Implant-to-implant diagnostics and programming of dual-chamber leadless pacemaker in an orthotopic heart transplant recipient

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Introduction

The Abbott Aveir™ DR (Abbott, Park, IL) is the first and only dual-chamber leadless pacemaker, and was recently approved by the U.S. Food and Drug Administration on July 5, 2023. Prior leadless pacemakers include the Medtronic Micra™ VR and the Abbott Aveir VR single-chamber leadless pacemakers, which provide VVI(R) pacing capability, and the Medtronic Micra AV single-chamber leadless pacemaker with atrial-synchronous VDD(R) pacing via tracking of mechanical atrial contraction.[1,2] The Aveir leadless pacemakers are unique in that they allow for mapping of intracardiac electrical measurements (including assessment of current of injury) before device deployment in order to reduce the number of repositioning attempts, and their active fixation helix enables safe and successful chronic retrieval.[2] The Aveir DR dual-chamber leadless pacemaker optimizes atrioventricular (AV) synchrony by providing atrial pacing, expanding the options for patients who require DDD(R) pacing and for whom the potential complications of conventional transvenous pacemakers are undesired or prohibitive to implantation.

The development of a dual-chamber leadless pacemaker with DDD(R) pacing and wireless communication between separate atrial and ventricular devices has required the innovation of unique device programming and pacing behavior. The Aveir DR atrial and ventricular pacemakers are paired at implant with implant-to-implant (i2i) communication, which occurs beat-by-beat via transmission of subthreshold electrical signals through blood and myocardium between the atrial and ventricular devices to provide AV synchrony and uninterrupted ventricular pacing.[3,4] The i2i communication can be interrupted in different directions with consequent changes in pacing behavior. Of note, i2i communication may improve with long-term observation in Aveir DR recipients. Position changes may transiently affect i2i communication. Furthermore, hospital equipment (eg, the Philips electrocardiogram [ECG] patient monitoring systems, external defibrillators) may interfere with i2i communication while connected, with restoration of i2i on equipment removal (Personal communication, Abbott Medical, Park, IL).

With the loss of i2i communication between Aveir DR atrial and ventricular leadless pacemakers, there is a compensatory switch in functional pacing mode to an "automatic

KEY TEACHING POINTS

- The Abbott Aveir DR is the first and only dual-chamber leadless pacemaker available for implantation. The atrial and ventricular leadless pacemakers are paired with implant-to-implant (i2i) communication, which occurs beat-by-beat via wireless transmission of subthreshold electrical signals.
- With loss and recovery of i2i communication, there are compensatory switches in functional pacing modes that occur beat-by-beat to maintain atrioventricular synchrony (atrial tracking and/or pacing) when possible and provide uninterrupted ventricular demand pacing.
- We present an electrocardiogram from the first reported patient post–orthotopic heart transplant who received the Aveir DR, demonstrating changes in functional pacing modes during the intermittent loss of ventricular-to-atrial i2i communication.
- Owing to novel programming and function of dual-chamber leadless pacemakers, clinicians must recognize and interpret previously undescribed ECG patterns to distinguish normal vs abnormal pacemaker behavior.

KEYWORDS Atrioventricular synchrony; Automatic safeguard mode; Dual-chamber leadless pacemaker; Dual P wave; Implant-to-implant (i2i) communication; Orthotopic heart transplant; Pacing mode; Programming; Wireless communication

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safeguard mode" to maintain AV synchrony (atrial tracking and/or pacing) when possible and provide uninterrupted ventricular demand pacing (Figure 1).[3,4] Atrial-to-ventricular (A2V) communication is required for atrial tracking and thus atrial-triggered ventricular pacing. Ventricular-to-atrial (V2A) communication is required to pace the atrium at the appropriate ventriculoatrial interval in the absence of intrinsic atrial activity. In a patient with a dual-chamber Aveir DR leadless pacemaker, intact A2V and V2A communication allows for DDD(R) pacing. With the loss of A2V i2i communication, triggered ventricular pacing is not possible and the device mode switches to DDI(R). With the loss of V2A i2i communication, atrial pacing is withheld, and the pacing mode switches to VDD(R). With simultaneous loss of both A2V and V2A i2i communication, the functional pacing mode becomes VDI(R), with the atrial leadless pacemaker programmed OAO and the ventricular leadless pacemaker programmed VVI(R). Because i2i communication is assessed beat-by-beat, these changes in functional pacing modes during i2i loss can occur rapidly on a beat-by-beat basis. Whether AV synchrony is preserved depends on the patient's underlying rate and rhythm. For example, DDI can provide AV synchrony when atrial pacing is required but cannot track intrinsic atrial activity. VDD can provide AV synchrony by tracking intrinsic atrial activity but cannot provide atrial pacing or AV synchrony in the setting of sinus bradycardia or arrest. Importantly, regardless of the direction and duration of i2i interruption, ventricular demand pacing will continue.

We present an ECG demonstrating the unique programming and pacing features of the Aveir DR. This ECG is from the first reported patient post–orthotopic heart transplant who received the Aveir DR as part of the Abbott Aveir Dual-Chamber Leadless i2i IDE clinical trial, conducted at Advocate Aurora St. Luke's Medical Center in Milwaukee, Wisconsin.[5]

Case Report

The patient is a 43-year-old man with a history of nonischemic cardiomyopathy and an ejection fraction of 5%–10%, who presented with cardiogenic shock. He underwent an orthotopic heart transplant with modified biatrial anastomosis. Post-transplant, he had sinus node dysfunction and symptomatic chronotropic incompetence managed with terbutaline, which caused new-onset atrial fibrillation. A dual-chamber pacemaker was recommended owing to his dependency on terbutaline for adequate heart rates. The advantages of a leadless pacemaker compared to a conventional transvenous device for our patient, who is young and on chronic immunosuppressive therapy, include a decreased risk of infection; absence of chronic indwelling leads, which predispose to subclavian vein stenosis and occlusion; and the ability to retrieve the device in the future. The Aveir DR was implanted as part of a clinical trial. Multiple post-transplant ECGs demonstrated dual P waves at different sinus rates, representing dissociated atrial depolarizations originating from recipient tissue and donor

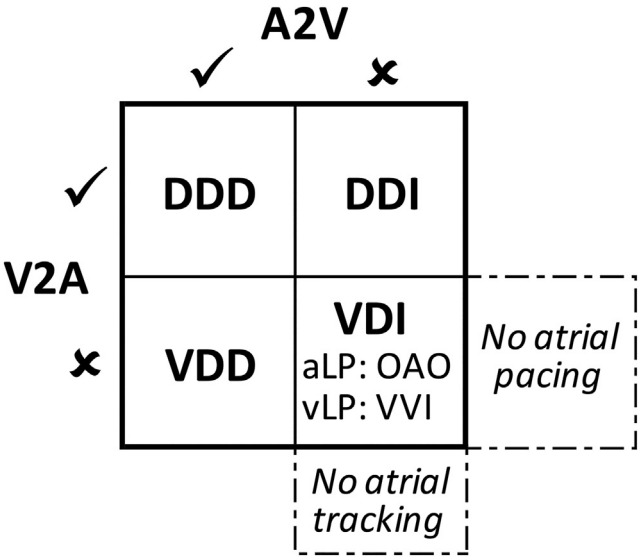

Figure 1 Functional pacing modes (automatic safeguard modes) during i2i loss in the Aveir™ DR dual-chamber leadless pacemaker (Abbott, Park, IL).[3,4] The Aveir DR is uniquely programmed to switch functional pacing modes with interruption of implant-to-implant (i2i) communication between the atrial leadless pacemaker (aLP) and ventricular leadless pacemaker (vLP). In a device programmed DDD, the diagram outlines the automatic safeguard modes in the event of atrial-to-ventricular (A2V) and/or ventricular-to-atrial (V2A) interruption. Check mark indicates intact i2i communication; x mark indicates loss of i2i communication.

atrial depolarizations that conducted to the ventricles. During device implantation, it was challenging to select the best atrial location for deployment to ensure selective and accurate sensing and tracking of donor P waves.

After deployment and sensitivity programming, both the atrial and ventricular leadless pacemakers were paired successfully with i2i communication. The final interrogation showed an atrial threshold of 2.5 V at 0.4 ms, sensing at 1.0 mV, and impedance of 320 ohms; and a ventricular threshold of 0.5 V at 0.4 ms, sensing at 9.1 mV, and impedance of 1210 ohms. The devices were programmed DDD(R) at a rate of 60–120 beats per minute (bpm).

On postimplant day 1, the dual-chamber leadless pacemaker interrogation showed 55% atrial pacing, 9% ventricular pacing, 69% V2A i2i communication, and 90% A2V i2i communication.

Electrocardiogram

An ECG from postimplant day 1 demonstrates device programming and behavior when i2i interruption occurs (Figures 1 and 2). The possibility of an automatic mode-switching episode was excluded by device interrogation.

The ECG shows donor sinus P waves with associated QRS complexes and recipient P waves originating from electrically dissociated remnant atrial tissue. There is progressive fusion of intrinsic and ventricular-paced QRS complexes across the ECG with shortening PR intervals, as the ventricular-paced rate is faster than the intrinsic sinus (and associated intrinsic ventricular) rate. Owing to rate-responsive pacing in this

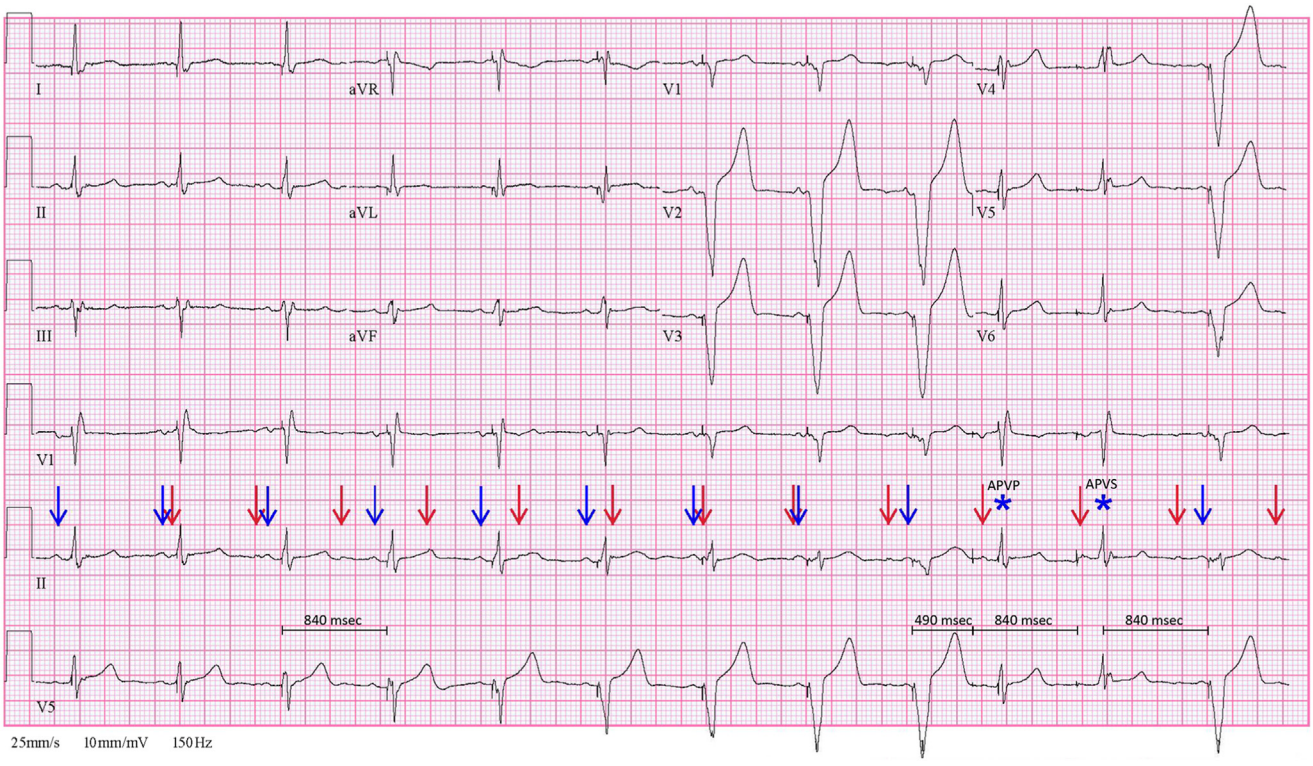

Figure 2 Electrocardiogram demonstrating changes in functional pacing modes with intermittent ventricular-to-atrial (V2A) i2i loss. * = Atrial-paced ventricular-paced (APVP) and atrial-paced ventricular-sensed (APVS) PQRS complexes indicating brief restoration of V2A implant-to-implant (i2i) communication. APVP complex is a fusion beat of intrinsic and paced QRS. This electrocardiogram was obtained 1 day after Aveir DR (Abbott, Park, IL) implant in a heart transplant recipient. It shows sinus rhythm with dual donor and recipient P waves (blue arrows: donor P waves, sensed and tracked by the leadless pacemaker; red arrows: recipient P waves from electrically dissociated remnant atrial tissue). There is progressive fusion of intrinsic and ventricular-paced QRS complexes with shortening PR intervals, as the V-paced rate is faster than the intrinsic sinus and native QRS rate. Atrial tracking cannot be detected when the intrinsic atrial rate is slower than the base V-pacing rate. Therefore, we cannot prove atrial-to-ventricular communication. This electrocardiogram demonstrates changes in functional pacing modes during V2A i2i loss, with brief restoration of V2A i2i for 2 PQRS complexes (*). The device is programmed DDD(R) 60–120 beats per minute (bpm), with both paced and sensed atrioventricular (AV) delays of 200 ms, and additional ventricular intrinsic preference (VIP) extension of 150 ms. The sensor-driven rate is ∼71 bpm; thus pacing cycle length is 840 ms. Programmed ventriculoatrial interval = sensor-driven base rate (840 ms) – AV delay (200 ms) – VIP extension (150 ms) = 490 ms. V-pacing (at pacing cycle length 840 ms) without A-pacing, with progressive QRS fusion, suggests VDI(R) or VDD(R) pacing owing to a loss of V2A i2i. On the first marked PQRS complex (*), A-pacing occurs at the programmed VA interval (490 ms), suggesting a switch to DDI(R) or DDD(R) (at same pacing cycle length, 840 ms) and thus restoration of V2A i2i. After these 2 complexes (*), V2A i2i is lost again, with pacing mode switching back to VDI(R) or VDD(R), again at the same pacing cycle length (840 ms).

device programmed DDD(R) 60–120 bpm, the sensor has increased the pacing rate from a base rate of 60 bpm to a sensor-driven rate of ∼71 bpm (840 ms). The presence or absence of atrial tracking cannot be assessed when the intrinsic atrial rate is slower than the sensor-driven base ventricular pacing rate. Therefore, we cannot determine whether A2V communication is intact or interrupted (loss of A2V would preclude atrial tracking). This ECG demonstrates changes in functional pacing modes with intermittent V2A loss.

With interruption of V2A communication, the system will not pace the atrium, and the pacing mode will switch to VDI (if simultaneous A2V loss) or VDD (with A2V intact). With restoration of V2A communication, the device can pace both the atrium and the ventricle, and the pacing mode will switch to DDI (with simultaneous A2V loss) or DDD (with A2V intact).

This ECG was obtained during interruption of V2A i2i communication, with brief restoration of V2A communication for 2 PQRS complexes (asterisks). Ventricular (and not atrial) pacing with progressive QRS fusion suggests VDI(R) or VDD(R) pacing owing to a loss of V2A i2i communication. On the first PQRS complex marked by asterisks, atrial pacing occurs at the end of the programmed ventriculoatrial interval (490 ms), suggesting a switch in pacing mode to either DDI(R) or DDD(R) (at the same cycle length, 840 ms) and thus a restoration of V2A i2i. After these A-paced V-paced and A-paced V-sensed complexes (asterisks), V2A i2i communication is lost again, with pacing mode switching back to VDI(R) or VDD(R). The duration between the last sensed ventricular beat (second asterisk) and the next paced ventricular complex remains at the same cycle length of 840 ms.

On follow-up 23 days post–pacemaker implant, the patient was doing well, without cardiac symptoms or postprocedural complications. He required 76% atrial pacing and 7% ventricular pacing. V2A i2i communication was 89%, and A2V i2i was 91%. It should be noted that V2A i2i communication, which was shown to be interrupted on ECG on postimplant day 1, significantly improved from 69% to 89% by

the 23-day follow-up. Device interrogation in the clinic showed overall improvement in atrial threshold of 0.5 V at 0.4 ms, sensing at 4.1 mV, and impedance of 370 ohms; and ventricular threshold of 0.5 V at 0.4 ms, sensing at 16.9 mV, and impedance of 620 ohms.

Discussion

This case demonstrates the unique programming of Aveir DR dual-chamber leadless pacemakers to address intermittent loss of i2i wireless communication between atrial and ventricular devices, with the goal of maintaining AV synchrony (atrial tracking and/or pacing) when possible and providing uninterrupted ventricular demand pacing. In a preclinical ovine study of the Aveir DR, i2i loss was uncommon and brief (<6 seconds) across a variety of postures, daily activities, cardiac rhythms (sinus rhythm and induced AV block), and heart rates, both acutely and chronically (up to 23 weeks postimplant).[4]

A problem comparable to i2i loss with conventional transvenous pacemakers may be lead dislodgement or fracture with transient or permanent issues with sensing and/or capture. Transvenous devices cannot switch functional pacing modes to compensate for transient sensing and pacing issues. They respond to oversensing/undersensing and failure to capture within the constraints of the currently programmed pacing mode. In transvenous devices, automatic mode switching only occurs in the setting of paroxysmal atrial tachyarrhythmias to avoid atrial-triggered rapid ventricular pacing. The pacemaker reprograms itself from a tracking mode, eg, DDD(R), to a no-tracking mode, eg, DDI(R), thereby avoiding tracking of rapid atrial rates during atrial fibrillation or flutter. The device reverts to a tracking mode when the atrial tachyarrhythmia terminates.

In contrast, the Aveir DR continuously assesses i2i communication on a beat-by-beat basis and is programmed to rapidly switch functional pacing modes to address transient losses of i2i communication, thereby avoiding ventricular underpacing.

This case demonstrates previously undescribed ECG patterns related to novel programming and function of dual-chamber leadless pacemakers. New ECG patterns may become more prevalent with widespread use of these devices. Accurate recognition and interpretation of these new ECG patterns is required for the clinician to understand the clinical relevance of changes in pacemaker behavior, and to determine if this is appropriate behavior or requires intervention.

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