Endoscopic retrograde cholangiopancreatography versus intraoperative cholangiography for diagnosis of common bile duct stones (Review)

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[Diagnostic Test Accuracy Review]

Endoscopic retrograde cholangiopancreatography versus intraoperative cholangiography for diagnosis of common bile duct stones

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ABSTRACT

Background

Endoscopic retrograde cholangiopancreatography (ERCP) and intraoperative cholangiography (IOC) are tests used in the diagnosis of common bile duct stones in people suspected of having common bile duct stones. There has been no systematic review of the diagnostic accuracy of ERCP and IOC.

Objectives

To determine and compare the accuracy of ERCP and IOC for the diagnosis of common bile duct stones.

Search methods

We searched MEDLINE, EMBASE, Science Citation Index Expanded, BIOSIS, and Clinicaltrials.gov to September 2012. To identify additional studies, we searched the references of included studies and systematic reviews identified from various databases (Database of Abstracts of Reviews of Effects (DARE)), Health Technology Assessment (HTA), Medion, and ARIF (Aggressive Research Intelligence Facility)). We did not restrict studies based on language or publication status, or whether data were collected prospectively or retrospectively.

Selection criteria

We included studies that provided the number of true positives, false positives, false negatives, and true negatives for ERCP or IOC. We only accepted studies that confirmed the presence of common bile duct stones by extraction of the stones (irrespective of whether this was done by surgical or endoscopic methods) for a positive test, and absence of common bile duct stones by surgical or endoscopic negative exploration of the common bile duct, or symptom-free follow-up for at least six months for a negative test as the reference standard in people suspected of having common bile duct stones. We included participants with or without prior diagnosis of cholelithiasis; with or without symptoms and complications of common bile duct stones; with or without prior treatment for common bile duct stones; and before or after cholecystectomy. At least two authors screened abstracts and selected studies for inclusion independently.

Data collection and analysis

Two authors independently collected data from each study. We used the bivariate model to summarise the sensitivity and specificity of the tests.

Main results

We identified five studies including 318 participants (180 participants with and 138 participants without common bile duct stones) that reported the diagnostic accuracy of ERCP and five studies including 654 participants (125 participants with and 529 participants without common bile duct stones) that reported the diagnostic accuracy of IOC. Most studies included people with symptoms (participants with jaundice or pancreatitis) suspected of having common bile duct stones based on blood tests, ultrasound, or both, prior to the performance of ERCP or IOC. Most studies included participants who had not previously undergone removal of the gallbladder (cholecystectomy). None of the included studies was of high methodological quality as evaluated by the QUADAS-2 tool (quality assessment tool for diagnostic accuracy studies). The sensitivities of ERCP ranged between 0.67 and 0.94 and the specificities ranged between 0.92 and 1.00. For ERCP, the summary sensitivity was 0.83 (95% confidence interval (CI) 0.72 to 0.90) and specificity was 0.99 (95% CI 0.94 to 1.00). The sensitivities of IOC ranged between 0.75 and 1.00 and the specificities ranged between 0.96 and 1.00. For IOC, the summary sensitivity was 0.99 (95% CI 0.83 to 1.00) and specificity was 0.99 (95% CI 0.95 to 1.00). For ERCP, at the median pre-test probability of common bile duct stones of 0.35 estimated from the included studies (i.e., 35% of people suspected of having common bile duct stones were confirmed to have gallstones by the reference standard), the post-test probabilities associated with positive test results was 0.97 (95% CI 0.88 to 0.99) and negative test results was 0.09 (95% CI 0.05 to 0.14). For IOC, at the median pre-test probability of common bile duct stones of 0.35, the post-test probabilities associated with positive test results was 0.98 (95% CI 0.85 to 1.00) and negative test results was 0.01 (95% CI 0.00 to 0.10). There was weak evidence of a difference in sensitivity (P value = 0.05) with IOC showing higher sensitivity than ERCP. There was no evidence of a difference in specificity (P value = 0.7) with both tests having similar specificity.

Authors' conclusions

Although the sensitivity of IOC appeared to be better than that of ERCP, this finding may be unreliable because none of the studies compared both tests in the same study populations and most of the studies were methodologically flawed. It appears that both tests were fairly accurate in guiding further invasive treatment as most people diagnosed with common bile duct stones by these tests had common bile duct stones. Some people may have common bile duct stones in spite of having a negative ERCP or IOC result. Such people may have to be re-tested if the clinical suspicion of common bile duct stones is very high because of their symptoms or persistently abnormal liver function tests. However, the results should be interpreted with caution given the limited quantity and quality of the evidence.

PLAIN LANGUAGE SUMMARY

Endoscopic retrograde cholangiopancreatography versus intraoperative cholangiography for the diagnosis of common bile duct stones

Background

The liver has various functions. Production of bile is one of these functions. The common bile duct (CBD) is the tube through which bile flows from the gallbladder (where bile is temporarily stored) into the small bowel. Stones in the CBD (CBD stones) can obstruct the flow of bile from the liver into the small bowel. Usually such stones are formed in the gallbladder and migrate into the CBD. Obstruction of the flow of bile can lead to jaundice (yellowish discolouration of skin and white of the eyes, and dark urine), infection of the bile duct (cholangitis), and inflammation of the pancreas (pancreatitis), which can be life threatening. Various diagnostic tests can be performed to diagnose CBD stones. Depending upon the availability of resources, these stones are removed endoscopically (a tube inserted into the stomach and upper part of small bowel through mouth; usually the case), or may be removed as part of the laparoscopic operation (key hole surgery) or open operation performed to remove the gallbladder (cholecystectomy; it is important to remove the gallbladder since the stones continue to form in the gallbladder and can cause recurrent health problems). If the stones are removed endoscopically, presence of stones is confirmed by endoscopic retrograde cholangiopancreatography (ERCP) (injection of dye into the CBD using an endoscope) before endoscopic removal of CBD stones. Alternatively, intraoperative cholangiography (IOC) (injection of dye into the biliary tree during an operation to remove the CBD stones, usually combined with an operation to remove gallstones) can be performed to detect CBD stones prior to operative removal of the stones. We performed a thorough search for studies that reported the accuracy of ERCP or IOC for the diagnosis of CBD stones. The evidence is current to September 2012.

Study characteristics

We identified five studies including 318 participants that reported the diagnostic test accuracy of ERCP and five studies including 654 participants that reported the diagnostic test accuracy of IOC. Most studies included people with symptoms (participants with jaundice or pancreatitis) who were suspected of having CBD stones based on blood tests, ultrasound (use of sound waves higher than audible range to differentiate tissues based on how they reflect the sound waves), or both, prior to the having ERCP or IOC. Most studies included participants who had not previously undergone cholecystectomy.

Key results

Given an average sensitivity of 83% for ERCP, we would expect that on average 83 out of 100 people (this may vary between 72 and 90 out of 100 people) with CBD stones would be detected while the remaining 17 people would be missed and would not receive appropriate treatment. Based on an average specificity of 99% for ERCP, we would expect that on average 99 out of 100 people without CBD stones would be identified as not having CBD stones; 1 out of 100 (this could vary between 0 and 17 out of 100 people) would be false positive and would not receive appropriate treatment. For IOC, an average sensitivity of 99% means that on average 99 out of 100 people (this may vary between 83 and 100 out of 100 people) with CBD stones would be detected while only one person would be missed and would not receive appropriate treatment. In terms of specificity, an average of 99% for IOC means that 99 out of 100 people without CBD stones would be identified as not having CBD stones with only one false positive (this could vary between 0 and 5 out of 100 people) who would not receive appropriate treatment. It appears that both tests are fairly accurate in guiding further invasive treatment as most people diagnosed with CBD stones by these tests have CBD stones. However, some people may have CBD stones in spite of having a negative ERCP or IOC test result. Such people may have to be re-tested if the clinical suspicion of CBD stones is very high because of their symptoms.

Quality of evidence

All the studies were of low methodological quality, which may question the validity of our findings.

Future research

Further studies of high methodological quality are necessary.

BACKGROUND

Biliary stones are conglomerates of precipitated bile salts that form in the gallbladder or common bile duct. The common bile duct carries bile from the liver to the duodenum (first part of the small intestine). The term 'gallstones' generally refers to the stones in the gallbladder, while 'common bile duct stones' refers to stones in the common bile duct. Common bile duct stones may form inside the common bile duct (primary common bile duct stones), or they may form in the gallbladder and migrate to the common bile duct (secondary common bile duct stones) (Williams 2008). A significant proportion of people presenting with common bile duct stones may be asymptomatic (Sarli 2000). In some people, the stones pass silently into the duodenum, and in other people, the stones cause clinical symptoms such as biliary colic, jaundice, cholangitis, or pancreatitis (Caddy 2006). The prevalence of gallstone disease in the general population is about 6% to 15% with a higher prevalence in females (Barbara 1987; Loria 1994). Only 2% to 4% of people with gallstones become symptomatic with biliary colic (pain), acute cholecystitis (inflammation), obstructive jaundice, or gallstone pancreatitis in one year (Attili 1995; Halldestam 2004), and removal of gallbladder is recommended in people with symptomatic gallstones (Gurusamy 2010). Among people who undergo laparoscopic cholecystectomy (removal of gallbladder) for symptomatic gallstones, 3% to 22% also have concomitant common bile duct stones (Arnold 1970; Lill 2010; Yousefpour Azary 2011).

Common bile duct stones present in multiple ways. Central and right-sided upper abdominal pain is a common presentation (Anciaux 1986; Roston 1997). Jaundice, caused by an impacted stone in the common bile duct leading to obstruction of bile passage into the duodenum, is another presentation. It may subsequently resolve if the common bile duct stone passes spontaneously into the duodenum. This happens in 54% to 73% of people with common bile duct stones in whom cholecystectomy is performed for gallstones (Tranter 2003; Lefemine 2011). Another, more dangerous, complication of common bile duct stones is acute

cholangitis. Cholangitis is clinically defined by Charcot's triad, which includes elevated body temperature, pain under the right ribcage, and jaundice (Raraty 1998; Salek 2009). Acute cholangitis is caused by an ascending bacterial infection of the common bile duct and the biliary tree along with biliary obstruction. This complication is present in 2% to 9% of people admitted for gallstone disease (Saik 1975; Tranter 2003), and a mortality of approximately 24% is recorded (Salek 2009). Common bile duct stones may also cause acute pancreatitis, accounting for 33% to 50% of all people with acute pancreatitis (Corfield 1985; Toh 2000). Acute pancreatitis is usually a self limiting disease and is usually sufficiently treated by conservative measures in its mild form (Neoptolemos 1988). However, a more severe pancreatitis may evolve in approximately 27% to 37% of people with common bile duct stone-induced pancreatitis, with mortality around 6% to 9% (Mann 1994; Toh 2000).

Suspicion of common bile duct stones can be confirmed by laboratory liver function tests (Barkun 1994), or diagnostic tests such as abdominal ultrasound (Ripolles 2009). Further testing may include endoscopic ultrasound (EUS) (Aljebreen 2008), magnetic resonance cholangiopancreatography (MRCP) (Stiris 2000), endoscopic retrograde cholangiopancreatography (ERCP) (Geron 1999), and intraoperative cholangiography (IOC) (Fiore 1997).

IOC can only be done during an operation, as this test requires surgical cannulation of the common bile duct during cholecystectomy. EUS, MRCP, and ERCP may be used preoperatively or postoperatively.

Currently, recommended diagnostic tests for diagnosis of common bile duct stones are liver function tests, abdominal ultrasound, MRCP, EUS, ERCP, and IOC. There are other tests such as conventional computed tomogram (CT scan), CT cholangiogram, laparoscopic ultrasound, and ERCP-guided intraductal ultrasound used for diagnosing common bile duct stones but these are of limited use (Maple 2010).

Usually, the first diagnostic tests that most people will undergo are liver function tests and abdominal ultrasound. Invasive diagnostic tests are usually reserved for people with suspected common bile duct stones based on non-invasive diagnostic tests, or when therapeutic measures are necessary (Freitas 2006).

Target condition being diagnosed

Common bile duct stones. We did not differentiate the target condition with respect to common bile duct stone size, degree of common bile duct obstruction, and the presence or absence of symptoms.

Index test(s)

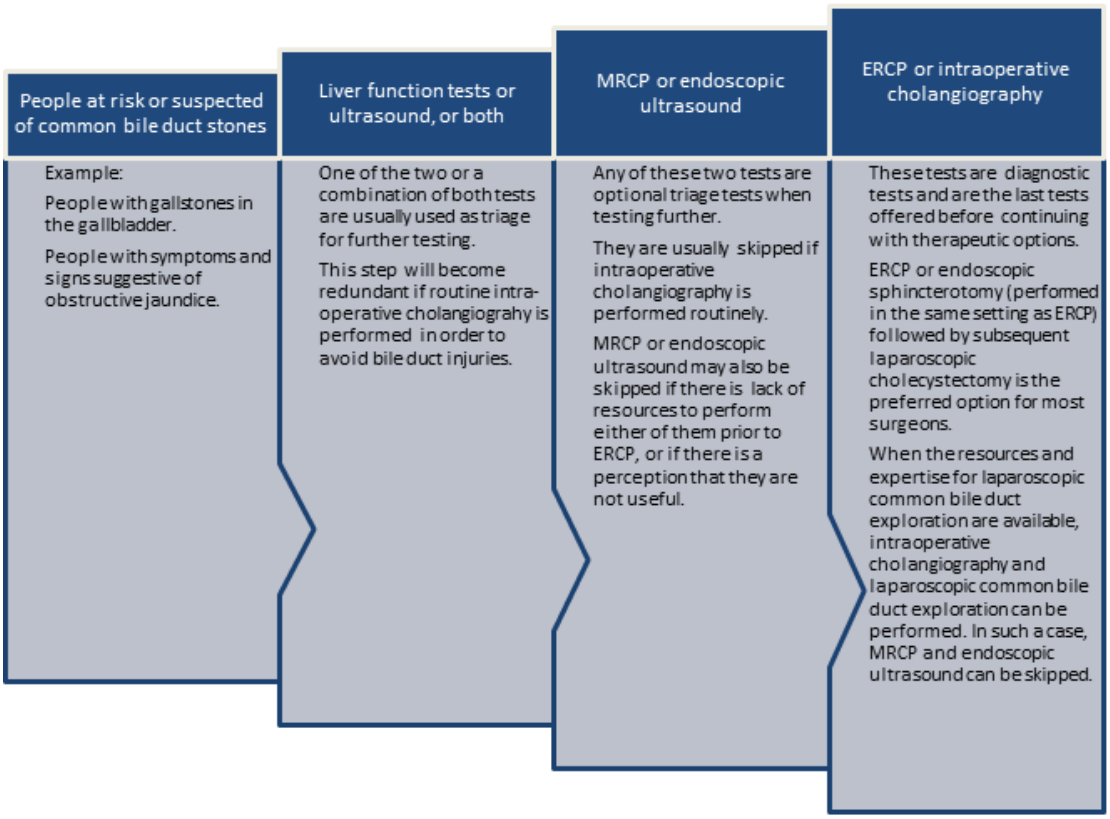
ERCP is a diagnostic test and therapeutic method that uses an endoscope with side-viewing camera for visualisation of the opening of the common bile duct into the duodenum. A series of tubes with electrocautery knives for cutting, injection tubes for contrast material, or guidewire tubes for placing tools such as balloons or baskets can be inserted into the common bile duct (Prat 1996). When diagnosing common bile duct stones, radio-opaque contrast material is injected into the common bile duct and a series of x-rays are taken to visualise filling defects that indicate the presence of common bile duct stones. This method also has therapeutic possibilities because common bile duct stones can be extracted using baskets (such as a Dormia basket that is inserted through the endoscope) or crushed by mechanical lithotripsy and extracted by baskets or balloons (Prat 1996; Maple 2010). It is also combined with sphincterotomy (incision of the opening of the common bile duct into the duodenum) to make both the procedure and passage of possible stones easier. Endoscopic retrograde cholangiography is used predominantly as a therapeutic tool and it is usually preceded by other diagnostic tests such as EUS or MRCP (Maple 2010).
IOC is a diagnostic test used during cholecystectomy. A radio-opaque material is injected into the common bile duct and series of x-rays are taken to visualise possible filling defects in the common bile duct. As it is used intraoperatively; surgical steps to remove the identified stones can then be taken. As with ERCP, a positive test shows as a filling defect within the common bile duct (Amott 2005; Moon 2005).

Clinical pathway

Figure 1 shows a diagnostic pathway. People that are at risk of having common bile duct stones or suspected of having common bile duct stones (such as people with gallbladder stones or people who show symptoms and signs of obstructive jaundice or pancreatitis) undergo liver function tests and abdominal ultrasound as the first step. An abdominal ultrasound is usually available by the time the person is at risk or suspected of having common bile duct stones. Usually both tests is used as triage tests before further testing is done in the second step, but these can be used as the definitive diagnostic test to carry out a therapeutic option directly (e.g., endoscopic or surgical common bile duct exploration) (Williams 2008; ASGE Standards of Practice Committee 2010). MRCP or EUS are tests in the second step of the diagnostic pathway and are used as optional triage tests prior to the tests used in the third step of the diagnostic pathway, but can also be used as definitive diagnostic tests to carry out a therapeutic option directly. MRCP and EUS are usually not combined, since a positive or negative result of one or the other test is usually accepted for making further clinical decisions without taking into consideration the results of liver function tests or transabdominal ultrasound because it is generally believed that MRCP and EUS have better diagnostic accuracy than liver function tests or transabdominal ultrasound. ERCP and IOC are used in the third step of the diagnostic pathway. Both these tests are

done just before the therapeutic intervention. Therapeutic interventions, such as endoscopic or surgical stone extraction, can then be undertaken during the same session. ERCP is done before endoscopic sphincterotomy and removal of common bile duct stones using Dormia basket or balloon during the same endoscopic session (Prat 1996; Maple 2010), while IOC is done before surgical common bile duct exploration and removal of common bile duct stones using surgical instruments during the operation for cholecystectomy (Targarona 2004; Freitas 2006; Chen 2007; Williams 2008; ASGE Standards of Practice Committee 2010; Kelly 2010). Thus, ERCP and IOC can be considered as the final diagnostic tests prior to intervention. The choice of whether the person undergoes ERCP or IOC is very much dependent upon the surgical preference for management of common bile duct stones. There is currently no evidence to suggest that endoscopic management is better than surgical management and vice versa (Dasari 2013). Generally, ERCP followed immediately by endoscopic sphincterotomy performed preoperatively (before the person undergoes laparoscopic cholecystectomy) is the preferred method of management of common bile duct stones in people with an intact gallbladder (Ludwig 2001). IOC followed immediately by surgical exploration of common bile duct during the cholecystectomy operation is the less preferred operation (Ludwig 2001). Thus, ERCP and IOC can be considered as replacement tests for each other. However, it should be pointed out that a small proportion of surgeons also perform endoscopic sphincterotomy after the laparoscopic cholecystectomy (Ludwig 2001). In this small proportion of people who undergo endoscopic sphincterotomy after the laparoscopic cholecystectomy, IOC can be considered as an add-on test similar to MRCP or EUS prior to ERCP in people with positive ultrasound or liver function tests, and the results of IOC is used to determine whether the person undergoes ERCP and endoscopic sphincterotomy irrespective of the results of the liver function tests or transabdominal ultrasound.

Figure 1. The diagnostic pathway for diagnosis of common bile duct stones. Note that ultrasound is generally performed in all people at risk or suspected of common bile duct stones.ERCP: endoscopic retrograde cholangiopancreatography; MRCP: magnetic resonance cholangiopancreatography.



In people with gallstones and common bile duct stones anaesthetically suitable to undergo a major surgical procedure, the choice between ERCP and IOC depends upon surgical preference. However, if such people undergo a roux-en-Y gastric anastomosis, ERCP can be challenging (Lopes 2011), and IOC and surgical exploration may be the preferred option. In people who are not anaesthetically suitable to undergo major surgery, ERCP and endoscopic sphincterotomy is the only option available for the diagnosis and subsequent treatment of common bile duct stones.

Implications of negative tests

In general, people with negative test results in one step do not undergo further testing. For example, a person with no suggestion of common bile duct stones on liver function tests and ultrasound will not undergo further testing for common bile duct stones. Similarly, people with no suggestion of common bile duct stones on MRCP or EUS will not undergo further testing for common bile duct stones and people with no suggestion of common bile duct stones on ERCP or IOC will not undergo common bile duct clearance. People with a false-negative test result can develop complications of common bile duct stones such as cholangitis and pancreatitis but the natural history of such people in terms of the frequency with which these complications develop, is unknown. However, it is generally recommended that common bile duct stones be removed when they are identified because of the serious complications that may develop (Williams 2008). Although this practice is not evidence-based, this shows the perception among hepato-pancreato biliary surgeons and gastroenterologists that it is important not to miss common bile duct stones.

Rationale

There are several other benign and malignant conditions that may cause obstructive jaundice where there are no identifiable common bile duct stones. Benign (non-cancerous) causes of obstructive jaundice include primary sclerosing cholangitis (Penz-Osterreicher 2011), primary biliary cirrhosis (Hirschfield 2011), chronic pancreatitis (Abdallah 2007), autoimmune pancreatitis (Lin 2008), inflammatory strictures of the common bile duct (Krishna 2008), and strictures of the common bile duct caused by prior instrumentation (Lillemoe 2000; Tang 2011). Malignant (cancerous) causes of obstructive jaundice include cholangiocarcinoma (Siddiqui 2011), cancer of the ampulla of Vater as well as other periampullary cancers (Hamade 2005; Choi 2011; Park 2011), and carcinoma of the pancreas (Singh 1990; Kalady 2004). It is important to differentiate between the causes of obstructive jaundice in order to initiate appropriate treatment. The correct diagnosis of common bile duct stones is an essential contribution to this differentiation.

Common bile duct stones are responsible for a range of complications and may lead to pancreatitis in about 33% to 50% of the people who have them (Corfield 1985; Toh 2000), and cause mortality in about 6% to 9% of these people (Mann 1994; Toh 2000). Acute cholangitis appears in 2% to 9% of people admitted for gallstone disease, with mortality around 24% (Salek 2009). Therefore, it is important to diagnose common bile duct stones in order to treat people and prevent such complications.

The preferred option for the treatment of common bile duct stones is currently endoscopic sphincterotomy with balloon trawling followed by laparoscopic cholecystectomy (Ludwig 2001; Spelsberg 2009). Other options include open cholecystectomy with open common bile duct exploration, laparoscopic cholecystectomy with laparoscopic common bile duct exploration, and laparoscopic cholecystectomy with endoscopic sphincterotomy (Hong 2006; Dasari 2013). Approximately half of people with jaundice, abnormal liver function tests, and common bile duct dilation on ultrasound do not actually have common bile duct stones (Hoyuela 1999), and, therefore, these people undergo invasive procedures unnecessarily. Accurate diagnosis of common bile duct stones may avoid unnecessary procedures and complications associated with these procedures. Invasive tests can result in complications, for example, ERCP with endoscopic sphincterotomy can have life-threatening complications such as pancreatitis (Gurusamy 2011). Accurate diagnosis of common bile duct stones using non-invasive tests can avoid these complications.

Currently, there are no Cochrane reviews of studies assessing the accuracy of different tests for diagnosing common bile duct stones. This review is one of three reviews evaluating the diagnostic accuracy of different tests used in the diagnosis of common bile duct stones and will help in the development of an evidence-based algorithm for diagnosis of common bile duct stones.

OBJECTIVES

To determine and compare the accuracy of ERCP and IOC for the diagnosis of common bile duct stones.

Secondary objectives

The secondary objective of this review is to investigate variation in the diagnostic accuracy of ERCP and IOC according to the following potential sources of heterogeneity.

1. Studies at low risk of bias versus studies with unclear or high risk of bias (as assessed by the quality assessment tool for diagnostic accuracy studies (QUADAS-2) tool (Table 1)).
2. Full-text publications versus abstracts (this may indicate publication bias if there is an association between the results of the study and the study reaching full publication) (Eloubeidi 2001).
3. Prospective versus retrospective design.
4. Symptomatic versus asymptomatic common bile duct stones (the presence of symptoms may increase the pre-test probability). People with symptoms were defined as people showing upper right quadrant abdominal pain, jaundice, acute

cholangitis, or acute pancreatitis (Anciaux 1986; Roston 1997; Raraty 1998; Toh 2000; Tranter 2003).

5. Prevalence of common bile duct stones in each included study. The prevalence of common bile duct stones in the population analysed by each included study may vary and cause heterogeneity. Prevalence may also change with people with co-morbidities that would predispose them to common bile duct stones, such as primary sclerosing cholangitis, Caroli's disease, hypercholesterolaemia, sickle cell anaemia, and sphincter of Oddi dysfunction.

6. Proportion of people with previous cholecystectomy. Cholecystectomy may cause dilation of the common bile duct (Benjaminov 2013), and subsequently change the accuracy of the index test particularly imaging modalities.

7. Proportion of people with common bile duct strictures (only for index tests that use contrast material, as strictures may prevent contrast material filling the common bile duct completely and, therefore, change the accuracy of the index test).

8. MRCP or EUS, if performed, prior to the index test.

METHODS

Criteria for considering studies for this review

Types of studies

We included studies providing cross-sectional information comparing one or more of the index tests against a reference standard in the appropriate patient population (see Participants). We included studies irrespective of language or publication status, or whether data were collected prospectively or retrospectively. We included comparative studies in which ERCP and IOC were performed in the same study population either by giving all participants both index tests or by randomly allocating participants to receive ERCP or IOC. We excluded diagnostic case-control studies if there were at least four cross-sectional or comparative studies.

Participants

People at risk of or suspected of having common bile duct stones, with or without prior diagnosis of cholelithiasis; with or without symptoms and complications of common bile duct stones, with or without prior treatment for common bile duct stones; and before or after cholecystectomy.

Index tests

ERCP and IOC.

Target conditions

Common bile duct stones.

Reference standards

We accepted the following reference standard.

1. For test positives, we accepted confirmation of a common bile duct stone by extraction of the stone (irrespective of whether this was done by surgical or endoscopic methods).

2. For test negatives, we acknowledged that there was no way of being sure that there were no common bile duct stones. However, we accepted negative results by surgical or endoscopic negative exploration of the common bile duct, or symptom-free follow-up for at least six months as the reference standard. Surgical or endoscopic exploration s adequate, but it is not commonly used in people with negative index tests because of its invasive nature. Therefore, we accepted follow-up as a less adequate reference test. Negative exploration of common bile duct is likely to be a better reference standard than follow-up for at least six months since most stones already present in the common bile duct are likely to be extracted in this fashion. Six months is an arbitrary choice, but we anticipated most common bile duct stones will become manifest during this period.

Search methods for identification of studies

Electronic searches

We searched MEDLINE via PubMed (January 1946 to September 2012), EMBASE via OvidSP (January 1947 to September 2012), Science Citation Index Expanded via Web of Knowledge (January 1898 to September 2012), BIOSIS via Web of Knowledge (January 1969 to September 2012), and Clinicaltrials.gov (September 2012). Appendix 1 shows the search strategies. We used a common search strategy for the three reviews of which this review is one. The other two reviews assess the diagnostic test accuracy of transabdominal ultrasound, liver function tests, EUS, and MRCP (Giljaca 2015; Gurusamy 2015). We also identified systematic reviews from the Database of Abstracts of Reviews of Effects (DARE), Health Technology Assessment (HTA), Medion, and ARIF (Aggressive Research Intelligence Facility) databases in order to search their reference lists (see Searching other resources).

Searching other resources

We searched the references of included studies and systematic reviews related to the topic to identify further studies. We also searched for additional articles related to included studies by performing the 'related search' function in MEDLINE (PubMed) and EMBASE (OvidSP) and a 'citing reference' search (search the articles that cited the included articles) (Sampson 2008) in Science Citation Index Expanded and EMBASE (OvidSP).

Data collection and analysis

Selection of studies

Two authors (VG and DH or GP) independently searched the references for identification of relevant studies. We obtained full texts for the references that at least one of the authors considered relevant. Two authors (VG and DH or GP) independently assessed the full-text articles. One author (KG) arbitrated any differences in study selection. We selected studies that met the inclusion criteria for data extraction. We included abstracts if sufficient data to create a 2 x 2 table were provided.

Data extraction and management

Two authors (KG and VG) independently extracted the following data from each included study.

1. First author of report.
2. Year of publication of report.
3. Study design (prospective or retrospective; cross-sectional studies or randomised clinical trials).
4. Inclusion and exclusion criteria for individual studies.
5. Total number of participants.
6. Number of males and females.
7. Mean age of the participants.
8. Tests carried out prior to index test.
9. Index test.
10. Reference standard.
11. Number of true positives, false positives, true negatives, and false negatives.

We sought further information on diagnostic test accuracy and assessment of methodological quality (see Assessment of methodological quality) from the authors of the studies, if necessary. We resolved any differences between the review authors by discussion until we reached a consensus. We extracted data excluding the indeterminates but recorded the number of indeterminates and the reference standard results of participants with indeterminate results.

Assessment of methodological quality

We adopted the quality assessment of diagnostic accuracy studies assessment tool (QUADAS-2) for assessment of the methodological quality of included studies as described in Table 1 (Whiting 2006; Whiting 2011). We considered studies classified at low risk of bias and low concern regarding applicability to the review question as studies at low risk of bias. We resolved any differences in the methodological quality assessment by discussion between the review authors until a consensus was reached. We sought further information from study authors in order to assess the methodological quality of included studies accurately.

Statistical analysis and data synthesis

We plotted study estimates of sensitivity and specificity on forest plots and in receiver operating characteristic (ROC) space to explore between-study variation in the performance of each test. Because our focus of inference was summary points, we used the bivariate model to summarise jointly the sensitivity and specificity of each test (Reitsma 2005; Chu 2006). This model accounts for between-study variability in estimates of sensitivity and specificity through the inclusion of random effects for the logit sensitivity and logit specificity parameters of the bivariate model. Where sparse data precluded reliable estimation of the covariance matrix of the random effects, we simplified the model by assuming an exchangeable covariance structure (i.e., common variances for the random effects and a covariance) instead of the more complex unstructured covariance matrix that allows for separate variances for each random effect and a covariance.

We compared the diagnostic accuracy of ERCP and IOC by including covariate terms for test type in the bivariate model to estimate differences in the sensitivity and specificity of the two tests. We allowed the variances of the random effects and their covariance to depend also on test type thus allowing the variances to differ between tests. We assumed an exchangeable covariance structure for the variances of the random effects for each test. We used likelihood ratio tests to compare the fit of different models, and we compared the estimates of sensitivity and specificity between models to check the robustness of our assumptions about the variances of the random effects. If studies that evaluated ERCP and IOC in the same study population were available, we also performed a direct head-to-head comparison by limiting the test comparison to such studies. We performed meta-analyses using the xtmelogit command in Stata version 13 (Stata-Corp, College Station, Texas, USA). Confidence regions on summary ROC plots generated using Review Manager 5 are excessively conservative when there are few studies and they may appear inconsistent with the estimated confidence intervals (CI) (RevMan 2012). While estimation of the CIs relies on the standard errors, the confidence regions rely on the number of studies in addition to the standard errors and the covariance of the estimated mean logit sensitivity and specificity. Therefore, if fewer than 10 studies evaluated a test included in a meta-analysis, we used 10 as the number of studies for generating the regions. This number is arbitrary but seems to provide a better approximation than using a small number of studies.

We created a table of pre-test probabilities (using the observed median and range of prevalence from the included studies) against post-test probabilities. We calculated the post-test probabilities using these pre-test probabilities and the summary positive and negative likelihood ratios. We calculated the summary likelihood ratios and their CIs using the Stata ˙diparm command and functions of the parameter estimates from the bivariate model that we fitted to estimate the summary sensitivities and specificities.

Investigations of heterogeneity

We visually inspected forest plots of sensitivity and specificity, and summary ROC plots to identify heterogeneity. We investigated the sources of heterogeneity stated in the Secondary objectives. Where possible, given the number of included studies, we formally explored heterogeneity by adding each potential source of heterogeneity listed above as a covariate in the bivariate model (meta-regression with one covariate at a time).

Sensitivity analyses

Exclusion of participants with uninterpretable results can result in overestimation of diagnostic test accuracy (Schuetz 2012). In practice, uninterpretable test results would be generally considered as test negatives. Therefore, we performed sensitivity analyses by including uninterpretable test results as test negatives if sufficient data were available.

Assessment of reporting bias

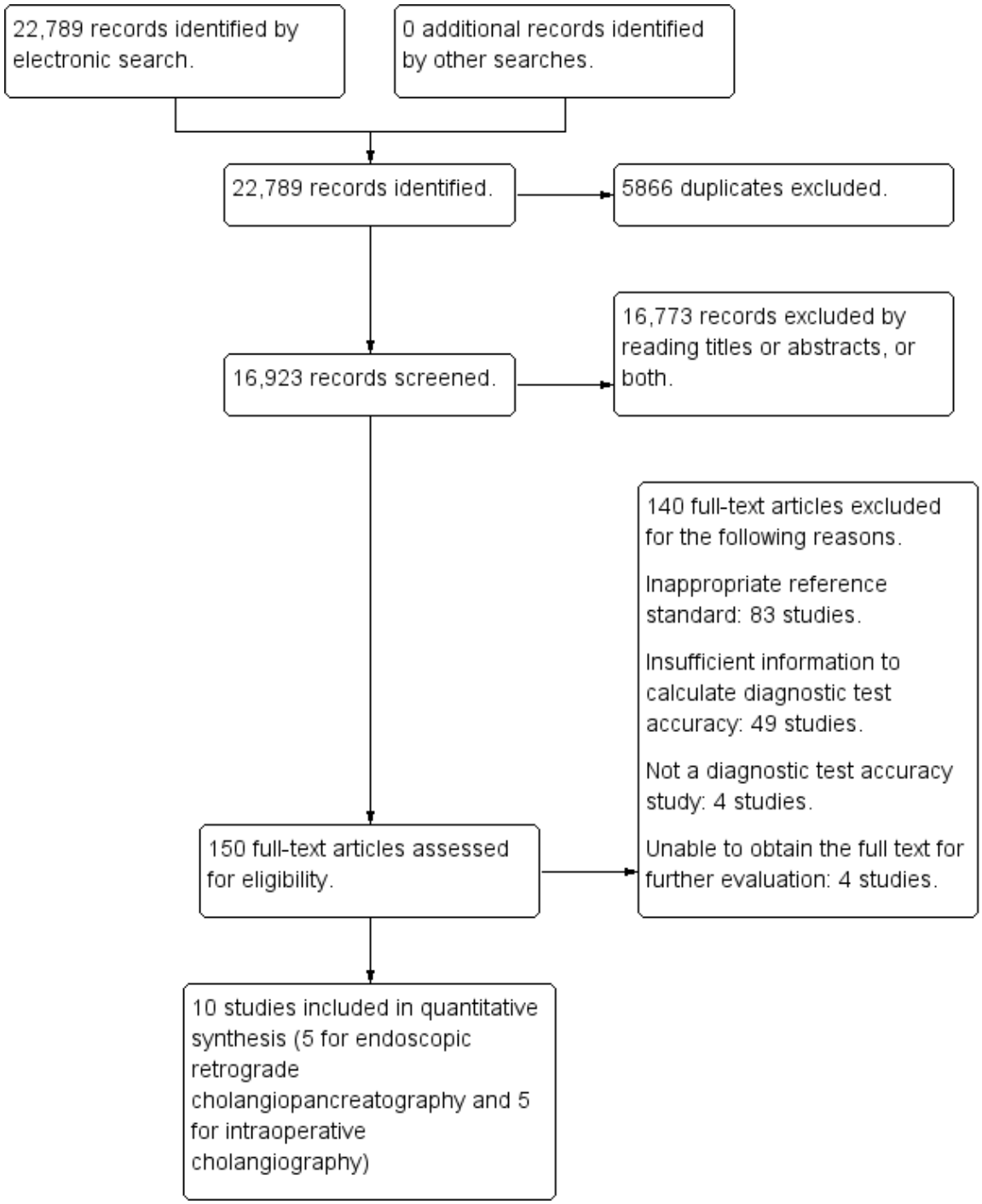
As described in the section on Investigations of heterogeneity, we planned to investigate whether the summary sensitivity and specificity of the tests differed between studies that were published as full texts and those that were available only as abstracts.

RESULTS

Results of the search

We identified 22,789 references through electronic searches of MEDLINE (8292 references), EMBASE (10,029 references), Science Citation Index Expanded and BIOSIS (4276 references), and DARE and HTA in *The Cochrane Library* (192 references). We identified no additional studies by searching the other sources. We excluded 5866 duplicates and 16,773 clearly irrelevant references through reading abstracts. We retrieved 150 references for further assessment. We excluded 140 references for the reasons listed in the Characteristics of excluded studies table. Ten studies fulfilled the inclusion criteria and provided data for the review. We were able to obtain additional information from the authors of two studies (Prat 1996; Montariol 1998). Figure 2 shows the flow of studies through the selection process.

Figure 2. Flow of studies through the screening process.



Characteristics of included studies

We included 10 studies (Characteristics of included studies table). None of the studies compared ERCP and IOC in the same study population. Five studies including 318 participants (180 participants with and 138 participants without common bile duct stones) reported the diagnostic test accuracy of ERCP (Prat 1996; Norton 1997; Fazel 2002; Katz 2004; Ney 2005), and five studies including 654 participants (125 participants with and 529 participants without common bile duct stones) reported the diagnostic test accuracy of IOC (Fenton 1989; Montariol 1998; Silverstein 1998; Wu 2005; Li 2009). None of the 10 studies was diagnostic case-control studies. The median pre-test probability of common bile duct stones in the 10 studies was 0.35 (range 0.12 to 0.68). Except for one study (Fazel 2002), the studies were full-text publications. Five studies were prospective (Prat 1996; Montariol 1998; Silverstein 1998; Katz 2004; Li 2009), one was retrospective (Fenton 1989), and It was not clear whether the remaining studies were prospective or retrospective (Norton 1997; Fazel 2002; Ney 2005; Wu 2005). Based on the inclusion and exclusion criteria stated in nine studies, it appears participants were screened by ultrasound, liver function tests, or both prior to the performance of either ERCP or IOC but this information on prior testing was unclear in one study (Fenton 1989). Seven studies included people with suspicion of common bile duct stones based on the presence of clinical symptoms of obstructive jaundice or pancreatitis, or ultrasound or liver function tests suggestive of common bile duct stones (Prat 1996; Norton 1997; Silverstein 1998; Fazel 2002; Katz 2004; Wu 2005; Li 2009). One study excluded people with obstructive jaundice or pancreatitis with ultrasound or liver function tests suggestive of common bile stones (Montariol 1998). One study excluded people with obstructive jaundice or pancreatitis with unequivocal evidence of common bile duct stones on ultrasound or computed tomography scan or MRCP (Ney 2005). One study did not state whether participants were selected on the basis of symptoms or abnormal transabdominal ultrasound or liver function tests (Fenton 1989). It did not appear that EUS or magnetic resonance pancreatography was used prior to the index tests in any of the studies other than one study where some participants received magnetic resonance cholangiopancreatography (Ney 2005). Eight studies included only participants who had not undergone previous cholecystectomy (Fenton 1989; Norton 1997; Montariol 1998; Silverstein 1998; Katz 2004; Ney 2005; Wu 2005; Li 2009). For the remaining two studies, about 34% of participants had previously undergone cholecystectomy in one study (Prat 1996), and It was not clear whether the participants had undergone cholecystectomy in the other study (Fazel 2002). The proportion of people with common bile duct strictures was not stated in any of the studies.

Methodological quality of included studies

Figure 3 and Figure 4 summarise the methodological quality of the included studies. All the studies were of poor methodological quality.

Figure 3. Risk of bias and applicability concerns graph: review authors' judgements about each domain presented as percentages across included studies. Each bar shows the number of studies in each category. The index test domain was evaluated separately for each test. Of the 10 included studies, 5 studies evaluated endoscopic retrograde cholangio pancreatography (ERCP) and 5 studies evaluated intraoperative cholangiogram (IOC).

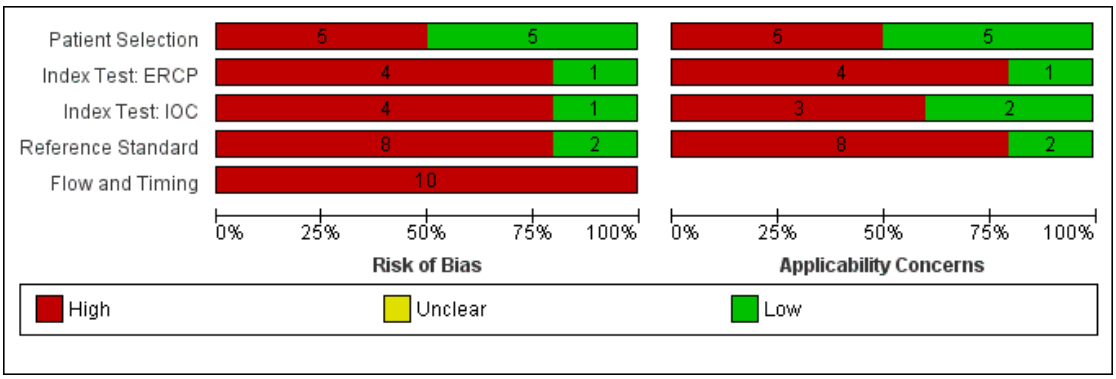
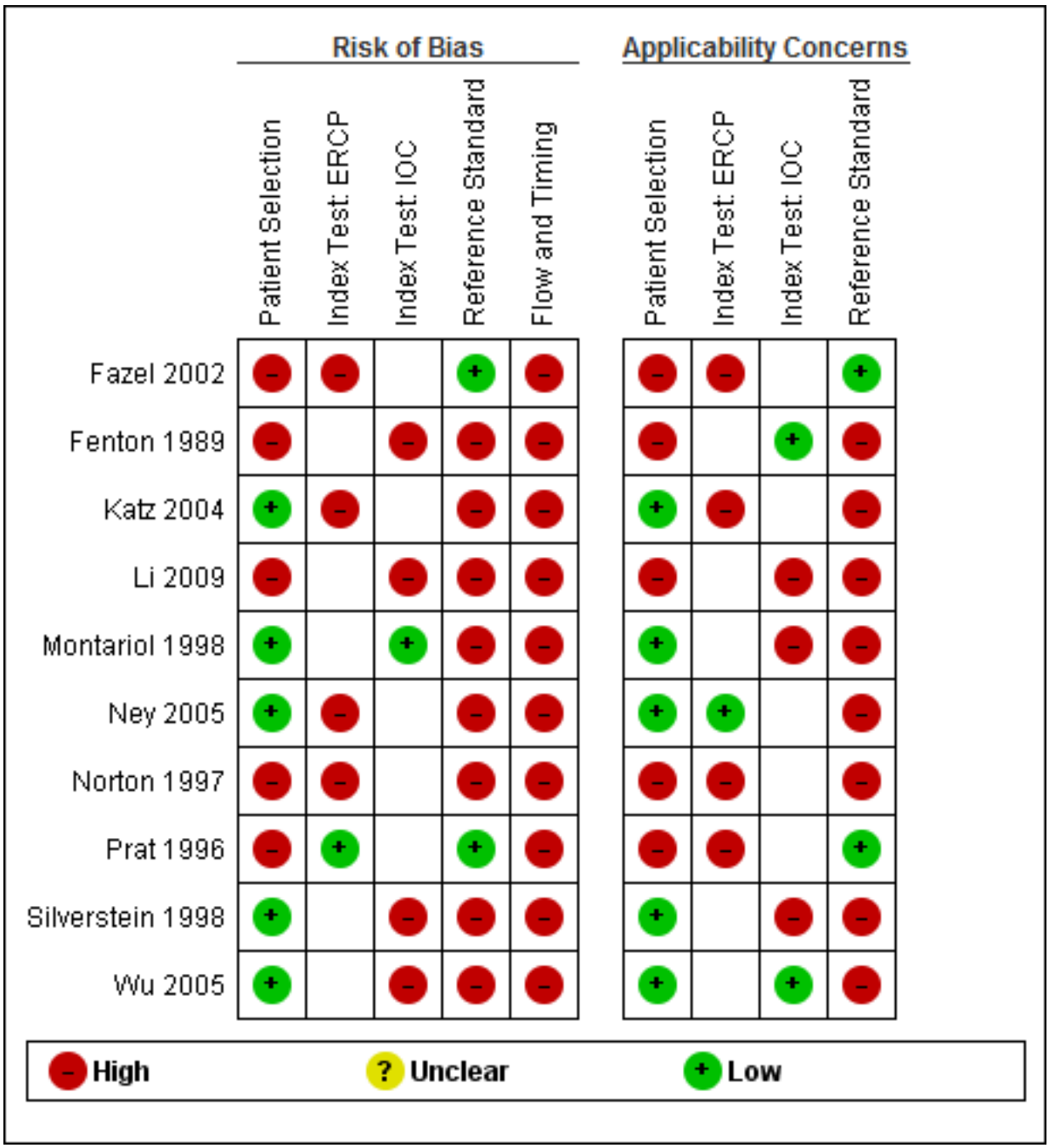


Figure 4. Risk of bias and applicability concerns summary: review authors' judgements about each domain for each included study. In the index test domain, the empty white cell indicates that the study did not evaluate the test.



Patient selection

Five studies were at low risk of bias in the 'patient selection' domain (Montariol 1998; Silverstein 1998; Katz 2004; Ney 2005; Wu 2005). The same five studies were of low concern about applicability in this domain. The remaining five studies were at high risk of bias and with high concern about applicability because they either did not mention whether a consecutive or random sample of participants were included in the study (Fenton 1989; Norton 1997; Fazel 2002), or they excluded participants inappropriately (Prat 1996), or both (Li 2009).

Index test

Only one study of ERCP (Prat 1996) and one study of IOC (Montariol 1998) were at low risk of bias in the 'index study' domain. The remaining studies were at high risk of bias because it was not clear whether the index test results were interpreted without knowledge of the reference standard results. For two studies of IOC (Fenton 1989; Wu 2005) and one study of ERCP (Ney 2005), there was low concern about applicability. The remaining studies were of high concern regarding applicability because the studies did not mention the criteria for a positive test result (Prat 1996; Norton 1997; Montariol 1998; Silverstein 1998; Fazel 2002; Katz 2004; Li 2009).

Reference standard

Only two studies were at low risk of bias in the 'reference standard' domain (Prat 1996; Fazel 2002). The remaining studies were at high risk of bias in the 'reference standard' domain because it was either not clear whether the reference standards were interpreted without knowledge of the index test results (Fenton 1989; Norton 1997; Silverstein 1998; Katz 2004; Ney 2005; Wu 2005; Li 2009), or it was clear that the reference standards were interpreted with the knowledge of the index test results (Montariol 1998). We assess two studies as low concern about applicability (Prat 1996; Fazel 2002), while the remaining studies were of high concern because endoscopic or surgical clearance of common bile duct was achieved in people with a positive test result and clinical follow-up was performed in people with negative test results (Fenton 1989; Norton 1997; Montariol 1998; Silverstein 1998; Katz 2004; Ney 2005; Wu 2005; Li 2009).

Flow and timing

None of the studies was at low risk of bias in the 'flow and timing' domain. Four studies did not report the time interval between the index test and reference standard (Fenton 1989; Fazel 2002; Katz 2004; Li 2009). In eight studies, the same reference standard was not used because endoscopic or surgical clearance of common bile duct was achieved in people with a positive test result and clinical follow-up was performed in people with a negative test result (Fenton 1989; Norton 1997; Montariol 1998; Silverstein 1998; Katz 2004; Ney 2005; Wu 2005; Li 2009). It was not clear whether all the participants were included in the analysis in three studies (Norton 1997; Fazel 2002; Li 2009), while some participants were excluded from the analysis in four studies (Fenton 1989; Prat 1996; Montariol 1998; Wu 2005).

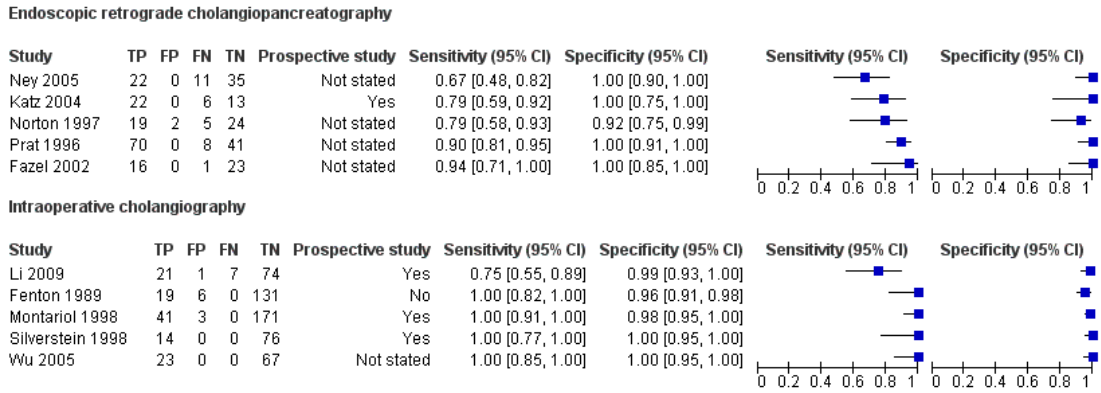
Findings

Summary of findings summarises the results. The pre-test probability (proportion with common bile duct stones out of the total number of participants) was computed for each included study. Based on the 10 studies, the minimum value was 0.12, the lower quartile was 0.19, the median was 0.29, the upper quartile was 0.40, and the maximum was 0.59.

Endoscopic retrograde cholangiopancreatography

Five studies including 318 participants reported the diagnostic accuracy of ERCP (Prat 1996; Norton 1997; Fazel 2002; Katz 2004; Ney 2005). The sensitivities ranged between 0.67 and 0.94, and the specificities ranged between 0.92 and 1.00 (Figure 5). The summary sensitivity was 0.83 (95% CI 0.72 to 0.90) and the summary specificity was 0.99 (95% CI 0.94 to 1.00). The summary positive likelihood ratio was 64 (95% CI 14 to 292) and summary negative ratio was 0.18 (95% CI 0.11 to 0.29). At the median pre-test probability of 0.35, the post-test probability associated with positive test result was 0.97 (95% CI 0.88 to 0.99) and negative test result was 0.09 (95% CI 0.05 to 0.14). At the minimum pre-test probability of 0.12, the post-test probability associated with positive test results was 0.90 (95% CI 0.66 to 0.98) and negative test results was 0.02 (95% CI 0.01 to 0.04). At the maximum pre-test probability of 0.68, the post-test probability associated with positive test results was 0.99 (95% CI 0.97 to 1.00) and negative test results was 0.28 (95% CI 0.18 to 0.39).

Figure 5. Forest plot of endoscopic retrograde cholangiopancreatography (ERCP) and intraoperative cholangiography (IOC) for diagnosis of common bile duct stones. Studies are ordered by sensitivity and study identifier. CI: confidence interval; FP: false positive; FN: false negative; TN: true negative; TP: true positive.



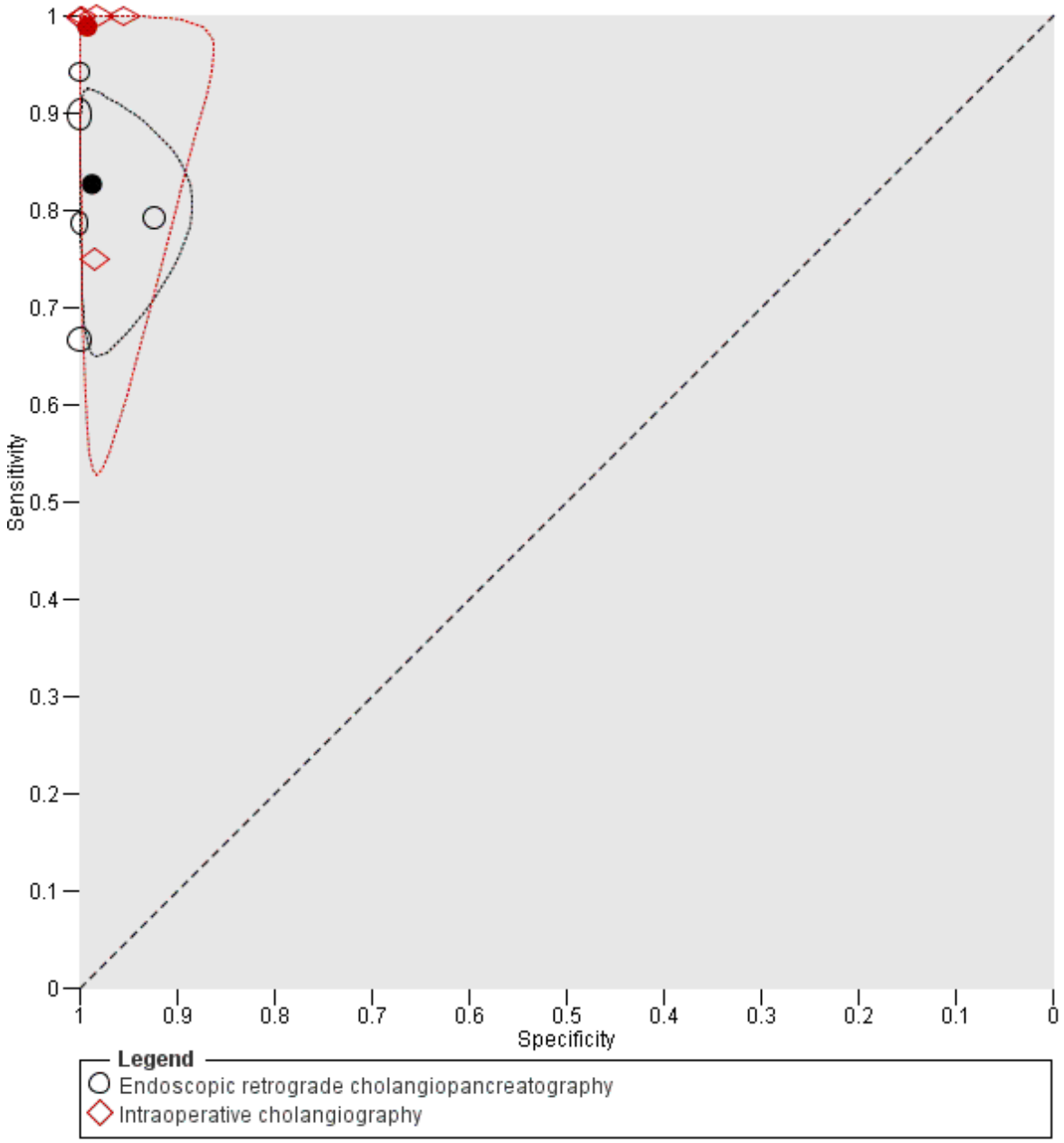
Intraoperative cholangiography

Five studies including 654 participants reported the diagnostic accuracy of IOC (Fenton 1989; Montariol 1998; Silverstein 1998; Wu 2005; Li 2009). The sensitivities ranged between 0.75 and 1.00, and the specificities ranged between 0.96 and 1.00 (Figure 5). The summary sensitivity was 0.99 (95% CI 0.83 to 1.00) and the summary specificity was 0.99 (95% CI 0.95 to 1.00). The summary positive likelihood ratio was 121 (95% CI 11 to 1370) and summary negative ratio was 0.01 (95% CI 0.00 to 0.20). At the median pre-test probability of 0.35, the post-test probability associated with positive test results was 0.98 (95% CI 0.85 to 1.00) and negative test results was 0.01 (95% CI 0.00 to 0.10). At the minimum pre-test probability of 0.12, the post-test probability associated with positive test results was 0.94 (95% CI 0.60 to 0.99) and negative test results was 0.00 (95% CI 0.00 to 0.03). At the maximum pre-test probability of 0.68, the post-test probability associated with positive test results was 1.00 (95% CI 0.96 to 1.00) and negative test results was 0.02 (95% CI 0.00 to 0.30).

Endoscopic retrograde cholangiopancreatography versus intraoperative cholangiography

We performed an indirect test comparison by including all studies in which either ERCP or IOC was performed. We had planned to include the information obtained only from a subgroup of the studies in order to ensure that the participants were similar in the studies included in the indirect comparison. However, all the studies included similar participants (i.e., most studies included participants identified at high risk of common bile duct stones based on the results of transabdominal ultrasound and liver function tests who did not undergo prior testing by MRCP or EUS and not undergone previous cholecystectomy) and so we included all the studies for the indirect comparison. Figure 6 shows the summary ROC plot comparing the accuracy of EUS and IOC. There was a statistically significant difference in sensitivity (P value = 0.05) with IOC showing higher sensitivity (0.99, 95% CI 0.83 to 1.00) compared to ERCP (0.83, 95% CI 0.72 to 0.90). In contrast, there was no evidence of a difference in specificity (P value = 0.7) with IOC having similar specificity (0.99, 95% CI 0.95 to 1.00) to that of ERCP (0.99, 95% CI 0.94 to 1.00).

Figure 6. Summary receiver operating characteristic (ROC) plot comparing endoscopic retrograde cholangiopancreatography (ERCP) and intraoperative cholangiography (IOC) for diagnosis of common bile duct stones. The solid circles represent the summary estimates of sensitivity and specificity for each test, and are shown with 95% confidence regions (dotted lines around each summary point).



Investigations of heterogeneity

We carried out none of the planned investigations of heterogeneity using meta-regression because few studies of each index test were included in the review.

Sensitivity analyses

Because there were only two participants with indeterminate test results in two studies (one participant in Prat 1996 and one participant in Wu 2005) and data were sparse, we did not perform sensitivity analyses.

Summary of findings

Population	People suspected of having common bile duct stones based on symptoms, liver function tests, and ultrasound				
Settings	Secondary and tertiary care setting in Brazil, China, France, the UK, and the USA				
Index tests	ERCP and IOC.				
Reference standard	Endoscopic or surgical extraction of stones in people with a positive index test result or clinical follow-up (minimum 6 months) in people with a negative index test result				
Target condition	Common bile duct stones.				
Number of studies	5 studies (180 cases, 318 participants) of ERCP and 5 studies (125 cases, 654 participants) of IOC. None of the studies evaluated both tests in the same participants				
Methodological quality concerns	All the studies were of poor methodological quality; most studies were at high risk of bias or gave high concern about applicability across all domains of quality assessment, or both				
Pre-test probability[1]	**Test**	**Summary sensitivity (95% CI)**	**Summary specificity (95% CI)**	**Positive post-test probability (95% CI)**[2]	**Negative post-test probability (95% CI)**[3]
0.12	ERCP	0.83 (0.72 to 0.90)	0.99 (0.94 to 1.00)	0.90 (0.66 to 0.98)	0.02 (0.01 to 0.04)
	IOC	0.99 (0.83 to 1.00)	0.99 (0.95 to 1.00)	0.94 (0.60 to 0.99)	0.00 (0.00 to 0.03)
0.21	ERCP	0.83 (0.72 to 0.90)	0.99 (0.94 to 1.00)	0.94 (0.78 to 0.99)	0.04 (0.03 to 0.07)
	IOC	0.99 (0.83 to 1.00)	0.99 (0.95 to 1.00)	0.97 (0.74 to 1.00)	0.00 (0.00 to 0.05)
0.35	ERCP	0.83 (0.72 to 0.90)	0.99 (0.94 to 1.00)	0.97 (0.88 to 0.99)	0.09 (0.05 to 0.14)
	IOC	0.99 (0.83 to 1.00)	0.99 (0.95 to 1.00)	0.98 (0.85 to 1.00)	0.01 (0.00 to 0.10)
0.48	ERCP	0.83 (0.72 to 0.90)	0.99 (0.94 to 1.00)	0.98 (0.93 to 1.00)	0.14 (0.09 to 0.22)
	IOC	0.99 (0.83 to 1.00)	0.99 (0.95 to 1.00)	0.99 (0.91 to 1.00)	0.01 (0.00 to 0.16)

0.68	ERCP	0.83 (0.72 to 0.90)	0.99 (0.94 to 1.00)	0.99 (0.97 to 1.00)	0.28 (0.18 to 0.39)
	IOC	0.99 (0.83 to 1.00)	0.99 (0.95 to 1.00)	1.00 (0.96 to 1.00)	0.02 (0.00 to 0.30)

Comparison of the diagnostic accuracy of ERCP and IOC:
For ERCP: at a pre-test probability of 0.12, out of 100 people with positive ERCP test results, common bile duct stones would be present in 90 people; at a pre-test probability of 0.35, common bile duct stones would be present in 97 people; and at a pre-test probability of 0.68, common bile duct stones would be present in 99 people
For ERCP: at a pre-test probability of 0.12, out of 100 people with negative ERCP test results, common bile duct stones would be present in 2 people; at a pre-test probability of 0.35, common bile duct stones would be present in 9 people; and at a pre-test probability of 0.68, common bile duct stones would be present in 28 people
For IOC: at a pre-test probability of 0.12, out of 100 people with positive IOC test results, common bile duct stones would be present in 94 people; at a pre-test probability of 0.35, common bile duct stones would be present in 98 peoplecommon bile duct stones and at a pre-test probability of 0.68, common bile duct stones would be present in 100 people
For IOC: at a pre-test probability of 0.12, out of 100 people with negative IOC test results, common bile duct stones would be present in 0 people; at a pre-test probability of 0.35, common bile duct stones would be present in 1 person; and at a pre-test probability of 0.68, common bile duct stones would be present in 2 people
CI: confidence interval; **ERCP:** endoscopic retrograde cholangiopancreatography; **IOC:** intraoperative cholangiography.

Conclusions: Although the sensitivity of IOC appeared to be better than that of ERCP, the finding may be unreliable because none of the studies compared both tests in the same study population and most of the studies were methodologically flawed. It appeared that both tests were fairly accurate in guiding further invasive treatment as most people diagnosed with common bile duct stones by these tests have common bile duct stones. However, the results should be interpreted with caution, given the limited quantity and quality of the evidence

[1] We computed the pre-test probability (proportion with common bile duct stones out of the total number of participants) for each included study. These numbers represented the minimum, lower quartile, median, upper quartile, and maximum values from the 10 studies.

[2]Post-test probability of common bile duct stones in people with positive index test results.

[3]Post-test probability of common bile duct stones in people with negative index test results.

DISCUSSION

Summary of main results

Summary of findings summarises the results. There was weak evidence to suggest that IOC had superior sensitivity (0.99, 95% CI 0.83 to 1.00) compared to ERCP (0.83, 95% CI 0.72 to 0.90). The specificities of the two tests were very similar; the specificities of IOC was 0.99 (95% CI 0.95 to 1.00) and of ERCP was 0.99 (95% CI 0.94 to 1.00). At the median pre-test probability of common bile duct stones of 0.35 from the included studies, the post-test probabilities associated with positive test results was 0.97 (95% CI 0.88 to 0.99) and negative test results was 0.09 (95% CI 0.05 to 0.14) for ERCP and positive test results was 0.98 (95% CI 0.85 to 1.00) and negative test results was 0.01 (95% CI 0.00 to 0.10) for IOC. The forest plots showed that specificity was consistent across the studies for both ERCP and IOC. With the exception of Li 2009, all studies of IOC reported 100% sensitivity but there was more variation in sensitivity for studies of ERCP. We were unable to explore heterogeneity because we included few studies evaluating ERCP or IOC in the review.

Strengths and weaknesses of the review

A major strength of this review was that we used recommended methods and searched the literature thoroughly, including full-text publications and abstracts without any language restrictions. The determinants and extent of publication bias and selective reporting are not well known for diagnostic test accuracy studies. Inclusion of abstracts and non-English articles may decrease the impact of publication bias to a certain extent even if publication bias existed in this field. The use of diagnostic test accuracy filters may lead to the elimination of some studies (Doust 2005), and so we did not use any diagnostic test accuracy filters. Two authors independently identified and extracted data from the studies potentially decreasing the errors related to single data extraction (Buscemi 2006).

There were some limitations. First, we were unable to explore heterogeneity formally because few studies were included in the review. We observed heterogeneity mainly in the estimates of the sensitivity of ERCP. Nevertheless, similar participants were included in the studies (i.e., people with abnormal liver function tests, transabdominal ultrasound, or both about to undergo cholecystectomy). The differences in sensitivity may be due to different intrinsic (or implicit) thresholds; however, one would expect a corresponding decrease in specificity in such a situation, which is not the case here. Overall, the heterogeneity in sensitivity remains unexplained.

Second, it was not possible to perform a direct comparison of the tests because none of the studies performed both tests within the same study population. It should be pointed out that indirect comparisons might give different results compared to the more reliable direct comparisons because differences in test accuracy may be confounded by differences in characteristics of the population and study methods (Takwoingi 2013). The preferred option for the treatment of gallbladder stones and common bile duct stones is currently endoscopic sphincterotomy followed by laparoscopic cholecystectomy (Ludwig 2001; Spelsberg 2009), which means that the same person is unlikely to receive both the tests (i.e., people with common bile duct stones on ERCP undergo endoscopic sphincterotomy during the same procedure and have their common bile duct stones removed before surgery). Randomised clinical trials comparing ERCP and IOC are possible but unlikely to be conducted since the choice of the test is usually based on the choice of treatment (i.e., endoscopic sphincterotomy versus operative exploration of the common bile duct). In this current era of laparoscopic surgery, endoscopic sphincterotomy and laparoscopic common bile duct exploration have similar results (Dasari 2013). The surgeon's preference determines the choice of the procedure and hence the test used prior to the procedure. Without evidence to support a significant difference in diagnostic test accuracy, the choice of treatment is likely to be based on surgeon's preference unless a value of information analysis can show that there is significant value in the question of which test to use for the diagnosis of common bile duct stones (Claxton 2006). Until then, the diagnostic accuracy of ERCP and IOC is likely to be compared indirectly despite the limitations of using this approach.

Third, none of the studies was of good methodological quality. The proportion of studies at high risk of bias and high concern regarding applicability was high in all the four domains. This makes the results unreliable. We considered endoscopic or surgical extraction of common bile duct stones in all participants as a better reference standard rather than a combination of extraction of common bile duct stones in participants with positive index test results and clinical follow-up in those with negative index test. Endoscopic or surgical extraction was used in all participants in only two studies (Prat 1996; Fazel 2002). In the remaining eight studies, endoscopic or surgical clearance of common bile duct was achieved in people with a positive index test and clinical follow-up was performed in people with a negative index test result (Fenton 1989; Norton 1997; Montariol 1998; Silverstein 1998; Katz 2004; Ney 2005; Wu 2005; Li 2009). This might result in overestimation of the diagnostic test accuracy although there is no evidence that this is the case. However, we acknowledge that even the best reference standard of endoscopic or surgical extraction of common bile duct stones can result in misclassification and hence alteration in diagnostic test accuracy if one or more stones reach the small bowel without the knowledge of the person who performed the common bile duct stone extraction. The use of different reference standards may also reflect the belief of the study authors about the probability of participants harbouring common bile duct stones. It is quite possible that in studies in which surgical or endoscopic clear-

ance was performed in all participants (Prat 1996; Fazel 2002), included participants were at greater risk of having common bile duct stones because of their symptoms (i.e., they were more symptomatic) compared to the study in which participants with positive index test results underwent surgical or endoscopic extraction of stones and participants with negative index test results were followed clinically (Fenton 1989; Norton 1997; Montariol 1998; Silverstein 1998; Katz 2004; Ney 2005; Wu 2005; Li 2009). This was not evident from pre-test probabilities of common bile duct stones in studies in which all participants underwent endoscopic or surgical extraction compared to those in which participants received different reference standards.

Another issue is that it is likely for the same person to perform the index test and the reference standard as part of the same clinical procedure since this is the usual clinical practice. This makes interpretation of index test blinded to the results of reference standard difficult and can result in overestimation of diagnostic test accuracy. This can be avoided if the index test results are documented prior to the performance of the reference standard and by documenting all subsequent alterations to the interpretation of the index test.

It has to be noted that most of the participants included in this study had not undergone EUS or MRCP. Using these tests prior to ERCP or IOC may improve the diagnostic test accuracy of ERCP and IOC.

Despite all these shortcomings, it should be pointed out that these studies provide the best available evidence on this topic.

Applicability of findings to the review question

Most of the participants included in this review were people who had not undergone previous cholecystectomy and were fit to undergo cholecystectomy with IOC or ERCP. Therefore, the findings of this review are applicable only to people suspected of common bile duct stones before they undergo cholecystectomy and are fit to undergo cholecystectomy with IOC or ERCP. Most participants either had symptoms of common bile duct obstruction (such as jaundice or pancreatitis) or features suggestive of common bile duct obstruction based on liver function tests and ultrasound. The findings of this review are applicable to only such people.

Previous research

This is the first systematic review on this topic.

AUTHORS' CONCLUSIONS

Implications for practice

Some people may have common bile duct stones in spite of having a negative ERCP or IOC result. Such people may have to be retested if the clinical suspicion of common bile duct stones is very high because of their symptoms or persistently abnormal liver function tests. However, it should be noted that the results of this review are based on few studies of poor methodological quality and so the results should be interpreted with caution.

Implications for research

Studies of high methodological quality are necessary to assess the diagnostic accuracy of ERCP and IOC in the diagnosis of common bile duct stones. Considering that most people undergo triage tests such as ultrasound, liver function tests, and MRCP or EUS prior to ERCP or IOC, it is recommended that future studies either focus on such people or present the results separately for people with positive and negative triage test results so that it is possible to calculate the diagnostic test accuracy of ERCP and IOC separately for people with positive and negative triage test results. We acknowledge that differential verification cannot always be avoided if endoscopic sphincterotomy and extraction of stones is used as the reference standard because of the complications associated with this procedure (Gurusamy 2011). Surgical exploration of the common bile duct is a major surgical procedure and cannot be taken lightly. Based on these, people with positive test results are likely to undergo endoscopic sphincterotomy and extraction of stones or surgical exploration of the common bile duct while people with negative test results are likely to be followed up. Such people would benefit from being followed up for at least six months to ensure that they do not develop the symptoms of common bile duct stones. Future studies that avoid inappropriate exclusions would be useful to ensure that the true diagnostic accuracy of the tests for a given clinical context can be calculated. Long-term follow-up of people with negative tests will help in understanding the implications of false-negative results and aid clinical decision making.

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Disclaimer of the Department of Health: "The views and opinions expressed in the review are those of the authors and do not necessarily reflect those of the National Institute for Health Research (NIHR), National Health Services (NHS), or the Department of Health".

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* *Indicates the major publication for the study*

CHARACTERISTICS OF STUDIES

Characteristics of included studies *[ordered by study ID]*

Fazel 2002

Study characteristics			
Patient sampling	Type of study: unclear whether prospective or retrospective study. Consecutive or random sample: unclear.		
Patient characteristics and setting	Sample size: 40. Females: not stated. Age: not stated. Presentation: Inclusion criteria: 1. People with suspicion of biliary stone disease on the basis of symptoms and signs suggestive of choledocholithiasis (biliary colic, abnormal liver function tests, abnormal transabdominal ultrasound, or a combination). Setting: care setting: not stated, USA.		
Index tests	Index test: endoscopic retrograde cholangiography. Further details: Technical specifications: not stated. Performed by: not stated. Criteria for positive diagnosis: not stated.		
Target condition and reference standard(s)	Target condition: common bile duct stones. Reference standard: attempted endoscopic extraction of stones in all participants. Further details: Technical specifications: not applicable. Performed by: endoscopists and surgeons. Criteria for positive diagnosis: presence or absence of stones during endoscopic clearance		
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated. Number of participants who were excluded from the analysis: not stated		
Comparative			
Notes	Attempted to contact the authors in June 2013. Received no replies		
Methodological quality			
Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		

Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Yes		
			High
DOMAIN 2: Index Test ERCP			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
			High
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Yes		
			Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	Unclear		

Fenton 1989

Study characteristics	
Patient sampling	Type of study: retrospective study. Consecutive or random sample: unclear.
Patient characteristics and setting	Sample size: 156. Females: not stated. Age: not stated. Presentation: Inclusion criteria: 1. People with histological confirmation of acute cholecystitis. Setting: Department of Surgery, USA.
Index tests	Index test: intraoperative cholangiography. Further details: Technical specifications: not applicable. Performed by: surgeon. Criteria for positive diagnosis: filling defect.
Target condition and reference standard(s)	Target condition: common bile duct stones. Reference standard: extraction of stones in people with positive intraoperative cholangiography and clinical follow-up of minimum 12 months in people with negative intraoperative cholangiography. Further details: Technical specifications: not applicable. Performed by: surgeons and clinicians. Criteria for positive diagnosis: extraction of stones in people with positive intraoperative cholangiography and clinical follow-up of minimum 12 months in people with negative intraoperative cholangiography
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated. Number of participants who were excluded from the analysis: 15 (8.8%)
Comparative	
Notes	Attempted to contact the authors in June 2013. Received no replies

Methodological quality

Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		

Fenton 1989 (*Continued*)

Did the study avoid inappropriate exclusions?	Yes		
			High
DOMAIN 2: Index Test IOC			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
			Low
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
			High
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	No		
Were all patients included in the analysis?	No		

Katz 2004

Study characteristics	
Patient sampling	Type of study: prospective study. Consecutive or random sample: consecutive participants.

Patient characteristics and setting	Sample size: 41. Females: not stated. Age: not stated. Presentation: Inclusion criteria: 1. People with suspicion of biliary stone disease on the basis of dilated common bile duct > 10 mm, abnormal liver function tests, or pancreatitis. Setting: Department of Surgery, USA.
Index tests	Index test: endoscopic retrograde cholangiography. Further details: Technical specifications: not stated. Performed by: endoscopist. Criteria for positive diagnosis: not stated.
Target condition and reference standard(s)	Target condition: common bile duct stones. Reference standard: endoscopic extraction of bile duct stones in people with positive endoscopic retrograde cholangiography and follow-up for at least 1 year for people with negative endoscopic retrograde cholangiography. Further details: Technical specifications: not applicable. Performed by: endoscopists and surgeons. Criteria for positive diagnosis: presence of stones during endoscopic clearance and clinical follow-up with negative endoscopic retrograde cholangiography
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated. Number of participants who were excluded from the analysis: not stated
Comparative	
Notes	Attempted to contact the authors in June 2013. Received no replies

Methodological quality

Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Yes		
			Low

Katz 2004 (*Continued*)

DOMAIN 2: Index Test ERCP			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
			High
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
			High
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	No		
Were all patients included in the analysis?	Yes		

Li 2009

Study characteristics	
Patient sampling	Type of study: prospective study. Consecutive or random sample: unclear.
Patient characteristics and setting	Sample size: 103. Females: 65 (63.1%). Age: 49 years. Presentation: Inclusion criteria:

	People undergoing cholecystectomy with ≥ 1 of the following features 1. History of obstructive jaundice. 2. History of biliary pancreatitis. 3. Common bile duct diameter > 10 mm in calibre. 4. Elevated liver function tests. Setting: Department of Surgery, China.
Index tests	Index test: intraoperative cholangiography. Further details: Technical specifications: not applicable. Performed by: surgeon. Criteria for positive diagnosis: not stated.
Target condition and reference standard(s)	Target condition: common bile duct stones. Reference standard: extraction of stones in people with positive intraoperative cholangiography (surgical or endoscopic) and clinical follow-up of minimum 12 months in people with negative intraoperative cholangiography. Further details: Technical specifications: not applicable. Performed by: surgeons and clinicians. Criteria for positive diagnosis: extraction of stones in people with positive intraoperative cholangiography (surgical or endoscopic) and clinical follow-up of minimum 12 months in people with negative intraoperative cholangiography
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated. Number of participants who were excluded from the analysis: not stated
Comparative	
Notes	Attempted to contact the authors in June 2013. Received no replies

Methodological quality

Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	No		
			High
DOMAIN 2: Index Test IOC			

Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
			High
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
			High
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Unclear		
Did all patients receive the same reference standard?	No		
Were all patients included in the analysis?	Unclear		

Montariol 1998

Study characteristics	
Patient sampling	Type of study: prospective study. Consecutive or random sample: consecutive participants.
Patient characteristics and setting	Sample size: 240. Females: 171 (71.3%). Age: 57 years. Presentation: Inclusion criteria: 1. People with symptomatic cholelithiasis, scheduled for elective cholecystectomy or emergency operations within 48 hours for acute cholecystitis.

	Exclusion criteria: 1. Cholelithiasis was asymptomatic. 2. Preoperative risk of common bile duct stones < 5% 3. People had symptomatic choledocholithiasis defined as combination of clinical symptoms (pancreatic pain and jaundice), biochemical abnormalities (serum aminotransferase, alkaline phosphatase or γ-glutamyl transpeptidase levels more than twice normal values, serum bilirubin levels > 50 µmol/L, serum amylase level > 4-fold, and serum lipase levels > 3-fold), and morphological features (presence of hyperechoic image in the common bile duct on ultrasonography. Setting: Surgery Departments, France.
Index tests	Index test: intraoperative cholangiography. Further details: Technical specifications: not applicable. Performed by: surgeon. Criteria for positive diagnosis: not stated.
Target condition and reference standard(s)	Target condition: common bile duct stones. Reference standard: surgical extraction of stones in people with positive intraoperative cholangiography and clinical follow-up of minimum 12 months in people with negative intraoperative cholangiography. Further details: Technical specifications: not applicable. Performed by: surgeons and clinicians. Criteria for positive diagnosis: surgical extraction of stones in people with positive intraoperative cholangiography and clinical follow-up of minimum 12 months in people with negative intraoperative cholangiography
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated. Number of participants who were excluded from the analysis: 25 (10.4%)
Comparative	
Notes	Attempted to contact the authors in June 2013. Received replies in July 2013

Methodological quality

Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		
Did the study avoid inappropriate exclusions?	Yes		

Montariol 1998 (*Continued*)

			Low
DOMAIN 2: Index Test IOC			
Were the index test results interpreted without knowledge of the results of the reference standard?	Yes		
			High
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Were the reference standard results interpreted without knowledge of the results of the index tests?	No		
			High
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Yes		
Did all patients receive the same reference standard?	No		
Were all patients included in the analysis?	No		

Ney 2005

Study characteristics	
Patient sampling	Type of study: prospective study. Consecutive or random sample: consecutive participants.
Patient characteristics and setting	Sample size: 68. Females: 49 (72.1%). Age: 57 years.

Ney 2005 (*Continued*)

	Presentation: Inclusion criteria: 1. Dilated common bile duct (> 7 mm on conventional ultrasound) or hepatic biochemical parameter abnormalities (aspartate transaminase > 2 times normal; elevated alkaline phosphatase), or both. Exclusion criteria: 1. Jaundiced or had clinical signs of cholangitis. 2. Acute pancreatitis. 3. Unequivocal evidence of common bile duct stones on ultrasound or computed tomography scans or magnetic resonance cholangiopancreatography. Setting: Department of Surgery, Brazil.
Index tests	Index test: endoscopic retrograde cholangiography. Further details: Technical specifications: standard videoduodenoscope. Performed by: experienced endoscopist. Criteria for positive diagnosis: filling defects in cholangiography
Target condition and reference standard(s)	Target condition: common bile duct stones. Reference standard: endoscopic or surgical extraction of stones in people with positive endoscopic retrograde cholangiography and clinical follow-up minimum 11 months in people with negative endoscopic retrograde cholangiography. Further details: Technical specifications: not applicable. Performed by: endoscopists, surgeons, and clinicians. Criteria for positive diagnosis: endoscopic or surgical extraction of stones in people with positive endoscopic retrograde cholangiography and clinical follow-up minimum 11 months in people with negative endoscopic retrograde cholangiography
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated. Number of participants who were excluded from the analysis: not stated
Comparative	
Notes	Attempted to contact the authors in June 2013. Received no replies

Methodological quality

Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		

Ney 2005 (*Continued*)

Did the study avoid inappropriate exclusions?	Yes		
			Low
DOMAIN 2: Index Test ERCP			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
			Low
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
			High
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Yes		
Did all patients receive the same reference standard?	No		
Were all patients included in the analysis?	Yes		

Norton 1997

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study. Consecutive or random sample: unclear.

Patient characteristics and setting	Sample size: 50. Females: 34 (68.0%). Age: 63 years. Presentation: Inclusion criteria: 1. People with confirmed symptomatic gallstone disease and suspected bile duct stones because of the presence of ≥ 1 of the following features. i) Dilated (> 7 mm) bile duct on abdominal ultrasonography. ii) Clinical jaundice. iii) Gallstone pancreatitis. iv) Deranged liver function. Setting: Surgery Department, UK.
Index tests	Index test: endoscopic retrograde cholangiography. Further details: Technical specifications: not stated. Performed by: not stated. Criteria for positive diagnosis: not stated.
Target condition and reference standard(s)	Target condition: common bile duct stones. Reference standard: endoscopic or surgical extraction of stones in people with positive endoscopic retrograde cholangiography and clinical follow-up minimum 6 months in people with negative endoscopic retrograde cholangiography. Further details: Technical specifications: not applicable. Performed by: endoscopists, surgeons, and clinicians. Criteria for positive diagnosis: endoscopic or surgical extraction of stones in people with positive endoscopic retrograde cholangiography and clinical follow-up minimum 6 months in people with negative endoscopic retrograde cholangiography
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated. Number of participants who were excluded from the analysis: not stated
Comparative	
Notes	Attempted to contact the authors in June 2013. Received no replies

Methodological quality

Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Unclear		
Was a case-control design avoided?	Yes		

Did the study avoid inappropriate exclusions?	Yes		
			High
DOMAIN 2: Index Test ERCP			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
			High
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
			High
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Yes		
Did all patients receive the same reference standard?	No		
Were all patients included in the analysis?	Unclear		

Prat 1996

Study characteristics	
Patient sampling	Type of study: prospective study. Consecutive or random sample: consecutive participants.

Prat 1996 (*Continued*)

Patient characteristics and setting	Sample size: 121. Females: 69 (57.0%). Age: 70 years. Presentation: Inclusion criteria: 1. Strong suspicion of choledocholithiasis as determined by a combination of clinical symptoms (history of biliary colic, pancreatic pain, fever, jaundice), biochemical abnormalities (raised serum aminotransferases, alkaline phosphatase, or gamma glutamyl transpeptidase more than twice the normal value, serum bilirubin > 50 μmol/L), and morphological features (common bile duct dilated to > 8 mm in people with the gallbladder in situ and 10 mm in people with previous cholecystectomy, or the presence of a hyperechoic image in the common bile duct). 2. Endoscopic treatment would be chosen for the treatment of the stones. Exclusion criteria: 1. People aged < 50 years who had not had cholecystectomy. 2. People who declined to take part. Setting: Gastroenterology Department, France.
Index tests	Index test: endoscopic retrograde cholangiography. Further details: Technical specifications: TJF 100 videoduodenoscope (Olympus). Performed by: expert endoscopist. Criteria for positive diagnosis: not stated.
Target condition and reference standard(s)	Target condition: common bile duct stones. Reference standard: attempted endoscopic extraction of stones in all participants. Further details: Technical specifications: not applicable. Performed by: endoscopists and surgeons. Criteria for positive diagnosis: presence or absence of stones during endoscopic clearance
Flow and timing	Number of indeterminates for whom the results of reference standard was available: 1 (0.8%) Number of participants who were excluded from the analysis: 1 (0.8%)
Comparative	
Notes	Attempted to contact the authors in June 2013. Received replies

Methodological quality

Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		

Prat 1996 (*Continued*)

Did the study avoid inappropriate exclusions?	No		
			High
DOMAIN 2: Index Test ERCP			
Were the index test results interpreted without knowledge of the results of the reference standard?	Yes		
			High
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Yes		
			Low
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Yes		
Did all patients receive the same reference standard?	Yes		
Were all patients included in the analysis?	No		

Silverstein 1998

Study characteristics	
Patient sampling	Type of study: prospective study. Consecutive or random sample: consecutive participants.

Patient characteristics and setting	Sample size: 90. Females: not stated. Age: not stated. Presentation: Inclusion criteria: 1. People undergoing cholecystectomy with ≥ 1 of the following features. i) Abnormal liver function tests. ii) History of obstructive jaundice or pancreatitis. iii) Common bile duct diameter > 6 mm in calibre on ultrasound. Setting: Department of Surgery, USA.
Index tests	Index test: intraoperative cholangiography. Further details: Technical specifications: not applicable. Performed by: surgeon. Criteria for positive diagnosis: not stated.
Target condition and reference standard(s)	Target condition: common bile duct stones. Reference standard: surgical extraction of stones in people with positive intraoperative cholangiography and clinical follow-up of minimum 2 years in people with negative intraoperative cholangiography. Further details: Technical specifications: not applicable. Performed by: surgeons and clinicians. Criteria for positive diagnosis: surgical extraction of stones in people with positive intraoperative cholangiography and clinical follow-up of minimum 2 years in people with negative intraoperative cholangiography
Flow and timing	Number of indeterminates for whom the results of reference standard was available: not stated. Number of participants who were excluded from the analysis: not stated
Comparative	
Notes	Attempted to contact the authors in June 2013. Received no replies

Methodological quality

Item	**Authors' judgement**	**Risk of bias**	**Applicability concerns**
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		

Did the study avoid inappropriate exclusions?	Yes		
			Low
DOMAIN 2: Index Test IOC			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
			High
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
			High
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Yes		
Did all patients receive the same reference standard?	No		
Were all patients included in the analysis?	Yes		

Wu 2005

Study characteristics	
Patient sampling	Type of study: unclear whether prospective or retrospective study. Consecutive or random sample: consecutive participants.

Wu 2005 (*Continued*)

Patient characteristics and setting	Sample size: 91. Females: not stated. Age: not stated. Presentation: Inclusion criteria: 1. People undergoing laparoscopic cholecystectomy with ≥ 1 of the following features. i) Abnormal liver function tests. ii) History of obstructive jaundice or pancreatitis. iii) Common bile duct diameter > 9 mm. Setting: Department of Surgery, Taiwan.
Index tests	Index test: intraoperative cholangiography. Further details: Technical specifications: not applicable. Performed by: surgeon. Criteria for positive diagnosis: filling defect.
Target condition and reference standard(s)	Target condition: common bile duct stones. Reference standard: surgical extraction of stones in people with positive intraoperative cholangiography and clinical follow-up of minimum 2 years in people with negative intraoperative cholangiography. Further details: Technical specifications: not applicable. Performed by: surgeons and clinicians. Criteria for positive diagnosis: surgical extraction of stones in people with positive intraoperative cholangiography and clinical follow-up of minimum 2 years in people with negative intraoperative cholangiography
Flow and timing	Number of indeterminates for whom the results of reference standard was available: 1 (1.1%) Number of participants who were excluded from the analysis: not stated
Comparative	
Notes	Attempted to contact the authors in June 2013. Received no replies

Methodological quality

Item	Authors' judgement	Risk of bias	Applicability concerns
DOMAIN 1: Patient Selection			
Was a consecutive or random sample of patients enrolled?	Yes		
Was a case-control design avoided?	Yes		

Did the study avoid inappropriate exclusions?	Yes		
			Low
DOMAIN 2: Index Test IOC			
Were the index test results interpreted without knowledge of the results of the reference standard?	Unclear		
			Low
DOMAIN 3: Reference Standard			
Is the reference standards likely to correctly classify the target condition?	Yes		
Were the reference standard results interpreted without knowledge of the results of the index tests?	Unclear		
			High
DOMAIN 4: Flow and Timing			
Was there an appropriate interval between index test and reference standard?	Yes		
Did all patients receive the same reference standard?	No		
Were all patients included in the analysis?	No		

Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
Abdul Ghani 1989	Insufficient information to calculate diagnostic test accuracy
Al Quorain 1996	Inappropriate reference standard.
Alhayaf 2008	Insufficient information to calculate diagnostic test accuracy
Almersjo 1966	Inappropriate reference standard.
Ang 2007	Inappropriate reference standard.
Ashton 1998	Inappropriate reference standard.
Askew 1992	Inappropriate reference standard.
Aubertin 1995	Insufficient information to calculate diagnostic test accuracy
Aubertin 1996	Inappropriate reference standard.
Azary 2011	Inappropriate reference standard.
Barkun 1993	Inappropriate reference standard.
Barr 1999	Inappropriate reference standard.
Barteau 1995	Inappropriate reference standard.
Beliveau 1964	Inappropriate reference standard.
Bennion 2002	Inappropriate reference standard.
Berci 1994	Insufficient information to calculate diagnostic test accuracy
Berdah 2001	Inappropriate reference standard.
Bergamaschi 1999	Inappropriate reference standard.
Bodula 2011	Inappropriate reference standard.
Bokobza 1988	Not a diagnostic test accuracy study.
Bornman 1981	Inappropriate reference standard.
Bostanci 2003	Unable to obtain this article.

(*Continued*)

Buckley 1987	Inappropriate reference standard.
Calero Ayala 1983	Insufficient information to calculate diagnostic test accuracy
Canto 1995	Insufficient information to calculate diagnostic test accuracy
Cariani 2006	Inappropriate reference standard.
Carroll 1996	Inappropriate reference standard.
Catheline 1997	Inappropriate reference standard.
Catheline 2000	Inappropriate reference standard.
Catheline 2002	Inappropriate reference standard.
Chaib 1990	Inappropriate reference standard.
Chattopadhyay 1992	Insufficient information to calculate diagnostic test accuracy
Chen 1993	Inappropriate reference standard.
Chen 2012	Not a diagnostic test accuracy study.
Chernev 2001	Inappropriate reference standard.
Chodoff 1960	Insufficient information to calculate diagnostic test accuracy
Chowdhury 1999	Insufficient information to calculate diagnostic test accuracy
Coppola 2001	Inappropriate reference standard.
Corff 1957	Inappropriate reference standard.
Csendes 1998	Inappropriate reference standard.
Cwik 2003	Unable to obtain this article.
Dalton 2005	Inappropriate reference standard.
de Dios Vega 1982	Insufficient information to calculate diagnostic test accuracy
Derodra 1986	Not a diagnostic test accuracy study.
di Angelo 2010	Insufficient information to calculate diagnostic test accuracy

(*Continued*)

di Angelo 2011	Insufficient information to calculate diagnostic test accuracy
Diez 2000	Inappropriate reference standard.
Duchmann 1999	Insufficient information to calculate diagnostic test accuracy
Elizondo 1989	Insufficient information to calculate diagnostic test accuracy
Endo 2007	Inappropriate reference standard.
Endo 2011	Inappropriate reference standard.
Eshghi 2008	Insufficient information to calculate diagnostic test accuracy
Familiari 2004	Inappropriate reference standard.
Famos 1990	Inappropriate reference standard.
Faris 1975	Inappropriate reference standard.
Farrands 1982	Insufficient information to calculate diagnostic test accuracy
Fiore 1997	Insufficient information to calculate diagnostic test accuracy
Flowers 1992	Inappropriate reference standard.
Friedrichs 1981	Not a diagnostic test accuracy study.
Garcia-Caballero 1994	Inappropriate reference standard.
Geron 1999	Inappropriate reference standard.
Goletti 1995	Insufficient information to calculate diagnostic test accuracy
Gregg 1979	Inappropriate reference standard.
Griffin 2003	Inappropriate reference standard.
Grundy 1972	Inappropriate reference standard.
Hammarstrom 1996	Inappropriate reference standard.
Hoyuela 1999	Inappropriate reference standard.
Huddy 1989	Inappropriate reference standard.

(*Continued*)

Huynh 1996	Insufficient information to calculate diagnostic test accuracy
Ijzermans 1989	Inappropriate reference standard.
Jakimowicz 1987	Inappropriate reference standard.
Joyce 1991	Insufficient information to calculate diagnostic test accuracy
Karakan 2009	Inappropriate reference standard.
Kent 1994	Insufficient information to calculate diagnostic test accuracy
Kielar 2005	Inappropriate reference standard.
Kitahama 1986	Inappropriate reference standard.
Kruis 1997	Inappropriate reference standard.
Kullman 1984	Inappropriate reference standard.
Kushnirenko 1988	Insufficient information to calculate diagnostic test accuracy
Lakoma 1996	Inappropriate reference standard.
Lane 1982	Inappropriate reference standard.
Ledniczky 2006	Inappropriate reference standard.
Lenriot 1993	Insufficient information to calculate diagnostic test accuracy
Lim 2003	Inappropriate reference standard.
Lin 1997	Inappropriate reference standard.
Linghu 2004	Inappropriate reference standard.
Liu 2005	Inappropriate reference standard.
Lomanto 1999	We were unable to obtain this article.
Low 1992	Inappropriate reference standard.
Machi 1999	Inappropriate reference standard.
Macmahon 1993	Inappropriate reference standard.

(*Continued*)

Madhavan 1995	Insufficient information to calculate diagnostic test accuracy
Mala 2000	Insufficient information to calculate diagnostic test accuracy
Matzen 1981	Insufficient information to calculate diagnostic test accuracy
McCormick 1974	Inappropriate reference standard.
Meduri 1998	Inappropriate reference standard.
Miao 2008	Insufficient information to calculate diagnostic test accuracy
Mlynek 1971	Insufficient information to calculate diagnostic test accuracy
Moon 2005	Inappropriate reference standard.
Nataly 2002	Insufficient information to calculate diagnostic test accuracy
Neitlich 1997	Inappropriate reference standard.
Neoptolemos 1986a	Inappropriate reference standard.
Neoptolemos 1986b	Inappropriate reference standard.
Neri 2000	Inappropriate reference standard.
Nevah 2011	Insufficient information to calculate diagnostic test accuracy
Nickkholgh 2006	Inappropriate reference standard.
Nies 1997	Inappropriate reference standard.
Oconnor 1986	Insufficient information to calculate diagnostic test accuracy
Ohtani 1997	Insufficient information to calculate diagnostic test accuracy
Osnes 1978	Insufficient information to calculate diagnostic test accuracy
Pamos 2003	Inappropriate reference standard.
Pasanen 1993	Insufficient information to calculate diagnostic test accuracy
Pasanen 1994	Inappropriate reference standard.
Polat 2000	Inappropriate reference standard.

(*Continued*)

Polkowski 2001	Insufficient information to calculate diagnostic test accuracy
Potashov 1987	Inappropriate reference standard.
Puri 2012	Insufficient information to calculate diagnostic test accuracy
Rahman 2010	Inappropriate reference standard.
Rijna 2000	Insufficient information to calculate diagnostic test accuracy
Rives 1981	Insufficient information to calculate diagnostic test accuracy
Robinson 1995	Insufficient information to calculate diagnostic test accuracy
Rogers 2010	Insufficient information to calculate diagnostic test accuracy
Roig 1995	Insufficient information to calculate diagnostic test accuracy
Romano 2002	Insufficient information to calculate diagnostic test accuracy
Sauerbruch 1979	Inappropriate reference standard.
Schulenburg 1969	Insufficient information to calculate diagnostic test accuracy
Shafiq 2003	Insufficient information to calculate diagnostic test accuracy
Shah 2011	Inappropriate reference standard.
Sheen-Chen 1990	We were unable to obtain this article.
Siddiqui 1994	Insufficient information to calculate diagnostic test accuracy
Sigel 1982	Inappropriate reference standard.
Sikic 1996	Insufficient information to calculate diagnostic test accuracy
Singh 2000	Inappropriate reference standard.
Skorka 1982	Inappropriate reference standard.
Snow 2001	Inappropriate reference standard.
Stiris 2000	Insufficient information to calculate diagnostic test accuracy
Stuart 1998	Inappropriate reference standard.

(*Continued*)

Tobin 1984	Insufficient information to calculate diagnostic test accuracy
Ueno 1997	Insufficient information to calculate diagnostic test accuracy
Videhult 2009	Inappropriate reference standard.

DATA

Presented below are all the data for all of the tests entered into the review.

Tests. Data tables by test

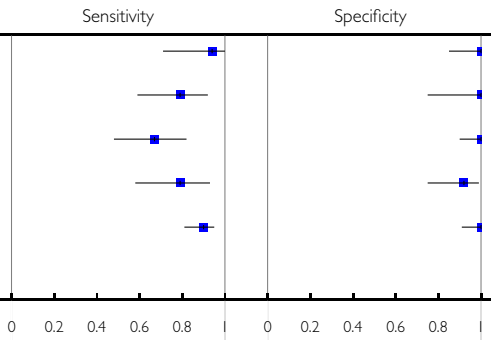
Test	No. of studies	No. of participants
1 Endoscopic retrograde cholangiopancreatography	5	318
2 Intraoperative cholangiography	5	654

Test 1. Endoscopic retrograde cholangiopancreatography.

Review: Endoscopic retrograde cholangiopancreatography versus intraoperative cholangiography for diagnosis of common bile duct stones

Test: 1 Endoscopic retrograde cholangiopancreatography

Study	TP	FP	FN	TN	Sensitivity	Specificity
Fazel 2002	16	0	1	23	0.94 [0.71, 1.00]	1.00 [0.85, 1.00]
Katz 2004	22	0	6	13	0.79 [0.59, 0.92]	1.00 [0.75, 1.00]
Ney 2005	22	0	11	35	0.67 [0.48, 0.82]	1.00 [0.90, 1.00]
Norton 1997	19	2	5	24	0.79 [0.58, 0.93]	0.92 [0.75, 0.99]
Prat 1996	70	0	8	41	0.90 [0.81, 0.95]	1.00 [0.91, 1.00]

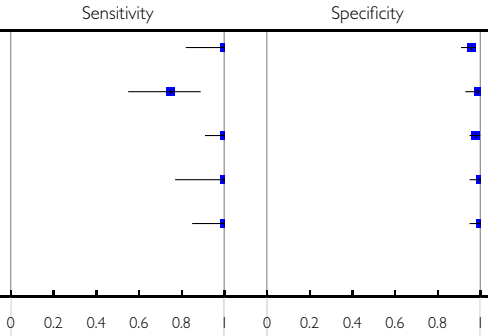


Test 2. Intraoperative cholangiography.

Review: Endoscopic retrograde cholangiopancreatography versus intraoperative cholangiography for diagnosis of common bile duct stones

Test: 2 Intraoperative cholangiography

Study	TP	FP	FN	TN	Sensitivity	Specificity
Fenton 1989	19	6	0	131	1.00 [0.82, 1.00]	0.96 [0.91, 0.98]
Li 2009	21	1	7	74	0.75 [0.55, 0.89]	0.99 [0.93, 1.00]
Montariol 1998	41	3	0	171	1.00 [0.91, 1.00]	0.98 [0.95, 1.00]
Silverstein 1998	14	0	0	76	1.00 [0.77, 1.00]	1.00 [0.95, 1.00]
Wu 2005	23	0	0	67	1.00 [0.85, 1.00]	1.00 [0.95, 1.00]



ADDITIONAL TABLES

Table 1. The QUADAS 2 tool for assessing methodological quality of included studies

Domain 1: Participant sampling	Signalling question	Signalling question	Signalling question	Risk of bias	Concerns for applicability
Domain 1: Participant sampling					
Patient sampling	Was a consecutive or random sample of participants enrolled?	Was a case-control design avoided?	Did the study avoid inappropriate exclusions?	Could the selection of participants have introduced bias?	Were there concerns that the included participants and setting did not match the review question?
	Yes: all consecutive participants or random sample of participants with suspected common bile duct stones were enrolled No: selected participants were enrolled. Unclear: this was not clear from the report.	Yes: case-control design was avoided. No: case-control design was not avoided. Unclear: this was not clear from the report.	Yes: the study avoided inappropriate exclusions (i.e., people who were difficult to diagnose) No: the study excluded participants inappropriately. Unclear: this was not clear from the report.	Low risk: 'yes' for all signalling questions. High risk: 'no' or 'unclear' for at least 1 signalling question	Low concern: the selected participants represent the people in whom the tests would be used in clinical practice (see diagnostic pathway (Figure 1). High concern: there was high concern that participant selec- tion was performed

Table 1. The QUADAS 2 tool for assessing methodological quality of included studies (*Continued*)

					in a such a way that the included participants did not represent the people in whom the tests will be used in clinical practice
Domain 2: Index test					
Index test(s)	Were the index test results interpreted without knowledge of the results of the reference standard?	If a threshold was used, was it pre-specified?	-	Could the conduct or interpretation of the index test have introduced bias?	Were there concerns that the index test, its conduct, or its interpretation differed from the review question?
	Yes: index test results were interpreted without knowledge of the results of the reference standard No: index test results were interpreted with knowledge of the results of the reference standard Unclear: this was not clear from the report.	Yes: if the criteria for a positive test result were pre-specified No: if the criteria for a positive test result were not pre-specified Unclear: this was not clear from the report.	-	Low risk: 'yes' for all signalling questions. High risk: 'no' or 'unclear' for at least 1 of the 2 signalling questions	High concern: there was high concern that the conduct or interpretation of the index test differed from the way it is likely to be used in clinical practice Low concern: there was low concern that the conduct or interpretation of the index test differed from the way it is likely to be used in clinical practice
Domain 3: Reference standard					
Target condition and reference standard(s)	Was the reference standard likely to classify the target condition correctly?	Were the reference standard results interpreted without knowledge of the results of the index tests?	-	Could the reference standard, its conduct, or its interpretation have introduced bias?	Were there concerns that the target condition as defined by the reference standard did not match the review question?
	Yes: all participants underwent the acceptable reference standard No: if all participants did not un-	Yes: reference standard results were interpreted without knowledge of the results of the index test	-	Low risk: 'yes' for all signalling questions. High risk: 'no' or 'unclear' for at least 1 of the 2 signalling questions	Low concern: participants underwent endoscopic or surgical exploration for common bile duct stone

Table 1. The QUADAS 2 tool for assessing methodological quality of included studies (*Continued*)

	dergo an acceptable reference standard. Such studies were excluded from the review Unclear: if the reference standard that the participants underwent was not stated. Such studies were excluded from the review	No: reference standard results were interpreted with the knowledge of the results of the index test Unclear: this was not clear from the report.			High concern: no participants underwent endoscopic or surgical exploration for common bile duct stone
Domain 4: Flow and timing					
Flow and timing	Was there an appropriate interval between index test and reference standard?	Did all participants receive the same reference standard?	Were all participants included in the analysis?	Could the participant flow have introduced bias?	-
	Yes: the interval between index test and reference standard (including any repeat procedures) was ≤ 4 weeks (arbitrary choice) No: the interval between index test and reference standard was > 4 weeks Unclear: this was not clear from the report.	Yes: all participants underwent endoscopic or surgical exploration for common bile duct stone irrespective of the index test results No: participants underwent endoscopic or surgical exploration if the index test results were positive and underwent clinical follow-up for at least 6 months if the index test results were negative Unclear: this was not clear from the report. Such studies were excluded	Yes: all participants meeting the selection criteria (selected participants) were included in the analysis, or data on all the selected participants were available so that a 2 x 2 table including all selected participants could be constructed No: not all participants meeting the selection criteria were included in the analysis or the 2 x 2 table could not be constructed using data on all selected participants Unclear: this was not clear from the report.	Low risk: 'yes' for all signalling questions. High risk: 'no' or 'unclear' for at least 1 signalling question	-

APPENDICES

Appendix 1. Search strategies

Database	Period of Search	Search Strategy
MEDLINE (PubMed)	1946 to September 2012.	(((bile duct[tiab] or biliary[tiab] OR CBD[tiab]) AND (stone[tiab] OR stones[tiab] OR calculus[tiab] OR calculi[tiab])) OR choledocholithiasis[tiab] OR cholelithiasis[tiab] OR "Choledocholithiasis"[Mesh] OR "Common Bile Duct Calculi "[MESH] OR "Cholelithiasis "[MESH]) AND (CT[tiab] OR tomodensitometry[tiab] OR MRI[tiab] OR NMRI[tiab] OR zeugmatogra*[tiab] OR ((computed[tiab] OR computerised[tiab] OR computerized[tiab] OR magneti*[tiab] OR MR[tiab] OR NMR[tiab] OR proton[tiab]) AND (tomogra*[tiab] OR scan[tiab] OR scans[tiab] OR imaging[tiab] OR cholangiogra*[tiab])) OR "Tomography, X-Ray Computed"[Mesh] OR "Magnetic Resonance Imaging"[Mesh] OR echogra*[tiab] OR ultrason*[tiab] OR ultrasound[tiab] OR EUS[tiab] OR "Ultrasonography"[Mesh] OR "Endosonography"[Mesh] OR cholangiogra*[tiab] OR cholangio?pancreatogra*[tiab] OR cholangiosco*[tiab] OR choledochosco*[tiab] OR ERCP[tiab] OR MRCP[tiab] OR "Cholangiography"[Mesh] OR "Cholangiopancreatography, Magnetic Resonance"[Mesh] OR liver function test[tiab] OR liver function tests[tiab] OR "Liver Function Tests"[Mesh])
EMBASE (OvidSP)	1947 to September 2012.	1. (((bile duct or biliary or CBD) adj5 (stone or stones or calculus or calculi)) or choledocholithiasis or cholelithiasis).tw. 2. exp common bile duct stone/ or exp bile duct stone/ or exp cholelithiasis/ 3. 1 or 2 4. (CT or tomodensitometry or MRI or NMRI or zeugmatogra* or ((computed or computerised or computerized or magneti* or MR or NMR or proton) adj5 (tomogra* or scan or scans or imaging or cholangiogra*))).tw. 5. exp computer assisted tomography/ 6. exp nuclear magnetic resonance imaging/ 7. (echogra* or ultrason* or ultrasound or EUS).tw. 8. exp ultrasound/ 9. (cholangiogra* or cholangio?pancreatogra* or cholangiosco* or choledochosco* or ERCP or MRCP).tw. 10. exp cholangiography/ 11. (liver function test or liver function tests).tw. 12. exp liver function test/ 13. 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 14. 3 and 13

(*Continued*)

Science Citation Index Expanded (ISI Web of Knowledge)	1898 to September 2012.	#1 TS=(((bile duct or biliary OR CBD) AND (stone OR stones OR calculus OR calculi)) OR choledocholithiasis OR cholelithiasis) #2 TS=(CT OR tomodensitometry OR MRI OR NMRI OR zeugmatogra* OR ((computed OR computerised OR computerized OR magneti* OR MR OR NMR OR proton) AND (tomogra* OR scan OR scans OR imaging OR cholangiogra*))) #3 TS=(echogra* OR ultrason* OR ultrasound OR EUS) #4 TS=(cholangiogra* OR cholangio?pancreatogra* OR cholangiosco* OR choledochosco* OR ERCP OR MRCP) #5 TS=(liver function test OR liver function tests) #6 #5 OR #4 OR #3 OR #2 #7 #1 AND #6
BIOSIS (ISI Web of Knowledge)	1969 to September 2012.	#1 TS=(((bile duct or biliary OR CBD) AND (stone OR stones OR calculus OR calculi)) OR choledocholithiasis OR cholelithiasis) #2 TS=(CT OR tomodensitometry OR MRI OR NMRI OR zeugmatogra* OR ((computed OR computerised OR computerized OR magneti* OR MR OR NMR OR proton) AND (tomogra* OR scan OR scans OR imaging OR cholangiogra*))) #3 TS=(echogra* OR ultrason* OR ultrasound OR EUS) #4 TS=(cholangiogra* OR cholangio?pancreatogra* OR cholangiosco* OR choledochosco* OR ERCP OR MRCP) #5 TS=(liver function test OR liver function tests) #6 #5 OR #4 OR #3 OR #2 #7 #1 AND #6
Clinicaltrials.gov	September 2012.	(bile duct) OR CBD OR choledocholithiasis OR cholelithiasis
Database of Abstracts of Reviews of Effects (DARE) and Health Technology Assessment (HTA) in *The Cochrane Library* (Wiley)	September 2012.	#1 (((bile duct or biliary or CBD) NEAR/5 (stone OR stones OR calculus OR calculi)) OR choledocholithiasis OR cholelithiasis):ti,ab,kw #2 MeSH descriptor Choledocholithiasis explode all trees #3 (#1 OR #2) #4 (CT OR tomodensitometry OR MRI OR NMRI OR zeugmatogra* OR ((computed OR computerised OR computerized OR magneti* OR MR OR NMR OR proton) NEAR/5 (tomogra* OR scan OR scans OR imaging OR cholangiogra*))):ti,ab,kw #5 MeSH descriptor Tomography, X-Ray Computed explode all trees #6 MeSH descriptor Magnetic Resonance Imaging explode all trees #7 (echogra* OR ultrason* OR ultrasound OR EUS):ti,ab,kw

(*Continued*)

		#8 MeSH descriptor Ultrasonography explode all trees #9 MeSH descriptor Endosonography explode all trees #10 (cholangiogra* OR cholangio?pancreatogra* OR cholangiosco* OR choledochosco* OR ERCP OR MRCP):ti,ab,kw #11 MeSH descriptor Cholangiography explode all trees #12 MeSH descriptor Cholangiopancreatography, Magnetic Resonance explode all trees #13 (liver function test OR liver function tests):ti,ab,kw #14 MeSH descriptor Liver Function Tests explode all trees #15 (#4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14) #16 (#3 AND #15)
Medion (www.mediondatabase.nl/)	September 2012.	We will conduct four separate searches of the abstract using the terms: bile duct CBD choledocholithiasis cholelithiasis
ARIF (www.birmingham.ac.uk/research/activity/mds/projects/HaPS/PHEB/ARIF/databases/index.aspx)	September 2012.	(bile duct) OR CBD OR choledocholithiasis OR cholelithiasis

CONTRIBUTIONS OF AUTHORS

KG extracted the data from identified studies and wrote the review.

VG, GP, and DH evaluated studies for inclusion.

VG extracted the data from included studies.

YT analysed the data and contributed to the draft of the review.

DS and BRD critically commented on the review.

DECLARATIONS OF INTEREST

None.

SOURCES OF SUPPORT

Internal sources

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- National Institute of Health Research, UK.

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

1. We used the statistical package Stata instead of SAS to fit the bivariate models.

2. We performed one main analysis. In this analysis, we excluded indeterminates test results. We considered the planned sensitivity analyses inappropriate because there were only two participants with indeterminate test results and data were sparse.

NOTES

This review is based on a common protocolwhich needed to be split into three reviews (Giljaca 2013).