J Interv Card Electrophysiol (2007) 19:121–127
DOI 10.1007/s10840-007-9148-3

Impact of a computer assisted navigation system on radiation exposure during pediatric ablation procedures

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Received: 3 April 2007 / Accepted: 26 June 2007 / Published online: 1 August 2007

Abstract
Background During catheter ablation procedures, non-radiologic navigation systems may reduce fluoroscopic exposure and energy applications, as well as improve procedural success rates.
Objective To examine the impact of a non-radiologic navigation system on ablation procedures in pediatric patients, the procedural characteristics and success rates prior to and following incorporation of the LocaLisa® (LL) navigation system into a pediatric electrophysiology laboratory were compared.
Methods Between January 2000 and April 2005, 246 consecutive patients underwent catheter ablation for either Atrioventricular Reentry Tachycardia AVRT (168) or Atrioventricular Nodal Reentry Tachycardia AVNRT (78). Ablation procedures performed prior to LL (108) were compared to ablation procedures performed using LL (113). The first 25 patients using LL were censored to remove the bias of a learning curve.
Results There was no difference in demographic features between the two groups. Statistically significant decreases were found in the diagnostic (11.4±6.1 min v 18.8±9.8 min w/o LL), ablation (5.7±10.3 vs 18.5±20.1 min w/o LL) and total (17.2±12.6 vs 37.3±21.3 min w/o LL) fluoroscopy times for the LL group, as well as in the total number of energy applications (9.0±8.5 vs 12.3±12.2 w/o LL). Success rates were 99.1% w/ LL v 97.2% w/o LL (p=NS). No major complications were observed in either group.
Conclusions The use of a computer assisted navigation system significantly decreased the diagnostic, ablation, and total fluoroscopy times, as well as the number of energy applications, without affecting procedural success or complication rates. Non-radiologic navigation systems reduce radiation exposure during transcatheter electrophysiologic procedures and thus lower the lifetime radiation cumulative risk, a goal particularly important in children.

Keywords Atrioventricular nodal reentrant tachycardia · Atrioventricular reentrant tachycardia · Catheter ablation · Children · Fluoroscopy · Intracardiac Navigation · LocaLisa®

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1 Introduction

Electrophysiologic studies and catheter ablation procedures have historically been associated with significant fluoroscopy exposure [1]. Multiple reports in both children and adult patients cite fluoroscopy times ranging from 40 min to over an hour for routine ablation procedures [2–4]. The most recent data from the Pediatric Radiofrequency Ablation Registry as well as PAPCA (Prospective Assessment after Pediatric Cardiac Ablation) have demonstrated a steady decrease in mean fluoroscopy times from nearly an hour in 1991–1992, to 40 min in 1995–1996, and a further decrease to 36 min in 2004 [5–7].

Exposure to fluoroscopy presents a long term adverse effect of procedures performed in the catheterization laboratory [8]. Each hour of fluoroscopic imaging is estimated to increase the lifetime risk of developing a fatal malignancy by up to 1%, as well as an increased risk of

transmitting a genetic defect of up to 20 per 1 million births [1, 9–11]. While these risks are not prohibitive, they carry significant morbidity and possible mortality. Measures to decrease fluoroscopic exposure are of particular interest in a pediatric population, given the longer lifespan in which to recognize these risks.

The recent introduction of computer assisted non-fluoroscopic mapping systems has provided the possibility for manipulation of intracardiac catheters with significantly less use of fluoroscopy. Studies in adult subjects have demonstrated a decrease in procedural fluoroscopy time utilizing non-fluoroscopic mapping systems [12, 13], however, there are very limited data on their use in children [14–16]. To assess the impact of a non-radiation navigation system on radiation exposure and ablation outcomes, procedural characteristics and success rates were evaluated prior to and following incorporation of the LocaLisa® (Medtronic Inc, Minneapolis, MN) navigation system into a pediatric electrophysiology laboratory.

2 Methods

Clinical data from the Division of Pediatric Cardiology, C. S. Mott Children's Hospital's computer-based electrophysiological records were reviewed for all ablation procedures performed for supraventricular tachycardia (SVT) between January 2000 and April 2005. Demographic data, procedural characteristics (including fluoroscopy time and number of energy applications), procedural success rates, and complication rates were extracted. Total fluoroscopy time was divided into diagnostic (defined as fluoroscopy time until the first application of energy) and ablative components (defined as all fluoroscopy time after the first application of energy). Procedural success was defined as a lack of inducible tachycardia at the conclusion of the procedure, and maintenance of a normal sinus rhythm through hospital discharge. Procedures performed prior to LocaLisa® were then compared to procedures performed using LocaLisa®. By design, the first 25 procedures performed using LocaLisa® were censored from the analysis to reduce the bias of a learning curve. Continuous data was analyzed using an unpaired Student's *t*-test. A chi square analysis was performed on all categorical data. Linear regression analysis of the total fluoroscopy time as well as number of energy applications was performed to evaluate for confounding trends in both data groups. A p-value ≤ 0.05 was taken to denote significance. The study was approved by the Medical Institutional Review Board at the University of Michigan.

All patients with SVT underwent a standard electrophysiological study with three or four intracardiac catheters [17]. During the early part of the study period, radiofrequency (RF) energy was utilized for all ablative procedures. Later in the study period, cryothermal energy was used for all Atrioventricular Nodal Reentrant Tachycardia (AVNRT) ablations, para-septal accessory pathways, as well as for patients in whom application of RF energy was not successful in terminating their tachycardia and cryoablation was felt to offer a potential benefit. All cryoablations performed during the study period utilized the CryoCath Freezor® 7F 4 mm tip cryoablation catheter (CryoCath Technologies, Montreal, Quebec) as has been previously described [18]. For procedures that involved the application of cryothermal energy, the number of energy applications was defined as the number of cryoablation lesions placed at or below −70°C; cryomapping lesions (placed at −30°C) were not included in the total number of energy applications for the procedure. A separate analysis was also performed comparing the number of RF applications for procedures performed prior to LocaLisa® to those procedures performed using LocaLisa® in which RF was the only mode of energy utilized.

3 Results

The study population consisted of 246 consecutive patients undergoing ablation procedures for SVT between January 2000 and April 2005. In 168 patients, the tachycardia was supported by an accessory pathway, and in 78 patients, AVNRT was found.

There was no significant difference between the two groups in regards to gender, age at the time of procedure, or mechanism of SVT (Table 1). There was no statistically significant difference in procedural success rates between the two groups: 99.1% with LocaLisa® and 97.2% without LocaLisa®. No major complications occurred in either group. All patients had structurally normal cardiac anatomy with the exception of 3 patients in the LocaLisa® group (patent foramen ovale (1), mitral valve prolapse (1), and Ebstein's anomaly with pulmonary stenosis (1)), and 4 patients in the non-LocaLisa® group (Ebstein's anomaly (2), and small ventricular septal defect (2)).

Table 1 Procedural characteristics

	Without LocaLisa	With LocaLisa
Number of procedures	108	113
Male/female	56% / 44%	53% / 47%
Mean age	13.0±5.2	13.8±5.1
AVRT	68%	67%
AVNRT	32%	33%
Procedural success	97.2%	99.1%

The mean total fluoroscopy time for all ablation procedures performed prior to LocaLisa® was 37.3±21.3 min (median=32.8 min); with the use of the LocaLisa® navigation system, the overall mean total fluoroscopy time decreased to 17.0±12.6 min (median=13.2 min) ($p<0.0001$) (Fig. 1). The diagnostic component of the total fluoroscopy time decreased from 18.8±9.8 min (median=16.4 min) to 11.4±6.1 min (median=10.8) with LocaLisa® ($p<0.0001$), and the mean ablation fluoroscopy time decreased from 18.5±20.1 min (median=10.6 min) to 5.7±10.3 min (median=2.1 min) ($p<0.0001$) (Fig. 2). A significant decrease in the overall number of energy applications was also found in the LocaLisa® group, (12.3±12.2 to 9.0±8.5) ($p=0.026$) (Fig. 3).

Subgroup analysis of the data classified by mechanism of SVT, as well as accessory pathway location, revealed a significant decrease in the total fluoroscopy time for each category (Table 2). Procedural fluoroscopy times involving left sided accessory pathways were not significantly different from fluoroscopy times recorded for right sided accessory pathways (both with and without the use of LocaLisa®).

A separate analysis of the 67 cases performed using LocaLisa® in which RF was the only mode of energy delivered also demonstrated a decrease in the mean number of RF applications (12.3±12.2 to 8.6±8.3) ($p=0.021$), as well as fluoroscopy times (Table 2). A linear regression analysis of the total fluoroscopy time and number of RF energy applications prior to and following incorporation of the LocaLisa® system did not demonstrate a statistically significant decrease with time (Fig. 4).

4 Discussion

The risks of both prolonged and cumulative fluoroscopy exposure are well documented [19–21]. Children are at an increased risk from radiation exposure, as their longer life expectancy allows for a longer latency period for the development of malignancy following exposure [3, 11]. Children also receive a greater effective dose of radiation during interventional catheterization procedures as scatter radiation has a shorter distance to travel to reach sensitive organs such as the bone marrow, liver, and breast tissue [20]. For these reasons, decreasing fluoroscopic exposure during electrophysiologic ablation procedures carries a greater benefit in children compared with adults. This study demonstrates that the use of a transcatheter non-radiation dependent navigation system can significantly reduce radiation exposure for the most commonly performed types of ablation procedures in children.

In our study, the overall mean fluoroscopy time for ablation procedures performed prior to LocaLisa® was 37 min, which compared favorably to the mean fluoroscopy time reported by the PAPCA [7]. However, with the use of the navigation system, the overall mean total fluoroscopy time was decreased by 55% to just over 17 min. The diagnostic component of the total mean fluoroscopy time

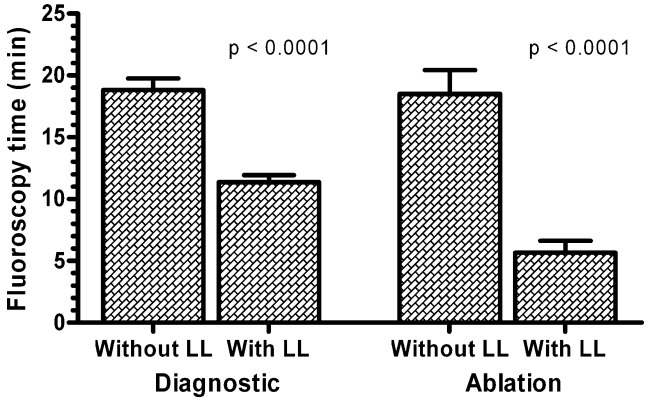

Fig. 2 Comparison of mean diagnostic and ablation components of the total fluoroscopy time after incorporation of a navigation system (*LL* = LocaLisa®)

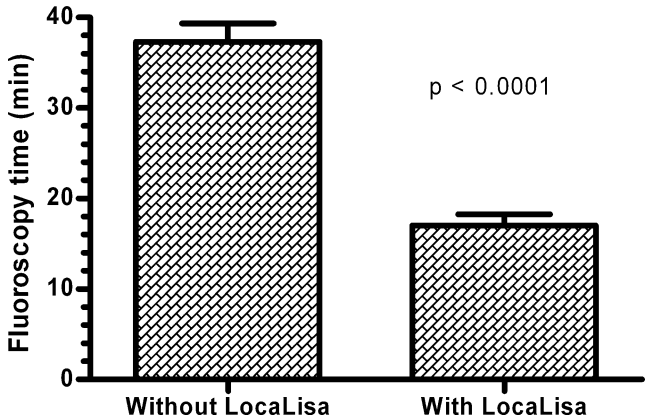

Fig. 1 Mean total fluoroscopy time after incorporation of an intracardiac navigation system

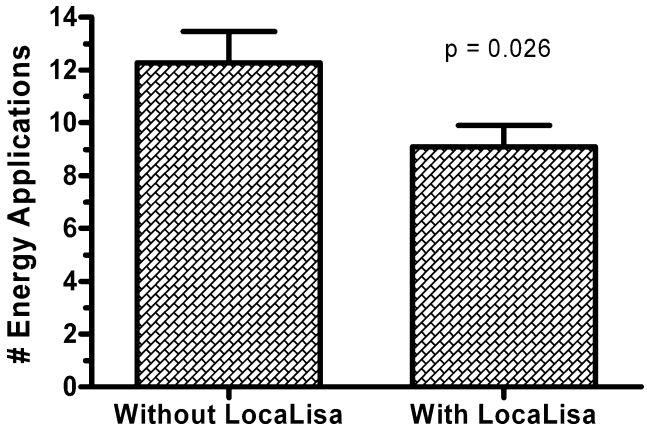

Fig. 3 Mean number of energy applications after incorporation of the LocaLisa® system

Table 2 Procedure and fluoroscopy times for AV nodal reentrant tachycardia, accessory pathways (by location), and procedures in which RF was the only mode of energy delivered

Procedure		Procedure Time (min)	Fluoroscopy Time (min)		
			Diagnostic	Ablative	Total
AVNRT	Without LL (35)	241.9±76.7	15.7±8.5	21.0±18.7	36.8±21.5
	With LL (37)	225±68.7	9.5±4.4	3.8±3.9	13.3±6.8
	P-value	NS	<0.001	<0.001	<0.001
Accessory pathways	Without LL (73)	233.8±86.5	20.3±10.0	17.3±20.7	37.6±21.4
	With LL (76)	198.1±77.6	12.1±6.3	6.8±12.3	18.9±14.3
	P-value	0.009	<0.001	<0.001	<0.001
Left sided	Without LL (43)	229.0±80.0	21.3±10.1	14.6±17.1	35.9±19.8
	With LL (46)	169.5±54.5	12.1±6.1	5.0±11.2	17.1±13.1
	P-value	<0.001	<0.001	0.002	<0.001
Right posterior and lateral	Without LL (14)	254.2±114	17.6±9.8	27.2±26.3	44.8±26.7
	With LL (16)	228.4±88.0	12.5±7.7	13.1±16.6	25.5±19.2
	P-value	NS	NS	NS	0.03
Right septal	Without LL (16)	228.7±78.3	20.0±10.2	15.7±22.9	35.7±20.4
	With LL (14)	267.0±85.8	11.5±5.1	5.4±6.3	16.9±8.8
	P-value	NS	0.008	NS	0.003
RF only	Without LL (108)	233.1±80.3	18.7±9.8	17.4±18.5	36.1±19.5
	With LL (67)	184.5±70.2	12.6±6.9	5.5±2.1	18.1±13.1
	P-value	<0.001	<0.001	<0.001	<0.001

decreased 39% from 18.8 min, to 11.4 min with LocaLisa®. This observation is likely a direct result of the system's ability to accurately and reliably localize points of interest within the heart [22]. For example, during a typical AVNRT ablation procedure, both a coronary sinus catheter and His catheter would be placed under fluoroscopic guidance, and the position of each electrode marked on the LocaLisa® system. Using these defined landmarks, the ablation catheter could then be maneuvered in and around the anatomic region of the slow pathway with only minimal additional fluoroscopic imaging. The largest reduction was seen in the mean ablation fluoroscopy time, which decreased by nearly 70% from 18.5 to 5.7 min. This profound decrease, along with the observed 30% decrease in total number of energy applications, no doubt arose from the enhanced ability to exhaustively map an area of interest, mark points of interest and then return to and apply secondary lesions only at the location which provided the most benefit, all with little to no additional radiation exposure.

The compatibility of the navigation system with all types of electrode catheters and energy delivery systems was also found to be valuable during this study. In six cases, use of the navigation system assisted in the application of both RF and cryothermal energy to a location of interest when issues arose related to either catheter stability (RF) or lesion size and tissue penetration (cryoablation). This combination of both RF and cryothermal energy application led to a successful procedural outcome in each of these cases. Subjectively, the ability to note subtle changes in catheter position, particularly during RF application, was felt to be improved with the use of the navigation system, without the need for continuous fluoroscopic observation. Such observations are paramount to improving the safety of ablation procedures, particularly when working in the area of the compact AV node or other vital cardiac structures.

Although not measured in this study, the decrease in radiation exposure to the patients would logically equate to a decrease in radiation exposure to the operating physician. While the per-case decrease in fluoroscopy time is significant, this reduction becomes even more dramatic for each operator when multiplied by the number of procedures performed utilizing the mapping system.

The technology utilized in the LocaLisa® system has been acquired by Endocardial Solutions (now St. Jude Medical, St Paul, MN), who have expanded the technology and integrated it into their multifaceted mapping system. Papagiannis, *et al.,* recently reported that the use of this system (Ensite® NavX™) in 40 pediatric patients successfully reduced the fluoroscopy time necessary for catheter ablation procedures by 42% [14]. The NavX system has the advantage of being able to create a complete 3-dimensional model of the chamber of interest as well as displaying a greater number of electrodes. However, the cost for the NavX™ system is greater and the cost per case is higher due to a difference in cost for surface patches required to run the system (roughly $55 versus $900).

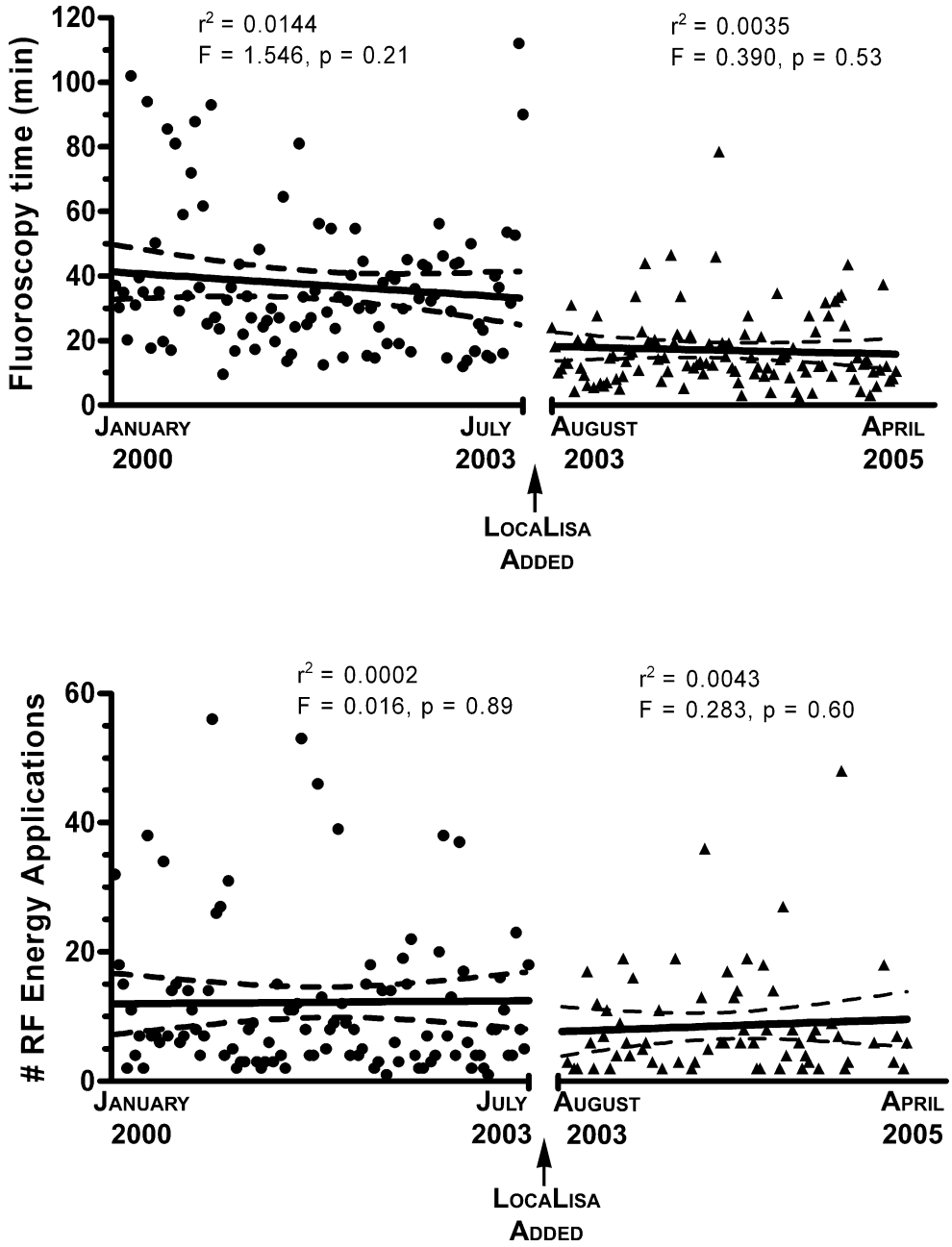

Fig. 4 There was no statistically significant trend toward reduction in the total fluoroscopy time (*top*) or number of RF energy applications (*bottom*) before or after incorporation of the LocaLisa® system

5 Study limitations

As with any study in which a historical cohort is used as the control group, overall improvement in technique by the two primary operators with the passage of time and increased experience can be a confounding factor. Independent regression analysis of the total mean fluoroscopy use over time in both the control and study groups, however, did not demonstrate a statistically significant improvement with time. A similar comparison of the number of RF energy applications also did not show a statistically significant trend (Fig. 4). These data suggest that it was the addition of the navigation system, and not a progressive learning curve, that was responsible for the reduction in fluoroscopy times and number of energy applications.

A second potential confounding factor in this study involves the use of cryothermal energy in 46 patients during the study period. During the application cryothermal energy, once the ablation catheter has adhered to the tissue it is no longer necessary to continuously observe the catheter position fluoroscopically. However, a separate analysis of the 67 cases performed using LocaLisa® in which RF was the only mode of energy delivered also demonstrated a marked reduction in both fluoroscopy times and number of energy applications (Table 2). Furthermore, these reductions were on a similar scale to those seen in the

LocaLisa® group as a whole, suggesting that the decreased fluoroscopy requirement during cryoablation procedures did not have a significant impact on the overall fluoroscopy use for the case.

6 Future direction

These data indicate that the use of an intracardiac navigation system can significantly reduce the fluoroscopic exposure for typical SVT ablation procedures in children. Although newer 3D mapping systems (CARTO™, NavX™, RPM™) provide electro-anatomical mapping of cardiac chambers along with catheter navigation capabilities, no study to date has demonstrated an added benefit in terms of reduced fluoroscopy time from these electro-anatomic mapping features. Further investigation will be necessary to determine if the additional information provided by the anatomical mapping aspects of these systems can further decrease fluoroscopy times.

7 Conclusions

The use of a computer assisted navigation system can significantly decrease the diagnostic, ablation, and total fluoroscopy times for catheter ablation procedures in children. Use of this system can also significantly reduce the number of energy applications. Procedural success rates were high and complication rates low in both groups. This study demonstrates that non-radiologic navigation systems reduce radiation exposure during transcatheter electrophysiologic procedures and thus lower the lifetime radiation cumulative risk, a goal which is particularly important in children.

Acknowledgement Disclosures: The authors received no financial support in relation to this study.

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