Pulmonary vein isolation and left atrial catheter ablation using a three-dimensional navigation system for the treatment of atrial fibrillation

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L Macle, P Novak, P Khairy, et al. Pulmonary vein isolation and left atrial catheter ablation using a three-dimensional navigation system for the treatment of atrial fibrillation. *Can J Cardiol* 2009;25(6):e169-e172.

BACKGROUND: Atrial fibrillation (AF) is often triggered by ectopic foci originating from pulmonary veins (PVs), with the posterior left atrium (LA) comprising part of the substrate for maintenance. Catheter ablation strategies targeting PVs and the posterior LA may be further refined by incorporating technology beyond standard fluoroscopy.

OBJECTIVES: To prospectively assess the usefulness of a navigation system to guide a radiofrequency catheter ablation strategy, combining PV isolation (PVI) with anatomical LA ablation.

METHODS: Sixty-four patients (51 men; mean $\pm$ SD] age 52 ± 8 years) who were referred for catheter ablation of paroxysmal ($n=49$) or persistent ($n=15$) AF underwent this ablation strategy using the NavX system (Endocardial Solutions Inc, USA). Electrical PVI was guided by a circular mapping catheter. Anatomical ablation consisted of lines drawn along the posterior aspect of the LA from the superior PVs to the inferior PVs. NavX was used for the construction of three-dimensional LA and PV maps with projection of mapping and ablation catheters on the image in real time and for tracking of lesions during posterior LA ablation.

RESULTS: Electrical PVI was achieved in 100% of procedures and all patients underwent the linear posterior LA ablation described above. Procedural and fluoroscopy times were 188 ± 41 min and 60 ± 12 min, respectively. Repeat procedures for AF recurrence were required in 38 (59%) patients. After a mean follow-up period of 16 ± 10 months, 59 (92%) patients remained arrhythmia-free, including 52 (81%) without antiarrhythmic drugs.

CONCLUSIONS: An AF ablation strategy that combines nonfluoroscopic visualization of catheters with electrical PVI and anatomical LA ablation is feasible, safe and effective, but often requires repeat procedures.

Key Words: Atrial fibrillation; Catheter ablation; Navigation system

L'exclusion de la veine pulmonaire et l'ablation par cathéter d'une fibrillation auriculaire gauche au moyen d'un système de navigation tridimensionnel

HISTORIQUE : La fibrillation auriculaire (FA) est souvent déclenchée par des foyers ectopiques provenant des veines pulmonaires (VP), l'oreillette gauche (OG) postérieure constituant une partie du substrat d'entretien. Il est peut-être possible d'améliorer les stratégies d'ablation par cathéter visant les VP et l'OG postérieure en y intégrant d'autres technologies que la fluoroscopie classique.

OBJECTIFS : Procéder à une évaluation prospective de l'utilité d'un système de navigation pour orienter une stratégie d'ablation par cathéter radioélectrique qui associe l'exclusion des VP (EVP) à l'ablation anatomique de l'OG.

MÉTHODOLOGIES : Soixante-quatre patients (51 hommes; âge moyen $\pm$ ÉT] de 52 ± 8 ans) aiguillés pour subir l'ablation par cathéter d'une FA paroxysmique ($n=49$) ou persistante ($n=15$) ont subi cette stratégie d'ablation au moyen du système NavX (Endocardial Solutions Inc, États-Unis). L'EVP électrique était orientée par un cathéter de cardiographie circulaire. L'ablation anatomique a été effectuée par des lignes dessinées le long de l'aspect postérieur de l'OG entre les VP supérieures et inférieures. Le système NavX a permis de construire des cartes tridimensionnelles de l'OG et des VP avec des projections des cathéters de cartographie et d'ablation sur l'image en temps réel et de repérer les lésions pendant l'ablation de l'OG postérieure.

RÉSULTATS : On a obtenu une EVP électrique dans 100 % des interventions, et tous les patients ont subi l'ablation linéaire de l'OG postérieure décrite ci-dessus. Les durées d'intervention et de fluoroscopie étaient de 188 ± 41 min et de 60 ± 12 min, respectivement. On a dû reprendre l'intervention en raison d'une récurrence de la FA chez 38 patients (59 %). Après un suivi moyen de 16 ± 10 mois, 59 patients (92 %) n'avaient plus d'arythmie, y compris 52 (81 %) qui ne prenaient pas d'antiarythmiques.

CONCLUSIONS : Une stratégie d'ablation de la FA qui associe une visualisation non fluoroscopique des cathéters à une EVP électrique et une ablation anatomique de l'OG est faisable, sécuritaire et efficace, mais exige souvent la reprise des interventions.

The importance of pulmonary vein (PV) ectopics initiating atrial fibrillation (AF) has been the subject of numerous studies in recent years (1,2). Ablation of these triggering foci, while beneficial in the treatment of AF, has been associated with significant recurrence rates (3). The contribution of the posterior left atrium (LA) is increasingly recognized as a source of non-PV triggering foci and as a substrate for maintaining AF. This has led to ablation strategies designed to address both of these mechanisms (3-5).

Targeting these different substrates (PVs and the posterior LA) using only standard fluoroscopy can prove to be cumbersome. In particular, visualizing both circular mapping and ablation catheters in only two dimensions does not provide an accurate view of the spatial

relationship between these catheters and PVs. Furthermore, tracking linear lesions in posterior LA anatomy can be challenging without the help of three-dimensional (3D) mapping. For these reasons, we sought to prospectively evaluate the usefulness of the NavX 3D nonfluoroscopic navigation system (Endocardial Solutions Inc, USA) in guiding a combined AF ablation strategy of PV isolation (PVI) and anatomical posterior LA ablation.

METHODS

Study population

The study population consisted of 64 consecutive patients (51 men; mean $\pm$ SD] age 52 ± 8 years) referred to the Montreal Heart Institute

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Received for publication August 5, 2007. Accepted December 9, 2007

(Montreal, Quebec) for catheter ablation of symptomatic paroxysmal ($n=49$) or persistent ($n=15$) AF. In accordance with the 2006 American Heart Association/American College of Cardiology/European Society of Cardiology guidelines (6), AF was designated as paroxysmal if the arrhythmia terminated spontaneously and was persistent if it sustained beyond seven days. Patients experienced AF a mean of 5.5 ± 5.0 years before ablation, with episodes ranging from 1 h to 157 days (median of 12 h). They had been refractory to a mean of 3.2 ± 0.9 antiarrhythmic drugs, including amiodarone in 34 patients (53%).

Comorbidities included hypertension in 11 patients (17%) and structural heart disease in seven patients (11%). The mean LA dimension was 39 ± 5 mm.

Preprocedure

All patients had documented recurrent AF and underwent a baseline evaluation with a clinical history, physical examination and a transthoracic echocardiogram. After a minimum of four weeks of oral anticoagulation titrated to an international normalized ratio value of 2.0 to 3.0, a transesophageal echocardiogram was systematically performed. In the absence of detected LA thrombus, patients were admitted for ablation.

Nonfluoroscopic navigation system

The NavX nonfluoroscopic 3D mapping and navigation system was used to create a 3D map of the LA, PVs, LA appendage and mitral valve annulus. This system may detect any electrode-tip catheter by sensing a 5.6 kHz low current electrical field generated in the thorax by externally placed electrodes. It has the ability to generate an anatomical map onto which the precise location of up to 64 catheter electrodes in real time may be superimposed. An additional feature includes the acquisition of geometric points from any electrode on any intracardiac catheter. Thus, in the current study, real-time 3D imaging was used to project the catheter location to facilitate mapping and ablation. All ablation lesions were superimposed on the acquired 3D cardiac geometry.

Mapping and ablation

Written informed consent was obtained from all patients and the ablation procedure was performed under conscious sedation. A decapolar catheter (St Jude Medical, USA) was positioned in the coronary sinus for pacing and used as a reference for the NavX system. After obtaining trans-septal access to the LA, all patients received a 5000 U bolus of heparin, accompanied by a continuous infusion to maintain an activated clotting time (ACT) of longer than 250 s. Selective PV angiography was systematically performed to assess vein calibre and help localize the PV ostia. Two catheters were inserted into the LA – an irrigated-tip radiofrequency RF ablation catheter (Thermocool; Biosense Webster, USA) and a circular mapping catheter (Lasso 2515; Biosense Webster, USA).

Cardiac geometry was systematically created by first inserting the circular mapping catheter in all PVs, the LA appendage and the body of the LA. The ablation catheter was then used to delineate the mitral annulus and all PV ostia. If patients were in AF at the time of the procedure, they underwent external electrical cardioversion before ablation. RF energy was delivered in a temperature-controlled mode (temperature limit of 50°C) at 25 W to 35 W. Saline irrigation was set to 2 mL/min for mapping and 20 mL/min during ablation.

Lasso catheter localization within each PV was confirmed in two simultaneous orthogonal views using the NavX system to ensure a position perpendicular to and proximal within the PV (Figure 1). PV potentials were identified on the Lasso catheter. Sites with bipoles showing earliest electrical activation were targeted using NavX to guide positioning of the ablation catheter. Ostial placement of the ablation catheter was reconfirmed with the 3D system before RF energy application. Ablation was performed during distal coronary sinus pacing for left-sided PVs and during sinus rhythm for right-sided PVs. PVI was considered to be acutely successful if all PV potentials were dissociated or entirely abolished.

Following PVI, posterior LA linear ablation was performed. This consisted of continuous delivery of RF, while tagging lesions on the 3D cardiac geometry to create contiguous lines from the superior to the inferior aspects of the PVs, approximately 1 cm from their ostia. The anterior LA-PV junction was not systematically ablated unless required to achieve PVI in the previous step (Figure 2). In the event of a repeat procedure, all conducting PVs were reisolated. In sinus rhythm, if any fractionated electrograms were still present at sites of ablation at the LA-PV junction in the posterior LA, these were targeted as well. At the end of each procedure, PV angiography was repeated to re-evaluate PV diameter.

Postprocedure and follow-up

Warfarin was reinitiated the night of the procedure and subcutaneous low molecular-weight heparin injections were commenced the following day and continued until therapeutic international normalized ratio levels were achieved. Patients were discharged from the hospital the day after the procedure. Antiarrhythmic drugs were discontinued at discharge in patients with paroxysmal AF and two months following ablation in patients with persistent AF.

Arrhythmia recurrence was defined as any episode of AF, atrial tachycardia or atrial flutter exceeding 3 min in duration. Patients were routinely evaluated at three, six and 12 months postprocedure with a clinical assessment, a 12-lead electrocardiogram and a Holter monitor. In case of symptoms suggestive of arrhythmia recurrence, an event recorder was used to confirm the rhythm. Imaging surveillance for PV stenosis was not routinely performed. Anticoagulation was pursued for a minimum of three months following the procedure.

Statistical analysis

Continuous variables are summarized by the mean ($\pm$ SD) or the median and range, depending on the normality of the distribution. Categorical variables are represented by frequencies and percentages. Two group comparisons were performed by χ^2 or Student's *t* tests, where appropriate. Predictors of recurrent AF after one procedure were explored with univariate logistic regression analysis from which ORs and 95% CIs were generated. Characteristics assessed included age, sex, number of antiarrhythmic agents used before the first ablation attempt, amiodarone use, history of hypertension, underlying structural heart disease, time from the first episode of AF, duration of the longest AF episode, and whether AF was paroxysmal or persistent. Two-tailed *P*-values of less than 0.05 were considered to be statistically significant. Analyses were performed with SAS software version 9.1 (SAS Institute Inc, USA).

RESULTS

Procedural data

PVI was acutely successful in all PVs of all patients. A mean of 61 ± 12 min of RF energy delivery was required to isolate all PVs and ablate the posterior LA. The mean procedural and fluoroscopy times were 188 ± 41 min and 60 ± 12 min, respectively.

Repeat ablation

A total of 38 (59%) patients required a repeat ablation procedure for AF recurrence (no recurrence consisted of atrial tachycardia or atrial flutter). Thirty patients underwent two procedures and eight patients underwent three procedures, for a total of 110 procedures. At the time of repeat ablation, all patients had recovered conduction from at least one PV. The only predictor of recurrent AF after a single procedure was the number of antiarrhythmic agents used before ablation (OR 1.9, 95% CI 1.1 to 3.6; $P=0.03$).

Complications

Cardiac tamponade requiring percutaneous pericardiocentesis occurred in one patient during manipulation of the catheters in the LA. No patient suffered a stroke during the study period, although one had a transient ischemic attack with complete resolution. No cases of PV stenosis or atriopharyngeal fistula were identified.

Figure 1 NavX (Endocardial Solutions Inc, USA)-created geometry showing the left atrium, pulmonary veins (PVs) and catheters (ablation, Lasso [Biosense Webster, USA] and coronary sinus). The left panel shows the left superior PV (LSPV) as viewed from the atrium. The Lasso catheter is clearly perpendicular to the vein and ablation catheter contact (green shadow) near Lasso bipole 16-17 can be visualized. The right panel is a simultaneous view in the left anterior oblique projection showing the ablation catheter (green bipoles) and its proximal location at the vein os. LAA Left atrial appendage; MV Mitral valve annulus

Clinical outcome

During a mean follow-up period of 16 ± 10 months after the last procedure, 59 (92%) patients remained arrhythmia-free. Of these patients, 52 (81%) were no longer taking antiarrhythmic agents, whereas seven (11%) required antiarrhythmic drug therapy that had previously been ineffective. There were no significant differences when comparing arrhythmia-free patients with paroxysmal versus persistent AF (46 of 49 patients [94%] versus 13 of 15 patients [87%], respectively; $P=0.61$).

DISCUSSION

The current study assessed the addition of linear lesions to the standard ablation protocol for PVI. Ablation strategies that incorporate LA linear lesions appear to have higher success rates than PVI alone (3-5,7). The technique of performing wider linear ablations in the LA may aid in targeting different substrates that help to maintain or perpetuate AF. However, these techniques can be associated with challenges such as incidence of LA flutter (8) and complications such as atrioesophageal fistula. Furthermore, achieving complete linear block in certain anatomical regions (particularly the mitral isthmus) can be difficult (7). For these reasons, we chose to perform standard PVI complemented by the addition of linear lesions in areas of the LA less likely to present such anatomic impediments and potential complications.

Because PVI remained the cornerstone of the current combined approach, the NavX system, with its ability to show Lasso positioning within the PVs while still allowing for tracking of the linear lesions, seemed best suited to help achieve this goal. Different orthogonal views allow the spatial relationship between the catheters and the LA to be appreciated. Effective positioning of the Lasso (central and perpendicular to the PV, in contact with the vein wall, and as proximal as possible to the LA) is made possible by this system. In addition, by displaying the Lasso electrode numbering on the 3D image, targeting ostial areas with earliest electrical activation is facilitated. Our study could not directly quantify the reduction in fluoroscopy time due to 3D navigation. However, a crude analysis comparing fluoroscopy times in our population with a historical cohort consisting of the 40 preceding patients who underwent PVI procedures at the Montreal Heart Institute revealed significantly shorter fluoroscopy times (60 ± 12 min versus 108 ± 29 min; $P < 0.0001$) in patients with 3D navigation.

In our study population, a significant number of patients required repeat procedures to achieve an arrhythmia-free state. The current study did not randomize patients without linear lesions, thereby precluding comparisons with techniques solely involving PV isolation. Given the concerns regarding potential complications, more extensive posterior LA ablations (as opposed to superior to inferior PV linear lesions alone) were not performed, although this technique

Figure 2) A Posterior view of the left atrium (LA) showing contiguous radiofrequency (RF) lesions superimposed on the three-dimensional cardiac geometry after the posterior LA linear ablation set was performed. **B** Left anterior oblique view of the LA showing RF lesions delivered on the anterior aspect of the LA-pulmonary vein (PV) junction as required for PV isolation in this particular case. CS Coronary sinus; LAA Left atrial appendage; LIPV Left inferior PV; LSPV Left superior PV; MV Mitral valve annulus; RIPV Right inferior PV; RSPV Right superior PV

may potentially increase single-procedure success rates (3-5). Also, alternate ablation strategies such as ablation of complex fractionated atrial electrograms, as described by Nademanee et al (9), in addition to PV isolation, may potentially reduce the need for repeat procedures, but this was not evaluated in our patients. Studies assessing the incremental benefit of combined approaches are currently being performed.

CONCLUSIONS

A combined electrical PVI and anatomical posterior LA ablation using a 3D nonfluoroscopic navigation system is feasible, safe and effective. Although more than one-half of the patients required repeat procedures, after a mean follow-up period of 16 months, 92% of patients remained arrhythmia-free, including 81% without antiarrhythmic drug therapy.

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