Catheter ablation for atrial fibrillation on uninterrupted warfarin: can it be done without echo guidance?

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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.

CRD summary
This study examined the costs and effectiveness of catheter ablation, without intracardiac echocardiography, for adults with atrial fibrillation, who were on uninterrupted warfarin. The authors concluded that uninterrupted warfarin was effective and safe, with fewer bleeding complications, compared with bridging low-molecular weight heparin. The methods and results were mostly clear and comprehensive, but the unclear quality of the data and some limitations in the analysis, mean that the conclusions reached by the authors are uncertain.

Type of economic evaluation
Cost-effectiveness analysis

Study objective
The aim was to examine the costs and effectiveness of catheter ablation, without intracardiac echocardiography, for adult patients with first-time or repeated atrial fibrillation, who were on uninterrupted warfarin.

Interventions
The two anticoagulation options, for patients undergoing catheter ablation for atrial fibrillation, were bridging low-molecular weight heparin (LMWH) and uninterrupted warfarin. Bridging with LMWH involved stopping warfarin five days before the procedure and self-administering subcutaneous injections of LMWH (enoxaparin 1.5mg per kg) once daily for four days. This was the most common anticoagulation protocol. The uninterrupted warfarin was continued throughout the time around the procedure, including the evening before ablation.

Location/setting
UK/secondary care.

Methods
Analytical approach:
A prospective single-centre study provided the clinical and resource evidence. The analytic time frame was from treatment to four-to-six weeks after discharge. The authors did not report the perspective.

Effectiveness data:
The effectiveness data were from a prospective study, with a before-and-after design. A total of 198 patients were consecutively enrolled in the study, with the first 109 allocated to bridging LMWH and the next 89 allocated to uninterrupted warfarin. A questionnaire was completed by telephone four-to-six weeks after discharge. The baseline characteristics were mostly balanced across groups, except for higher creatinine levels and a higher proportion of hypertension in the bridging LMWH group. An intention-to-treat analysis was conducted, using the Student’s t-test and chi-square tests, where appropriate. The key clinical outcome was a composite of the major and minor bleeding complications, which were defined. Strokes or transient ischaemic attacks were recorded. Outcomes were collected prospectively by regularly inspecting the access site and by transthoracic echocardiography at the end of treatment.

Monetary benefit and utility valuations:
Not relevant.

Measure of benefit:
The measure of benefit was any bleeding complication (major or minor).

Cost data:
The direct medical costs included medications and hospitalisations. Local pharmacy prices were used for drug costs, and local tariffs were used for hospital unit costs. The resource quantities were those accrued by the study participants. All costs were reported in US dollars ($).

Analysis of uncertainty:
None reported.

Results
In patients who received LMWH, 85 (78%) had a bleeding complication, which was significantly (p=0.001) higher than the 50 (56%) patients who received uninterrupted warfarin. No significant differences were found for major complications and stroke. There were significantly (p=0.001) more patients with minor complications in the LMWH group 84 (77%) than in the uninterrupted warfarin group 49 (55%), which was due solely to access-site pain.

The average drug cost was $64.77 (SD 31.86) for LMWH and $20.76 (SD 15.00) for warfarin (p=0.005). In the LMWH group, compared with the expected average days, an additional 16 bed days were accrued to treat bleeding complications and an additional nine bed days were accrued in the uninterrupted warfarin group. The mean cost per patient was $883.96 (SD 278.78) for LMWH and $816.59 (SD 182.72) for uninterrupted warfarin (p=0.06).

Authors’ conclusions
The authors concluded that catheter ablation for atrial fibrillation, using uninterrupted warfarin without intracardiac echocardiography, was effective and safe, with fewer bleeding complications, compared with bridging LMWH, and a low risk of stroke.

CRD commentary
Interventions:
The two strategies were well described, including the catheter ablation procedure and devices used. The comparators might be relevant in other settings.

Effectiveness/benefits:
The evidence for the clinical effectiveness of the two options was from a single-centre observational study that might be open to bias from a lack of blind assessment and randomisation. The results of this clinical study were clearly and fully reported. The clinical effects were superior for minor bleeding complications, but this was access-site pain only and it affected few patients, making the differential significance tenuous. The authors noted that bleeding complications resulted in increased patient discomfort and morbidity; quality-adjusted life-years might have been more appropriate as a measure of benefit, to include this morbidity in the analysis.

Costs:
The perspective was not stated, but a hospital perspective appears to have been taken. The resource types included medications and hospitalisations for catheter ablation, but the details of these resources were not described, making it unclear if all the relevant items were included. The price year was not stated and it was unclear if the costs were adjusted for inflation. The costs were from UK sources, but a currency conversion from UK pounds sterling to US dollars was not reported.

Analysis and results:
The health outcomes and costs were not combined into incremental cost-effectiveness ratios and a cost-consequences analysis was performed. Confidence intervals were provided, which allowed the statistical significance of the results to be determined, but sensitivity analyses would have allowed the impact of uncertainty in the data estimates on the final results to be assessed.

Concluding remarks:
The methods and results were mostly clear and comprehensive, but the unclear quality of the data and some limitations...
in the analysis mean that the conclusions reached by the authors are uncertain.

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