Nonfluoroscopic Catheter Navigation for Radiofrequency Catheter Ablation of Supraventricular Tachycardia in Children

JOHN PAPAGIANNIS,* ALEXANDROS TSOUTSINOS,* GEORGE KIRVASSILIS,† IOANNA SOFIANIDOU,† THEOFILI KOISSI,† CLEO LASKARI,* MARIA KIAFFAS,* SOTIRIA APOSTOLOPOULOU,* and SPYRIDON RAMMOS*

From the *Divisions of Pediatric Cardiology and †Pediatric Cardiac Anesthesia, Onassis Cardiac Surgery Center, Athens, Greece

Background: Radiofrequency catheter ablation (RCA) of supraventricular tachycardia (SVT) in children is highly successful but requires exposure to radiation. Nonfluoroscopic mapping systems may significantly reduce fluoroscopy time.

Methods: Forty consecutive pediatric patients who underwent RCA for accessory pathways (AP) or AV nodal reentrant tachycardia (AVNRT) with use of a nonfluoroscopic navigation system (Ensite® NavX®) (group A) were compared retrospectively to 40 consecutive patients with similar diagnoses who underwent RCA with fluoroscopic guidance only (group B).

Results: Group A (mean age 12.1 ± 2.9 years, mean weight 47 ± 13.9 kg) consisted of 11 patients (27.7%) with AVNRT and 29 (72.5%) with AP. Group B (mean age 10.9 ± 3.1 years, mean weight 47.1 ± 17.1 kg) consisted of 7 patients (17.5%) with AVNRT and 33 (82.5%) with AP. There were no significant differences in AP location, patients with congenital heart disease, and number of radiofrequency lesions. Fluoroscopy time was significantly shorter in group A than in group B (10.4 ± 6.1, range 3.1–28.8 minutes, vs 24.9 ± 16.0, range 4.4–82.0 minutes, P < 0.0001). Procedure duration was also significantly shorter in group A than in group B (170 ± 68.5, range 90–420 minutes, vs 218 ± 69.3, range 90–360 minutes, P < 0.0001). Initial success was 95% in group A and 100% in group B. Tachycardia recurrences occurred in two patients in group A (5%) and six patients in group B (15%). Final success, including repeat ablations for recurrences or failures, was 100% in both groups.

Conclusions: The use of a nonfluoroscopic system for catheter navigation significantly reduced fluoroscopy exposure and total procedure duration of RCA of common SVT substrates in children. (PACE 2006; 29:971–978)

Introduction

Radiofrequency ablation provides definitive treatment of supraventricular tachycardia (SVT) substrates in children.1–3 The standard method for catheter insertion and navigation is fluoroscopy, which has potential dose-related side effects such as carcinogenesis, skin erythema and necrosis, cataracts, and possibly genetic effects.4–7 The required exposure to radiation for such effects to occur is relatively high and rarely seen with increasing operator experience and with contemporary fluoroscopy systems and the use of pulsed fluoroscopy. However, children are growing organisms with a longer life period of risk for malignancies and other side effects. In addition, repeat procedures may be required in a certain number of cases, because of primary failures or recurrence of the same or a different arrhythmia substrate. It is for these reasons that a nonfluoroscopic catheter navigation system may provide significant benefits to the pediatric population. There are very few published studies, however, that compare the fluoroscopic to the nonfluoroscopic methods in terms of efficacy, actual reduction of fluoroscopy time, and other procedural parameters. The purpose of this study was to compare purely fluoroscopic guidance to a combination of fluoroscopy and a nonfluoroscopic system, i.e., Ensite® NavX® (Endocardial Solutions Inc., St. Paul, MN, USA), to assess the impact of the new system on fluoroscopy time, total procedure duration, number of lesions, and efficacy (immediate success and recurrence rates, as well as final outcome).
Methods

Patients

Eighty consecutive pediatric patients (<19 years) who underwent radiofrequency ablation for SVT due to accessory pathways (AP), asymptomatic Wolff-Parkinson-White syndrome with rapid antegrade conduction of the AP, or AV nodal reentrant tachycardia (AVNRT) were included in the study. We have developed a policy of using the NavX system in relatively simple SVT cases (such as AP and AVNRT) since July 2004. Therefore, we compared the group of patients who had a radiofrequency ablation procedure for an AP or AVNRT after this date, with a similar group who was performed before this date with fluoroscopic guidance only. This provided two groups of patients who underwent an ablation of similar arrhythmia substrates, at two different but closely related time periods. All procedures were performed by an experienced pediatric electrophysiologist and patients were consecutive. We have decided to limit the arrhythmia substrates to AP and AVNRT, because of the small number of other arrhythmias such as ectopic atrial tachycardia and atrial flutter and the difficulty in finding comparable patients with such arrhythmias in the two different periods. Forty patients underwent 42 procedures with the use of the NavX system (group A) and 40 patients underwent 40 procedures with the exclusive use of fluoroscopy (group B). The parents (or the patients if older than 18) gave informed consent before the procedures.

Electrophysiology Study

The procedures were performed in the postabsorptive state. General anesthesia with intravenous anesthetics such as propofol and fentanyl and inhaled isoflurane or sevoflurane was used in 36 patients in group A and 35 patients in group B. Conscious sedation (midazolam and morphine) and local anesthesia with 1–2% lidocaine were used in four group A and five group B patients. Quadrupolar electrode catheters (Bard Electrophysiology Division, Lowell, MA, USA) were placed in all patients through the femoral veins to the high right atrium, His bundle, and right ventricular apex. Deflectable quadrupolar catheters (Bard Electrophysiology Division) or fixed curve decapolar catheters (SupraCS, Biosense-Webster, Diamond Bar, CA, USA) were placed in the coronary sinus through the femoral veins or through the internal jugular vein, respectively. Diagnostic electrophysiologic study was performed in all patients and included decremental atrial pacing, atrial and ventricular extrastimulus testing, and rapid atrial and ventricular pacing, at baseline and with the use of isoproterenol (titrated to achieve 25–40% increase in heart rate) when necessary. In patients with manifest preexcitation, AP effective refractory period and the shortest preexcited RR interval during atrial fibrillation—whenever it was inducible—were measured to determine the potential risk from rapidly conducted atrial fibrillation. After diagnostic electrophysiologic study, a mapping/ablation catheter (Celsius™, Cordis-Webster, Diamond Bar, CA, USA, or Blazer II™, EP Technologies, Boston Scientific, San Jose, CA, USA) was inserted through a right femoral venous sheath. In cases of left-sided APs the transseptal approach was used to insert the catheter through a long sheath (Fast-Cath™, Daig Division, St. Jude Medical, Minnetonka, MN, USA) into the left atrium. Long sheaths were also used to stabilize catheters in the right atrium when necessary. Heparin was administered immediately after confirming sheath insertion into the left atrium, or after confirming that the tachycardia substrate was right sided, to achieve an activated clotting time between 200 and 300 seconds.

Mapping was performed during sinus rhythm or atrial pacing in cases of manifest preexcitation. In cases of concealed APs, mapping was performed during ventricular pacing or atrioventricular reciprocating tachycardia. The endpoint of ablation was the elimination of AP conduction in both directions. In cases of AVNRT, the catheter tip was positioned on the tricuspid annulus in the area of the triangle of Koch, attempting to record a small atrial and larger ventricular electrogram (ratio of 1:2 or less). Attempts were first started in posterior locations, i.e., at the level of the coronary sinus ostium and, if no accelerated junctional rhythm was observed, the catheter was advanced to the midseptal area. The endpoint was the noninducibility of AVNRT, but no attempt was made to completely eliminate slow pathway conduction. Following successful ablation, a 30-minute waiting period was allowed and if retesting was negative, the procedure was terminated. If recurrence occurred, further mapping and ablation were performed. Fluoroscopy time was the total x-ray exposure time (including catheter placement and mapping). Procedure time included the whole period starting from anesthesia induction until extubation. All ablation lesions were counted (even brief ones, less than 10 seconds).

Nonfluoroscopic Catheter Navigation

In the group of patients where the NavX system was used, three orthogonal pairs of cutaneous electrode patches were placed on the patients’ body surface in standard locations, i.e., anteroposterior, lateral, and superoinferior as previously described.8,9 Low-amplitude electrical signals (5.68 kHz) transmitted through these patches created a
Figure 1. Right anterior oblique view (A) and left anterior oblique view (B) of right atrial three-dimensional model created by the NavX system. The tricuspid valve annulus is created by collecting points at four different sites (TV3, TV6, TV9, and TV12) corresponding to 3, 6, 9, and 12 o’clock at left anterior oblique view. Additional points are collected as the mapping catheter is swept around in the right atrium. His = location of His bundle; IVC = inferior vena cava; SVC = superior vena cava. The catheters are color coded: The high right atrial catheter is yellow, the His bundle catheter is green, the coronary sinus catheter is blue, the right ventricular apical catheter is red, and the mapping/ablation catheter is orange.

The transthoracic electrical field. The potential difference between these electrode pairs and the intracardiac catheters allowed continuous visualization of up to eight intracardiac electrodes (diagnostic and ablation) with a spatial accuracy of 0.6 mm. A three-dimensional anatomic map of the chamber of interest could be created by moving the mapping catheter through the specific chamber, and the location of specific points was marked (Fig. 1).

Diagnostic catheters were generally placed with intermittent use of fluoroscopy and were subsequently constantly displayed on the screen of the NavX system. Some parts of catheter placement were done with use of the NavX system only. One of the catheters which showed the greatest stability (either the coronary sinus or the right ventricular apical one) was used as a reference for creation of three-dimensional geometry of the chamber that was mapped. The usual baseline geometry included location of the caval veins, the His bundle and coronary sinus, and the tricuspid valve annulus in cases of right-sided substrates. The mitral annulus was not depicted in detail in cases of left-sided pathways. Other points were collected while moving the catheter, but no effort was made to create a complete and anatomically accurate model of the chamber that was mapped, since the points of interest for both types of arrhythmia substrates included in this study were rather discrete and located very close to the AV valve annuli and not in the atrial myocardium.

Mapping was then performed according to the methods described above. An attempt was made to navigate the catheter with as little fluoroscopy as possible, utilizing the model that had been created with the NavX system on which the mapping catheter and the other diagnostic catheters were continuously displayed in real time. When difficulties or uncertainties occurred, brief fluoroscopy pulses were used for orientation and confirmation of catheter location. When deciding that a site was a good candidate for ablation, RF energy was delivered and catheter stability was monitored again continuously nonfluoroscopically. The lesions that were created were marked on the chamber model for future reference. In the case of recurrence of AP or slow pathway conduction, the catheter could be repositioned accurately at the previously successful site using the lesion marks that had been placed on the map. In order to decrease extensive catheter movements caused by...
mechanical ventilation, most lesions were created during held expiration.

**Statistical Analysis**

Variables that were compared included demographic data (age and weight), SVT types and AP location, and procedural variables (lesion number, fluoroscopy time, procedure time, complications, final outcome, and recurrences). Data were expressed as means ± standard deviations (SD). Pearson χ² test and Fisher's exact test were used whenever appropriate to compare categorical values. Continuous variables were compared using independent sample t-test or Mann-Whitney U-test for nonparametric values. P-values ≤ 0.05 were considered significant. The analysis was performed using SPSS 11.0 for Windows.

**Results**

There were 40 patients in each group. The demographic data, the number of patients with congenital heart disease (CHD) in each group, and the diagnostic categories are depicted in Table I. In group A there were five left lateral, five left posterolateral, two left posterior, two left posteroseptal, eight right posteroseptal, five right posterior, one right posterolateral, two right lateral, and one right anterolateral AP. In group B there were 12 left lateral, 4 left posterolateral, 2 left posterior, 1 middle cardiac vein, 9 right posteroseptal, 1 right midseptal, 1 right anteroseptal, 2 right posterior, and 1 right posterolateral AP. The locations of the APs in the two groups are depicted schematically in Figure 2. There was no statistically significant difference in any of the demographic or diagnostic variables between the two groups.

Six patients (15%) in each group had CHD. In group A there were two patients with Ebstein's anomaly, one with postoperative tetralogy of Fallot, one with Marfan's syndrome and ascending aortic aneurysm, one with left superior vena cava draining to the coronary sinus and one with congenitally corrected transposition and Ebstein's anomaly of the left-sided AV valve. In group B there were two patients with Ebstein's anomaly, one with postoperative tetralogy of Fallot, two with postoperative ventricular septal defect, and one with subaortic stenosis.

The procedural variables are depicted in Table II. As can be seen, there was a statistically significant difference in two procedural variables, i.e., fluoroscopy time and procedure duration between the two groups. The use of the NavX system resulted in significantly less fluoroscopy use (10.4 ± 6.1 vs 24.9 ± 16.0 minutes, P < 0.001). In addition, the new system also resulted in decreased total procedure duration (170 ± 68.5 vs 218 ± 69.3 minutes, P < 0.0001). Separate analysis of these two procedural variables for AVNRT patients...
demonstrated that while there was a definite trend toward reduced fluoroscopy time and procedure duration in group A, this did not reach statistical significance. Specifically, fluoroscopy time in group A was 10.9 ± 5.3 (range 3.1–22.0, median 10.5) minutes versus 14.9 ± 7 (range 4.4–27, median 16.0) minutes in group B (P = 0.23). Procedure duration was 145.3 ± 33.2 (range 120.0–210.0, median 127.5) minutes in group A versus 171.4 ± 41.4 (range 90.0–210.0, median 180) minutes in group B (P = 0.16). Analysis of the patients with AP showed a highly significant reduction in both variables in group A compared to group B. Specifically, fluoroscopy time was 10.2 ± 6.5 (range 3.1–28.8, median 7.8) minutes in group A versus 27.1 ± 16.6 (range 5.6–82.0, median 23) minutes in group B (P < 0.0001). Procedure duration was 178 ± 75.7 (range 90.0–420.9, median 180) minutes in group A versus 227.8 ± 70.4 (range 120.0–360.0, median 240) minutes in group B (P = 0.002).

During follow-up of 49.4 ± 12.5 (33–72) months, six group B patients had a recurrence of tachycardia or WPW pattern on ECG. All recurrences occurred within 2 months from the ablation date. Five of these patients underwent seven repeat procedures. One patient, who originally had a left free-wall pathway ablation, required three repeat procedures during which two additional left-sided pathways (one left posterosetal and one left posterior), as well as AVNRT were ablated. The final success rate was 100% in all patients who underwent a repeat procedure.

Two group A patients, who had an initially unsuccessful procedure, underwent a second procedure which was successful. During a follow-up period of 11.8 ± 4.7 (5–22) months, there were recurrent tachycardias in two patients, both within 2 months from the initial ablation date. One patient with a right posterosetal AP underwent a successful repeat ablation of his pathway 2 months after the original procedure. One patient with AVNRT had recurrent palpitations which were never of duration long enough to allow ECG documentation. During a repeat electrophysiologic study, no AVNRT could be induced. Recurrent atrial fibrillation was inducible, but the clinical significance of this finding was unknown. Because of persistent dual AV nodal physiology, it was felt that a possibility existed that the clinical episodes were AVNRT which was not inducible under anesthesia. Therefore, additional lesions were placed empirically to further modify the slow pathway. At the end of these lesions, the slow pathway effective refractory period had increased significantly. Neither AVNRT nor atrial fibrillation was inducible. Thus, the final success rate was 100% in both groups.

There were no significant complications in either group.

Discussion

One of the most important limitations of radiofrequency ablation in children has been the need for exposure to significant amounts of radiation, especially in the early era of RF ablation. With increasing experience, the duration of fluoroscopy decreased, but remained significant. Kugler et al., using data from the Pediatric RF Ablation Registry, compared the fluoroscopy exposure in two different eras (1991–1995 and 1995–1999). Mean fluoroscopy time overall decreased 21% from 50.9 ± 39.9 to 40.1 ± 35.1 minutes. All though significant side effects from these amounts of fluoroscopy are rare, there remains a concern for long-term problems which may not be immediately obvious. The excess lifetime risk of developing fatal cancer in various diagnostic and therapeutic pediatric and adult catheterization studies and radiofrequency ablation procedures has been estimated at 0.08–0.1%. Any further reduction in fluoroscopy exposure would therefore be welcomed. Various types of nonfluoroscopic mapping systems have been developed. All of them provide increased anatomic accuracy and some also assist in better understanding of activation patterns and origin of tachycardias. There is generally an impression that these systems also reduce fluoroscopy exposure.

This is the first comparative study between conventional fluoroscopic catheter navigation and nonfluoroscopic navigation using a novel mapping system (NavXTM, Endocardial Solutions, Inc.) in

Table II.

Procedural Variables in the Two Patient Groups

<table>
<thead>
<tr>
<th>Variable</th>
<th>Group A</th>
<th>Group B</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>CL (ms)</td>
<td>307 ± 53.5</td>
<td>313.6 ± 56.5</td>
<td>0.629</td>
</tr>
<tr>
<td>Fluoroscopy time (minute)</td>
<td>10.4 ± 6.1</td>
<td>24.9 ± 16.0</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Procedure duration (minute)</td>
<td>170 ± 68.5</td>
<td>218 ± 69.3</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Lesion number</td>
<td>9.2 ± 10.0</td>
<td>10.3 ± 9.5</td>
<td>0.613</td>
</tr>
<tr>
<td>Success rate</td>
<td>40 (95%)</td>
<td>40 (100%)</td>
<td>0.494</td>
</tr>
</tbody>
</table>

CL = cycle length of tachycardia.
children with the two most common types of SVT (APs and AVNRT). Our results suggest that routine use of this system leads to significant reductions in fluoroscopy and procedure times in these two SVT substrates, with no compromise in success rates and safety. Other investigators have reported the use of the NavX system to assist in radiofrequency ablation of SVTs. Krum et al. have reported the use of this system in 16 patients and demonstrated the feasibility of chamber geometry construction, landmark labeling, and real-time catheter tracking in all patients. They concluded that this approach may be useful when ablation therapy is primarily anatomically based. Ventura et al. have performed a randomized study of 40 patients with common-type atrial flutter to compare traditional fluoroscopic-based mapping versus NavX. They reported significant reduction in fluoroscopy time with NavX (5.1 ± 1.4 minutes vs 20 ± 11 minutes) and total x-ray exposure (5.1 ± 3.1 vs 24.9 ± 1.6 Gy cm²), with no difference in the number of RF pulses and total procedure times.

One may argue that based on the separate analysis of the results in AVNRT and AP patients, the benefits of the new system in our study were only due to the reduction in fluoroscopy and procedure times in the AP patients. We believe, however, that even in AVNRT patients the use of the system is beneficial. There was a clear-cut trend toward lower fluoroscopy exposure, even if this did not reach statistical significance (perhaps due to the small number of patients in each group). Other investigators, using a different three-dimensional mapping system, as discussed later, have reported a significant reduction in fluoroscopy time for AVNRT ablation.

Other mapping systems have been created and used to improve the accuracy of mapping and to reduce fluoroscopy. Electroanatomic mapping (CARTO, Biosense-Webster Inc.) is a nonfluoroscopic three-dimensional mapping system that uses a dedicated catheter for mapping and ablation and an external triangular-shaped electromagnetic source that is positioned under the fluoroscopy table, to create a three-dimensional geometric model of the chamber of interest, on which activation mapping can be performed. Using this system, Drago et al. have reported successful ablation of right-sided APs in 20 of 21 children, with no use of fluoroscopy in eight of them. Kopelman et al. have performed a randomized comparison of electroanatomic mapping versus the conventional method, for slow pathway ablation of AVNRT and reported significantly reduced fluoroscopy and procedure times with the former method. Khong-phatthanayothin et al. have performed a nonrandomized comparative study between conventional mapping and CARTO in patients with four different types of tachycardias (AVNRT, atrial tachycardia/flutter, ventricular tachycardia, and bypass tract tachycardia). Significant reduction in fluoroscopy time was achieved in all types of tachycardia with use of the CARTO system. Specifically, the fluoroscopy time in AVNRT patients was reduced from 27 ± 15 to 10 ± 7 minutes and in bypass tract patients from 53 ± 32 to 21 ± 14 minutes. Although these results are excellent, there are aspects of the NavX system, which make it more suitable for pediatric patients compared to electroanatomic mapping. First the electroanatomic system uses a dedicated catheter. The NavX system, instead, is compatible with any type and size of radiofrequency catheter and even with cryoablation catheters. This is especially important in children, in whom radiofrequency ablation of arrhythmia substrates near the normal conducting system often poses a significant risk of AV block, or when ablation needs to be performed inside the coronary sinus. We have previously reported the combined use of cryoablation and the NavX system for ablation of a nodoventricular fiber. Eckardt et al. have reported the combined use of the NavX system and cryoablation in a patient with an AP located in a coronary sinus diverticulum. In addition the simultaneous demonstration of multiple intracardiac catheters (up to 8 catheters with 48 electrodes) is a significant advantage of the NavX system. Finally, it is our impression that collection of points and creation of the 3D model of the chamber of interest are faster with the NavX system compared to the CARTO system. The NavX system collects points automatically with each catheter movement, whereas the CARTO system requires active operator involvement in point collection. This is a subjective issue, however, and speed of data collection is also dependent on operator experience. The CARTO system on the other hand provides both anatomic information and activation mapping. Although we used the NavX system only for chamber geometry and catheter location, a new feature of the system allows also for creation of an activation map after data acquisition.

The LocaLisa system (Medtronic EP Systems, Minneapolis, MN, USA) is another nonfluoroscopic system that has been used for guidance of radiofrequency ablation. Kammeraad et al reported the use of this system to ablate AVNRT in children, with a mean fluoroscopy time of 16 minutes. No comparison was made with regular fluoroscopic guidance in terms of fluoroscopy time, total procedure time, and final outcome. Schneider et al. performed a prospective randomized study between fluoroscopic mapping and LocaLisa for atrial flutter ablation, and demonstrated a reduction in fluoroscopy time from 15.9 ± 10.6 to 7.5 ± 6.5 minutes. Like the NavX system, the LocaLisa...
system can be used with any type of catheter, allowing the use of cryoablation and different curves and sizes that may be necessary in children. However, the LocaLisa system cannot display multiple catheters simultaneously and does not create chamber geometry. The differences between the three mapping systems are summarized in Table III.

An additional feature of the NavX system (and of the other nonfluoroscopic systems) is the ability to “tag” important sites, such as catheter locations and lesion sites, which can be revisited with great accuracy (as long as the reference electrode has remained stable). The NavX system can also create “shadows” of the catheters, which can be used for the repositioning of the catheters in the case of dislodgment. In our experience, the most stable catheter has been the right ventricular catheter when positioned at the RV apex, and we routinely use it now as the reference catheter.

A drawback of the routine use of the NavX system is the additional cost of the cutaneous electrode patches. The cost could be potentially balanced with the use of fewer diagnostic catheters. This could be done by using the catheter shadows and markers that the system can create, to mark specific anatomic locations such as the coronary sinus ostium and the His bundle. However, the use of fewer catheters might compromise diagnostic accuracy at a time of the procedure when simultaneous electrograms from multiple sites might be important and prove inconvenient and potentially risky to the patient. We have chosen therefore to continue using the standard diagnostic catheters in addition to the cutaneous patches. We have not seen a single case of venous thrombosis from use of multiple catheters. We believe that the increased safety of the procedure and the reduced exposure to radiation are significant benefits for the extra cost of the NavX system.

**Study Limitations**

This study has important limitations. First, it was a nonrandomized study and the procedures were performed in two successive time periods. It could be argued that fluoroscopy and procedure times decreased in part because of increased experience. However, a significant number of cases had already been performed by the same operator before the start of the study and the mix of cases was very similar, including the number of patients with CHD. Second, the follow-up period was much shorter in group A (the NavX group), and some late recurrences may occur. However, all recurrences in both groups occurred in the first 2 months postablation, and all patients in group A have been followed up at least 5 months. A recent prospective study on pediatric RF ablation showed that 70% of recurrences occur in the first 2 months and 90% in the first 6 months.17

**Conclusions**

The use of a nonfluoroscopic system for chamber geometry creation and catheter navigation allowed for significant shortening of fluoroscopy and total procedure times during radiofrequency ablation of two common SVT substrates in children, without any adverse effects. The new system offers significant advantages over the other already available nonfluoroscopic systems.

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