Atrial flutter ablation: efficacy and cost-effectiveness of a single decapolar electrode to demonstrate bidirectional isthmus block


Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

Health technology
The use of a single decapolar catheter electrode, deployed in the anterolateral and inferior part of the right atrium, to map the flutter circuit and to detect bidirectional isthmus block during atrial flutter ablation. This intervention was compared with a "Halo" catheter.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients referred to hospital for radiofrequency ablation of atrial flutter. All patients had clinically documented classical anti-clockwise or clockwise rotation atrial flutter.

Setting
The study setting was secondary care. The economic analysis was undertaken at the Cardiothoracic Centre, Guy's & St. Thomas' Hospital, London, UK.

Dates to which data relate
The dates to which the effectiveness data related were not reported. The price year was not reported.

Source of effectiveness data
The effectiveness data were derived from a single study.

Link between effectiveness and cost data
The costing was undertaken prospectively on the same patient sample as that used in the effectiveness study.

Study sample
No power calculations to determine the sample size were reported. In addition, no specific sample size was determined in the planning phase of the study. Thirty-six consecutive patients were referred to the authors' centre for radiofrequency ablation. Twenty-four patients (12 males) were studied using a decapolar electrode, while in 12 patients (7 males) a Halo catheter was placed in the right atrium. The mean age of the patients was 50 (+/- 16) years in the electrode group and 40 (+/- 13) years in the Halo group. One patient in the Halo group did not proceed to atrial flutter ablation because of the presence of sustained atrial fibrillation. Therefore, 35 patients were studied.
Study design
This was a randomised controlled trial that was carried out at the Cardiothoracic Centre, Guy's & St. Thomas' Hospital, London. The patients were randomly assigned on the basis of a 2:1 ratio (two patients to decapolar electrode to one to the Halo catheter). The duration of follow-up was 8 (+/- 4) months in the decapolar electrode group and 5 (+/- 2.3) months in the Halo group. The authors quoted no loss to follow-up.

Analysis of effectiveness
The analysis of the clinical study was conducted on the basis of treatment completers only. The outcomes used were:

- the number of radiofrequency ablation applications;
- the procedure and fluoroscopy time;
- the number of patients where bidirectional isthmus block was completed;
- the number of patients with incomplete isthmus block;
- the success rate; and
- the recurrence of atrial flutter.

When ablation was performed during the arrhythmia, the successful target was determined as the termination of atrial flutter followed by demonstration of bidirectional isthmus block. The groups were shown to be comparable in terms of age, gender, presence of heart disease, type of atrial flutter, and the number of arrhythmic drugs used before ablation.

Effectiveness results
The number of radiofrequency ablation applications was 34 (+/- 23) in the electrode decapolar group versus 34 (+/- 31) in the Halo group, (p=0.89).

The procedure time was 107 (+/- 36) minutes in the electrode decapolar group versus 114 (+/- 65) minutes in the Halo group, (p=0.62).

The fluoroscopy time was 27 (+/- 47) minutes in the electrode decapolar group versus 14 (+/- 19) in the Halo group, (p=0.14).

Bidirectional isthmus block was completed in 22 patients of the electrode decapolar group and in 9 patients of the Halo group, (p=0.37).

Incomplete isthmus block was detected in 2 patients of each group, (p=0.37).

The success rate was 92% (22 out of 24) for the electrode decapolar procedure and 82% (9 out of 11) for the Halo procedure, (p=0.37).

Recurrence of atrial flutter occurred in 3 of the 24 patients (12.5%) in the electrode decapolar group, and in 2 of the 11 patients (18%) in the Halo group, (p=0.51).

Clinical conclusions
The study showed that a single decapolar electrode deployed in the anterolateral and low right atrium was equally as effective as the Halo catheter in mapping the flutter circuit, and in demonstrating bidirectional isthmus block during atrial flutter ablation.
Measure of benefits used in the economic analysis
No summary measure of benefit was derived. The study was, in effect, a cost-consequences analysis.

Direct costs
The direct costs to the hospital were included in the analysis. The only costs included were those of the two catheters. Prices for these were derived from the current price, including value added tax, in the UK. Discounting was not relevant, as all the costs were incurred during a very short time, and was not performed. The study reported the average costs. The price year was not reported. The authors also estimated the expected cost implications in a low-volume (approximately 50 cases/year), medium-volume (approximately 150 cases/year) and high-volume (approximately 300 cases/year) electrophysiology centre, assuming that 30% of the cases were atrial flutter.

Statistical analysis of costs
The costs were treated as point estimates (i.e. the data were deterministic).

Indirect Costs
The indirect costs were not included.

Currency
UK pound sterling (£) and US dollars ($).

Sensitivity analysis
No sensitivity analyses were carried out.

Estimated benefits used in the economic analysis
See the 'Effectiveness Results' section.

Cost results
The current price in the UK for the decapolar electrode with its connector was 358 (£572), whilst that of the Halo catheter with its two connectors was 1,507 (£2,411). In the medium- and high-volume electrophysiology centre, the annual savings of using a decapolar catheter instead of a Halo catheter were approximately $75,000 (medium-volume) and $160,000 (high-volume), respectively.

Synthesis of costs and benefits
The costs and benefits were not combined.

Authors’ conclusions
The decapolar catheter electrode is a reliable, easily deployed alternative to the routinely used Halo catheter. Its use would confer a very substantial cost-saving if electrophysiological practice were to change from the use of a Halo catheter to a decapolar electrode.

CRD COMMENTARY - Selection of comparators
A justification was given for using the Halo catheter as the comparator. It represented current practice. You should decide if this is a widely used health technology in your own setting.
Validity of estimate of measure of effectiveness
The analysis was based on a randomised controlled trial. This was appropriate for the study question as well-conducted randomised controlled trials are the ‘gold’ standard study design when comparing health interventions. However, randomisation does not appear to have been conducted in a purely random concealed fashion, as consecutive patients were allocated on the basis of a 2:1 ratio (two patients to decapolar electrode to one to the Halo catheter), which could lead to selection bias. The patient groups were shown to be comparable in terms of age, gender and prognostic features. The study sample was representative of the study population. However, the study sample was very small and all the outcome differences between the two groups were not statistically significant. It would appear that the study was underpowered to detect any differences.

Validity of estimate of measure of benefit
The authors did not derive a summary measure of health benefit. The analysis was, in effect, a cost-consequences analysis.

Validity of estimate of costs
Only the costs of the catheters were included in the analysis. It is unclear if the inclusion of any other costs would have affected the authors' conclusions. The prices were derived from the current UK prices. No sensitivity analysis of the prices was conducted. Discounting was unnecessary since all the costs were incurred during a very short time. The authors presented the costs in both pounds sterling and US dollars. The dates to which the prices related were not reported, which will hamper any possible inflation exercises.

Other issues
The authors made appropriate comparisons of the findings with those from other studies that found similar results. The issue of generalisability to other settings was not addressed. The authors commented that the results on cost-savings only applied to the UK, as reimbursement systems are different in other European countries and in the USA. The authors do not appear to have presented their results selectively. However, with such a small study sample, further study to determine whether both catheters are equally effective seems warranted, as reported in the study. The authors reported several further limitations to their study. In particular, that misinterpretation of bidirectional isthmus block due to a significant intra-atrial conduction delay at the low right atrium could not be excluded. The authors also could not rule out asymptomatic partial or full late recovery of conduction in the inferior vena cava-tricuspid annulus isthmus.

Implications of the study
From the authors’ results and conclusions, they appear to recommend the use of a single decapolar electrode to demonstrate bidirectional isthmus block.

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