LEADLESS CARDIAC PACING

# Leadless cardiac pacing in resource-limited settings: A Groote Schuur hospital experience with the Micra leadless pacemaker

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## ABSTRACT

**Background: Cardiac pacemakers improve survival and quality of life in patients with atrioventricular (AV) block. However, conventional pacemakers carry a small risk of both acute and chronic lead and pacemaker generator complications. Leadless pacemakers negate these risks by not having a pacing lead and a subcutaneous generator. We report our Groote Schuur Hospital experience with the Medtronic Micra transcatheter pacing system (TPS).**

**Methods: We report a consecutive case series of patients that received the Micra leadless pacemaker. The Micra transcatheter pacemaker, a single chamber ventricular pacemaker, is inserted using a TPS via the femoral vein into the right ventricle. Implantation data were obtained, and medical records were reviewed for the 6 weeks and 1-year follow-up visits.**

**Results: A total of 5 patients were implanted with a Micra leadless pacemaker from 11 March 2015 - 2 November 2016. Four patients were male and 1 female, with an average age of 64 years. Four patients received the pacemaker for a second- or third-degree AV block and 1 patient received the pacemaker for unexplained syncope and right bundle branch block. The Micra leadless pacemaker was successfully implanted in all patients with no acute implantation-related complications. One-year follow-up was available for 4 patients with good pacing thresholds, sensitivity and impedance. One patient demised after 9 months post Micra implantation due to unrelated causes (acute myeloid leukaemia).**

**Conclusion: The Micra leadless pacing system is safe and effective and shows good short-term results in a real-world, resource-limited setting. This form of pacing offers a viable option for patients who require pacing for AV block, especially in patients with vascular access problems or who are at high risk of lead or pacemaker generator complications.** SAHeart 2020;17:194-199

## BACKGROUND

Cardiac pacemakers have been in clinical practice for more than 60 years. They remain the only treatment for symptomatic life-threatening bradycardias[1,2] and improve quality of life and survival.[3-5] Currently, more than 700 000 pacemakers are implanted around the world annually.[6] The annual incidence of pacemaker implantations is increasing, particularly in older people.[7,8] A conventional cardiac pacemaker consists of a pacemaker generator containing the electronics and battery implanted in a subcutaneous pocket in the pectoral region and one or more leads connecting the generator to the heart (Figure 1a).[9,10] Conventional cardiac pacemakers are associated with a 12.4% risk of acute complications.[11] These are due to pocket hematomas, pocket infections, pneumothorax/haemothorax and many others.[10,11] In experienced hands, the complication rates are as low as 4%.[12] In addition, chronic complications related to transvenous leads like lead infection, lead malfunction, venous thrombosis and obstruction, are not uncommon.[10,11,13] Thus, there is a need for a cardiac pacing system that overcomes the pocket and lead-related complications of conventional cardiac pacing.

The MicraTM (Medtronic USA) Transcatheter Pacing System (TCP) is a 0.8 $cm^3$, 2.0 grams self-contained unit that has the pulse generator, sensing and pacing electrodes fully contained within a single unit.[14] The device is 25.9mm long and has an outer diameter of 6.7mm[14] (Figure 1b). This device is delivered via a catheter through the femoral vein and is directly implanted inside the right ventricle of the heart where it is

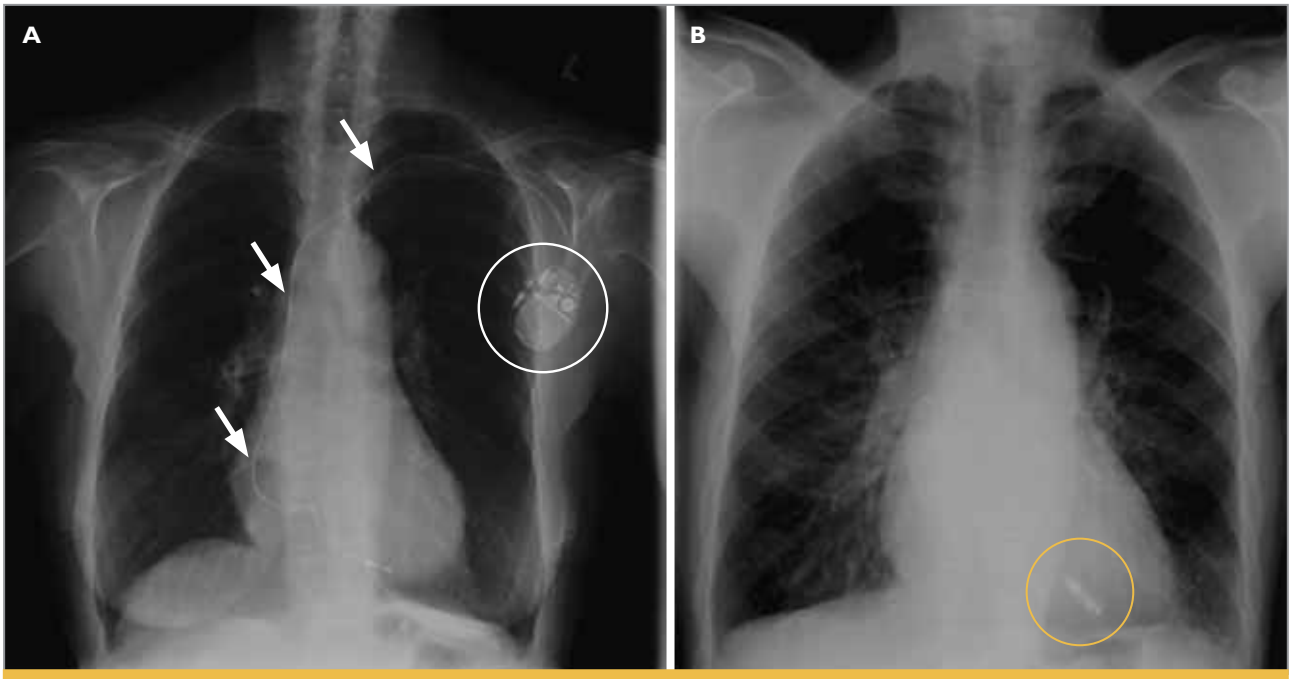


**FIGURE 1:** (A) Chest radiograph of a patient with a conventional pacemaker, white arrows indicates pacemaker lead extending from the generator (white circle) to the right ventricular apex. (B) Chest radiograph of a patient with a MicraTM in the right ventricular apex (yellow circle).

fixed by nitinol tines.[9] The MicraTM was designed to negate the complications related to conventional pacemakers, i.e. pocket and lead-related problems. Prospective studies have shown good safety and performance endpoints of the Micra™ in patients that require permanent pacemaker implantation with very low adverse events. Herein we present a case series of the first MicraTM leadless pacemakers to be implanted in South Africa.

## METHODS

Consecutive patients implanted with a Micra™ from 1 January 2015 - 31 December 2016 were included. All the devices were implanted in the Department of Medicine, Division of Cardiology at Groote Schuur Hospital. The Micra™ was delivered into the right ventricle with a deflectable delivery catheter via a 23 French internal diameter/27 French outer diameter femoral sheath in the right femoral vein (Figure 2a). The sheath is advanced using a guidewire and a dilator into the right atrium.[15] The guidewire and dilator are then removed and a steerable delivery system catheter with the Micra™ preloaded and tethered is then advanced into the right ventricle (Figure 2b).[15] The Micra™ is deployed by retraction of the device containing cup at the distal end of the delivery catheter positioned against the right ventricular endocardium and is fixed into the myocardium by protraction of nitinol tines. Once the device is placed in the right ventricle and adequate fixation is confirmed, sensitivity, pacing thresholds and impedance are measured.[15]

## RESULTS

A total of five patients had the Micra™ implanted. The indications for Micra™ implantation were complete heart block in a patient with previous pocket sepsis, lead malfunction in a patient with superior vena cava obstruction with complete heart block, symptomatic 2:1 atrioventricular (AV) block, symptomatic Mobitz I AV block, and, lastly, a patient with right bundle branch block and first-degree AV block presenting with syncope (Table 1). The Micra™ was successfully implanted in all 5 patients via the right femoral vein. All patients had a 1-year follow-up, except for patient number 4 who died before his 1-year follow-up from Acute Myeloid Leukemia (AML). All the other patients were clinically well at 1-year follow-up post MicraTM implantation.

The ranges of ventricular pacing thresholds at implantation, 6 weeks and 1 year were 0.25 - 0.75V, 0.38 - 0.5V and 0.38 - 0.75V (all with a pulse width of 0.24ms) respectively (Figure 3). The ranges of R wave amplitudes at implantation, 6 weeks and 1 year were 11.4 - 20mV, 4.8 - 20mV and 16 - 18.1mV respectively (Figure 5). The ranges of pacing impedances at implantation, 6 weeks and 1 year were 690 - 970Ω, 530 - 810Ω and 550 - 670Ω respectively (Figure 4).

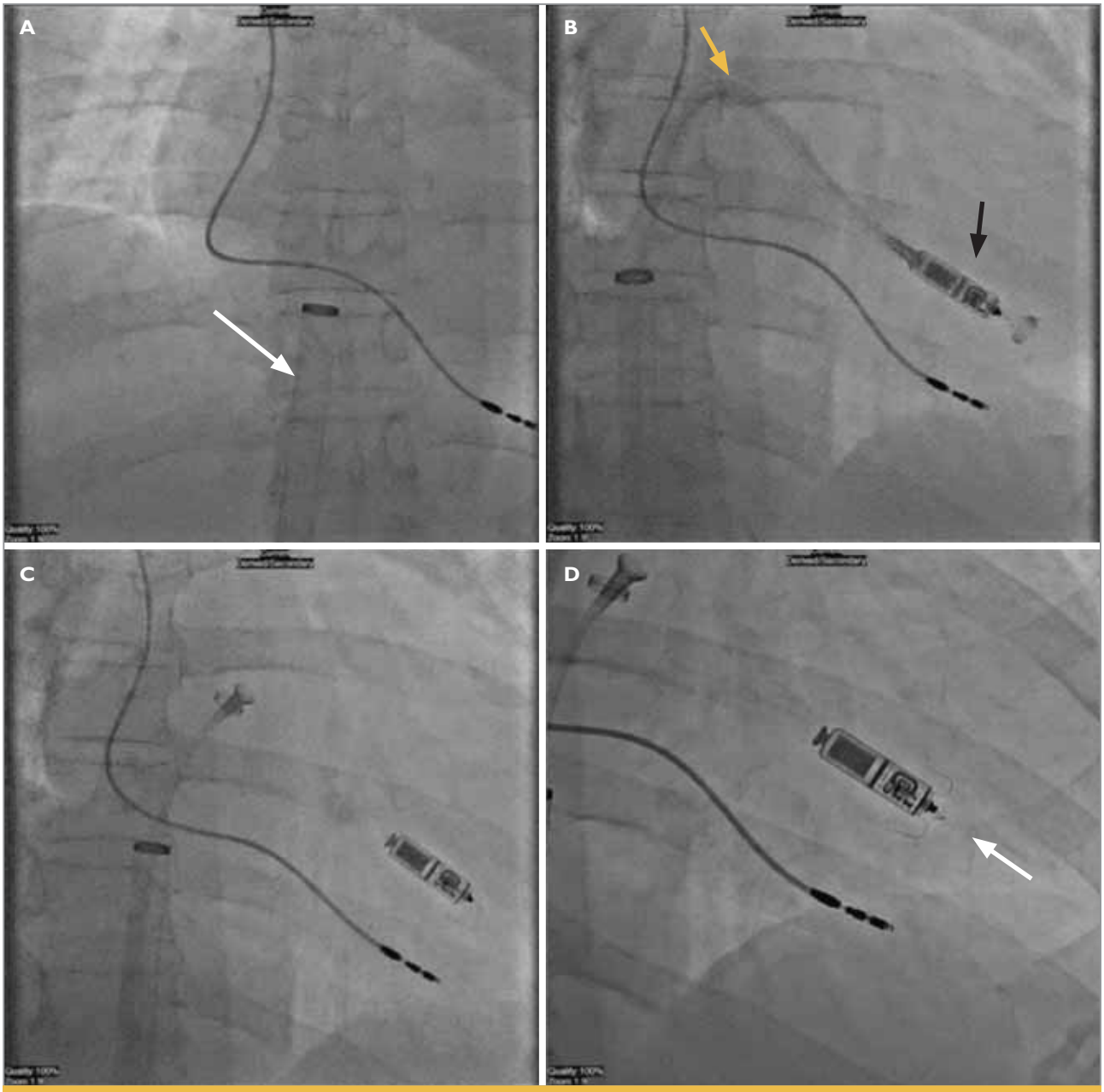


**FIGURE 2:** (A) The white arrow depicts a 27 French outer diameter sheath in the inferior vena cava via the right femoral vein. (B) The yellow arrow depicts a steerable delivery catheter with Micra™ preloaded (black arrow). (C) Micra™ is deployed in the right ventricle apex by retraction of the device containing cup. (D) Micra™ attached to the right ventricular endocardium by nitinol tines (white arrow).

There were no acute or chronic implantation-related complications.

## DISCUSSION

Ever since the first fully implantable cardiac pacemaker was implanted in 1958, the shortcomings of conventional pacing secondary to pocket and lead-related complications have been evident.[16] Investigational work on a miniaturised fully implantable cardiac pacemaker started as early as the 1970s.[17,18] More than 30 years later, leadless and miniaturised cardiac pacing has become clinically available.

Three of the 5 patients included in this series were inserted as part of the Micra transcatheter Pacing study, which was a prospective, non-randomised single-study group multicentre landmark study to evaluate safety and efficacy of this new technology. In brief, 725 patients with a class I or class II indication for cardiac pacing and who were considered suitable for single-chamber ventricular demand (VVI) pacing

**TABLE I: Clinical details and indications for a permanent pacemaker.**

| Patient No | No 1 | No 2 | No 3 | No 4 | No 5 |
|---|---|---|---|---|---|
| Date of Birth | 7 September 1934 | 14 August 1955 | 9 July 1951 | 16 April 1941 | 2 August 1970 |
| Age (years) | 80 | 61 | 64 | 73 | 46 |
| Indication for PPM | RBBB, 1st degree AV block with Syncope | Post AVR CHB | Symptomatic Mobitz I AV block with frequent PVCs | Symptomatic 2:1 AV block | Complete Heart Block |
| Indications for Micra | RBBB, 1st degree AV block with Syncope | Lead Malfunction Obstructed SVS | Symptomatic Mobitz I AV block with frequent PVCs | Symptomatic 2:1 AV block | Multiple Pocket Sepsis |
| Date of Implantation | 11 March 2015 | 18 October 2016 | 11 March 2015 | 11 March 2015 | 2 November 2016 |
| Background Med History | Myasthenia Gravis COPD Systemic HPT | Rheumatic AS AVR in 1984 | Rheumatic MS/AR DVR and CABG 1995 Systemic HPT | Acute Myeloid Leukemia COAD Alcoholic Liver Disease | Nil |
| Chronic Medications | CCB HCTZ Aza | Warfarin Statin | Warfarin CCB ACEi HCTZ Statin | Nil | Nil |
| Last Follow-up | 17 April 2018 | 16 November 2017 | 13 September 2016 | 9 June 2015 | 8 December 2016 |
| **Months since Implantation** | | | | | |
| Patient status | Doing Well | Doing Well | Doing Well | AML for Palliative Care Demised 20/12/2015 | Doing well |

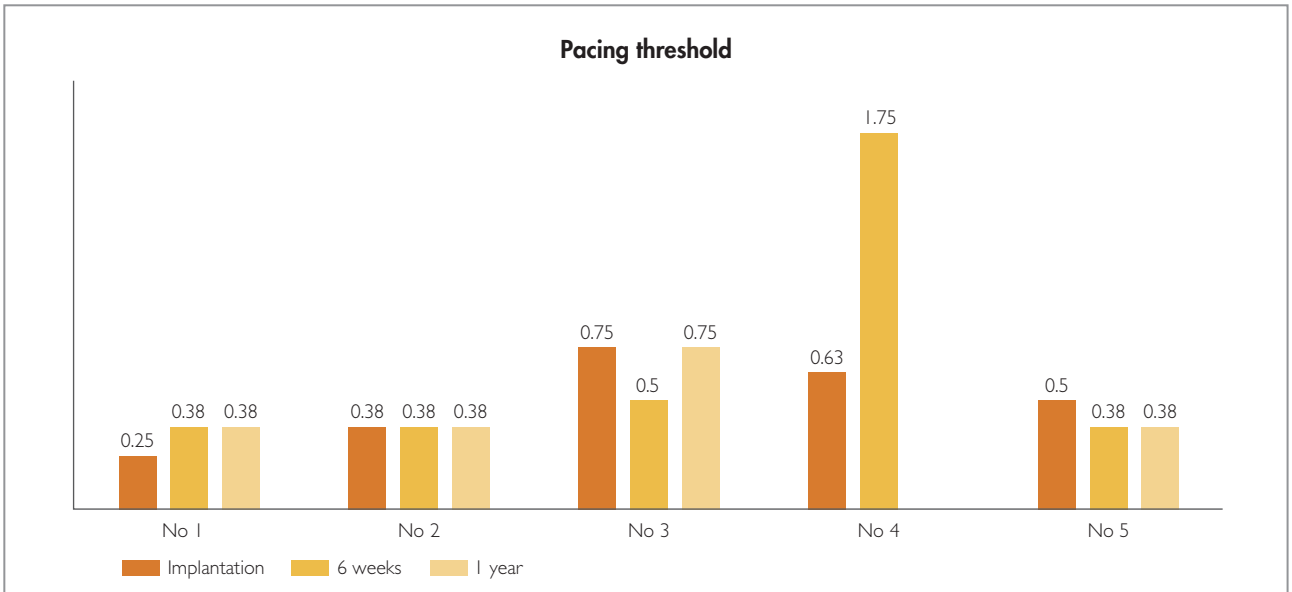


**FIGURE 3: Micra thresholds at implantation, 6 weeks and 1 year.**

were implanted with a Micra TPS.[19] The device was successfully implanted in 99.2% of the patients. These patients achieved a 96% freedom from major complications (95% Confidence Interval [CI], 93.9 - 97.3; p <0.001) and this was statistically significant when compared with the safety performance goal of 83%.[19] These investigators defined primary efficacy as the percentage of patients with low thresholds and stable pacing capture at 6 months (≤2.0V at 0.24ms and an increase of ≤1.5V from implantation). The rate of primary efficacy was 98.3% (95% CI, 96.1 - 99.5; p <0.001 when com-

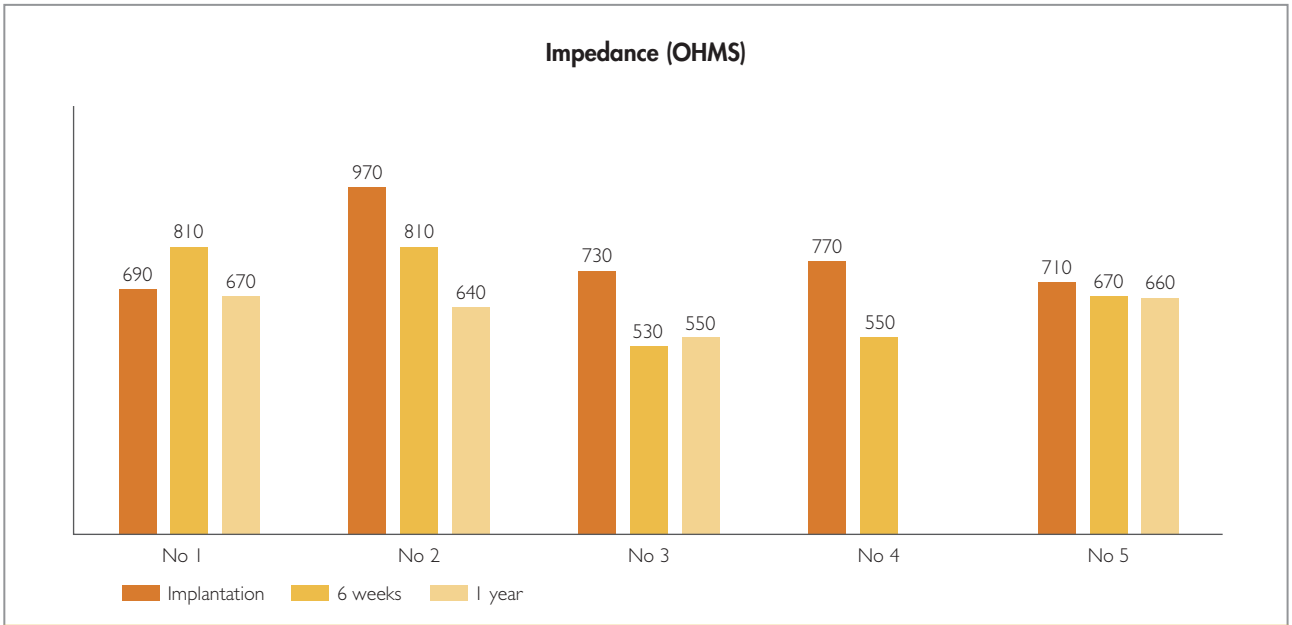


**FIGURE 4: Micra impedance at implantation, 6 weeks and 1 year.**

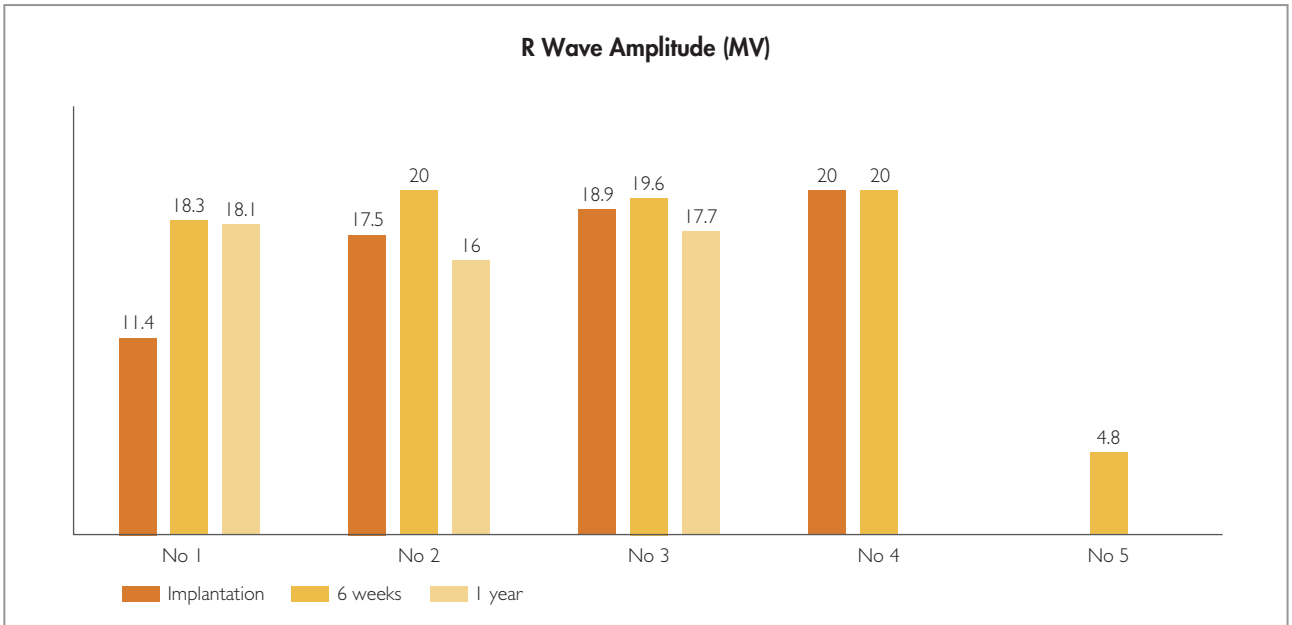


**FIGURE 5: Micra R wave at implantation, 6 weeks and 1 year. Patient 5 had no escape, and no R wave at implantation and 6 weeks.**

pared with the efficacy performance goal of 80%) among 292 patients at 6 months.[19] These data confirmed the safety and efficacy of the Micra TPS at 6 months. Registry data have subsequently confirmed the safety, efficacy and limited complication rates of the Micra TPS in the real world setting, with patient follow-up to 12 months.[20,21]

In this case series, we report the first consecutive 5 patients implanted with a Micra TPS leadless pacemaker in South Africa. These patients represent the first patients to receive this ground-breaking technology in our country. The Micra TPS was successfully implanted in all patients. There were no implantation-related complications or device-related compli-

cations at 1 year of follow-up. There was 1 death in this patient cohort, which was not related to device implantation.

## CONCLUSION

This small series of leadless pacemaker implantations confirms the safety and efficacy of the Micra TPS system in a resource-constraint setting over a 1-year follow-up period. A leadless pacemaker is a good option for patients who require pacing and who are at high risk of pocket or lead-related complications or when conventional pacing is not possible.

**Conflict of interest: none declared.**

## REFERENCES


1. Kusumoto FM, Schoenfeld MH, Barrett C, et al. 2018 ACC/AHA/HRS Guideline on the evaluation and management of patients with bradycardia and cardiac conduction delay. A Report of the American College of Cardiology/American Heart Association Task Force on clinical practice guidelines and the Heart Rhythm Society. JACC 2019;74(7):932-987 https://doi.org/10.1016/j.jacc.2018.10.043.
2. Members ATF, Brignole M, Auricchio A, et al. 2013 ESC Guidelines on cardiac pacing and cardiac resynchronisation therapy: The Task Force on cardiac pacing and resynchronisation therapy of the European Society of Cardiology (ESC). Developed in collaboration with the European Heart Rhythm Association (EHRA). European Heart Journal 2013;34:2281-2329. https://doi.org/10.1093/europace/eut206.
3. Lopez-Jimenez F, Goldman L, Orav EJ, et al. Health values before and after pacemaker implantation. American Heart Journal 2002;144:687-692. https://doi.org/10.1067/mhj.2002.124835.
4. Shen W-K, Hayes DL, Hammill SC, et al. Survival and functional independence after implantation of a permanent pacemaker in octogenarians and nonagenarians: A population-based study. Annals of Internal Medicine 1996; 125:476-480. DOI: 10.7326/0003-4819-125-6-199609150-00008.
5. Shen W-K, Hammill SC, Hayes DL, et al. Long-term survival after pacemaker implantation for heart block in patients ≥65 years. The American Journal of Cardiology 1994;74:560-564. DOI: https://doi.org/10.1016/0002-9149(94)90744-7.
6. Mond HG, Proclemer A. The 11th World survey of cardiac pacing and implantable cardioverter-defibrillators: Calendar year 2009 – A World Society of Arrhythmia's Project. Pacing and Clinical Electrophysiology 2011;34:1013-1027. https://doi.org/10.1111/j.1540-8159.2011.03150.x.
7. Bradshaw PJ, Stobie P, Knuiman MW, et al. Trends in the incidence and prevalence of cardiac pacemaker insertions in an ageing population. Open Heart 2014;1:e000177. doi:10.1136/openhrt-2014- 000177.
8. Uslan DZ, Tleyjeh IM, Baddour LM, et al. Temporal trends in permanent pacemaker implantation: A population-based study. American Heart Journal 2008;155:896-903. https://doi.org/10.1016/j.ahj.2007.12.022.
9. Ritter P, Duray GZ, et al. The rationale and design of the Micra Transcatheter Pacing Study: Safety and efficacy of a novel miniaturised pacemaker. EP Europace 2015;17:807-813. https://doi.org/10.1093/europace/euv026.
10. Miller MA, Neuzil P, Dukkipati SR, et al. Leadless cardiac pacemakers. Journal of the American College of Cardiology 2015;66:1179. https://doi.org/10.1016/j.jacc.2015.06.1081.
11. Udo EO, Zuithoff NPA, van Hemel NM, et al. Incidence and predictors of short- and long-term complications in pacemaker therapy: The FOLLOWPACE study. Heart Rhythm 2012;9:728-735. DOI: https://doi.org/10.1016/j.hrthm.2011.12.014.
12. Tobin K, Stewart J, Westveer D, et al. Acute complications of permanent pacemaker implantation: Their financial implication and relation to volume and operator experience. American Journal of Cardiology 2000;85:774-776. DOI: https://doi.org/10.1016/S0002-9149(99)00861-9.
13. Guo F, Li Y, Li X, et al. Prevalence of venous occlusion in patients referred for lead extraction: Implications for tool selection. EP Europace 2014; 16:1795-1799. https://doi.org/10.1093/europace/euu124.
14. MicraTM Transcatheter Pacing System MC1VR01. 2016. Retrieved April 22, 2019: https://www.medtronic.com/content/dam/medtronic-com/01_crhf/brady/pdfs/2018-05-micra-specification-sheet.pdf.
15. Ritter P, Duray GZ, Steinwender C, et al. Early performance of a miniaturised leadless cardiac pacemaker: The Micra Transcatheter Pacing Study. European Heart Journal 2015;36:2510-2519. https://doi.org/10.1093/eurheartj/ehv214.
16. Mulpuru SK, Madhavan M, McLeod CJ, et al. Cardiac pacemakers: Function, troubleshooting, and management: Part 1 of a 2-Part Series. Journal of the American College of Cardiology 2017;69:189-210. https://doi.org/10.1016/j.jacc.2016.10.061.
17. Spickler JW, Rasor NS, Kezdi P, et al. Totally self-contained intracardiac pacemaker. Journal of Electrocardiology 1970;3:325-331. https://doi.org/10.1016/S0022-0736(70)80059-0.
18. Lown B, Kosowsky BD. Artificial cardiac pacemakers. New England Journal of Medicine 1970;283:907-916. DOI: 10.1056/NEJM197011052831905.
19. Reynolds D, Duray GZ, Omar R, et al. A leadless intracardiac transcatheter pacing system. New England Journal of Medicine 2016;374:533-541. DOI: 10.1056/NEJMoa1511643.
20. Roberts PR, Clementy N, Al Samadi F, et al. A leadless pacemaker in the real-world setting: The Micra transcatheter pacing system post-approval registry. Heart Rhythm 2017;14:1375-1379. DOI: https://doi.org/10.1016/j.hrthm.2017.05.017.
21. El-Chami MF, Al-Samadi F, Clementy N, et al. Updated performance of the Micra transcatheter pacemaker in the real-world setting: A comparison to the investigational study and a transvenous historical control. Heart Rhythm 2018;15:1800-1807. DOI: https://doi.org/10.1016/j.hrthm.2018.08.005.