A novel miniaturized adult pacemaker system for small neonates with congenital heart block

Emily A. Pena, PA-C,[a,b] David G. Gamboa, MD,[c] Frank J. Zimmerman, MD,[c] Narutoshi Hibino, MD, PhD,[a,b] Chawki F. El-Zein, MD,[a] Kristen Nelson McMillan, MD,[d] and Luca A. Vricella, MD,[a,b] Oak Lawn and Chicago, Ill

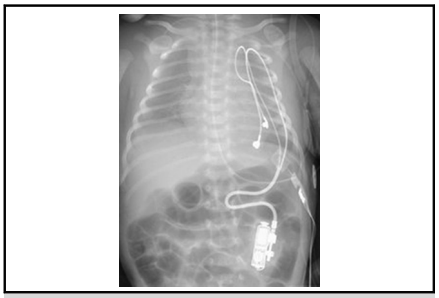
From the Divisions of [a]Cardiovascular Surgery and [c]Cardiac Electrophysiology, Advocate Children's Heart Institute, Advocate Children's Hospital, Oak Lawn, Ill; and Divisions of [b]Pediatric Cardiac Surgery, Department of Surgery and [d]Critical Care, Department of Pediatrics, University of Chicago Medicine, Chicago, Ill.

Received for publication Nov 8, 2023; revisions received Nov 17, 2023; accepted for publication Nov 20, 2023; available ahead of print Dec 2, 2023.

Address for reprints: Luca A. Vricella, MD, Advocate Children's Hospital, Advocate Children's Heart Institute, 4440 W 95th St, Oak Lawn, IL 60453 (E-mail: luca.vricella@aah.org).

JTCVS Techniques 2024;23:86-8
2666-2507

https://doi.org/10.1016/j.xjtc.2023.11.012



Miniaturized pacemaker system placed via left thoracotomy and abdominal counterincision.

Preterm or small babies with congenital heart block (CHB) represent a unique challenge, as currently available pacing systems are exceedingly large and lead placement often requires a sternotomy. We present a case of CHB in a small newborn who was treated with implantation of a novel miniaturized device that is well-suited for this particular patient population.

CENTRAL MESSAGE

A novel, minimally invasive approach to pacemaker implantation; this technique is suitable for small neonates with congenital heart block and uses an adapted adult transvenous leadless pacemaker.

CASE PRESENTATION

A 2.1-kg male neonate born at term was diagnosed in utero with CHB secondary to maternal Sjögren syndrome. Fetal echocardiogram demonstrated a structurally normal heart with atrial rate of 115 to 137 and ventricular rate of 62 to 68 beats per minute. Birth history was otherwise uncomplicated. The patient initially remained hemodynamically stable despite ventricular rates between 60 and 80 beats per minute, without requiring inotropic support. Over the ensuing days, however, a downward trend of ventricular rates to the mid-50s with adequate cardiac output was observed, in conjunction with poor oral intake requiring nasogastric tube supplementation. The decision was then made to pursue epicardial pacemaker implantation. Given the patient's size of 2.5 kg at age 19 days, we opted to implant a bipolar ventricular lead and a miniaturized, adult leadless pacemaker (Medtronic Micra) coupled with an adaptor in order to use it as a generator for an epicardial lead (Figure 1). Ad-hoc Food and Drug Administration approval was obtained (compassionate use). The patient's mother provided written consent for this publication. Institutional review board approval was not required.

Intraoperatively, a limited sixth intercostal space left anterior thoracotomy was performed, resulting in excellent exposure of the ventricular apex and of the left ventricle posterior to the left anterior descending coronary artery (Figure E1). A 25-cm bipolar lead (Medtronic 4968-25) was then sutured in place, with each of the 2 electrodes secured to the epicardium with three 6-0 polypropylene sutures. The lead was then tested and tunneled from the chest to the left hypochondrium, where a limited counterincision had been performed and a pocket developed anterior to the transversus abdominis and ventral to the posterior rectus sheath. The lead was placed into the socket of the adaptor and the generator lodged within the pocket, coiling some of the redundant lead within the left chest. Pacemaker thresholds were interrogated again (Table 1) before wound closure (Figure E2).

The patient was discharged home on the sixth postoperative day. Most recent follow-up at 4 months demonstrated optimal thresholds and projected battery life of 2.5 years.

DISCUSSION

Complete CHB is a rare yet serious diagnosis that carries substantial morbidity and mortality.[1] Surgical

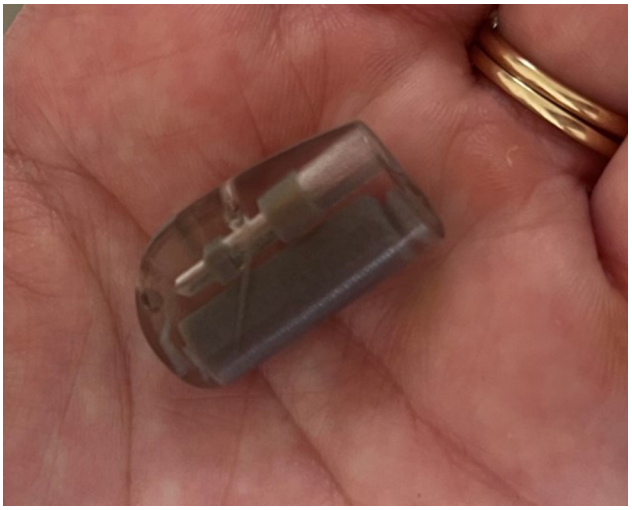


FIGURE 1. Miniaturized adaptor (Medtronic Micra) housing both a bipolar lead socket (*top*) and transvenous miniaturized pacemaker (*bottom*). Dimensions: 29.4 × 16.6 × 9.6 mm; weight: 5 g; volume: 3.5 cc.

treatment is made even more challenging by small body size (<3 kg) and is associated with greater chronic stimulation thresholds, greater lead failure/fracture rates with somatic growth, and shortened battery life.[2] The primary objective is that of achieving a stable and reliable heart rate until the patients grows to a body weight adequate for conventional transvenous pacemaker implantation. Traditional epicardial pacemaker insertion involves placement of at least a ventricular lead and, if possible, an atrial lead to obtain atrioventricular synchrony. Whereas epicardial ventricular leads can be placed through a small subxiphoid incision, reaching the right atrium can be challenging in small neonates without extending the incision to a full sternotomy. The issue also becomes that of where to create a pocket large enough to accommodate a bulky generator without the potential risk of wound disruption. Larger generators can either be placed in the epigastrium (therefore occupying a large portion of the upper abdomen) or lodged within the left chest over the left diaphragm (easier if approached via a full sternotomy).[3]

Berul and colleagues[4] first reported in early 2023 the use of the custom-designed Medtronic Micra device for emergency use in 5 neonates with congenital complete heart block. As per reported manufacturer's data, this report was followed to date (therefore excluding the patient described herein) by another 9 patients, all approached via a full sternotomy.

TABLE 1. Intraoperative results from transcutaneous pacemaker interrogation

Programmed rate and output	Pacing threshold (@1.0 ms)	P/R wave, mV	Impedance (Ω)
VVI 100 3.5 V @1.0 ms	1.75	20	2410

Through a left thoracotomy, access to the fragile left atrial appendage could only be accomplished with a larger thoracotomy. In a small newborn, this would also call for 2 bipolar leads to be retained into the diminutive space of the left chest. Furthermore, adequate intermediate-term cardiac output can be accomplished with ventricular pacing only, and timing of reoperation will be dictated regardless by duration of battery life.[5] If initially done via a thoracotomy, reoperation can be easily accomplished with atrial and ventricular leads inserted through a nonreoperative field in the larger child. Lastly, this approach is also cosmetically pleasing and avoids the need for a full sternotomy in a small newborn.

Conflict of Interest Statement

The authors reported no conflicts of interest.

The *Journal* policy requires editors and reviewers to disclose conflicts of interest and to decline handling or reviewing manuscripts for which they may have a conflict of interest. The editors and reviewers of this article have no conflicts of interest.

References

1. Pruetz JD, Miller JC, Loeb GE, Silka MJ, Bar-Cohen Y, Chmait RH. Prenatal diagnosis and management of congenital complete heart block. *Birth Defects Res*. 2019;111:380-8.
2. Paech C, Kostelka M, Dähnert I, Flosdorff P, Riede FT, Gebauer RA. Performance of steroid eluting bipolar epicardial leads in pediatric and congenital heart disease patients: 15 years of single center experience. *J Cardiothorac Surg*. 2014;9:84.
3. Roubertie F, Le Bret E, Thambo JB, Roques X. Intra-diaphragmatic pacemaker implantation in very low weight premature neonate. *Interact Cardiovasc Thorac Surg*. 2009;9:743-4.
4. Berul CI, Dasgupta S, LeGras MD, Peer SM, Alsoufi B, Sherwin ED, et al. Tiny pacemakers for tiny babies. *Heart Rhythm*. 2023;20:766-9.
5. Kubus P, Materna O, Gebauer RA, Matejka T, Gebauer R, Tláskal T, et al. Permanent epicardial pacing in children: long-term results and factors modifying outcome. *Europace*. 2012;14:509-14.

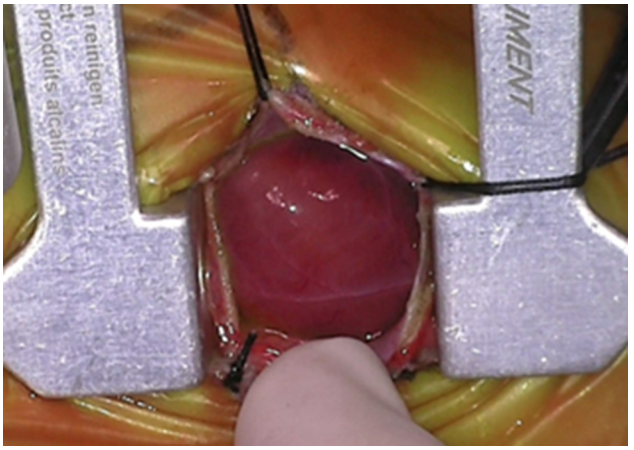


FIGURE E1. Operative exposure of the left ventricular apex, showing the left ventricle between left anterior coronary artery and left circumflex branch (*coursing horizontally* in the photograph).

FIGURE E2. Limited anterior thoracotomy and abdominal counterincision at completion of the procedure.