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

Short title: Leadless pacemaker Aveir VR implantation: pioneer experience in Poland

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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 FDA 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 for R wave sensing, impedance, and initial pacing capture threshold prior to fixation, allowing early identification of the need for repositioning, which can prevent complications [5].

The first implantation of LPM Aveir in Poland was made 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 the present study, we aimed to evaluate the initial experiences of nearly thirty procedures regarding the safety and success rate of Aveir VR implantation.

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 maker on the device's body. A post-procedural threshold <2 V at 0.4 ms was desired. The decision to reposition was at the implanter's discretion, considering the electrical measurement and fixation security demonstrated in the deflection test. After the device was released, the electrical parameters assessment 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, and numerical variables, after assessment for normality with the use of the Shapiro-Wilk test, were presented either with median and quartile 1 and 3 for non-normal distribution or mean and standard deviation for normally distributed variables. The STATISTICA 13 (StatSoft Inc., Tulsa, OK, US) software was used for all calculations, and two-sided P <0.05 was considered as statistically significant.

RESULTS AND DISCUSSIO

The study included 28 consecutive patients who underwent Aveir VR implantation procedure at referral cardiology centers in Kraków, Poznań, Rzeszów, Warszawa and Zabrze between September 2023 and February 2023 (Supplementary material, *Figure S1*). The cohort has 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 LPM choice was the high risk of PM infection (35.7%). The analysis of risk-benefits legitimized 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 successfully performed, and acceptable electrical parameters were observed with mean post-procedural threshold 0.75 V/0.4 ms. No serious adverse events, including device dislodgment, were recorded. In one patient, a local hematoma and another patient, a post-procedural arteriovenous fistula treated conservatively were reported. It should be emphasized, that during the Aveir implantation procedure veonus large bore access is needed. Therefore, the operator should be familiar with the anatomical variations, equipment requirements, and potential complications and their prevention, including the routine ultrasound guidance use for venous access [6]. Details about baseline characteristics, indication for PM and LPM, procedures 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, aiming to reduce many short and long-term 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 2 trial encompassing 200 patients, the mean age was 75.6 years, 62.5% of the participants were male, pacemaker indication was AF with an atrioventricular block (52.5%), and implant success 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-comers patients, as reported by Tam et al. [10]. The limitation of the present study is its design: relatively small and rather "typical" group of patients treated and peri-procedural device performance studied. The safety and effectiveness of the new leadless pacemaker, cost-effectiveness [11] and 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 programme 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 programme under grant agreement no 847999 — PROFID-EHRA Project; MT — speaking fees and educational grants: Abbott. Other authors none declared.

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Table 1. Baseline clinical and procedural characteristics

Variable		**Overall population (n = 28)**
Age, years, median (Q1–Q3)		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 (Q1–Q3)		55 (50–61)
Indications		
	Sick sinus syndrome, n (%)	4 (14.3)
	AV IIº degree/advanced block, n (%)	6 (21.4)
	AV IIIº 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 (Q1–Q3)		55 (40–70)
Total fluoroscopy time, minutes, median (Q1–Q3)		12 (8–18)
Total fluoroscopy dose, mGy, median (Q1–Q3)		146 (61–231)
Post-procedural impedance, Ohm, median (Q1–Q3)		760 (572–928)
Post-procedural sensing, mV, median (Q1–Q3)		8.0 (5.5–9.5)

Post-procedural threshold, V/ms, median (Q1–Q3)	0.75/0.4 (0.7–0.88)
Threshold higher or equal to 1.0 V/0.4 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 (Q1–Q3)	3 (3–7)

[a]In 2 patients, more than one periprocedural reposition was necessary. [b]Based on: [13]. [c]Based on fluoroscopy

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