

Methodological issues in a systematic review of a rapidly developing intervention: catheter ablation for atrial fibrillation (AF)

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Background

Curative catheter ablation for the treatment of cardiac arrhythmias involves the percutaneous insertion of catheters which are guided by fluoroscopy to the heart. Small areas of tissue responsible for the propagation of abnormal electrical activity through the heart are destroyed (ablated) using radiofrequency or another energy source to restore normal sinus rhythm.

Use of radiofrequency catheter ablation (RFCA) in AF has expanded rapidly over the last 5 years. Technical aspects of RFCA continue to evolve such that the clinical studies represent experience with many variations in equipment and technique. Our objective was to establish whether RFCA is effective as a curative treatment for AF.

Methods

We conducted a systematic review of studies of RFCA in patients with AF, searching 19 databases. Included studies were:

- randomised (RCTs) and non-randomised controlled trials comparing RFCA with alternative treatment strategies.
- case series of RFCA of at least 100 patients.
- RCTs comparing techniques of RFCA. To capture the data on efficacy of RFCA from these trials, they were treated as case series.

The primary outcome was freedom from arrhythmia at 12 months. We synthesised clinical trial and case series data separately.

Quality assessment

- An 18-item checklist was used to assess the quality of the included studies.
- All 18 items were applicable to controlled studies.
- A subgroup of eight items was applicable to case series.
- Depending upon which specific quality criteria were met and the subsequent potential for bias, controlled studies could receive an overall quality rating of 'poor', 'satisfactory', 'good' or 'excellent' and case series could be rated as 'poor', 'satisfactory', or 'good'.

Results

After screening over 4800 abstracts and 482 full papers, we identified seven clinical trials comparing RFCA with alternative treatments and 42 uncontrolled case series. There were 11 trials comparing ablation techniques. Five of the seven controlled studies were rated as 'good' or 'satisfactory', but 48 out of 53 case series (including trials comparing ablation techniques) were rated 'poor' (Figure 1), mainly because of lack of reporting of follow-up.

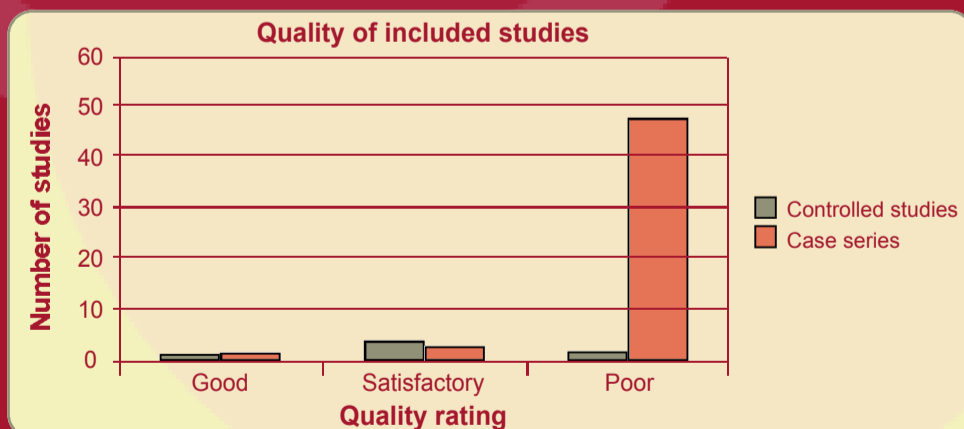


Figure 1. Quality ratings of included studies

Freedom from arrhythmia at 12 month follow-up

Three RCTs (298 patients) provided evidence that at 12 month follow-up RFCA is more effective than long-term anti-arrhythmic drug (AAD) therapy in patients with drug-refractory AF.

In these RCTs the rates of freedom from arrhythmia at 12 month follow-up achieved with RFCA were 79%, 88% and 86%.

Freedom from arrhythmia at 12 months in case series (where reported) ranged from 28% to 85.3% with a weighted mean of 76%.

The Galbraith plot (Figure 2), which gives a graphical representation of the homogeneity of the estimates of effect, indicates that the estimates derived from case series are not systematically different from those derived from RCTs.

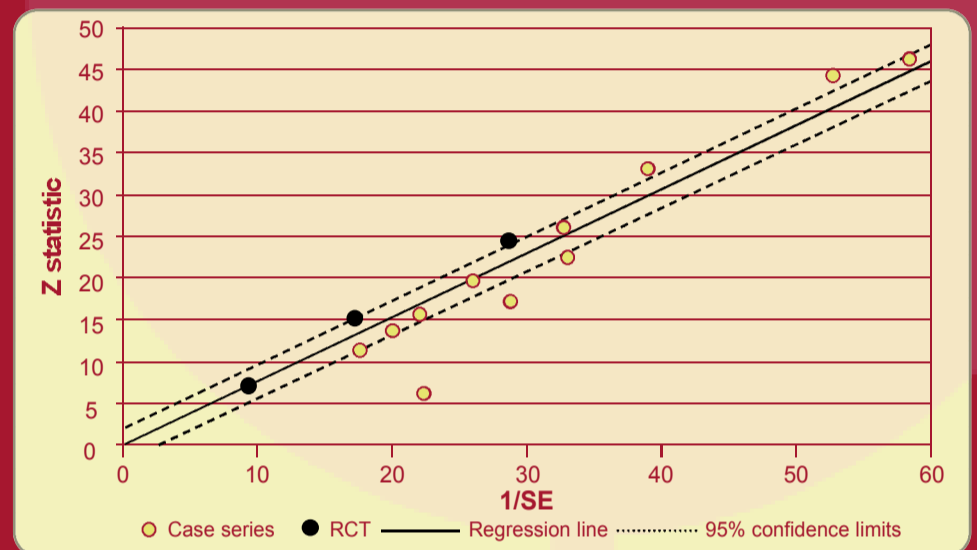


Figure 2. Galbraith plot for freedom from arrhythmia at 12 months in RCTs and case series of RFCA for AF

Discussion

- RFCA for AF is a relatively new and evolving intervention characterised by a large number of uncontrolled studies and few randomised trials.
- It was necessary to include both randomised and uncontrolled studies in this review to reflect the range of available evidence and ensure the clinical credibility of the review.
- The case series represent the bulk of the evidence for the effectiveness of curative RFCA for AF in clinical practice.
- The findings from the case series reflect and support those from the RCTs.
- Success rates in case series were lower than those in RCTs, suggesting that the case series may better reflect outcomes achievable in clinical practice. However, it must be noted that a high percentage of the series come from a number of 'pioneering centres' that have specialised in RFCA and so may not be any more generalisable to routine practice elsewhere than are the RCTs.
- The case series had longer follow-up than the RCTs and provided greater numbers of events for assessing safety.
- Some centres have published multiple case series covering overlapping time periods and it is likely that some patients were counted more than once in the included series.
- Quality assessment of uncontrolled studies is problematic. We used criteria derived from those used in earlier reviews.^{1, 2} We have not searched systematically for other scales but development of validated quality assessment tools for uncontrolled studies may be an interesting area for research.
- Unanswered questions include whether good rates of freedom from arrhythmia can be achieved in routine practice at non-pioneering centres and identification of the optimal technique for RFCA in AF.

References

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