

Single-chamber leadless pacemaker Aveir VR implantation: Pioneer experience in Poland. Insights and preliminary report from a multicenter national registry

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DOI: 10.33963/v.phj.101020

Received:
March 28, 2023

Accepted:
June 04, 2024

Early publication date:
June 7, 2024

INTRODUCTION

Conventional pacemakers (PMs) consist of a surgically implanted pulse generator connected with transvenous leads. Notwithstanding high effectiveness, technological advances, and knowledge about optimal implantation routines, conventional PMs are strongly and continually affected by lead- and pocket-related complications [1]. Leadless pacemakers (LPM) are designed to prevent the abovementioned complications of transvenous PMs [2, 3].

The Aveir VR (Abbott, Sylmar, CA, US) pacemaker was approved by the Food and Drug Administration in April 2022 [4]. The Aveir VR LP is 38 mm long, weighs less than 3 grams, and is delivered by a 25-French inner (27 French outer) diameter sheath. It utilizes an active fixation mechanism, which allows for mapping R wave sensing, impedance, and initial pacing capture threshold before fixation, which facilitates early identification of the need for repositioning and prevents complications [5].

The first implantation of LPM Aveir in Poland was performed on September 20, 2023. Moreover, reimbursement for LPMs has recently been introduced in Poland, which leads to the belief that the number of LPM implantations will increase. In this study, we aimed to evaluate the initial experiences of nearly thirty procedures, particularly, the safety and success rates of Aveir VR implantations.

METHODS

We evaluated the LPM single-chamber system (Aveir VR, Abbott Medical) in a retrospective, national, multicenter, investigator-driven registry. All consecutive patients who underwent LPM Aveir implantation were enrolled in the registry. No sponsorship from the industry was involved. The implantation technique was standard [5]. The procedures were performed *via* the right femoral vein using local anesthesia. The implantation target was the interventricular septum. Once a position with good electrical measurements was achieved, the device was fixated to the myocardium by

slow clockwise rotation of the delivery catheter grip with 1–1.25 clockwise rotations as evaluated by the radiopaque chevron marker on the device's body. A post-procedural threshold $<2\text{ V}$ at 0.4 ms was considered optimal. A decision to reposition was at the implanter's discretion, after considering the electrical measurement and fixation security demonstrated in the deflection test. After the device was released, assessment of electrical parameters was repeated. The study was approved by an appropriate institutional review board and ethics committee.

Statistical analysis

The categorical variables were presented as absolute numbers and percentages. Numerical variables, after assessment for normality with the use of the Shapiro–Wilk test, were presented either as medians and quartiles 1 and 3 for non-normal distribution or means and standard deviations for normally distributed variables. STATISTICA 13 (StatSoft Inc., Tulsa, OK, US) software was used for all calculations, and a two-sided $P < 0.05$ was considered statistically significant.

RESULTS AND DISCUSSION

The study included 28 consecutive patients who underwent Aveir VR implantation procedure at tertiary cardiology centers in Kraków, Poznań, Rzeszów, Warszawa, and Zabrze between September 2023 and February 2023 (Supplementary material, *Figure S1*). The cohort had a median age of 75, and 42.9% were females. The most common indication for pacing was the third-degree atrioventricular block in patients with persistent atrial fibrillation (AF) (64.3%), whereas the main reason for choosing LPM was the high risk of PM infection (35.7%). Analysis of risk-benefits justified the use of LPM in 4 patients (14.3%) with the leading diagnosis of sick sinus syndrome.

The median procedural time was 55 minutes. All procedures were successful, and acceptable electrical parameters were observed with a mean post-procedural threshold of $0.75\text{ V}/0.4\text{ ms}$. No serious adverse events, including device dislodgment, were recorded. One patient experienced a local hematoma and another patient developed a post-procedural arteriovenous fistula treated conservatively. It should be emphasized, that during the Aveir implantation procedure, large bore venous access is needed. Therefore, the operator should be familiar with anatomical variations, equipment requirements, and potential complications and their prevention, including the routine ultrasound guidance used for venous access [6]. Details about baseline characteristics, indications for PM and LPM, procedure findings, and electrical parameters are shown in *Table 1* and Supplementary material, *Figure S2*.

Since the introduction of cardiac PMs, efforts towards their improvement and boosting the efficacy, durability, and safety of pacing therapy have been undertaken. Leadless pacemakers are utterly self-contained devices to pace the endocardium to reduce many short and long-term

Table 1. Baseline clinical and procedural characteristics

Variable	Overall population (n = 28)
Age, years, median (IQR)	75 (70–80)
Female gender, n (%)	12 (42.9)
History of any ablation, n (%)	1 (3.6)
History of TAVI, n (%)	3 (10.7)
Severe tricuspid regurgitation, n (%)	4 (14.3)
LVEF, %, median (IQR)	55 (50–61)
Indications	
Sick sinus syndrome, n (%)	4 (14.3)
AV II° degree/advanced block, n (%)	6 (21.4)
AV III° degree block, n (%)	18 (64.3)
Baseline rhythm	
Sinus rhythm, n (%)	6 (21.4)
Paroxysmal atrial fibrillation, n (%)	2 (7.1)
Persistent atrial fibrillation, n (%)	20 (71.4)
Primary indication for leadless pacing (more than one may have occurred in some patients)	
High risk of CIED infection, n (%)	10 (35.7)
Prior CIED infection, n (%)	9 (32.1)
Vascular access issues, n (%)	2 (7.1)
Chronic kidney disease on dialyses, n (%)	2 (7.1)
Chronic inflammatory state, n (%)	3 (10.7)
Immunosuppressive therapy, n (%)	1 (3.6)
Patient's preference, n (%)	3 (10.7)
Procedural characteristics	
Routine ultrasonography guided approach for venous access, n/n (%)	14/24 (50.0)
Total procedural time, minutes, median (IQR)	55 (40–70)
Total fluoroscopy time, minutes, median (IQR)	12 (8–18)
Total fluoroscopy dose, mGy, median (IQR)	146 (61–231)
Post-procedural impedance, Ohm, median (IQR)	760 (572–928)
Post-procedural sensing, mV, median (IQR)	8.0 (5.5–9.5)
Post-procedural threshold, V/ms, median (IQR)	0.75/0.4 (0.7–0.88)
Threshold higher or equal to $1.0\text{ V}/0.4\text{ ms}$, n (%)	7 (25.0)
Need for device reposition, n (%)	6 (21.4) ^a
Device landing zone in the low-IVS ^c , n (%)	22 (78.6)
Device landing zone in the mid-IVS ^c , n (%)	6 (21.4)
Postprocedural stay (days), median (IQR)	3 (3–7)

^aIn 2 patients, more than one periprocedural reposition was necessary. ^bBased on: [13]. ^cBased on fluoroscopy

Abbreviations: CIED, cardiac implantable electronic device; IQR, interquartile range; IVS, intraventricular septum; LVEF, left ventricular ejection fraction; SD, standard deviation; TAVI, transcatheter aortic valve implantation

complications of transvenous PMs in adequately selected patients. Currently, two LPMs are commercially available: Micra (Medtronic) and Aveir (Abbott).

The first LPM assessed in a clinical study was the Nanostim (St. Jude Medical) in 2013 [7]. However, the device was removed from the market due to the reported technical issues [8]. Therefore, the Nanostim LPM was redesigned and re-named Aveir VR LPM (Abbott). In the LEADLESS-II (phase II) trial encompassing 200 patients, the mean age was 75.6 years, 62.5% of the participants were male, and pacemaker indication was AF with an atrioventricular block (52.5%). The implant success rate was 98%, which is in line with our outcomes [9]. The presented study confirmed the satisfactory feasibility and safety of Aveir VR implantation in a cohort of real-life, all-comer patients, as

reported by Tam et al. [10]. The limitation of the present study is its design: a relatively small and rather “typical” group of patients treated and the peri-procedural device performance studied. The safety and effectiveness of the new leadless pacemaker, its cost-effectiveness [11], and its applications in rare challenging clinical cases [12] warrant further observations.

Supplementary material

Supplementary material is available at https://journals.viamedica.pl/polish_heart_journal.

Article information

Conflict of interest: MS — investigator, proctoring, trainer and lecturer’s fees: Abbott, Biotronik, Hammermed, Medtronic, Zoll, European Union’s Horizon 2020 research and innovation program under grant agreement No 945260 — EHRA-PATHS Project; AP — proctoring fees: Abbott Polska; AO — traveling and lecture fees: Biotronik Polska, Abbott Polska, traveling fees from Medtronic Polska, Hammermed, Philips; JZK — traveling fees from Biotronik Polska, Medtronic Polska, Hammermed, Philips; PM — fees, advisory: Medtronic, Abbott; LCM — fees: Medtronic, Abbott; MM — speaking fees and educational grants: Abbott; MG — speaking fees and educational grants: Abbott; RL — Abbott, Boston Scientific — consultant and lecture fees, European Union’s Horizon 2020 research and innovation program under grant agreement no 847999 — PROFID-EHRA Project; MT — speaking fees and educational grants: Abbott. Other authors none declared.

Funding: None.

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