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Efficacy and Safety of Leadless Pacemaker Implantation in Octogenarians

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Keywords
Leadless pacing · Elderly population · Efficacy · Complication rates

Abstract
Introduction: Long-term complication rates in standard transvenous pacemakers are reported around 4–12% with a higher incidence in the elderly population. We report our experience in octogenarians undergoing leadless pacemaker implantation in two large-volume centers in Switzerland. ***Methods:*** Consecutive patients undergoing leadless pacemaker implantation at two Swiss large volume centers (University Hospital Zurich, Zurich and Cardiocentro Ticino Institute, Lugano) between October 2015 and March 2020 were included in this retrospective analysis. Demographic information, clinical data, and procedural characteristics were recorded at the day of implantation and during follow-up. ***Results:*** Two hundred and twenty patients (mean age 80.6 ± 7.7 years, male 66%) were included. The main indication for pacemaker implantation was slow ventricular rate atrial fibrillation (111 of 220 patients, 50.4%). Out of the 220 patients, 124 (56.3%) were ≥80 years. Overall successful implantation rate was 98.6%. In the octogenarian population, the median procedure time (45 ± 20.2 min vs. 40 ± 19.6 min, $p = 0.03$) and radiation duration (6.1 ± 8.2 min vs. 5.0 ± 7.2 min, $p = 0.03$) were longer compared to patients <80 years. Major complications (2.7%, $n = 6$) and device measurements during follow-up were similar between patients ≥80 and <80 years. ***Conclusion:*** Implantation of a leadless pacemaker device in octogenarians is safe and effective with a similarly low complication rate compared to non-octogenarians.

Introduction

Permanent pacemaker systems represent the standard of treatment for bradyarrhythmias with nearly one million devices implanted each year worldwide [1, 2]. Even though the implantation procedure is a low-risk intervention in experienced hands, complication rates including long-term technical issues related to the transvenous lead are reported in the range of 4–12% with a higher complication risk in the elderly population [3]. This is of great clinical relevance as nearly 80% of pacemakers are implanted in this group

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of patients [4]. To overcome these potentially serious complications, leadless pacemaker devices have been developed which do not require a transvenous electrode. The safety and efficacy of the currently approved leadless pacemaker (Micra transcatheter pacing system [Micra TPS] Medtronic, Minneapolis, MN, USA) [5] have been demonstrated in a non-randomized, prospective study [6] and were confirmed in large retrospective registries [7, 8]. By foregoing the need for a device pocket and insertion of a transvenous lead, the leadless pacemaker system avoids the main source of complications of conventional pacing systems. Indeed, indirectly compared to a historical transvenous pacemaker cohort, the major complication rate of 2.7% 1 year after implantation was significantly lower in the leadless pacemaker compared to the transvenous group (7% major complication rate) [8]. Similar to conventional transvenous lead implantation, low body weight (BMI <20 kg/m^2), female gender, chronic obstructive lung disease, and advanced age (≥85 years) have been identified as risk factors for complications during leadless pacemaker implantation [6, 9]. In addition to advanced age being a risk factor for cardiac complications during implantation, there have been concerns about the use of the Micra TPS device in frail elderly patients due to the size of the insertion tool. However, previous reports have demonstrated that implantation of a leadless pacemaker in advanced age is safe and effective [10–13]. Since the number of elderly patients in need for a pacemaker increases, it is of paramount importance to gain more information on the efficacy and especially safety of Micra TPS implantation in this population. In this retrospective analysis, we report our experience in older patients undergoing Micra TPS implantation from two experienced centers in Switzerland.

Materials and Methods

Study Population

Consecutive patients undergoing Micra TPS implantation at two centers in Switzerland (University Hospital Zurich, Zurich and Cardiocentro Ticino Institute, Lugano) between October 2015 and March 2020 providing informed consent were included in this retrospective analysis. Demographic and clinical data, procedure characteristics including success and complication rates were recorded at the day of implantation and the day after, as well as during follow-up. A subset of patients from this cohort comparing left- versus right-sided Micra TPS pacemaker implantation has been previously published by our group [14].

Leadless Pacemaker Implantation

The Micra TPS pacemaker is implanted according to the manufacturer's recommendation and as previously described [7]. Briefly, after gaining femoral venous access, a super stiff wire is advanced into the superior vena cava. After pre-dilatation of the access site, the Micra TPS introducer sheath is advanced into the right atrium. Through this access, the Micra TPS delivery tool together with the device is advanced into the heart. After crossing the tricuspid valve, the device is placed into the septal wall of the right ventricle. Once adequate fixation of the device tines is confirmed by the "pull-and-hold" test, electrical parameters are tested. If these are within the acceptable limit, the tether is cut and slowly pulled out. Vascular closure was performed by modified Z-suture or use of a Perclose ProGlide™ (Abbott Vascular Devices, Redwood City, CA, USA) system as preferred by the operator. All patients were immobilized for ≥5 h after implantation and hospitalized for ≥1 night after leadless pacemaker implantation.

Definition of Implantation Complications

Major complications were defined according to previous publications and included death within 30 days as a result of device implantation, permanent loss of device function, pericardial effusion (with or without need of interventional or surgical treatment), device-revision within 30 days, infection, device dislodgement, severe damage to tricuspid valve, and relevant femoral vessel injury or hematoma requiring intervention [6, 7].

Statistical Analysis

Demographics, procedural characteristics, and outcome data were extracted from electronic medical records. Differences in interpretation were solved by consensus. Statistical analysis was performed using JMP Pro 10 (SAS Institute Inc., Cary, NC, USA, 1989–2019). Categorical data are expressed as counts and percentages and analyzed using the χ^2 test, and continuous data as means and standard deviations and analyzed using the ANOVA test. A two-tailed p value <0.05 was considered statistically significant.

Results

Study Population and Baseline Characteristics

Descriptive statistics of the study population are provided in Table 1. Two hundred and twenty patients were included in this analysis. The mean age at implantation was 80.6 ± 7.7 years and 66% of the population was male. Underlying heart disease was coronary artery disease in 36% of patients. Average left ventricular ejection fraction was 55 ± 10%. Atrial fibrillation was present in 174 patients (79.5%), of which 172 (98.2%) were orally anticoagulated. The main indications for pacemaker implantation were slow ventricular rate atrial fibrillation and atrial fibrillation with complete AV block (111 of 220 patients, 50.4%). Out of the 220 patients, 124 were ≥80 years (56.3%). Except for the presence of coronary artery disease (41.4% vs. 28.1%, $p = 0.03$) as well atrial fibrillation with complete AV block (15.3% vs. 7.3%,

Table 1. Baseline characteristics of the patient population

Characteristics	All patients (n = 220)	Non-octogenarians (n = 96)	Octogenarians (n = 124)	p value
Age, average±SD, years	80.6±7.7	74.2±6.6	85.5±4.2	**0.0001**
Male, n (%)	145 (66)	60 (41.4)	85 (58.6)	**0.0001**
LVEF, average±SD, %	55.4±10.4	55.9±10.6	55.0±24.9	0.51
Comorbidities, n (%)				
Coronary artery disease	78 (35.5)	27 (28.1)	51 (41.4)	**0.03**
Valvular disease	57 (25.9)	22 (22.9)	35 (28.2)	0.3
Chronic renal failure	117 (53.2)	44 (45.8)	73 (58.9)	0.09
Peripheral artery disease	33 (15.0)	12 (12.5)	21 (16.9)	0.2
COPD	33 (15.0)	14 (14.6)	19 (15.3)	0.9
Diabetes mellitus	49 (22.3)	19 (19.8)	30 (24.2)	0.7
Stroke	29 (13.2)	13 (13.5)	16 (12.9)	0.8
Cancer	39 (17.7)	21 (21.9)	18 (14.5)	0.3
Atrial fibrillation, n (%)	175 (79.5)	75 (78.1)	100 (80.7)	0.6
Anticoagulation, n (%)	172 (78.2)	75 (78.1)	97 (78.2)	0.98
Pacing indication, n (%)				
Slow AF	85 (38.6)	35 (36.5)	50 (40.3)	0.5
AF and complete AV Block	26 (11.8)	7 (7.3)	19 (15.3)	**0.01**
Tachy-Brady syndrome	37 (16.8)	20 (20.8)	17 (13.7)	0.5
Post-conversion pause	11 (5.0)	4 (4.2)	7 (5.6)	0.3
Sinus node dysfunction	13 (5.9)	6 (6.3)	7 (5.6)	0.8
SR with complete AV Block	30 (13.6)	14 (14.6)	16 (12.9)	0.6
Others	18 (8.2)	10 (10.4)	8 (6.5)	0.57

Other causes (left bundle branch block post TAVI; cardioinhibitory response; syncope prevention with bradycardia, right bundle branch block, and left anterior hemiblock). AV, atrioventricular; COPD, chronic obstructive pulmonary disease.

Table 2. Implantation characteristics

Characteristics	All patients (n = 220)	Non-octogenarians (n = 96)	Octogenarians (n = 124)	p value
Capture threshold, V/0.24 ms, mean±SD	0.58±0.33	0.53±0.26	0.60±0.36	**0.04**
Sensing, mV, mean±SD	10.63±4.84	10.65±4.85	10.62±4.86	0.9
Impedance, Ohm, mean±SD	733±170	754±173.2	716±167.0	0.1
Procedure time, min, median (range)	42 (131)	40 (121)	45 (130)	**0.03**
Fluoroscopy time, min, median (range)	6.1 (62)	5.0 (62)	6.1 (57)	**0.03**

Data are presented as mean value ± standard deviation (SD) or median value (range).

p = 0.01, Table 1), which were more prevalent in octogenarians, there were no statistically significant differences between both groups.

Procedural Characteristics

All device implantations were performed in an electrophysiology catheter laboratory using fluoroscopy. Average implantation duration was 49.2 ± 20.1 min with a successful implantation rate of 98.6%. In 3 patients, the implantation was not successful due to tortuous anatomy in 2 patients, and unacceptable device parameters even after multiple repositioning during implantation in the third patient. Average sensing was 10.6 ± 4.8 mV with an impedance of 733 ± 170 Ohm and a pacing threshold of 0.58 ± 0.33 V at 0.24 ms (Table 2). Device placement was septal in all patients, and in the majority of patients in the mid-septal area of the right ventricle (58%).

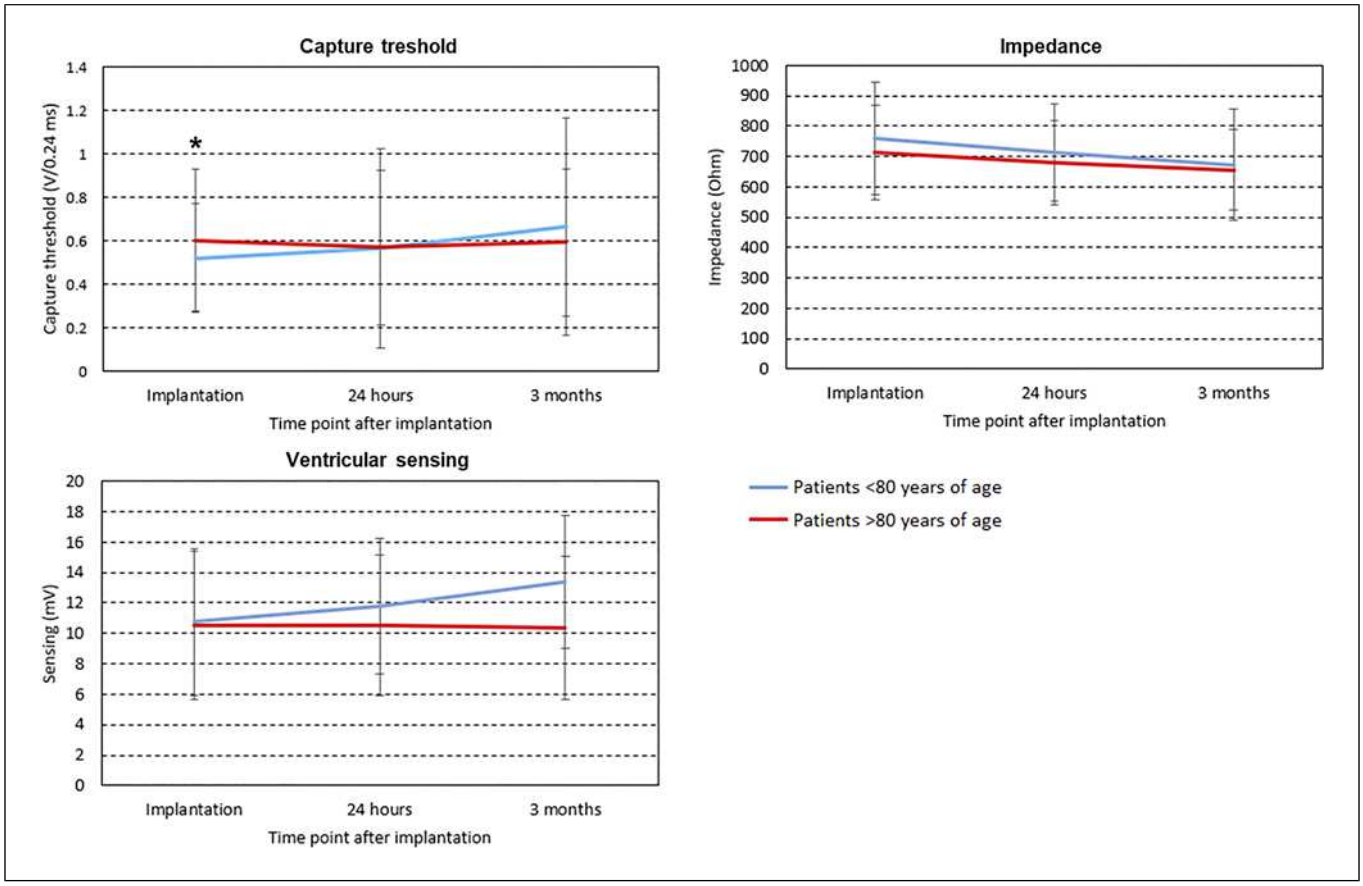

Fig. 1. Development of device parameters over time.

Comparison of Implantation Parameters in Octogenarians versus Non-Octogenarians

In the octogenarian population, the total median procedure time (45 ± 20.2 min vs. 40 ± 19.6 min, p = 0.03) as well as radiation duration (6.1 ± 8.2 min vs. 5.0 ± 7.2 min, p = 0.03) were longer (Table 2). While ventricular sensing and device impedance were similar between the two groups, a clinically not meaningful (but statistically significant) difference in the pacing threshold during implantation was noted in octogenarians versus non-octogenarians (0.60 ± 0.36 vs. 0.53 ± 0.26 V at 0.24 ms, p = 0.04). On the day after implantation these differences were no longer observed and values remained stable up to 3 months after the intervention (Fig. 1).

Peri-Interventional and 30-Day Complication Rate

Periprocedural as well as post-interventional major complications occurred in 2.7% (n = 6, Table 3). Three pericardial effusions were either treated conservatively (n = 1) or with a pericardial drainage (n = 2). None had to undergo cardiac surgery, and all 3 recovered uneventfully. Relevant femoral vessel injury occurred in 3 patients, of which one required interventional covered stenting of an injured femoral artery. The 2 other patients had significant femoral venous bleeding, which could be treated conservatively without further sequelae.

Discussion

The main observations from this study of 220 consecutive patients including 124 octogenarians undergoing a Micra TPS implantation are:

1. Micra TPS implantation in octogenarians is a safe and effective intervention at experienced centers and hands.
2. There are no differences in procedural outcomes between patients older than 80 years as compared to the younger population.

Table 3. Complications during intervention and in the 30-days postoperative period

Characteristics	All patients (n = 220)	Non-octogenarians (n = 96)	Octogenarians (n = 124)
Total major complications	6 (2.7%)	1	5
Pericardial effusion	3	1	2
Femoral bleeding	3	0	3
Minor femoral hematoma	1	0	3
Device dislodgement	0	0	0
Device infection	0	0	0

As the power of the study was $n < 5$ for all complications a p value could not be calculated reliably.

General Comparison between Octogenarians and Non-Octogenarians

The success rate of Micra TPS implantation in the total population was 98.6% which is in line with data from the IDE (99.2%) as well as the post-market registry (PAR) (99.1%) [8]. Furthermore, it is comparable to observational data from other registries focusing on the elderly population which also reported successful implantation rates of >98% [10–13]. However, previous studies on Micra TPS in octogenarians have either included a lower number of patients or focused on the comparison of leadless versus conventional transvenous pacemaker implantation in octogenarians, while our study included a higher number of patients in the octogenarian group and focused on the comparison of clinical outcome of Micra TPS implantation in non-octogenarians versus octogenarians. Therefore, we consider this study clinically relevant suggesting that Micra TPS implantation is as safe and feasible in octogenarians versus non-octogenarians, but the procedure and radiation time may be prolonged. The reason for the longer procedure time in the elderly population in our cohort is not completely known. Potential contributing factors are more complex anatomy of the groin vessels, more tortuous abdominal veins, and a higher number of device implantations after transcutaneous valve interventions. The latter may indeed result in a changed RV geometry and function [15], which could potentially impact the complexity of a Micra TPS implantation. However, despite prolonged implantation duration, device parameters remained stable over time in both groups without a significant difference at 2 weeks follow-up.

Indication for Device Implantation

Nearly 20% of the total population underwent a leadless pacemaker implantation despite the presence of sinus node activity as the underlying, predominant atrial rhythm. This percentage is similar to published data from other groups [6]. Various reasons, such as low expected pacing burden and risk for complications associated with transvenous lead-based devices are common considerations to choose a leadless device system over a conventional device in frail populations [11]. Prior to the introduction of the VDD Micra system ("Micra AV") [16], which offers atrioventricular-synchronized ventricular pacing, there was a concern for pacemaker syndrome in this population of patients with sinus rhythm. None of our patients, however, reported typical symptoms, which is in line with the reported low rate of this phenomenon in only 1 of 1,817 Micra TPS recipients in the updated PAR [8]. This may be in contrast to previously published data in transvenous devices, where up to 20% of patients suffered from pacemaker syndrome [17]. Even though conflicting and differing results have been published regarding the development of pacemaker syndrome, a potential reason for the very low presence of these symptoms could be that the elderly population is physically less active and therefore less likely to perceive symptoms upon exertion. Furthermore, the absence of visual device "markers" such as a scar or physical limitation in daily living due to the presence of the pacemaker box in conventional devices may result in less patient stigmatization regarding their devices [18].

Low Complication Rate of Leadless Pacemaker Implantation

The risk of major complications in our cohort of patients was 2.7%, which is similar with that observed in other large registries (2.9% in the IDE registry [19], 1.9% in the PAR at 30 days) [8] and also with data from registries investigating the outcome in elderly patients (complication rate between 2.3 and 3.3%) [11, 13]. However, there is a learning curve with the implantation of leadless pacemaker, and it has been reported that at

the early stage, the risk for complications during leadless pacemaker implantation may be higher (up to 9.8%) [20]. It needs to be kept in mind that implantation of a leadless pacemaker in the elderly can potentially be more challenging, especially due to anatomical issues. The potentially more fragile and tortuous veinous anatomy may at least partially explain the higher number of femoral bleedings in the octogenarian group in this cohort. Pericardial effusions, of which advanced age is a reported risk factor [6, 8], were rare in our cohort and occurred both in octogenarians and non-octogenarians. None of the patients had to undergo cardiac surgery which is in line with data from the IDE and the post-market analysis [6, 8]. Placement of leadless pacemakers was septal instead of apical in all our patients as previously recommended to reduce the risk of cardiac perforation, which may be even more important in a frail population like octogenarians [7].

Other Endpoints of Interest

There were no device-related infections in our cohort, which is consistent with the combined data from the IDE pivotal study and the PAR [8]. Indeed, reports about infected leadless pacemakers are very rare [21]. Several factors have been described as a reason for the very low infection rate of such devices: the absence of a subcutaneous pocket, a smaller surface area (616 mm^2 vs. 3,500 mm^2 of a transvenous system) of the device, and turbulent blood flow surrounding the Micra TPS device compared to the laminar, slow flow around pacemaker leads in the venous system [22] are likely to be some of the contributing factors. Our data are of great clinical relevance as especially the elderly, frail population with typically lower body weight, a higher burden of infection-related comorbidities such as renal insufficiency and diabetes mellitus, carries a relevant risk for pocket-infections, and may therefore benefit even more from a leadless pacing system.

Furthermore, not only peri- but also post-interventional care is essential to reduce the risk of complications, especially hematoma, infection, and lead dislodgement. Body movement restriction is essential for a favorable wound-healing process, which is often difficult to ensure in frail patients with cognitive dysfunction. Since this is of less importance for the device function in a Micra TPS system, a leadless pacemaker may also offer an advantage over conventional systems from this point of view [10].

Study Limitations

The main limitation of this analysis is its retrospective design as well as the fact that patients were collected from two experienced centers, which may hence not be representative of the situation in other healthcare settings. Additionally, patients were followed up for only 30 days in our centers and by their primary care referring cardiologists thereafter, rendering long-term outcome unavailable.

Summary and Conclusion

The safety and efficacy of leadless pacemaker implantation was similar between patients younger versus older than 80 years of age, supporting the general usability of this type of device also in the elderly population.

Statement of Ethics

The gathering and analysis of all patient data for this paper adheres to the Swiss Ordinance on Human Research with the Exception of Clinical Trials (Human Research Ordinance). This study protocol was reviewed and approved by "Kantonale Ethikkomission Zürich," approval number 2020-00811. Written informed consent and consent for publication was acquired. This study was conducted according to the guidelines for good clinical practice and the Declaration of Helsinki. All patient data were anonymized.

Conflict of Interest Statement

D.H. has received educational grants, speaker fees, or fellowship support from Abbott, Medtronic, Biotronik, Boston Scientific, Biosense Webster, Novartis, Bayer, Pfizer, Spectranetics. F.R. has received speaker fees from Daiichi Sankyo and Medtronic. A.M.S. received educational grants through his institution from Abbott, Bayer Healthcare, Biosense Webster, Biotronik, Boston Scientific, BMS/Pfizer, and Medtronic and speaker fees from Bayer, BMS/Pfizer, and Daiichi Sankyo. V.G. reports stock of Bayer Healthcare and Novartis. J.S. has received consultant and/or speaker fees from Abbott, Alexion, Amgen, AstraZeneca, Bayer, Berlin-Chemie, Biosense Webster, Biotronik, Boehringer-Ingelheim, Boston Scientific, Bristol-Myers Squibb, Daiichi Sankyo, Medscape, Medtronic, Merck/MSD, Novartis, Roche Diagnostics, Pfizer, Saja, Servier, and WebMD. He reports ownership of CorXL. J.S. has received grant support through his institution from Abbott, Bayer Healthcare, Biosense Webster, Biotronik, Boston Scientific, Daiichi Sankyo, and Medtronic. A.A. is a consultant to Boston Scientific, Backbeat, Biosense Webster, Cairdac, Corvia, Microport CRM, EPD-Philips, Radcliffe Publisher. He received speaker fees from Boston Scientific, Medtronic, and Microport. He participates in clinical trials sponsored by Boston Scientific, Medtronic, EPD-Philips. He has intellectual properties with Boston Scientific, Biosense Webster, and Microport CRM. A.B. has received consultant and/or speaker fees from Abbott, Bayer Healthcare, Biosense Webster, Biotronik, Boston Scientific, Bristol-Myers

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Author Contributions

All authors have contributed significantly to the content of this manuscript. All authors agree with the content of the manuscript. D.H. and A.B. were involved in conceptualization, patient inclusion, generating the data, statistical validation, writing the manuscript, critically correcting the manuscript. A.S. and J.S. were involved in patient inclusion, generating the data, and critically correcting the manuscript. G.C., J.J., F.R., M.L.C., V.G., L.G.G., A.G., and A.A. were involved in conceptualization, statistical validation, critically correcting the manuscript.

Data Availability Statement

Upon urgent request and associated need, our data will be available, while our utmost intention is to protect our patient's privacy. Data are not publicly available due to ethical reasons. Further inquiries can be directed to the corresponding author.

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