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Electrical isolation of pulmonary veins in patients with atrial fibrillation: reduction of fluoroscopy exposure and procedure duration by the use of a non-fluoroscopic navigation system (NavX®)

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Aims The aim of the study was to investigate the feasibility of performing segmental pulmonary vein (PV) isolation guided by the NavX® (Endocardial Solutions, St Jude Medical, Inc., St Paul, MN, USA) system without the three-dimensional (3D) geometric reconstruction option and whether the use of NavX system will reduce the radiation exposure and procedure duration.
Methods and results The study included 64 patients with symptomatic paroxysmal or permanent atrial fibrillation, in whom PV isolation was performed using fluoroscopic guidance ($n = 32$) or the NavX system ($n = 32$). Pulmonary vein mapping with a circular mapping catheter allowed the identification and localization of myocardial connections between the PV and the left atrium. PV isolation was performed by radiofrequency ablation of these connections at the atrial aspect of the PV ostium. Primary success rate for isolated PVs did not differ significantly in patients ablated under fluoroscopic guidance vs. those ablated under guidance of NavX system [100/107 PVs (93.5%) vs. 120/124 PV (96.8%; $P =$ n.s.)]. Compared with fluoroscopy guided procedures, NavX-guided procedures showed a significant reduction in the fluoroscopy time (75.8 $\pm$ 24.5 vs. 38.9 $\pm$ 19.3 min, $P < 0.05$), total X-ray exposure (93.2 $\pm$ 51.6 vs. 56.6 $\pm$ 37.9 Gy cm^2, $P = 0.03$), and total procedural time (237.7 $\pm$ 65.4 vs. 188.6 $\pm$ 62.7 min, $P = 0.01$). The mean follow-up was 9.5 $\pm$ 3.0 months. One patient in each group was lost to follow-up. Seven-day Holter monitoring showed that 23 of 31 patients (74.2%) in the NavX-guided group and 21 of 31 patients (67.7%) in the fluoroscopy-guided group were in sinus rhythm ($P = 0.57$).
Conclusion The 3D visualization of the catheters by NavX system allows a rapid and precise visualization of the mapping and ablation catheters at the PV ostia and markedly reduces fluoroscopy time, total X-ray exposure, and procedural duration during PV isolation compared with ablation performed under fluoroscopy guidance.

Introduction

Pulmonary veins (PVs) are a dominant source of triggers that initiate atrial fibrillation (AF) and it has also been suggested that they play a role in the maintenance of this arrhythmia.[1–3] Different ablation techniques have been developed in recent years with satisfactory clinical outcomes.[4–6] Catheter-based PV isolation is commonly performed by recording electrical activity in the PVs using a circular mapping catheter and then delivering ablation energy through a separate catheter that is navigated to proximity with the mapping electrodes.[7–9] This procedure may be laborious, in part, due to the limitations of fluoroscopy in navigating the ablation catheter to being very close to the mapping electrodes of interest. Even with biplane fluoroscopy systems, the exact location of the ablation catheter tip in relation to the mapping catheter may be difficult to determine due to complexity of catheter curve projection in two-dimensional planes. Previous work from our group demonstrated that LocaLisa® (Medtronic Inc., Minneapolis, MN, USA) navigation system significantly reduced radiation exposure time during ablation of common atrial flutter.[10]

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The use of LocaLisa navigation system in segmental PV isolation can significantly reduce fluoroscopy duration compared with the conventional approach.[11,12] EnSite NavX® (Endocardial Solutions, St Jude Medical, Inc., St Paul, MN, USA) is a novel navigation system that measures the local voltage on every standard intra-cardiac electrode and calculates the electrode position in three-dimensional (3D) space. Additionally, the EnSite NavX System labels any individual electrode of each catheter in 3D space. The ability to visualize and label electrodes on both the circular mapping and the ablation catheters may offer a great benefit in ablation procedures. We investigated the feasibility of performing segmental PV isolation by sequential display of the circular mapping catheter in each PV, without reconstruction of left atrium (LA) geometry. Our hypothesis was that the use of the feature of visualization and tracking of catheters without complete 3D geometry reconstruction would reduce the radiation exposure and potentially the procedure time in segmental PV isolation procedures in patients with AF.

Methods

Study population

This study included 64 consecutive patients (58.1 $\pm$ 11.0 years old, 48 were male) referred for radiofrequency (RF) ablation of drug refractory symptomatic AF. The first 32 patients were assigned to PV isolation by conventional fluoroscopic guidance (Group 1, $n = 32$, 2 patients with persistent AF); in the remaining 32 patients, the same ablation approach was carried out under the guidance of EnSite NavX system (Group 2; $n = 32$, 4 patients with persistent AF). The patients had a history of AF for 66.6 $\pm$ 47.8 months and had failed a minimum of two antiarrhythmic drug treatments prior to ablation. Fifty-eight patients (90.6%) had paroxysmal and six (9.4%) had persistent AF. Twenty-two patients had structural heart disease (34.4%). The mean transverse left atrial diameter was 46.8 $\pm$ 7.0 mm and the ventricular fractional shortening was 33.2 $\pm$ 6.8%. All patients provided written informed consent for the study.

Electrophysiological study

All patients had effective anticoagulation for $\geq$1 month with a weekly assessed INR $>$ 2. Transoesophageal echocardiography was performed prior to ablation to exclude left atrial thrombi. Electrophysiological study was performed in the post-absorptive state with conscious sedation. All antiarrhythmic drugs, except amiodarone, were withdrawn five or more half-lives prior to the ablation. Surface electrocardiogram and bipolar endocardial electrograms were continuously monitored and stored on optical disc for off-line analysis (Bard EP Division, Lowell, MA, USA). Intracardiac electrograms were filtered from 30 to 500 Hz and recorded at a speed of 100 mm/s.

Electrical isolation of PV

Pulmonary vein isolation was performed as previously described.[13] In brief, a steerable octapolar catheter (Bard EP) was positioned in the coronary sinus; a circumferential mapping catheter (Lasso, Biosense Webster, Diamond Bar, CA, USA, 10 poles or Orbiter PV, Bard EP, 14 poles) was introduced following transseptal access and stabilized with the aid of a long sheath (Preface multipurpose, Biosense Webster). Ablation was carried out with a 4 mm open irrigated tip catheter (Celsius thermocool, Biosense Webster). The ablation catheter was manoeuvred towards the PV–LA ostium and in the vicinity of electrode pairs showing PV potentials; discrete LA–PV inputs were targeted by RF energy. Following transseptal access, the activated clotting time was maintained between 280 and 320 s with controls every 30 min. Selective PV angiography was performed before and after ablation by hand injection of a contrast agent.

Pulmonary vein ablation was performed with a target temperature of 48°C, a power limit of 25–35 W with an open irrigated tip catheter and an irrigation rate of 30 mL/min. Left atrium–pulmonary vein inputs were mapped with the circumferential mapping catheter positioned just distally to the PV ostium, which was defined by angiography. To achieve PV isolation, the electrical LA–PV breakthroughs were sequentially ablated. The endpoint of PV ablation was the electrical disconnection of all PVs with elimination or dissociation of PV potentials from the LA. No attempt to map or ablate extra-pulmonary foci was made. If AF persisted, electrical cardioversion was performed for the assessment of the LA–PV conduction block.

Non-fluoroscopic mapping and navigation

The EnSite NavX system is built on the principles of LocaLisa.[14] It creates 3D images of the catheters, based on a low-current electrical field of 350 μA at a frequency of 5.7 kHz, generated by three pairs of nominally orthogonal skin patches in *X*, *Y*, and *Z* axes. The measured voltage and impedance sensed by these catheter electrodes are proportional to the distance of the electrode from the patches, thus allowing calculation of the location of the catheter in 3D space. The potentials are defined with respect to a reference electrode that presents the origin of the coordinate system. The reference may be a surface electrode or an internal fixed electrode such as a coronary sinus catheter electrode. After impedance calibration, the position in space of each electrode can be determined for a wide range of patient body masses (34–115 kg). To control variations related to the cardiac cycle, acquisition can be gated to any electrogram. In the present study, acquisition was gated to peak deflection of the QRS complex. Compensation for respiratory movements was also performed. The respiration motion artefact was measured and subtracted from the measurement or roving electrode position. Minimizing respiratory artefact helps to preserve the true tissue location in the chamber, especially at the PV ostia. In all patients, only catheter location and tracking was visualized, no 3D geometry of heart chambers was performed. The mapping system was also used to record the location of ablation lesions and also for marking a stable position of the circumferential mapping catheter positioned distal to the PV ostia by preserving a 'shadow' position. Because Ensite NavX labels the poles of the circumferential mapping catheter, it is possible to navigate the ablation catheter non-fluoroscopically to the electrode showing the earliest input in the PV.

In the case of PV isolation, NavX System fluoroscopy was primarily used to move the circumferential mapping catheter to the targeted PV. The system allowed precise navigation of the ablation catheter to the labelled pole of the circumferential mapping catheter without the assistance of fluoroscopy. During RF energy delivery, assessment of catheter stability and dragging around the ostium was also performed without the use of fluoroscopy.

Details of follow-up

After discharge, patients were scheduled for repeat visits in the ambulatory arrhythmia clinic of our hospital at 1, 3, 6, and 12 months after ablation. Multislice CT of the PVs was obtained before and 3 months after ablation for detection of possible PV stenosis. Seven-day continuous Holter monitoring was performed at 3-month intervals after ablation procedure to assess the rhythm status and detect asymptomatic fibrillation episodes.

Statistical analysis

Data are expressed as mean ± SD, counts or proportions (%). Univariate comparisons between groups were made by χ^2 test or Fisher's exact test for categorical variables and two-tailed unpaired *t*-test or Mann–Whitney test for continuous variables. A $P < 0.05$ was considered to indicate statistical significance.

Results

The study included a consecutive series of 64 patients with AF; the first 32 patients were ablated by conventional ablation using fluoroscopic guidance alone and the remaining 32 patients were ablated using additional NavX navigation system. The groups were balanced for their demographic and clinical characteristics (*Table 1*).

Ablation was performed in 17 patients (26.6%) during ongoing AF, because repeated external/internal cardioversions failed to restore sinus rhythm. In five patients (7.8%) AF was ongoing during the isolation of at least one PV. In the remaining 42 patients, the PV isolation was performed during stable sinus rhythm. At the end of the procedure, stable sinus rhythm was achieved in 56 patients (87.5%). One patient (1.6%) developed atypical atrial flutter after ablation. Seven patients (10.9%) remained in AF after successful PV isolation despite several cardioversion attempts to restore sinus rhythm.

The procedural characteristics are shown in *Table 2*. In the fluoroscopy-guided group, 107/128 PVs (83.6%) were targeted vs. 124/124 PVs (100%) in the NavX-guided group ($P < 0.01$). This difference was mostly due to the frequency of targeting the right inferior PV. As NavX displays a shadow of the prior mapping catheter position and it allows the re positioning of this catheter after dislocation, the right inferior PV vein could be ablated even without completely stabilizing the mapping catheter. However, in the fluoroscopy-guided group, 100/107 veins (93.5%) were successfully ablated compared with 120/124 PV (96.8%) in the NavX-guided group (P = n.s.).

The mean total fluoroscopy time was 75.8 ± 24.5 min in the fluoroscopy-guided group vs. 38.9 ± 19.3 min in the non-fluoroscopic-guided group ($P < 0.01$). Similarly, total fluoroscopy dosage was 93.2 ± 51.6 Gy cm^2 in the fluoroscopy-guided group vs. 56.6 ± 37.9 Gy cm^2 in the NavX-guided group ($P = 0.03$). Total procedure time (from inserting the first catheter to removing the last catheter) was reduced from 237.7 ± 65.4 min in the fluoroscopy-guided group to 188.6 ± 62.7 min in the NavX-guided group ($P = 0.01$). Thus, all three parameters were significantly reduced in the NavX-guided group compared with respective parameters in the fluoroscopy-guided group.

Complications

In the NavX-guided group, a major stroke occurred in one patient. In this patient, sustained atypical atrial flutter occurred after segmental PV isolation. Electroanatomic mapping (Carto®, Biosense Webster) of newly developed atypical flutter was performed, which resulted in a long-lasting procedure. The stroke was confirmed by brain computerized tomographic angiography to be of embolic nature. We strongly believe that the stroke was not device-related but attributable to the length of the procedure. No other complications were observed in the two groups. A displacement of the reference electrode (CS catheter) occurred in 2 of the 32 NavX-guided studies. The catheter could be repositioned to the previously marked position using NavX catheter navigation, with no impact on the ablation outcome.

Table 1 Demographic and clinical data

Parameter	Fluoroscopy group ($n = 32$)	NavX group ($n = 32$)	*P*-value
Age (years)	57.6 ± 11.5	58.5 ± 10.7	n.s.
Male patients	24/32 (75.0%)	24/32 (75.0%)	n.s.
LA (mm)	47.6 ± 7.3	46.0 ± 6.8	n.s.
FS (%)	32.4 ± 7.2	33.9 ± 6.5	n.s.
Arterial hypertension	15	16	n.s
CAD	6	2	n.s.
DCM	1	0	n.s
Valvular disease	9	4	n.s.
Type of AF			
Paroxysmal	30/32 (93.7 %)	28/32 (87.5 %)	n.s.
Persistent	2/32 (6.3 %)	4/32 (12.5 %)	n.s.
Duration of AF (months)	65.4 ± 48.4	67.9 ± 47.9	n.s

Data are mean ± SD or counts (%). CAD, coronary artery disease; DCM, dilated cardiomyopathy; FS, fractional shortening; LA, left atrium; n.s., not significant.

Table 2 Procedural data

Parameter	Fluoroscopy group ($n = 32$)	NavX group ($n = 32$)	*P*-value
Targeted PVs (%)	107/128 (83,6)	124/124 (100)	<0.01
Successfully isolated PVs (%)	100/107 (93.5)	120/124 (96.8)	n.s.
Fluoroscopy time (min)	75.8 ± 24.5	38.9 ± 19.3	<0.01
Dosage (Gy cm^2)	93.2 ± 51.6	56.6 ± 37.9	0.03
Procedure duration (min)	237.7 ± 65.4	188.6 ± 62.7	0.01

Data are mean ± SD. n.s., not significant.

Follow-up data

The mean follow-up was 9.5 ± 3.0 months (9.0 ± 3.0 months, range 3–12 months, in the NavX-guided group and 10.0 ± 2.9 months, range 3–12 months, in the fluoroscopy-guided group; $P = 0.18$). All but two patients (one patient in the NavX-guided group and one patient in the fluoroscopy-guided group) completed the follow-up period. At the end of this follow-up period, 28 of 31 patients (90.3%) in the NavX-guided group and 27 of 31 patients (87.1%) in the fluoroscopy-guided group reported no symptoms suggestive of AF recurrence during follow-up. Seven-day Holter monitoring showed that 23 of 31 patients (74.2%) in the NavX-guided group and 21 of 31 patients (67.7%) in the fluoroscopy-guided group were in sinus rhythm ($P = 0.57$). Asymptomatic AF episodes occurred in five patients (16.1%) in the group guided by NavX system and six patients (19.3%) in the group guided by conventional fluoroscopy ($P = 0.99$).

Discussion

Catheter ablation has become a well-established therapeutic approach to AF. NavX navigation system has been used to guide PV isolation in patients with AF.

In a recent study by Tondo *et al.*, the NavX system with 3D geometry reconstruction of the LA and the PVs was used to guide PV isolation and for creation of LA linear lesions in patients with persistent AF. The authors demonstrated that NavX system reduced the mean RF delivery and fluoroscopy times. The mean procedural time, however, was longer in the NavX group probably due to the time needed to create the 3D map.[15] Rotter *et al.*[16] demonstrated, in a prospective randomized study for left atrial linear ablation, that using the supplementary non-fluoroscopic imaging system resulted in the reduction of fluoroscopy and procedure duration. In these studies, reconstruction of the left atrial geometry was performed because of the application of the left atrial linear ablation for substrate modification.

Our study presents the first that used NavX for segmental isolation of PVs without reconstruction of LA anatomy. The 3D real-time visualization of the mapping and ablation catheter was a reliable guide to navigation. Using NavX for left atrial geometric reconstruction, we observed that the geometry was pulled in towards the centre and the surface reconstruction was not reliable. Gating to the QRS complex attenuated the effect but could not entirely prevent it. Because of this experience, we did not perform reconstruction of LA geometry and defined the ablation sites based on the location of the mapping catheter images only. In other words, a detailed (anatomical) definition of whole-chamber anatomy is not crucially important for ablation procedures guided by fluoroscopy.

It is noteworthy that NavX technology enables a significant reduction in fluoroscopy time and total procedure duration compared with the conventional-fluoroscopy-based approach. The observed reduction in fluoroscopic exposure obtained was nearly 50%. Indeed, the non-fluoroscopic navigation system allows a real-time assessment of wall contact and catheter stability as well as the assessment of the spatial relationship between ablation and circumferential mapping catheters. The possibility to label the electrodes of the circumferential mapping catheter was extremely helpful for the orientation of the mapping catheter directly to the targeted mapping electrode (*Figure 1*). Because ablation does not interfere with the localization of the catheters, the operator knows in real time the position of the ablation catheter and can reposition it if required. Thanks to these capabilities, catheter displacement and insufficient wall contact are readily recognized without the use of fluoroscopy, resulting in reduction of fluoroscopy and procedure duration. In addition, the feature of acquiring shadows of the circumferential mapping catheter when reaching a stable position in the PV ostia allows repositioning of the catheter without fluoroscopy guidance enabling control of abolition of PV potentials after a waiting period. Pulmonary vein stenosis, a potential complication of AF ablation has been attributed to inadvertent distal dislocation of the catheter, particularly in small diameter PVs. NavX may help to prevent inadvertent ablation inside the PVs because of the continuous real-time monitoring of the catheter position. Further studies with a larger number of patients are needed to prove the advantage of the system.

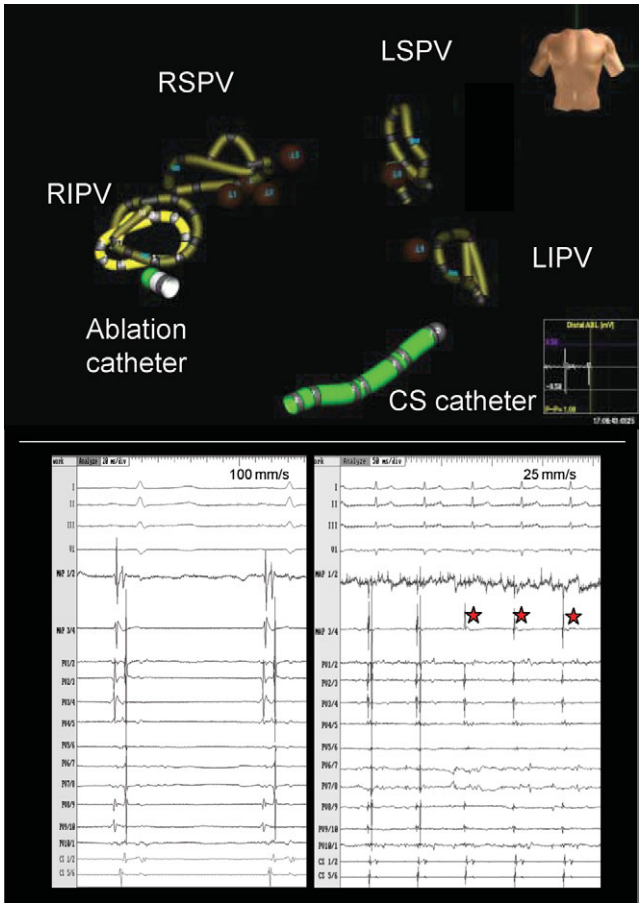

Figure 1 Three-dimensional visualization of a circumferential mapping (yellow), coronary sinus (green), and ablation catheter (white with green tip) in anterior–posterior view: The actual position of the circumferential mapping catheter (bright yellow) is in the right inferior PV and the image demonstrates the labelled electrodes of the catheter. The dark yellow circumferential mapping catheters are shadows registered after reaching a stable position in the PV ostia. The ablation catheter (with electrodes 1 and 2) is seen in perpendicular orientation to the mapping catheter contacting electrode 5. Brown dots show ablation points near PV ostia. In the lower left window, bipolar electrograms are shown from the circumferential mapping catheter, placed in the right inferior PV and bipolar electrograms of the mapping catheter in spatial relationship to pole 5. In the lower right window, asterisk points to the successful elimination of PV potential.

In the NavX-guided group, significantly more PVs were targeted than in the conventional group. In most cases, this was because the right inferior PV ablation in the fluoroscopy-guided group was not performed in cases with unstable position of the mapping catheter. By the use of NavX technology with the feature of taking a 'shadow' of the stable position of the circumferential catheter, repositioning of the catheter after a displacement is much easier than during fluoroscopic guidance. Furthermore, isolation of PVs, in which the mapping catheter cannot be completely stabilized, was enabled which resulted in a higher rate of targeted PVs in the NavX-guided group.

Limitations of the study

This study is not a randomized trial. However, this was a consecutive series of patients who were recruited for the study in a short period of time. The baseline data of the patients were equally distributed between the groups so they are not expected to have influenced the results of the study. Because the patients in the NavX-guided group were included in the study later than patients whose ablation was guided by fluoroscopy, a learning curve effect has to be considered. However, the operators for both procedures have several years experience of PV isolation. Thus, this factor seems not to have had any important influence in the results obtained in the NavX or fluoroscopy-guided PV isolation groups. With EnSite NavX system, the operator should be aware that the impedance detected on the ablation catheter is higher than in conventionally guided procedures. Nevertheless, impedance changes can still be used as markers of inadvertent dislocation inside the PV. Limitations of a technical nature have been seen in other studies.[17,18] In addition, a deformation of the circular mapping catheter shape, potentially reflecting no uniformities in the applied electrical field was observed in our study. This may limit the accuracy of mapping by obscuring the relationship between the circular catheter electrode pairs and the PV ostium.

Conclusion

This study demonstrates the feasibility of the non-fluoroscopic imaging system NavX to guide segmental pulmonary isolation in paroxysmal or persistent AF without 3D geometric reconstruction of LA and PV. The 3D visualization of the catheters by NavX system allows rapid and precise visualization of the mapping and ablation catheters at the PV ostia and markedly reduces fluoroscopy time, total X-ray exposure, and procedural duration during PV isolation compared with ablation performed under fluoroscopic guidance.

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