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Assessment of a novel radiation reduction protocol for pediatric and adult congenital device implantation

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Abstract

Purpose Device implantation requires fluoroscopic guidance, which carries inherent risks of ionizing radiation. We evaluated the impact of a low-dose fluoroscopic protocol on radiation exposure during device implantation.

Methods All patients who underwent pacemaker or ICD implantation with new transvenous leads from July 2011 to January 2018 were included. A novel ALARA protocol consisting of ultra-low frame rates (2–3 frames/s), low dose/frame (6–18 mGy/frame), and use of the "air-gap" technique in patients < 20 kg was employed. Demographics, procedural data, and radiation exposure levels were collected and analyzed.

Results Thirty patients underwent device implantation without additional catheterization, electrophysiology study, or ablation procedure (median age 15 years; range 5–50) with a total of 43 leads placed. Forty-seven percent of patients had a primary rhythm disturbance, 33% had cardiomyopathy, and 20% had congenital heart disease. Fifty percent were pacemakers (53% dual-chamber, 27% ventricle, 20% atrial) and 50% of devices implanted were ICDs (87% single-chamber). All implants were acutely successful with acceptable atrial and ventricular sensing and capture thresholds. The median fluoroscopy time was 11.5 min (inter-quartile range (IQR) 8.0–18.2), median air kerma dose 4.0 mGy (IQR 2.5–19.5), and median dose-area product 27.8 μGy/m^2 (IQR 17.1–106.5). Median implant procedure time was 133 min. One patient required revision secondary to device migration without lead derangement 2 days post-procedure.

Conclusions Use of a novel fluoroscopic protocol may help decrease radiation exposure to patients and staff without affecting efficacy or risk. These data may represent benchmarks against which future device implantation procedures can be compared.

Keywords Radiation reduction · Fluoroscopy · Pacemaker · Implantable cardioverter defibrillator · Pediatric · Adult congenital

1 Introduction

The importance of minimizing radiation exposure to patients and staff has been well established in the pediatric electrophysiology (EP) laboratory. The use of ALARA (as low as reasonably achievable) protocols has been evaluated in both pediatric EP and catheterization settings [1, 2]. The risk of radiation exposure is substantially greater in pediatric and adult congenital heart disease (CHD) patients, especially given periods of rapid growth and the likelihood of multiple repeat radiation exposing procedures with potential chromosomal damage throughout their lifetime [3]. Recent multicenter work has shown an increased frequency and earlier age for procedures involving ionizing radiation in children and adults with CHD, with the median age of first interventional procedure or study now below 1 year of age [4]. Although it is difficult to predict and estimate the long-term risk of malignancy secondary to the stochastic effects of radiation, the risk is believed to be substantially higher in children and ACHD patients compared to that in the general population [5]. Clay et al. evaluated radiation exposure during ablation procedures performed with fluoroscopy at 15 frames/s and calculated a lifetime risk of fatal malignancy at 0.02% per radiofrequency

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ablation [6]. While the practice of zero or low-fluoroscopy pediatric and adult CHD ablation and EP procedures have been well studied [7–12], there are scant studies demonstrating efforts to reduce radiation exposure in pacemaker (PM) or implantable cardioverter defibrillator (ICD) implantation procedures. In this investigation, we sought to evaluate the use of a novel low-dose fluoroscopic protocol and its impact on patient radiation exposure during pediatric and adult CHD device implantation procedures.

2 Methods

This study was approved by the Institutional Review Board of the Albert Einstein College of Medicine and Children's Hospital at Montefiore. All patients who underwent PM or ICD implantation with the implantation of new transvenous lead(s) between July 2011 and January 2018 were evaluated. Inclusion criteria were all patients who had their device implanted in the pediatric EP laboratory, utilizing Siemens technology (Siemens Artis Zee Biplane Fluoroscopy System, Siemens Medical Solutions, Malvern, PA), where the low-dose fluoroscopic protocol could be utilized. A novel ALARA protocol based upon a similar protocol used for ablations in children [2, 13] consisting of ultra-low frame rates (2–3 frames/s), low dose/frame (6–18 mGy/frame), proper collimation, and use of the "air-gap" technique for children < 20 kg (including removal of the anti-scatter grid) was employed in all cases. Fluoroscopy save was utilized for axillary/subclavian venography instead of cine recording as an additional method to decrease radiation exposure.

Data collected included demographic information, diagnosis and indication for device placement, device implant procedural information, lead diagnostics, and radiation exposure parameters. Data are presented as either mean ± standard deviation or median with inter-quartile range (IQR) for non-parametric data.

3 Results

Thirty patients underwent device implantation without additional catheterization, EP study, or ablation procedure, with a total of 43 leads placed (1.3 leads/patient). Median age was 15 years (IQR 11–17, range 5–50) and median weight was 55 kg (IQR 39.4–66.8, range 18.9–137.9). Forty-seven percent of patients had a primary rhythm disturbance, 33% had cardiomyopathy, and 20% had CHD. Demographic information and specific indications for device placement and the presence of structural or congenital heart disease are listed in Table 1. Fifty percent of devices were pacemakers (53% dual-chamber, 27% single-chamber ventricle, 20% single-chamber atrial) and 50% were ICDs (87% single-chamber). All implants were acutely successful with acceptable atrial and ventricular impedances, sensing, and capture thresholds (Table 2). Figure 1 shows typical examples of fluoroscopic images for vital portions of the device implantation procedure.

The median radiation dose was 4.0 mGy (IQR 2.5–19.5) and the median dose-area product was 27.8 $\mu Gy/m^2$ (IQR 17.1–106.5). Fifty-two percent of patients received less than 5 mGy during their device implantation procedure. The median fluoroscopy time was 11.5 min (IQR 8.0–18.2) with an average implant procedure time of 133 min (IQR 108–167); fluoroscopy and procedural times for individual cases are demonstrated in Fig. 2. There was one procedural complication that was not thought to be related to fluoroscopic technique. This patient required a revision secondary to device migration without lead derangement 2 days post-procedure.

4 Discussion

A novel low-fluoroscopy protocol for pediatric and adult CHD device implantation procedures was successfully implemented with good efficacy and no fluoroscopy-related complications. To our knowledge, this work represents the first comprehensive report regarding radiation exposure during pediatric and adult CHD device implantation procedures.

While significant efforts have been made to reduce radiation dose during invasive EP study and ablation procedures, there is limited published literature on radiation reduction during device cases. Attanasio et al. recently published a series of adult device implants before and after the institution of a new dose reduction protocol that consisted of low frame rates (4 frames/s), introduction of copper filtration, decrease in peak kilovoltage, lower detector dose, selection of smaller focus, and shorter pulse width [14]. They reported results from device implants in 584 adult patients (mean age 71) with 280 implants performed prior to the new radiation reduction protocol and 304 after the new dose reduction protocol. The authors report no differences in fluoroscopy time (13 ± 15 min) or procedural time (93 ± 52 to 92 ± 52 min) after instituting the new protocol. However, they reported a significant reduction in dose-area product (DAP) (3792 ± 5025 vs. 1372 ± 2659 cG/cm^2) with their new ALARA protocol. While it is difficult to extrapolate an adult population to pediatrics, especially with an average BMI > 25 in the Attanasio group, it is notable that despite the important steps noted by Attanasio to reduce radiation dose, the additional measures reported herein can further reduce radiation exposure. The mean dose-area product values reported in this series are approximately 18 times lower (mean DAP 77.3 $\mu Gy/m^2$) than those reported in Attanasio report, despite nearly identical fluoroscopy times. There are many possible reasons for this. First, most fluoroscopic systems use automatic brightness control in order to obtain adequate penetration and a larger patient will necessarily require more radiation. However, the order of magnitude difference in dose is substantially out of proportion with

Table 1 Demographic information and indication for pacemaker and ICD implantation procedures, data presented as median and inter-quartile ranges; *IQR* inter-quartile range, *AVB* atrioventricular block, *CHD* congenital heart disease, *DORV* double-outlet right ventricle, *OHT* orthotopic heart transplant, *CM* cardiomyopathy, *ASD* atrial septal defect, *VSD* ventricular septal defect

	Pacemaker (*n* = 15)	ICD (*n* = 15)
Age (years)	13.0 (IQR 9.5–16.0)	17.0 (IQR 13.5–17.5)
Weight (kg)	52.0 (IQR 32.1–57.0)	63.0 (IQR 50.5–74.0)
Indication		
AV block	10	
	Congenital AVB (7)	
	CHARGE syndrome (1)	
	Repaired DORV (1)	
	No structural heart disease (1)	
Sinus node dysfunction	5	
	No structural heart disease (2)	
	s/p OHT (1)	
	Muscular dystrophy/CM (1)	
	Tricuspid atresia s/p Fontan (1)	
CM with ventricular arrhythmia		6
		Restrictive CM (2)
		Dilated CM/muscular dystrophy (2)
		Hypertrophic CM (1)
		Hypertrophic and dilated CM (1)
CHD or repaired CHD		4
		Repaired tetralogy of Fallot (2)
		Ebstein's anomaly (1)
		Repaired ASD/VSD (1)
Primary prevention		4
Secondary prevention		1

the difference in body habitus between patients in this report and that of Attanasio. Perhaps most important in accounting for the difference is the use of ultra-low fluoroscopic frame rates (most 2–3 fps) as well as very low dose per frame (6–18 nGy/frame). These values, particularly the dose per frame, are notably low and far lower than those typically utilized in most EP and cardiac catheterization laboratories.

Recently, Ghelani et al. evaluated radiation benchmarks related to cardiac catheterization procedures in pediatric patients [15] and a recent review described methods to decrease radiation exposure in children that is similar to our low-fluoroscopy protocol [16]. The primary techniques reported in that series included removal of anti-scatter grid in patients < 20 kg, proper collimation, and the use of low-dose fluoroscopy [16]. Currently, there are no specific radiation benchmarks for pediatric EP procedures, including electrophysiology studies, ablation procedures, and device implantations. Given the relative paucity of pediatric EP radiation exposure data [2, 13, 17–19] and the lack of pediatric device implantation data, our results could be utilized as an initial benchmark for future PM and ICD implantation procedures in pediatric and adult CHD patients.

At the present time, there are no data on radiation dose during standard cardiac device implantation in children or adults with CHD. However, there is a growing literature on efforts to reduce radiation dose during pediatric and adult CHD ablation procedures. Patel et al. recently published ablation radiation exposure data on 84 patients (median age 14.9 years) after implementation of a modest radiation reduction protocol [18]. In that work, the median fluoroscopy time was 28.6 min (IQR 16.1–47.3), total air kerma dose 250.1 mGy (IQR 79.1–669.7), and DAP 1741.1 μGy/m^2 (IQR 595.9–4952.6). Clark et al. evaluated radiation exposure after the advent of CARTO3 for pediatric and adult CHD ablation procedures. Following the implementation of CARTO3, the mean fluoroscopy time was 4.2 min, air Kerma 61.3 mGy, and DAP 668.2 μGy/m^2 [17]. Pass et al. demonstrated that a change from ALARA alone [13] during ablation procedures to ALARA + CARTO3 electroanatomic mapping [2] decreased the median radiation exposure from 45.4 mGy (only ALARA [13]) to 4.5 mGy with 42% of cases in the ALARA + CARTO3 data series [2] receiving < 1 mGy of radiation.

Table 2 Atrial and ventricular lead measures during low-fluoroscopic device implantation procedures; values are mean ± standard deviation

	Atrial lead	Ventricular lead
Impedance (Ω)	603 ± 121	661 ± 134
Sensing threshold (mV)	3.5 ± 2.5	14.0 ± 6.2
Capture threshold (V at 0.4 ms)	0.9 ± 0.6	1.0 ± 1.3

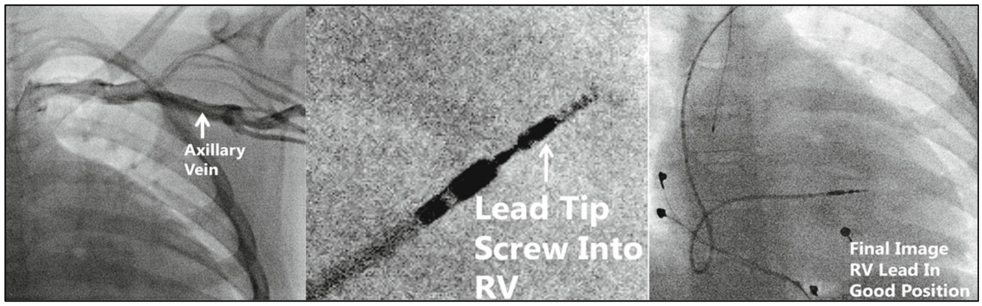

Fig. 1 Examples of fluoroscopic quality for **a** axillary venography, **b** zoomed-up image during lead fixation, and **c** final image demonstrating lead position and cardiac size

While zero-fluoroscopy ablation procedures in pediatric patients have been reported, there are few documented cases of PM (or ICD) implantations performed without the aid of fluoroscopy in adult patients [20, 21]. At the current time, zero-fluoroscopy device implants are only being utilized in special circumstances, such as pregnancy [20, 21]. Compared to EP studies or ablation procedures, fluoroscopy use provides benefits including guidance for venous access, confirmation of wire position, and atrial and ventricular lead positioning and monitoring during lead fixation. There are recent reports, though, of non-fluoroscopic approaches to device implantation with the Ensite-NavX system. These approaches may become more commonplace, but are associated with the additional costs associated with use of electroanatomical mapping systems. While our approach does not completely remove the stochastic risk of radiation exposure, the low median implant dose of 4 mGy described here may help mitigate the risk of radiation exposure in this vulnerable population.

It is important to note that attempts to reduce radiation dosage during a medical procedure require the operator to accept worsened image quality. This inverse relationship between dose and image quality is, unfortunately, a present day fact of fluoroscopic imaging [22]. For many operators, a learning curve will be necessary as most physicians are used to operating with outstanding image quality. However, we have demonstrated in both prior ablation and catheterization works that it is not always necessary to have optimal image quality [1, 13] to achieve similar outcomes. Given the very high contrast of leads in the heart, a low-dose approach with increased graininess and slower frame rates is typically adequate for pacemaker and ICD implantation. Over time, operators may need to accept these constraints. Additionally, and importantly, there should always be the ability, at tableside, to adjust and increase the settings so that image quality can be improved if necessary. While the vast majority of these cases were performed with 2–3 fps with only 6 nGy/frame, it is also true that on rare occasions, higher settings were briefly required to better visualize certain aspects of these procedures (e.g., screwing a lead into the endocardium and confirming that the screw has engaged).

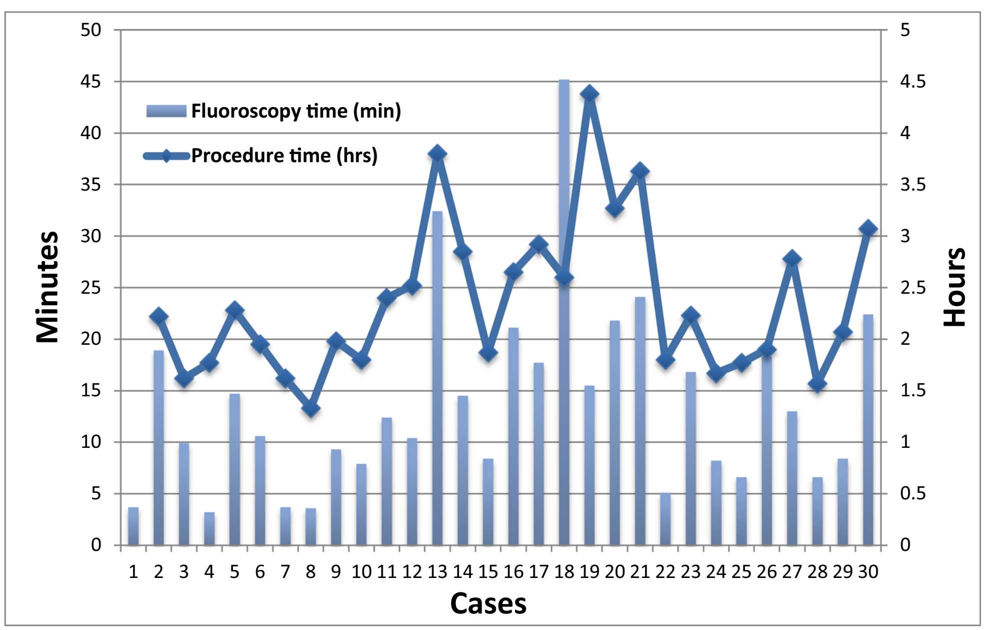

Fig. 2 Procedure and fluoroscopy times by individual case for pacemaker and ICD implant procedures

There are several limitations to this report. This is a retrospective review of procedures performed after implementation of a low-fluoroscopy protocol and subject to all the usual biases associated with such a protocol. Device implantation cases that included additional catheterization procedures were not included since it was not possible to assess the relative radiation doses used during implantation vs. the catheterization. Finally, the authors acknowledge that different fluoroscopic vendors have different capabilities and the approach described in this work may not be fully applicable to all laboratories. However, the principles of trying to go as low as possible for a particular laboratory coupled to attempts to not use fluoroscopy when not needed (e.g., ALARA) are applicable to all labs performing these procedures.

5 Conclusion

A novel low-fluoroscopy protocol for pediatric and adult pacemaker and ICD implantations was demonstrated to be safe and efficacious. The radiation exposure measures reported in this work are substantially lower when compared to both the current pediatric ablation literature and adult low-fluoroscopy device literature. As this is the first published data on low-fluoroscopy pediatric and adult congenital device implantation, these data may serve as an initial benchmark against which future efforts in this arena are measured.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflicts of interest.

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the Institutional Review Board at the Einstein College of Medicine and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

Informed consent Informed consent was not obtained as this manuscript represents a retrospective review of prior studies.

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