Comparison of the efficacy of cooled-tip and 8-mm-tip catheters for radiofrequency catheter ablation of the cavotricuspid isthmus: a meta-analysis

CRD summary
The authors of this review concluded that cooled-tip and 8-mm-tip catheters are equally effective and safe for catheter ablation. Review limitations included incomplete reporting of review methods and the lack of an assessment of study quality. In addition, the review provided evidence of no statistically significant difference between cooled-tip and 8-mm-tip catheters rather than equivalence of the two interventions.

Authors' objectives
To compare the safety and efficacy of 8-mm-tip catheters and cooled-tip radiofrequency ablation (cRFA) catheters for cavotricuspid isthmus (CTI) ablation in patients with atrial flutter (AFL).

Searching
MEDLINE (from 1967), EMBASE (from 1974), Current Contents (from 1967) and CardLine (from 1986) were searched to April 2004; the search terms were not reported. In addition, abstracts presented at four relevant named association meetings from 1994 were screened, reference lists in reviews and trials were scanned, and colleagues, investigators and manufacturers of ablation catheters were contacted for details of missing or unpublished studies.

Study selection
Study designs of evaluations included in the review
Randomised controlled open trials (RCTs) were eligible for inclusion. Four studies provided long-term follow-up data (mean 11.5 months).

Specific interventions included in the review
Studies that compared 8-mm-tip catheters with cRFA were eligible for inclusion.

Participants included in the review
Studies of patients undergoing AFL ablation were eligible for inclusion. All participants in the included studies were adults undergoing a first AFL RFA who had electrocardiographic and electrophysiological confirmation of AFL. Where reported, the mean age of the participants ranged from 61 to 69 years and most of the participants were male (78% to 89%).

Outcomes assessed in the review
Studies that assessed primary success, 'number of application in minutes', X-ray exposure and procedure duration were eligible for inclusion. Primary success was defined as complete bi-directional block (BIB) achievement. The review assessed primary intent success and intention-to-treat success, as well as the long-term recurrence of AFL.

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 did not state that they assessed validity. However, they did report on the baseline comparability of the treatment groups with respect to some patient characteristics.

Data extraction
Three reviewers independently extracted the data and resolved any disagreements through consensus. The number of events of interest and the mean values of outcome measures were extracted for each treatment group. Where required, authors were contacted for missing data.

**Methods of synthesis**

How were the studies combined?
The pooled relative risk (RR) with 95% confidence interval (CI) or pooled weighted mean difference (WMD) with 95% CI were calculated. The type of model (fixed or random) was determined by the presence or absence of heterogeneity. A value of 0.5 was attributed to treatment groups with zero events.

How were differences between studies investigated?
Statistical heterogeneity was assessed using the I-squared statistic and other unreported methods.

**Results of the review**

Seven RCTs (n=603) were included.

In all studies, treatment groups were comparable at baseline with respect to age, gender and, where reported, the proportion of patients with pre-existing structural heart disease.

There were no significant differences between groups treated using 8-mm and cRFA with respect to:

- BIB achievement with the primary intent catheter (84% versus 85%; RR 0.96, 95% CI: 0.92, 1.01; I-squared 3%),
- BIB achievement in intention-to-treat analysis after crossover (99.4% versus 99.7%),
- total radiofrequency application time (13.2 versus 12.5 minutes; WMD 0.88, 95% CI: -0.36, 2.12; heterogeneity p=0.76),
- X-ray exposure time (21 versus 18.9 minutes; WMD 1.07, 95% CI: -0.81, 2.95; heterogeneity p=0.45), and
- the duration of the ablation procedure (82.2 versus 81 minutes; WMD 0.68, 95% CI: -3.37, 4.73; heterogeneity p=0.07).

Statistically significant heterogeneity was only found for the analysis of duration of ablation procedure.

Long-term recurrence rates of AFL were similar (2.3% versus 1.6%; based on 4 RCTs).

**Authors’ conclusions**

Cooled-tip and 8-mm-tip catheters are equally effective and safe for cardiotricuspid isthmus ablation in patients with AFL.

**CRD commentary**

The review question was clear in terms of the study design, participants, intervention and outcomes. Several relevant sources were searched and attempts were made to identify unpublished studies, thus minimising the possibility of publication bias. The search strategy was not reported in full and no attempts to minimise language bias were reported. Methods were used to minimise reviewer errors and bias in the extraction of data, but it was unclear whether similar steps were taken at the study selection stage. Only RCTs were included but study validity was not assessed, thus the results from these studies and any synthesis may not be reliable.

Statistical heterogeneity was assessed, although the methods used were not reported in full; it appears that studies were generally appropriately pooled in meta-analyses. In the one meta-analysis where heterogeneity was found, there was no investigation of potential sources of heterogeneity. The reporting of review methods was incomplete and study quality
was not adequately assessed; this made it difficult to assess the reliability of results. In addition, the review provided evidence of no statistically significant difference between cooled-tip and 8-mm-tip ablation catheters rather than equivalence of the two interventions.

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

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

Research: The authors stated that further studies are required to determine whether there are differences between catheters in terms of success rates in subgroups.

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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.