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Radiofrequency ablation of arrhythmias guided by non-fluoroscopic catheter location: a prospective randomized trial

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KEYWORDS
Arrhythmia;
Catheter ablation;
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Mapping

Aims To compare the utility of non-fluoroscopic mapping systems (Carto and Ensite NavX) with that of conventional mapping in patients referred for catheter ablation of a wide variety of arrhythmias.
Methods and results Patients referred for catheter ablation (excluding atrial fibrillation, atypical atrial flutter, ventricular tachycardia in structural heart disease, and complete AV nodal ablation) were randomized equally to a procedure guided by Carto, Ensite NavX, or conventional mapping. A total of 145 patients were recruited (82 men, aged 49 $\pm$ 16, range 18–85). In 19 patients, no ablation was performed, and in the remaining, typical atrial flutter, atrioventricular nodal re-entrant tachycardia, and atrioventricular re-entrant tachycardias [including Wolff–Parkinson–White (WPW)] accounted for 93% of ablations. Overall procedure time, immediate and short-term success, complication rate, and freedom from symptoms at follow-up were identical for all groups. NavX led to the least X-ray exposure: Navx vs. conventional, median (range): 4 (0–50) vs. 13 (2–46) min ($P < 0.001$); NavX vs. Carto, median (range): 4 (0–50) vs. 6 (1–55) min ($P = 0.008$). Both Carto and NavX increased disposable costs by 50% when compared with conventional ($P < 0.001$). For typical atrial flutter, Carto and NavX reduced screening times without increasing procedure cost. If ablation was not performed, NavX was twice as expensive as Carto or conventional.
Conclusion Ensite NavX and Carto procedures have similar effectiveness and safety to a conventional approach; however, they both reduce X-ray exposure, with NavX producing a significantly greater effect than Carto. Although this benefit is achieved at a greater financial cost, there may be long-term benefits to catheter laboratory staff.

Introduction

X-ray during catheter ablation is associated with an increased lifetime risk of malignancy and all possible measures should be taken to minimize exposure.[1,2] Non-fluoroscopic mapping technology has been of great value in the ablation of complex arrhythmias such as atrial fibrillation, atypical atrial flutter, and ventricular tachycardia; however, their effectiveness has not been demonstrated for more straightforward cases.[3] Location of the ablation catheter using magnetic fields (electro-anatomic mapping, Carto™, Biosense Webster, Diamond Bar, CA, USA) reduces radiation exposure.[4,5] This technology allows the construction of a three-dimensional geometry to guide catheter navigation and ablation lesion placement; however, it is not possible to visualize all the catheters used. This is possible, however, when the catheters are located by electrical fields (LocaLisa™, Medtronic Inc., Minneapolis, MN, USA), which has also demonstrated reduced screening times.[6,7]

A further technology, Ensite NavX™ (St Jude Medical, St Paul, MN, USA), combines the ability to locate all catheters non-fluoroscopically and, if necessary, construct a three-dimensional geometry. Although the utility of NavX has been demonstrated in specific arrhythmias,[8,9] there are no data comparing it against Carto or in a wide variety of arrhythmias.

The aim of this prospective randomized study was to compare routine use of Ensite NavX and Carto with that of conventional fluoroscopically guided catheter localization in patients referred for catheter ablation.

Methods

Patients

Patients referred to two attending cardiac electrophysiologists at our institution for catheter ablation were invited to participate in this study. Those patients in whom it was perceived that ablation

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of the arrhythmia would definitely benefit from a non-fluoroscopic mapping system (atrial fibrillation, atypical atrial flutter, or ventricular tachycardia with structural heart disease) or definitely not benefit (complete AV node ablation) were excluded. An independent, third party used a computerized random-number generator to create 150 assignments to conventional, Carto, or Ensite NavX mapping, which were then enclosed in sequentially numbered, opaque envelopes. The investigator did not open the envelope until written informed consent (approved by the local Ethics Committee) had been obtained from the patient. All patients were seen as an outpatient ~6 weeks following their procedure.

Electrophysiology and ablation procedure

The diagnoses of Wolff–Parkinson–White (WPW), typical atrial flutter, and ventricular tachycardia were known prior to the procedure from ECG analysis. The remaining tachycardias were grouped as paroxysmal supraventricular tachycardias (PSVTs), which comprised atrioventricular nodal re-entrant tachycardia (AVNRT), atrioventricular re-entry tachycardia (AVRT) via a concealed accessory pathway, and a few cases of atrial tachycardia. The general approach used for PSVT, WPW, and typical atrial flutter for each of the mapping techniques is described subsequently in detail. Fluoroscopy was performed with a GE Innova 2000 digital fluoroscopy unit with flat plate detector (GE Healthcare, Chalfont St Giles, UK) from which the anti-scatter grid was removed. We used settings that led to the minimum fluoroscopy dose compatible with adequate imaging. A Bard EP recording system was used for all procedures (CR Bard Inc., Billerica, MA, USA). Percutaneous access for all catheters was via the femoral veins.

Paroxysmal supraventricular tachycardia

Conventional and NavX

Guided by X-ray or the NavX locator, quadripolar catheters were positioned in the high right atrium and right ventricular apex (*Figure 1*). A decapolar catheter was placed in the coronary sinus and either a quadripolar or decapolar catheter was positioned across the His bundle. Programmed ventricular and atrial stimulation was performed in order to determine tachycardia mechanism, and if tachycardia was induced, an ablation catheter was taken.

Carto

If there had been no documented arrhythmia prior to the procedure, a diagnostic electrophysiological study was performed using two or three quadripolar catheters to ensure that tachycardia could be induced before applying the reference locator patch and opening the ablation catheter. If tachycardia was previously documented, only a quadripolar pacing/reference catheter was positioned in the right ventricle. An electro-anatomic mapping/ablation catheter was used to delineate the His bundle, tricuspid annulus, and coronary sinus. Atrial activation mapping around the tricuspid annulus and coronary sinus was performed during steady-state ventricular pacing. If the earliest retrograde activation was at the site of the His bundle, anterograde conduction was examined with the pacing/reference catheter in the high right atrium and the mapping catheter across the His bundle to detect the characteristic onset of AVNRT. Activation mapping during tachycardia confirmed the diagnosis (*Figure 1*).

Ablation

Radiofrequency energy was delivered via a 4 mm tip catheter (Celsius™ or Navistar, Biosense Webster) at the site of earliest atrial activation in the case of AVRT and at the slow pathway in the case of AVNRT. When using Carto or NavX, markers were left at ablation sites, which was useful in difficult cases as it provided a three dimensional map of unsuccessful sites and allowed navigation of the catheter to new sites for ablation. The endpoint for ablation of a concealed accessory pathway was either VA block

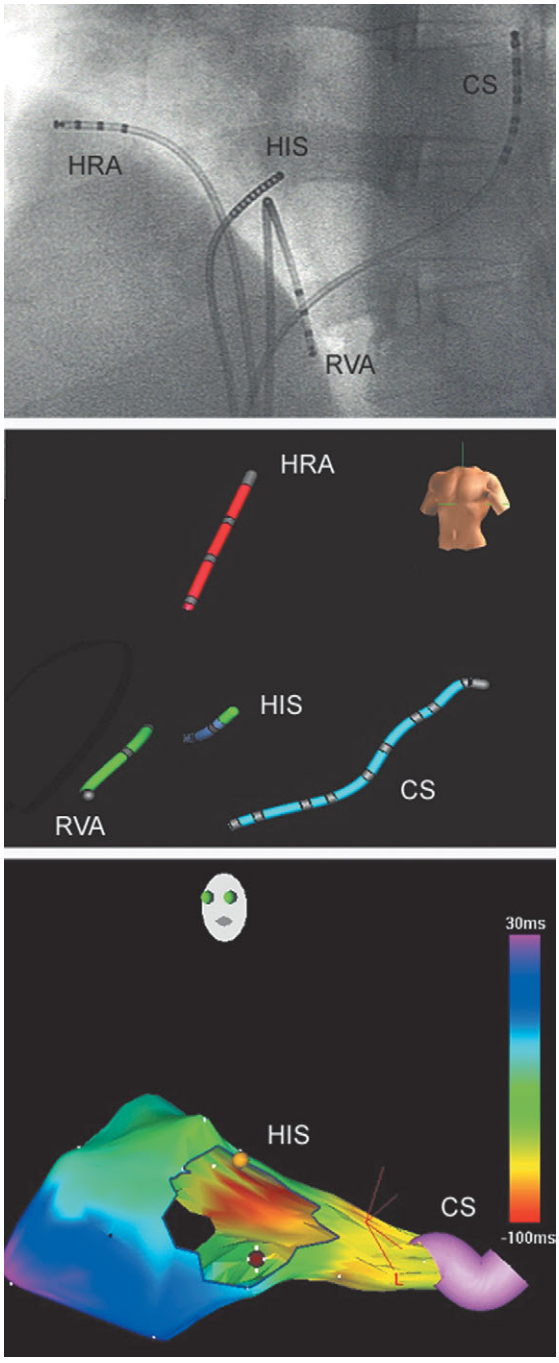

Figure 1 Displaying the use of the three different catheter location systems for mapping PSVT, all viewed from the LAO perspective. The top figure demonstrates the four diagnostic catheters positioned under fluoroscopic guidance for conventional mapping. A narrow spaced decapolar catheter is positioned at the His bundle and a wide spaced decapolar catheter in the coronary sinus. In the middle figure, the same four catheters have been positioned under Ensite NavX guidance except that a quadripolar catheter is at the His bundle. In the lower figure, an electro-anatomic (Carto) ablation catheter has been used to delineate the His bundle (orange sphere), tricuspid annulus, and coronary sinus (pink tube) during pacing from the right ventricular apex. An endocardial geometry has been created in which the colours represent local atrial activation time after the ventricular pacing spike (the colour key on the right displays the timings). The earliest atrial activation can be seen at the superior tricuspid valve annulus close to the His bundle (fast pathway), consistent with normal retrograde atrial activation. This patient found to have atrioventricular re-entrant nodal tachycardia and a successful ablation (red sphere) was applied at the inferior tricuspid valve annulus (slow pathway). HRA, high right atrium; RVA, right ventricular apex; CS, coronary sinus.

or normalization of retrograde activation with decremental conduction, earliest activation at the His bundle and VA block after administration of adenosine. The endpoint for slow pathway ablation was either slow pathway block or a single atrial echo beat where AVNRT previously had been sustained.

WPW syndrome

Conventional

The same four diagnostic catheters were used as for PSVT. Programmed ventricular and atrial stimulation was performed in order to maximize pre-excitation and to localize the accessory pathway.

NavX

A quadripolar catheter was placed in the right atrium and standard mapping catheter guided by the locator signal was moved around the tricuspid annulus and coronary sinus to locate the earliest ventricular activation either during sinus rhythm or during atrial pacing to maximize pre-excitation.

Carto

A quadripolar pacing/reference catheter was placed in the right atrium. A Navistar electro-anatomic mapping/ablation catheter was used to delineate the His bundle, tricuspid annulus, and coronary sinus. Ventricular activation mapping around the tricuspid annulus and coronary sinus was performed during steady-state atrial pacing to maximize pre-excitation.

Ablation

Left free-wall accessory pathways were mapped on the mitral annulus via a transseptal or retrograde aortic approach. Radiofrequency energy was delivered via a 4 mm tip catheter at the site of earliest ventricular activation. The endpoint was loss of pre-excitation with AV and VA block following the administration of adenosine.

Typical atrial flutter

Conventional

A quadripolar catheter was placed in the proximal coronary sinus and a duodecapolar catheter around the tricuspid annulus.

NavX

A cutaneous patch was used as a positional reference for the majority of cases unless creation of a chamber geometry was necessary for completion of the ablation procedure in which cases a screw in temporary pacing wire was laced in the right atrium. The system reference has no significant influence on any of the results. A quadripolar catheter was positioned in the proximal coronary sinus and the mapping catheter was positioned at the His bundle. Three-dimensional labels were placed at the sites of the two catheters to delineate the position of the His and coronary sinus and to indicate whether the coronary sinus catheter had displaced. Following ablation, bidirectional isthmus conduction block was confirmed by pacing from either the coronary sinus or low lateral right atrium and by mapping activation around the tricuspid annulus. Activation timings were displayed as 3D labels to confirm the expected activation pattern if isthmus block was present.

Carto

An electro-anatomic mapping/ablation catheter was used to delineate the tricuspid annulus, inferior vena cava, and His bundle. If the patient was in atrial flutter, an activation map around the tricuspid annulus was used to confirm typical atrial flutter. Following ablation, bidirectional isthmus conduction block was confirmed by activation mapping around the tricuspid annulus during coronary sinus and low lateral right atrial pacing.

Ablation

A deflectable saline-irrigated tip catheter (Celsius™ or Navistar Thermocool, Biosense Webster) was positioned at the ventricular end of the cavo-tricuspid isthmus and either serial or continuous radiofrequency energy was delivered as the catheter was withdrawn into the inferior vena cava. If Carto or NavX was used, a series of ablation markers were created on the three-dimensional map when there was attenuation of the local electrogram recorded on the ablation catheter. This series of markers helped produce a straight-line of ablation and revealed potential gaps in the desired line of conduction block. Ablation was performed during either atrial flutter or coronary sinus pacing. In either case, the desired endpoint of bidirectional isthmus conduction block was confirmed by coronary sinus and low lateral right atrial pacing.

Data collection and study endpoints

All data were collected prospectively. At follow-up, further data were added to the same data set. If patients did not attend for their scheduled follow-up, they were telephoned and, if this failed, their family doctor was contacted in order to establish the patient's current level of symptoms and whether there had been a recurrence.

Procedural endpoints

(I) Fluoroscopy time: total duration of fluoroscopy during procedure (minutes).
(II) Radiation dose: calculated dose area product (DAP) to the patient (Gy cm^2).
(III) Procedure duration: time from entering to leaving the catheterization laboratory (minutes).
(IV) Procedural success: achievement of the endpoint described earlier for each arrhythmia if ablation attempted.
(V) Complications: important complications are reported individually.
(VI) Number of catheters: total number of catheters (ablation or diagnostic) used.
(VII) Cost of catheters used in procedure: calculated in units, where one unit equals the price of a quadripolar diagnostic catheter. Costs include the locator 'patch set' for Ensite NavX and the reference patch catheter for Carto if used. Costs are based on company published UK list prices (*Table 1*).

6 week follow-up endpoints

(I) Incidence of recurrence: documented ECG of the index arrhythmia for which they were referred or re-induction of this arrhythmia during a follow-up electrophysiology procedure (%).
(II) Freedom from symptoms: freedom from symptoms related to previous arrhythmia (%). Patients who had symptoms consistent with atrial ectopy only were considered symptom-free.

Table 1 Unit cost of each catheter based on company published UK list price

Catheter	Unit cost
Quadripolar diagnostic	1.0
Decapolar diagnostic	2.0
Duodecapolar diagnostic	6.7
4 mm tip RF	4.0
Irrigated RF	6.5
Navistar 4 mm	7.1
Navistar irrigated RF	8.3
Carto reference patch	4.0
NavX location patches	4.0

RF, radiofrequency.

Risk of fatal malignancy

Using median values of the X-ray DAP for each of the three different mapping systems in AVNRT, accessory pathways, and typical atrial flutter, we estimated the lifetime risk of malignancy for each system in each arrhythmia. We converted the median DAP into effective dose using the effective dose/DAP coefficients for cardiac posterior anterior (PA), 30° left anterior oblique (LAO), and 45° right anterior oblique (RAO) views at 80 kV as described by Hart *et al.*[10] The distribution of screening time between each of the views for the different procedures was taken as: AVRNT PA 20% and RAO 80%; accessory pathways and typical atrial flutter PA 10% and LAO 90%. We assumed the risk of fatal cancer in a 40-year-old adult at one in 25 000 per mSv.

Statistics

All data were analysed using an intention-to-treat analysis. In two patients randomized to Carto, there was equipment failure and their cases were performed using conventional mapping; however, their outcomes were analysed in the Carto group. A Kolmogorov–Smirnov test was performed on continuous variables to examine whether there was a normal distribution, which was true only for patient age. A non-paired Student's *t*-test was used to compare the mean age between each group. All other continuous variables are expressed as median (range) and a Mann–Whitney *U* test to compare between each group in pairs. For categorical data, analysis was performed between each group using the χ^2 test. Statistical analyses were performed using commercially available software (WinSTAT™, R. Fitch Software, Germany). A *P*-value (two tailed) of $<5\%$ was considered significant.

Results

Of a total of 461 electrophysiology cases performed during the study period, 145 patients were randomized (*Table 2* and *Figure 2*). There were no significant differences in any of the baseline or clinical characteristics of the patients in each of the three treatment arms. Of the 316 patients excluded, 146 (46%) underwent an atrial fibrillation or atypical atrial flutter ablation, 22 (7%) ablation of ventricular tachycardia in structural heart disease, and 15 (5%) complete AV node ablation. The remaining 133 (42%) either declined to participate or it was not possible to obtain informed consent prior to the procedure. The electrophysiological diagnoses for which ablation was performed in the study were 42 typical atrial flutter, 40 AVNRT, 35 pathway-related tachycardias (AVRT and WPW), six atrial tachycardia, and three normal heart VT. Typical atrial flutter, accessory pathway-related tachycardias, and AVNRT therefore accounted for over 90% of cases ablated. The study included only a handful of normal heart ventricular tachycardias and atrial tachycardias and no further analyses were performed on these patients. In 19 cases, no ablation was performed. This was because tachycardia could not be induced in 18 cases and pre-excitation was lost during mapping in one.

Table 2 Baseline and clinical characteristics of the study population

	Conventional	Carto	NavX
n	51	49	45
Age	52 ± 15	48 ± 16	47 ± 16
Male/female (*n*)	30/21	29/20	23/22
Structural heart disease (*n*)	12	14	7
Hypertension	2	1	1
Valvar heart disease	1	1	0
Ischaemic	4	6	6
Cardiomyopathy	3	4	0
Congenital	2	2	0
Ablation performed (*n*)	44	43	39
AVNRT	17	10	13
AVRT	12	14	9
Atrial flutter	14	14	14
Other	1	5	3

Of the 126 patients in whom ablation was performed, 120 (95%) attended the follow-up clinic. Of the six patients who did not attend follow-up data was obtained by a telephone call to the patient in three and by contacting their family doctor in the remainder. The overall results are presented in *Table 3*. There were no differences between the three groups for procedure time, procedural success complication rate, and freedom from symptoms at follow-up.

Fluoroscopy time and radiation dose

Fluoroscopy time and radiation dose were dramatically lower in the Carto and NavX groups when compared with the conventional mapping group. Furthermore, the lowest fluoroscopy time and radiation exposure were seen in the NavX group and were significantly lower than in the Carto group. In 27% (12/45) of NavX cases, X-ray was not used throughout the procedure.

Catheter usage and cost

The fewest number of catheters were used in the Carto group; however, the lowest catheter costs occurred in the conventional mapping group. There was no significant difference in cost between Carto and NavX.

Complications

There was one minor complication using NavX which occurred when diagnostic catheters were entangled in the inferior vena cava and had to be freed using fluoroscopic guidance. There was also one complication in the Carto group; however, this was not related to the use of the non-fluoroscopic system. This occurred when a patient had transient ST elevation during a transseptal puncture prior to ablating a left lateral accessory pathway. This was presumed to be caused by an air embolus. There were no complications in the conventional group.

Impact of mapping technique for specific arrhythmias

Figure 3 displays the impact of mapping technique on screening times, procedure times, and costs for the three main arrhythmia groups ablated.

For AVNRT, NavX had a significantly lower screening time: 4 (0–13) min than conventional mapping; 12 (4–38) min ($P < 0.001$) but not Carto 5.5 (2–55) min ($P = 0.06$). Carto procedure times, 115 (75–180) min, were significantly longer than conventional mapping, 75 (60–180), $P = 0.02$. Conventional mapping required the shortest procedure times and was the least expensive.

For pathway-mediated tachycardias (including WPW), conventional mapping required longer screening times,

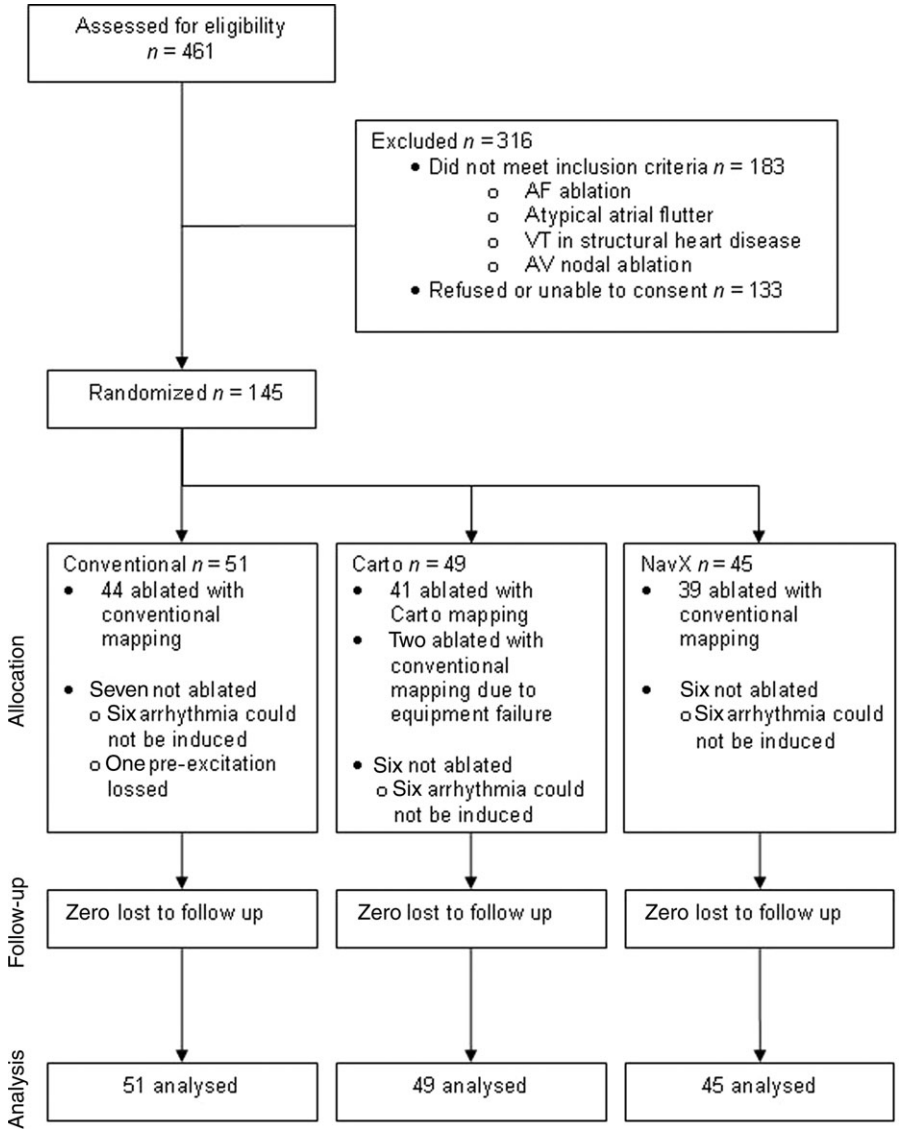

Figure 2 A chart showing the flow of patients through the three arms of the randomized trial.

Table 3 Procedural and 6 week follow-up outcomes for all randomized patients

	Conventional	Carto	NavX	*P*-values		
				Conventional vs. Carto	Conventional vs. NavX	Carto vs. NavX
Procedure						
Duration (min)	90 (25–180)	90 (30–180)	90 (45–200)	0.15	0.23	0.26
X-ray time (min)	13 (2–46)	6 (1–55)	4 (0–50)	<0.001	<0.001	0.006
X-ray dose (Gy cm^2)	12 (1–106)	5 (1–89)	2 (0–54)	0.008	<0.001	0.008
Catheters (*n*)	5 (1–6)	2 (1–6)	4 (2–5)	<0.001	0.016	<0.001
Cost (units)	9 (1–16.9)	12.7 (1–20)	13 (6–21)	<0.001	<0.001	0.07
Acute success, *n* (%)	51 (100)	48 (98)	44 (98)	0.31	0.28	0.95
Complication, *n* (%)	0 (0)	1 (2)	1 (2)	0.31	0.28	0.95
6 week follow-up						
Freedom from index arrhythmia, *n* (%)	47 (92)	42 (86)	39 (87)	0.30	0.38	0.89
Freedom from symptoms, *n* (%)	44 (86)	43 (88)	39 (87)	0.83	0.96	0.87

All continuous numerical data are expressed as median (range) and categorical data as number (%). Significance testing has been performed in pairs between each of or the three treatment groups. A Mann–Whitney *U* test has been used for the continuous data and a χ^2 for the categorical data.

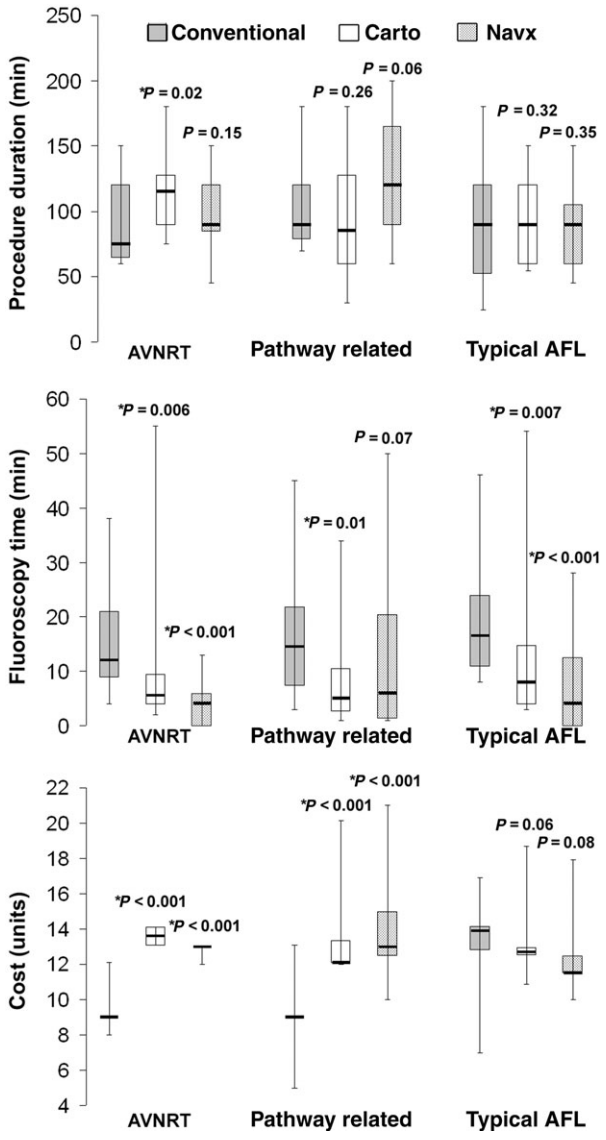

Figure 3 A box and whisker diagram comparing the impact of mapping technique on procedure duration (top), fluoroscopy time (middle), and catheter costs (bottom), for the three principal arrhythmias ablated: AVNRT, pathway-related tachycardia, and typical atrial flutter (AFL). The bold line represents the median value, the box the inter-quartile range, and the whiskers the full range for each group. The *P*-value for Carto and NavX compared with conventional mapping are displayed above the Carto and NavX columns. There were no significant differences between Carto and NavX for any parameter (significance measured using Mann–Whitney *U* test).

14.5 (3–45) min, than Carto 5 (1–34) min ($P = 0.01$) but not NavX 6 (1–50) min ($P = 0.07$); however, it was the least expensive. The procedure times were similar for all technologies. Only for typical atrial flutter, procedure times and costs were similar for all groups; however, both Navx 4 (0–28) min ($P < 0.001$) and Carto 8 (3–54) min ($P = 0.007$) had significantly shorter screening times when compared with conventional mapping 16.5 (8–46) min.

Reduction in risk of malignancy

The estimated lifetime risk of malignancy for each technique for AVNRT and pathway related and typical atrial flutter are presented in *Table 4*. Using our modern imaging equipment, the effective doses and consequently absolute risks are very low. Even for typical atrial flutter using conventional fluoroscopic mapping, the risk is only one in 6600; however, this risk can be halved using Ensite NavX. However, to prevent one fatal malignancy, 13 500 patients would need to have their atrial flutter mapped with NavX rather than conventionally. The fluoroscopy technology used in this study was able to deliver very low radiation doses and the risks in other catheter labs may be higher.

Table 4 Effective doses and lifetime risk of malignancy for each arrhythmia using the different mapping techniques

Effective dose (mSv)	Lifetime risk of malignancy (number of cases per fatality)		
	Conventional	Carto	NavX
AVNRT	2.9 (1:8 700)	2.7 (1:9200)	1.3 (1:18 800)
Accessory pathway mediated	3.0 (1:8 300)	2.5 (1:10 000)	2.2 (1:11 200)
Typical atrial flutter	3.8 (1:6 600)	3.2 (1:7 700)	1.9 (1:12 900)

Discussion

Main findings

The principal findings of this randomized study are that Ensite NavX exposes patients to the least amount of radiation. Carto also reduces fluoroscopy time when compared with conventional mapping, however the effect is smaller. These reductions are achieved without compromising the duration, effectiveness, or safety of the procedure. This benefit however is offset by the greater expense of using these technologies with catheter and disposable costs increased by 50% over conventional mapping.

The most marked reductions in radiation exposure were seen when Ensite NavX was used for AVNRT or typical atrial flutter where 46% (6/13) and 43% (6/14) of cases, respectively, were performed using <2 min fluoroscopy, including the positioning of catheters. Carto reduced fluoroscopy time for AVNRT, accessory pathway-related tachycardias, and typical atrial flutter, consistent with the findings of a previous randomized trial comparing Carto with conventional mapping in unselected cases.[5] Only for the ablation of typical atrial flutter, Carto and NavX were cost neutral because their excess cost is balanced by not using a duodecapolar catheter.

The absolute risk to the individual patient from X-ray exposure is low using a modern X-ray system, which has been optimized to produce the lowest doses compatible with adequate imaging. Any reduction in patient doses however will also reduce the risk to the staff involved in interventional procedures.

Previous studies

Although these non-fluoroscopic technologies are widely used in clinical practice, there has been little objective

assessment of their use. Most of the evidence is from studies looking at specific arrhythmia, particularly typical atrial flutter. Two randomized trials of 80 and 50 patients with typical atrial flutter have demonstrated that Carto used significantly less screening when compared with conventional mapping: 3.9 vs. 22 and 7.7 vs. 29.2 min.[4,11] In another trial of 40 patients using NavX, a comparable reduction was found (24.9 vs. 5.1 min).[9] These results are similar to our subset of 42 typical atrial flutter patients. The only other randomized study demonstrated that in 20 patients with AVNRT, Carto reduced X-ray exposure from 15.9 to 4.2 min.[12] In our own laboratory, we have previously demonstrated across a wide variety of arrhythmias that Carto drastically reduces the need for screening when compared with the conventional approach.[5] Our current study is the first randomized, controlled trial to compare the utility of these technologies in typical, catheter ablation cases.

Limitations of the study

The study was designed to look at a wide range of typical cases admitted for catheter ablation. Consequently, when the results of three technologies on individual arrhythmias were analysed, the numbers in each group were smaller, thus the power of this study to demonstrate differences between Carto and NavX was reduced. Our approach to conventional electrophysiological mapping is to use four diagnostic catheters for PSVT and a duodecapolar catheter for typical atrial flutter. It is possible to use less or different catheters for these procedures and this should be taken into account when reviewing cost implications for any other institution.

Conclusions

When considering catheter ablation of the commonly ablated SVTs (i.e. AVNRT, AVRT, WPW, and typical atrial flutter), Ensite NavX and Carto have similar effectiveness and safety to that found for the conventionally fluoroscopically guided approach. They are likely to be more effective for ablation of complex arrhythmia but this was not examined in this study. Both techniques however reduce X-ray exposure, with NavX producing a significantly greater effect than Carto. Although this benefit is achieved at a greater cost, there may be long-term benefits to the community and catheter laboratory staff.

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Conflict of interest: R.J.S. is a member of the Speakers Bureau for St Jude Medical and of the Scientific Advisory Board of Biosense Webster. D.J.A. is a member of the Speakers Bureau for St Jude Medical.

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