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Retrievable leadless pacemakers (Aveir VR) may be beneficial in adult patients with congenital heart disease

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A B S T R A C T

Introduction: Congenital heart disease may present in up to 1.6 % of newborns. Given high burden of pacing need in adult patients with repaired congenital heart disease and availability of different pacing options, more information on outcomes of newer pacemaker types are needed. Retrievable leadless pacemaker implants in adult congenital patients have not been described.
Methods: Retrospective review of three Aveir (Abbott) retrievable leadless pacemaker implants were reviewed at the UC Davis Medical Center. All patients underwent implant via femoral access.
Results: All patients had one deployment only, after mapping prior. No complications occurred. Implant thresholds were 0.5 V (V) @0.2msilliseconds (ms) for patients 1 and 2 and 1 V @0.4 ms for patient 3. With impedances between 500 and 1290 Ω. Sensing was 5.5–8 mV (mV). Follow-up occurred up to one year (for two patients) with similar values overall. The predicted longevities of each device were between 22.6 and >25 years.
Conclusion: Safety and short-mid-term parameters of retrievable leadless pacemaker implantation is reported in three patients with adult congenital heart disease.

1. Introduction

Congenital heart disease may present in up to 1.6 % of newborns [1]. Due to advances in medical and surgical treatment, mortality in patients with congenital heart disease has shifted from childhood to adulthood for several types of congenital heart disease [2]. Patients with congenital heart disease are at risk for pacing need due to sinus node dysfunction or early, as well as late, atrioventricular block [3,4]. Atrial and ventricular pacing may be needed due to atriotomy scars or atrial arrhythmia ablations with subsequent sinus node dysfunction or due to prior ventricular septal defect repair or altered His-purkinje anatomy due to their underlying defect [3,4]. Traditionally, transvenous pacemaker placement has been the standard mode of treatment for these patients, however some patients with Grown-up Congenital Heart Disease GUCH have anatomical barriers that obscure this mode of treatment. For example, some patients have occlusions in their venous system due to prior procedures, and some have complicated venous anatomy [5] (see Table 1).

Leadless pacemakers may offer a feasible solution to patients with complex anatomy and other contra-indications to transvenous pacemakers [6]. Risk factors associated with transvenous pacemakers include pocket infections, lead dislodgement, cardiac perforation, and pneumothorax. Long term risks include venous obstruction and tricuspid regurgitation among others [6]. A major advantage of leadless pacemakers is the elimination of majority of these short term and long-term complications.

Ninety percent smaller than a transvenous pacemaker, leadless pacemakers can be implanted into the myocardium of the right ventricle directly [7]. Two examples of leadless pacemakers currently in use include the Micra leadless pacemaker (Minneapolis, USA) and the Aveir VR and DR dual chamber pacing system (Abbott, Chicago, USA), and the latter can be implanted in the right atrium or ventricle, has a retrieval success rate of 88 %, and an efficacious procedure rate of over 98 % in a study with 300 participants [8]. Along with reducing the risk of complications, retrievable leadless pacemakers have a battery longevity closer to 16 years based on most recent Aveir VR performance, which is longer than the 8–10 years' average battery life of a transvenous pacemaker [9].

We demonstrate the first retrievable leadless pacemaker implantations in patients with adult congenital heart disease with short to mid-term outcomes up to one-year post-implant.

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Table 1
Demographics, implant and follow-up parameters for patients 1–3.

	Patient 1	Patient 2	Patient 3
Age at implant (years)	27	50	36
Gender	Male	Male	Female
Congenital heart disease	tetralogy of Fallot with RV to PA conduit 7 years prior, bi-fascicular block,	VSD repair at 2 years of age via ventriculotomy,	interrupted aortic arch type B, s/p repair 10 years prior
Indication	Symptomatic high grade AV block with baseline bifasicular block	Sinus pauses of 10 s and bi-fascicular block, high grade AV block	bi-fascicular block with intermittent, symptomatic high grade AV block
Implant values			
Threshold	0.5V@0.2ms	0.5V@0.2ms	1V@0.4ms
Impedance	760 Ω	500 Ω	1290 Ω
Sensing	5.5 mV	8 mV	6.5 mV
Deployments	1	1	1
Follow-up (months)	3	12	12
Follow-up values			
Threshold	0.5V@0.2ms	0.5V@0.2ms	0.75V@0.2ms
Impedance	600 Ω	560 Ω	640 Ω
Sensing	5 mV	8.5 mV	17.5 mV
Pacing (%)	<1 %	12 %	1 %
Predicted longevity (years)	22.7	>25	22.6
Programmed	VVI 50	VVI 40	VVI 50

AV = atrioventricular, mV = milliVolts, ms = milliseconds, V=Volts.

2. Methods

The study was performed as a retrospective review of patients over 18 years of age with congenital heart disease who met class I indication for pacemaker placement by the American Heart Association's recent Guidelines and needed intermittent pacing only [5]. The study was approved by the Internal Review Board of the University of California at Davis, with retrospective review noted.

3. Procedure

For all patients, femoral venous access was obtained utilizing the Seldinger technique with subsequent A super stiff Amplatz 180 cm 0.035 cm wire was passed through the 8-Fr sheath and consecutive up-sizing via a 2-French size increase to 24-French dilator and subsequently the 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 then connected to heparinized saline.

Subsequently the Aveir, on deployment catheter (23-Fr), was passed through the 27-Fr outer sheath. The sheath was removed to the junction of the inferior vena cava and right atrium. The Catheter/Aveir were moved across the tricuspid valve into a mid-RV septal position. Angiograms were used with contrast, and for every case deployment of the Aveir into the septal location was successful on first attempt after mapping thresholds, impedances and sensing taken prior to deployment, thus typical implant values can be assessed prior to coiling the device into the myocardium (Fig. 1). For each patient, a Figure of 8 stitch was placed.

4. Case descriptions

Three patients underwent placement of a retrievable leadless pacemaker with age ranges 27–50 years. Patients 1 and 2 had ablation procedures prior with retrievable leadless placement during the same procedure, while patient 3 had the leadless pacemaker placement only. Patients 1 and 2 were male, while patient 3 was female. Indications for

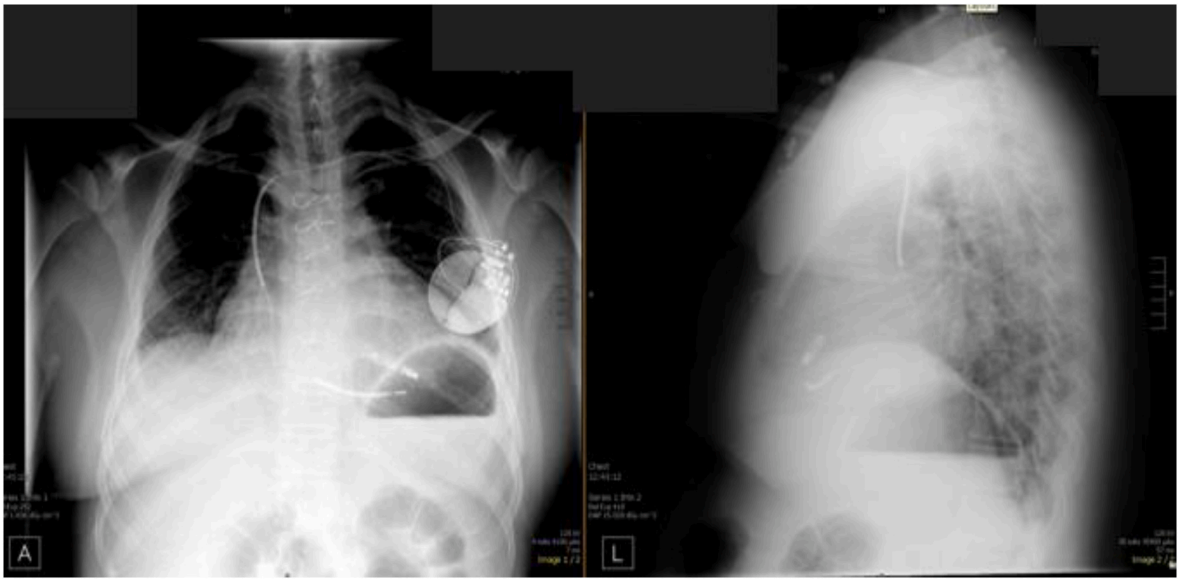

Fig. 1. Posterior-anterior (PA, left) and left lateral (right) views of the Aveir leadless pacemaker in patient 1.

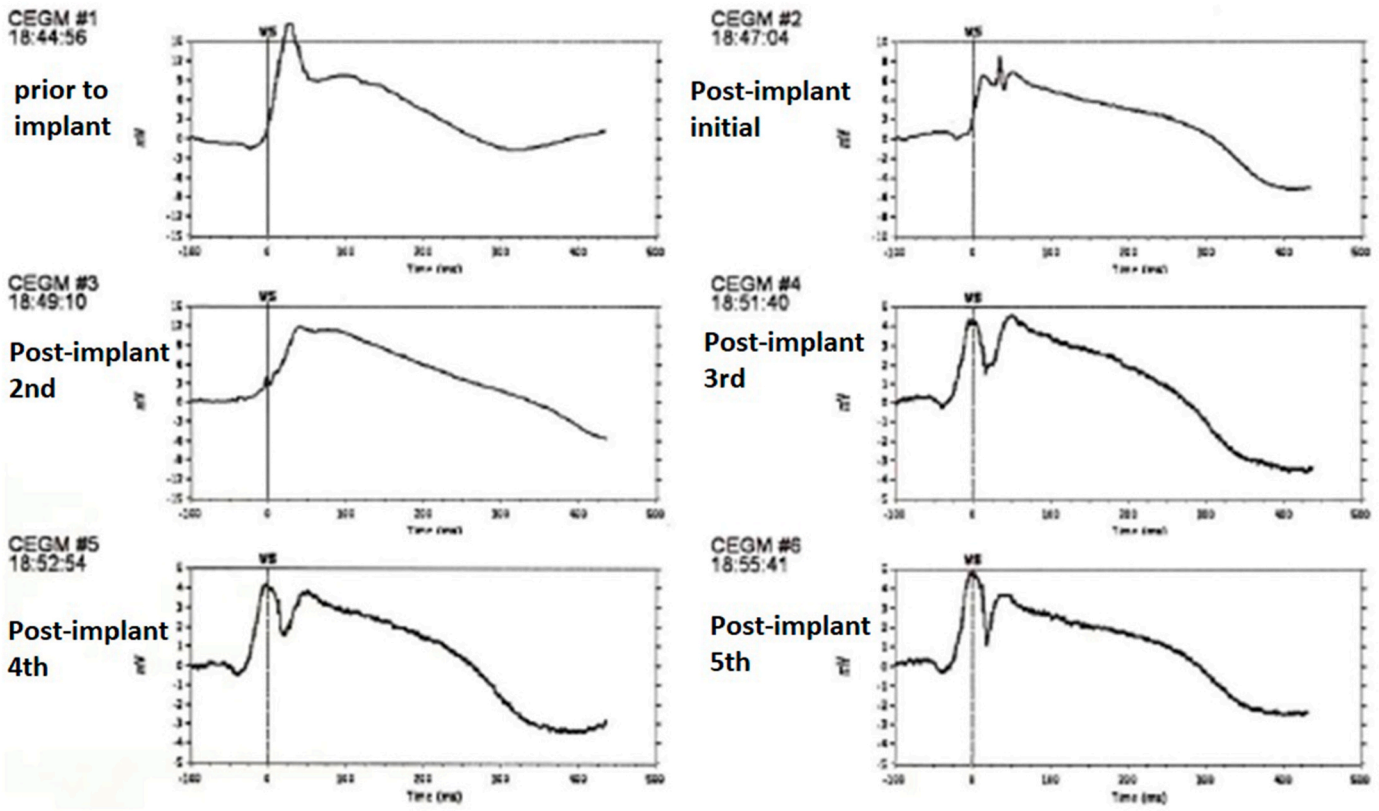

Fig. 2. Electrical injury and ECG of the R-wave in patient 3 prior to implant and post-implant.

placement in all patients included high grade AV block in the setting of bi-fascicular block at baseline or established pacing need in patient 1 (had prior ICD). Congenital heart disease included tetralogy of Fallot, ventricular septal defect via ventriculotomy and interrupted aortic arch with large Dacron graft. All patients were given options of transvenous, epicardial and leadless, given low likelihood of high ventricular pacing burden. Also given ability to upgrade to dual chamber leadless system, Aveir ventricular pacemaker was given as an option.

All patients had one deployment only, after mapping prior. No complications occurred. In patients 1 and 2 numerous locations were mapped prior to deployment. Implant thresholds were 0.5 V (V) @0.2msilliseconds (ms) for patients 1 and 2 and 1 V @0.4 ms for patient 3. With impedances between 500 and 1290 Ω. Sensing was 5.5–8 mV (mV). Fig. 2 shows pre-implant to post-implant injury on patient 3. The electrocardiogram of the pre-operative and post-operative/paced QRS complex is demonstratedin Fig. 3. While fluoroscopic steps to deployment of the Aveir in patient 3 are demonstrated in Fig. 4.

Follow-up range was 3 months–12 months. Follow-up thresholds were 0.5V@0.2ms for patients 1 and 2 and 0.75V@0.4ms for patient 3. Follow-up impedances were 560–6400 Ω with sensing of 5.0 mV–9.5 mV in patients 1 and 2, and 17.5 mV in patient 3. Pacing was 1 % for patients 1 and 3 and pacing was needed 12 % of the time for patient 2. Predicted longevity was 22.6 to >25 years at least follow-up. Patient 1 had tetralogy of Fallot and syncope and thus was discussed as a need for pacing versus ICD based on EP study. Patient 2 had atrial flutter which was ablated prior to implant, and he had a loop recorder implant in place which has not shown any further flutter since his ablation.

5. Discussion

There were several important findings from our study of leadless pacemaker placements in adults with GUCH. Each patient in our study had unique congenital anatomies, and some were corrected with surgical procedures. One patient had Tetralogy of Fallot with bi-fascicular block, one had a repaired ventricular septal defect, and one patient had a repaired interrupted aortic arch type B with bi-fascicular block. Although deployment of the Micra pacemaker in patients with complex anatomies proves difficult in other studies, our study demonstrates one successful deployment needed only in patients with various CHDs without any complications [10]. Predicted longevities of the devices were over 20 years, but likely due to lower pacing need.

All the deployed pacemakers had a threshold less than 1.5 V with a pulse width of less than 0.5 ms, which is in the acceptable range [11]. Sensing for each pacemaker was also in the adequate range of 5–25 mV. In addition, each pacemaker in our study had a predicted longevity of over 22 years at last follow-up.

Micra pacemakers used in other case reports described the added challenges of pacemaker dependency, complete blocking of the superior vena cava, bilateral venous access block, and an unsuccessful epicardial pacing system [12]. One study described the necessity for using an electroanatomical mapping system such as CARTO, for the successful deployment of Micra in an adult GUCH patient with complex anatomical barriers such as an unrepaired sinus venosus atrial septal defect [13]. Many CHD patients unsuitable for epicardial pacemaker implantation, such as those with single ventricle physiology, can also benefit from the use of leadless pacemakers such as Micra. However, limited previous reports on the safety and efficacy of leadless pacemakers in patients, especially with a single ventricle, limit its widespread use [14].

The Aveir (retrievable) leadless pacemaker might be preferred in patients with congenital heart defects due to the mapping ability prior to implant. For instance, lower voltage substrates with poor pacing capture thresholds can be checked prior to implant, thus less re-captures are needed. Furthermore, in this patient population where intermittent complete heart block may progress, the ability to add an atrial Aveir

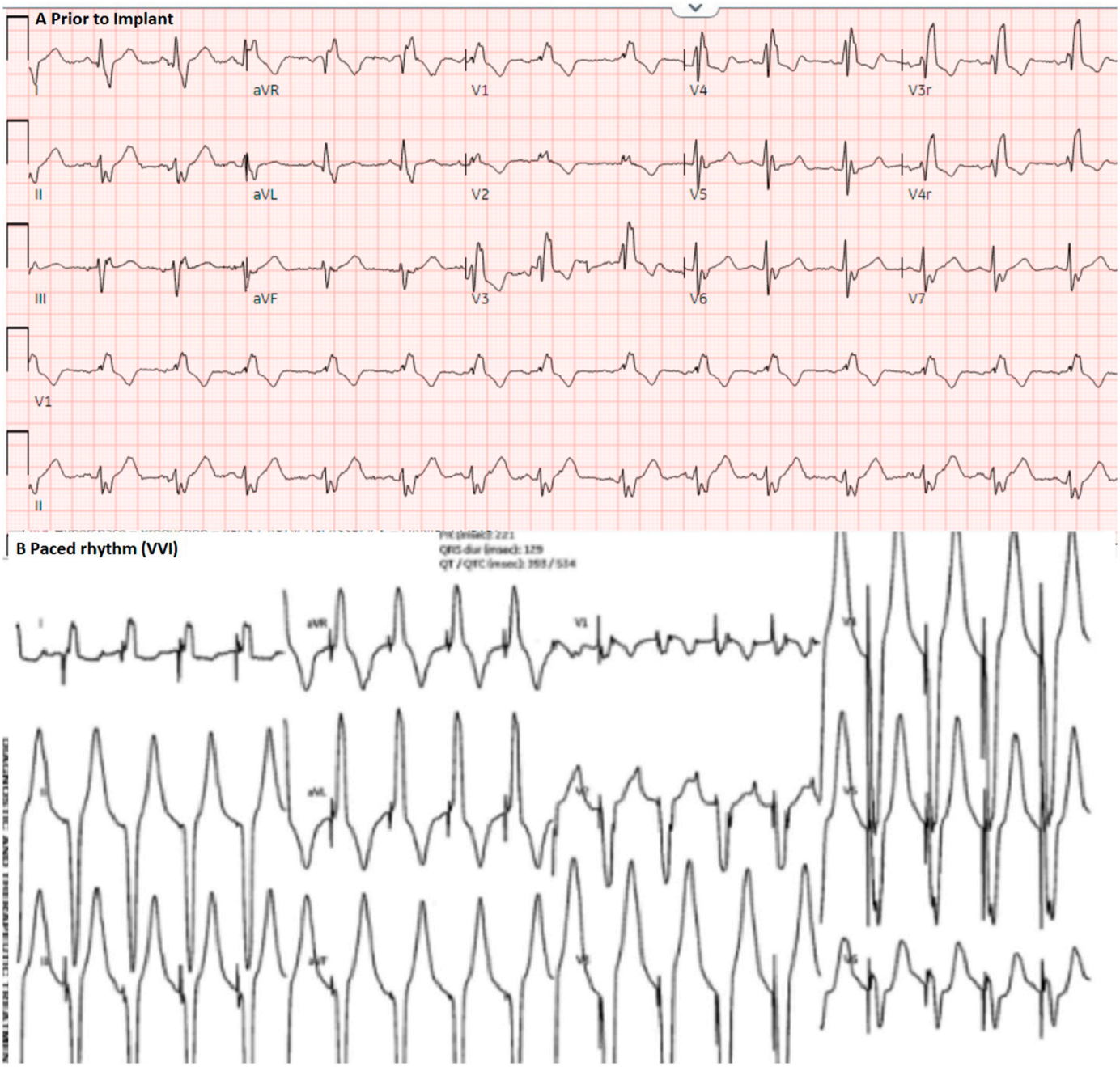

Fig. 3. A (top): Baseline electrocardiogram with bifascicular block and B (bottom): subsequent paced EKG during procedure to demonstrate paced morphology.

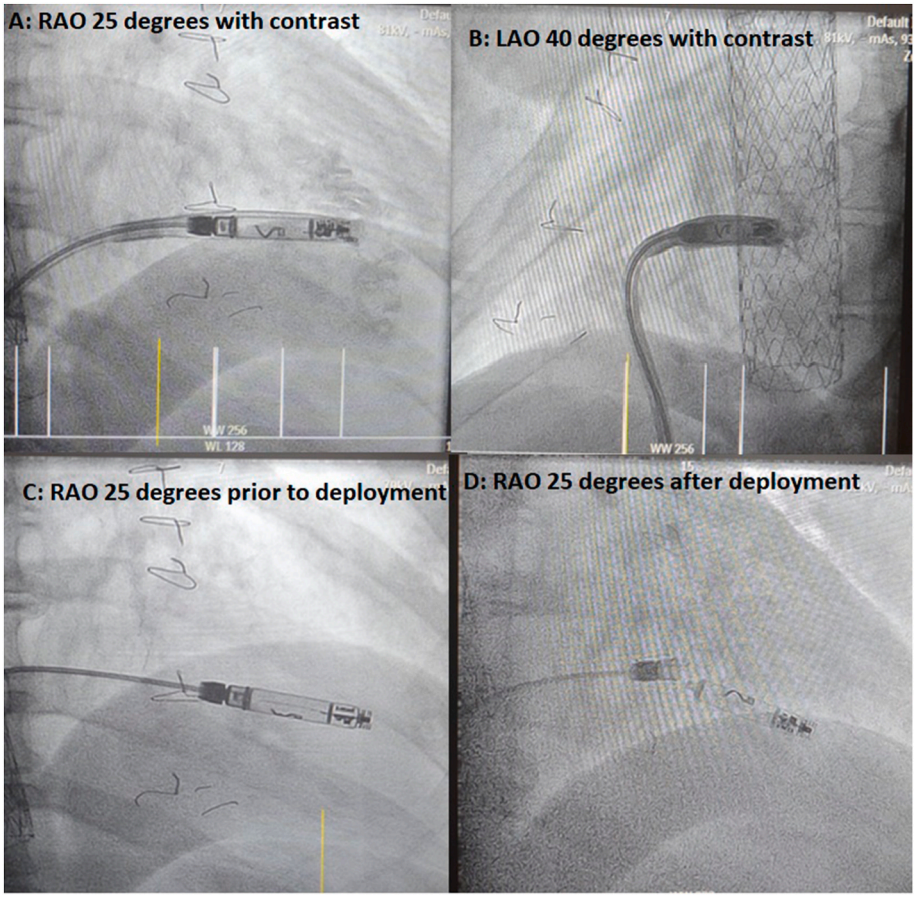

Fig. 4. A: catheter positioning in RAO 25° with contrast, B: LAO 40° with contrast, C: RAO 25° prior to deployment (sheath retracted), C: RAO 25° after deployment.

(now FDA approved) may be of importance for future dual chamber pacing needs (upgradability). Additionally, extraction of a coil-based predecessor of the Aveir leadless pacemaker has been successfully demonstrated up to 9 years post-implant [15].

Another potential complication of the use of leadless pacemakers is cardiac perforation resulting from erosion [14]. As described in the two-year follow up of the Micra CED study, the risk of pericardial effusions was greater in association with leadless VVI pacemaker implants as compared to the transvenous pacemaker group [15]. The rates of pericarditis were also higher in those patients who received a leadless pacemaker. Although less than the transvenous pacemaker group, patients with the leadless pacemaker also experienced hemothorax as a complication [14].

6. Conclusion

The use of the Aveir leadless pacemaker in adults with CHD proved beneficial without any major complications. The successful use of the Aveir retrievable leadless pacemaker in patients with complex anatomical barriers, including long-term retrievability may be a helpful adjunct when considering pacing alternatives in adults with congenital heart disease.

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Declaration of competing interest

No competing interests exist between authors and submitted material.

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