Systematic review

Systematic review of endoscopic ultrasonography *versus* endoscopic retrograde cholangiopancreatography for suspected choledocholithiasis

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Background: **Endoscopic ultrasonography (EUS) has emerged as an accurate diagnostic alternative to endoscopic retrograde cholangiopancreatography (ERCP). The aim of this study was to perform a systematic review of all randomized controlled trials of EUS-guided ERCP *versus* ERCP alone in patients with suspected choledocholithiasis.**

Methods: **The search for eligible studies was carried out using the MEDLINE, Cochrane Central Register of Controlled Trials, and Science Citation Index electronic databases. Meta-analysis was conducted using a random-effects model.**

Results: **Four trials containing 213 patients randomized to EUS-guided ERCP and 210 to ERCP alone were selected. In the EUS-guided ERCP group, ERCP was avoided in 143 patients (67·1 per cent) when EUS did not detect choledocholithiasis. The use of EUS significantly reduced the risk of overall complications (relative risk 0·35 (95 per cent confidence interval (c.i.) 0·20 to 0·62); $P < 0·001$) and post-ERCP acute pancreatitis (relative risk 0·21 (95 per cent c.i. 0·06 to 0·83); $P = 0·030$).**

Conclusion: **By performing EUS first, ERCP may be safely avoided in two-thirds of patients with common bile duct stones. Application of EUS in the selection of patients for therapeutic ERCP significantly reduces the complication rate.**

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Introduction

The prevalence of gallstones among adults in North American and European populations ranges from 10 to 20 per cent[1,2]. Treatment of patients with symptomatic choledocholithiasis with no suspicion of common bile duct (CBD) stones is straightforward and includes planned elective laparoscopic cholecystectomy. In contrast, the management of patients with suspected choledocholithiasis is technically more challenging and usually requires preoperative or intraoperative visualization of the biliary tree with the aim of detecting the stones in the bile duct.

For years, the 'gold standard' for preoperative visualization of the bile duct has been endoscopic retrograde cholangiopancreatography (ERCP). However, the non-selective use of ERCP in all patients with suspected choledocholithiasis detects CBD stones in less than 50 per cent[3,4]. This method may, of course, be both a diagnostic and a treatment modality (ERCP-only strategy), but it results in over half of patients undergoing an unnecessary invasive procedure, with its attributable morbidity and mortality. The first publications on the usefulness of the alternative, non-invasive modality – endoscopic ultrasonography (EUS) – in diagnosing CBD stones appeared around 1990[5,6]. Since then, more than 25 prospective studies, incorporating more than 2500 patients with suspected choledocholithiasis, have shown excellent accuracy for EUS, coupled with safety. The overall diagnostic performance of EUS in the detection of choledocholithiasis has been evaluated in two recent meta-analyses[7,8]; the pooled sensitivity and specificity of EUS were 89–94 per cent and 94–95 per cent respectively.

However, the reference standard for the presence or absence of CBD stones in the above studies was mainly ERCP, which might miss some stones, especially small ones. This does not allow inferences to be made regarding

the comparative performance of the two modalities. The utility of an EUS-guided ERCP strategy, that is, the utility of EUS in the selection of patients for therapeutic ERCP, cannot yet be said to be established. Only the results of direct randomized comparisons of EUS-guided ERCP and ERCP-only strategies can establish EUS as a valid modality in the management of patients with suspected CBD stones. As far as the authors are aware, such trials have never been reviewed systematically. The present aim, therefore, is to compare the usefulness of an EUS-guided ERCP strategy with an ERCP-only strategy using randomized controlled trials (RCTs) of patients with suspected choledocholithiasis.

Methods

Search strategy

Three electronic databases (MEDLINE, Cochrane Central Register of Controlled Trials and Science Citation Index) were searched for the period from 1 January 1989 to 1 January 2009. The following combination of search terms was used: 'EUS' or 'endosonography' or 'endoscopic ultrasonography' and 'ERCP' or 'endoscopic retrograde cholangiopancreatography'. Reference sections of the retrieved articles were cross-searched. The search was constrained to studies on adult humans. Language restrictions were not applied.

Inclusion criteria

The title and abstract of all identified articles were screened for the following inclusion criteria: study design (RCT); intervention (EUS followed by ERCP with or without endoscopic sphincterotomy in the case of choledocholithiasis – EUS-guided ERCP strategy); comparator (ERCP with or without endoscopic sphincterotomy – ERCP-only strategy); population (patients with suspected choledocholithiasis).

Data extraction

Full-text articles of trials that met all the inclusion criteria were retrieved. Data on the following items were abstracted: number of patients, number of dropouts, patients' baseline characteristics, number of EUS and ERCP examinations in each group, number of failures with the use of both endoscopic procedures, procedure-related complications, other clinically relevant outcomes.

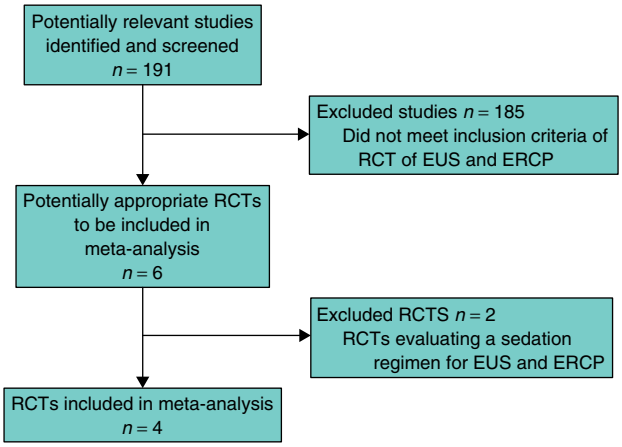

Fig. 1 Flow diagram of study selection process. RCT, randomized controlled trial; EUS, endoscopic ultrasonography; ERCP, endoscopic retrograde cholangiopancreatography

Any difference of opinion between authors was agreed by consensus.

Quality assessment

The quality of each RCT was assessed according to the criteria of the Cochrane Collaboration (method of randomization, concealment of allocation, blinding, loss to follow-up and selective outcome reporting)[9]. In addition, the number of dropouts was evaluated.

Statistical analysis

Where applicable, the results of individual trials were statistically aggregated to obtain a pooled relative risk (RR) and corresponding 95 per cent confidence interval (c.i.) for each outcome. The between-study heterogeneity was assessed using I^2 and χ^2 measures.[10] I^2 values below 25 per cent were considered as indicating absence of heterogeneity, those of 26–50 per cent as low heterogeneity, those of 51–75 per cent as moderate heterogeneity, and those over 75 per cent as high heterogeneity[11]. A P value of χ^2 below 0·05 was considered to indicate high heterogeneity. Regardless of the presence or absence of heterogeneity among the trials, a random-effects model was applied. The meta-analysis software Review Manager (RevMan), version 5.0, 2008 (Nordic Cochrane Centre, The Cochrane Collaboration, Copenhagen, Denmark) was used for all comparisons.

Results

Of 191 articles retrieved by electronic and hand searching, a total of six potentially suitable RCTs was identified (*Fig. 1*). Two trials were subsequently excluded because they did not evaluate EUS-guided ERCP *versus* ERCP-only strategies in patients with suspected choledocholithiasis[12,13]. The remaining four trials initially enrolled 426 patients (213 in the EUS-guided ERCP group and 213 in the ERCP-only group[14–17], but three patients (all in the ERCP-only group) were withdrawn after randomization, leaving 210 patients in the ERCP-only group. The baseline characteristics of patients and inclusion criteria in the primary studies are presented in *Table 1*[18]. *Table 2* shows the methodological quality of these studies.

The 213 patients in the EUS-guided ERCP group underwent a total of 295 endoscopic procedures (1·4 procedures per patient), whereas the 210 patients in the ERCP-only group underwent a total of 243 endoscopic procedures (1·2 procedures per patient) (*Table 3*). The risk of undergoing an additional endoscopic procedure (EUS or ERCP) was nearly 2·5 times greater for EUS-guided ERCP *versus* ERCP alone (RR 2·46 (95 per cent c.i. 1·34 to 4·52); $P = 0·004$) (*Fig. 2*). There was one unsuccessful EUS in the EUS-guided ERCP group, compared with 25 initially unsuccessful ERCPs and two repeatedly failed ERCPs in the ERCP-only group (RR 0·08 (95 per cent c.i. 0·02 to 0·33); $P < 0·001$). In the EUS-guided ERCP group, EUS failed to detect CBD stones in two (0·9 per cent) of the 213 patients, and a total of 143 ERCPs were avoided when EUS did not detect choledocholithiasis (67·1 per cent) (*Table 3*).

Clinical outcomes are presented in *Table 4*. There were a total of 14 complications in 213 patients (6·6 per cent) in the EUS-guided ERCP group *versus* 40 complications in

Table 1 Study characteristics of the four included trials

	Liu *et al.*[14]	Polkowski *et al.*[15]	Lee *et al.*[16]	Karakan *et al.*[17]
Age (years)				
EUS	67 (50–76)*	58 (51–71)*	65 (29–85)†	59(12)‡
ERCP	70 (53–79)*	61 (47–68)*	65 (20–92)†	64(11)‡
Sex ratio (M : F)				
EUS	32 : 38	4 : 46	16 : 17	13 : 47
ERCP	30 : 40	8 : 42	15 : 17	19 : 41
Total serum bilirubin on admission (μmol/l)				
EUS	38 (17–66)*	15 (9–23)*	37 (3–557)†	15(5)‡
ERCP	43 (21–82)*	14 (11–18)*	33 (2–353)†	19(9)‡
CBD dilatation on US				
EUS	n.s.	9	4	32
ERCP	n.s.	8	2	19
Inclusion criteria in primary studies	First episode of acute biliary pancreatitis	Probability of CBD stones no greater than 67%[18]	Derangement of LFTs or dilated CBD on US	Probability of CBD stones no greater than 67%[18]
Prevalence of CBD stones (%)	32	26	23	43

Values are *median (interquartile range), †median (range) and ‡mean(s.d.). EUS, endoscopic ultrasonography (EUS)-guided endoscopic retrograde cholangiopancreatography (ERCP) group; ERCP, ERCP-only group; CBD, common bile duct; US, transabdominal ultrasonography; n.s., not stated; LFTs, liver function tests.

Table 2 Methodological quality of the included trials

	Liu *et al.*[14]	Polkowski *et al.*[15]	Lee *et al.*[16]	Karakan *et al.*[17]
Method of randomization	Unclear	Computer-generated	Unclear	Computer-generated
Allocation concealment	Sealed envelopes	Sealed envelopes	Sealed envelopes	Sealed envelopes
Double blinding	No	No	No	No
Loss to follow-up	Unclear	Yes	No	No
Selective outcome reporting	No	No	No	No
No. of dropouts				
EUS	0	0	0	0
ERCP	0	2	1	0

EUS, endoscopic ultrasonography (EUS)-guided endoscopic retrograde cholangiopancreatography (ERCP) group; ERCP, ERCP-only group.

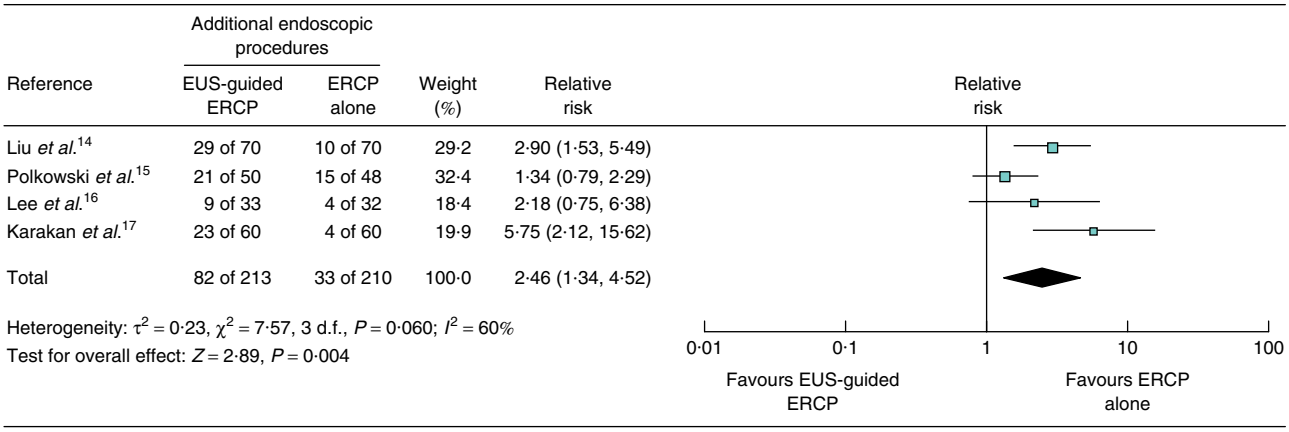

Fig. 2 Meta-analysis of risks of additional endoscopic procedures after endoscopic ultrasonography (EUS)-guided endoscopic retrograde cholangiopancreatography (ERCP) *versus* ERCP alone. Relative risks are shown with 95 per cent confidence intervals

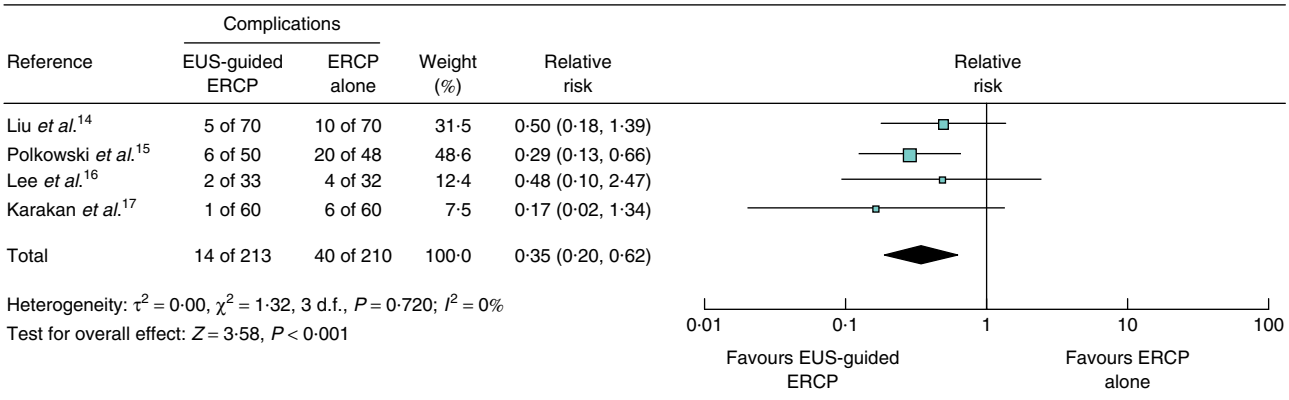

Fig. 3 Meta-analysis of over-all complication risk after endoscopic ultrasonography (EUS)-guided endoscopic retrograde cholangiopancreatography (ERCP) *versus* ERCP alone. Relative risks are shown with 95 per cent confidence intervals

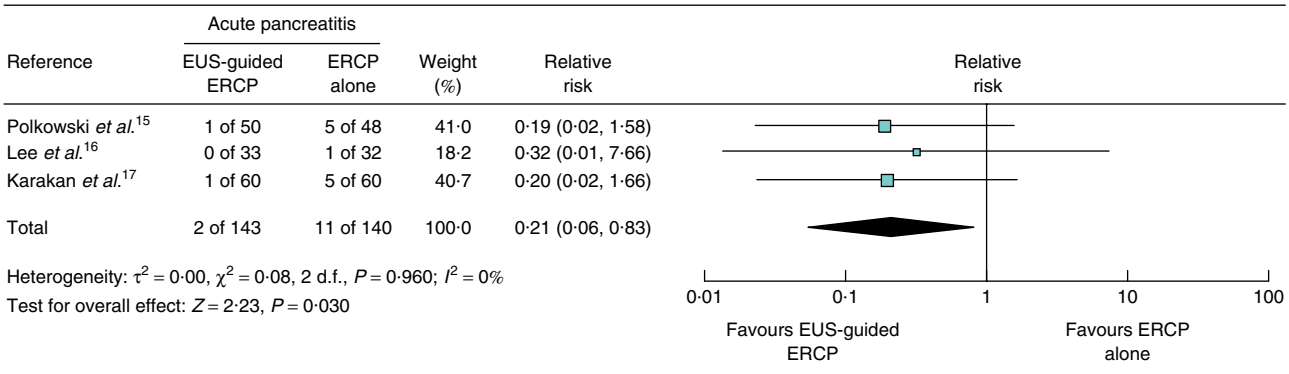

Fig. 4 Meta-analysis of risks of acute pancreatitis following endoscopic ultrasonography (EUS)-guided endoscopic retrograde cholangiopancreatography (ERCP) *versus* ERCP alone. Relative risks are shown with 95 per cent confidence intervals

Table 3 Endoscopic procedures in the two study groups

	Liu *et al.*[14]	Polkowski *et al.*[15]	Lee *et al.*[16]	Karakan *et al.*[17]	Total
No. of initial endoscopic procedures*					
EUS	70	50	33	60	213
ERCP	70	48	32	60	210
No. of ERCPs avoided by EUS	45	36	25	37	143
No. of failed initial endoscopic procedures*					
EUS	0	1	0	0	1
ERCP	10	12	3	0	25
No. of additional endoscopic procedures*					
EUS	29	21	9	23	82
ERCP	10	15	4	4	33
Total no. of ERCPs					
EUS	29	19	9	23	80
ERCP	80	55	35	64	234
Total no. of endoscopic procedures*					
EUS	99	71	42	83	295
ERCP	80	63	36	64	243

*Endoscopic procedure indicates endoscopic ultrasonography (EUS) and endoscopic retrograde cholangiopancreatography (ERCP). EUS, EUS-guided ERCP group; ERCP, ERCP-only group.

Table 4 Clinical outcomes in the two study groups

	Liu *et al.*[14]	Polkowski *et al.*[15]	Lee *et al.*[16]	Karakan *et al.*[17]	Total
No. of patients					
EUS	70	50	33	60	213
ERCP	70	48	32	60	210
No. of overall complications					
EUS	5	6	2	1	14
ERCP	10	20	4	6	40
Complications per patient (%)					
EUS	7	12	6	2	7*
ERCP	14	42	13	9	19*
Complications per ERCP procedure (%)					
EUS	17	32	22	4	18*
ERCP	13	36	11	6	15*
In-hospital mortality					
EUS	2	0	0	0	2
ERCP	1	0	0	0	1

*Mean value. EUS, endoscopic ultrasonography (EUS)-guided endoscopic retrograde cholangiopancreatography (ERCP) group; ERCP, ERCP-only group.

210 patients (19·0 per cent) in the ERCP-only group. Use of the EUS-guided ERCP strategy was associated with a significantly lower risk of overall complications (RR 0·35 (95 per cent c.i. 0·20 to 0·62); $P < 0·001$) (*Fig. 3*) and of post-ERCP acute pancreatitis (RR 0·21 (95 per cent c.i. 0·06 to 0·83); $P = 0·030$) (*Fig. 4*). The risk of bleeding, however, did not differ significantly between the groups (RR 0·49 (95 per cent c.i. 0·10 to 2·44); $P = 0·380$). There was also no difference with regard to in-hospital mortality (RR 2·00 (95 per cent c.i. 0·19 to 21·56); $P = 0·570$).

Discussion

Several previous meta-analyses of observational studies have revealed a high pooled sensitivity (89–94 per cent) and specificity (94–95 per cent) for EUS in the detection of CBD stones[7,8]. The present study is the first systematic review of the comparison of an EUS-guided ERCP strategy with an ERCP-only strategy in patients with choledocholithiasis. Its main finding is that the use of EUS for the selection of patients who will need therapeutic ERCP results in a significantly lower risk of complications in comparison with the use of ERCP for both diagnosis and treatment of choledocholithiasis. As there was no difference between the groups with regard to the risk of complications per ERCP procedure, the observed risk reduction is probably due to the avoidance of ERCPs in 67·1 per cent of patients in the EUS-guided ERCP group. It is worth noting that, although relatively rare events, ERCP-related complications may be life threatening[19,20]. However, 38·5 per cent (82 of 213) of patients in the EUS-guided ERCP group needed at least one additional endoscopic procedure. Another important finding of the present review, therefore, is that an EUS-guided ERCP strategy requires significantly more endoscopic procedures than an ERCP-only strategy. To summarize these findings, the cost of an additional endoscopic procedure in around one-third of patients is balanced against the risks of ERCP-related complications in about two-thirds of patients with suspected choledocholithiasis.

Given that both EUS and ERCP are costly procedures, the economics of performing endoscopy is becoming one of the determinative factors in management. A study from the University of Chicago Medical Center tracked the billing records of 70 patients who underwent endoscopic procedures in June 2006[21]. EUS alone had the lowest direct cost ($880 per procedure), followed by ERCP alone ($2170) and combined EUS and ERCP ($2356). Although the cost of combined EUS and ERCP in this retrospective study is of concern, these figures should be interpreted with caution. First, only three patients underwent the combined procedure, each of whom was a Medicare beneficiary. Second, the Medicare revenue for the combined EUS and ERCP was only 34 per cent of total cost, as opposed to 95–97 per cent in the case of a single endoscopic procedure. Third, the authors did not report on the characteristics of included patients and, in particular,

on the number of patients with choledocholithiasis and pretest probability of CBD stones in those patients.

Several other studies have assessed the cost-effectiveness of the various approaches to biliary imaging with respect to the pretest probability of choledocholithiasis[22–24]. Arguedas and colleagues[22] demonstrated that an EUS-guided ERCP strategy was cost-effective when the risk of choledocholithiasis was 7–45 per cent, whereas an ERCP-only strategy was cost-effective when the risk of choledocholithiasis was more than 45 per cent. Similarly, Buscarini and co-workers[23] found that for all levels of risk of CBD stones below 61 per cent an EUS-guided ERCP strategy was least costly, whereas for risk greater than 61 per cent an ERCP-only strategy was least costly. In addition, the Markov decision model analysis comparing four different initial approaches (EUS, EUS followed by ERCP, magnetic resonance cholangiopancreatography (MRCP) and ERCP) showed that EUS followed by ERCP had the highest probability of cost-effectiveness in patients with an intermediate probability of CBD stones; ERCP had the highest probability of cost-effectiveness in patients with a high probability of CBD stones[24].

Previous studies have shown that a risk of choledocholithiasis greater than 60 per cent usually corresponds to signs of acute cholangitis and/or CBD stones detected by transabdominal ultrasonography. However, as criteria differ between authors, it may sometimes be difficult to convert clinical, laboratory and instrumental findings into a definite risk of choledocholithiasis in percentage terms. It seems reasonable, therefore, to assess the usefulness of both EUS-guided ERCP and ERCP-only strategies taking into account a clinical and laboratory picture of patients with suspected CBD stones. This was done in a recent study by Ang *et al.*[25] which revealed significant cost benefits for an ERCP-only strategy exclusively in patients with suspected acute cholangitis. There was no difference between the two strategies in cost terms for other clinical and laboratory presentations (cholestatic jaundice, acute biliary pancreatitis, abnormal liver function tests with normal bilirubin). Therefore, as the prevalence of CBD stones in the present review varied from 23 to 43 per cent, and patients with acute cholangitis were excluded in all studies, the EUS-guided ERCP strategy may be assumed to be the most cost-effective in patients with an intermediate probability of choledocholithiasis (those without signs of acute cholangitis).

EUS-guided ERCP may be performed at a single session (ERCP performed in the same endoscopic and anaesthesia session as EUS) or at two separate sessions (ERCP performed at a separate session). A recent non-randomized study[26] of one-session *versus* two-session EUS-guided ERCP showed no difference between groups in terms of the complication rate. The single-session strategy, however, resulted in a reduction in mean hospital stay of 3 days and in mean anaesthesia time of 30 min. On the basis of these data, the single-session approach seems to be more cost-effective, although these approaches should really be compared in a randomized fashion. The future development of combined EUS and therapeutic ERCP scopes should speed up the implementation of an EUS-guided ERCP strategy[27].

In addition to its excellent diagnostic performance, EUS may also offer some extra advantages over ERCP in certain settings. For example, EUS can detect causes other than stones that might cause biliary obstruction, such as sludge, ampullary or pancreatic tumours, and chronic pancreatitis[28–30]. Unfortunately, EUS is still not widely available and it is a very operator-dependent technique with a steep learning curve[31]. One should also be aware that MRCP is a non-invasive alternative to EUS with a similar diagnostic performance. MRCP can provide high spatial resolution, although it is less sensitive than EUS for detecting CBD stones smaller than 6 mm[32]. The limited evidence available on patient satisfaction suggests that MRCP is preferable to diagnostic ERCP[33]. Any detailed discussion of the usefulness of MRCP and other diagnostic options, such as intraoperative cholangiography during cholecystectomy, is beyond the scope of the present systematic review.

This study has several limitations. First, the sample size might be considered too small for meaningful comparison of two treatment strategies. A power calculation shows that an adequately powered study would need to enrol 120 patients per arm in order to demonstrate an equivalence between the groups in terms of overall complications with 80 per cent power and two-sided $\alpha = 0{\cdot}05$. As the present meta-analysis included a total of 423 patients, the authors believe it is sufficiently powered to draw a valid conclusion. Second, there may be concerns that the study populations in the included trials were different; one study included only patients with suspected acute biliary pancreatitis[14], whereas two trials excluded such patients[16,17]. It is worth considering, however, that the authors aimed to assess the efficacy of both treatment strategies not in patients with or without a certain disease, but in patients with signs of choledocholithiasis, the prevalence of which was fairly similar (between 23 and 43 per cent) in the trials. Third, the reported endpoint of 'overall complications' is a composite one, comprising several different pathologies. In particular, it included 'transient abdominal pain' (two of six complications in the EUS-guided ERCP group and 13 of 20 in the ERCP-only group) in one of the primary

studies[15]. This feature might explain the finding of an unexpectedly high rate of over-all complications in the ERCP-only group. However, sensitivity analysis yielded no principal changes in study findings (data not shown). Furthermore, it is worth noting that the risk of such a uniformly defined complication as post-ERCP acute pancreatitis was significantly reduced with the use of an EUS-guided ERCP strategy.

Overall, this systematic review demonstrates that around two-thirds of patients with suspected CBD stones do not require diagnostic ERCP. Compared with an ERCP-only strategy, an EUS-guided ERCP strategy significantly reduces the risk of overall complications and post-ERCP acute pancreatitis. These findings, coupled with the cost-effectiveness of EUS-guided ERCP and the excellent diagnostic performance of EUS in patients with an intermediate risk of choledocholithiasis, suggest that EUS should be a routine procedure in this category of patients to select those eligible for therapeutic ERCP. An ERCP-only strategy should no longer be considered appropriate in future RCTs in patients with a low or intermediate probability of choledocholithiasis. It should be reserved solely for patients with a high probability of CBD stones.

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