



2018 surveillance of gallstone disease: diagnosis and management (NICE clinical guidance CG188)

Surveillance report Published: 31 August 2018

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Surveillance decision

We will not update the NICE guideline on gallstone disease: diagnosis and management at this time.

Reasons for the decision

New evidence was identified during the surveillance review which supports the currently recommended diagnostic interventions and management strategies for gallstone disease, including to offer early laparoscopic cholecystectomy to people with acute cholecystitis.

New evidence was also identified concerning investigations for the diagnosis of gallbladder disease that are not currently recommended including procedures used in the management of common bile duct (CBD) stones, the timing of both endoscopic retrograde cholangiopancreatography (ERCP) and surgery in the management of CBD stones and the timing of cholecystectomy following a diagnosis of gallstone pancreatitis. However, it was concluded that in the absence of further evidence synthesis or additional published evidence, this evidence would not be sufficient to trigger an update at this time. We identified relevant Cochrane reviews on the timing of ERCP and surgery in these populations through the surveillance review. We will monitor these Cochrane reviews and consider the updated conclusions when these become available.

For further details and a summary of all evidence identified in surveillance, see <u>appendix</u> <u>A</u>: summary of evidence from surveillance.

Overview of 2018 surveillance methods

NICE's surveillance team checked whether recommendations in gallstone disease: diagnosis and management (NICE guideline CG188) remain up to date.

The surveillance process consisted of:

- Initial feedback from topic experts via a questionnaire.
- Literature searches to identify relevant evidence.
- Assessing the new evidence against current recommendations and deciding whether or not to update sections of the guideline, or the whole guideline.
- Consulting on the decision with stakeholders, except if we propose to update and replace the whole guideline.
- Considering comments received during consultation and making any necessary changes to the decision.

For further details about the process and the possible update decisions that are available, see <u>ensuring that published guidelines are current and accurate</u> in developing NICE guidelines: the manual.

Evidence considered in surveillance

Search and selection strategy

We searched for new evidence related to the whole guideline.

We found 54 studies in a search that included systematic reviews, meta-analyses, randomised controlled trials, economic evaluations, and observational studies on the diagnosis and management of gallstone disease published between 1 February 2014 and 3 April 2018.

We also included:

4 relevant studies identified by topic experts

From all sources, we considered 56 studies to be relevant to the guideline.

See <u>appendix A</u>: summary of evidence from surveillance for details of all evidence considered, and references.

Selecting relevant studies

The standard surveillance review process of using randomised controlled trials, full economic evaluations of relevance to the UK and systematic reviews was used for this search.

The only deviation from this was the inclusion of a qualitative study for patient, family member and carer information and observational studies for the diagnosis of gallstone disease.

Ongoing research

We checked for relevant ongoing research; of the ongoing studies identified, 2 studies were assessed as having the potential to change recommendations; therefore we plan to regularly check whether these studies have published results, and evaluate the impact of the results on current recommendations as quickly as possible. These studies are:

- A randomised controlled trial comparing laparoscopic cholecystectomy with observation/conservative management for preventing recurrent symptoms and complications in adults with uncomplicated symptomatic gallstones
- A randomised controlled trial to establish the clinical and cost effectiveness of
 expectant management versus pre-operative imaging with MRCP in patients with
 symptomatic gallstones undergoing laparoscopic cholecystectomy at low or moderate
 risk of common bile duct stones: The Sunflower Study

Intelligence gathered during surveillance

Views of topic experts

We sent questionnaires to 10 topic experts and received 6 responses. The topic experts either:

- · participated in the guideline committee who developed the guideline, or
- were recruited to the NICE Centre for Guidelines Expert Advisers Panel to represent their specialty.

One topic expert questioned whether conservative management is better than surgery for some patients with an episode of acute cholecystitis, as the expert highlighted that these patients may not have a further attack of gallstone symptoms. However evidence identified during this surveillance review indicates that acute cholecystitis patients receiving conservative management have a significantly greater likelihood of gallstone-related complications and, if they ended up requiring surgery, they have more surgery-related complications compared to patients receiving planned laparoscopic cholecystectomy. As such the evidence supports recommendation 1.2.4 which says to 'offer early laparoscopic cholecystectomy (to be carried out within 1 week of diagnosis) to people with acute cholecystitis'. A topic expert also suggested that recommendation 1.3.2 should be updated to include postoperative endoscopic retrograde cholangiopancreatography (ERCP) for clearing the bile duct, however evidence identified during this surveillance review did not clearly demonstrate that postoperative ERCP was superior to other procedures.

Topic experts also highlighted papers on the timing of laparoscopic cholecystectomy after ERCP and the cost effectiveness of early cholecystectomy, which have been included as evidence in this surveillance review.

Other sources of information

We considered all other correspondence received since the guideline was published, including correspondence received based on a coroner's report. This formed the basis of a decision to consider the timing of surgery following the diagnosis of gallstone pancreatitis, which is currently out of scope for NICE guideline CG188. An optimal timing for surgical treatment of gallstone pancreatitis following diagnosis/onset of symptoms was not

demonstrated in the evidence identified through surveillance. We will keep abreast of research in this area to assess whether operation intervals can be more clearly defined and any implications for NICE guideline CG188.

Views of stakeholders

Stakeholders are consulted on all surveillance decisions except if the whole guideline will be updated and replaced. Because this surveillance decision was to not update the guideline, we consulted on the decision.

Overall, 4 stakeholders commented: 2 agreed with the decision; and 2 noted that they had no comments to make on the proposal. One stakeholder highlighted 2 references to be considered in a future surveillance review of the guideline, concerning the management of gallbladder drainage in acute cholecystitis in high surgical risk patients. One reference did not fit the evidence type inclusion criteria, whilst the other ongoing study was assessed as having the potential to change recommendations:

 A randomised controlled trial on endoscopic ultrasound-guided gallbladder drainage versus percutaneous cholecystostomy for acute cholecystitis

We will check for publication of this study and evaluate the impact of the results on current recommendations as quickly as possible.

See appendix B for full details of stakeholders' comments and our responses.

See <u>ensuring that published guidelines are current and accurate</u> in developing NICE guidelines: the manual for more details on our consultation processes.

Equalities

No equalities issues were identified during the surveillance process.

Overall decision

After considering all evidence, views of topic experts and stakeholders and other intelligence, we decided that no update is necessary.

ISBN: 978-1-4731-3074-6