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Leadless pacemakers in patients with different stages of chronic kidney disease: Real-world data from the updated i-LEAPER registry

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ABSTRACT

BACKGROUND Limited data are available on leadless pacemaker (LPM) outcomes according to different stages of chronic kidney disease (CKD).

OBJECTIVE The purpose of this study was to investigate differences in the safety and efficacy of LPMs among patients stratified per different stages of renal function.

METHODS Consecutive patients enrolled in the multicenter international i-LEAPER registry (International LEAdless PacemakEr Registry) were analyzed. Patients were divided into 3 groups according to CKD stage. The primary end point was the comparison of LPM-related major complication rate at implantation and during follow-up. Differences in electrical performance were deemed secondary outcomes.

RESULTS Of the 1748 patients enrolled, 33% were in CKD stage G3a/G3b and 9.4% were in CKD stage G4/G5. Patients with CKD presented cardiovascular comorbidities more frequently. During a median follow-up of 39 months (interquartile range [IQR] 18–59 months), major complication rate did not differ between groups (normal kidney function [NKF] group 1.8% vs CKD stage G3a/G3b group 2.9% vs CKD stage G4/G5 group 2.4%; $P = .418$). All-cause mortality resulted higher in the CKD stage G4/G5 group than in the NKF group (19.5% vs 9.8%; adjusted hazard ratio 1.9; 95% confidence interval 1.25–2.89; $P = .003$). LPM electrical performance was comparable between groups, except for patients with CKD who showed a slightly higher pacing threshold during 1-month follow-up (NKF group 0.50 V [IQR 0.35–0.70 V] vs G3a/G3b group 0.56 V [IQR 0.38–0.81 V] vs G4/G5 group 0.51 V [0.38–0.84 V] @ 0.24 ms; $P < .001$).

CONCLUSION In a real-world setting, patients with advanced CKD who underwent LPM implantation were underrepresented. Although all-cause mortality was higher in end-stage CKD, periprocedural complications and LPM performance were overall

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comparable between NKF and different stages of CKD, except for higher values of pacing threshold in patients with CKD up to first-month follow-up.

KEYWORDS Leadless pacemaker; Renal function; Chronic kidney disease; Micra; CIED

Introduction

Patients with chronic kidney disease (CKD) are at an increased risk of bradyarrhythmias, which often require permanent cardiac pacemaker (PM) implantation.[1,2] Despite the benefits of transvenous (TV) pacing, TV leads can cause central venous stenosis, a critical issue for patients with end-stage kidney disease (ESKD) who may need an arteriovenous fistula for hemodialysis (HD).[3] Abnormal renal function is an independent risk factor for adverse events related to cardiac implantable electronic devices (CIEDs), such as pocket hematomas and infections.[4,5] Since their introduction, leadless PMs (LPMs) have proven to be an effective alternative to TV-PMs in certain settings,[6] reducing the risks of device-related infections and upper extremity venous occlusions.[7] Recent improvements in LPMs, which now have the capability to maintain atrioventricular (AV) synchrony, have expanded their indications.[8] However, data on LPMs implanted in patients at high risk for kidney function deterioration toward ESKD or HD are scarce. This study aimed to provide information on the safety and efficacy of LPMs at implantation.

Methods

Registry population

The data for this study were obtained from the updated i-LEAPER registry (International LEAdless PacemakEr Registry; ClinicalTrials.gov identifier NCT05528029), an international, multicenter, physician-initiated observational registry.[9] From June 2015 to October 2023, consecutive patients who received LPMs (MC1VR01 or MC1AVR1 Transcatheter Pacing System, Medtronic, Inc., Minneapolis, MN) at 15 institutions in Europe and the United States were included. The device implantation technique has been previously reported.[10,11] This study was conducted in accordance with the principles of the Helsinki Declaration on human research and was approved by the local institutional review board. Data are available from the corresponding author upon reasonable request.

Abbreviations

AV: atrioventricular

CIEDs: cardiac implantable electronic devices

CKD: chronic kidney disease

eGFR: estimated glomerular filtration rate

ESKD: end-stage kidney disease

HD: hemodialysis

LPM: leadless pacemaker

NKF: normal kidney function

PM: pacemaker

TV: transvenous

Definitions and study outcomes

Data collection methods for the patients enrolled in this registry have been previously presented.[12,13] CKD was defined by the presence of an estimated glomerular filtration rate (eGFR) of $\leq$60 mL/(min·1.73 m^2), calculated using the Chronic Kidney Disease Epidemiology Collaboration creatinine equation. To ascertain LPM outcomes according to CKD stage, patients with CKD were classified on the basis of the KDIGO 2024 Clinical Practice Guideline for the Evaluation and Management of Chronic Kidney Disease.[14] Considering the clinical progression of CKD and to simplify the study analysis, patients were divided into 3 groups:

1. NKF (normal kidney function) group: patients with NKF (eGFR $\geq$ 90 mL/(min·1.73 m^2); stage G1) and mild (eGFR 60–89 mL/(min·1.73 m^2); stage G2) kidney function reduction
2. CKD stage G3a/G3b group: patients with mild-moderate (eGFR 45–59 mL/(min·1.73 m^2); stage G3a) and moderate-severe (30–44 mL/(min·1.73 m^2); stage G3b) kidney function reduction
3. CKD stage G4/G5 group: patients with severe kidney function reduction (eGFR 15–29 mL/(min·1.73 m^2); stage G4) and kidney failure (eGFR <15 mL/(min·1.73 m^2); stage G5).

Follow-up strategy was left to each center's policy, with patients mostly being evaluated at discharge, at 1- to 3-month and 12-month follow-up, and every 12 months thereafter. A minimum of 6-month follow-up was necessary for study inclusion. Procedural data and adverse events were derived from electronic medical reports. Electrical parameters were obtained over the entire follow-up (during in-clinic device interrogation), as well as data regarding in-hospital readmissions and cardiovascular mortality. The primary outcome of our study was the comparison of major adverse event rates among the 3 cohorts. Adopting the same criteria as the Micra Investigational Device Exemption Study, *major complications* were defined as system- and procedure-related events resulting in death, permanent loss of device function, hospitalization, prolonged hospitalization >48 hours, or system revision.[15] Overall all-cause mortality and comparison of LPM-related electrical parameters (pacing threshold [PT], impedance, and R-wave sensing) across the cohorts at implantation and during follow-up were deemed secondary outcomes.

Statistical analysis

Continuous data are presented as mean ± SD if normally distributed or as median (interquartile range [IQR]) if not normally distributed according to the D'Agostino-Pearson test and compared using analysis of variance or the Kruskal-Wallis test, as appropriate. Categorical data are presented as absolute number and percentage and compared using the Pearson χ^2 test or Fisher exact test, as appropriate according to frequency distribution. The time-to-event analysis of major adverse events according to strata of kidney function was investigated by using cumulative incidence function and univariable and multivariable Cox regression analyses, taking into account

the competing risk of mortality. In Cox models for these events, the data were expressed as subdistribution hazard ratio (HR), 95% confidence interval (CI), and *P* value. The incidence rate of all-cause mortality by strata of kidney function was investigated by using reverse Kaplan-Meier survival curves plotting the cumulative hazard as a function of time. In Cox models of all-cause mortality, the data were expressed as HR, 95% CI, and *P* value. We adjusted Cox models for all variables that showed significance with a 2-sided *P* value of <.05 across the 3 groups. Statistical analysis was performed using SPSS Statistics version 26.0 (IBM Corporation, Armonk, NY).

Results

Baseline characteristics

The overall registry population included 1748 patients; 1007 had NKF, 577 were in CKD stage G3a/G3b, and 164 were in CKD stage G4/G5, with 123 (75%) undergoing HD. A comparison of baseline characteristics shows that there were significant differences between the 3 groups (Table 1). Patients with NKF were more likely to be male than those with CKD stage G3a/G3b and CKD stage G4/G5. Patients with CKD stage G4/G5 and G3a/G3b were older than those with NKF. In addition, the G3a/G3b group was older than the G4/G5 group. Both groups of patients with CKD (G3a/G3b and G4/G5) were more likely than the NKF group to have diabetes, hypertension, and heart failure. These comorbidities were more prevalent in the CKD stage G4/G5 group than in the G3a/G3b group. Coronary artery disease was more frequent in the G4/G5 group than in both the G3a/G3b group and the NKF group.

LPM indication according to CKD stage

Data regarding the underlying indications for LPM implantation are summarized in Online Supplemental Table 1. Patients with NKF and CKD stage G3a/G3b were more likely to be implanted with an LPM because of atrial fibrillation (AF) with slow ventricular rate or intermittent/complete AV block than those with CKD stage G4/G5 (NKF group 48.4% vs CKD stage G4/G5 group 39.6%; $P = .003$ and CKD stage G3a/G3b group 52.9% vs CKD stage G4/G5 group 39.6%; $P = .032$, respectively). Conversely, sinus rhythm with intermittent/complete AV block was the main reason for LPM implantation in patients with CKD stage G4/G5 when compared with those with NKF (40.2% vs 27%; $P < .001$) as well as those with CKD stage G3a/G3b (40.2% vs 24.8%; $P = .003$). There was an extensive use of Micra AV in advanced CKD stage compared with NKF and CKD stage G3a/G3b (CKD stage G4/G5 31.7% vs NKF 16.1%; $P < .001$ and CKD stage G4/G5 31.7% vs CKD stage G3a/G3b 12.8%; $P < .001$).

LPM was preferred to a traditional TV-PM mostly because of the higher infection risk (58.2%); this risk was more frequently perceived in both patient groups with CKD than in the NKF group (G4/G5 group 68.3% vs NKF group 54.2%; $P < .001$ and G3a/G3b group 62.4% vs NKF group 54.2%; $P = .002$). Vascular access concern was more likely to be the main reason to choose an LPM in the CKD stage G4/G5 group than in the other groups (G4/G5 group 29.9% vs NKF group 13.7%; $P < .001$ and G3a/G3b group 16.5% vs NKF group 13.7%; $P < .001$).

Procedural characteristics

Procedural characteristics are summarized in Table 2. Longer procedure durations were reported in CKD stage G3a/G3b and G4/G5 groups as compared with the NKF group, along with longer radiological times in the CKD stage G4/G5 group. The proximal septum was more frequently targeted in the CKD stage G4/G5 group, while the distal septum was the

Table 1 Baseline characteristics of the study cohort stratified for kidney function according to CKD-EPI score for eGFR and significances between groups

Characteristic	Overall (N = 1748)	Normal kidney function (n = 1007)	CKD stage G3a/G3b (n = 577)	CKD stage G4/G5 (n = 164)	*P* G3a/G3b vs NKF	*P* G4/G5 vs NKF	*P* G4/G5 vs G3a/G3b
Male sex	1052 (60.2)	690 (68.5)	275 (47.7)	87 (53.0)	<.001	<.001	.221
Age (y)	80 (73–85)	78 (69–84)	82 (78.5–87)	81 (74.8–86)	<.001	<.001	.030
BMI (kg/m^2)	25.2 (23.0–28.1)	25 (22.9–28)	25.7 (23–28.4)	24.7 (22.4–29.3)	.270	.871	.907
Obesity (BMI ≥ 30 kg/m^2)	412 (23.5)	248 (24.6)	129 (22.4)	34 (20.7)	.307	.280	.656
Diabetes	422 (24.1)	181 (18.0)	168 (29.1)	73 (44.5)	<.001	<.001	<.001
Hypertension	1161 (66.4)	603 (59.9)	424 (73.5)	134 (81.7)	<.001	<.001	.032
CAD	425 (24.3)	224 (22.3)	146 (25.3)	55 (33.5)	.166	.002	.037
Valvular disease	390 (22.3)	208 (20.7)	141 (24.4)	41 (25.0)	.081	.208	.881
Cardiac surgery	255 (14.6)	137 (13.6)	89 (15.4)	29 (17.7)	.319	.166	.490
CABG	112 (6.4)	55 (5.5)	45 (7.8)	12 (7.3)	.067	.345	.839
HF	242 (13.8)	86 (8.5)	102 (17.7)	54 (32.9)	<.001	<.001	<.001
Dialysis	–	–	–	123 (75)			

Values are presented as median (interquartile range) or n (%).

BMI = body mass index; CABG = coronary artery bypass graft; CAD = coronary artery disease; CKD = chronic kidney disease; CKD-EPI = Chronic Kidney Disease Epidemiology Collaboration; eGFR = estimated glomerular ejection fraction; HF = heart failure; NKF = normal kidney function.

Table 2 LPM implantation features and outcomes in the study cohort stratified for kidney function according to CKD-EPI score for eGFR and significances between groups

Variable	Overall (N = 1748)	Normal kidney function (n = 1007)	CKD stage G3a/G3b (n = 577)	CKD stage G4/G5 (n = 164)	*P*		
					G3a/G3b vs NKF	G4/G5 vs NKF	G4/G5 vs G3a/G3b
Duration of the procedure (min)	50 (40–68)	45 (38–60)	50 (40–70.5)	53 (40–75)	.032	.025	.713
Radiological time (min)	6 (3.2–9)	5.25 (3.2–8.1)	6 (3–9)	6.1 (4.1–8.5)	.464	.037	.494
In-hospital stay (d)	3 (2–5)	3 (2–4)	3 (2–5)	6 (4–8)	.944	<.001	<.001
Deployments							
1	1465 (83.8)	849 (84.3)	475 (82.3)	141 (86)	.304	.584	.273
2	222 (12.7)	128 (12.7)	77 (13.3)	17 (10.4)	.718	.399	.314
3	40 (2.3)	18 (1.8)	16 (2.8)	6 (3.7)	.196	.125	.557
≥4	21 (1.2)	12 (1.2)	9 (1.6)	0	.538	.685	.582
LPM final positioning							
Proximal septum	716 (41)	414 (41.1)	211 (36.6)	91 (55.5)	.075	<.001	<.001
Distal septum	889 (50.9)	520 (51.6)	310 (53.7)	59 (36.0)	.423	<.001	<.001
RVOT	43 (2.5)	22 (2.2)	14 (2.4)	7 (4.3)	.756	.118	.216
Apex	100 (5.7)	51 (5.1)	43 (7.5)	6 (3.7)	.054	.440	.092
LPM-related complications*	75 (4.3)	39 (3.9)	31 (5.4)	5 (3)	.164	.608	.228
Pericardial effusion	11 (0.6)	7 (0.7)	2 (0.3)	2 (1.2)	.870	.482	.208
Cardiac tamponade	5 (0.3)	1 (0.1)	3 (0.5)	1 (0.6)	.151	.198	.889
LPM dislodgment/ embolization	1 (0.1)	0	1 (0.2)	0	.501	.999	.872
Battery premature depletion	3 (0.2)	2 (0.2)	1 (0.2)	0	.904	.813	.772
Periprocedural stroke	2 (0.1)	0	1 (0.2)	1 (0.6)	.640	.567	.747
Femoral artery injury	9 (0.5)	3 (0.3)	6 (1.0)	0	.076	.800	.537
Groin hematoma	37 (2.1)	22 (2.2)	14 (2.4)	1 (0.6)	.752	.208	.178
Systemic/LPM infection	1 (0.1)	1 (0.1)	0	0	.763	.846	.866
Other	6 (0.3)	2 (0.2)	3 (0.5)	1 (0.6)	.291	.359	.889
Major complications	39 (2.2)	18 (1.8)	17 (2.9)	4 (2.4)	.135	.570	.730
Minor complications	36 (2.1)	21 (2.1)	14 (2.4)	1 (0.6)	.654	.226	.179
Intraprocedure	37 (2.1)	18 (1.8)	16 (2.8)	3 (1.8)	.196	.871	.503
Early postprocedure	32 (1.8)	19 (1.9)	11 (1.9)	2 (1.2)	.978	.562	.556
Late postprocedure	6 (0.3)	2 (0.2)	4 (0.7)	0	.141	.777	.490
All-cause mortality	207 (11.8)	99 (9.8)	76 (13.2)	32 (19.5)	.042	<.001	.044

Values are presented as median (interquartile range) or n (%).
CKD = chronic kidney disease; CKD-EPI = Chronic Kidney Disease Epidemiology Collaboration; eGFR = estimated glomerular ejection fraction; LPM = leadless pacemaker; NKF = normal kidney function; RVOT = right ventricular outflow tract.
*Not mutually exclusive.

more frequent target in both the NKF group and the CKD stage G3a/G3b group. Overall, the number of LPM deployments was similar across all groups.

Outcomes

After a median follow-up of 39 months (IQR 18–59 months), the cumulative incidence of major adverse events did not differ between the 3 groups either in a crude event analysis or in a Cox analysis adjusted for potential confounders (Figure 1 and Online Supplemental Table 2). The LPM-related major complication rate was comparable between the NKF and CKD stage G3a/G3b groups (adjusted HR 1.35; 95% CI: 0.64–2.86; *P* = .44) and between the NKF and CKD stage G4/G5 groups (adjusted HR 1.12; 95% CI 0.36–3.52; *P* = .84). The all-cause mortality rate was significantly higher in the CKD stage G4/G5 and CKD G3a/G3b groups than in the NKF group (19.5% vs 9.8%; *P* < .001 and 13.2% vs 9.8%; *P* = .042, respectively), so patients with CKD stage G4/G5 had crude and adjusted HRs of mortality that were 2.66 and 1.90 times higher, respectively, than those of patients with NKF (see Figure 1 and Online Supplemental Table 3). In crude analysis, the incidence rate of mortality was higher in patients with CKD stage G3a/G3b than in those with NKF (HR 1.41; 95% CI 1.04–1.90; *P* = .025) but this risk excess disappeared after data adjustment for confounders (see Online Supplemental Table 3).

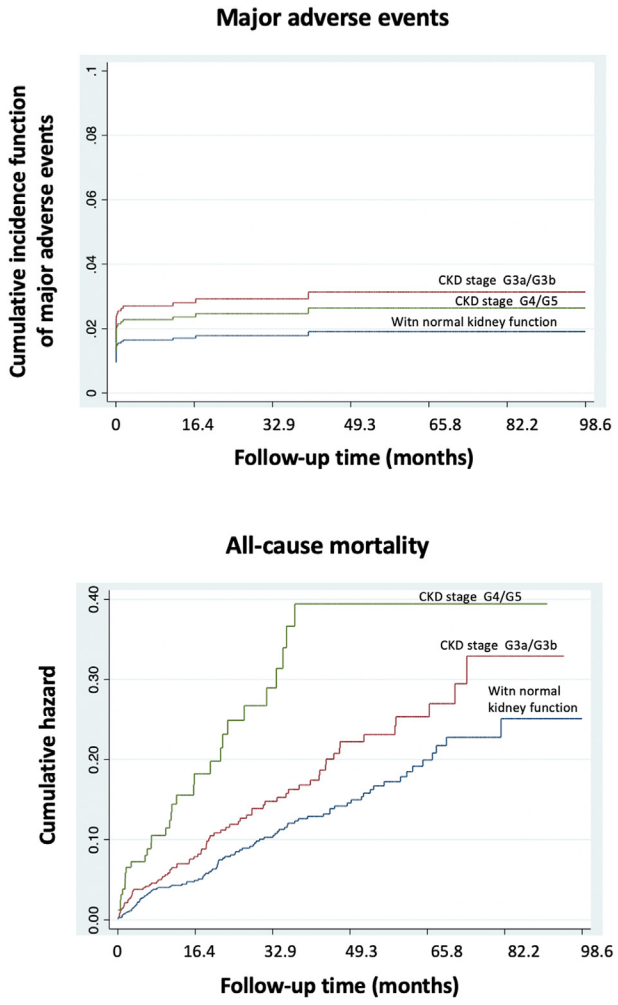

Figure 1

Top: Cumulative incidence function of major adverse events by patients grouped according to kidney function, taking into account the competing risk of death. **Below:** Cumulative hazard of all-cause mortality by patients grouped according to kidney function. CKD = chronic kidney disease; NKF = normal kidney function.

LPM electrical performance

Median R-wave sensing amplitude, PT, and pacing impedance at discharge and during follow-up are presented in Online Supplemental Figure 1 and reported in Online Supplemental Table 4. Pacing impedance and right ventricular sensing did not show any significant difference over the entire follow-up period between groups. Instead, the median PT was higher in CKD stage G3a/G3b and G4/G5 groups than in the NKF group at implantation (NKF group 0.50 V [IQR 0.35–0.70 V] vs G3a/G3b group 0.56 V [IQR 0.38–0.81 V] vs G4/G5 group 0.51 V [IQR 0.38–0.84 V] @ 0.24 ms; $P < .001$). This difference normalized after 1-month follow-up (last follow-up: NKF group 0.50 V [IQR 0.38–0.75 V] vs G3a/G3b group 0.63 V [IQR 0.37–0.88 V] vs G4/G5 group 0.50 V [IQR 0.38–0.88 V] @ 0.24 ms; $P = .110$). No specific concerns regarding differences between patients with a high PT (>1–2 V @ 0.24 ms) and those with a very high PT (>2 V @ 0.24 ms) were found (Figure 2 and Online Supplemental Table 4).

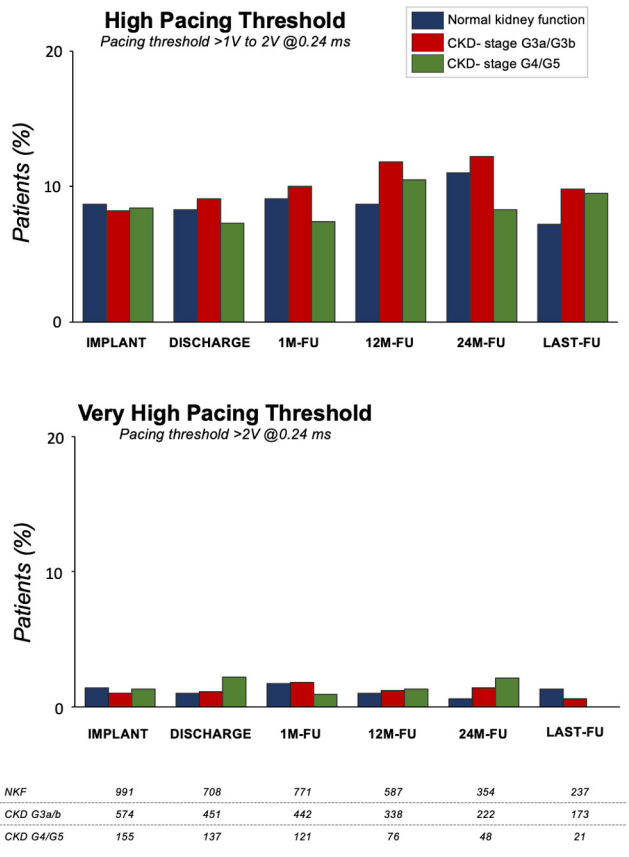

Figure 2

Comparison of leadless pacemakers with a high pacing threshold (>1–2 V @ 0.24 ms) and a very high pacing threshold (>2 V @ 0.24 cm) at different time points between the 3 groups. 1M-FU = 1-month follow-up; 12M-FU = 12-month follow-up; 24M-FU = 24-month follow-up; CKD = chronic kidney disease; Last-FU = last follow-up; NKF = normal kidney function.

Discussion

This study offers a comprehensive evaluation of LPM outcomes, comparing patients with NKF and CKD over a consistent follow-up period. The most notable findings were as follows:

1. Despite patients with CKD representing 42.4% of the overall population, only a small group (9.4%) consisted of patients with advanced stages of CKD (G4/G5).
2. The safety of LPMs, evaluated in terms of major complication rates, was similar between patients without CKD and those with CKD regardless of the stage of kidney impairment. However, all-cause mortality was higher in patients with advanced stages of CKD.
3. While R-wave sensing and pacing impedance were overall comparable between the cohorts, patients with CKD showed higher PT values only from implantation to first-month follow-up.

LPM indications in patients with CKD

Patients with CKD stages G3–G5 represent nearly 33% of patients undergoing CIED implantation, with an incidence rate 5.93-fold higher when undergoing HD.[1,16] In our study, 741 patients (42.4%) were those with CKD (stages G3–G5), thus confirming that patients with CKD represent a high proportion of patients requiring PM implantation. Nevertheless, only 9.4% of patients were in CKD stage G4/G5, of whom 75% were on HD. These data on LPM are slightly lower than data from the Micra CED study, which accounted for 48.8% of patients with LPMs and CKD, of whom 12% had ESKD.[17]

Sudden cardiac death in patients with advanced CKD is attributable to severe bradyarrhythmia in >20% of cases, which emerged rather than tachyarrhythmias as the most common and significant arrhythmic event in patients on HD.[18,19] However, despite LPM implantation preventing bradycardia, patients with more advanced renal disease showed higher all-cause mortality, even after adjusting for confounders (adjusted HR 1.90; 95% CI 1.25–2.89; $P = .003$). This potentially suggests that arrhythmic events may only be the expression of the advanced systemic clinical status of patients with advanced stages of CKD, thus confirming this population's fragility.

In addition, CKD is strongly associated with an increased and stepwise incidence of AF, which is proportional to the decrease in renal function.[20] Nevertheless, the primary reason for LPM implantation in patients with stage G4/G5 was more likely to be sinus rhythm with advanced AV block rather than slow AF. This resulted in a larger use of AV-LPMs in this subgroup. Given the very low rate of LPM implantation (9.4%) in patients with advanced CKD (stage G4/G5), one possible explanation is that patients with lower life expectancy, due to advanced renal disease and concomitant cardiovascular comorbidities (such as AF), are less likely to be offered an invasive procedure. In our cohort, the choice of an LPM over a TV-PM was primarily due to the perceived high risk of infection in patients with CKD. This choice was particularly crucial for patients with advanced CKD (stage G4/G5) because of the concomitant or potential need for HD treatment (Online Supplemental Table 1). Another issue with TV devices is the risk of central vein stenosis and thrombosis.[21,22] Because of CKD progression, these patients may depend on patent central venous access for the creation of an arteriovenous fistula, and losing a central venous access could significantly affect their survival.

Procedural characteristics

Procedural characteristics highlight how patients with CKD are perceived and underscore that they represent a more vulnerable subgroup. Therefore, particular caution during implantation is often exercised, with a septal position typically favored over alternative right ventricular sites to minimize severe complications such as pericardial effusion or cardiac tamponade. Longer procedural and radiological times may reflect these efforts and also indicate more complex procedures due to several factors, including a previously reported higher rate of transvenous lead extraction (TLE),[23] and the need to use larger amounts of contrast to ensure proper device positioning. In addition, the more advanced the CKD, the longer the in-hospital stay, likely because of concerns related to contrast-mediated kidney function deterioration and/or more complex anticoagulation management.

LPM outcomes in patients with CKD

ESKD is a well-known risk factor for CIED infection, often leading to TLE.[24,25] Notably, the absence of device-related infection or bacteremia requiring LPM removal represents a major advantage for this subset of patients.[7] To date, evidence on TV-PMs is limited to patients on HD, but no data analyzing differences across various stages of CKD have been reported. The most important finding of our study is that the major complication rate was similar between patients without CKD and those with CKD, regardless of the stage of kidney impairment. The valuable safety profile of LPM implantation in our CKD cohort is even more relevant, considering that most patients with CKD stage G4/G5 (75%) were on HD and thus at very high risk for CIED-related infection. The major complication rate in patients with CKD stage G4/G5 (2.4%) was slightly lower than what was reported by El-Chami et al[7] in patients on HD (4.9%). This could be partially explained by the overall lower number of patients on HD. No LPM-related infection events were reported in patients with CKD. A single case of device-related infection, managed with systemic antibiotic therapy, was reported in the non-CKD group. This patient, who had previously undergone a TV lead extraction procedure for endocarditis, received an LPM during the same procedure. However, this isolated event occurred in an overall high-risk cohort, given the high number of patients who had previously undergone TLE for CIED infection (12.3% in the CKD stage G3a/G3b group and 11.6% in the CKD stage G4/G5 group).

Electrical performance of the LPM in the population with CKD

The electrical features of the LPM remained within the range from implantation to last follow-up, regardless of renal function. The cumulative rates of a high PT (8.3%) and a very high PT (0.9%) after >3 years of follow-up are consistent with historical data.[26,27] However, it is noteworthy that PT was slightly higher from implantation to the 30-day follow-up period, with no differences observed during the subsequent follow-up. The higher PT in patients with CKD may be attributed to several factors affecting LPM electrical features:

1. Lower pressure applied during LPM delivery in fragile patients to minimize adverse events.
2. Higher prevalence of patients who had previously undergone TLE.
3. Light clots overlap between the LPM tines and the endocardial surface because of longer procedures.

Limitations

First, this was a nonrandomized study with inherent drawbacks due to its design. Second, CKD severity was defined on the basis of baseline renal function data, so renal disease progression was not evaluated in the 3 cohorts during follow-up. Third, the results reported are limited to the Micra LPM model and therefore should not be extended to other LPMs. Lastly, a direct comparison between patients with Micra LPM and those with TV-PM was beyond the scope of this research protocol and was thus not reported.

Conclusion

In a real-world setting, despite the high prevalence of CKD in patients undergoing LPM implantation, those with ESKD were underrepresented. Although all-cause mortality was higher in advanced CKD stages, major complications and LPM electrical performance were generally comparable across non-CKD and different CKD stages, including patients on HD. Higher PT values were observed in patients with CKD during first-month follow-up, but these differences normalized subsequently. Nonetheless, a small number of patients with a high PT were identified during follow-up, irrespective of renal function. Patients with CKD should not be excluded from LPM implantation because of frailty, as these devices are safe and offer clinical benefits for this population.

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