Systematic review

Systematic review of intraoperative cholangiography in cholecystectomy

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Background: **Intraoperative cholangiography (IOC) is used to detect choledocholithiasis and identify or prevent bile duct injury. The aim of this study was systematically to review the randomized clinical trials of IOC for these two indications.**

Methods: **MEDLINE, Embase, the Cochrane Library, clinicaltrials.gov and the World Health Organization database of clinical trials were searched systematically (January 1980 to February 2011) to identify trials. Two authors performed the literature search and extracted data independently. Primary endpoints were bile duct injury and retained common bile duct (CBD) stones diagnosed at any stage after surgery. Preliminary meta-analysis was undertaken, but the trials were too methodologically heterogeneous and the outcome events too infrequent to allow meaningful meta-analysis.**

Results: **Eight randomized trials were identified including 1715 patients. Six trials assessed the value of routine IOC in patients at low risk of choledocholithiasis. Two trials randomized all patients (including those at high risk) to routine or selective IOC. Two cases of major bile duct injury were reported, and 13 of retained CBD stones. No trial demonstrated a benefit in detecting CBD stones. IOC added a mean of 16 min to the total operating time.**

Conclusion: **There is no robust evidence to support or abandon the use of IOC to prevent retained CBD stones or bile duct injury. Level 1 evidence for IOC is of poor to moderate quality. None of the trials, alone or in combination, was sufficiently powered to demonstrate a benefit of IOC. Further small trials cannot be recommended.**

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Introduction

Although intraoperative cholangiography (IOC) has been used in cholecystectomy for over two decades, its clinical application remains variable. Many surgeons do not perform IOC at all, whereas most of the literature on the topic is devoted to a discussion of its routine or selective use. The two purposes of IOC are to detect choledocholithiasis, so that these stones can be removed during or after surgery, and to prevent or diagnose bile duct injury (BDI).

Many cohort or case–control studies have looked at the question of IOC and the detection of choledocholithiasis[1–5]. Large population studies have examined the association between BDI and IOC[6–14]. However, level 1 evidence in the form of randomized clinical trials (RCTs) remains the best evidence for informing clinical practice. Several, mostly relatively small, trials comparing no IOC, selective IOC and/or routine IOC have been performed[15–23]. No meta-analysis or systematic review of these trials has hitherto been published. Therefore, a systematic review of RCTs of IOC was performed, with regard to the outcomes of retained common bile duct (CBD) stones and BDI, with the intention of performing meta-analyses of these effects.

Methods

The study was completed in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement[24]. A literature search of studies published between January 1980 and February

2011 was carried out. Only RCTs comparing cholecystectomy with routine, selective or no IOC were included. There were no language restrictions, and both published and unpublished studies were included. MEDLINE, Embase, the Cochrane Library, clinicaltrials.gov and the World Health Organization database of clinical trials were searched. The following keywords were used in the search strategy: cholecystectomy/laparoscopic cholecystectomy and cholangiogram/cholangiography/intraoperative cholangiography/selective cholangiography/routine cholangiography and clinical trial/randomised controlled trial. Searches were limited to adults. References of included studies and relevant review articles were also screened. Studies were screened independently by two authors for eligibility, and differences of opinion regarding included studies were resolved by a senior author.

Data were entered into a standard pro forma. Two authors extracted data independently and any disagreement concerning interpretation of the data was resolved by the senior authors. The primary outcomes were the rate of retained CBD stones and the incidence of BDI confirmed radiologically. Secondary outcomes extracted included duration of operation, IOC success rate, length of hospital stay, morbidity and mortality. Risk of bias was assessed at study level using the Cochrane risk-of-bias table and Jadad scores[25]. Authors were contacted for information on unpublished studies, but not for missing data relating to published trials.

Statistical analysis

The intention was to perform a meta-analysis, but it became apparent that the trials were too heterogeneous methodologically and the outcome events too infrequent to allow meaningful meta-analysis. Methodological heterogeneity was measured by assessing the similarity of three criteria: baseline populations including demographics and inclusion/exclusion criteria; interventions randomized to each arm; and outcomes including outcomes measured, method of measurement and follow-up time. Preliminary meta-analysis was undertaken to assess statistical heterogeneity, but a descriptive method was used to report primary and secondary outcomes. Statistical heterogeneity was measured using I^2 scores calculated using Review Manager (The Nordic Cochrane Centre, Copenhagen, Denmark).

Results

The review process is detailed in *Fig. 1*. From 520 studies identified during the literature search, eight (1715 patients) met the inclusion criteria (*Table 1*). Two studies were translated from German before analysis[17,18]. Eleven studies were excluded because of a non-randomized design[26–36].

Trial design

Most participants underwent laparoscopic surgery. However, in two studies the participants had open procedures[19,22], in one study both laparoscopic and open procedures were included[17], and in another study the type of procedure was not specified[21].

Two main study designs could be discerned (*Table 1*). A 'low-risk' design was used in six studies[15,17–19,21,23] that excluded patients with biochemical, radiological or clinical indicators of CBD stones. The exact criteria for exclusion varied between studies. In three trials[17,19,22] these were a complex set of 11 criteria described by Hauer–Jensen and colleagues[37], whereas others used a variety of similar criteria (*Table 1*). Only patients at low risk of choledocholithiasis were included in these studies, and they were randomized to routine IOC or no IOC.

A 'non-selective' design was used in two studies[16,22]. In this group all patients presenting for cholecystectomy who did not have overt CBD stones (frankly jaundiced or with CBD stones on imaging) were randomized to either routine or selective IOC. The selective IOC group was defined by similar criteria as those used in the low-risk trial design.

Follow-up ranged from 6 weeks to 8 years (*Table 1*). In four studies this was done by questionnaire, either postal[20,21] or by telephone[16,18], with clinical follow-up then arranged as indicated. In the remaining studies follow-up was with the general practitioner[15] or at a hospital clinic[17,22,23].

Study quality and heterogeneity

Overall the quality of the studies was poor (*Table 2*). In only three studies was there a description of adequate sequence generation, and in only two was there a description of allocation concealment. None of the studies described masking of patients or assessors at follow-up.

Preliminary meta-analysis allowed measurement of statistical heterogeneity. However, meta-analysis of retained CBD stones, duration of operation, complications and length of hospital stay in studies with the non-selective trial design, and BDI in both trial designs, was impossible because there were insufficient events in each trial or incomplete reporting. Meta-analysis was possible for operating time and retained CBD stones in the trials with a low-risk design but, in the authors' opinion, was inappropriate. Among studies with a low-risk design there was high statistical heterogeneity for operating

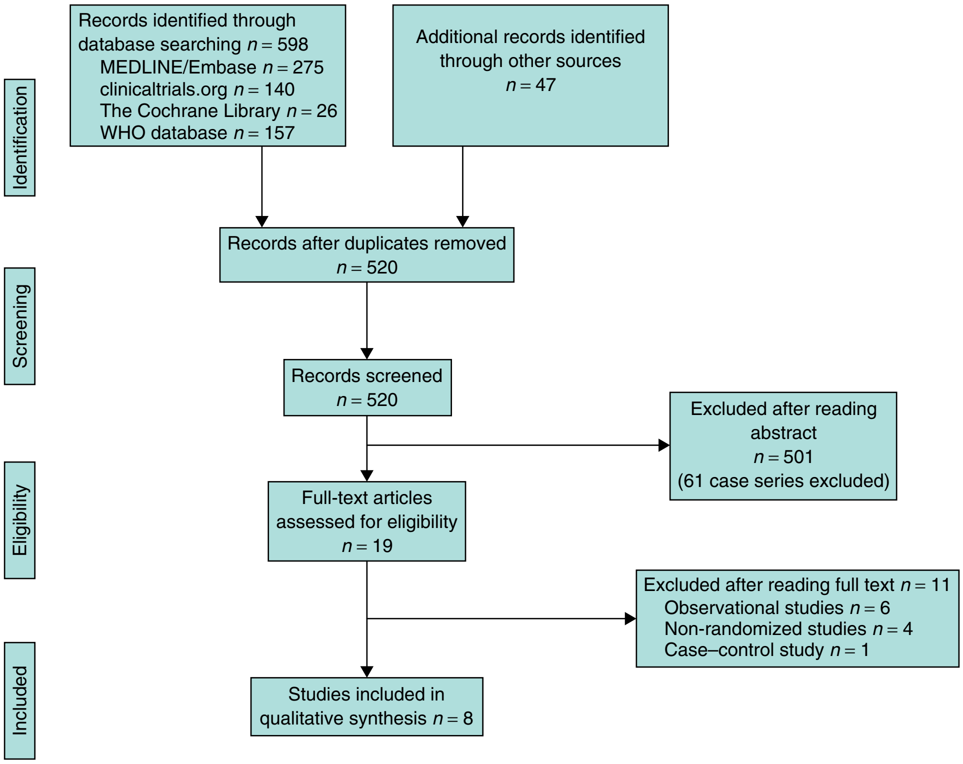

Fig. 1 PRISMA diagram. WHO, World Health Organization

Table 1 Randomized trials of intraoperative cholangiography

Reference	Year	Risk of stones	No. of participants	Type of procedure	Risk factors for CBD stones	Follow-up
Khan *et al.*[15]	2011	Low risk	190	Laparoscopic	Abnormal LFTs; dilated CBD on ultrasonography or ERCP; history of jaundice or pancreatitis	1 year
Amott *et al.*[16]	2005	Non-selective	303	Laparoscopic	Abnormal LFTs; dilated CBD on ultrasonography (>5 mm)	1 year
Nies *et al.*[17]	1997	Low risk	275	Open and laparoscopic	Hauer–Jensen criteria	1 year
Tusek *et al.*[18]	1997	Low risk	100	Laparoscopic	Abnormal LFTs (raised bilirubin, ALP >250 units/l); dilated CBD on ultrasonography (>7 mm)	Median 7·1 months
Hauer-Jensen *et al.*[19,20]	1986, 1993	Low risk	280	Open	Hauer–Jensen criteria	6–8 years
Murison *et al.*[21]	1993	Low risk	285	Not specified	Abnormal LFTs; history of jaundice or pancreatitis	3–6 years
Sharma *et al.*[22]	1993	Non-selective	167	Open	Hauer–Jensen criteria	6 weeks
Soper and Dunnegan[23]	1992	Low risk	115	Laparoscopic	Abnormal LFTs; preoperative ERCP; dilated CBD on ultrasonography; history of jaundice, pancreatitis; findings at surgery of choledocholithiasis, unclear anatomy, cystic duct stones or dilated cystic duct	2–12 months
Total			1715			

CBD, common bile duct; LFT, liver function test; ERCP, endoscopic retrograde cholangiopancreatography; ALP, alkaline phosphatase.

Table 2 Risk-of-bias table

	Sequence generation	Allocation concealment	Blinding	Incomplete data addressed	Free from selective outcome reporting	Free from other bias	Jadad score
Khan *et al.*[15]	Yes	Yes	Unclear	Yes	Yes	Yes	3
Amott *et al.*[16]	No	No	Unclear	Yes	Yes	Yes	1
Nies *et al.*[17]	Yes	Yes	Unclear	Yes	Yes	Yes	3
Tusek *et al.*[18]	Unclear	Unclear	Unclear	Yes	Yes	Yes	1
Hauer-Jensen *et al.*[19,20]	Unclear	Unclear	Unclear	Yes	Yes	Yes	2
Murison *et al.*[21]	Unclear	Unclear	Unclear	No	Yes	No	2
Sharma *et al.*[22]	Unclear	Unclear	Unclear	Yes	Yes	Yes	1
Soper and Dunnegan[23]	Yes	Unclear	Unclear	Yes	Yes	Yes	3

Table 3 Main outcomes for randomized trials of intraoperative cholangiography *versus* no intraoperative cholangiography

	CBD injury		Intraoperative stones		Retained stones at follow-up			
Reference	IOC	No IOC	IOC	No IOC	IOC	No IOC	True-positive cholangiograms	False-positive cholangiograms
Khan *et al.*[15] ($n = 190$)	0	1*	3	–	0	0†	3	0
Nies *et al.*[17] ($n = 275$)	0	1	3	–	0	4	3	1
Tusek *et al.*[18] ($n = 100$)	NR	NR	4	–	0	0	4	0
Hauer-Jensen *et al.*[19,20] ($n = 280$)	0	0	4	–	0	0	4	3
Murison *et al.*[21] ($n = 285$)	NR	NR	12	–	1‡	0	12	16
Soper and Dunnegan[23] ($n = 115$)	0	0	3	–	0	0	3	3

*Common hepatic duct injury requiring conversion to open surgery. †Three patients re-presented with abnormal liver function tests (LFTs) consistent with choledocholithiasis but ultrasonography showed no significant common bile duct (CBD) or biliary dilatation; one further patient re-presented with deranged LFTs secondary to a biliary stricture. ‡Intraoperative cholangiography (IOC) performed and reported as normal. NR, not reported.

Table 4 Main outcomes for randomized trials of routine *versus* selective intraoperative cholangiography

	CBD injury		Intraoperative stones		Retained stones at follow-up			
Reference	Routine IOC	Selective IOC	Routine IOC	Selective IOC	Routine IOC	Selective IOC	True-positive cholangiograms	False-positive cholangiograms
Amott *et al.*[16] ($n = 303$)	1*	1*	12	5	3†	5‡	12	0
Sharma *et al.*[22] ($n = 167$)	NR	NR	10	7	0	0	10	1

*Intraoperative cholangiography (IOC) performed. †None had successful IOC. ‡One negative IOC, one failed IOC, and IOC not indicated in three. NR, not reported.

time ($I^2 = 97$ per cent), but low statistical heterogeneity for retained CBD stones ($I^2 = 7$ per cent), length of stay ($I^2 = 14$ per cent) and complications ($I^2 = 0$ per cent).

Duration of operation and success rate of intraoperative cholangiography

In every study in which it was reported, the mean duration of operation for patients undergoing cholecystectomy plus IOC was longer than that for patients having cholecystectomy alone (*Fig. S1*, supporting information). The mean difference was 16 (range 10–23) min. The longest operating times occurred in the earlier study of open cholecystectomies[20].

In the studies with a low-risk design, the percentage of patients who were randomized to IOC and successfully underwent the procedure was high (range 80·4–98·9 per cent). Typically these studies were performed in academic centres. By contrast, in the non-selective study carried out in a rural centre the overall success rate of IOC was 66 per cent[16].

Accuracy of intraoperative cholangiography

Positive intraoperative cholangiograms prompted transcystic duct exploration[15,17] or CBD exploration[16,21,22].

In some studies the type of exploration was not specified[18,19,23]. There were 24 false-positive cholangiograms (patients who were thought to have a CBD stone on IOC, which was not present on duct exploration) (*Tables 3* and *4*). Sixteen of these false-positives were from one study[21]. The remaining trials had considerably lower false-positive rates.

Retained stones

In the six studies that included only patients at low risk of choledocholithiasis, five patients had retained stones detected at follow-up (*Table 3*). Four of these patients did not have IOC, and one had a normal cholangiogram although a retained stone was subsequently found. Four of the five retained stones occurred in one study[17], making interpretation problematic.

One of the two non-selective studies reported no retained stones (*Table 4*)[22]. Three patients in the other study had retained stones following routine IOC, and five patients in the selective cholangiography group[16]. Notably, however, among patients with retained stones in the routine IOC group, cholangiography had been attempted but was unsuccessful.

Bile duct injuries

There were two major BDIs reported among the 1715 patients, and neither patient underwent IOC (*Table 3*). In one patient a hepatic duct injury occurred, requiring conversion to open surgery and primary repair[15]. In the second patient the hepatic duct was clipped[17]. There were also two avulsion injuries of the cystic duct following IOC[16] (*Table 4*). Therefore, there was an overall BDI rate of 0·2 per cent and a major BDI rate of 0·1 per cent.

Secondary outcomes

Three studies recorded length of hospital stay[17,19,23] and there was no demonstrable difference between the groups. Length of stay ranged from 1·0 to 6·3 days, depending on type of procedure.

Four trials reported mortality[17,20,21,23]. Only two studies described deaths in each group[17,23]. There were five deaths in the IOC group and three in the non-IOC group. All deaths were described by the authors as being not directly related to surgery.

Five studies recorded morbidity[15,17,20,21,23] but only two recorded complications in any detail[17,20]. In one of these there were ten complications in the IOC group and eight in the no-IOC group. In the other trial, of open cholecystectomy, there was a significantly higher morbidity rate in the IOC group (14·8 *versus* 5·8 per cent)[20]. The additional complications were due to subhepatic collections and lower respiratory tract infections. One study reported a marginally higher rate of wound sepsis in the IOC group compared with the no-IOC group (7·6 *versus* 5·2 per cent)[21]. Neither of the non-selective studies reported morbidity. Owing to the heterogeneity in reporting, it was not possible to perform a meta-analysis for morbidity.

Discussion

The incidence of BDI increased with the arrival of laparoscopic surgery[38] and population data have suggested a protective effect of IOC[6–8]. Over the next decade the incidence of BDI decreased[12,39–41], although some studies have reported persistently high rates[7]. The consequences of BDI are not only detrimental to patients' quality of life[42]; their treatment also carries a significant financial burden[8,43,44]. In addition to preventing BDI, IOC may prevent complications and healthcare costs from unsuspected CBD stones[29,30]. Meta-analysis has demonstrated the effectiveness, safety and cost utility of laparoscopic CBD exploration[42] and IOC is a prerequisite for exploration. Advocates of selective IOC suggest that, because BDI is rare and most CBD stones can be demonstrated before operation, routine IOC is not required[45,46]. Moreover, with the advent of non-invasive imaging such as magnetic resonance cholangiopancreatography (MRCP) and the effectiveness of endoscopic retrograde cholangiopancreatography, IOC has fallen out of favour with many surgeons. In addition, routine IOC extends operating time, there is a false-positive rate, and interpretation of the cholangiogram by the surgeon can be problematic. In one study the anatomy was interpreted correctly in less than 25 per cent of intraoperative cholangiograms when a BDI occurred[39].

The present study reviewed the available level 1 evidence with respect to routine IOC in cholecystectomy. There were two separate study designs among the RCTs. Six studies excluded all patients with an indication for IOC and randomized the remainder. Essentially these studies asked the question whether patients without a preoperative indication for CBD stones should undergo routine IOC. The second study design involved randomization of unselected patients to either routine or selective IOC. These studies examined whether there is a benefit of routine over selective IOC.

Neither of these study designs addresses the question of whether 'unselected' patients (who do not have obvious CBD stones) should undergo routine IOC or no IOC. A randomized trial comparing no IOC with routine IOC in this unselected group may be more relevant to current practice. Such a study would ideally include preoperative imaging such as MRCP or computed tomography cholangiography in its design, which was not the case in any of the RCTs included in the present review.

There was considerable heterogeneity in the methodology of the included trials. There were two different study designs, three studies included open cholecystectomies, follow-up varied from 6 weeks to 8 years, the definition of risk for CBD stones was not consistent, and the last trial was performed 25 years after the first. In addition to methodological heterogeneity, the low, or zero, event rates meant that some analyses were impossible. Study quality was questionable with Jadad scores ranging from 1 to 3. Pooling data with this degree of heterogeneity and questionable quality would have been unsound, producing oversimplified results[47]. It is also important to note that most of the studies were published over 10 years ago and different circumstances now apply.

There was a trend favouring IOC in the rate of retained stones. This was especially the case when outcomes were examined on the basis of successful IOC. However, such an analysis contravenes the intention-to-treat principle. The primary outcomes occurred at very low rate and even a large multicentre RCT would be unlikely to provide enough power to prove a benefit of IOC. In the trials evaluated, the overall BDI rate was only 0·2 per cent (0·1 per cent for major injuries) and there were only 13 patients with retained CBD stones, eight reported in one study[16]. For example, a BDI rate without IOC of 0·4 per cent and a BDI rate with IOC of 0·2 per cent would require a sample size of 15 712 to give 90 per cent power for detecting a difference. A retained stone rate of 2 per cent in the IOC group and 4 per cent in those not having IOC would need a sample size of 1527 to give 90 per cent power. Therefore, although a multicentre trial with retained stones as the primary endpoint might be possible, a trial to demonstrate a difference in BDI rates is unrealistic.

Although not part of the present analysis, it is relevant to look at other sources of evidence (*Table S1*, supporting information)[6–14]. Overall these data suggest that IOC does reduce the rate of BDI; however, in four studies the reduction was not statistically significant. There is additionally a meta-analysis of 40 case series including 327 523 patients[9], where a significantly lower BDI rate was found in patients who had undergone IOC. However, there are also significant limitations to interpreting data from cohort and case series. These include variability in the definition of BDI, and the lack of quality control over reporting standards. Moreover, these types of study only demonstrate an association between IOC and a lower BDI rate. Whether this association is causal or confounded by another variable is unknown. In particular, IOC may be a marker for more experienced or hepatobiliary-trained surgeons, or surgery being done in higher-volume centres or teaching hospitals.

Although the RCT evidence is found wanting, the overall evidence suggests that IOC reduces the BDI rate, that selective and routine use of IOC have similar outcomes, and that there is not enough robust evidence to support or abandon the current use of IOC.

Disclosure

The authors declare no conflict of interest.

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Supporting information

Additional supporting information may be found in the online version of this article:

Fig. S1 Operating times (Word document)

Table S1 Risk of bile duct injury using intraoperative cholangiography in large cohort studies (Word document)

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