Systematic review of intraoperative ablation for the treatment of atrial fibrillation

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CRD summary
This review assessed the efficacy and safety of intra-operative surgical ablation in the treatment of atrial fibrillation. The authors concluded that intra-operative ablation is at least as effective as surgery alone or the Maze-III procedure. The lack of evidence from randomised controlled trials and the poor quality of the available evidence justify the limited conclusions; however, some of the review methods were unclear.

Authors’ objectives
To assess the safety and efficacy of intra-operative ablation techniques for the treatment of atrial fibrillation (AF).

Searching
MEDLINE, EMBASE, the Cochrane Library, the Science Citation Index, ClinicalTrials.gov, the NHS Centre for Reviews and Dissemination and Health Technology Assessment databases, the National Research Register, the National Institute of Health and meta Register of Controlled Trials were searched from inception to January 2004; the search terms were reported. No language restrictions were applied, but foreign language papers were not translated unless they appeared to contain significantly different or more extensive results than those reported in English language papers. Online abstracts from relevant conferences (listed) were also searched, as were the reference lists of all publications retrieved.

Study selection
Study designs of evaluations included in the review
Randomised controlled trials (RCTs), historical and/or non-randomised comparative studies, case series and case reports were eligible for inclusion.

Specific interventions included in the review
Studies of intra-operative ablation using cryotherapy, radiofrequency, microwave or laser energy were eligible for inclusion. Operations involved median sternotomy with cardiopulmonary bypass performed as either a concomitant or lone procedure. Procedures using video or robotic assistance were excluded. Eligible comparator interventions were surgical treatment, including isolated surgery or the Maze-III procedure (surgical ablation), and medical management of AF. Studies of the Maze-III procedure (where the comparator was not intra-operative ablation) were also included to provide a benchmark indirect comparison.

Participants included in the review
Studies of participants aged over 18 years with AF were eligible for inclusion. Most of the participants in the included studies were middle-aged or older.

Outcomes assessed in the review
Studies were eligible if they reported on peri- and post-operative mortality or morbidity; patient factors such as operation time, length of intensive care unit stay, reoperation and readmission; outcomes related to convalescence; or costs and resource use. The primary efficacy outcome was return to normal heart rhythm (sinus rhythm).

How were decisions on the relevance of primary studies made?
Two reviewers independently assessed papers for relevance.

Assessment of study quality
Study quality was assessed on a number of criteria, including: quality of study methodology reporting; randomisation and allocation concealment (RCTs); blinding of the patients or outcome assessors; attempts to minimise bias;
appropriate sample size; losses to follow-up; generalisability of results; and statistical methods used.

The authors did not state how many reviewers performed the quality assessment.

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

Extensive data on study populations, interventions and results were tabulated in the text and appendices. Relative risks (RRs) and 95% confidence intervals (CIs) were calculated for some dichotomous outcomes in RCTs. For non-randomised studies, median values were calculated for sets of comparable interventions.

**Methods of synthesis**

How were the studies combined?
The studies were combined in a narrative. The results for different types of ablation (cryotherapy, radiofrequency and microwave) and study designs were considered separately. Left atrial and biatrial ablation were also considered separately.

How were differences between studies investigated?
Differences between the studies were discussed in the text.

**Results of the review**

Sixty-nine studies were included in the review: 2 RCTs (n=73), 26 non-randomised comparative studies (n=4,224) and 41 case series (n=1,975).

The included studies mostly provided poor-quality evidence and differed in the type of ablation and the specific lesion pattern, thereby limiting the ability to draw conclusions from them.

In general, conversion to normal sinus rhythm was greater with intra-operative ablation than with cardiac surgery alone. In RCTs, the RRs for being in sinus rhythm after intra-operative ablation compared with cardiac surgery alone were 3.82 (95% CI: 1.35, 10.81) after 12 months in one study of radiofrequency ablation and 3.24 (95% CI: 1.09, 9.65) after 3 months in a study of microwave ablation. Across all included studies, conversion to sinus rhythm at the end of follow-up was at least 68% for all ablation types.

There were no consistent differences in efficacy between intra-operative cryotherapy ablation and the Maze-III procedure, and there was insufficient evidence to compare other energy sources with Maze-III. The addition of ablation significantly increased cardiopulmonary bypass and cross-clamping times compared with surgery alone. There were no consistent differences in mortality when ablation was compared with cardiac surgery alone or the Maze-III procedure. There did not appear to be any greater risk of bleeding with cryoablation or radiofrequency ablation compared with cardiac surgery alone. There was insufficient evidence to draw any conclusions about incidence of stroke. Small numbers of cases of oesophageal perforation and circumflex artery stenosis were reported in patients undergoing intra-operative ablation. There were no studies that compared intra-operative ablation with medical management of AF.

**Authors’ conclusions**

Intra-operative ablation is at least as efficacious as cardiac surgery alone or the Maze-III procedure. There was insufficient evidence to determine the relative safety of intra-operative ablation compared with surgery alone or the Maze-III procedure.

**CRD commentary**

This review addressed a clear question and the inclusion and exclusion criteria were clear. The authors searched a wide range of sources without language restrictions, thereby minimising the risk of missing relevant published studies.
However, foreign language papers were not translated unless their results differed from those of the English language papers, which raises the risk of language bias in the review. There was no systematic attempt to locate unpublished studies. Measures were taken to reduce the risk of bias and errors during study selection (use of two independent reviewers), but the methods used for quality assessment and data extraction were not reported. Study quality was assessed using standard criteria and full details of the included and excluded studies were provided. The narrative synthesis was appropriate in view of the heterogeneity of the included studies, and better quality evidence was given more weight. The authors' main conclusions are in line with the evidence presented, and appeared appropriately cautious in view of the lack of RCT evidence and low evidence quality of the available studies.

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

Practice: The authors did not state any implications for practice.

Research: The authors stated that an RCT of intra-operative ablation against cardiac surgery alone, designed and powered to measure long-term survival and stroke incidence, is required. The authors also stated that further studies are required to determine which lesion sets and energy sources provide the best safety and efficacy for intra-operative catheter ablation. Future studies should also assess the risk of stroke and other thromboembolisms, quality of life, exercise tolerance and cost-effectiveness.

**Bibliographic details**


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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.