Meta-analysis of endoscopy and surgery versus surgery alone for common bile duct stones with the gallbladder in situ

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CRD summary
The authors found no difference between surgery alone and endoscopy plus surgery for the management of choledocholithiasis in association with cholecystolithiasis, in outcomes including successful duct clearance, morbidity and mortality. The authors’ conclusions appear to be supported by the data, but the lack of a validity assessment and incomplete reporting of review methods mean that the reliability of the conclusions is uncertain.

Authors’ objectives
To determine whether surgery alone or combined endoscopy and surgery is more effective in the management of choledocholithiasis (common bile duct stones) in association with cholecystolithiasis (gall bladder stones).

Searching
MEDLINE and ISI databases were searched for studies published up until the end of March 2006; the keywords were listed. Bibliographies of identified papers and review articles were handsearched. Only English language articles were eligible for inclusion; abstracts were excluded.

Study selection
Study designs of evaluations included in the review
Randomised controlled trials (RCTs) were eligible for inclusion in the review.

Specific interventions included in the review
Studies in which endoscopy (endoscopic retrograde cholangiopancreatography, ERCP) plus surgery was compared with surgery alone were eligible for inclusion. The included studies compared endoscopy plus surgery with either open or laparoscopic surgery.

Participants included in the review
Although no inclusion criteria for the participants were explicitly stated, it was clear that patients undergoing common bile duct surgery were eligible for inclusion. All of the participants had choledocholithiasis in association with cholecystolithiasis. The authors reported no details of the participants in the included studies, other than that two trials excluded patients from undergoing laparoscopic exploratory surgery if the duct was less than 6 mm in diameter.

Outcomes assessed in the review
No outcome inclusion criteria were stated. The included studies reported on the following outcomes: successful duct clearance, total morbidity, mortality, major morbidity and additional procedures after initial intervention. In the review, conversion from laparoscopy to open surgery was considered a morbidity event. Major complications were defined as intra-abdominal sepsis, cholangitis, clinical pancreatitis, pneumonia, major bleeding requiring transfusion or intervention, myocardial infarction, stroke and early unplanned reoperation. Minor complications were defined as biochemical pancreatitis, minor bile leak, atelectasis, wound infection and urinary tract infection.

How were decisions on the relevance of primary studies made?
The authors did not state how the papers were selected for the review, or how many authors performed the selection.

Assessment of study quality
Studies were assessed for validity using the Consolidated Standards of Reporting Trials (CONSORT) checklist. Since the authors stated that any disagreements were resolved through discussion with all the authors, it appeared that validity
was assessed by more than one reviewer.

**Data extraction**
Two authors independently extracted the data for the review onto a customised data extraction form. For each study, the numbers of patients with events of interest were presented for each treatment group.

**Methods of synthesis**
How were the studies combined?
Mantel-Haenszel random-effects models were used to combine the results. Pooled odds ratios or relative risks were calculated with 95% confidence intervals. The data were analysed on an intention-to-treat basis.

How were differences between studies investigated?
Heterogeneity between the studies was evaluated using the Q statistic. Subgroup analyses of studies using laparoscopic surgery as the control intervention were performed.

**Results of the review**
Twelve trials (1,352 participants) were included in the review. Seven trials (608 participants) compared endoscopy and surgery with open surgery; 5 trials (744 participants) compared endoscopy and surgery with laparoscopic surgery.

The results of the validity assessment were not presented in the review.

There was no significant difference between the endoscopy plus surgery and surgery groups in any of the following outcomes: successful duct clearance (12 studies), total morbidity (12 studies), mortality (5 studies), major morbidity (11 studies), or additional procedures after initial intervention (10 studies). There was no evidence of statistical heterogeneity between the studies for any of these outcomes. Subgroup analyses comparing endoscopy plus surgery with laparoscopic surgery showed the same results.

**Authors' conclusions**
The use of endoscopy plus surgery results in similar outcomes to surgery alone in the treatment of choledocholithiasis in association with cholecystolithiasis. The choice of technique should be determined by resources and the expertise of the operating team.

**CRD commentary**
This review answered an identified research question which was defined in terms of the intervention and study design; criteria for the outcomes and participants were not defined. The reviewers searched two electronic databases for published trials, but appear not to have searched for unpublished studies. The exclusion of non-English language articles and those not published in full (e.g. abstracts) increases the potential for publication and language bias. The authors did not report whether appropriate steps were taken to reduce the risk of bias and errors during the study selection process. Although a validity assessment was carried out, no results of this assessment were given in the review, making it difficult for the reader to assess the reliability of the findings.

The lack of any details about the participants in the included studies makes it hard to assess the generalisability of the findings of the review. The use of meta-analytical methods was an appropriate way to combine the statistically homogeneous results, as was the subgroup analysis. The authors’ conclusions appear to be supported by the data presented, but the lack of a validity assessment and incomplete reporting of review methods mean that the reliability of the conclusions is uncertain.

**Implications of the review for practice and research**
Practice: The authors stated that in centres where access to ERCP is difficult, the preferred approach should be surgery;
where operating room time is limited or the list for cholecystectomy is long, the preferred approach should be simple cholecystectomy and endoscopic clearance.

Research: The authors did not state any implications for further research.

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This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.