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Case Report

Retrievable dual-chamber leadless pacemaker implant (Aveir DR) in an adult patient with congenital heart disease

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ABSTRACT

Leadless pacemakers have demonstrated potential as a transvenous pacing option in Adult Congenital Heart Disease patients. Aveir™ single-chamber (VR) leadless pacemakers have demonstrated safety in patients without congenital heart disease in a dual chamber approach. We present a case of dual-chamber pacing using the Aveir dual-chamber (DR) leadless pacemaker in a patient with repaired dextro-transposition of the great arteries with ventricular septal defect (VSD) surgical closure.

A 26-year-old male patient with a history of transposition of the great arteries status post arterial switch and VSD repair neonatally had complicated second degree atrioventricular block and sinus node dysfunction necessitating pacemaker placement. Epicardial single-chamber ventricular pacemaker was placed neonatally, which was switched to dual-chamber pacemaker at age 17 due to malfunction. Recent fracture of pacemaker leads led to implantation of new dual chamber leadless pacemaker.

Removal of previous pacemaker leads via mechanical extraction occurred and implantation of Aveir DR leadless pacemaker was performed under anesthesia via right femoral vein access without complication. Follow-up demonstrated Aveir VR threshold of 1.0V@0.2 ms, R-wave of 8.9mV, impedance of 490Ω, and the Aveir AR threshold of 0.75V@0.2 ms, P-wave of 3.7mV, and impedance of 400Ω.

This case demonstrates safety and efficacy of dual chamber leadless pacemaker implantation in an ACHD patient.

1. Introduction

Congenital heart disease (CHD) makes up a significant portion of congenital anomalies, and has been increasing in prevalence over the past few decades [1]. This global prevalence increase continues to the present day [2]. Part of this prevalence increase results from improved treatment for CHD, which also leads to an increase in an increased age at death [3]. While the heterogeneity of patients with CHD and the lack of randomized trials limit the creation of guidelines, device therapy is nonetheless increasing in usage for the management of the disease [4].

Currently, transvenous pacing has been shown to generally yield better results than epicardial pacing in these patients [5]. Leadless pacemakers have further shown potential as an option to transvenous pacing, and can address problems such as complex anatomy and contraindications to transvenous pacemakers such as risk of lead-related complications [6,7]. However, safety of dual chamber leadless pacemaker implants have yet to have been demonstrated in the same population.

Leadless pacemakers includes devices which can be implanted into both the right atrium and right ventricles [8]. The Aveir DR (Abbott, Chicago, USA) can be implanted in both the right atrium and right ventricle. In previous cases, single-chamber leadless pacemaker implantation has been achieved using the Aveir VR pacing system, which was beneficial to ACHD patients without major complications in a small study [9]. We demonstrate a case of dual-chamber implantation of the Aveir DR in an adult patient with congenital heart disease.

2. Case report

We present a case of a 26-year-old active male with a history of transposition of the great arteries, status post arterial switch and VSD repair neonatally. He had complicated second degree AV block and sinus node dysfunction necessitating pacemaker placement. Initially, an epicardial single-chamber ventricular pacemaker was placed neonatally.

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At age 17, due to pacemaker malfunction of the epicardial system he underwent a pacemaker revision with implantation of a dual-chamber pacemaker via the left axillary vein, along with explantation of the old abdominal generator. Due to a left precordial twitching sensation that was thought to likely be due to extracardiac skeletal muscle stimulation, he underwent a pacemaker revision a month later. During the revision, the old ventricular lead was extracted and a new ventricular lead was placed. Following that procedure, the patient continued to have the same sensation, but with less intensity and decreased frequency. He was also very active including weight-lifting and wanted to maintain an active lifestyle.

The patient recently had fracture of his atrial lead (noted after exercise) with programming to VVIR and subsequent syncope in the setting of pending ventricular lead fracture (impedance 1320 Ω, rising threshold and intermittent capture). Chest radiograph taken at the time with can be seen in Fig. 1A. A KardiaMobile EKG recording of a symptomatic event can be seen in Fig. 1B, showing significant pauses. Implantation of dual chamber leadless pacemaker was performed, with Fig. 1C showing a 2-view chest X-ray post implantation. After discussion regarding risks and benefits of another transvenous device, versus leadless device, the patient preferred the leadless pacemaker option, citing ability to remain fairly active without arm restrictions regarding weight-lifting and other sports he wanted to pursue recreationally.

3. Methods

The patient was placed under anesthesia, and using the Seldinger technique, a 5-Fr sheath was placed in the left femoral vein. A temporary pacemaker was prepped to be placed in the right ventricle if needed. Subsequently, a 6-Fr and then a 12-Fr sheath were placed in the right femoral vein with a Super stiff wire placed through, positioned at the superior vena cava/internal jugular vein junction. A Bridge balloon was positioned between the innominate vein and high RA and balloon catheter marked at the entrance to the sheath. The Bridge balloon was withdrawn with sheath and wire maintained in place.

Seldinger Technique was used for arterial access with a 4F sheath at the left femoral artery and arterial blood pressure monitoring was obtained.

Following lidocaine injection, an incision was made at the prior pacemaker scar and dissection was made to the level of the device. Lead adhesions were removed via cautery, coagulation, and mechanical dissection. A straight Stylet was placed into each 5076 lead and positioned towards the end of the lead under fluoroscopy. Subsequently locking stylets (EZ Stylet) were placed into each lead's lumen and activated. Of note, the atrial lead lumen was not intact and stylet was only passed 8 cm into the lead. After gentle traction, the leads did not appear to move from their positions in the heart. Sutures were placed around the leads and around the pectoralis muscle.

A 9-Fr and then an 11-Fr Philips' Tightrail Sub-C mechanical rotating dilator sheath were placed over EZ stylet/lead to remove the ventricular lead first with gentle traction. Rotating cut was performed at the level of mid-SVC. Philips' Tightrail Sub-C mechanical rotating dilator sheath was then placed over EZ stylet/lead to remove the atrial lead with gentle traction. Unfortunately, lead insulation broke off and a new suture and Bulldog sheath attachment were placed. Tightrail Sub-C 11-Fr catheter was used over the EZ/Bulldog/suture system and rotating cut was performed into the subclavian vein and the atrial lead was removed with all of its components. Both leads were noted to be fractured.

After leads were removed, original suture ties were tightened and pressure held to suppress bleeding. The device pocket was then closed via 2.0, 3.0, and 4.0 Vicryl and Monocryl sutures with Steri-strips and Dermabond on the edges of the Steri strips.

After extraction, transthoracic echocardiogram showed no effusion, no tricuspid regurgitation, and no SVC tear.

The RFV 2-Fr sheath (Bridge balloon) was upsized sequentially via 14-Fr, 16-Fr, 18-Fr, 20-Fr, 22-Fr, and 24-Fr dilators. A 27-Fr (outer diameter) Abbott Aveir sheath (after flushing) was passed over wire into the mid-right atrium. The inner sheath was removed and the outer sheath was connected to heparinized saline and passed into the distal IVC.

The Aveir VR on deployment catheter (23-Fr) was passed through the 27-Fr outer sheath. Interrogation/communication was established with the device. The Catheter/Aveir were moved across the tricuspid valve into a mid-RV septal position. Angiograms revealed good placement after injection of contrast. Deployment of the Aveir into the septal location was successful on the first attempt, with a good threshold of 1V@0.4 ms, R-wave of 4.5mV, impedance of 450Ω. Stability test noted device in good position still with movement and deflection. The capture tether was removed and the catheter was removed from the sheath.

The Aveir AR on deployment catheter (23-Fr) was passed through the 27-Fr outer sheath. The Catheter/Aveir was moved into the right atrial appendage base. Angiograms revealed good placement when 10mL of contrast was injected. Deployment of the Aveir into the septal location was successful on first attempt with a good threshold of 1V@0.4 ms, P-wave of 1.2mV, impedance of 350Ω. Stability test noted device in good position still with movement and deflection. The capture tether was removed and the catheter was removed from the sheath.

The 27-Fr sheath was removed and a Figure-of-8 stitch was performed. Further pressure was held bilaterally with pressure bandage placed on right femoral venous site.

Post-device implant checking yielded similar numbers as during the procedure, with the Aveir VR showing a threshold of 1V@0.4 ms, R-wave of 8.8mV, impedance of 500Ω, and the Aveir AR showing a threshold of 1V@0.4 ms, P-wave of 1.2mV, impedance of 420Ω. The device was set in DDDR mode, 60-160bpm, SAVD 200 ms, PAVD 200 ms, VIP 150 ms.

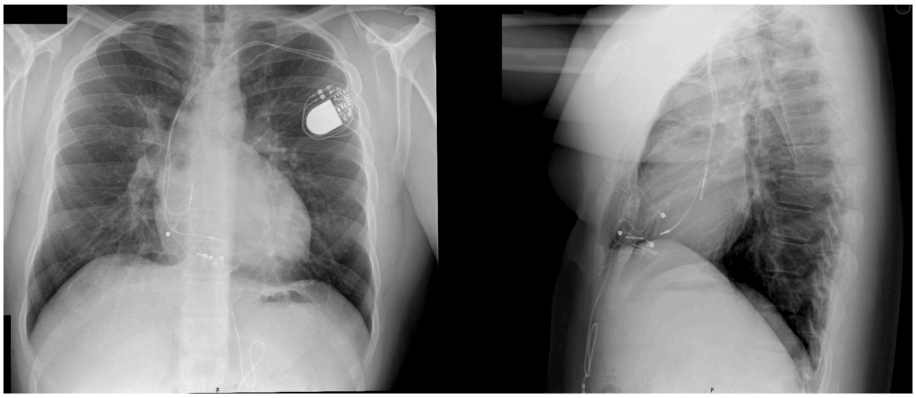

Fig. 1A. 2-view chest Xray of dual chamber transvenous leads.

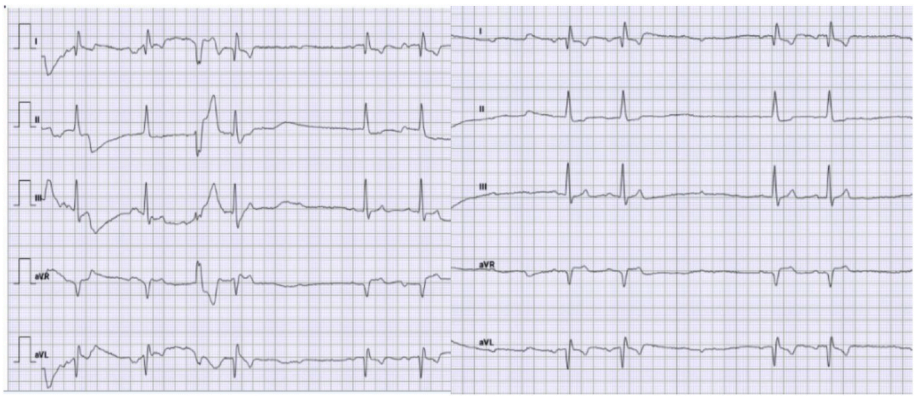

Fig. 1B. Kardia Mobile recording of pauses and lack of capture of device.

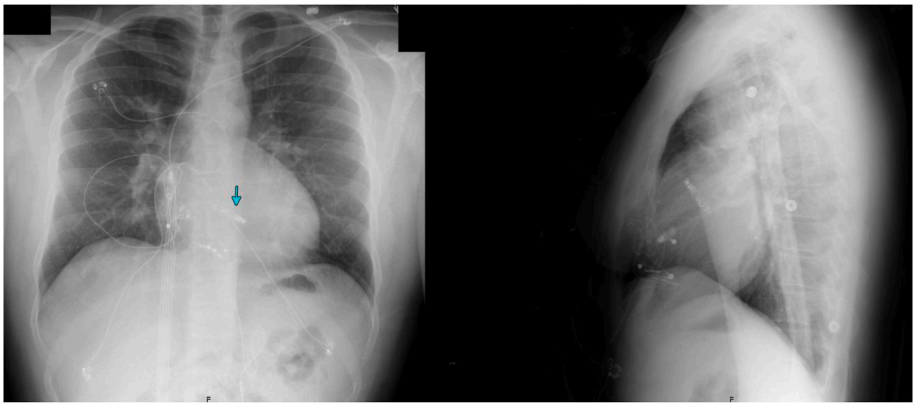

Fig. 1C. 2-view chest Xray after lead extraction and dual leadless pacemaker implant.

Follow up with the patient showed the Aveir VR with a threshold of 1.0V@0.2 ms, output 2.25V@0.2 ms, R-wave of 8.9mV, impedance of 490Ω, and the Aveir AR demonstrated a threshold of 0.75V@0.2 ms, output 2V@0.2 ms, P-wave of 3.7mV, impedance of 400Ω. Atrial battery longevity prediction was at 8.3 years, while ventricular battery was at 11.4 years. Atrial pacing demonstrated a 2 % burden with Ventricular-pacing at an 8 % burden. The device was programmed DDDR, 60-160bpm, SAVD 275 ms, PAVD 275 ms, post-ventricular atrial refractory period (PVARP) at 225 ms VIP at 150 ms.with I:I Atrial to ventricular decreased from 4 to 3 (with 92 % of beats communicated) and ventricular to atrial direction decreased from 7 to 4 (93 % of beats communicated).

4. Discussion

We demonstrated a case of dual-chamber Aveir leadless pacemaker implantation in an adult patient with transposition of the great arteries and ventricular septal defect post-repair who underwent dual chamber leadless pacemaker placement.

In the past, leadless pacemakers were limited from their lack of atrial pacing [8]. Dual chamber leadless pacemakers now offer that option, and have increased the types of patients who can use leadless pacemakers, as well as improve metrics such as AV synchrony.

The safety and efficacy of dual chamber leadless pacemakers has been demonstrated in a variety of patients who were indicated for dual-chamber pacing [8,10]. However, the safety of this form of the implant had yet to have been demonstrated in adult patients with congenital heart disease. Otherwise, regarding retrieval, atrial leadless retrieval has only been demonstrated in an ovine model (9/9 retrieved without complication), it is yet to be seen chronically in humans, thus this is an important consideration when discussion dual chamber leadless as an option for younger patients [11].

5. Conclusion

Implantation of dual-chamber Aveir leadless pacemaker can be achieved in adult patients with congenital heart disease without complication. Further data is needed to assess the long-term safety of this treatment.

Ethical statement

Dr. Raja J. Selvaraj, Editor-in-chief of the Indian Pacing and Electrophysiology Journal.

We thank you for your time in reviewing our submission and for the opportunity to revise the manuscript, entitled, “Retrievable dual-chamber leadless pacemaker (Aveir DR) in adult patient with congenital heart disease.”

All authors mentioned in the manuscript have agreed on authorship, have read and approved the manuscript, and given consent for submission and subsequent publication of the manuscript. Figures are original. Conflicts of interest: Dr. Cortez provides consultant work for Abbott (Chicago, USA) regarding education of other physicians. However, no funding was provided in creation of this study and manuscript.

Declaration of competing interest

“Retrievable dual-chamber leadless pacemaker (Aveir DR) in adult patient with congenital heart disease”.

Dr. Cortez provides consultant work for Abbott (Chicago, USA) regarding education of other physicians. However, no funding was provided in creation of this study and manuscript. However, no funding

was provided for the creation of any part of this manuscript.

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