Electroanatomic versus fluoroscopic mapping for catheter ablation procedures: a prospective randomized study

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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.

Health technology
Two alternative catheter ablation procedures for patients with cardiac arrhythmias were studied. The two procedures were routine electroanatomic imaging (CARTO) and conventional fluoroscopically guided activation mapping.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients with arrhythmia diagnoses of paroxysmal supraventricular tachycardia, (pSVT), atrial flutter (AFL), focal atrial tachycardia (AT), Wolff-Parkinson-White syndrome (WPW) and ventricular tachycardia (VT). Patients undergoing complete AV nodal ablation were excluded.

Setting
The setting was a hospital. The economic study was conducted in the UK.

Dates to which data relate
The dates to which the effectiveness and resource use referred were not reported. The price year was not reported.

Source of effectiveness data
The effectiveness evidence was derived from a single study.

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

Study sample
Power calculations were not reported. A sample of 102 consecutive eligible patients was identified at the study hospital. There were 47 patients in the CARTO group and 55 patients in the conventional group. Overall, the mean age of the sample was 48 (+/- 16) years (age range: 17 - 76). There were 50 male and 52 female patients. It was not stated whether some patients refused to participate or were excluded for any reason from the study sample.

Study design
This was a prospective, randomised clinical trial that was performed at a single centre, the Bart's and The London NHS Trust in London. The patients' allocation to the study groups was obtained using a computer-generated random number immediately before starting the procedure. The length of follow-up was not reported. No patient was lost to the follow-up assessment.

**Analysis of effectiveness**
The analysis of the clinical study appears to have been conducted on an intention to treat basis. The outcomes used were:

- the duration of the procedure (i.e. time from entering to leaving the catheterisation laboratory),
- acute success (i.e. achievement of the end point),
- the rate of complications,
- the rate of asymptomatic follow-up (patients who did not experience recurrence of their symptoms and no electrocardiographic evidence of tachycardia or accessory pathway recurrence),
- fluoroscopy time,
- radiation dose, and
- the number of catheters used.

The baseline comparability of the study groups was not discussed.

**Effectiveness results**
For the whole sample of patients (regardless of type of arrhythmia), the procedure lasted 144 (+/- 58) minutes with CARTO and 125 (+/- 58) minutes with the conventional procedure, (p=0.07).

The rate of acute success was 91% with CARTO versus 93% with the conventional procedure, (p>0.5).

The rate of complications was 2.1% with CARTO versus 1.8% with the conventional procedure, (p>0.5).

The rate of asymptomatic follow-up was 84% with CARTO versus 94% with the conventional procedure, (p>0.5).

Fluoroscopy time was 9.3 (+/- 7.6) minutes with CARTO versus 28.8 (+/- 19.5) minutes with the conventional procedure, (p<0.001).

The radiation dose was 6.2 (+/- 6.1) Gray with CARTO versus 20.8 (+/- 32.7) Gray with the conventional procedure, (p<0.01).

The number of catheters used was 2.5 (+/- 0.7) with CARTO versus 4.4 (+/- 1.1) with the conventional procedure, (p<0.001).

Similar conclusions were reached when the patients were grouped according to the type of arrhythmia, (pSVT, WPW, AFL, AT, or VT). However, owing to the very small sample size, the differences did not reach statistical significance in the sub-group of VT.

**Clinical conclusions**
The effectiveness analysis showed that CARTO and the conventional procedure had a similar efficacy and safety profile. However, radiation dose, fluoroscopy time, and the number of catheters used were significantly lower in the CARTO group.
Measure of benefits used in the economic analysis
The health outcomes were left disaggregated and no summary benefit measure was used in the economic analysis. In effect, a cost-consequences analysis was conducted.

Direct costs
Discounting was not relevant since the costs were incurred during a short timeframe. The cost analysis considered only the cost of the catheter. The cost/resource boundary of the study appears to have been that of the hospital. The catheter costs were calculated in units, based on the actual purchase price, where one unit was the cost of a non-steerable quadripolar catheter. The quantities of resources used were derived from actual patient-level data derived from the sample of patients who were included in the effectiveness study. The price year was not reported.

Statistical analysis of costs
Student's unpaired t-test was used to test the statistical significance of differences in the estimated costs.

Indirect Costs
The indirect costs were not considered.

Currency
No currency was used as the costs were presented in units.

Sensitivity analysis
Sensitivity analyses were not carried out

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

Cost results
The catheter costs were 13.8 (+/- 2.2) units with CARTO and 9.3 (+/- 2) with the conventional procedure, (p<0.001). Similar results were observed in the sub-groups of patients.

Synthesis of costs and benefits
A synthesis of costs and benefits was not relevant since a cost-consequences analysis was conducted.

Authors' conclusions
The routine use of electroanatomic imaging (CARTO) for the radiofrequency ablation of cardiac arrhythmias was as effective and safe as the conventional approach. CARTO reduced catheter use and radiation exposure, but led to a significant increase in catheter costs as more expensive catheters were required.

CRD COMMENTARY - Selection of comparators
The choice of the comparators was appropriate since a conventional approach was compared with a newer strategy for catheter ablation. Both approaches were satisfactorily described for each type of arrhythmia. You should decide whether this is a valid comparator in your own setting.

Validity of estimate of measure of effectiveness
The effectiveness evidence came from a clinical trial, which was appropriate for the study question. The randomisation procedure reduced the impact of potential confounding factors, although the baseline comparability of the study groups was not discussed. The evidence came from a single centre and it was unclear whether the study sample was representative of the patient population. The analysis of the clinical study appears to have been conducted on an intention to treat basis. The length of follow-up was not reported. Power calculations were not reported and the study could have been underpowered to detect statistically significant differences in the outcome measures. This issue was even more apparent in the sub-group analyses. These issues tend to limit the internal validity of the analysis.

**Validity of estimate of measure of benefit**
No summary benefit measure was used in the analysis because a cost-consequences analysis was conducted.

**Validity of estimate of costs**
The authors did not state explicitly the perspective adopted in the study and only the catheter costs were included in the analysis. The source of the data was reported and the costs were presented in units based on actual purchase prices. The cheapest catheter was attributed a cost of 1 unit. The price year was not reported, which makes reflaction exercises in other settings difficult. The cost estimates were specific to the study setting and no sensitivity analyses were conducted. Statistical tests were performed when the costs were compared. The authors stated that a comprehensive cost comparison of the two approaches was not attempted, owing to the substantial variations in both the capital and disposable costs.

**Other issues**
The authors did not make extensive comparisons of their findings with those from other studies. They also did not address the issue of the generalisability of the study results to other settings. Sensitivity analyses were not conducted, which further reduced the external validity of the analysis. The authors stated that whether the reduction in fluoroscopy time associated with CARTO was of clinical importance was a debatable issue. The impact of increasing experience of the system was considered in the study. Some potential disadvantages of the CARTO approach were also considered.

**Implications of the study**
The study results suggested that, in a wide variety of arrhythmias, CARTO has similar procedural duration, success and complication rates to a conventional fluoroscopically guided approach. However, CARTO is associated with less radiation exposure. Such a result is particularly relevant for both patients and health care workers.

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**Other publications of related interest**


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