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Original Research

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Safety and Performance of the Micra VR Leadless Pacemaker in a South Korean Cohort: A Comparison to Global Studies

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AUTHOR'S SUMMARY

This study aims to fill the knowledge gap regarding the performance and safety of the Micra VR leadless pacemaker in a South Korean population. This prospective observational study demonstrated that the Micra leadless pacemaker was successfully implanted in a high percentage of patients (99%). The rate of major complications observed was low (1.0%) through 12 months. Additionally, there were no pericardial effusions, no device infections requiring removal, no dislodgements, and no system or procedure-related deaths. Collectively, these data suggest that the Micra VR pacemaker is a viable and beneficial option for patients requiring pacemaker therapy in South Korea.

ABSTRACT

Background and Objectives: The Micra leadless pacemaker demonstrated a favorable safety and efficacy profile in global trials, but its performance and safety in a South Korean-specific population are unknown.

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Conflict of Interest

Youngjin Cho receives consulting fee/payment or Honoria for lectures, presentations, speakers bureaus, manuscript writing or educational events. Kurt Stromberg, Jeffrey Murphy, Dedra H. Fagan are employees and shareholders of Medtronic. The other authors have no financial conflicts of interest.

Data Sharing Statement

The data required to reproduce these findings cannot be shared due to privacy concerns.

Author Contributions

Formal analysis: Stromberg K, Murphy J; Investigation: Cha MJ, Park SJ, Cho Y, Cho MS, On YK, Kim JY, Kim TH, Yu HT, Oh YS, Lee SR, Shim J, Choi JI, Choi EK, Hwang J, Joung B; Methodology: Stromberg K; Validation: Stromberg K, Murphy J; Visualization: Stromberg K, Fagan DH; Writing - original draft: Cha MJ, Fagan DH; Writing - review & editing: Cha MJ, Park SJ, Cho Y, Cho MS, On YK, Kim JY, Kim TH, Yu HT, Oh YS, Lee SR, Shim J, Choi JI, Choi EK, Hwang J, Stromberg K, Murphy J, Fagan DH, Joung B.

Methods: The prospective, single-arm Micra Acute Performance South Korean registry was designed to study the performance of the Micra VR leadless pacemaker in patients from South Korea. The primary objectives were to characterize the rate of acute (30 days) and longer-term (12 months) major complications. Electrical performance and quality of life at baseline and follow-up were also characterized.

Results: A total of 100 enrolled patients underwent Micra VR implant at 8 centers in South Korea between July 2021 and February 2022 with 99% successfully implanted. Mean pacing capture threshold was 0.57±0.46 V at implant and remained stable through 12 months (0.65±0.44 V). Korean valuation of health status significantly increased from baseline (0.78±0.24) to 12 months (0.84±0.21) (p=0.016). Compared with global patients, South Korean patients were younger, had a lower body mass index, and fewer had a prior cardiovascular implantable electronic device (all p<0.01). During the follow-up period 1 major complication was reported (implant site hematoma) at 26 days post-implant. No pericardial effusion or tamponade events were observed. Through 12 months post-implant the major complication rate was 1.0% (95% confidence interval, 0.03%, 5.45%).

Conclusions: In a South Korean cohort, the Micra VR leadless pacemaker was implanted with a high success rate and low major complication rate.

Keywords: Pacemaker, artificial; Clinical trial; Bradycardia; Humans; Arrhythmias, cardiac/therapy

INTRODUCTION

The advent of leadless pacemakers marks a significant advancement in cardiac pacing technology, aimed at mitigating complications associated with traditional transvenous pacemakers (TV-PMs), such as lead dislodgement, infection, and pocket-related issues. The Micra™ leadless pacemaker, developed by Medtronic, Inc. (Minneapolis, MN, USA), represents a pioneering innovation in this field, offering a less invasive option with promising safety and efficacy profiles as demonstrated in various global clinical trials.[1)2)]

Initial evaluations of the Micra VR pacemaker were conducted through the Micra Investigational Device Exemption (IDE) study, which reported a high implantation success rate of 99.2% and a relatively low complication rate of 4% at 6 months.[3)] Subsequent studies, including the Micra Post-Approval Registry (PAR), further validated these findings, showcasing a major complication rate of 4.5% at 5 years and stable device performance metrics over time.[4)] Despite these encouraging results, regional variations in patient demographics and clinical practices necessitate localized studies to assess the device's performance in specific populations.

The clinical landscape in South Korea presents unique challenges and opportunities for evaluating the Micra pacemaker. South Korean patients are often characterized by unique clinical profiles compared to Western cohorts, including lower body mass index (BMI) and different prevalence of comorbidities, which may result in distinct outcomes.[5)] Prior research in Japanese cohorts has highlighted the importance of such regional studies, demonstrating comparable safety and efficacy to global findings, albeit with specific considerations such as higher pericardial effusion risk.[6)]

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This study aims to fill the knowledge gap regarding the performance and safety of the Micra VR leadless pacemaker in a South Korean population. By analyzing a cohort from multiple South Korean centers, this research seeks to determine the device's acute and longer-term complication rates, procedural success, and overall patient outcomes, providing a comprehensive comparison to existing global data.[7] This localized evaluation will offer valuable insights into the applicability of the Micra pacemaker in South Korea, supporting informed clinical decisions and potentially guiding future technological and procedural optimizations.

METHODS

Ethical statement

The study enrolled patients with indications for pacing with no comorbidity restrictions. Ethics committee approval was obtained from each participating center (Severance Hospital, 1-2001-0024; Korea University Anam Hospital, 2021AN0289; Keimyung University Dongsan Medical Center, DMC 2021-07-088-004; Samsung Medical Center, SMC 2021-05-175-003; Seoul National University Hospital, H-2106-122-1228; Seoul Nation Universtiy Bundang Hospital, B-2109-708-402; The Catholic University of Korea Seoul St. Mary's Hospital, 2021-1677-0003; and Asan Medical Center, 2021-0955). All system and procedure related adverse events were adjudicated by a clinical events committee.

Study design

The Micra Acute Performance (MAP) Asia Pacific South Korea specific cohort study was a prospective, observational, nonrandomized multicenter study to further evaluate the safety and performance of the Micra VR system in a South Korean specific cohort.

Patients and procedures

Patients who were intended to be implanted with a Micra VR (model MC1VR01; Medtronic, Inc.) device were eligible to be enrolled. Informed written consent was given by all patients prior to implantation of the device. Following consent, patients underwent implant attempt. The implant procedure for the Micra VR leadless pacemaker has been previously described.[3] In brief, a catheter guides the Micra device through the femoral vein to the right ventricle (RV) where it is fixated into the myocardium via flexible tines. Patient and device status were assessed at implant, predischarge, and in accordance with routine care practices by their respective care provider. Follow-ups were expected to occur approximately every 6 to 18 months post implant.

Endpoints

The primary endpoint of this study was the safety of the Micra VR system in a South Korean specific population as indicated by the acute (30 day) major complication rate. Major complications were defined as adverse events related to the Micra system or implantation procedure that resulted in death, permanent loss of device function due to mechanical or electrical dysfunction of the device, hospitalization, prolonged hospitalization by ≥48 hours, or system revision (explant, repositioning, replacement, permanently programming device to off). The major complication rate was also calculated at 12 months post-implantation, and both the acute and 12-month complication rates were compared with those from the Micra PAR and IDE studies.[1][8] Electrical performance and quality of life (using the 5-level EuroQol-5 dimension [EQ-5D-5L]) at baseline and follow-up were also characterized.

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Statistical methods

A sample size of 100 patients was selected to ensure that an acute major complication occurring at a rate of 1.0% could be estimated with a precision of 5.4% (i.e., distance from upper to lower 2-sided 95% confidence interval [CI] is 5.4%). Summary statistics were obtained and reported using mean and standard deviation (SD) or median and interquartile range (IQR) for continuous variables and frequencies and percentages for categorical variables. The rate of acute major complications was calculated as the number of patients with at least one acute major complication divided by the number of patients with a Micra VR implant attempt. A 2-sided 95% CI for this rate was computed using the exact binomial method. Kaplan-Meier methods were used to compute the rate of major complications at 12 months (365 days) post-implant. The 12-month major complication rate and its associated 95% CI was estimated using the Kaplan-Meier method with the log-log transformation of the Greenwood variance estimate. Electrical parameters were summarized at implant and follow-up intervals using means and SDs. Quality of life was assessed by summarizing responses to the individual EQ-5D-5L component questions at each visit (baseline and 12-month follow-up). Additionally, paired t-tests were used to compare changes and construct 95% CIs for health status constructed from the EQ-5D-5L responses using South Korea specific valuations[9] and the visual analog scores (VAS) between baseline and 12-months. The t-test (continuous variables) or Fisher's exact test (categorical variables) were used to compare baseline and medical history variables between the MAP South Korea, global PAR, and global Micra VR IDE cohorts. Patients from each study were implanted with a Micra VR (model MC1VR01; Medtronic, Inc.) device. As a post hoc analysis, the major complication rate through 12 months post-implant from the South Korea cohort was compared to that of the Micra IDE study and the Micra VR PAR using a Fine-Gray competing risk model where death unrelated to the Micra VR system or procedure was considering the competing risk.

As a sensitivity analysis, a Fine-Gray competing risk model using propensity score overlap weights was used to derive adjusted hazard ratios for the risk of major complication between studies after accounting for differences in baseline and co-morbid conditions. To compute the propensity score, the probability of each patient to be in each study was estimated using a multinomial regression model that included all baseline and co-morbidities found in **Supplementary Table 1**. The resulting propensity scores were used to derive an overlap weight for each patient. Incorporating the overlap weights into the analysis allows the most emphasis to be placed on patients with the most similarity across the 3 studies.[10] Maximum pairwise standardized mean differences were used to assess balance among covariates included in the propensity model following weighting.

All analyses were performed with SAS version 9.4 (SAS Institute Inc., Cary, NC, USA) or the R statistical package (www.r-project.org; R Foundation for Statistical Computing, Vienna, Austria). The PSweight package in R was used to obtain overlap weights.[11]

RESULTS

Patients and implant procedure

A total of 100 patients were enrolled in the study across 8 South Korean centers from July 6, 2021 to February 24, 2022 with the last follow-up visit occurring on April 14, 2023. Average age was 71.9±11.5 years, 40.0% were female, and 31.0% had a history of diabetes (**Table 1**). The primary pacing indication was bradycardia with atrial fibrillation (AF).

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Table 1. Baseline characteristics of Micra South Korean patients

Patient characteristics	Korea Micra VR (n=100)
Age (years)	
Mean ± SD	71.9±11.5
Median	72.5
25th percentile–75th percentile	66–81
Minimum–Maximum	28–92
Number of subjects with measure available	100 (100.0%)
BMI (kg/m^2)	
Mean ± SD	23.9±2.9
Median	24.1
25th percentile–75th percentile	22–26
Minimum–Maximum	18–32
Number of subjects with measure available	100 (100.0%)
Height (cm)	
Mean ± SD	162.3±9.0
Median	162
25th Percentile–75th Percentile	156–168
Minimum–Maximum	142–186
Number of subjects with measure available	100 (100.0%)
Weight (kg)	
Mean ± SD	63.3±11.1
Median	63.3
25th percentile–75th percentile	57–70
Minimum–Maximum	38–106
Number of subjects with measure available	100 (100.0%)
Female (%)	40.0% (40/100)
Co-morbidities (%)	
AF	61.0% (61/100)
CHF	11.0% (11/100)
COPD	3.0% (3/100)
CAD	12.0% (12/100)
Hypertension	62.0% (62/100)
Diabetes	31.0% (31/100)
Renal dysfunction	12.0% (12/100)
Dialysis	7.0% (7/100)
Prior CIED	2.0% (2/100)
Pacing indication (%)	
Bradycardia with AF	60.0% (60/100)
Sinus node dysfunction	19.0% (19/100)
AV block	10.0% (10/100)
Syncope	7.0% (7/100)
Other	4.0% (4/100)
Pericardial effusion risk level (%)	
Low risk	75.0% (75/100)
Medium risk	20.0% (20/100)
High risk	5.0% (5/100)

AF = atrial fibrillation; AV = atrioventricular; BMI = body mass index; CAD = coronary artery disease; CHF = congestive heart failure; CIED = cardiac implantable electronic device; COPD = chronic obstructive pulmonary disease; SD = standard deviation.

The device was successfully implanted in 99 of 100 patients (99.0%), and patients were followed for an average of 12.2±3.0 months. The unsuccessful implant was due to the inability to obtain an adequate pacing capture threshold due to patient anatomy; this patient was ultimately implanted with a conventional transvenous pacing system. The median procedure duration (introducer in – introducer out) was 25.0 minutes (IQR, 15–33 minutes). Most (86.3%) implants were successfully achieved with ≤3 deployments. The final implant location was primarily in the RV septum (94.9%), with 5.1% of implants in the apex. Over half of patients (59%) were on oral anticoagulation at baseline, but had it interrupted during the

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procedure; 5% had anticoagulation therapy continued, and the remaining 36% were not on anticoagulation therapy at baseline. Intravenous anticoagulation was used in 80.0% of cases, while reversants were used in 1.0%.

Safety

There was one major complication reported among the 100 South Korean patients included in the cohort. This event was a hematoma at the groin access site that was identified 26 days post-implant in a patient who was on oral anticoagulation therapy at baseline, but had it interrupted during the procedure. The acute major complication rate was 1.0% (95% CI, 0.03%, 5.45%). Notably, there were no pericardial effusions regardless of severity reported among South Korean patients. Additionally, there were no procedure related deaths, device dislodgements, or device related infections reported. There was one system revision at 307 days post-implant due to heart failure aggravation and right ventricular dysfunction; this event was not related to the Micra device or procedure. The Micra device was left in the RV and programmed to OOO mode and an implantable cardioverter defibrillator was implanted.

Electrical performance

Mean pacing capture threshold was 0.57±0.46 V at implant and remained stable through 12 months (0.65±0.44 V; **Figure 1A**). Mean R-wave amplitude was 10.2±5.0 mV at implant and 13.0±5.8 mV at 12 months (**Figure 1B**). Mean impedance was 792±205 Ω at implant and 569±125 Ω at 12 months (**Figure 1C**).

Quality of life

Figure 2 displays the distribution of the EQ-5D-5L responses to each of the EQ-5D-5L domains by study visit for all respondents. The mean elapsed time between baseline and follow-up EQ-5D-5L assessments was 13.7±1.9 months. The average baseline VAS was 72.4±22.6% at baseline compared to 74.8±17.8% at 12-months for a difference of 2.5±21.1% (95% CI, −2.2%, 7.1%; p=0.292; **Figure 3**).The average baseline Korean valuation of health status, constructed from the EQ-5D-5L responses, increased significantly from baseline (0.78±0.24) to 12 months (0.84±0.21) for a difference of 0.06±0.23 (95% CI, 0.01, 0.11; p=0.016; **Figure 4**).

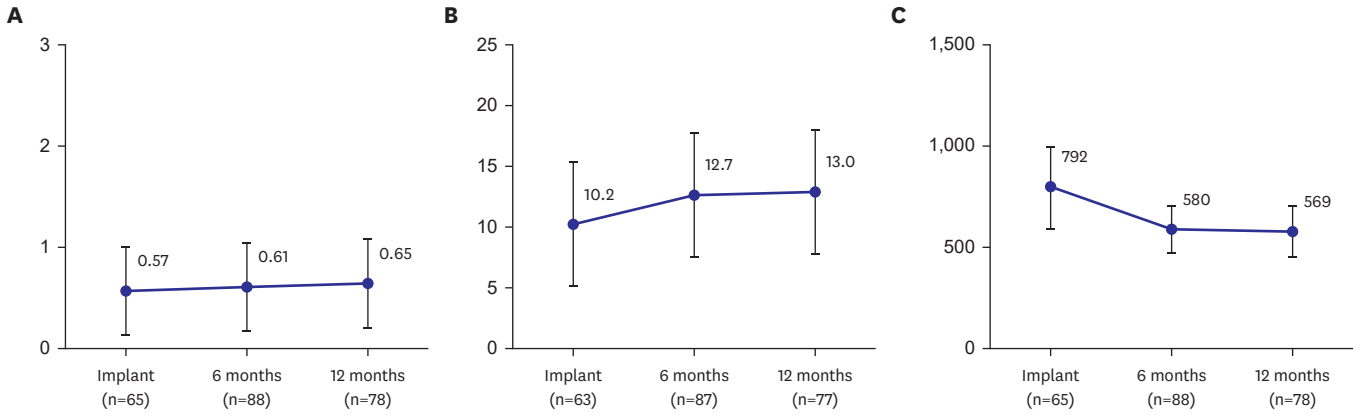

Figure 1. Electrical parameters by visit. Average pacing capture threshold at 0.24 ms over time (A), average R-wave sensing amplitude over time (B), and average pacing impedance over time (C). Error bars represent mean ± standard deviation.

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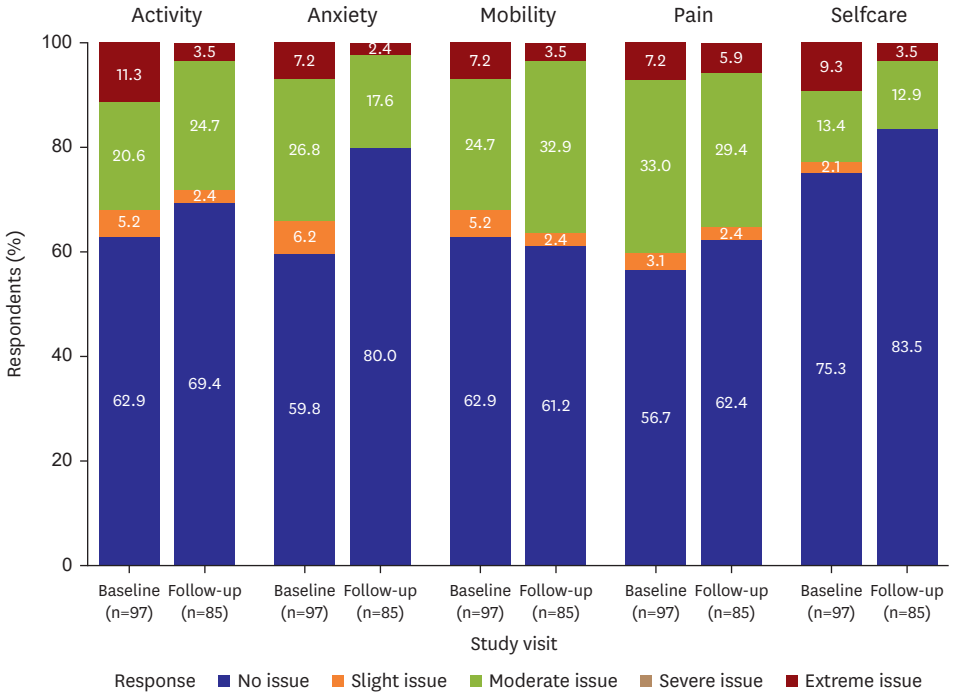

Figure 2. Distribution of EQ-5D-5L responses by visit. Distribution of individual components of the EQ-5D-5L at baseline and follow-up. Responses are graded from no issue to extreme issue.
EQ-5D-5L = 5-level EuroQol-5 dimension.

Comparison to global studies

The South Korean cohort was significantly younger, had a lower BMI, and had lower rates of AF, chronic obstructive pulmonary disease (COPD), coronary artery disease (CAD), and renal dysfunction (**Supplementary Table 1**). Fewer patients had a prior cardiovascular implantable electronic device than global patients. Bradyarrhythmia with AF was the most common pacing indication in all 3 studies; however, a higher proportion of South Korean patients had a primary pacing indication of sinus node dysfunction compared to patients in the Micra VR global registry (19.0% vs. 9.6%; p=0.018).

Figure 5 displays the observed major complication rate through 12 months by Micra study. There was no evidence to suggest that the risk for major complication through 12-months on an unadjusted basis in the South Korea cohort differed from the Micra IDE (p=0.160) or Micra VR PAR (p=0.220).

After including the overlap weights, the studies were well balanced with respect to the variables in **Supplementary Table 1** with all standardized mean differences less than 0.1 (**Supplementary Figure 1**). Following adjustment for baseline characteristics and co-morbid conditions the results remained consistent with the unadjusted model (**Supplementary Figure 2**).

DISCUSSION

This prospective observational study demonstrated that the Micra leadless pacemaker was successfully implanted in a high percentage of patients (99%) in a South Korean cohort. The rate of major complications observed was low (1.0%) through 12 months, aligning

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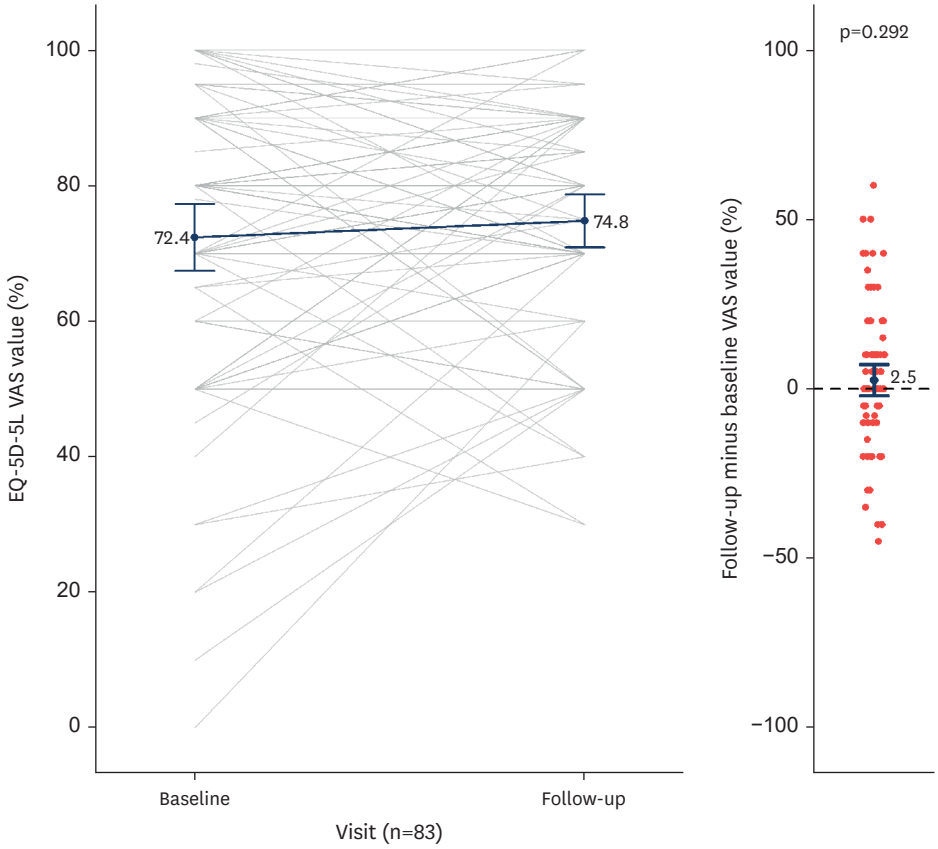

Figure 3. EQ-5D visual analog scale by visit. In the left panel, the gray lines indicate individual patient values at each visit while the dark blue line indicates the estimated mean and its 95% confidence interval at each visit. The right panel displays the change from the baseline value to the 12-month follow-up value. In this plot, the red circles indicate individual patient values, and the dark blue dot displays the estimated mean change with error bars representing the 95% confidence interval for the change.
EQ-5D-5L = 5-level EuroQol-5 dimension; VAS = visual analog scores.

well with the results from prior global Micra trials. Specifically, there were no pericardial effusions of any severity, no device infections requiring removal, no device dislodgements, and no system or procedure-related deaths. These findings underscore the device's safety and efficacy profile. Additionally, health status, as measured by patient-reported outcomes, significantly improved from baseline to follow-up, primarily driven by improvements in the activity, anxiety, and self-care components of the EQ-5D-5L.

An important implication of this study is that it provides robust evidence supporting the safety and efficacy of the Micra VR leadless pacemaker in the South Korean population. The absence of major complications such as pericardial effusions, device infections, and dislodgements further emphasizes the device's safety. This is crucial as it reassures both clinicians and patients about the reliability of the device, given that patient demographics and clinical characteristics can vary significantly between regions. The high success rate of implantation and the low complication rate suggest that the Micra VR pacemaker is a viable and beneficial option for patients requiring pacemaker therapy in South Korea.

The significant improvement in health status from baseline to follow-up highlights the potential of the Micra VR pacemaker to enhance patient quality of life. This improvement is consistent with results from other studies that have reported positive patient outcomes

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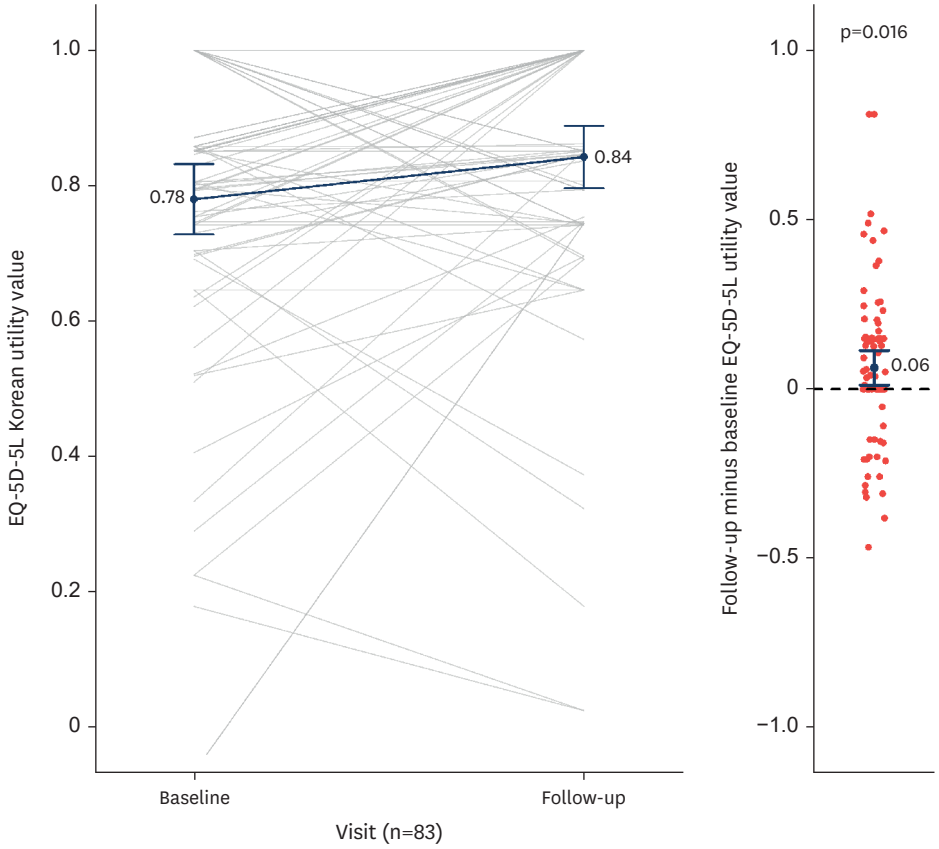

Figure 4. Korean valuation of health status by visit. In the left panel, the gray lines indicate individual patient values at each visit while the dark blue line indicates the estimated mean and its 95% confidence interval at each visit. The right panel displays the change from the baseline value to the 12-month follow-up value. In this plot, the red circles indicate individual patient values, and the dark blue dot displays the estimated mean change with error bars representing the 95% confidence interval for the change.
EQ-5D-5L = 5-level EuroQol-5 dimension.

following leadless pacemaker implantation. Specifically, prior single-arm studies have found an improvement in quality of life (assessed via the SF-36) following Micra implantation. Additionally, patients reported high satisfaction with their esthetic appearance and discharge instructions were rated as less restrictive than transvenous pacemaker systems.[12] Comparative regional studies from China, Spain, and Italy have demonstrated greater improvements in quality of life following leadless pacemaker implantation vs transvenous pacemakers.[13-15]

Comparing the South Korean data to other international cohorts, several distinctions are notable. The previously published MAP Japan cohort was older on average (82.6 years) compared to the South Korean cohort (71.9 years). Additionally, the Japanese cohort had higher incidences of comorbidities such as renal dysfunction (37% in Japan vs. 12% in Korea) and chronic heart failure (27% in Japan vs. 11% in Korea).[6] Despite these differences, the Japanese study reported similar high success rates of implantation (100%) and low major complication rates (3.33%).[6] In China, the Micra VR study showed a high implantation success rate of 98.5% and a major complication rate of 2.0% through 12 months.[16]

The lower rate of pericardial effusions and major complications in the South Korean cohort compared to global data might be attributed to differences in patient demographics, procedural techniques, and healthcare practices. The relatively younger aged population

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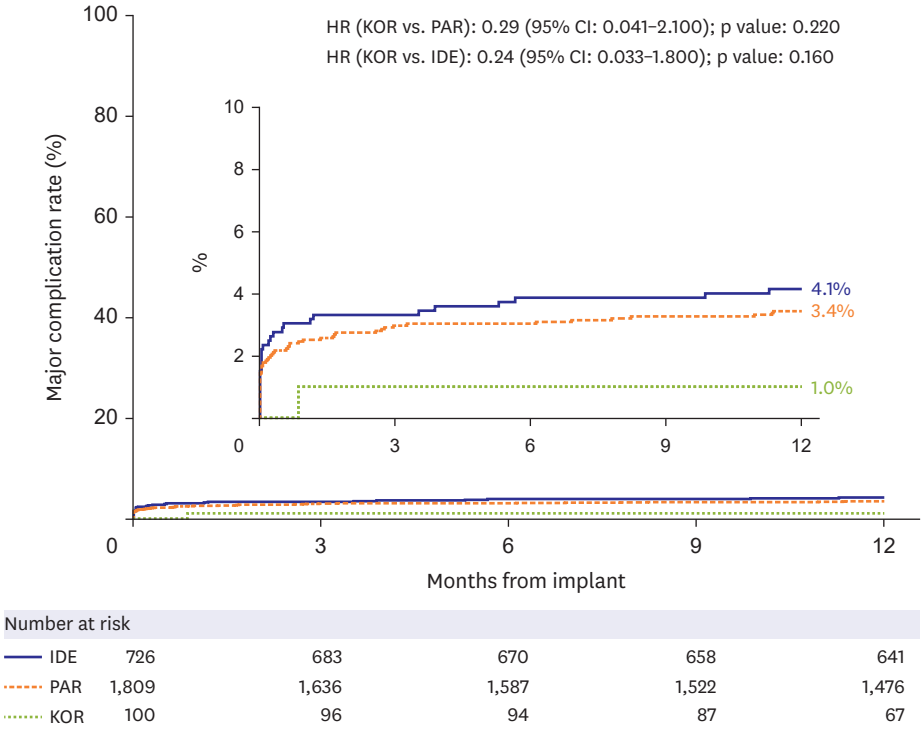

Number at risk					
IDE	726	683	670	658	641
PAR	1,809	1,636	1,587	1,522	1,476
KOR	100	96	94	87	67

Figure 5. Major complication rates through 12 months by Micra VR study. Fine-Gray competing risks were used to compare major complication rates between studies at 12 months.
CI = confidence interval; HR = hazard ratio; IDE = Micra VR global IDE study; KOR = Micra VR MAP South Korea study; PAR = Micra VR global post-approval registry study.

and lower rates of comorbidities such as CAD and COPD, in the South Korean cohort might have contributed to the overall low complication rate. Additionally, the higher prevalence of septal placement in South Korea (94.9% vs. 65.1% in the Micra PAR) may contribute to the reduced risk of pericardial effusions and perforations. Furthermore, careful attention to procedural techniques by experienced operators likely played a significant role in minimizing complications. This highlights the importance of training and expertise in achieving optimal outcomes with new medical technologies.

Despite the encouraging results, this study has several limitations. The study was not a randomized controlled trial, and thus, direct comparisons to other devices or procedures were not possible. Although not specifically powered to statistically test for non-inferiority, comparisons were made to prior cohorts, which may introduce bias. The study was conducted at a limited number of centers, which may not be representative of all institutions in South Korea. This could affect the generalizability of the findings. Additionally, the follow-up period was relatively short, limiting the ability to assess long-term outcomes and complications comprehensively. The sample size, although sufficient to estimate the rates of major complications in Korea, may still be considered small relative to larger international studies. Moreover, the lack of a control group limits the ability to draw definitive conclusions about the comparative effectiveness of the Micra VR pacemaker. Further studies with larger sample sizes and longer follow-up periods are recommended to validate these findings and to assess the long-term performance and safety of the device.

In a South Korean cohort, the Micra VR leadless pacemaker was implanted with a high success rate and a low major complication rate in line with results from prior global Micra

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studies. This study supports the use of the Micra VR leadless pacemaker as a safe and effective option for patients requiring pacemaker therapy in South Korea.

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SUPPLEMENTARY MATERIALS

Supplementary Table 1

Baseline characteristic comparison between Korea and global cohorts

Supplementary Figure 1

Maximum standardized mean differences between baseline and co-morbidities before and after balancing with the overlap weights. A pacing indication associated with AF was considered the reference group for comparison of pacing indication between studies. Similarly, a risk level of low for pericardial effusion was considered the reference groups for the comparison of risk level between studies. Vertical line shown at a standardized mean difference of 0.1.

Supplementary Figure 2

Adjusted major complication rates through 12 months by study. A Fine-Gray competing risk model using propensity score overlap weights was used to derive adjusted HRs and major complication rates through 12 months between studies after accounting for differences in baseline and co-morbid conditions.

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