Comparison of endoscopic sphincterotomy and laparoscopic exploration of the common bile duct

Tranter S E, Thompson M H

Authors' objectives
To compare endoscopic sphincterotomy with laparoscopic exploration of the common bile duct.

Searching
MEDLINE, PubMed and the Cochrane Controlled Trials Register were searched for studies published after 1990; the search terms were stated. In addition, the reference lists in identified studies and reviews were checked. Studies published in any language were eligible.

Study selection
Study designs of evaluations included in the review
Randomised controlled trials (RCTs) with any number of patients, and other designs (unspecified) or other series with more than 50 patients were eligible for inclusion.

Specific interventions included in the review
The inclusion criteria were not specified in terms of the interventions, but it was clear that the review focused on studies of endoscopic sphincterotomy and studies of laparoscopic exploration of the common bile duct. The included studies were of endoscopic sphincterotomy followed by laparoscopic cholecystectomy compared with bile duct exploration (open or laparoscopic), endoscopic sphincterotomy alone or bile duct exploration alone.

Participants included in the review
The inclusion criteria were not specified in terms of the participants, but studies of patients with bile duct stones seem to have been eligible for inclusion.

Outcomes assessed in the review
The review assessed effectiveness, mortality and complications in the short-, medium- and long-term for endoscopic sphincterotomy; short-term efficacy, and short- and medium-term complications were assessed for laparoscopic bile duct exploration. Specific complications included pancreatitis, haemorrhage, cholangitis, duodenal perforation, missed and retained stones, biliary symptoms, papillary stenosis and bile duct cancer. The review did not define time periods for short-, medium- and long-term results. Studies of endoscopic sphincterotomy classified as medium term reported outcomes after a median follow-up of 7 to 15 years, or a mean follow-up of 1 to 14.2 years, where the timing was reported. The length of follow-up for long-term studies was not reported.

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 reviewers performed the selection.

Assessment of study quality
The authors stated that validity was assessed, but no details were provided.

Data extraction
The authors did not state how the data were extracted for the review, or how many reviewers performed the data extraction.

The success rates and complication rates for observational studies of endoscopic sphincterotomy and bile duct exploration were tabulated. For RCTs, the success and complication rates were tabulated separately for the endoscopic sphincterotomy and bile duct exploration treatment arms.
Methods of synthesis
How were the studies combined?
The studies were grouped by study design and a narrative synthesis was undertaken. The range and median percentage of patients with specified outcomes were reported separately for endoscopic sphincterotomy and bile duct exploration. Medium- and long-term complications were discussed separately.

How were differences between studies investigated?
Differences between the studies were discussed with respect to the year of publication, sample size, age of the patients and length of follow-up.

Results of the review
Seven RCTs (957 patients) and 19 observational studies (23,116 patients) assessed short-term efficacy and complications. Fourteen observational studies (n=13,119) assessed the medium-term complications of endoscopic sphincterotomy, while 11 observational studies assessed the long-term complications of endoscopic sphincterotomy. Thirty observational studies (n=4,727) assessed the success and complication rates of bile duct exploration.

Short-term results for endoscopic sphincterotomy.
The therapeutic success rates ranged from 75 to 96% in the RCTs (7 studies), with duct clearance ranging from 75 to 96% (3 studies). In case series, successful sphincterotomy rates in case series ranged from 79 to 98% and successful bile duct clearance rates ranged from 82 to 96%. These rates were not increased in larger or more recent studies. The overall complication rates ranged from 2 to 24% (median 8), and mortality ranged from 0 to 6% (median 1).

Pancreatitis rates ranged from 1 to 19% (median 3). Three studies suggested an increase in pancreatitis in younger patients. Cholangitis rates ranged from 1 to 4%, haemorrhage rates ranged from 1 to 6% (mortality about 2%), and duodenal perforation rates were 1 or 2% (mortality was reported to be high but no values were stated). The complication rates appeared to remain similar over time. The authors stated that the data suggest that postoperative pancreatitis may have increased: the rates ranged from 1 to 4% (median 1) in the 1980s compared with 1 to 19% (median 3) in the 1990s.

Medium-term results for endoscopic sphincterotomy. The rates for late biliary symptoms ranged from 7 to 11%. The most common complications were recurrent stones (2 to 16%) with or without sphincterotomy stenosis (1 to 7%) and cholangitis (1 to 6%). The authors stated that the studies suggest that the recurrent stone rate increases with the length of follow-up.

Long-term results after sphincterotomy or biliary bypass procedure (study design unclear).
The long-term complications included bacterobilia, mucosal hyperplasia and bile duct cancer (two reports of cancer following endoscopic sphincterotomy).

Results for laparoscopic exploration of the common bile duct from studies of any design. Most (70%) of the studies reported bile duct clearance rates above 90%. The rates of retention of stones ranged from 0 to 19% (median 5). The rates of conversion to open operation ranged from 1 to 20% (median 4). Mortality ranged from 0 to 5% (median 1) and the total complication rates ranged from 2 to 17% (median 8). Success, mortality and complication rates did not seem to improve in larger studies.

For results from RCTs comparing endoscopic sphincterotomy followed by laparoscopic cholecystectomy with bile duct exploration (open or laparoscopic), the authors stated that summary rates for duct clearance and length of hospital stay were similar for both types of surgery, but summary data were not presented. In addition, it was unclear which studies followed sphincterotomy with cholecystectomy.

Endoscopic sphincterotomy significantly increased mortality (2% versus 1%, P=0.03) and morbidity compared with laparoscopic exploration.
No long-term results for laparoscopic bile duct exploration were identified.

**Authors' conclusions**
Laparoscopic exploration of the common bile duct may be a better treatment option for the removal of bile stones than endoscopic sphincterotomy followed by laparoscopic cholecystectomy

**CRD commentary**
The inclusion criteria for the study design, intervention, participants and outcomes were not explicitly stated. Two relevant databases were searched without any language restrictions and the search terms were stated. However, the date the search ended was not reported. The methods used to select the studies, assess validity and extract the data were not described; hence, efforts made to reduce errors and bias cannot be judged. The authors stated that validity was assessed, but the criteria used were not reported and neither were the results of any such assessment. Also, the findings were not discussed in the context of study quality.

Some relevant data on the included studies were tabulated, but there was little information on the characteristics of the participants and the criteria used to determine ‘success’ in the individual studies were not reported. Patients in the non-randomised studies treated with endoscopic sphincterotomy may have differed from patients undergoing bile duct exploration. The results from RCTs comparing endoscopic sphincterotomy followed by laparoscopic cholecystectomy with bile duct exploration were not directly compared. In addition, the results from studies of any design appear to have been combined in the narrative. The evidence presented was insufficient to reach definitive conclusions about the relative efficacy and safety of endoscopic sphincterotomy compared with bile duct exploration, or subgroups for whom a particular treatment may be more appropriate.

**Implications of the review for practice and research**

**Practice:** The authors stated that laparoscopic exploration of the bile duct appeared to be the preferred treatment in young fit patients, but that the best treatment for patients with co-morbidity has yet to be determined.

**Research:** The authors stated that RCTs are required to determine the optimal treatment in patients with co-morbidity. They also stated that RCTs should clearly report results from intention-to-treat analysis and that long-term follow-up studies are required.

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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.