Novel use of an atrial sensing leadless pacemaker to treat complete heart block in a patient with repaired tetralogy of Fallot with pre-existing dual-chamber pacemaker with ventricular lead fracture



Matthew Needleman, MD, FHRS,* John Symons, MD, FHRS,* Lauren A. Weber, MD,* Michael Mulreany, MD,[†] Joseph May, MD,[†] Mark C. Haigney, MD[‡]

From the *Department of Cardiology, Walter Reed National Military Medical Center, Bethesda, Maryland, [†]Department of Pediatrics, Walter Reed National Military Medical Center, Bethesda, Maryland, and [‡]Department of Cardiology, Uniformed Services University of Health Sciences, Bethesda, Maryland.

Introduction

Management of ventricular lead fractures in pacemakerdependent patients remains a clinical challenge for electrophysiologists. We present the first reported case involving the placement of an atrial sensing leadless ventricular pacemaker following a ventricular lead fracture in a patient with a pre-existing dual-chamber pacemaker. This case is unique because it is the first to show that atrial pacing from the pre-existing pacemaker can be mechanically sensed by a leadless ventricular pacemaker. This case also highlights special considerations of leadless pacemaker implant in an adult patient with palliated congenital heart disease.

Case report

We present the case of a 74-year-old woman who underwent repair of tetralogy of Fallot at age 27 at our institution. She did well for decades, with clinical symptoms only present in association with atrial flutter, which was managed with ablation. Because of progressive pulmonic valve regurgitation and aortic root dilation with aortic valve regurgitation, she subsequently underwent a pulmonary valve replacement, aortic valve replacement, and right ventricular outflow tract root and aortic root repairs approximately 5 years prior to her current presentation. The procedure was successful but was complicated by complete heart block, requiring a dualchamber pacemaker (St. Jude Medical, Assurity DR Model

KEYWORDS Leadless pacemaker; Pacemaker lead fracture; Mechanical atrial sensing; Tetralogy of Fallot; Crosstalk (Heart Rhythm Case Reports 2020;6:777–781)

KEY TEACHING POINTS

- Leadless pacemakers can sense atrial mechanical signals from atrial pacing from a separate pacemaker generator.
- Managing 2 pacemaker generators during implant is challenging, and careful investigation to prevent crosstalk is required.
- Patients with tetralogy of Fallot have unique leadless pacemaker implant considerations and in the 2 reported cases they typically have small A4 signals, which may reduce the ability for atrial tracking.

2240; Abbott Cardiovascular, Plymouth, MN) in the postoperative period. During follow-up, the patient was noted to require near 100% atrioventricular (AV) sequential pacing.

The patient continued to thrive, but 3 months prior to her current presentation she developed evidence of ventricular lead fracture with inappropriately sensed noise on the ventricular lead, which resulted in inappropriate ventricular pacing inhibition. Because she was initially asymptomatic, the device was programmed to the least sensitive programming setting with unipolar sensing to reduce the inappropriate sensed noise. Although this programming initially worked, she subsequently developed presyncope corresponding with oversensing on her pacemaker. In addition, the device's auto-threshold test showed occasional high thresholds, suggestive of potential early capture failure.

Because she was dependent on the pacemaker with no clinically stable escape rhythm, plans for expedited pacemaker system revision were then undertaken. The patient was initially offered 3 options: extraction and reimplantation of the right ventricular lead, addition of a new right

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors. Conflicts of Interest: No authors have conflicts of interest related to this article. **Address reprint requests and correspondence:** Dr Matthew Needleman, Department of Cardiology, Walter Reed National Military Medical Center, 8901 Rockville Pike, Bethesda, MD 20889. E-mail address: matthew.needleman@usuhs. edu.

^{2214-0271/}Published by Elsevier Inc. on behalf of Heart Rhythm Society. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).

ventricular lead with capping of the fractured lead, or upgrade to a biventricular pacemaker system. All these traditional options involved standard pacemaker leads, and the patient was appropriately concerned about repeat lead fracture and the need for reoperation. We also discussed the option of implanting an atrial-sensing leadless pacemaker and programming the pre-existing dual-chamber pacemaker to a rate-responsive atrial pacing only mode, thus allowing her to have a "hybrid" pacing system with 2 different pacemaker generators. Despite the risks of crosstalk between the 2 systems and the uncertainty in mechanical sensing of an atrial-paced rhythm, this nontraditional option appealed most to the patient. Through a process of shared decision-making, she elected to undergo an atrial-sensing leadless pacemaker system implantation with reprogramming of her pre-existing dual-chamber pacemaker.

After informed consent was obtained, the patient was brought to the electrophysiology laboratory and the preexisting dual-chamber pacemaker was programmed to a nontracking mode (DOO 80) to prevent inappropriate sensing during the leadless pacemaker implant. Right ventricular angiography was then performed, which confirmed the right ventricular geometry and location of the preexisting right ventricular lead (See Supplementary Video). Using the standard 27F sheath (Medtronic Micra Introducer; Medtronic, Minneapolis, MN) and the transcatheter delivery system (Medtronic Micra Integrated Delivery Catheter), the atrial-sensing leadless pacemaker (Medtronic Micra AV Model MC1AVR01) was initially delivered and deployed to the right ventricular midseptal region. To test the leadless pacemaker, the leadless pacemaker was programmed to an asynchronous mode at maximum output (VOO 90 with an output of 5 volts and a pulse width of 1.0 ms). The preexisting pacemaker was then programmed to AAI to allow impedance and capture tests in the leadless pacemaker. Unfortunately, this initial site was suboptimal, with a high threshold and borderline low impedance, perhaps related to the patch of the ventricular septal defect. Prior to recapture of the pacemaker, the pre-existing leaded pacemaker was programmed back to a dual-chamber asynchronous mode (DOO 80). The leadless pacemaker was then programmed off, recaptured, and repositioned multiple times until an apical septal location was found. Testing in this location showed adequate thresholds and impedances (threshold 1.13 volts at 0.24 ms and impedance of 860 ohms). The pre-existing dualchamber pacemaker was then programmed to an atrial pacing mode at maximal output (7.5 volts at 1.5 ms) and no artifact or inhibition was seen on the leadless pacemaker. Furthermore, when the leadless pacemaker was programmed to maximal output, no oversensing was noted on the preexisting dual-chamber pacemaker. Given the adequate fixation and electrical performance of the leadless pacemaker on the septal apical myocardium, with no oversensing noted on either device, it was felt that her dual-generator system would perform adequately. The tether was removed from the leadless pacemaker without event. Figure 1 shows the posterior-anterior and lateral chest radiograph positioning of the new leadless pacemaker on the first postprocedure day.

During the implant, 2 important pacemaker programmer issues were noted. First, during the placement of the leadless pacemaker programmer's (Medtronic CareLink 2090 Programmer) head on the chest wall, the preexisting dual-chamber pacemaker occasionally went into magnet mode, as evidenced by asynchronous AV pacing at a rate of 100 beats per minute. This was typically shortlived and resulted in no adverse events. In addition, it was noted that when the leadless pacemaker programmer's head was over the chest wall, the pre-existing pacemaker programmer (St. Jude Merlin Medical Patient Care System Model 3650; Abbott Cardiovascular) had difficulty initiating a connection with the pre-existing pacemaker. Once the head of the leadless pacemaker programmer (Medtronic CareLink 2090 Programmer) was removed, the pre-existing



Figure 1 Posterior-anterior and lateral chest radiographs of the final dual-chamber pacemaker system. The pre-existing dual-chamber pacemaker system was programmed to AAIR 60–90 beats/min and the leadless pacemaker was programmed to VDD 55.



Figure 2 An example of the atrial mechanical sense test showing the programmed A3 and A4 windows. Evan at maximal sensitivity, the A4 signal is small, just above the 0.7 m/s^2 that resulted in the occasional atrial undersensing.

pacemaker programmer (St. Jude Merlin Medical Patient Care System Model 3650) was able to adequately connect with the preexisting pacemaker. This was likely caused by the magnetic field in the programming head of the Medtronic CareLink 2090 Programmer.

After the leadless pacemaker completed the automatic setup process, it sensed and tracked 27% of the atrial paced events. Manual atrial mechanical sensing tests were run, and there was noted to be a small A4 component. To avoid oversensing of the A3 signal, the A3 blanking window was lengthened, and the A4 sensitivity was programmed to the most sensitive value (0.7 m/s^2). In addition, to increase the A4 signal maximally, the accelerometer vectors (1 and 3) were used in the sensing algorithm. With these manual changes to the atrial sensing algorithm, the atrial tracking and sensing on the leadless pacemaker increased to 74%. Figure 2 shows an example of the small A4 signal. The final pre-existing pacemaker was programmed to AAIR 60–90 beats per minute, and the leadless pacemaker was programmed to VDD 55 beats per minute with an upper track rate of 120 beats per minute. Figure 3 shows an example of a rhythm strip of the final programming, with AV sequential pacing from both pacemakers and a high percentage of atrial tracking that used the leadless pacemaker's atrial mechanical sensing algorithm. In short-term follow-up, the threshold of the leadless pacemaker decreased to 0.63 volts at 0.24 ms and the patient noted no more presyncope or pacemaker syndrome symptoms.

Discussion

Traditional leaded pacemakers have a combined short- and long-term system failure rate of up to 20% at 5 years, and 5% of these complications are lead-related—a conundrum all too familiar to practicing clinical electrophysiologists.¹ Leadless pacemakers have recently been shown to reduce long-term complications by 66%, compared with traditional pacemakers, in a large prospective registry of Medicare patients.² Although the second-generation pacemaker can atrial



Figure 3 An example of the rhythm strip of the final programming, with atrioventricular (AV) sequential pacing from both pacemakers. The stars represent AV synchrony. The first 2 stars and last 3 stars are examples of atrial mechanical tracking of the paced atrial rate. The third star likely shows an example of the atrial acceleration algorithm "rate smoothing," as evidence by a slightly longer atrial sensed–to–ventricular paced interval. The fourth through sixth stars represent AV synchrony that was serendipitous. The x marks represent nontracked atrial events. The first and third x marks are premature atrial contractions and all the x-marked P waves occur in the ventricular refractory period. Note that even during the nontracked atrial events, the atrial acceleration algorithm prevents a sudden drop in the ventricular rate.

sense, many patients still require atrial pacing and may not be traditional candidates for leadless pacemakers. The ability of the atrial sensing algorithm to sense paced rhythms had not been previously reported, and this case highlights that, though difficult, it is feasible.

Although the AV synchrony was only 74% in our patient, the leadless pacemaker has a unique atrial acceleration algorithm that provides stable ventricular rates even when atrial undersensing occurs. This atrial acceleration algorithm, called "Rate Smoothing" (Medtronic), measures every atrial-sensed ventricular-triggered event and constantly updates the rate. When atrial undersensing occurs, the previous ventricular paced rate plus the programmable rate smoothing interval (an interval from 50 to 200 ms) slightly extends the pacing interval, allowing a faster rate than the programmed lower rate limit. This increases AV synchrony above the atrial-mechanical sensing algorithm. In the MARVEL 2 trial,³ this atrial acceleration algorithm increased AV synchrony over what the device reported by 9%; and an example of this algorithm in action is seen on the third star in Figure 3. An important feature of this algorithm is that it provides more stable ventricular rates when tracking atrial rates above the lower rate limit when atrial undersensing is more likely to occur. By slightly extending the paced rate with atrial undersensing, this algorithm also prevents overtracking of premature atrial contractions or atrial tachycardias.

Major challenges with the implantation and follow-up of this strategy involve having 2 pacemaker generators that do not directly communicate, posing a high risk of crosstalk between the devices. We did not see any evidence of this, even when the atrial pacemaker was programmed at maximal output. One might expect this to be the case, given the relatively long postventricular blanking period following ventricular pacing nominally programmed on the atrial sensing leadless systems. The long A3 window functions as a refractory period as well, which makes for an exceptionally long postventricular blanking and refractory period, resulting in significantly less opportunity for crosstalk to occur. In addition, the atrial sensing algorithm is novel in that it does not sense electrical signals and only senses mechanical "motion" on the accelerometer, further reducing potential crosstalk. Despite these potential advantages, the lack of 100% AV synchrony means that atrial pacing could happen outside the postventricular atrial blanking period. In addition, the automatic ventricular threshold tests occur only in using a ventricular sensing algorithm, which could also be at risk for crosstalk from the atrial pacemaker. When the leadless pacemaker automatic threshold test was run with atrial pacing at maximal output, no oversensing was seen, and the same threshold was seen during the manual test-suggesting that there was no crosstalk between the pacemaker systems as programmed. Our patient's right atrial and right ventricular dilation also provided a large anatomic distance between the leadless pacemaker and right atrial lead, which made

crosstalk less likely; however, in patients with smaller hearts, this could be a significant concern.

Another unique aspect of this case was placement of the leadless pacemaker in an adult with a repaired tetralogy of Fallot. There are 2 case reports of leadless pacemakers in pediatric patients,^{4,5} but there have been no large case series in adults with congenital heart disease. Given the ventricular septal defect repair, the pulmonic valve replacement, and the right ventricular outflow tract revision, the deployment of the leadless pacemaker was challenging in our patient, and the right ventricular angiogram aided in procedural planning.

The MARVEL 2 trial³ showed that the average AV synchrony at rest was nearly 90%. In the single patient in this trial with repaired tetralogy of Fallot, the atrial sensing was only 33.4%, similar to our patient's nominal atrial mechanical settings. Even with programming optimization, our patient's A4 remained small using all available sensing vectors, which may be a result of the tetralogy of Fallot or an intrinsic feature of septal or right atrial appendage depolarization of the right atrium. Additional cases will be needed to more fully evaluate the atrial mechanical signals seen on leadless pacemakers from atrial pacing.

Conclusions

We present the first case of atrial pacing being sensed on an atrial mechanical-sensing leadless pacemaker system, which shows a potentially novel method to treat heart block in patients with concomitant sinus node dysfunction. Our case highlights the difficultly in managing device-device interactions and potential crosstalk associated with 2 operational pacemaker generators. Finally, our case also underscores the special considerations needed to place leadless pacemakers in patients with repaired tetralogy of Fallot.

Acknowledgment

Disclosure: The identification of specific products or scientific instrumentation is considered an integral part of the scientific endeavor and does not constitute endorsement or implied endorsement on the part of the author, Department of Defense, or any component agency. The views expressed in this article are those of the author and do not reflect the official policy of the Department of Army/Navy/Air Force, Department of Defense, or U.S. Government.

Appendix Supplementary data

Supplementary data associated with this article can be found in the online version at https://doi.org/10.1016/j.hrcr.2020. 07.019.

References

- Udo EO, Zuithoff NPA, Van Hemel NM, et al. Incidence and predictors of shortand long-term complications in pacemaker therapy: The FOLLOWPACE study. Heart Rhythm 2012;9:728–735.
- Piccini JP, Wherry K, Bockstedt L, et al. Comparison of outcomes among patients implanted with a tined, leadless versus transvenous single-chamber ventricular

pacemaker in the novel micra coverage with evidence development study. Heart Rhythm D-LBCT04-01; Presented Virtually at the Heart Rhythm Scientific Sessions on May 8, 2020.

- Steinwender C, Khelae SK, Garwed C, et al. Atrioventricular synchronous pacing using a leadless ventricular pacemaker: Results from the MARVEL 2 Study. JACC Clin Electrophysiol 2020;6:94–106.
- McCanta AC, Morchi GS, Tuozo F, et al. Implantation of a leadless pacemaker in a pediatric patient with congenital heart disease. HeartRhythm Case Rep 2018; 4:506–509.
- McGill M, Roukoz H, Jimenez E, et al. Leadless pacemaker placement in a pediatric tetralogy of Fallot patient with previous transcatheter valve replacement. J Electrocardiol 2019;56:52–54.