Pure versus mixed electrosurgical current for endoscopic biliary sphincterotomy: a meta-analysis of adverse outcomes

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CRD summary
This review concluded that the type of current used during electrosurgery for endoscopic biliary sphincterotomy made no significant difference to the rate of pancreatitis; however, pure current was associated with more episodes of primarily mild bleeding. Given the flaws in the analysis, the limited number of small studies and the variation between studies, these findings may not be reliable.

Authors' objectives
To compare the rates of adverse events and complications associated with pure current versus mixed current electrosurgery for endoscopic biliary sphincterotomy.

Searching
PubMed was searched from January 1995 to December 2005 using the listed search terms. In addition, the reference lists of published trials and review articles were screened. Only studies published in peer-reviewed journals and indexed in MEDLINE were eligible for inclusion in the review.

Study selection
Study designs of evaluations included in the review
Randomised controlled trials (RCTs) with no loss to follow-up were eligible for inclusion in the review.

Specific interventions included in the review
Studies comparing pure versus mixed electrosurgical current for endoscopic biliary sphincterotomy were eligible for inclusion. Studies of pancreatic sphincterotomy were excluded from the review, as were studies where other prophylactic or therapeutic interventions were used in either treatment arm. The following interventions were excluded from the meta-analysis: electrosurgery using a sequential combination of different types of current along the length of the sphincterotomy; electrosurgery via needle-knife sphincterotomy; and pancreatic sphincterotomy or combined biliary and pancreatic sphincterotomy. Two of the four included studies compared the Valleylab Force 2 generator using 30 Watts/second pure current versus 30 Watts/second combined current.

Participants included in the review
Studies of patients undergoing endoscopic biliary sphincterotomy during endoscopic retrograde cholangiopancreatography (ERCP) were eligible for inclusion. The mean age of included participants ranged from 53 to 64 years, and the ratio of males to females ranged from 1:1.05 to 1:3.1.

Outcomes assessed in the review
Eligible studies had to report levels of complications including bleeding, perforation and post-ERCP pancreatitis. Complications were graded according to the consensus criteria for pancreatitis; bleeding was graded according to severity (mild, moderate or severe).

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
Two reviewers independently assessed study validity using the Overview Quality Assessment Questionnaire, which assesses both methodology and reporting. The authors did not state what criteria were used, how the scores were awarded, or how any discrepancies were resolved.

Data extraction
Two reviewers independently extracted the study data. Aggregated rates (ARs) with 95% confidence intervals (CIs) were calculated for each study.

**Methods of synthesis**

How were the studies combined?

Pooled ARs with 95% CIs were calculated using a random-effects analysis, and the differences between the pooled ARs of the two intervention types were reported.

How were differences between studies investigated?

Statistical homogeneity was assessed, but the authors did not report the type of test used. A subgroup analysis was performed by eliminating one outlying study.

**Results of the review**

Four RCTs (n=804; 396 pure and 408 mixed electrosurgical current) were included in the review.

The median quality score was 21.

There was no significant difference in pancreatitis between the pure and mixed current groups. There were insufficient data to carry out a stratified analysis based on pancreatitis severity. There was a significant difference between the rate of postsphincterotomy bleeding (difference 0.251, 95% CI: 0.123, 0.379), with more bleeding in the pure group (AR 37.3%, 95% CI: 27.3, 47.3) than in the mixed current group (AR 12.2, 95% CI: 16.3, 41.4). Mild bleeding was significantly more in the pure group (AR 28.9, 95% CI: 16.3, 41.4) than in the mixed group (AR 9.4, 95% CI: 2.1, 16.8); the difference was 0.195 (95% CI: 0.049, 0.341). There was no significant difference in moderate bleeding and too little data to calculate the rate of severe bleeding. Sensitivity analyses that removed one outlying study did not differ significantly from the main analyses.

**Authors’ conclusions**

The type of current used for electrosurgery made no significant difference to the rate of pancreatitis but pure current, as compared with mixed current, was associated with more episodes of primarily mild bleeding. There were insufficient data to assess the risk of perforation.

**CRD commentary**

This review answered a clear review question and made some attempts to reduce the risk of review bias and error when extracting the data and assessing its quality. However, there is a risk of publication bias as only published peer-reviewed studies were eligible for inclusion in the review. The quality of the data was assessed but, since no details of the assessment were provided, it is difficult to determine the reliability of individual study data.

Differences between the studies were also assessed statistically and clinically, although little data were reported. One study was excluded in sensitivity analyses as an outlier, but little attempt was made to investigate or describe the possible effects of differences between the studies. The authors appear to have pooled each intervention arm separately and then compared the two pooled arms, thereby cancelling out the benefits of randomisation and suggesting that the analyses are not reliable. Given the flaws in the analysis, the limited number of small studies and the presence of heterogeneity, the findings of this review may not be reliable.

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

The authors did not state any implications for practice or further research.

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