Nonfluoroscopic imaging systems reduce radiation exposure in children undergoing ablation of supraventricular tachycardia

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BACKGROUND The current standard of care for imaging during supraventricular tachycardia (SVT) ablation uses fluoroscopy, which exposes otherwise healthy children to the potential harmful effects of radiation.

OBJECTIVE The purpose of this study was to determine whether the adjunct use of nonfluoroscopic imaging reduces radiation exposure during SVT ablation among children.

METHODS This was a prospective, controlled, single-center study of patients age ≥8 years, weight ≥25kg, with SVT and normal cardiac anatomy. Patients were randomized to control (fluoroscopy only) or study group (fluoroscopy + AcuNav intracardiac ultrasound + NavX electroanatomic mapping), stratified by operator to one of five electrophysiologists. Fluoroscopy times (minutes) and radiation doses (mGy) were recorded, and outcomes and adverse events were noted.

RESULTS Seventy-four patients were enrolled (37 control, 37 study). Median age was 14.7 years (range 8.6–22.3 years); 61% had accessory pathways and 39% had atrioventricular nodal reentrant tachycardia. Nonfluoroscopic imaging reduced median fluoroscopy time by 59% (18.3 minutes vs 7.5 minutes, $P < .001$) and radiation exposure by 72% (387 vs 110 mGy, $P < .001$). In the study group, 26 of 37 had ≤10 minutes of fluoroscopy, including 2 with no fluoroscopy exposure and 2 with <30 seconds. Electrophysiologic procedure time was not affected by use of nonfluoroscopic imaging, but total case times were prolonged by 31 minutes ($P < .001$). Acute success was 97% in control and 100% in study patients, with no difference in adverse events.

CONCLUSION Use of nonfluoroscopic imaging during SVT ablation in children resulted in substantial and immediate reductions in fluoroscopy time and radiation exposure without change in acute success or adverse event rates but did increase overall procedural time.

KEYWORDS Ablation; Arrhythmia; Electroanatomic mapping; Fluoroscopy; Intracardiac echocardiography; Nonfluoroscopic imaging; Pediatrics; Radiation; Supraventricular tachycardia

ABBREVIATIONS **AV** = atrioventricular; **AVNRT** = atrioventricular nodal reentrant tachycardia; **ECG** = electrocardiogram; **ICE** = intracardiac echocardiography; **mGy** = milligray; **SVT** = supraventricular tachycardia; **WPW** = Wolff-Parkinson-White

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Introduction

Since 1990, catheter-guided radiofrequency ablation has been available as an option for treatment of supraventricular tachycardia (SVT), the most prevalent arrhythmia among healthy children. Catheter-based ablations for SVT are the most common procedures performed by pediatric electrophysiologists. The procedures are generally regarded as safe and effective, with an overall acute success rate of 95%.[1,2] The use of fluoroscopy to guide catheter manipulation during the procedure is the current standard of care. Average fluoroscopy time based on national data from the PAPCA study for children undergoing SVT ablation between 1999 and 2003 was 28.5 to 38.3 minutes, with 20% of children requiring greater than 50 minutes,[1] and an adult study of ablation showed a median fluoroscopy time of 25.5 minutes.[3] The exposure of children to significant amounts of ionizing radiation is concerning because they are more radiosensitive than are adults and have a longer anticipated lifespan during which they may develop cancers and express genetic injuries.[4–9]

Technologies for nonfluoroscopic imaging and catheter navigation are now widely used in invasive electrophysiologic procedures. Previous reports have demonstrated the feasibility of nonfluoroscopic ablation procedures in children, but to date there have been no prospective clinical trials of this approach.[10–14] The primary aim of this study was to determine whether the adjunct use of nonfluoroscopic imaging systems could decrease radiation exposure among children undergoing catheter-based ablation procedures for SVT.

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Methods

Study design

This was a prospective, randomized, controlled, single-center study performed at a large academic hospital. The study was registered at clinicaltrials.gov (identification number NCT00979303). All patients referred to Children's Hospital Boston for electrophysiologic study and ablation for SVT were evaluated. Inclusion criteria included age ≥8 years, weight ≥ 25 kg, and normal cardiac anatomy. Patients with trivial structural heart defects (e.g., bicuspid aortic valve, left superior vena cava to coronary sinus) were included. Patients were excluded if they had more than trivial congenital heart disease, prior cardiac surgery, or a history of prior ablation. The study protocol was approved by the Institutional Review Board at Children's Hospital Boston, and signed consent was obtained from the patient and one parent.

Randomization and study intervention

Randomization was stratified by operator to account for variation in practice and to ensure that the total number of control and study patients randomized to each operator was similar. Patients randomized to control underwent a standard ablation procedure using fluoroscopy only. Patients randomized to the study group underwent an ablation procedure with the additional use of intracardiac ultrasound (AcuNav, Acuson Corporation, Mountain View, CA, USA) and three-dimensional electroanatomic mapping (EnSite NavX, St. Jude Medical, St. Paul, MN, USA). Operators were instructed to use as much fluoroscopy as necessary to perform a safe and effective ablation, but they were aware that the goal in both groups was to minimize exposure. In the study group, use of each of the nonfluoroscopic imaging devices to achieve this goal was encouraged but not required.

Primary and secondary outcomes

Because the absorbed, bioequivalent radiation dose is difficult to measure and is significantly affected by body size, the primary outcome was chosen to be fluoroscopy time in minutes. Although this measure is only modestly correlated to total radiation dose, it is our opinion that it is an accurate measure of operator performance in procedure development. Radiation dose (measured in milligray [mGy]) was used as a secondary outcome. Radiation exposure was a computer-reported dose based on tube output, distance from the image intensifier, and patient chest depth. Additional secondary outcomes were procedural times, acute success, and adverse events. Follow-up was obtained at 1 to 3 months and at 1 year after the procedure.

Clinical management

All patients underwent a preablation electrocardiogram (ECG) and echocardiogram. Procedures were performed with patients under general anesthesia with endotracheal intubation performed by a cardiac anesthesiologist. Patients underwent placement of four catheters via femoral venous access (7F sheath in right femoral vein, two 6F and one 5F sheath in left femoral vein) and included positions in the coronary sinus, His-bundle position, right ventricular apex, and high right atrium. Patients in the study group had an additional 9F sheath placed in the right femoral vein for the intracardiac echocardiography (ICE) catheter. They also had placement of NavX surface patches and an esophageal electrode, which was used as the reference for NavX mapping. Right internal jugular cannulation was performed at the discretion of the operator for either coronary sinus and/or tricuspid annulus mapping. Procedural times (clock time and fluoroscopy time) and radiation exposure were documented for each segment of the procedure (Figure 1). Senior electrophysiology fellows began all cases, obtained venous access, and placed all catheters. In general, use of ICE in study group patients required two operators at the table; therefore, both the attending physician and the fellow worked together during these cases.

Patients with right-sided ablations were discharged the same day, whereas patients with left-sided ablations remained overnight for heparin infusion and were discharged the following morning. All patients were examined within 4 hours after the procedure and again prior to discharge if they has been admitted overnight. An ECG was obtained for all patients prior to discharge. Nursing staff was instructed to inform study investigators of any patient complaints or adverse events.

Nonfluoroscopic imaging techniques

The procedures were identical in both groups except for the additional ability to use ICE and the three-dimensional electroanatomic mapping (NavX) in the study group. Venous access and placement of femoral sheaths were performed without imaging except for fluoroscopy as needed. NavX was used to create femoral vessels and an inferior

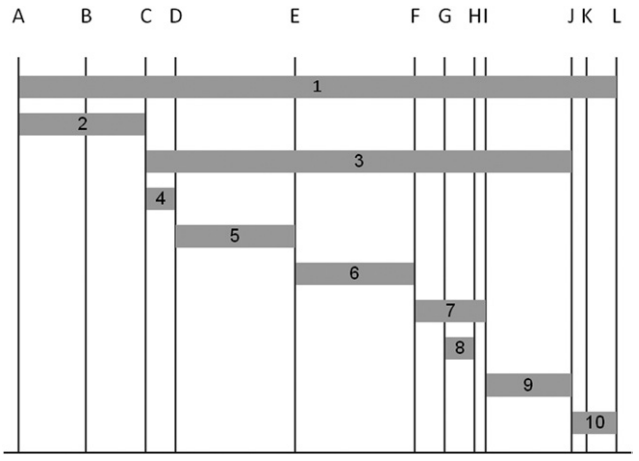

Figure 1 Breakdown of procedure into functional components. A: Patient enters laboratory. B: Patient intubated. C: Start of vascular access. D: Vascular access complete. E: All catheters in standard position within the heart. F: Start of mapping. G: Start of transseptal. H: End of transseptal. I: First ablation lesion. J: End of 30-minute waiting period after last ablation lesion. K: All vascular sheaths removed. L: Patient exits room. 1: Total case/laboratory time. 2: Set up. 3: Total electrophysiologic procedure time. 4: Vascular access. 5: Catheter placement. 6: Diagnostic electrophysiologic study. 7: Mapping. 8: Transseptal. 9: Ablation and 30-minute wait period. 10: Postprocedure care and transfer.