Can early precut implementation reduce endoscopic retrograde cholangiopancreatography-related complication risk? Meta-analysis of randomized controlled trials

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CRD summary
This well-conducted review found that early implementation of pre-cut cannulation and persistent cannulation attempts had similar overall cannulation rates; early pre-cut implementation reduced post-endoscopic retrograde cholangiopancreatography pancreatitis risk, but not the overall complication rate. Further research is required to confirm these findings. These conclusions are likely to be reliable.

Authors' objectives
To compare cannulation and complication rates of the two different techniques of early institution of pre-cutting versus standard cannulation persistent attempts for deep biliary cannulation.

Searching
PubMed, EMBASE, and the Cochrane Library were searched to November 2009. Additional online clinical trials registries including meta-Register of Controlled Trials and National Institutes for Health were also searched over the same period. Search terms were reported. Google Scholar was also searched. Relevant conference proceedings were handsearched. No language restrictions were applied.

Study selection
Randomised controlled trials (RCTs) that compared early institution of pre-cutting versus standard cannulation involving persistent attempts, with or without pre-cut in case of failure, for deep biliary cannulation were eligible for inclusion. Trials had to report intention-to-treat data on cannulation rates and major complications (post endoscopic retrograde cholangiopancreatography pancreatitis, cholangitis, endoscopic retrograde cholangiopancreatography-related bleeding and perforation).

Included trials either randomised all patient referred to endoscopic units or randomised patients if no biliary cannulation was achieved after five to 12 minutes of cannulation attempts or after up to three accidental pancreatic duct cannulations occurred. Some trials included patients with a history of pancreatitis and/or sphincter of Oddi dysfunction. Indications to perform endoscopic retrograde cholangiopancreatography included biliary diseases requiring therapeutic biliary endoscopy or diagnostic procedures. Pre-cut techniques varied across trials and included the needle-knife, freehand pre-cut starting from the papillary orifice, freehand fistulotomy starting above the orifice; one trial used both freehand pre-cut techniques. In persistent attempt groups, wire guided techniques, contrast-assisted cannulation techniques or both were used. In the persistent attempt groups, standard cannulation was attempted for 10 to 20 minutes before either considering late pre-cut implementation or aborting the procedure.

Two reviewers independently assessed studies for inclusion. Disagreements were resolved through consensus.

Assessment of study quality
Two reviewers independently assessed trial quality based on randomisation, sequence generation, allocation concealment, blinding, description of follow-up, definition of outcome measures, statistical power, intention-to-treat analysis, and baseline assessment of treatment group characteristics. Disagreements were resolved through consensus.

Data extraction
Two reviewers extracted data to calculate odds ratios (ORs) together with 95% confidence intervals (CIs) on an intention-to-treat basis. Disagreements were resolved through discussion.

Methods of synthesis
Summary odd ratios together, with 95% confidence intervals, were estimated using random-effects and Mantel-Haenszel fixed-effect models. Heterogeneity was assessed using Galbraith plots and with the Q statistic and I². Sensitivity analysis was conducted to analyse the effects of individual trials on summary estimates. Publication bias
Results of the review
Six RCTs were included in the review (n=966 patients). Five trials had adequate generation of allocation sequence; four of these had adequate concealment of treatment allocation. None of the trials were double blinded. Only one trial was adequately powered.

Cannulation rates: There was no difference in the incidence of cannulation between the early pre-cut group and the persistent attempts group (treatment group (OR 1.20, 95% CI 0.55 to 2.69). There was evidence of heterogeneity between trials (p=0.04; I²=60%). Excluding two trials that performed immediate pre-cut did not alter the results. There was no evidence of publication bias.

Risk of complications: The risk of post-endoscopic retrograde cholangiopancreatography pancreatitis was reduced in the early pre-cut group compared with the persistent attempts group (OR 0.47, 95% CI 0.24 to 0.91). There was no significant difference between the two treatment groups for post-procedural bleeding, endoscopic retrograde cholangiopancreatography-related perforation, and cholangitis, or in the overall complication rates.

Authors' conclusions
Available evidence suggested that, in experienced hands, the early implementation of pre-cut and persistent cannulation attempts had similar overall cannulation rates; early pre-cut implementation reduced post-endoscopic retrograde cholangiopancreatography pancreatitis risk, but not the overall complication rate.

CRD commentary
This review addressed a clear question and inclusion criteria were defined. The literature search was adequate and included some attempts to locate unpublished studies. Publication bias was assessed in the review and no evidence was found. Appropriate steps were taken to minimise bias and errors at all stages of the review process.

Trial quality was formally assessed using relevant criteria; the results were discussed in the review. Methods used to pool data were appropriate and included investigation of heterogeneity.

The authors' conclusions are supported by the results and are likely to be reliable; their call for additional research is justified based on the small number of included trials with small sample sizes.

Implications of the review for practice and research
Practice: The authors did not state any implications for practice.

Research: The authors stated that further large, well-conducted RCTs are needed to confirm the review findings.

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