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Reduction of fluoroscopy in conduction system pacing guided by electroanatomical mapping in pediatrics and congenital heart disease

Erick Jimenez [a, b], Amanda Gordon [a], Daniel Cortez [a, c, *]

[a] University of Minnesota, Department of Pediatrics, Division of Pediatric Cardiology, Minneapolis, USA
[b] Cincinnati Children's Hospital, Division of Pediatric Cardiology, Cincinatti, USA
[c] University of California at Davis Medical Center, Division of Pediatric Cardiology, Sacramento, USA

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1. Introduction

Left ventricular dysfunction secondary to right ventricular (RV) pacing is a well-documented phenomenon. It presents in up to 20% of pediatric patients receiving this type of therapy [1]. The ventricular desynchrony resulting from RV pacing, that mimics a left bundle branch block, is thought to be the main mechanism by which this dysfunction occurs [2]. Furthermore, pediatric patients and those with congenital heart disease (CHD) are especially vulnerable to left ventricular dysfunction in the setting of chronic RV pacing [3,4]. Alternative pacing strategies with a more physiologic approach, like cardiac resynchronization therapy or direct pacing of the bundle of His, have demonstrated to be effective for prevention and treatment of pacing-induced cardiomyopathy in children and adults [5–9].

Traditional conduction system pacing techniques involve fluoroscopic guidance and is associated with higher radiation exposure compared to traditional RV pacing [10]. The effect of cumulative radiation is a growing concern in pediatric patients, and those with CHD are exposed to increasing numbers of low-dose radiation emitting cardiac procedures [11].

In adult patients, permanent His-bundle pacing under 3-dimensional (3D) electroanatomic mapping has been demonstrated to be feasible and safe with similar short-term pacing outcomes compared with conventional fluoroscopic-guided methods [12–14]. However, given the novelty of this approach, the data in pediatric patients is limited [15].

We demonstrate the feasibility of a low-fluoroscopy approach, as well as the difference in fluoroscopy time, dosage, and major complications in pediatric patients undergoing His- and left-bundle pacing when guided and not guided by 3-dimensional mapping.

2. Methods

After approval by the Institutional Review Board (IRB), a retrospective chart review of all cases of selective and nonselective His bundle, and left bundle branch pacing was performed. Consent was waived as part of the IRB approval, given the retrospective nature of this study.

Patients were captured from the electrophysiology database from the University of Minnesota, Division of Pediatric Cardiology. All procedures were performed under general anesthesia, with either intubation or laryngeal mask placement and without paralysis except while securing the airway. His bundle pacing and left bundle pacing were performed by standard method [9].

In April of 2020, we switched to a “minimal fluoroscopy” approach for the placement of permanent His-bundle pacing in order to reduce radiation to as low as reasonably achievable. For this approach, 3D mapping was used before lead placement. The EnSite Precision System (Abbott Medical, Abbott Park, IL) was used to create an electroanatomic map of the right atrium and the RV

* Corresponding author. Director of Pediatric Electrophysiology, Pediatric and Adult Congenital Cardiology/Electrophysiology, University of California at Davis Medical Center/University of Minnesota, 2516 Stockton Boulevard, room 210, Sacramento, CA, 95817, USA.

E-mail address: dancortez@ucdavis.edu (D. Cortez).

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based on activation, voltage and pace mapping. The His-bundle region was marked on the 3D map based on the earliest ventricular activation with His-bundle signal, in the setting of AV conduction, or via retrograde His-bundle activation when antegrade conduction was not present. If unable to record a His-bundle signal, we use high output pacing from a more apical position. The paced area that produces a rSR' pattern in V1 is then marked to attempt left-bundle pacing.

Then, a C315 guiding sheath (Medtronic, Minneapolis, USA) was inserted over an octopolar Livewire (St Jude Medical, Saint Paul, MN, USA), and positioned slightly distal to the strongest His-bundle signal on the 3D map. Subsequently, the Livewire was replaced with a 3830 ventricular pacing lead (Medtronic, Minneapolis, USA). Live tracking of the pacing lead was obtained via unipolar mapping to assess its location within the 3D map. When a His signal was not recordable during mapping, unipolar pace mapping was used to identify an optimal site. The pacing lead was then fixed at the point where the His signal was present and adequate sensing and threshold were obtained. Prior to coiling in the lead, pacing at high output was performed to assess His-bundle capture. Subsequently an atrial lead location was found for the atrial lead, which was mostly directed towards the atrial septum. The rest of the procedure and attachment to the pacemaker generator was performed as per standard technique. All 3830 ventricular leads were of 69 cm in length. Atrial leads were either 49 cm or 59 cm depending on patient size.

Fluoroscopy use was reserved for confirmation of the site of the delivery sheath or the pacing lead when the location is uncertain; for deployment of the pacing lead; and to assess the final position of the pacing lead to verify adequate tension and slack.

Statistical analysis included basic demographics, fluoroscopy time, dose area product (DAP), procedure duration and pacing parameters at the time of implantation. Parametric and non-parametric data are presented. Parametric data are presented as mean ± standard deviation. Non-parametric data are presented as median value with total ranges reported due to low number of patients in study. A p value ≤ 0.05 was considered significant.

3. Results

A total of 20 patients underwent conductive tissue pacing (selective and non-selective His bundle, and left bundle pacing) between December of 2019 and January of 2021. The mean age was 14 years (8–39 years). The median follow-up was 338 days (44–474 days). Half of the patients (50%) had CHD. Six patient (66.7%) had postsurgical complete AV block and three also (33.3%) had sinus node dysfunction. All patients had two functional ventricles (no single ventricle patients included)and 3 patients in each group had posterior inferior His-bundles (complete and incomplete atrioventricular canal defects with the other 2 patients having ventricular septal defects otherwise [peri-membranous] and 2 patients had aortic valve replacements. Three patients (15%) had congenital

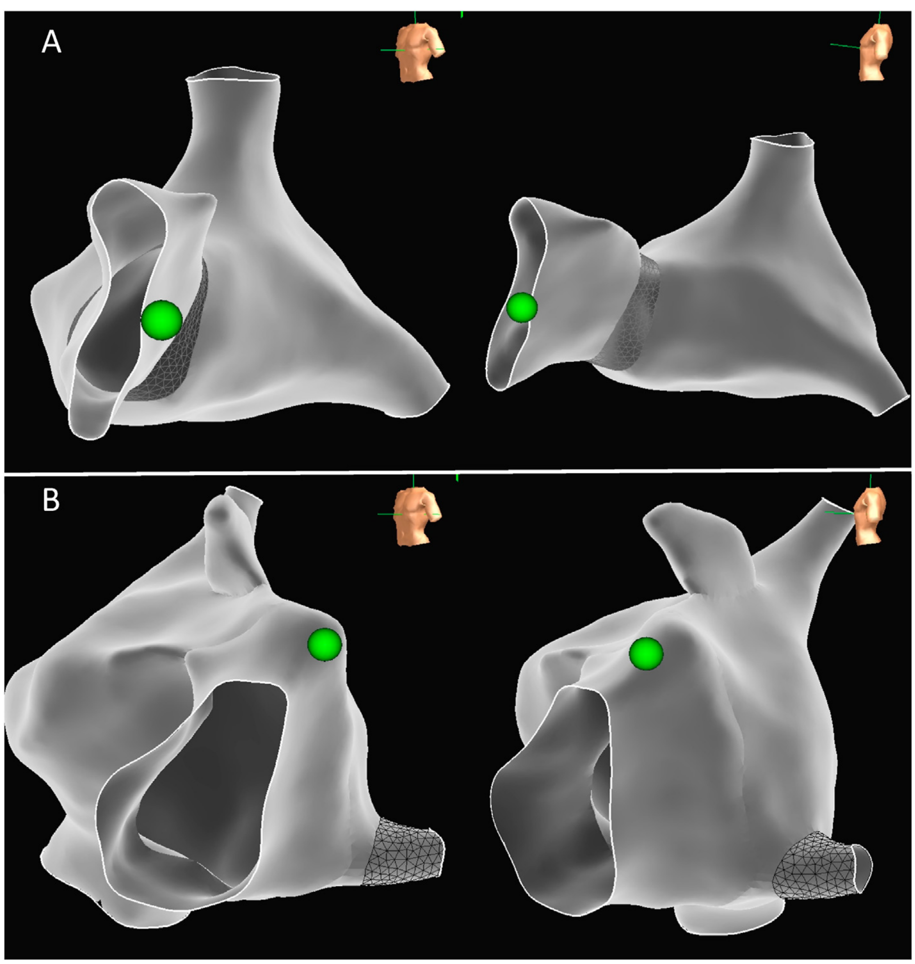

Fig. 1. Electroanatomical maps demonstrating the areas where His bundle signals were recorded. 1A, postero-inferior displacement of the His-bundle (green dot) due to complete atrioventricular septal defect. 1B, usual antero-cephalic position of the His-bundle (green dot) in a structurally normal heart with congenital complete heart block.

Table 1
Demographics and procedural details with mean values presented as mean ± standard deviation and median values presented as median (interquartile range).

	3-dimensional mapping (N = 10)	Standard approach (N = 10)	*p*-value
Age (years)	15.5 (8–33)	13 (8–39)	0.265
Sex (female)	60%	60%	1.000
Weight (kg)	49.5 ± 17.18	45.06 ± 19.01	0.921
Left sided generator	80%	70%	0.622
Procedure time (min)	306.50 ± 69.19	299.80 ± 72.32	0.841
Fluoro time (min)	13.27 ± 10.69	41.83 ± 15.07	**<0.001**
Fluoro dose (mGy)	13.18 (3.82–125.38)	54.39 (19.96–192.59)	**0.026**
DAP (cGycm ^{2})	231.67 (16.62–2074)	950.73 (269.35–4508.84)	**0.017**
R wave (mV)	9.62 ± 4.94	9.74 ± 6.90	0.948
Impedance (ohm)	632.7 ± 204.99	705.1 ± 164.04	0.391
Threshold (V)	0.73 ± 0.21	0.54 ± 0.04	0.063
Pulse width (ms)	0.42 ± 0.04	0.42 ± 0.04	1.000
Paced QRS duration (ms)	95 ± 14	104 ± 21	0.271
Complications	0%	0%	N/A

DAP (cGycm^2) = dose area product in centi-Gray per centimeter squared, Kg = kilogram, min-minute, mV = millivolt, ms = millisecond, V=Volt.

heart block and seven (35%) had idiopathic, progressive high degree or complete heart block.

Ten patients (50%) underwent the minimal fluoroscopy technique using 3D mapping (see His-localization Fig. 1) and 10 patients via the standard technique. There was no significant difference in the median age or weight between the two groups. The mean procedural time was 306.5 ± 69.2 min (3D mapping) and 299.8 ± 72.3 min (standard technique). Pacing parameters at implantation for both groups included stimulation thresholds of 0.73 ± 0.21 V and 0.54 ± 0.04 V (*p* 0.06), R wave amplitudes of 9.62 ± 4.94 mV and 9.74 ± 6.9 mV (*p* 0.95), and impedance of 632.7 ± 204.9 and 705.1 ± 164.04 (*p* 0.39), respectively for the 3D mapping versus standard technique (Table 1).

In terms of radiation exposure, fluoroscopy time for the 3D mapping group and standard technique group were 13.3 ± 10.7 min and 41.8 ± 15.1 min (*p* 0.0002), with fluoroscopy doses of 13.2 (3.8–125.4) mGy and 54.4 (19.9–192.6) mGy (*p* 0.026), and DAP of 231.7 (16.6–2074) cGycm2 and 950.73 (269.4–4508.8) cGycm2 (*p* 0.017), respectively. No complications were seen in this cohort (Table 1). No peri-procedural complications were seen in either group (Table 1). Three patients had left bundle pacing performed, all of them from the standard technique group.

4. Discussion

Permanent pacing of the conduction system has emerged as an alternative method to achieve a more physiological depolarization, and thus, to prevent or treat pacing induced cardiomyopathy. Recently, our group reported feasibility, safety and encouraging outcomes of this type of physiologic pacing in pediatric patients with and without congenital heart disease [9]. Several studies have reported positive outcomes using a minimal fluoroscopy technique for conductive system pacing in the last few years [12], [-17] however, data about the results of this approach in pediatrics and patients with CHD are rather scarce [15,17–20]. In our experience, His bundle and left bundle pacing guided by electroanatomic mapping is a feasible and safe procedure in pediatric patients with and without congenital heart disease. We found that the use of this technique reduces the fluoroscopy time and total radiation dose by about 70%, when compared to the standard technique.

When our group switched to a minimal fluoroscopy technique, given that this was a novel approach, the main points of concerns were the possibility of extending the procedural time or achieving suboptimal pacing parameters. However, it is remarkable that the procedural time and the pacing parameters at the time of implantation were not significantly different between the two groups. This may reflect the fact that aiming for an electroanatomical target, rather than an anatomical target, could help for a more rapid and precise positioning of the lead. Also, we found that creating the electroanatomical map accessing the femoral vein was helpful for catheter manipulation, and additionally, since most of the patients were pacemaker-dependent, the mapping catheter was used for back-up pacing during the procedure.

The mean fluoroscopy time in our standard technique group was significantly higher than what was reported in a recent large multicenter study of adult patients without congenital heart disease (41.83 ± 15.07 vs 11.7 ± 12 min) [21]. Conversely, our results are in line with the results from Moore et al. where the median fluoroscopy time in adult patients with congenitally corrected transposition of the great arteries was 38 min (IQR 19–62) [18]. This difference is perhaps a consequence of the anatomic differences of the pediatric heart compared to the adult patients (smallest patient was 18 kg), especially in the setting of CHD, where the normal conduction system may be in an unusual position (Fig. 1).

Radiation exposure during cardiac interventions is high and may have deleterious effects, including an increased risk of developing cancer [22]. This is a special area of concern in patients with CHD, in whom the use of low-dose ionizing radiation procedures is a significant part of the initial evaluation and the long term follow up [11]. We believe the results of this study are encouraging, as we expect that the fluoroscopy time decreases even further with more experience, as it was seen in the study from Keene et al. [21] Nonetheless, we anticipate that achieving a close to zero fluoroscopic technique may be difficult in CHD and pediatric patients given the chamber sizes and anatomical variations.

5. Conclusion

Electroanatomical mapping for conduction system pacemaker implantation significantly reduces radiation exposure in pediatric patients with and without CHD, without increasing the procedural time or affecting pacing parameters. Further multicenter and prospective studies will be needed to account for operator differences and long-term follow-up implications.

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Declaration of competing interest

The authors do not have any relationship with industry and other relevant entities, financial or otherwise, that might pose a conflict of interest in connection with the content of this article.

Ethical statement

This study was approved by the Institutional Review Board of the University of Minnesota.

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