Patient and Procedural Correlates of Fluoroscopy Use During Catheter Ablation in the Pediatric and Congenital Electrophysiology Lab

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ABSTRACT

Objective. To identify factors associated with fluoroscopy use in pediatric and congenital heart disease (CHD) patients.
Design. Retrospective cohort.
Setting. Pediatric electrophysiology lab in a single tertiary-care children's hospital.
Patients. Three hundred eighty-three patients who underwent electrophysiology study and ablation between January 2010 and December 2012.
Methods. Ablation procedures in which nonfluoroscopic navigation was employed were reviewed. Procedures using ≥10 minutes of fluoroscopy (high-fluoroscopy time; HF) were compared with those using <10 minutes (low-fluoroscopy time; LF). Group comparison of characteristics was made in the entire cohort and in CHD and anatomically normal heart subsets.
Results. During the study period, 416 ablation procedures were performed involving 471 substrates in 383 patients. Median fluoroscopy time was 6.7 minutes overall and 5.1 minutes with anatomically normal hearts. LF comprised 61% of all ablation and 69% of anatomically normal hearts. LF procedures were associated with anatomically normal hearts (93% vs. 63%; $P < .0001$). In anatomically normal hearts, HF was associated with accessory pathways (64% vs. 47%; $P = .01$), posteroseptal substrates (22% vs. 9%; $P = .002$), and ventricular substrates (12% vs. 1%; $P < .0001$). All cases of intra-atrial reentrant tachycardia were HF. HF was associated with trans-septal puncture (47% vs. 23%; $P < .0001$) though not when controlling for atrioventricular nodal reentrant tachycardia. LF was associated with cryoablation (56% vs. 17%; $P < .0001$).
Conclusions. In pediatric and congenital EP, ablation procedures using cryoablation and in patients with anatomically normal hearts are associated with LF. In accessory pathway ablation, HF was not associated with trans-septal puncture.

Key Words. Electrophysiology; Catheter Ablation; Pediatric Cardiology; Fluoroscopy

Introduction

Catheter ablation in the pediatric and CHD population has offered effective treatment for arrhythmias for over 20 years.[1–4] Its early reliance on fluoroscopy-guided catheter navigation was reduced with the implementation and advancement of three-dimensional (3D)[3] mapping systems.[5,6] Given the known risks of ionizing radiation, particularly relevant to the pediatric population, there has been an increasing effort to limit its use.[7–11] Indeed, the era of low and even fluoroscopy-free electrophysiology study and ablation procedures has arrived.[12,13]

A significant reduction in fluoroscopic exposure has been demonstrated in these procedures when employing 3D mapping and intracardiac ultrasound without a compromise in success rate or increase in procedure time.[14,15] An increase in total case duration due to increased setup and catheter placement has, however, been noted. A recent study characterized factors associated with increased fluoroscopy time in a comparison between conventional ablation and 3D mapping-assisted ablation.[16] A prospective randomized controlled trial designed to assess this question is ongoing.[17] In laboratories employing concerted low-fluoroscopy efforts, including the consistent use of 3D mapping, the variables that characterize electrophysiology cases failing to achieve single-digit fluoroscopy times remain undefined.

Once radiation-reducing measures have been optimized, the most operator-dependent and generalizable metric of radiation use is fluoroscopy time. The aim of this study was to identify significant differences between high- and low-fluoroscopy procedures in patient and procedural characteristics that may contribute to fluoroscopy use.

Methods

Patient Selection

In a retrospective cohort study, records from consecutive patients who underwent first-time ablation at the University of Michigan Congenital Heart Center from January 1, 2010, to December 31, 2012, were reviewed. Computerized 3D mapping systems had been in consistent use in this center for more than 5 years prior to the study period. All patients who underwent catheter ablation during the study period were included.

Mapping and Ablation Procedure

All cases reviewed involved the use of 3D mapping with a capability of single or biplane conventional fluoroscopy. Cases were performed by any of three attending pediatric electrophysiologists, with the assistance of fellow trainees.

Data Collection

Patients and procedures were identified from the center's database, and additional clinical data were obtained from medical records. Patient and procedural factors were analyzed for the cohort as a whole. The cohort was then divided into two groups for comparison: a high-fluoroscopy time group (HF), defined as receiving ≥10 minutes of fluoroscopy time, and a low-fluoroscopy time group (LF), who received <10 minutes of fluoroscopy time.

Statistical Analysis

Data are presented as absolute number with percentage for categorical variables and median with range or interquartile range for continuous variables. Patient and procedural characteristics of the two fluoroscopy time groups (HF vs. LF) were compared using χ^2-test or Fisher's exact test for categorical variables and Wilcoxon rank-sum test for continuous variables. Separate analyses were completed for patients with anatomically normal hearts and those with CHD. Odds ratio and 95% confidence interval were also reported for the substrates significantly associated with HF. The analysis was completed based on the first procedure for each patient. An additional analysis was completed for all procedures during this time period, including repeat ablations, with similar results (data not shown). Logistic regression controlling for atrioventricular nodal reentrant tachycardia (AVNRT), using the Wilcoxon rank-sum test for continuous variables, was performed to determine if the association between trans-septal puncture and the two fluoroscopy groups was confounded by AVNRT. All analyses were performed using SAS Version 9.3 (SAS Institute Inc., Cary, NC, USA), with statistical significance set at a P value less than .05 using a two-sided test.

Results

Case Characteristics

During the study period, first-time ablations were performed on 383 patients, in whom a total of 432 arrhythmia substrates were addressed (339 patients with single substrates, 39 with two substrates, and 5 with three). There were an additional 33 (8.6%) repeat ablations (with initial ablations occurring before or during the study period) that were excluded from the primary analysis. Patients were 52% male with a median age of 14.4 years (range 0.4–56.1) and median weight of 55.1 kg at procedure (range 4.9–181.5) (Table 1). Of the 383 patients, acute success was achieved in 371 (97%). There were a total of 46 recurrences for all initial procedures in this group (12%).

In the 311 patients with anatomically normal hearts, 332 ablation procedures were performed, addressing 359 substrates. In the 72 patients with CHD, there were 84 ablations, addressing 112 substrates. Median fluoroscopy time for all patients was 6.7 minutes (range 0–107) and 5.1 minutes (0–80) for those with anatomically normal hearts. The skewed distribution of fluoroscopy

Table 1. Demographic and Procedural Characteristics of Patients Who Underwent Pediatric Catheter Ablation

Characteristics	All	High-fluoroscopy (≥10 min) (n = 150)	Low-fluoroscopy (<10 min) (n = 233)	$P^{\dagger}$
Male sex	200 (52.2)	80 (53.3)	120 (51.5)	.73
Caucasian race	326 (85.1)	128 (85.3)	198 (85.0)	.34
Age at procedure (years)	14.4 (10.6–16.8)	15.0	14.2	.02*
Weight (kg)	55.1 (39.4–67.7)	58.7	54.1	.12
Height (cm)	163 (146–172)	162	163	.89
Body surface area (m^2)	1.6 (1.3–1.8)	1.6	1.6	.19
Procedural				
Total procedural time (min)	174 (120–244)	235 (170–309)	140 (108–195)	<.0001*
Trans-septal puncture	116 (30.3)	65 (43.3)	51 (21.9)	<.0001*
Substrate				
Accessory pathway	176 (46.0)	68 (45.3)	108 (46.4)	.85
Right free wall accessory pathway	29 (7.6)	9 (6.0)	20 (8.6)	.35
Left free wall accessory pathway	91 (23.8)	35 (23.3)	56 (24.0)	.88
Posterior septal accessory pathway	44 (11.5)	22 (14.7)	22 (9.4)	.12
Anterior septal accessory pathway	12 (3.1)	2 (1.3)	10 (4.3)	.14
Atrioventricular nodal reentrant tachycardia	118 (30.8)	14 (9.3)	104 (44.6)	<.0001*
Atrial fibrillation	3 (0.8)	3 (2.0)	0 (0.0)	.06
Intra-atrial reentrant tachycardia	24 (6.3)	24 (16.0)	0 (0.0)	<.0001*
Atrial ectopic tachycardia	12 (3.1)	9 (6.0)	3 (1.3)	.01*
Ventricular tachycardia	21 (5.5)	17 (11.3)	4 (1.7)	<.0001*
Multiple	29 (7.6)	15 (10.0)	14 (6.0)	.15
Left or right-sided substrate				
Left	123 (32.1)	63 (42.0)	60 (25.8)	.0001*
Right	248 (64.8)	76 (50.7)	172 (73.8)	.0001*
Use of radiofrequency or cryo				
Radiofrequency	194 (50.7)	100 (66.7)	94 (40.3)	<.0001*
Cryo	150 (39.2)	23 (15.3)	127 (54.5)	<.0001*
Complication	36 (9.4)	16 (10.7)	20 (8.6)	.48
Anatomically normal heart (ANH)	311 (81.2)	95 (63.3)	216 (92.7)	<.0001*
Post-procedural				
Acute success	371(96.8)	138 (92.0)	233 (100.0)	<.0001*
Recurrence	46 (12.0)	24 (16.0)	22 (9.4)	.05*

Analysis based on the first procedure for each patient (n = 383).
Data are presented as n (%) for categorical variables and median (interquartile range) for continuous variables.
*$P < .05$.
†P value from χ^2-test or Fisher's exact test for categorical variables and Wilcoxon rank-sum test for continuous variables on comparison of each characteristic between two fluoroscopy groups.

time use is shown in Figure 1. There were 42 ablations (11%) performed without fluoroscopy. Fluoroscopy time was less than 2 minutes in 107 ablations (28%). LF comprised 61% of all ablation and 69% of ablation in anatomically normal hearts.

Fluoroscopy use by substrate type and location is shown in Figure 2. Ablation of accessory pathway substrates had median fluoroscopy times ranging from 5.0 (anteroseptal) to 9.9 (posteroseptal) minutes. Median fluoroscopy use for AVNRT was 0.9 minutes; for intra-atrial reentrant tachycardia (IART), atrial ectopic tachycardia (AET), ventricular tachycardia (VT), and multiple substrates, it ranged from 11.2 minutes (multiple substrates) to 27.5 minutes (IART).

LF procedures were associated with anatomically normal hearts (93% vs. 63%; $P < .0001$). LF was also highly associated with successful cases (100% vs. 92%; $P < .0001$). There was an association between HF and recurrence (16% vs. 9%; $P = .05$). The odds ratios of significant associations are shown in Table 2.

Anatomically Normal Hearts

Considering only anatomically normal hearts, HF was associated with increased procedure duration. Of 311 cases, 305 were acutely successful (98%). LF was highly associated with successful cases (100% vs. 94%; $P = .001$). In the anatomically normal heart cohort, the recurrence rate was 9% with no association between fluoroscopy use and recurrence. There was no difference between the groups with regard to attending electrophysiologist or the number of substrates addressed. Excluding the 7 cases in which remote magnetic or robotic navigation was used, the type of 3D mapping technology was not significantly different between the groups. Trans-septal puncture was performed in a greater number of HF than LF procedures (47% vs. 23%; $P < .0001$), though this relation was lost after excluding AVNRT from the

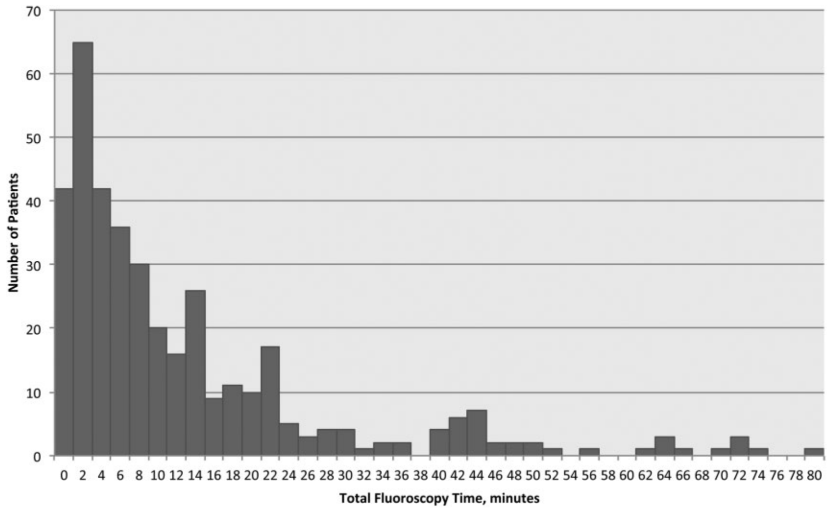

Figure 1. Histogram of fluoroscopy times for the series.

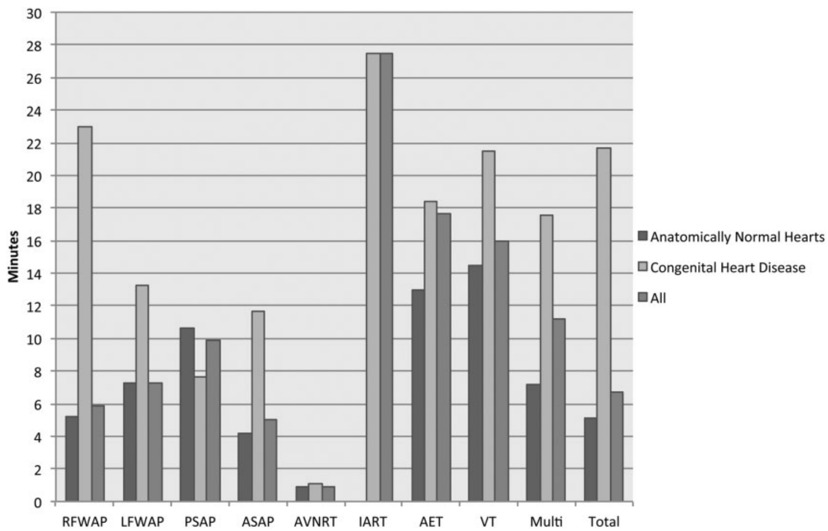

Figure 2. Fluoroscopy use by substrate. The median is reported due to non-normal distribution. RFWAP, right free wall accessory pathway; LFWAP, left free wall accessory pathway; PSAP, posteroseptal accessory pathway; ASAP, anteroseptal accessory pathway; AVNRT, atrioventricular nodal reentrant tachycardia; IART, intra-atrial reentrant tachycardia; AET, atrial ectopic tachycardia; VT, ventricular tachycardia; Multi, multiple substrates.

analysis. HF was associated with posteroseptal accessory pathways (22% vs. 9%; P = .002) and ventricular substrates (12% vs. 1%; P < .0001). When comparing all accessory pathways to other ablation substrates, HF was associated with accessory pathways (64% vs. 47%; P = .01). HF was associated with left-sided substrates (52% vs. 27%; P < .0001). LF was associated with cryoablation (56% vs. 17%; P < .0001). The odds ratios of the significant associations in this subset are shown in Table 3. There was no statistically significant difference between the groups relative to pathway (right free wall, left free wall, or anterior septal accessory), though the difference in left free wall pathways approached significance.

Congenitally Abnormal Hearts

In the procedures on patients with CHD, median age trended higher in HF cases. In these patients, 66 of 72 cases had acute success (92%). There was no association between fluoroscopy use and success in this population. The recurrence rate was 24%, with a trend toward HF association with recurrence (29% vs. 6%; P = .06) and older age (24 years vs. 17 years; P = .06). Excluding cases using magnetic or robotic navigation, the type of 3D

Table 2. Demographic and Procedural Characteristics Predicting High Fluoroscopy: All Patients, First Procedure Only (n = 383)

Characteristics	Odds Ratio	95% Confidence Interval
Age at procedure (years)	1.06	1.03, 1.09
Procedural		
Total procedural time (min)	1.01	1.01, 1.02
Success	0.04	0, 0.17
Trans-septal puncture	2.73	1.75, 4.29
Substrate		
Atrioventricular nodal reentrant tachycardia	0.13	0.07, 0.23
Intra-atrial reentrant tachycardia	62.4	13.6, infinity
Atrial ectopic tachycardia	4.87	1.19, 28.5
Ventricular tachycardia	7.32	2.64, 25.8
Left or right-sided substrate		
Left	2.38	1.53, 3.72
Right	Reference	
Use of radiofrequency or cryo		
Radiofrequency	5.87	3.52, 10.1
Cryo	Reference	
Anatomically normal heart	0.14	0.07, 0.24
Post-procedural		
Acute success	0.04	0, 0.17
Recurrence	1.83	0.98, 3.41

Only statistically significant analyses presented.

Table 3. Procedural Characteristics Predicting High Fluoroscopy: Patients with Anatomically Normal Hearts (n = 311)

Characteristics	Odds Ratio	95% Confidence Interval
Total procedural time (min)	1.01	1.01, 1.02
Trans-septal puncture	2.99	1.79, 5.00
Substrate		
Accessory pathway	2.01	1.23, 3.32
Posterior septal accessory pathway	2.78	1.42, 5.46
Atrioventricular nodal reentrant tachycardia	0.15	0.07, 0.29
Atrial ectopic tachycardia	9.45	1.38, 186
Ventricular tachycardia	13.9	2.94, 132
Left or right-sided substrate		
Left	3.16	1.90, 5.29
Right	Reference	
Use of RF or cryo		
RF	4.57	2.53, 8.62
Cryo	Reference	
Post-procedural		
Success	0.05	0, 0.27
Recurrence	0.85	0.34, 1.94

Only statistically significant analyses presented.

mapping technology did segregate between groups: HF with Carto (Carto XP and Carto 3, Biosense-Webster, Inc., Diamond Bar, CA, USA) and LF with Ensite (Ensite Velocity, St. Jude, Inc., St. Paul, MN, USA). HF was associated with longer procedural duration (270 minutes vs. 150 minutes; $P < .0001$) and trans-septal puncture (36% vs. 6%; $P = .02$). After excluding AVNRT

Table 4. Demographic and Procedural Characteristics Predicting High Fluoroscopy: Patients with Congenital Heart Disease (n = 72)

Characteristics	Odds Ratio	95% Confidence Interval
Age at procedure (years)	1.05	1.00, 1.10
Procedural		
Total procedural time (min)	1.02	1.01, 1.04
Trans-septal puncture	8.94	1.21, 402
Substrate		
Atrioventricular nodal reentrant tachycardia	0.19	0.03, 0.95
Intra-atrial re-entrant tachycardia	17.6	3.56, infinity
Use of RF or cryo		
RF	5.63	1.29, 26.1
Cryo	Reference	

Only statistically significant analyses presented.

cases from the analysis, HF's association with trans-septal puncture was not significant ($P = .09$). LF was associated with AVNRT (24% vs. 6%; $P = .05$) and cryoablation (41% vs. 11%; $P = .01$). All cases of IART were HF. The odds ratios of significant associations in this subset are shown in Table 4.

There were no major complications in either group, and the overall rates of minor complications were similar.

Discussion

The current era of pediatric catheter ablation provides for low- or zero-fluoroscopy procedures. Despite these procedural advances, cases involving significant use of fluoroscopy remain. The data presented describe the patient and procedural characteristics associated with increased use of fluoroscopy in a lab actively minimizing its use in favor of 3D nonfluoroscopic alternatives.

Analyzing fluoroscopy time as continuous data was considered, but the statistical tools available for this variable with very nonnormal distribution were complex. As such, we believed a nominal comparison to be more clinically meaningful. The 10-minute threshold was selected as a round value that divided the case series into comparable groups and was a reasonable threshold separating cases of lower and higher fluoroscopy use.

While there are many components (including minutes, frame rate, beam strength, etc.) that contribute to reduced radiation dose for a patient, total minutes of fluoroscopy is the most practitioner-dependent. Effective dose varies with equipment age, manufacturer, and other features selected by a facility or physician. Use of collimation, beam filtering, and the lowest usable frame rates all minimize radiation dose, in addition to prudent fluoroscopy pedal use. It is the practice of this lab to use 4 frames per second as a baseline and increase to 15–30 frames per second for precise catheter manipulations such as trans-septal puncture.

Not surprisingly, this study confirms that the use of fluoroscopy is higher in the congenital heart population than in pediatric patients with anatomically normal hearts. The small number of cases (9 total) using technology integrating MRI, CT, and real-time intravascular echo (ICE), which offer improved navigation in complex anatomy,[18] did not allow for an assessment of their impact on fluoroscopy use.

In the anatomically normal heart cohort, there were two key findings: (1) HF is associated with use of radiofrequency (RF) ablation compared with cryoablation; and (2) trans-septal puncture does not confer HF even in the setting of a fluoroscopy-guided puncture technique and fellow involvement.

The first of these may be attributable primarily to the almost exclusive performance of AVNRT ablation using cryoablation. These cases, even when of long duration and requiring many cryo lesions, could be completed with minimal fluoroscopy use. The safety of cryoablation allows for reduced fluoroscopy once there is a decision that it will be the ablation modality. We hypothesize that the second of these findings, that trans-septal punctures were found to a similar degree in HF and LF groups, results from the fact that while puncture was performed using fluoroscopy, the left-sided substrates required less subsequent fluoroscopy than other substrates to ablate successfully. Though not a frequent practice of this lab, it is possible that the use of ICE may serve to further decrease fluoroscopy use.

For posterior septal accessory pathways, often ablated with RF, HF may occur secondary to efforts verifying catheter position and the challenges of mapping in this region. These cases may therefore represent an opportunity to use cryoablation and reduce fluoroscopy time significantly.

Both AET and VT showed increased use of fluoroscopy, though they constitute a small minority of the substrates addressed. These too may represent opportunities to reduce fluoroscopy time, perhaps by relying more heavily on mapping technologies, including automated pace mapping (Carto Paso, Biosense-Webster) and noncontact mapping (EnSite Velocity 3D Array, St. Jude) technologies.

Congenital procedures involving not only complex arrhythmias but also varied and complex anatomy are notorious for prolonged case duration, another factor associated with increased fluoroscopy use. With multiple circuits to map, unique chamber dimensions, and extensive ablation lines, operators likely rely more heavily on fluoroscopy.

The study identified increased fluoroscopy use with the Carto 3D mapping systems compared with that of the Velocity/NavX. When looking at the subanalysis of normal vs. congenital heart disease, however, a difference was only seen in the congenital heart group. This association is confounded by a selection bias: early in the cohort, it was preferred to reserve the use of Carto XP for cases in which point-by-point activation mapping was anticipated. The ability of the system to visualize only the ablation catheter necessitated the use of fluoroscopy to position diagnostic catheters. Given the goal of zero fluoroscopy use, the Velocity/NavX was used for most other routine ablations. With the introduction of the Carto 3 later in the experience, this system was used more interchangeably with Velocity/NavX.

Study limitations include those inherent in a retrospective study at a single center. The selection of 3D mapping system by the three attending pediatric electrophysiologists was at times feature-based and at others arbitrary. It was also not possible to control for the involvement of individual operators, who included fellows and attending physicians of varying experience, as their involvement could not be quantified from records. Additionally, the use of fluoroscopy was not formalized and, we suspect, was influenced by such factors as involvement of trainees, the specific laboratory used, and preferred equipment.

In conclusion, higher fluoroscopy exposure was associated with procedures completed on patients with CHD and those using RF rather than cryoablation. Procedures involving an accessory pathway and even trans-septal puncture did not segregate into the high fluoroscopy time group. Recognition of factors associated with HF may assist in planning and executing ablation with improved safety for the pediatric catheter ablation patient. Anticipating minimal to no fluoroscopy use in cryoablation cases is reasonable using modern 3D mapping systems. Expanding the array of substrates addressed with cryoablation may be a means to reduce fluoroscopy use significantly.

Acknowledgement

We would like to thank Janet Donohue and the Michigan Congenital Heart Outcomes Research and Discovery (M-CHORD) program for research design and statistical support.

Author Contributions

Adam Kean was involved with conception and design, data collection, statistics, data analysis and interpretation, drafting the article, and critical revision of the article. Martin J. LaPage was involved with critical revision of the article. Sunkyung Yu was involved with statistics and critical revision of the article. Macdonald Dick II was involved with data analysis and interpretation, critical revision of the article, and approval of the article. David Bradley was involved with conception and design, data collection, statistics, data analysis and interpretation, critical revision of the article, and approval of the article.

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Conflict of interest: None.

Accepted in final form: June 6, 2014.

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