Meta-analysis of clinical outcomes of maze-related surgical procedures for medically refractory atrial fibrillation

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CRD summary
This review concluded that weak evidence supports a reduction in stroke rates, but an increase in need for pacemakers, amongst patients with medically refractory atrial fibrillation receiving a simultaneous maze procedure alongside mitral valve surgery compared with mitral valve surgery alone. The authors’ cautious conclusions appear to follow from the evidence presented; however additional relevant studies might have been missed.

Authors’ objectives
To assess whether a simultaneous maze procedure reduces the risk of stroke, death, post-operative bleeding or need for pacemaker in patients with chronic or paroxysmal atrial fibrillation (AF) who receive mitral valve surgery.

Searching
MEDLINE was searched up to June 2004 for articles reported in the English language; the search terms were not reported. The bibliographies of articles were checked for other relevant studies.

Study selection
Study designs of evaluations included in the review
Controlled trials were eligible for inclusion.

Specific interventions included in the review
Studies that compared the maze procedure (including variants with different incision patterns and energy sources) combined with mitral valve surgery to mitral valve surgery alone were eligible for inclusion. The specific maze procedures used in the included studies were Cox-maze I, Cox-maze II, Cox-maze III, modified Cox-maze III with electrocoagulation, radiofrequency modified maze, radiofrequency Cox-maze II, radiofrequency Cox-maze III, radiofrequency modified Cox-maze III and Kosakai maze.

Participants included in the review
Studies of patients with medically refractory AF were eligible for inclusion. Where reported, the average age of the participants in the included studies ranged from 40.6 to 69.7 years, and the average duration of AF ranged from 2.7 to 58 years. The majority of patients in most studies had permanent AF.

Outcomes assessed in the review
The primary outcomes of interest were stroke and mortality following the maze procedure. The secondary outcomes of interest included sinus rhythm restoration, need for permanent pacemaker and post-operative bleeding.

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
Study quality was assessed on the basis of the following criteria: the similarity of the test and control groups of each study at baseline in terms of risk of death during surgery; adequate adjustment for potential confounding; attrition accounted for; and consistency of follow-up times between groups.

Two reviewers independently performed the quality assessment. Any disagreements were resolved by discussion and consensus was achieved. Studies that were deemed to show a greater potential for biased results were included in the meta-analysis if the evidence showed an effect that was in the opposite direction to that expected based on the quality...
assessment, or if the outcome was considered independent of the patient's baseline risk.

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

Effect sizes were calculated using Cohen's h measure of effect.

**Methods of synthesis**

**How were the studies combined?**
The studies were combined statistically using a fixed-effect model.

**How were differences between studies investigated?**
Heterogeneity was assessed using the Q statistic and the I-squared statistic. Sensitivity analyses were performed by removing each study in turn to determine the effect of the study on the summary result, by conducting random-effects meta-analyses, and by repeating the original meta-analysis using Hedges d effect size measure instead of Cohen's h.

**Results of the review**

Four randomised controlled trials (RCTs; n=152) and 6 retrospective comparative studies (n=756) were included in the review.

In only 4 of the 10 studies were the patient characteristics deemed similar between groups at baseline in terms of risk of death during surgery. Adequate adjustment for potential confounding was made in 6 studies. Attrition was accounted for, and follow-up times were consistent between groups in all studies.

There was no statistically significant difference in mortality between patients receiving the maze procedure combined with mitral valve surgery and those receiving mitral valve surgery alone (8.4% versus 5.8%; 4 RCTs).

The stroke rate was statistically significantly reduced in the maze group compared with the control group (0% versus 5.8%; effect size 0.44, 95% confidence interval, CI: 0.12, 0.77, p=0.008; 4 RCTs). The sensitivity analysis in which one study was removed from the analysis reduced the difference to a non significant level.

Sinus rhythm restoration was statistically significantly higher in the maze group compared with the control group (80.7% versus 17.3%; effect size 1.39, 95% CI: 1.06, 1.71, p<0.000001; 4 RCTs).

The need for pacemaker following surgery was statistically significantly higher in the maze group compared with the control group (3.9% versus 1.5%; effect size -0.16, 95% CI: -0.29, -0.02, p=0.02; 10 studies). The sensitivity analysis using Hedges d statistic rather than Cohen's h reduced the difference to a non significant level.

The post-operative bleeding rate of maze with surgical incisions was statistically significantly higher than that for mitral valve surgery alone (4.3% versus 0%; effect size -0.41, 95% CI: -0.71, -0.11, p=0.007; 3 studies). The sensitivity analysis in which one study was removed from the analysis reduced the difference to a non significant level. The bleeding rate did not differ between radiofrequency maze and mitral valve surgery alone (1.9% versus 2.9%; 5 studies).

None of the meta-analyses showed statistically significant heterogeneity, and for all outcomes the results of fixed-effect and random effects meta-analyses did not differ.

**Authors' conclusions**

There was weak evidence to support a reduction in stroke rates, but an increase in need for pacemakers, amongst patients receiving the maze procedure over mitral valve surgery alone. Radiofrequency maze may avoid an excess risk of post-operative bleeding associated with maze incisions. However, the evidence suffered from several methodological shortcomings, particularly small sample sizes and selection bias. Larger well-designed RCTs are needed.
CRD commentary

The review question was clear in terms of the study designs, interventions, participants and outcomes of interest. The search for studies was restricted to only one electronic database and handsearching bibliographies; therefore, relevant studies might have been missed. No attempts were made to identify unpublished studies and only English language studies were included, thus increasing the potential for publication and language biases. The authors did not state the procedures for selecting studies or extracting data, so the potential for reviewer error or bias cannot be assessed. Two reviewers independently assessed the quality of the included studies, thereby reducing the potential for bias in this procedure. The quality assessment criteria used were adequate.

Adequate details of the included studies were reported. Appropriate measures of effect were calculated and statistical heterogeneity was assessed and sensitivity analyses performed. The authors’ cautious conclusions appear to follow from the evidence presented; however, additional relevant studies might have been missed.

Implications of the review for practice and research

Practice: The authors stated that experienced heart surgeons should continue treating medically refractory AF when feasible simultaneously with mitral valve surgery.

Research: The authors stated that larger, longer term RCTs are required to confirm their findings and to investigate survival and quality of life. They also stated that the results should be adjusted for patient risks and surgeon’s protocol for anticoagulation and anti-arrhythmic medication.

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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.