.

d) Timing of surgery for acute cholecystitis.

e) Management of acute cholecystitis in people for whom surgery is not appropriate.

4.3.2 Clinical issues that will not be covered

a) On-going management of the conditions caused by gallstones (such as cholangitis, jaundice, pancreatitis), except cholecystitis.

b) On-going management of other underlying conditions that cause cholelithiasis and cholecystitis.

c) Conditions that are not caused by cholelithiasis.

d) Gallbladder cancer.

e) Cost effectiveness of different types of surgery.

f) Relative effectiveness of different sub-types of open surgery (such small incision versus open surgery).

g) Relative effectiveness of different sub- types of laparoscopic surgery (such as single incision versus robot assisted).

h) Relative effectiveness of different sub-types of pharmacological interventions (such as opioids versus non opioids).

4.4 Main outcomes

a) Relief of symptoms (short and long term).

b) Symptomatic stones remaining post cholecystectomy.

c) Postcholecystectomy symptoms (onset of new symptoms as a result of gallbladder removal such as diarrhoea).

d) Mortality.

e) Complications of surgery (such as conversion rates from laparoscopic to open surgery, injury to ducts, perforation).

f) Health-related quality of life.

g) Resource-use and costs.

4.5 Review questions

Review questions guide a systematic review of the literature. They address only the key clinical issues covered in the scope, and usually relate to interventions, diagnosis, prognosis, service delivery or patient experience. Please note that these review questions are draft versions and will be finalised with the Guideline Development Group.

4.5.1 Diagnosis

a) What signs and symptoms should prompt a clinician to suspect symptomatic cholelithiasis and/or acute cholecystitis in adults presenting to healthcare services?

b) What is the optimum method for diagnosing cholelithiasis and/or cholecystitis in adults suspected of the condition?

4.5.2 Prognosis

a) Is there an assessment tool or process that can accurately stratify patients with symptomatic and asymptomatic cholelithiasis for their risk of adverse outcomes?

4.5.3 Interventions

b) What is the relative effectiveness of different types of interventions (surgical, radiological/gastroenterological, pharmacological) for

managing symptomatic and asymptomatic cholelithiasis and cholecystitis? Which type of intervention offers the best outcomes and does the optimal intervention vary for different subgroups of patients?

c) For patients with acute cholecystitis for whom cholecystectomy is appropriate, when should cholecystectomy be performed?

d) How should acute cholecystitis be managed in people for whom surgery is not appropriate?

4.6 Economic aspects

Developers will take into account both clinical and cost effectiveness when making recommendations involving a choice between alternative interventions. A review of the economic evidence will be conducted and analyses will be carried out as appropriate. The preferred unit of effectiveness is the quality-adjusted life year (QALY), and the costs considered will usually be only from an NHS and personal social services (PSS) perspective. Further detail on the methods can be found in 'The guidelines manual' (see ‘Further information’).

4.7 Status

4.7.1 Scope

This is the consultation draft of the scope. The consultation dates are 23 November to 21 December 2012.

4.7.2 Timing

The development of the guideline recommendations will begin in February 2013.

5 Related NICE guidance

5.1 Published guidance

5.1.1 Other related NICE guidance

- Single-incision laparoscopic cholecystectomy. NICE interventional procedure guidance 346 (2010). Available from www.nice.org.uk/IPG346.
- Surgical site infection. NICE clinical guideline 74 (2008). Available from www.nice.org.uk/CG74.
- Dyspepsia. NICE clinical guideline 17 (2004). Available from www.nice.org.uk/CG17.

5.2 Guidance under development

NICE is currently developing the following related guidance (details available from the NICE website):

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

6 Further information

Information on the guideline development process is provided in the following documents, available from the NICE website:

- 'How NICE clinical guidelines are developed: an overview for stakeholders the public and the NHS'
- 'The guidelines manual'.

Information on the progress of the guideline will also be available from the NICE website.