



Leadless Micra Pacemaker Use in the Pediatric Population: Device Implantation and Short-Term Outcomes

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Abstract

The development of Leadless cardiac pacemakers avoids the inherent complications that may occur secondary to lead insertion. A large number of devices have been inserted in adult patients although data in pediatric patients are lacking. We aimed to assess our experience with the Leadless device in the pediatric population. We performed a retrospective study on all pediatric patients who underwent insertion of a Leadless pacemaker in our center. Data were collected for demographic, procedural, and outcome variables. Nine patients with a median (IQR) age and weight of 13 (12–14) years and 37 (31–50) kg, respectively, were enrolled. The median (IQR) procedural time was 62 (60–65) min with insertion thresholds of 0.5 (0.35–1) Volts at 0.24 ms. All devices were successfully inserted without complication. One device was replaced with a single-lead endocardial pacemaker at 1 year for increased thresholds. Leadless pacemaker device insertion is feasible in pediatric patients. Further studies and long-term follow-up are needed to ascertain device longevity and complication rates.

Introduction

Pacemaker implantation is performed in pediatric patients with second and third degree heart block or sinus node dysfunction with prolonged sinus pauses. Complete heart block may develop in fetal life due to maternal antibodies (anti Ro and anti La) crossing the placenta and damaging electrical conduction across the atrioventricular node [1]. Cardiac surgery may also result in heart block and sinus node dysfunction necessitating pacemaker insertion [2–4].

The insertion of epicardial pacemaker systems is frequently employed as a first step in pediatric patients when weight precludes the insertion of a transvenous device. The epicardial system will eventually fail, requiring a replacement device. Murayama et al. report a failure rate of 27% at a median of 8.4 years; however, the review assessed predominantly older lead design which has since been superseded [5]. At approximately 10 kg, patients become eligible for a transvenous pacemaker. Transvenous systems have certain advantages. Ventricular depolarisation may be more physiological with septal lead placement. They also remove the rare but serious complication of cardiac lead strangulation

[6, 7]. However, several complications with endocardial leads exist. Although new lead technology appears to be more resilient, lead fracture and dislocation may still be problematic, as reported in a recent review of pediatric patients with congenital heart disease [8], resulting in the need for revision. Venous occlusion is a risk, especially in pediatric patients with small caliber vessels and the need for multiple revisions over a lifetime. Twiddler's syndrome has also been well described with these devices [9].

A leadless Micra pacemaker device has recently become available with early data in the adult population. It is a fully encapsulated 0.8 ml single-chamber pacemaker directly inserted into the right ventricle. Complications are reported to be 51% lower in the early post procedural period (6 months) and 48% lower at one year when compared with standard transvenous devices [10, 11]. The Global Clinical Trial reports a successful insertion rate of 99.2% with a lower revision rate (compared with standard transvenous devices) on short-term follow-up [12]. To date, however, minimal data exist regarding the use of this device in the pediatric setting. We review our data on Micra pacemaker insertion in a pediatric population. We hypothesize that use of this device without early complications is feasible in this patient cohort.

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Methods

We performed a retrospective review of all neonatal patients managed with implantation of the Micra pacemaker in a single tertiary pediatric cardiology center (Our Lady's Children's Hospital Dublin). Patients were identified from the Medtronic online database (G pace) between October 2017 and June 2019. Demographic and procedural data were correlated using information from G pace in addition to data documented in the patient's medical records.

Demographic and Outcome Data

Patient age, weight, gender, and the indication for the procedure were recorded. Device position (apical or septal) was noted and lead parameters at implantation including threshold, impedance, and R wave were also documented. Outcome measures included the duration of the procedure, complications, procedural success, and need for re-intervention. Device longevity was also noted. We have included follow-up duration and subsequent device parameters at 3 months, 6 months, and 1 year.

Procedural Technique

Patients were selected for Micra pacemaker insertion for the following reasons: (1) to avoid the complications of a transvenous pacemaker, (2) secondary to multiple revisions of a transvenous system, and (3) to allow continuation of contact sports by avoiding a pacemaker box. The patients/parents were fully informed about the complications and unknown medium to long-term data on the Micra device.

The Micra leadless system was inserted via right femoral venous access in all patients. A double subcutaneous purse string suture was placed to provide for pre-closure of the large venous entry site. A 5 F pigtail catheter was inserted and right ventricular angiography performed. The introducer sheath was upsized from a 6 to 23 F over an Amplatz Super stiff guidewire (Boston Scientific, Galway, Ireland) placed in the superior vena cava. The Micra system was delivered to a right ventricular septal or apical position using angiography with a high magnification. We observed deployment of the tines, assessing the number of tines deployed into the myocardium using a pull test. Lead thresholds were assessed and the device was repositioned until acceptable thresholds were obtained (we accepted ≤ 1.5 V @ 0.24 ms following implantation). The device was released and the tether slowly removed to avoid dislodgement of the device.

Results

The Micra Leadless device was implanted in 9 patients with a median (IQR) age and weight of 13 years (12–14) and 37 kg (31–50), respectively. Six patients were female. Indication for pacemaker use included congenital complete heart block in 5 patients, post-operative complete heart block in 3 patients and symptomatic prolonged sinus pauses in 1 patient (Table 1).

The device was successfully implanted with satisfactory thresholds in all 9 patients. The insertion point was in the RV apex in 6 patients with 3 patients receiving a septal placement. Vascular closure was performed using a double subcutaneous purse string closure in all 9 patients. The median (IQR) procedural duration was 62 min (60–65). Early threshold values were 0.5 V (0.35–1) at 0.24 ms, with an R wave of 11 mV (8.7–11.9) and an impedance of 690 ohms (600–780). The device longevity recorded was > 8 years in all patients. There were no procedural complications. Six-month follow-up revealed a sensitivity of 0.63 V (0.63–0.75), with an R wave of 11 mV (9.9–11) and an impedance of 470 ohms (460–480) (Table 2). Of note, pacemaker thresholds increased significantly in one patient at 1-year follow-up. The device was left in situ and a single endocardial lead sited on the RV septal surface.

Discussion

Our data describe a high success rate and low early complication rate for Micra device implantation. The current data from adult studies demonstrate that complications occur early following insertion. In a global cohort of 776 patients who underwent Micra pacemaker insertion 4% of patients had major complications at 1-year follow-up. Of these, 75% of complications occurred within the first

Table 1 Demographic details

	Patient number [9]
Age (years)	13 (12–14)
Weight (kg)	37 (31–50)
Gender	
Female	6
Male	3
Indication for pacing	
Post-operative AC block	3
Congenital AV block	5
Sinus pauses	1

Data are presented as median (IQR) or absolute count

Table 2 Procedural details and outcomes

	Patient number [9]
Procedure duration (min)	62 (60–65)
Device position	
Apex	6
Septum	3
Pacemaker parameters at insertion	
Threshold (V)	0.5 (0.35–1)
R wave (mv)	11 (8.7–11.9)
Impedance (ohms)	690 (600–780)
Device longevity (years)	> 8
Pacemaker parameters at 6 months	
Threshold (V)	0.63 (0.63–0.75)
R wave (mv)	11 (9.9–11)
Impedance (ohms)	470 (460–480)
Implantation success (%)	100
Procedural complications (%)	0
Need for re-intervention (%)	11

Data are presented as medians (IQR) or absolute count (%)

V volt, mV millivolt

30 days post insertion [10]. One patient in our cohort had elevated thresholds at a year requiring a new pacemaker device.

Data on Leadless Micra insertion in the pediatric population are extremely limited despite a growing pool of adult patients with device implantation. The limiting factor in pediatric patients is due to vascular access and the need for a large introducer sheath (23 Fr). The smaller ventricular cavity may also pose challenges in maneuvering the device. In our patient cohort, vessel caliber was not an issue in our smallest patients weighing 25 kg and 26 kg; however, positioning the device within the heart was more challenging as was retrieval for repositioning of the device. The absolute weight cut off is yet unknown and may vary slightly from patient to patient. In pediatric patients with borderline weight, right internal jugular venous access may allow safer sheath insertion and better alignment for device delivery. Although used in the adult population, this approach has yet to be tested in children [13].

The inherent removal of specific complications such as venous occlusion make the Micra leadless system desirable to the pediatric population who may be more at risk due to smaller vessel size and the need for lifelong pacing. Lead complications are particularly problematic in growing children due to fracture, dislocation, and inadequate redundant loop [14]. Patients managed with long-term pacing with transvenous devices will inevitably require lead extraction with the potential for significant morbidity and mortality [15]. A review by Grubman et al. from the

pre-market Micra transcatheter pacing study has shown good evidence to support a low rate of early revisions. They compare results at 24 months post insertion in the Micra group compared to a large cohort of patients who underwent standard transvenous device insertion. The revision rates were 1.4% compared to 5.3%.

A drawback of the Micra pacemaker is the insertion site into the RV mid to apical septal wall. The Micra device does not allow for effective “mapping” to optimize pacing. Long-term RV pacing may result in electromechanical dyssynchrony with a risk of heart failure ensuing. Perimembranous septal pacing allows for better physiological coupling and may lead to a reduced risk of pacemaker induced cardiomyopathy [16]. The Micra pacemaker does not offer this, with possible long-term repercussions.

In addition, concerns regarding device retrieval still exist. In an early review of leadless device retrievals, data were provided on 29 patients [17]. Of these, all devices were successfully retrieved without complication at a median duration of 46 days post insertion [17]. Micra retrieval has recently been demonstrated as late as 4 years from implantation and some now considerate it a safe option [18, 19]. The feasibility of long-term retrieval is yet unknown and may present challenges for pediatric patients requiring several devices throughout their lifetime. Abandonment of the leadless system is currently recommended unless a specific indication for retrieval occurs (infection, embolization) [17]. To avoid multiple devices in a smaller pediatric heart, we opted for this strategy in our patient with elevated thresholds. We inserted a single transvenous lead in this patient. Long-term data on device longevity are not currently available in the literature. However, from our experience on interrogation of the leadless system, all devices had an ERI of > 8 years. The estimated Micra longevity varies from 12 years if paced to 14 years for back-up pacemakers.

The study is limited by the retrospective nature of the design. Although this is the largest study to date outlining device insertion in pediatric patients the patient number is small so it is impossible to draw any definitive conclusion.

Conclusion

This case series highlights the feasibility of implanting this device in a younger patient group. Long-term follow-up studies with larger patient numbers are required to establish data on efficacy and complication rates in children.

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Compliance with Ethical Standards

Conflict of interest One of the authors Lisa Dunne is an employee with Medtronic. All other authors have no conflict of interest to disclose.

Ethical Approval All procedures performed in the study involving human participants were in accordance with the ethical standards of the institution and the na1964 Helsinki declaration and its later amendments.

References

- Jaeggi E, Laskin C, Hamilton R, Kingdom J, Silverman E (2010) The importance of the level of maternal anti-Ro/SSA antibodies as a prognostic marker of the development of cardiac neonatal lupus erythematosus a prospective study of 186 antibody-exposed fetuses and infants. *J Am Coll Cardiol* 55(24):2778–2784
- Ayyildiz P, Kasar T, Ozturk E, Ozyilmaz I, Tanidir IC, Guzelbas A et al (2016) Evaluation of permanent or transient complete heart block after open heart surgery for congenital heart disease. *Pacing Clin Electrophysiol* 39(2):160–165
- Cohen MI, Rhodes LA (1998) Sinus node dysfunction and atrial tachycardia after the Fontan procedure: the scope of the problem. Seminars in thoracic and cardiovascular surgery. *Pediatric Cardiac Surg Annu* 1:41–52
- Glatz AC, McBride MG, Paridon SM, Cohen MS, Walker SA, Gaynor JW et al (2010) Long-term noninvasive arrhythmia assessment after surgical repair of sinus venosus atrial septal defect. *Congenit Heart Dis* 5(2):141–148
- Murayama H, Maeda M, Sakurai H, Usui A, Ueda Y (2008) Predictors affecting durability of epicardial pacemaker leads in pediatric patients. *J Thorac Cardiovasc Surg* 135(2):361–366
- Hauser RG, Hayes DL, Kallinen LM, Cannom DS, Epstein AE, Almquist AK et al (2007) Clinical experience with pacemaker pulse generators and transvenous leads: an 8-year prospective multicenter study. *Heart Rhythm* 4(2):154–160
- Carreras EM, Duncan WJ, Djurdjev O, Campbell AI (2015) Cardiac strangulation following epicardial pacemaker implantation: a rare pediatric complication. *J Thorac Cardiovasc Surg* 149(2):522–527
- Sandrio S, Purbojo A, Toka O, Dittrich S, Cesnjevar R, Ruffer A (2016) Transmural placement of endocardial pacing leads in patients with congenital heart disease. *Ann Thorac Surg* 101(6):2335–2340
- Wilhelm BJ, Thone M, El-Scheich T, Livert D, Angelico R, Osswald B (2015) Complications and risk assessment of 25 years in pediatric pacing. *Ann Thorac Surg* 100(1):147–153
- Duray GZ, Ritter P, El-Chami M, Narasimhan C, Omar R, Tolosana JM et al (2017) Long-term performance of a transcatheter pacing system: 12-month results from the Micra Transcatheter Pacing Study. *Heart Rhythm* 14(5):702–709
- Piccini JP, Stromberg K, Jackson KP, Laager V, Duray GZ, El-Chami M et al (2017) Long-term outcomes in leadless Micra transcatheter pacemakers with elevated thresholds at implantation: results from the Micra transcatheter pacing system global clinical trial. *Heart Rhythm* 14(5):685–691
- Grubman E, Ritter P, Ellis CR, Giocondo M, Augostini R, Neuzil P et al (2017) To retrieve, or not to retrieve: system revisions with the Micra transcatheter pacemaker. *Heart Rhythm* 14(12):1801–1806
- Saleem-Talib S, van Driel VJ, Chaldoupi SM, Nikolic T, van Wessel H, Borleffs CJW et al (2019) Leadless pacing: going for the jugular. *Pacing Clin Electrophysiol* 42(4):395–399
- Welisch E, Cherlet E, Crespo-Martinez E, Hansky B (2010) A single institution experience with pacemaker implantation in a pediatric population over 25 years. *Pacing Clin Electrophysiol* 33(9):1112–1118
- Gomes S, Cranney G, Bennett M, Giles R (2016) Long-term outcomes following transvenous lead extraction. *Pacing Clin Electrophysiol* 39(4):345–351
- Patel B, Garg J, Chaudhary R, Sablani N, Gupta R, Shah M et al (2018) His bundle pacing: hemodynamics and clinical outcomes. *Cardiol Rev* 26(4):201–206
- Afzal MR, Daoud EG, Cunnane R, Mulpuru SK, Koay A, Husain A et al (2018) Techniques for successful early retrieval of the Micra transcatheter pacing system: a worldwide experience. *Heart Rhythm* 15(6):841–846
- Kiani S, Merchant FM, El-Chami MF (2019) Extraction of a 4-year-old leadless pacemaker with a tine-based fixation. *Heart-Rhythm Case Rep* 5(8):424–425
- Li J, Hou WB, Cao MK, Zhou WX, Wang Y, Fang Y et al (2019) Safety and efficacy of leadless pacemaker retrieval. *J Cardiovasc Electrophysiol*. <https://doi.org/10.1111/jce.14076>

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