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Original Research Article

Leadless pacemaker implantation for pediatric patients through internal jugular vein approach: A case series of under 30 kg

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ABSTRACT

Background: We demonstrate a case series of 8 pediatric patients, all under 30 kg, who had leadless pacemaker implants via the internal jugular vein.
Methods: A retrospective review of pediatric leadless pacing placement via the internal jugular vein at the University of Minnesota Masonic Children's Hospital and UC Davis Medical Center from 2018 through 2021 was performed. Rationales for pacing, demographics of patients, pacing thresholds, and longevity of devices were recorded.
Results: Eight internal jugular pacemaker insertions were performed successfully in patients weighing between 10.9 kg and 29 kg. Five patients had Micra implantation via the right internal jugular vein, whereas 3 patients had insertion via the left internal jugular vein. No surgical cut-downs were performed. No venous complications occurred. Up to 3 years of follow-up were noted.
Conclusion: Leadless pacemaker implantation, via left or right internal jugular veins, is feasible without surgical cutdown in patients <30 kg

1. Background

Pacemaker placement in pediatrics involves thoughtful concern regarding potential complications with the leads and with pocket erosion/infection being the main areas of concern [1]. Pocket infection may be present as high as 7.8% [2,3]. Due to these complications, a reliable leadless pacemaker is desired in the pediatric population; and with the introduction of the Micra (Medtronic, Minneapolis, MN, USA) leadless pacemaker, this potential broadly arrived, however with, initially, significant limitations regarding atrioventricular synchronous pacing [4]. Leadless pacing in pediatrics has only recently been reported [5–8]. Aside from device extractability, one main limitation of leadless pacing in smaller pediatric patients includes small size of the femoral vessels, as report of femoral venous occlusion/tear after placement via the femoral vein has occurred [9]. One option to avoid femoral venous tear is to utilize the internal jugular vein instead for access. Thus far only case reports have described this method in the pediatric population while case series have been described in the adult population [10–14].

We present a case-series of 8 pediatric patients undergoing leadless pacemaker placements via the internal jugular vein, we demonstrate feasibility of this implantation technique without the need for surgical cut-down, while preserving patency of the vessels.

2. Methods

A dual-center, single operator, retrospective study of leadless pacemaker implantation with the Micra (Medtronic, Minneapolis, MN, USA) device was performed between 2018 and 2021 including the University of Minnesota and UC Davis Medical Centers. A total of 8 patients underwent leadless pacemaker implantations via the internal jugular vein. This study was approved by the ethics committee at the University of Minnesota and waived at UC Davis. All procedures were performed by an electrophysiologist under sterile conditions. All patients had prior internal jugular vein assessment with and without Valsalva to assess which internal jugular vein to use. The jugular vein with diameter of 10 mm or more was used.

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2.1. Procedure description

All patients consented to each procedure and underwent general anesthesia for their operations. Each patient was discussed at an interdisciplinary cardiology conference and either had contraindication to epicardial device placement or leadless pacing was deemed to be the likely safest approach, based on factors such as prior epicardial leads placements (with poor functioning multiple epicardial leads), concern for infection risk/prior history of endocarditis, lack of incisional area for patient 8 (circumferential burns/grafting in almost all areas of the thorax) etc. Patients underwent ultrasound of femoral, subclavian and internal jugular veins prior to the procedure. No patients had femoral veins larger than their internal jugular veins. Vascular access in the largest diameter internal jugular vein was obtained in the right or left internal jugular veins via the Seldinger technique with serial dilation from 5 or 8 French size to 27 French (outer diameter, 23 French inner diameter) size by 2–3 French size increments under ultrasound guidance with increase in PEEP or with initial breath hold to increase the size of the IJ (Table 1). No surgical approach or cut-down was needed as all patients had patent vessel size for sheath placement by ultrasound (at least 1 cm maximum diameter without Valsalva). Patients were given 100 units per kilogram of heparin once the 27 French outer size sheath was deployed in the right atrium. The Micra (Medtronic) deployment catheter was used for Micra leadless pacemaker deployments using the standard technique. For internal

Table 1
Demographics of Pediatric patients with Micra implantation including implant and last (outpatient follow-up parameter).

Case number	1	2	3	4	5	6	7	8
Age (years)	7	7	8	7	7	10	10	2
Male/Female	F	F	F	M	F	F	F	F
weight (kilograms)	19	20	30	22	29	25	26.5	10.9
diagnosis	Pearson Marrow Pancrease Syndrome	AVSD	Primum AVSD LAVV valve repair	TGA, VSD repair	VSD	NKX2.5ASD s/p closure	Kearn's Sayre syndrome	CHB, Inadequate cardiac output, circumferential thoracic burns
Micra AV	no	no	No	no	No	yes	yes	yes
Pacing indication	Alternating BBB	CHB, lead malfunction	ICHB, lead malfunction	ICHB	ICHB	ICHB	Type II Mobitz, RBBB	CHB, low output heart failure
Access	RIJV	LIJV	RIJV	LIJV	RIJV	RIJV	RIJV	LIJV
Micra location	apical septum	apical septum	mid-septum	apical septum	apical septum	apical septum	apical septum	apical septum
Tug-test Tines	4	3	3	4	3	4	4	3
Deployments	1	1	1	1	1	1	1	2
Follow-up (months)	43	34	24	17	26	14	9	7
First threshold (volts@0.24ms)	0.77	0.88	0.38	0.38	0.38	0.38	0.63	0.38
First impedance (ohms)	480	540	860	840	680	820	620	620
First R-wave mV	7.2	12.4	3.4	10.4	3.8	8.6	9.1	6.9
Last threshold (volts@0.24ms)	0.63	1.63	0.38	0.5	0.38	0.5	0.38	0.5
Last impedance ohms	475	410	690	610	560	630	600	610
Last R-wave mV	8.5	10.5	6.5	13.5	5.6	8.0	13.8	8.9
Acute complications	pericardial effusion	None	None	none	none	none	none	none
Percentage pacing (%)	100	100	<0.1	0.1	<0.1	3.5	0.1	100
Last predicted longevity (years)	>8	4.2	>8	>8	>8	>8	>8	>8
IJ AP diameter	10	13	11	10	10	12	11	10

AVSD = Atrioventricular Septal Defect, CHB = complete heart block, ICHB = intermittent complete heart block, LAVV = left atrioventricular valve, LIJV = Let Internal Jugular Vein, RIJV = Right Internal Jugular Vein.

jugular placement, caution was made to only minimally deflect the Micra catheter as deflection caused anterior alignment towards the free wall of the right ventricle. Transthoracic echocardiography was used to assist with guidance across the tricuspid valve when not straight forward and to help with apical-septal deployment. After deployment, tine attachment was assessed by fluoroscopy in 30-degree right anterior oblique and 30-degree left anterior oblique views with a tug-test in all cases. Subsequently, capture threshold, sensing, and impedance were checked at implantation and at 5, 10, and 15 min prior to and after anchor string cut. All patients received a figure-of-eight stitch to close the skin at the access site. Manual pressure to access sites was applied after the procedure to achieve hemostasis. All patients had subsequent ultrasounds to assess vein patency.

The set-up of the room and table prior to the procedure is paramount. Extra foam pads and multiple towels near the head in the ipsilateral side of venous cannulation are needed to maintain stability of the sheath during placement as most of the sheath is out of the neck during the procedure. Caution to not allow venous sheer was important while the sheath was in the superior vena cava during right internal jugular placement. Similarly, the sheath was pulled back into the innominate and not the superior vena cava when performing left internal jugular placement of the leadless pacemaker. This was to prevent superior vena cava or right atrial perforation given the angle of the sheath. The patient was also lower down, further towards the foot of the bed, to allow the operator more sterile room for sheath, wire and pacemaker deployment catheter manipulation. We also recommend an L-shape to the table set-up to allow sterile space for the back of the wire to be manipulated in a safe and sterile fashion. Careful manipulation of the large sheath around neck vein access is critical and an assistant to help hold the end of the sheath in place while manipulating the catheter can be helpful.

Three patients (cases 2,4, and 5) had previously placed epicardial devices with malfunctioning leads and underwent generator removal with leads capped during the same procedure. Patient eight had a similar technique performed as above except via a 16-French esheath (Edwards Lifescience, Irvine CA, USA), given it's ability to expand to a 23-French size intermittently as the Micra was passed through it. All patients were admitted overnight for monitoring. Instructions to avoid exertion more than walking, including avoiding activities that would place a high gravitational pull on the patients or involve high impact, were given to the patients prior to discharge including bouncing on trampolines, riding rollercoasters, tumbling or cartwheels and riding on motorized boats, water or jet skiing.

2.2. Statistics

All data were nonparametric and are reported as median and range. Selection criteria for patients were based on size, availability of epicardial versus transvenous options, lifespan.

3. Results

3.1. Procedural

Eight pediatric patients, all under 30 kg, underwent internal jugular vein leadless pacemaker placement with median age of 7 years (range 2–10) and median weight of 23.5 kg (range 10.9–29 kg). The median follow-up was 20.5 months (range 7–43 months) as demonstrated in Table 1. Two patients had mitochondrial DNA deletion syndromes with short life-expectancy, while five patients had congenital heart disease. Patient 8 had congenital complete heart block with low cardiac output in the setting of thoracic circumferential burns and grafting. Three patients underwent the leadless pacemaker implantation via left internal jugular vein cannulation (due to larger sized left IJ than right IJ) and five were performed via right internal jugular vein cannulation. The largest median IJ diameter was 10 mm (range 10–17 mm, Fig. 1 demonstrates AP view of implant from above). Transesophageal echocardiography was used for 2 patients, while the rest had transthoracic echocardiographic guidance (Fig. 2A and B).

4. Follow-up

The median implant threshold was 0.38V@0.24ms (range 0.38V-0.77@0.24ms), with median impedance of 650 Ω (range 480–820 Ω) and median R-wave was 7.9 mV (range 3.8–9.1 mV). The median last follow-up threshold was 0.5V@0.24ms (range

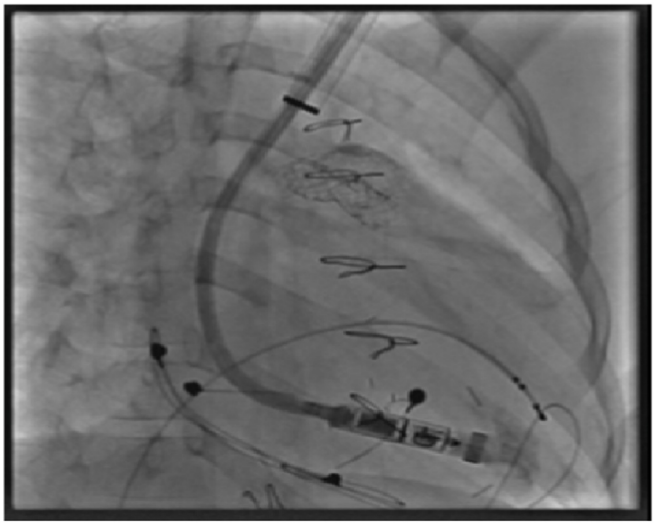

Fig. 1. Micra catheter and Micra implant via internal jugular vein from AP-view.

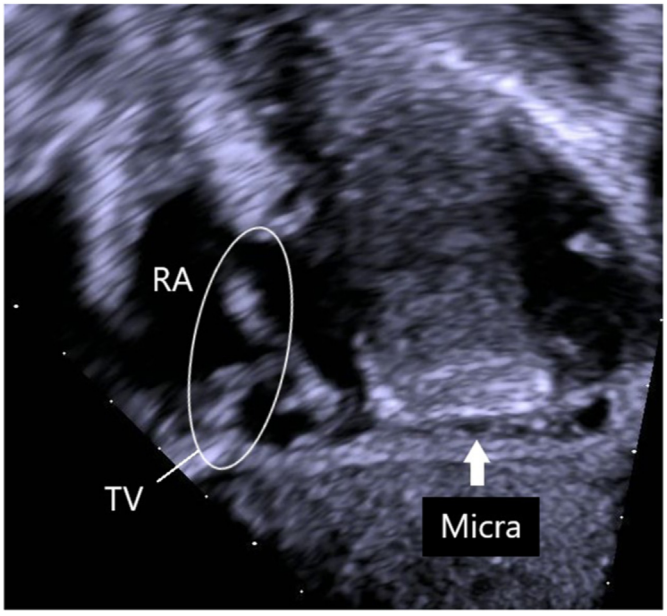

Fig. 2A. Micra subcostal echocardiographic view on 10.9-kg patient.

0.38V to 1.63V@0.24ms), with median impedance of 605 Ω (range 475–680 Ω) and median R-wave was 8.7 mV (range 5.6–13.5 mV).

No venous complications related to access were noted. One patient (19k RIJ, first cases performed) with thrombocytopenia and sideroblastic anemia developed a moderate pericardial effusion perioperatively thought to be related to a tine perforation of the right ventricular free-wall, given normal venogram and echocardiographic findings of tine in the RV free-wall. Prior to leaving the lab, after implant, she promptly underwent prophylactic drainage of a hemothorax percutaneously, prior to any tamponade physiology development, and stayed inpatient for three days. She received a blood transfusion for borderline Hgb 9.5 mg/dl. All other patients were discharged the next day after the procedure. A figure of 8 suture was used to close each point of access (0-ethibond stitch placed around each side of the sheath and tied once sheath removed. Additional mattress suture stitches were often placed through the sternocleidomastoid muscle heads to help with closure on 6/8 patients.

All patients met an indication for pacemaker implantation with ventricular-only pacing needed or had prophylactic leadless pacemaker placed based on likely pacing need (alternating bundle branch blocks, case 1, 7), had incisional contraindications, or was the patient and cardiology team preference after multi-disciplinary discussion. For instance, in case 8, an incisional approach was contraindicated given the area of burn wounds, grafting and risk of infection (Fig. 2A and B show echocardiographic views of this implant). Internal jugular veins were assessed at 6-12-month follow-up or last follow-up, whichever took place first (including patient 8) and no patients had stenoses or acute narrowing of their veins.

5. Discussion

We have demonstrated that leadless pacemaker implantation is possible in pediatric patients with and without congenital heart disease via the internal jugular vein. Careful consideration should be taken into patient selection, and one could consider future prognosis of the patient and future interventions prior to device implantation.

Furthermore, diameter of internal jugular vein versus femoral vein should be considered with and without Valsalva given this can be manipulated with a breath hold or by increasing positive end-expiratory pressure on the ventilator. This helps assess whether an implanter may encounter stenosis, as the stenotic area of a vein does not typically dilate with Valsalva. Also, all data for the age group presented in our manuscript, demonstrate larger internal jugular vein size compared to femoral vein size. For instance, although without Valsalva, and reporting minimum size, furthermore this has been reported the internal jugular vein is typically larger in children than femoral veins, and in particular a minimum mean internal jugular vein anterior-posterior diameter of 5.9 mm compared to mean femoral vein anterior-posterior diameter of 4.2 mm, respectively, in the 6–12 year old age group [15]., Similarly, in an age group of 7–12 year old patients, the mean antero-posterior diameters increase from 7.6 mm to 6.8 mm–11.5 mm and 9.8 mm, respectively for right and left internal jugular veins, with transverse diameters as large as 16.28 mm and 13.61 mm with the Valsalva maneuver [16]. Even in children aged 0–6 years, with Valsalva, the right and left internal jugular veins antero-posterior diameters were 8.7 mm and 8.3 mm for right and left internal jugular veins with transverse diameters of 12.6 mm and 10.8 mm for right and left jugular veins, respectively [17]. The discrepancy in size between our population and those reported is likely due to diastolic dysfunction/fluid overload in the setting of low cardiac output, hence no patients had IJ diameters lower than 10 mm.

One of the main limitations of leadless pacing in smaller pediatric patients includes smaller sized veins. Previous case reports have reported femoral venous occlusion/tear after device placement via the femoral vein [9]. Internal jugular vein access has been used and thus far only case reports have described this method in the pediatric population while case series have been described in the adult population [10]. In the largest case series to date of leadless pacemaker placements via the internal jugular vein in children, we demonstrate that the IJ cut-down may not necessary to safely place leadless pacemakers in the pediatric population [8]. We have previously demonstrated that patients under 30 kg can have device implantation via the right or left internal jugular vein without surgical cut down, however, also understanding at this stage this is by small case series and not by large case series [8]. We also have demonstrated vein patency following device placement with mid-term follow-up demonstrating good pacing parameters on almost all patients. Similar to adult centers which have demonstrated successful case series of internal jugular vein access for leadless pacemaker placements, a figure of 8 stitch is typically all that is needed to maintain venous stasis [14]. However, heparin should be reversed prior to completely pulling the sheath. We also added one additional stitch between the heads of the sternocleidomastoid muscle in nearly all patients as additional compression to help ensure venous stasis. Furthermore, limitations in size of the right ventricle itself are important, as Fig. 2B demonstrates the longitudinal distance occupied by the Micra in a 10.9 kg patient, thus right ventricular size should always be meticulously measured from implant size to tricuspid valve under echocardiographic guidance prior to tine deployment.

More important than technique is patient selection for leadless pacemaker placement. We acknowledge the significance of careful consideration of patient prognosis, expected pacing need, potential need for other cardiac surgeries as well as their comfort level with the surgical/electrophysiology teams. Device removal should also

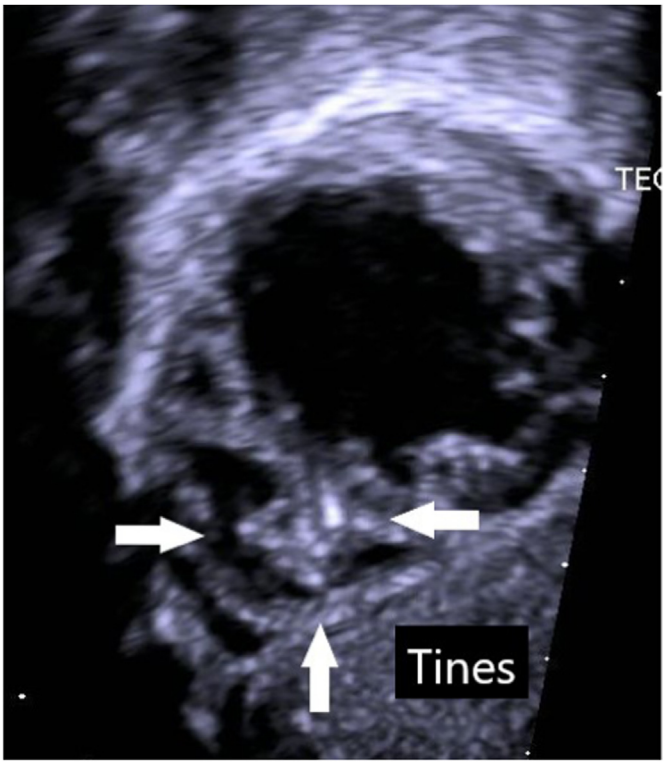

Fig. 2B. Micra apical view of tines in the lower (apical) septum in the 10.9-kg patient.

be considered with appropriate patient selection. At the current state, the first FDA-approved leadless pacemaker is not readily removable. However, as more removable leadless pacemakers become FDA approved, this technique may find even more use. Furthermore, complications of device implantation should be considered. While one of our cases developed a pericardial effusion, the rate of cardiac perforation with leadless pacemaker implantation has been suggested to be higher than in traditional pacemaker lead implantation up to 1.1% with multiple deployments as well as other factors such as body mass index less than 20 kg per meter squared and female sex, predictive of this development [18]. The FDA recently issued a letter to providers warning about a risk of major complications if cardiac perforation occurs during implantation of the Micra Leadless Pacemaker system. Overall similar complications rates in children receiving transvenous pacemaker systems has been reported at 9.5% in a study of 165 pediatric patients, but with different types of complications, including 3.5% with hemothorax, 5% for acute dislodgements, and 1% infection occurrence, however less so for a more recent smaller study of lumen-less leads where 1 acute dislodgement occurred (out of 40 patients) without other complication [19,20]. Regarding epicardial systems, recent reports indicate as high as 31% re-intervention rate in long-term follow-up but acutely only 7.7% acute failure/complication rate in patients with repaired congenital heart disease, who, in general, typically have higher reintervention rates [21]. Thus, overall our 12.5% overall complication rate (one patient with pericardial effusion) is higher than that reported for transvenous leads, but there is also a significant learning curve involved when placing a Micra through the IJ, and appropriate patient selection is paramount. This should always be thoroughly discussed regarding safety of implant compared to epicardial/transvenous implant, during surgical/cardiac catheterization conferences (which is how we approached these discussions).

Limitations of the device include the current utility of strictly ventricular pacing or limited rate atrioventricular synchronous pacing. Future considerations should include atrial devices with synchronous connection to ventricular devices via Bluetooth connection. The Micra AV device allows for VDD technology based on utilization of the accelerometer for atrial contraction sensing. Particularly, VDD pacing can currently allow synchronous pacing with an upper tracking rate of 115 bpm, as what is occurring in patient 8. Although her atrio-ventricular synchrony is only around 45% due to high atrial rate. To be readily implemented in the pediatric population, a higher synchronized heart rate may be needed. Additionally, the size of the device prevents this device from being implanted into smaller patients that might have congenital heart block. Given the smaller sizes of RV in pediatric patients, abandonment of a battery-depleted device may limit space for a new device implantation. Patients were only considered if they had minimal pacing need, a short life-span or Micra implant was considered least invasive/most beneficial by an interdisciplinary cardiology team. Clearly, least invasive and long-term benefit have to both be weighed when considering patient selection. We do feel that internal jugular veins under 9 or 10 mm in diameter would serve as a contraindication, as well as patients with RV's with apical to open tricuspid valve leaflet distance of less than the device length should not be considered, by our experience this is likely patients under 10 kg.

6. Conclusion

Leadless pacemakers may be implanted via the internal jugular veins in patients under 30 kg, without need for surgical cut-down with good short-term and mid-term vein patency. Further data and collaborative center patient study is needed to assess ideal patient population and success of this technique with multiple operators. We also recommend echocardiographic guidance to help minimize perforation risk.

Ethical approval

Approved by internal review boards at the University of Minnesota and UC Davis Medical Centers.

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Declaration of competing interest

None.

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