Radiofrequency Ablation of Accessory Pathways in Children and Congenital Heart Disease Patients: Impact of a Nonfluoroscopic Navigation System

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Background: *We sought to assess the impact of routine use of a nonfluoroscopic navigation system in the procedural aspects of radiofrequency ablation of accessory pathways (APs) in pediatric and congenital heart disease (CHD) patients and the reduction of fluoroscopy in different pathway locations.*

Methods: *This was a retrospective review of 192 patients, divided in two groups: group A (76 patients, fluoroscopic only ablation) and group B (116 patients, combined use of fluoroscopy and a nonfluoroscopic system (NavX^{TM}). Comparison of procedural aspects (procedure time, fluoroscopy time, success, complications, and recurrences) was performed.*

Results: *The two groups were comparable in terms of age, AP location, and presence of CHD. The mean age was 11.34 ± 4.65 years in group A versus 10.91 ± 3.68 years in group B. The procedure duration was significantly shorter in group B than in group A (177.06 ± 62.18 vs 242.45 ± 99.07) ($P < 0.001$). There was a significant reduction in the fluoroscopy time in group B compared to group A (8.27 ± 8.23 vs 39.77 ± 32.65 minutes) ($P < 0.001$). The difference between the two groups was statistically significant in all categories of APs. The success rate was 97.4% in group A and 96.6% in group B. There were no complications directly related to the use of the nonfluoroscopic system. There was no difference in the recurrence rate.*

Conclusions: *The use of a nonfluoroscopic system for catheter navigation resulted in significant reduction of total procedure and fluoroscopy time during catheter ablation of APs in pediatric and CHD patients, regardless of the location of the pathway, without a compromise in safety and efficacy. (PACE 2011; 34:1288–1296)*

accessory pathway, pediatric, congenital heart disease, ablation, nonfluoroscopic

Introduction

Catheter ablation has been a major development in the treatment of tachycardias in children and adolescents. Thousands of young patients suffering from recurrent or chronic tachycardias have been cured with this therapeutic modality, avoiding many years of treatment with antiarrhythmic medications and restrictions from daily and sports activities. Catheter ablation traditionally has been performed with fluoroscopic guidance. Although increasing experience has resulted in decreasing exposure to radiation, a significant amount of fluoroscopy is still needed in most pediatric ablation procedures performed with conventional methods.[1] The development of nonfluoroscopic navigation methods has allowed for limited use or even complete exclusion of fluoroscopy. However, the series that have been published so far consist of relatively small groups of patients.[4–9] In addition, it is not known if the beneficial effect of these methods is related to the location and substrate of tachycardia. We analyzed retrospectively our database of all ablation procedures performed for accessory pathways (APs) in children and adolescents to assess the impact of the routine use of a nonfluoroscopic method. We also investigated the effect of the location of the AP to the relative reduction of the fluoroscopy time.

Patients and Methods

Patient Population

There were 212 pediatric and congenital heart disease (CHD) patients who had an ablation procedure for an AP in our database. The procedures were performed from July 1, 1994 till June 22, 2010. For the purpose of uniformity, we excluded 20 patients in whom cryoablation was used. The remaining 192 patients (66 females,

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126 males) constituted our study population and were divided in two groups: group A consisting of 76 patients who underwent the ablation procedure using fluoroscopy only, and group B consisting of 116 patients, who underwent ablation under combined fluoroscopic and nonfluoroscopic guidance. We started using a nonfluoroscopic navigation system in 2003. Therefore, the mean follow-up time was significantly shorter in group B. The follow-up time was 9.93 ± 2.69 (range 2.03–16.19) years in group A and 3.19 ± 1.78 (range 0.21–6.15) years in group B. In order to account for the effect of learning curve, we divided each group in two equal subgroups (according to procedure date) and compared the procedure and fluoroscopy times between these subgroups.

Description of Procedure

Procedures were performed usually under general anesthesia with endotracheal intubation and use of intravenous propofol, inhaled sevoflurane, and muscle relaxants as necessary. Occasionally, in older adolescents, conscious sedation was used with midazolam and morphine. Our standard protocol included four diagnostic catheters inserted through the femoral veins and placed to the high right atrium (HRA), His, right ventricular apex (RVA), and coronary sinus (CS). When the CS catheter could not be advanced from the femoral vein approach, or if there was limited space in the femoral area, it was inserted via the right internal jugular vein. The diagnostic electrophysiologic study included measurement of the baseline intervals, incremental atrial and ventricular pacing, and extrastimulus testing from the atrium and the ventricle, in order to assess the AP effective refractory period, shortest preexcited RR during decremental atrial pacing, or atrial fibrillation and to induce reciprocating tachycardia. A mapping-ablation catheter was inserted after the diagnostic electrophysiologic study was completed. The antegrade AP conduction was mapped during sinus rhythm or atrial pacing, and the retrograde AP conduction was mapped during ventricular pacing or during reciprocating tachycardia.

Left-sided APs were mapped and ablated using a transseptal approach in the majority of cases with less common use of the retrograde transaortic approach.

Ineffective RF pulses were usually interrupted after 10–15 seconds. Successful sessions were continued for up to 60 seconds with insurance lesions placed according to the operator's judgment.

After a successful lesion, a waiting period of at least 30 minutes was allowed and repeat testing was performed.

Nonfluoroscopic System

Since 2003, a nonfluoroscopic system was introduced (Ensite NavX, St. Jude Medical Inc., St. Paul, MN, USA). The system has been described extensively in previous publications. Briefly, it consists of three pairs of adhesive electrode patches placed orthogonally on the body surface, emitting low-energy electromagnetic waves, which locate the catheters inside the body and can create a three-dimensional model of the chamber of interest. Up to 64 pairs of electrodes can be imaged in real time. One of the catheters is used as the reference electrode. An attempt was made to introduce and position catheters only with the use of nonfluoroscopic (NF) system. When necessary, however, brief pulses of fluoroscopy were used to confirm catheter position. More extensive use of fluoroscopy was made when a significant difficulty was met in catheter positioning, or there was concern about movement of the reference catheter. Specific locations, such as the His bundle, the CS ostium, and several points on the AV valve annulus were tagged for future reference (Fig. 1). Usually, an attempt was made to create a virtual image of the tricuspid valve annulus by connecting multiple points with equal atrial and ventricular electrograms. No similar attempt was made when mapping on the left side, where the CS catheter was used as a reference.

We mainly used the NF system for navigation and not for activation mapping. For the latter, we used classic electrogram-guided mapping. When a candidate site for ablation was found, energy was applied and the site was tagged with a colored circle for future reference (Fig. 1). When a successful lesion was interrupted due to catheter movement, or if there was recurrence of AP conduction, the catheter could be repositioned on the previously successful site with the use of the tags. A prerequisite for this was the stability of the reference catheter. Our usual choice for reference electrode was the RVA catheter as we did not always introduce a CS catheter, and in several cases we repositioned the CS catheter to achieve bracketing of left-sided pathways. In our experience, the RV catheter maintained a stable position in the majority of cases.

We did not use additional imaging modalities, such as transesophageal or intracardiac echocardiography. We also did not perform preprocedure magnetic resonance or computed tomography imaging.

AP Categories

We divided the AP locations in four categories: right free wall, septal, left, and multiple.

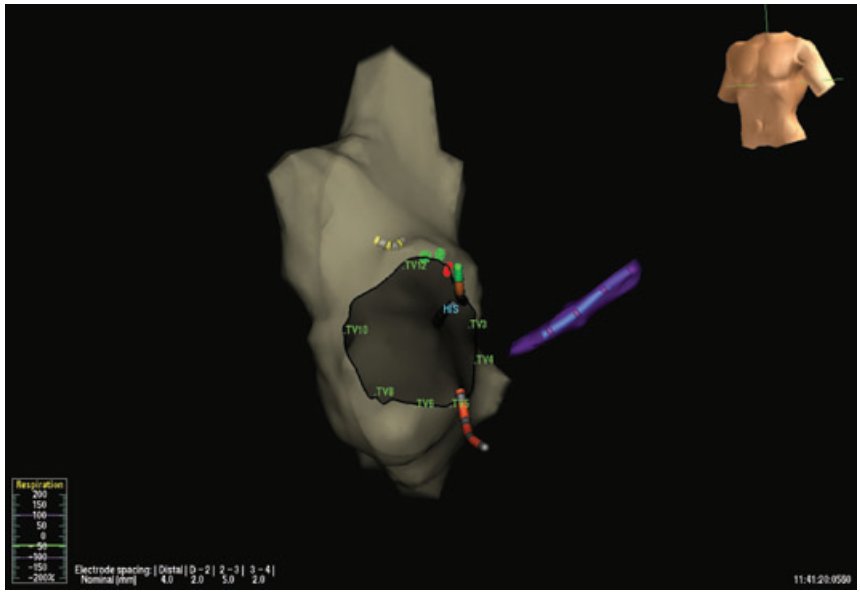

Figure 1. *Right atrial three-dimensional geometric model with diagnostic and mapping catheters. The tricuspid annulus has been drawn after collecting several points with equal A and V signals (TV3–TV12). The diagnostic catheters are color-coded (HRA = yellow, His = green, Coronary sinus = blue, and right ventricle = red). The location of the His bundle signal has been marked. The ablation catheter is orange with green tip. The location of successful lesion is depicted with a red tag.*

In right free wall, we included all APs that were on the right side and were not septal.

In septal, we included all APs that were on the right side, and were included between the His bundle catheter and the CS ostium. We included in this category those pathways that were left posteroseptal, but were approached through the CS from the right side. In the third category (left APs), we included all APs that were approached either through a transseptal approach, or rarely through a retrograde transaortic approach. Multiple APs constituted a separate category.

The following variables were assessed: procedure duration, number of lesions, fluoroscopy time, outcome, complications, and recurrences. Procedure duration was considered the whole time from patient entry to patient exit of the electrophysiology laboratory. We counted all lesions including brief ones regardless of duration.

Statistical Analysis

Data are expressed as means ± standard deviation (SD). Categorical variables by groups were compared using Pearson's χ^2 test. All continuous variables were tested for homogeneity of variance using Levene's test, and comparisons between normally distributed continuous variables were conducted using one-way ANOVA, whereas data without homogeneity of variance were compared using the Mann-Whitney test. For comparisons, a significance level of 0.05 was used. All statistical analyses were performed by using the SPSS package for windows (version 17 SPSS Inc., Chicago, IL, USA).

Results

Demographic and Clinical Features

Table I depicts the clinical and demographic characteristics of the two groups. The age distribution was similar in the two groups (mean age of 11.34 ± 4.65 years in group A vs 10.91 ± 3.68 years in group B). There was also no difference in terms of sex distribution. There were relatively more patients with asymptomatic manifest preexcitation in group B compared to group A (21% vs 10%), reflecting the impact of prospective studies regarding the risk of life-threatening arrhythmias in asymptomatic patients with Wolff-Parkinson-White syndrome.[2] There were relatively more patients with concealed APs in group A versus group B (38% vs 24%). There were more patients with CHD in group A (18.9%) than in group B (11.0%). However, the complexity of the CHD was similar in the two groups and the difference in numbers was of marginal statistical significance (Table II).

Table I.

Demographic and Clinical Data

	Group A	Group B	P-value
Male/Female	48/28	78/38	0.334
Age (mean ± SD)	0.28–32.6 (11.34 ± 4.65)	5.13–35.85 (10.91 ± 3.68)	
Asymptomatic WPW	7	25	0.018
Symptomatic WPW	34	59	0.247
Concealed AP	29	28	0.028
Other (PJRT, Mahaim)	6	4	0.153
CHD	14	13	0.033
Cardiomyopathy	3	2	0.308

†One-way ANOVA. WPW = Wolff-Parkinson-White. [Correction added after online publication 18-Aug-2011. The age of the patients in Group A and Group B has been updated.]

Procedural Characteristics

Table 3 depicts the procedural characteristics of the two groups. The distribution of AP locations did not differ significantly between the two groups.

General anesthesia was used more often in group B than in group A (95% vs 85%).

The transseptal approach was used in more patients in group B than in group A, but the difference was not statistically significant.

Despite the additional time required to set up the nonfluoroscopic system and to create the three-dimensional geometry, the procedure duration was significantly shorter in group B than in group A (177.06 ± 62.189 vs 242.45 ± 99.07 minutes). The number of RF applications was similar in the two groups.

There was a highly significant reduction in the fluoroscopy time in group B compared to group A (8.27 ± 8.23 vs 39.77 ± 32.65 minutes) (Fig. 2). The difference between the two groups was significant for all categories of APs (Fig. 3).

There was no statistical difference between early and late subgroup in group A (fluoroscopy only) in procedure times (251.55 ± 104.14 vs 235.5 ± 95.85 minutes, P = 0.51) and fluoroscopy times (35.85 ± 34.67 vs 28.02 ± 21.49, P = 0.9). Similarly, there was no statistically significant difference between early and late subgroup in group B (NavX + fluoroscopy) in procedure times (166.18 ± 61.46 vs 188.56 ± 61.46 minutes, P = 0.063) and fluoroscopy times (8.11 ± 6.80 vs 8.62 ± 8.85, P = 0.728).

Effect of Congenital Heart Disease

In regards to the reduction in fluoroscopy time, the beneficial effect of the NF system was equally obvious in patients with CHD as well as in those with structurally normal heart. Specifically, the fluoroscopy time in group A patients with CHD was 31.97 ± 28.90 minutes and in group B it was 11.21 ± 8.20 minutes (P = 0.002). The fluoroscopy time in group A patients without CHD was 31.52 ± 28.48 minutes and in group B it was 7.89 ± 7.73 minutes (P < 0.001). However, there was no reduction in procedure time in patients with CHD between group A and B (226.43 ± 81.67 vs 234.62 ± 86.76 minutes, P = 0.8). There was a significant drop in procedure time in patients without

Table II.

Associated Congenital Heart Disease

Types of CHD			
Group A		**Group B**	
Ventricular septal defect s/p repair	2	Atrial septal defect	2
Tetralogy of Fallot s/p repair	2	Bicuspid Aortic valve	1
Coronary sinus diverticulum	1	Pulmonary stenosis s/p balloon valvuloplasty	1
Congenitally corrected transposition in situs solitus	2	Ventricular septal defect s/p repair	1
Ebstein's anomaly	6	Subaortic stenosis s/p repair	1
Single right ventricle with DORV in situs inversus	1	Partial AV canal s/p repair	1
		Left superior vena cava to coronary sinus	1
		Ebstein's anomaly	3
		Congenitally corrected transposition in situs solitus	1
		Congenitally corrected transposition in situs inversus	1

AV = atrioventricular; DORV = double outlet right ventricle.

Table III.

Procedural Data

	Group A	Group B	P value
General anesthesia	65	111	0.014
Right AP	8	23	0.087
Septal AP	31	40	0.376
Left AP	34	48	0.646
Multiple APs	3	5	0.902
Transseptal approach	31	50	0.751
Procedure duration	242.45 ± 99.07	177.06 ± 62.189	<0.001*
RF applications	11.18 ± 12.36	10.79 ± 13.07	0.843†
Fluoroscopy time	31.608 ± 28.36	8.36 ± 7.84	<0.001*
Success	74	112	0.682
Complications	4	4	0.387

*Mann-Whitney Test. †One-way ANOVA.
AP = accessory pathway.

CHD between the two groups (246.68 ± 103.45 vs 169.1 ± 53.94 minutes, P < 0.001). Therefore, the relatively larger number of CHD patients in group A did not seem to bias overall results.

Success and Complication Rates

The complication rate was similar in the two groups. In group A, there were two patients with transient AV block, one with a large femoral hematoma and another with a small pericardial effusion. In group B, there was one patient with first-degree AV block, one with right bundle branch block and another with protamine allergy. There were no complications directly related to the use of the nonfluoroscopic system.

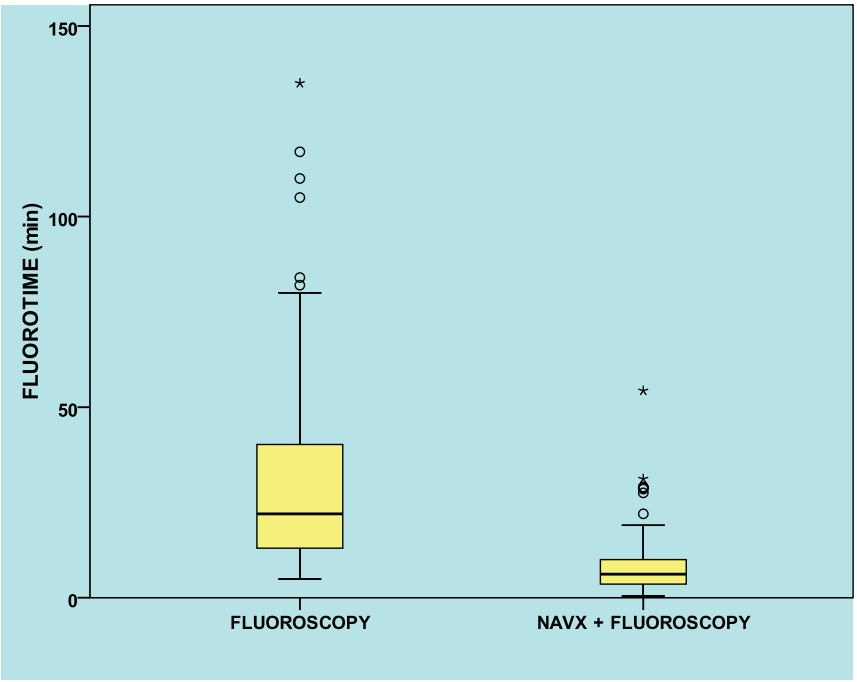

Figure 2. *Box-plot diagram showing the reduction in fluoroscopy times with the use of the NavX system.*

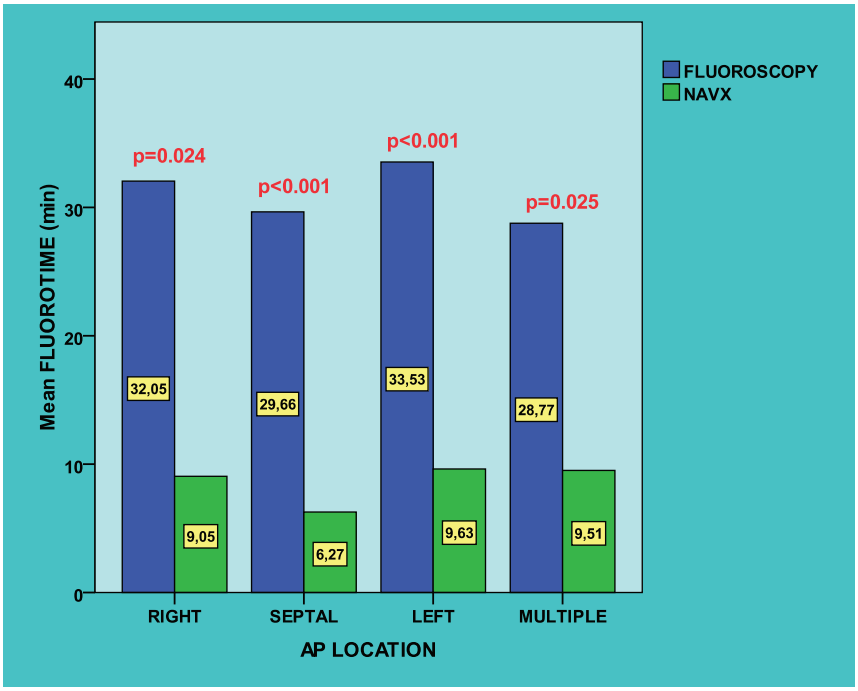

Figure 3. *Diagram depicting the reduction in fluoroscopy times in each location of accessory pathways.*

The success rate was 97.4% in group A and 96.6% in group B. The difference was not statistically significant. Similarly, there was no difference in the recurrence rate, although there was a trend for lower recurrence rate in the nonfluoroscopic group (17% in group A vs 12.1% in group B). However, the follow-up time was shorter in group B.

Discussion

Major Findings

To our knowledge, this is the largest study reporting the experience with the NavX system focusing exclusively on the ablation of APs in pediatric patients and young adults with CHD. The main findings of this study are: (1) the routine use of a nonfluoroscopic navigation system was very effective in reducing exposure to fluoroscopy in pediatric patients undergoing radiofrequency ablation procedures; (2) there was significant reduction of fluoroscopy regardless of AP location although the benefit was somewhat less evident in right free wall and multiple pathways; and (3) there was no evidence that using the nonfluoroscopic system increased the length of the procedure, the risk of complications, or the failure rate. On the contrary, there was improvement in most of these parameters with the nonfluoroscopic system, although this was statistically significant only for the procedure duration.

Fluoroscopic Ablation in Children

Despite improvements in technology and increasing experience in pediatric ablation, these procedures require significant exposure to radiation. Kugler et al.[1] using data from the pediatric RF ablation registry have shown a significant reduction in the fluoroscopy time comparing two different eras (1991–1995 and 1996–1999). Mean fluoroscopy time overall decreased 21% from 50.9 ± 39.9 minutes to 40.1 ± 35.1 minutes. However, even in the second era, the fluoroscopy times were still very significant.

The risk of malignancy from pediatric catheter ablation procedures was estimated in a small recent study of 15 children with dosimeters placed in five locations.[3] The median combined biplane fluoroscopy time was 14.4 minutes and the highest median radiation dose was 43 mGy (at the right scapular region). According to these measurements, the estimated increase in life-time risk of fatal malignancy from a single ablation procedure was estimated at 0.02%. This is a relatively small risk. However, when facing a nonfatal disease such as supraventricular tachycardia, even a small risk of inducing a fatal malignancy as a result of a therapeutic procedure is unacceptable. Therefore,

reduction or elimination of fluoroscopy is a very important aspect of our overall efforts to treat young patients with tachyarrhythmias.

Previous Studies with Nonfluoroscopic Ablation in Children

Other authors have already published their experience with nonfluoroscopic catheter navigation systems. We have summarized the main findings of the studies involving pediatric patients in Table 4.

Drago et al. first reported catheter ablation of right-sided APs with reduced or even no fluoroscopy with the use of an electroanatomic mapping system (CARTO, Biosense Webster, Diamond Bar, CA, USA) in a relatively limited number of patients.[4] This system can only visualize the mapping catheter nonfluoroscopically. These authors used a single-catheter approach in most of the patients. They were able to eliminate fluoroscopy completely in nine patients.

Other authors used different systems including Loca-Lisa (Medtronic Inc, MN, USA),[5] and Ensite NavX (Endocardial Solutions Inc., St. Paul, MN, USA)[6–10] to ablate a variety of substrates such as left-and right-sided APs, AV nodal reentrant tachycardia (AVNRT), and ectopic atrial tachycardia (EAT). Most authors demonstrated significant reduction in fluoroscopy times with unchanged or even increased procedure times except for our previous study,[6] which showed a reduction in both. Some authors have been able to eliminate fluoroscopy completely in the majority of their cases,[7–9] even in patients with left-sided APs (with the additional use of transesophageal echocardiography). Miyake et al. have recently published the only prospective randomized study on the subject, with the combined use of the NavX system and intracardiac echocardiography.[10]

Earley et al. performed a comparative study between the two main nonfluoroscopic systems (CARTO and NavX) and fluoroscopic guidance.[11] They demonstrated that both nonfluoroscopic systems reduced significantly the total fluoroscopy time, although NavX was more efficient in this respect. Both systems increased significantly the cost of the procedure, with NavX being more expensive. However, these authors expressed the opinion that the long-term benefits to the patients and to the personnel of the electrophysiology laboratory may outweigh the increased cost of the nonfluoroscopic system.

Current Study

The current study extends our previous experience and provides evidence in a much larger group of patients that use of the NavX system, without additional equipment such as intracardiac or transesophageal echocardiography can result in significant reduction of fluoroscopic exposure regardless of the location and number of the APs. We have not eliminated radiation completely in our study as other authors have reported,[7–9] although several procedures have been performed with less than 1–2 minutes of fluoroscopy and a few with exposure time of less than 10 seconds. Although there is no absolutely safe radiation dose in pediatric patients, this amount of exposure is very unlikely to result in significant side effects. We believe that complete elimination of fluoroscopy, although desirable, should not be considered an absolute goal. In our experience, confirmation of catheter position with brief pulses of fluoroscopy is often necessary, especially in order to create an accurate geometry, and during specific parts of the procedure, such as during transseptal puncture and when ablating close to the conduction system.

Based on the findings of this study, the reduction of fluoroscopy appears less significant in the group of right free wall and multiple pathways. This finding is paradoxic at first glance, given the fact that other authors have been able to perform completely nonfluoroscopic ablations in patients with right-sided substrates. Possible explanations are the inherent difficulty of stabilizing the ablation catheter on the right AV valve annulus (often with the need for long sheaths), and the lack of other landmarks such as the His bundle and the CS catheters, which can help nonfluoroscopic positioning of the ablation catheter.

Clinical Implications

The major advantage of nonfluoroscopic methods is reduction of exposure of the patient to ionizing radiation. There are also additional benefits to the medical personnel who will receive less cumulative radiation dose. In addition, some operators who feel confident that they can perform a completely nonfluoroscopic procedure can eliminate the use of protective lead aprons, thus reducing the risk of spinal trauma. Certainly, this is possible for the ancillary personnel (nurses and technicians) who can be covered behind lead screens when brief use of fluoroscopy becomes necessary to confirm catheter position. One additional group of patients that can benefit very significantly from nonfluoroscopic ablation is pregnant women and their fetuses.[12]

In the current era, there is a tendency for prophylactic catheter ablation in asymptomatic patients with preexcitation syndrome. Although this is still a controversial issue, the majority of pediatric electrophysiologists favor invasive electrophysiology study for risk assessment, and performance of catheter ablation in high-risk

Table IV

Previous Studies on Nonfluoroscopic Ablation in Pediatric Patients

Author	Date	No. of patients	Types of tachycardia	Age range (yrs)	Elimination versus reduction in fluoroscopy time (E vs R)	Success (S) Recurrence (R)	System	Complication related to NF system	Comments
F. Drago	2002	21	Right-sided APs	11.3 ± 3.2	E in 9/21	20/21	Carto	None	Safety and efficacy of ablation with NF system with single catheter
J. Papagiannis	2006	80	AVNRT + AP	Two groups (fluoro NavX) (12.1 ± 2.9) (10.9 ± 3.1)	R	S: 40/40 (fluoro) 38/40 (NavX) R: 6/40 (fluoro) 2/40 (NavX)	NavX	None	Significantly reduced fluoro exposure and total procedure duration
V. Tuzcu	2007	26	Right-sided APs	12.7 ± 7.5 years	E in 24/28	S: 16/19 (fluoro) 22/24 (NavX)	NavX	None	Significantly decrease or even elimination and total procedure time not significantly different
G. Smith	2007	30	AVNRT, AP	12.9 (4–27)	E in 24/30	S:30/30	NavX	None	Significant decrease or even elimination of fluoro
A. L. Papez	2007	246	AVNRT, AP		R	S:97.2% (fluoro) 99.1% (Loca-Lisa)	Loca-Lisa	None	Significant decrease in procedure, fluoroscopy time, application
J. Clark	2008	10	Left-sided APs		E	S:10/10 R:1/10	NavX and TEE	None	Safety and efficacy of ablation of left-sided APs with NF system with TEE assistance
C. Y. Miyake	2010	74	AVNRT, AP	14.7 (8.6–22.3)	R	S: 36/37 (Fluoro) 37/37(NavX)	NavX and ICE	None	Prospective randomized study, Reduction in fluoroscopy time and radiation exposure, with ICE assistance

TEE = transesophageal echocardiogram; ICE = intracardiac echocardiogram.

patients.[13] The reduction of exposure to radiation is a significant argument in the hands of the proponents of prophylactic ablation, as it removes an important risk of the procedure.

We would like to emphasize that although completely nonfluoroscopic ablation is possible, these procedures should still be performed in a room with fluoroscopic equipment, which may be necessary in case of an emergency such as potential perforation, or to investigate vascular access problems especially in patients with multiple previous catheterizations. In addition, there is often the need for a quick confirmation of catheter location, for example, in cases where there is proximity of the ablation site to the AV conduction system, or when there is concern of movement of the reference catheter. Although performance of completely nonfluoroscopic ablation is certainly desirable, especially in the case of left-sided substrates it requires the use of either transesophageal or intracardiac echocardiography. These additional imaging modalities increase either the personnel required or the size and number of femoral sheaths and the cost and duration of the procedure. One has to weigh the true benefit against the additional effort, risks, and costs.

Study Limitations

The most important limitation of this study is its retrospective nature. One could argue also that the group of fluoroscopic only procedures represents the early part of our ablation experience. In an effort to eliminate the effect of the learning curve, we divided each group into early and late subgroups and showed that the difference was minimal, and that the major factor that was responsible for the reduction of procedure and fluoroscopy times was the use of the NF system. Other large pediatric ablation studies[1] have shown similar amounts of fluoroscopy to ours even after several years of experience.

We did not report the exact radiation dosage that patients received. Although there is usually a close relationship between fluoroscopy time and radiation dose, it is not linear and it depends also on other factors such as body size, distance from the x-ray tube, and angle of fluoroscopy.

We also did not specifically attempt to identify reasons for using fluoroscopy in our study. We did not attempt to measure the fluoroscopy times needed for catheter placement versus mapping and ablation. We hope that future studies will focus on obstacles to complete nonfluoroscopic ablation.

Conclusions

The use of a nonfluoroscopic system for catheter navigation has resulted in significant reduction of fluoroscopy during catheter ablation of APs in pediatric patients, regardless of the location of the pathway, without the need for additional equipment. Although randomized studies are difficult to perform because of ethical reasons, future prospective studies with intention to eliminate fluoroscopy can be performed in order to assess for reasons that fluoroscopy is still required and for ways to overcome this problem.

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