Evidence-based guidelines for diagnosis of common bile duct stones

Vanja Giljaca
University Hospital Center Rijeka
Department of Gastroenterology

Trusted evidence.
Informed decisions.
Better health.
Outline

01  What are CPGs and how they are made.

02  Specifics of diagnostic CPGs.

03  Common bile duct stones overview.

04  Current recommendations for CBDs diagnosis.

05  Cochrane diagnostic test accuracy systematic review for diagnosis of CBDs.

06  What next?
Clinical Practice Guidelines (CPGs)

‘Statements that include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options.’

Committee on Standards for Developing Trustworthy CPGs, Institute of Medicine, 2011
When did guidelines first appear?
Ayurveda

Razi Book of Medicine, Iran

Ancient Medicine, Israel

Asclepius, Greece
Systematic reviews
Randomised controlled studies
Cohort studies
Case reports
Expert opinion

Do we need CPGs?
Cochrane Croatia

PubMed

(((common bile duct stones) OR choledocholithiasis) OR CBD stones) AND diagnostic accuracy) OR diagnostic test accuracy;

12482 citations

Publication date from 2014/01/01 to 2014/12/31

434 citations
Clinical Expertise

Patient Concerns/Welfare

Best research evidence
Who can use CPGs?

- Physicians/Nurses
- Patients
- Families
- Decision makers
- Public

EFFECTIVE HEALTHCARE

SAVES LIVES...

...AND MONEY
CPGs for diagnostic tests

Suspicions:
- Condition 1
- Condition 2
- Condition 3
- Condition 4
- Condition 5
- Condition 6

Diagnosis:
- Test 1
- Test 2
- Test 3
- Test 4

Interventions:
- Drug
- Surgery

Outcomes:
- Positive
- Inconclusive
- Negative
Sensitivity = \frac{TP}{TP+FN}

Specificity = \frac{TN}{TN+FP}

TP - true positive; FP - false positive; FN - false negative; TN - true negative
Or air?
Or bowel wall?
Or diverticulum?
Or sludge?
Or nothing?
Stone or Tumor???
2% to 4% of population has common bile duct stones (CBDS)

Common bile duct stones (CBDS)


Symptomatic CBDS

- 90% Pain
- 70% Jaundice
- 9% Acute cholangitis
- 9% Acute pancreatitis


Mortality 10%
Current diagnostic pathway

Symptoms & signs
(pain, jaundice, cholangitis, pancreatitis)

1. LFTs
   US
   Sens. 90%
   Spec. 30%

2. MRCP
   EUS
   Sens. 99%
   Spec. 97%

3. ERCP
   IOC
   Dx. ???
   Therapy

LFTs: liver function tests
US: abdominal ultrasound
MRCP: magnetic resonance cholangiopancreatography
EUS: endoscopic ultrasound
ERCP: endoscopic retrograde cholangiopancreatography
IOC: intraoperative cholangiography
CBDS after laparoscopic cholecystectomy: 3% - 5%

30% - 50% < IOC

- False+ IOC
- False– preop. & postop. workup
- Spontaneous evacuation

Which diagnostic test to choose?

No clear recommendations

A comprehensive systematic review and meta-analysis of all modern diagnostic tests for CBDS does not exist.

Guidelines are based on clinical experience, primary studies or comparative head to head meta-analyses.
Aims

Comparison

1. step

2. step

3. step

Diagnostic algorithm

LFTs
US
EUS
MRCP
ERCP
IOC

Diagnostic accuracy
## Diagnostic accuracy

<table>
<thead>
<tr>
<th></th>
<th>Ref. standard POS</th>
<th>Ref. standard NEG</th>
</tr>
</thead>
<tbody>
<tr>
<td>Index test POS</td>
<td>TP</td>
<td>FP</td>
</tr>
<tr>
<td>Index test NEG</td>
<td>FN</td>
<td>TN</td>
</tr>
</tbody>
</table>

\[
\text{Sensitivity} = \frac{TP}{TP+FN} \\
\text{Specificity} = \frac{TN}{TN+FP}
\]

TP—true positive; FP—false positive; FN—false negative; TN—true negative; PPV—positive predictive value; NPV—negative predictive value
Diagnostic accuracy – ROC curve

- ROC curve
- Summary sensitivity and specificity point
- 95% confidence region
Literature search

22790

16923

518

36

5867

16405

13

482

7

Incl. criteria not met

5

5

5

Duplicates

EFTs

US

EUS

MRCP

ERCP

IOC
LFTs vs US

Not statistically different
EUS vs MRCP

p = 0.686
ERCP vs IOC

$p = 0.494$
Diagnostic accuracy – post test probability

Clinically more useful measure of diagnostic accuracy

Prevalence-dependent
# Post-test probabilities summary

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Post test probability for positive test</th>
<th>Post test probability for negative test</th>
</tr>
</thead>
<tbody>
<tr>
<td>LFTs</td>
<td>91.5%</td>
<td>30.5%</td>
</tr>
<tr>
<td>US</td>
<td>84.5%</td>
<td>17.2%</td>
</tr>
<tr>
<td>EUS</td>
<td>96.0%</td>
<td>3.6%</td>
</tr>
<tr>
<td>MRCP</td>
<td>93.9%</td>
<td>4.9%</td>
</tr>
<tr>
<td>ERCP</td>
<td>99.0%</td>
<td>7.4%</td>
</tr>
<tr>
<td>IOC</td>
<td>98.0%</td>
<td>1.1%</td>
</tr>
</tbody>
</table>
Diagnostic pathway

Suspected CBDS

No cholecystectomy

Post-cholecystect.

LFT/US

EUS

Kcx/IOC?

Kcx/F-up

Simpt.

IOC

Surg. expl.

F-up

MRCP

ERCP

ES/Ex

F-up

F-up / other pathology

F-up / other pathology

F-up / other pathology

Screening???
Suspected CBDS

No cholecystectomy

- LFT/US
  + EUS
    + ERCP
      + ES/Ex
        + Kcx
      - Kcx/IOC?
        + Surg. expl.
        - IOC
          - F-up
    - Kcx/F-up
      + Simpt.

Post-cholecystect.

- LFT/US
  + MRCP
    + ERCP
      + ES/Ex
        + F-up
      - F-up
  - F-up / other pathology

F-up / other pathology
What next?

British Society of Gastroenterology plans to implement our results in new guidelines

Guidelines on the management of common bile duct stones (CBDS)

E J Williams, J Green, I Beckingham, R Parks, D Martin, M Lombard

ABSTRACT

The last 30 years have seen major developments in the management of gallstone-related disease, which in the United States alone costs over 6 billion dollars per annum to treat. Endoscopic retrograde cholangiopancreatography (ERCP) has become a widely available and routine procedure, whilst open cholecystectomy has largely been replaced by a laparoscopic approach, which may or may not include laparoscopic exploration of the common bile duct (LCBD). In addition, new imaging techniques such as magnetic resonance cholangiography (MR) and endoscopic ultrasound (EUS) offer the opportunity to accurately visualise the biliary system without instrumentation of the ducts. As a consequence clinicians are now faced with a number of potentially valid options for managing patients with suspected CBDS. It is with this in mind that the following guidelines have been written.

1.0 FOREWORD

This document, on the diagnosis and treatment of patients with common bile duct stones (CBDS), was commissioned by the British Society of Gastroenterology (BSG) as part of a wider initiative to develop guidelines for clinicians in several areas of clinical practice.

Guidelines are not rigid protocols and they should not be construed as interfering with local clinical judgment. Hence they do not represent a directive of prescribed routes, but a basis on which clinicians can consider the options available more clearly.

3.0 FORMULATION OF GUIDELINES

Guidelines were commissioned by the British Society of Gastroenterology and have been endorsed by the Clinical Standards and Services Committee (CSSC) of the BSG, the BSG Endoscopy Committee, the ERCP stakeholder group, the Association of Upper Gastrointestinal Surgeons of Great Britain and Ireland (AUGIS), Association of Laparoscopic Surgeons (ALS), and the Royal College of Radiologists (RCR). Contributions from all of these groups have been incorporated into the final version of the guideline document.

The method of formulation can be summarised as follows. In 2004 a preliminary literature search was performed by Earl Williams. Original papers were identified by a search of PubMed/EMBASE for articles containing the term common bile duct stones, gallstones, cholecystolithiasis, laparoscopic cholecystectomy or ERCP. Articles were first selected by title. Their relevance was then confirmed by review of the corresponding abstract. This initial enquiry focussed on full length reports of prospective design, though retrospective analyses and case reports were also retrieved if the topic they dealt with had not been addressed by prospective study. Missing articles were identified by manually searching the reference lists of retrieved papers.

A summary of the findings of this search was presented to the BSG Endoscopy Committee in 2004. Additional references were suggested and the principal clinical questions arising from the literature search agreed. Provisional guidelines were subsequently developed by a multi-disciplinary guideline writing group. This was com
What next?
Thank you!