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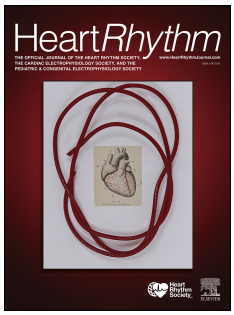

A Leadless Ventricular Pacemaker Providing Atrioventricular Synchronous Pacing in the Real-World Setting: 12-Month Results from the Micra AV Post-Approval Registry

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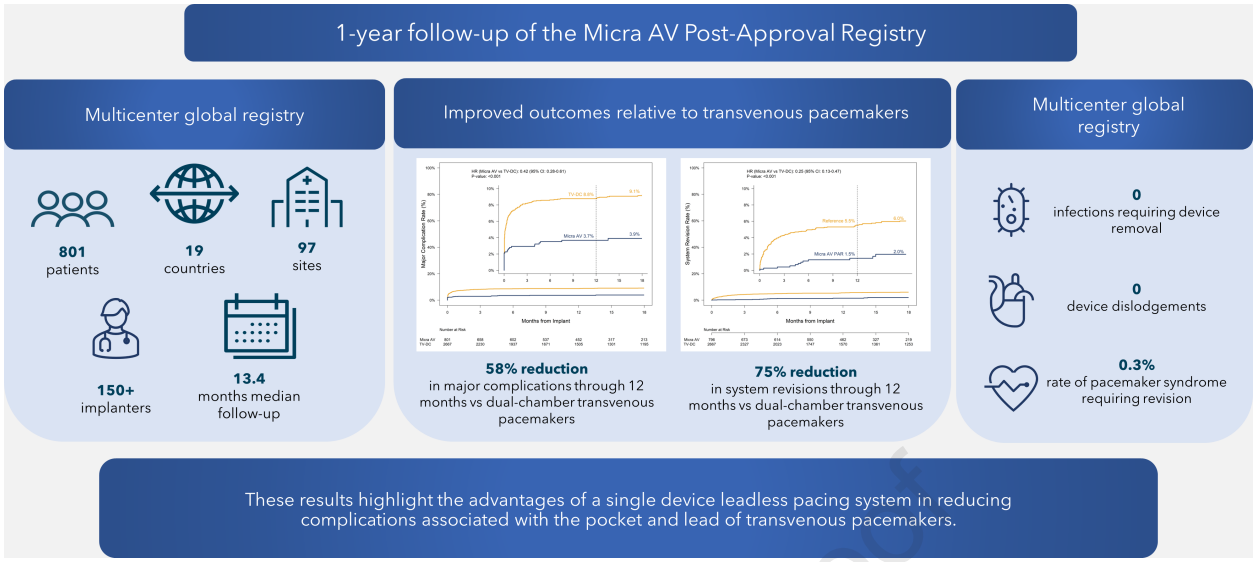

A Leadless Ventricular Pacemaker Providing Atrioventricular Synchronous Pacing in the Real-World Setting: 12-Month Results from the Micra AV Post-Approval Registry

Short title: Micra AV PAR results at 1 year

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Abstract

Background: Advances in leadless pacemaker technology have enabled accelerometer-based atrioventricular (AV) synchronous pacing by sensing atrial mechanical contraction.

Objectives: To report performance of the Micra AV leadless pacemaker from the worldwide Micra AV post-approval registry (PAR) through 12-months.

Methods: The Micra AV PAR is a prospective single-arm observational registry designed to assess safety and effectiveness of Micra AV in a real-world setting. For the present interim analysis, major complications and system revisions through 12-months were summarized and compared to a historical cohort of 2,667 transvenous dual-chamber pacing patients.

Results: The device was successfully implanted in 796 of 801 patients (99.4%) at 97 centers in 19 countries. Micra AV patients were older (74.1 vs. 71.1 years, P<0.0001) with a higher incidence of renal disease (22.3% vs. 9.8%, P<0.0001) compared to transvenous dual-chamber patients. Through 12-months, the major complication rate was 3.7% in Micra AV patients compared to 8.8% in transvenous dual-chamber patients (hazard ratio [HR]: 0.42, 95% confidence interval [CI]: 0.28-0.61; P<0.001). The system revision rate was 1.5% in Micra AV patients compared to 5.5% for transvenous dual-chamber patients (HR: 0.25, 95% CI: 0.13-0.47; P<0.001); this reduction was largely driven by the absence of lead dislodgements requiring revision. Median AV synchrony index was 79.4% (IQR:65.2%-86.4%) among patients paced >90%.

Conclusions: The Micra AV leadless pacemaker was implanted with a high rate of success in patients with multiple co-morbidities, with a significantly lower rate of complications and system revisions through 12-months compared to a historical cohort of patients with transvenous dual-chamber pacemakers.

Key words: leadless pacing; atrioventricular synchronous pacing; atrioventricular block; bradycardia; clinical trial

59 **Abbreviations**

Abbreviation	Meaning
%AM-VP	Percentage of ventricular paced events preceded by an atrial mechanical detection
%AM—VP/%VP	Atrial tracking index – percentage of ventricular paced events preceded by an atrial mechanical detection divided by ventricular pacing percentage
%VP	Ventricular pacing percentage
AV	atrioventricular
CI	Confidence interval
CRT-D	Cardiac resynchronization therapy defibrillator
CRT-P	Cardiac resynchronization therapy pacemaker
HR	Hazard ratio
IQR	Interquartile range
PAR	Post-approval registry

60

61

Introduction

Leadless ventricular pacemakers were introduced in 2013 to overcome lead and pocket related complications associated with transvenous pacemakers. Initial results from the Micra VR pivotal trial demonstrated a low 4% major complication rate, with a 48% reduction in major complications relative to transvenous pacemakers.[1] More recently, long-term observational data reported a major complication rate of 4.5% and a revision rate of 3.2% at 5 year follow-up and a reduction of 53% for both rates compared to transvenous devices[2]. These favorable results were achieved with single-chamber asynchronous ventricular pacing only-limiting its clinical use to a small percentage of pacemaker implantations. Therefore, efforts were undertaken to develop leadless atrioventricular (AV) synchronous pacing devices.

The Micra AV device was developed based on an upgrade of the software system to allow mechanical sensing of atrial contractions in order to provide AV synchronous pacing. The Accel AV study confirmed prior findings from feasibility studies[3, 4] and reported a mean AV synchrony at 3 months of 84.1%.[5]

The Micra AV Post-Approval Registry (PAR), mandated by the US Food and Drug Administration, was designed to study the safety and efficacy of the Micra AV pacemaker in “real-world” clinical practice. The primary goal of the Micra AV PAR is to estimate the rate of pacemaker syndrome resulting in system revision at 3-years post-implant. In this interim analysis, we report on the performance of the Micra AV system through 12-months post-implant.

Methods

Study Design

The Micra AV PAR is a prospective, nonrandomized, multicenter, post-approval registry designed to assess the safety and effectiveness of the Micra AV system in “real-world” clinical practice. The study enrolled patients with class I or II indications for pacing with no comorbidity restrictions and will follow

86 patients for a minimum of 3 years post-implant. The protocol was approved by the ethics committee at
87 each participating institution and all patients provided written informed consent. The research reported
88 in this paper adhered to the Declaration of Helsinki statement.

89 **Patients and Procedures**

90 All patients intended to be implanted with a market approved Micra AV device (Model MC1AVR1,
91 Medtronic, Inc, Minneapolis, MN) at participating centers were eligible. The Micra AV is implanted
92 directly into the right ventricle as previously described.[6] The Micra AV includes all the same features as
93 the predicate single-chamber Micra VR system[6] with the additional ability to use the device's
94 accelerometer to mechanically sense atrial contractions and facilitate a VDD pacing mode, promoting AV
95 synchrony in patients with normal sinus function. Detailed descriptions of the device's VDD algorithms
96 have been described previously.[3-5]

97 Following enrollment, patients underwent implant and were followed according to their
98 physicians' standard care practices. Patient and device status are reported at implant/prehospital
99 discharge, 30 days post-implant, and at least annually for a minimum of 3-years. All system- or
100 procedure-related adverse events or system revisions (e.g. device extraction, device upgrades) are
101 reported following center awareness. Additionally, for any system revisions, investigators indicated
102 whether the primary reason for revision was pacemaker syndrome as defined by HRS/ACC consensus
103 statement.[7] Centers were encouraged, but not required to transmit in-office device interrogations or
104 CareLink transmissions following each patient contact.

105 **End Points**

106 The objective of this interim analysis was to assess system- or procedure-related major complications,
107 system revision for any reason, and all-cause mortality through 12-months. Major complications were
108 defined as system- or procedure-related adverse events that resulted in death, permanent loss of device
109 function, hospitalization, prolonged hospitalization by ≥48 hours, or system revision. A clinical events

110 committee comprised of independent physicians reviewed and adjudicated all system- and procedure-
111 related events to determine relatedness and whether any related events met any of the major
112 complication criteria. System revisions included any invasive modification of the device (e.g.,
113 replacement, revision, explant) or cases where device was programmed off (OOO mode).

114 Electrical performance at implant and 6-month intervals was also characterized. In addition,
115 %AM-VP (percentage of ventricular paced events preceded by an atrial mechanical detection), atrial
116 tracking index (%AM-VP/%VP), and AV synchrony index (sum of %AM-VP, %AM-VS, and AV conduction
117 mode switch percentage) were reported for patients programmed to VDD mode at their last device
118 interrogation (provided it occurred at least 30 days following implant). The change in A4 amplitude was
119 also characterized at implant (defined as a transmission occurring within 30 days of implant) and last
120 device interrogation for patients programmed to an atrial tracking mode at both time points.

121 For comparative purposes, major complications and system revisions were compared to a
122 dataset of 2,667 patients with de novo pacemakers from 6 Medtronic sponsored studies of dual-
123 chamber pacemakers (historical transvenous dual-chamber pacemaker cohort).[6]

124 **Statistical Methods**

125 The study database was frozen for analysis on 31 July 2023. Summary statistics were obtained and
126 reported using mean ± SD or median and interquartile range (IQR) for continuous variables and
127 percentages for categorical variables. T-tests, the Wilcoxon rank-sum test (continuous variables), or the
128 Fisher's Exact test (categorical variables) were used to compare baseline and medical history variables
129 between Micra AV PAR and the historical transvenous dual-chamber cohort. All patients undergoing
130 implant attempt were included in the major complications analysis, whereas only patients with a
131 successful implant were included in the system revisions analysis. Cumulative incidence functions were
132 used to estimate the major complication rate through 12-months to account for varying follow-up time
133 and the competing risk of death unrelated to the pacing system. The Fine-Grey competing risk model

134 was used to compare the risk for system- or procedure-related major complications and system
135 revisions for any reason between the patients in the historical transvenous dual-chamber cohort and
136 patients in the Micra AV PAR with an implant attempt through 12-months implant. The Kaplan-Meier
137 method was used to estimate the all-cause mortality rate at 12-months post-implant. The Wilcoxon
138 signed-rank test was used to compare implant and follow-up A4 amplitude values.

139 Propensity score weighed Fine-Gray models were used to derive adjusted hazard ratios for the
140 comparison of major complications and system revisions between Micra AV patients and transvenous
141 patients (see **Supplement and Supplementary Table 1)**.

142 Projected battery longevity, standardized to years from implant, was computed by combining a
143 battery discharge model, circuit model, and actual use conditions obtained from each patient's last
144 available device interrogation provided it was at least 30 days post-implant. The battery longevity
145 projections assumed each patient would have six 30-minute telemetry sessions per year.

146 All analyses were performed with SAS version 9.4 (SAS Institute Inc., Cary, NC) or R statistical
147 package (www.r-project.org).

148 **Results**

149 **Patients and Follow-up**

150 A total of 801 enrolled patients underwent implant attempt at 97 centers in 19 countries between
151 February 2020 and April 2022 with a median follow-up duration of 13.4 months (IQR: 6.8 – 18.6) and
152 leading-edge follow-up of 37.9 months. Average patient age was 74.1 ± 15.1 years, 42.2% were female,
153 and reported co-morbidities included diabetes (29.7%), renal dysfunction (22.3%) including 6.5%
154 requiring dialysis, and congestive heart failure (12.1%) (**Table 1**). The most common pacing indication
155 was high degree AV block (55.8%) with 31.3% of patients having a condition precluding the use of a
156 transvenous pacemaker (see **Supplementary Table 2** for reasons for preclusion).

157 Micra AV was implanted successfully in 796 (99.4%) of the 801 patients. Reasons for
158 unsuccessful implant included 3 due to pericardial effusion, 1 due to tortuous veinous anatomy, and 1
159 due to inability to obtain a sufficiently low pacing threshold. Median procedure duration was 21.0
160 minutes (IQR: 15.0-32.0), median fluoroscopy duration was 5.0 minutes (IQR: 3.0-8.0), and 87.6% of
161 devices were placed on the right ventricular septum (**Supplementary Table 3**).

162 **Safety**

163 There were a total of 32 major complications related to the Micra AV system or procedure reported in
164 30 patients throughout the follow-up period. Of these complications, 30 occurred in 28 patients within
165 12-months post-implant for a rate of 3.7% (**Table 2**) with the majority (78.1%) occurring within 30 days
166 of implant. The most common major complication was pericardial effusion/perforation occurring in 10
167 patients (1.2%; all occurred on the day of implant). There were 8 groin access site events in 7 patients
168 (0.9%; all occurring within 30 days of implant), 3 device pacing issue events (0.4%; 2 from elevated
169 pacing threshold resulting in loss of capture and 1 due to inability to mechanically detect the atrium), 1
170 pulmonary embolism noted 3 days post-implant, and 1 ventricular dyssynchrony (AV dyssynchrony)
171 event. This event was noted 139 days post-implant during a hospitalization for dyspnea and the device
172 was programmed to VVI mode due to the inability to identify the atrial contractions on the
173 accelerometer signal.

174 There were 11 pericardial effusion events regardless of severity among the 801 patients (1.4%)
175 with 1 resulting in death following surgical intervention, 4 requiring surgical intervention, 5 requiring
176 pericardiocentesis, and 1 observed on echocardiogram, but requiring no intervention (this event was
177 not considered a major complication and is therefore not reported above). The death occurred due to
178 cardiogenic shock following cardiac tamponade and thoracotomy in an 83-year-old female with a history
179 of hypertension and a prior cardiac resynchronization therapy pacemaker (CRT-P). The pericardial
180 effusion rate increased significantly (P=0.007) with baseline pericardial effusion risk level, with patients

181 at low risk having a pericardial effusion rate of 0.6% compared to a rate of 3.8% in high risk patients
182 (**Supplementary Figure S1**).

183 **System Revisions**

184 There were 18 Micra AV system revisions in 15 patients during the follow-up period **(Figure 1)**, including
185 11 in 10 patients occurring within 12-months post-implant for a system revision rate of 1.5% through 12-
186 months. The most common reason for system revision included device upgrade/change in device type (9
187 revisions in 8 patients [3 CRT-P, 2 CRT-D, 2 dual chamber transvenous pacemaker, and 2 single chamber
188 pacemakers in 1 patient]) followed by high pacing thresholds. Three system revisions were for
189 pacemaker syndrome. The first revision occurred in a patient 113 days post-implant with the Micra AV
190 device successfully explanted and replaced with a dual chamber transvenous pacemaker. The second
191 occurred 133 days post-implant in a patient with a prior CRT-P. The Micra AV device was programmed to
192 OOO and the patient received a new CRT-P. In the third, which occurred 900 days post-implant, the
193 device was programmed to OOO and the patient received a CRT-D. There were 3 patients with a system
194 revision for pacemaker syndrome with 2 revisions occurring prior to 12-months yielding a rate of 0.29%
195 (95% CI: 0.06% - 1.00%) at 12-months. One patient had 3 separate Micra AV system revisions. The first
196 revision occurred 337 days post-implant when the patient received a single chamber transvenous
197 pacemaker (presumably with the lead placed in the conduction system) and the Micra AV was
198 programmed to OOO. Three days later the transvenous system required modification and the Micra AV
199 was programmed back to a pacing mode (therapy resumed). The transvenous system was modified 35
200 days later and the Micra AV was programmed to OOO mode.

201 Among the 18 Micra AV system revisions, the most common action to take with the device was
202 to program to OOO mode (see **Figure 1** for details on system revisions). However, the Micra AV device
203 was successfully explanted in 5 patients; there were no unsuccessful extraction attempts reported. The
204 first was explanted via a medial sternotomy 1-day post-implant due to the device being inadvertently

205 placed in the left ventricle after the delivery catheter pierced a patent foramen ovale. Following removal
206 of the device, a second Micra AV was successfully placed in the right ventricle. The remaining 4 cases
207 were percutaneous explants occurring 113 to 182 days post-implant.

208 **All-Cause Mortality**

209 There were 99 deaths during the follow-up period (**Supplementary Table 4**). Of the deaths, 1 was
210 considered procedure-related (described above). Of the remaining 98 deaths, 8 were classified as
211 sudden cardiac deaths, 15 were considered non-sudden cardiac deaths, 45 were considered non-cardiac
212 deaths (with 4 known COVID-19 deaths), with the remaining 30 having an unknown classification. The
213 all-cause mortality rate at 12-months post-implant was 9.9% and was 16.1% at 18-months
214 (**Supplementary Figure S2**).

215 **Ventricular Pacing and Atrioventricular Synchrony**

216 There were 421 patients with at least one device interrogation file that occurred 30-days post-implant
217 available for analysis. Average time from implant to last device interrogation was 16.6±9.3 months. Of
218 these patients, 326 (77.4%) were programmed to VDD mode at their last interrogation; median AV
219 synchrony index was 86.2% (IQR: 70.8%-97.3%). Median ventricular pacing was 64.3% with 133 (40.8%)
220 of patients paced >90% (**Figure 2A**). Among those paced >90%, measures of AV synchrony were similar
221 including a median %AM-VP of 79.3% (IQR: 64.9%-86.2%; **Figure 2B**), a median atrial tracking index of
222 79.4% (IQR: 66.3% - 87.0%; **Figure 2C**), and a median AV synchrony index of 79.4% (IQR: 65.2% - 86.4%;
223 **Figure 2D**). The median AV synchrony index was 98.9% (IQR: 97.1%-99.8%) in the 112 patients paced
224 <10%, indicating the benefits of the AV conduction mode switch for patients with low pacing burden.
225 Programming mode, percent ventricular pacing, and AV synchrony index varied by indication, as shown
226 in **Supplementary Table 5**. Of patients with a final interrogation and at least one device interrogation
227 within 30 days of implant (median: 0 days, IQR: 0 – 2 days), 85.5% (230 of 269) of patients programmed
228 to VDD mode at implant remained in VDD mode at their last device interrogation. Mean A4 amplitude

229 remained stable from implant (2.2±1.7 m/s^2) through follow-up (2.2±1.7 m/s^2; P=0.32; n=340 patients
230 with measure available (**Supplementary Figure S3**). Similarly, median AV synchrony index was generally
231 stable over time (**Supplementary Figure S4)**.

232 **Device Electricals**

233 Mean pacing capture threshold was 0.61±0.52 V at 0.24 ms (n=771) at implant and remained stable
234 through 18-months (0.67±0.59, n=319) (**Supplementary Figure S5**). Of the 319 patients with pacing
235 threshold data available at 18-months, 95.9% had a pacing threshold <2.0V. The mean impedance was
236 796±251Ω at implant and 567±111Ω at 18-months. The mean sensing amplitude was 10.8±4.9 mV at
237 implant and 13.5±5.5 mV at 18-months. For the 421 patients with at least one device interrogation file
238 that occurred more than 30-days post-implant median projected battery longevity was 12.1 years. For
239 the subset of 326 patients programmed to VDD mode, median projected battery longevity was 10.9
240 years with 67.8% exceeding 10 years. Among the 133 patients with >90% pacing, median projected
241 longevity was 9.8 years with 35.3% exceeding 10 years **(Supplementary Figure S6)**.

242 **Comparison to the Historical TV-DC Cohort**

243 Patients in the Micra AV PAR tended to be older, had higher incidences of diabetes and renal
244 dysfunction, but lower incidences of coronary artery disease and heart failure at baseline than did the
245 historical transvenous dual-chamber cohort (**Supplementary Table 1**).

246 Through 12-months post-implant the major complication rate for Micra AV patients was 3.7%
247 compared to 8.8% for the historical transvenous dual-chamber cohort (**Figure 3**, hazard ratio [HR]: 0.42,
248 95% confidence interval [CI]: 0.28–0.61, P<0.001). This was primarily driven by a reduction in access site
249 issues (which included pneumothorax) and pacing issues (which included lead dislodgement issues)
250 (**Supplementary Table 6**). The reduction in the risk for major complication through 12-months was
251 similar following propensity score adjustment (adjusted HR: 0.40, 95% CI: 0.24–0.67, P<0.001).

The all-cause system revision rate through 12-months for Micra AV patients was 1.5% compared to 5.5% for the historical transvenous dual-chamber cohort (HR: 0.25, 95% CI: 0.13–0.47, P<0.001) (**Figure 4**). The lower rate of system revisions was primarily driven by a reduction in revisions associated with lead dislodgement or high pacing thresholds (**Supplementary Table 7**). Following propensity score adjustment, the risk for system-revision remained lower for Micra AV patients compared to the historical transvenous dual-chamber cohort (adjusted HR: 0.37, 95% CI: 0.18–0.76, P=0.006).

Discussion

There are several notable findings from this multicenter observational registry representing the largest prospective international evaluation of the clinical safety and efficacy of the Micra AV device. First, the implant procedure was successful in 796 patients (99.4%) with a low (3.7%) rate of major complications through 12 months, confirming the high safety profile of the Micra device and procedure. Moreover, no Micra infections or dislodgements were reported in this interim analysis. Second, the system revision rate at one year was 1.5%, with only 0.3% of patients requiring system revision due to pacemaker syndrome. Finally, A4 amplitude remained stable from implant to follow-up and median AV synchrony index was 79.4% among patients paced >90%.

In addition to observing a low rate of major complications, there was a 58% reduction in major complications compared to a historical group of patients implanted with transvenous dual-chamber pacemakers. The reduction in major complications and also system revisions was primarily driven by reduction in access site events and lead dislodgements. These findings align with a recent report from the Micra AV Coverage with Evidence Development study, which reported significantly lower rates of complications at 6 months with Micra AV compared to a contemporaneous dual chamber transvenous control cohort.[8] The low rate of major complications observed with Micra AV is similar to the rates previously reported in the Micra VR IDE (4%)[1] and PAR (2.7%)[9] studies. Given that the device form factor

276 and implant procedure did not change between Micra VR and AV, safety profiles would be expected to
277 be similar.

278 The AV synchrony index reported in the present analysis (79.4%) is comparable with the
279 reported ambulatory AV synchrony reported in the AccelAV study (82.6% with programming
280 optimization).[5] A recently proposed strategy to improve AV synchrony in the first generation Micra AV
281 device in addition to a second generation device with improved AV synchrony at higher heart rates will
282 potentially enhance AV synchrony rates in the future. However, it is notable that despite achieving a
283 lower AV synchrony than would be expected from a transvenous dual-chamber pacemaker, short-term
284 (3 month) results from the AccelAV study reported no system revisions or device upgrades due to
285 pacemaker syndrome. Building upon those findings, the present analysis observed a low (0.3%)
286 incidence of pacemaker syndrome requiring system revision at 12-months. During the entire follow-up
287 period, 7 patients ultimately underwent system revision to a CRT system (5 upgrades and 2 due to
288 pacemaker syndrome). Small, single-center reports have suggested the preferential septal placement of
289 the Micra device may play a role in the low rates of pacing induced cardiomyopathy observed with
290 Micra.[10, 11] While these early results are encouraging, longer-term (3 year) follow-up of our cohort will
291 assess whether the low occurrence of pacemaker syndrome is maintained over time. Ultimately,
292 choosing this technology should involve consideration of the benefits provided by single-device leadless
293 pacing versus the need for higher degrees of AV synchrony.

294 A unique aspect of the Micra AV device is the ability to deliver AV synchronous pacing using a
295 single device implanted in the right ventricle. As Micra AV cannot stimulate the atrium, the target
296 population is patients presenting with high degree AV block and normal sinus rhythm. Although a small
297 proportion of patients with sinus node dysfunction were implanted with Micra AV in this study, this is
298 reflective of the real-world use of Micra AV as the protocol did not dictate the choice of device or pacing
299 indication. Moreover, these patients likely presented with significant comorbidities and/or a low

300 expected pacing burden , in line with class IIa HRS recommendations on pacing.[12] Schaer et al. found
301 that among patients with AV block implanted with a transvenous VDD pacemaker, only 1% of patients
302 required DDD upgrades for secondary sinus node dysfunction.[13] More recently, Breeman et al. evaluated
303 the need for atrial pacing in a population with high degree AV block and found that the need for atrial
304 pacing was very low (3-7%) and did not significantly change over time.[14] In the PAR, only 4 patients
305 underwent a system revision to a DDD transvenous pacemaker (2 due to need for device upgrade, 1 due
306 to pacemaker syndrome, and 1 due to elevated thresholds).

307 Finally, these findings confirm the safety and efficacy of a single leadless device to provide
308 atrioventricular synchronous pacing. The primary goal of a leadless pacing system is to reduce the rate
309 of acute and chronic complications relative to transvenous pacemakers. This study on Micra AV
310 emphasizes a clear reduction in major complications compared to a historical cohort of patients treated
311 with a transvenous dual-chamber pacemaker. Recently, a leadless dual chamber pacing device (Aveir
312 DR, Abbott Medical, Sunnyvale, CA) requiring the implantation of 2 separate fixed helix devices showed
313 adequate electrical performance with an overall complication rate of 8.3% at 30 days and 9.7% at 3-
314 months.[15] In the present analysis, 30 day major complications were 2.9% for Micra AV and 7.1% for DC-
315 TV. A more recent report among *de novo* patients implanted with the leadless dual chamber pacing
316 device reported stable electrical parameters through 6 months, with 3.6% of patients requiring system
317 revisions prior to their 6 month visits.[16] A similar stable electrical performance through 12 months was
318 observed with Micra AV, although the system revision rate was 1.5% through 12 months. The Aveir DR
319 leadless pacemaker was predominantly implanted in patients with sinus node disease (63.3%) with a
320 lower mean ventricular pacing rate (46%)[15] and may have potential advantages in patients with need of
321 atrial pacing.

322 **Study Limitations**

This is a prospective registry comparing the outcomes of Micra AV to a historical group of patients implanted with transvenous dual chamber devices with limitations inherent to the design of a registry. Only a randomized controlled study would allow for a direct comparison and would clearly define the benefits and drawbacks of leadless pacing compared to transvenous pacemakers. Nevertheless, this registry presents long-term prospective data on the largest international cohort of patients implanted with Micra AV. Additionally, the AV synchrony was evaluated using the AV synchrony index, a surrogate of AVS and was not verified by electrocardiogram recordings. Follow-up device transmission data frequency was left to site standard of care practices and were, therefore, not available for all patients. Additionally, the reason for pacing mode selection or changes to pacing mode was not collected. This real-world registry reflective of standard of care practices did not include prospective assessments of symptoms during exercise and instead assessed site reported major complications or system revisions due to pacemaker syndrome.

Conclusions

In this prospective, international registry, the Micra AV leadless pacemaker was implanted with a high rate of success with a low rate of major complications through 12 months. These results highlight the major advantages of a single device leadless pacing system in reducing complications associated with the pocket and lead of transvenous pacemakers. Long-term data will further assess the occurrence of chronic complications and pacemaker syndrome resulting in system revision.

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390 **Table 1: Baseline characteristics**

Patient Characteristics	Implant Attempt (N=801)
Age	
Mean ± Standard Deviation	74.1±15.1
Median	78.0
25th Percentile - 75th Percentile	68.0-84.0
Number of patients with measure available (n, %)	797 (99.5%)
LVEF (%)	
Mean ± Standard Deviation	57.9±8.9
Median	60.0
25th Percentile - 75th Percentile	55.0-64.0
Number of patients with measure available (n, %)	665 (83.0%)
Intrinsic QRS Duration (ms)	
Mean ± Standard Deviation	122.9±34.8
Median	120.0
25th Percentile - 75th Percentile	93.0 – 148.0
Number of patients with measure available (n, %)	711 (88.8%)
Gender (% Female)	42.2% (338/801)
Co-morbidities	
Atrial tachyarrhythmias	31.0% (248/801)
CHF	12.1% (97/801)
COPD	7.7% (62/801)
CAD	22.8% (183/801)
HTN	68.3% (547/801)
Diabetes	29.7% (238/801)
Renal Dysfunction	22.3% (179/801)
Dialysis	6.5% (52/801)
Condition that precludes the use of TV-PPM	31.3% (250/800)
Prior CIED	13.5% (108/801)
Pacing Indication (%)	
Bradyarrhythmia with AF	13.6% (109/801)
Sinus Node Dysfunction	13.0% (104/801)
AV Block	55.8% (447/801)
Syncope	13.4% (107/801)
Other	4.2% (34/801)
Pericardial Effusion Risk Level (%)	
Low	62.9% (487/774)
Medium	23.4% (181/774)
High	13.7% (106/774)

Abbreviations: AF = atrial fibrillation; AV = atrioventricular; CAD = coronary artery disease; CHF = congestive heart failure; CIED = cardiac implantable electronic device; COPD = chronic obstructive pulmonary disease; HTN = hypertension; TV-PPM = transvenous pacemaker

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393 **Table 2: Major complications for patients with an attempted Micra AV implant procedure (n=801)**

	Total Events (Total Patients, Cumulative %)			
Adverse Event Keyterm	**30-Days**	**12-Months**	**18-Months**	**All Events**
TOTAL EVENTS	**25 (23, 2.9%)**	**30 (28, 3.7%)**	**31 (29, 3.9%)**	**32 (30)**
THROMBOSIS	**1 (1, 0.1%)**	**1 (1, 0.1%)**	**1 (1, 0.1%)**	**1 (1)**
PULMONARY EMBOLISM	1 (1, 0.1%)	1 (1, 0.1%)	1 (1, 0.1%)	1 (1)
EVENTS AT GROIN PUNCTURE SITE	**8 (7, 0.9%)**	**8 (7, 0.9%)**	**8 (7, 0.9%)**	**8 (7)**
INCISION SITE HEMORRHAGE	1 (1, 0.1%)	1 (1, 0.1%)	1 (1, 0.1%)	1 (1)
INCISION SITE PAIN	1 (1, 0.1%)	1 (1, 0.1%)	1 (1, 0.1%)	1 (1)
POST PROCEDURAL HEMATOMA	3 (3, 0.4%)	3 (3, 0.4%)	3 (3, 0.4%)	3 (3)
POST PROCEDURAL HEMORRHAGE	1 (1, 0.1%)	1 (1, 0.1%)	1 (1, 0.1%)	1 (1)
VASCULAR ACCESS SITE HEMATOMA	1 (1, 0.1%)	1 (1, 0.1%)	1 (1, 0.1%)	1 (1)
VASCULAR PSEUDOANEURYSM	1 (1, 0.1%)	1 (1, 0.1%)	1 (1, 0.1%)	1 (1)
CARDIAC EFFUSION/PERFORATION	**10 (10, 1.2%)**	**10 (10, 1.2%)**	**10 (10, 1.2%)**	**10 (10)**
CARDIAC PERFORATION	1 (1, 0.1%)	1 (1, 0.1%)	1 (1, 0.1%)	1 (1)
CARDIAC TAMPONADE	6 (6, 0.7%)	6 (6, 0.7%)	6 (6, 0.7%)	6 (6)
PERICARDIAL EFFUSION	2 (2, 0.2%)	2 (2, 0.2%)	2 (2, 0.2%)	2 (2)
PERICARDIAL HEMORRHAGE	1 (1, 0.1%)	1 (1, 0.1%)	1 (1, 0.1%)	1 (1)
PACING ISSUES	**1 (1, 0.1%)**	**3 (3, 0.4%)**	**3 (3, 0.4%)**	**3 (3)**
DEVICE CAPTURING ISSUE	1 (1, 0.1%)	2 (2, 0.3%)	2 (2, 0.3%)	2 (2)
DEVICE SIGNAL DETECTION ISSUE	0 (0, 0.0%)	1 (1, 0.2%)	1 (1, 0.2%)	1 (1)
CARDIAC RHYTHM DISORDER	**0 (0, 0.0%)**	**1 (1, 0.1%)**	**1 (1, 0.1%)**	**1 (1)**
VENTRICULAR DYSSYNCHRONY*	0 (0, 0.0%)	1 (1, 0.1%)	1 (1, 0.1%)	1 (1)
OTHER	**5 (5, 0.6%)**	**7 (7, 0.9%)**	**8 (8, 1.2%)**	**9 (9)**
CARDIAC FAILURE	0 (0, 0.0%)	0 (0, 0.0%)	1 (1, 0.2%)	1 (1)
CEREBROVASCULAR ACCIDENT	1 (1, 0.1%)	1 (1, 0.1%)	1 (1, 0.1%)	1 (1)
DEVICE PLACEMENT ISSUE	1 (1, 0.1%)	1 (1, 0.1%)	1 (1, 0.1%)	1 (1)
DYSPNEA	1 (1, 0.1%)	1 (1, 0.1%)	1 (1, 0.1%)	1 (1)
PACEMAKER SYNDROME	1 (1, 0.1%)	3 (3, 0.4%)	3 (3, 0.4%)	3 (3)
PACING INDUCED CARDIOMYOPATHY	0 (0, 0.0%)	0 (0, 0.0%)	0 (0, 0.0%)	1 (1)
PNEUMONIA	1 (1, 0.1%)	1 (1, 0.1%)	1 (1, 0.1%)	1 (1)

Notes: 1-Month rate computed as patients with events divided by patients (801). 12-month and 18-month rates based on the cumulative incidence function. Events are grouped by a higher level grouping term (bold text) and then by the Medical Dictionary for Regulatory Activities Preferred term (plain text).

*Event description indicates this is atrioventricular dyssynchrony (see text for details).

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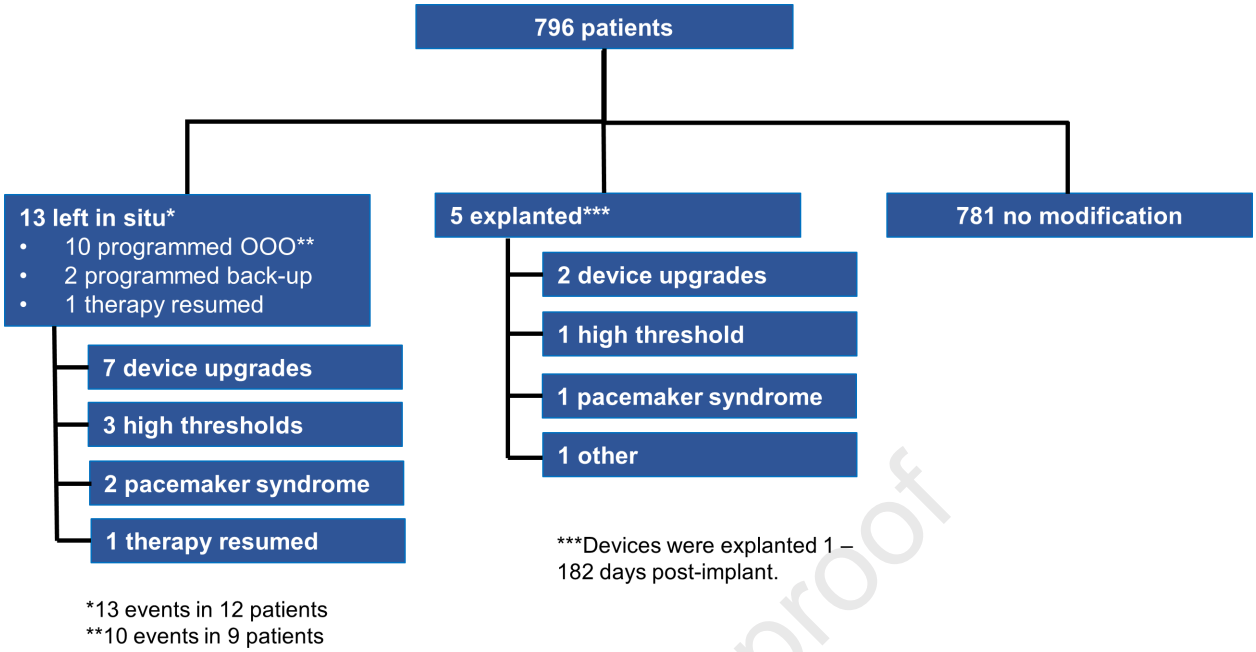
Figure legends

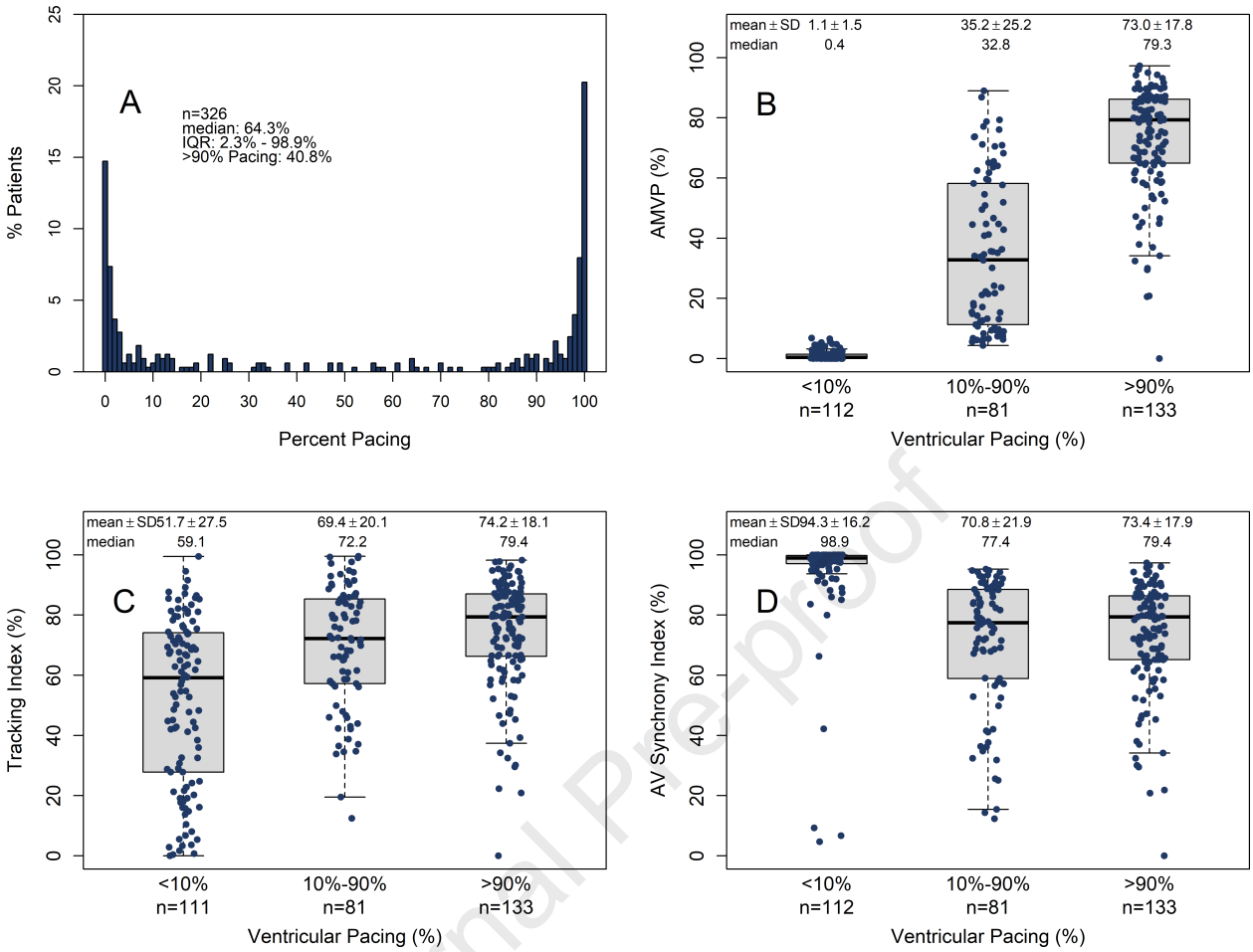
Figure 1. Disposition of system revisions. Diagram depicting number of system revisions, action taken, and reason for revision.

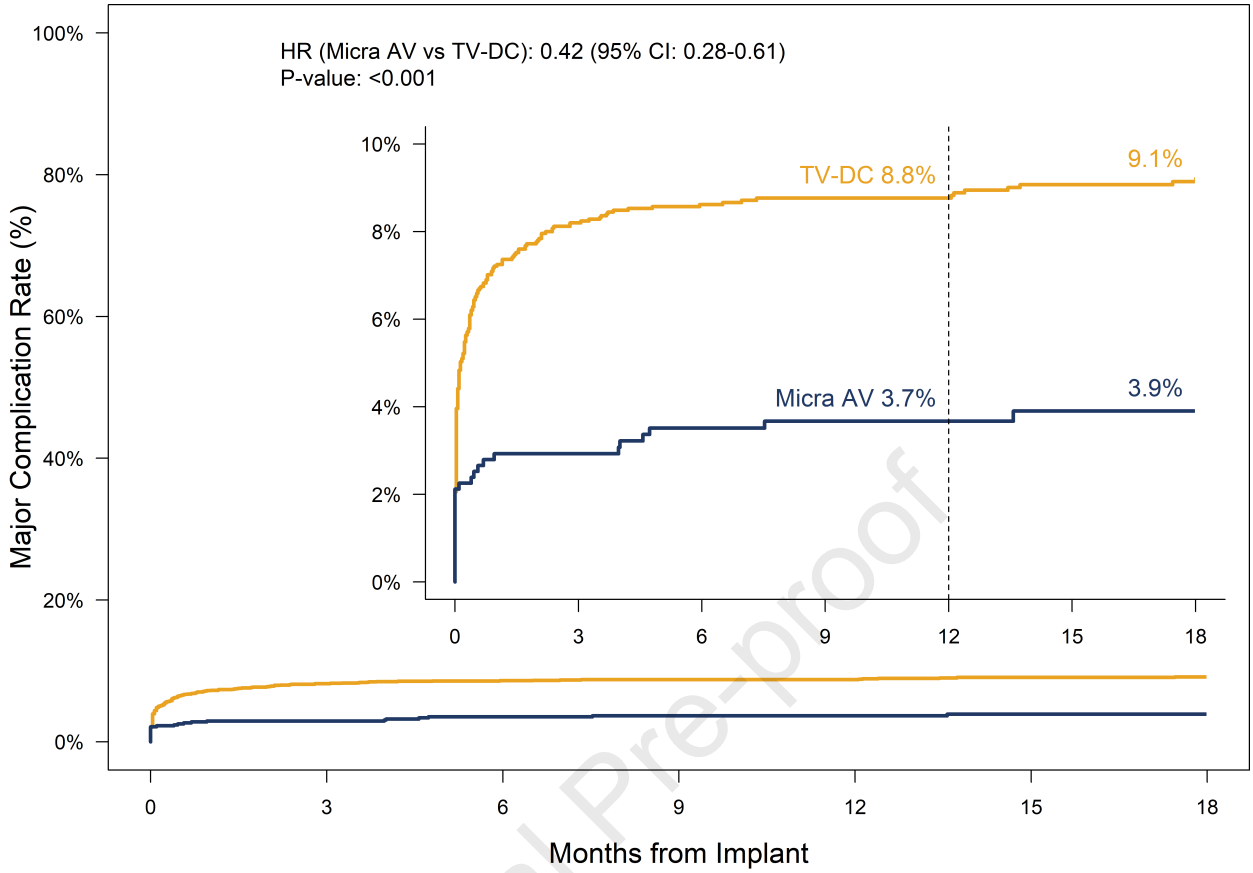
Figure 2: Ventricular pacing percentage (A), Percent ventricular paces preceded by an atrial mechanical detection (%AM-VP) by ventricular pacing percentage (B), Ventricular tracking index by ventricular pacing percentage (C), and AV synchrony index by ventricular pacing percentage (D) at last device interrogation occurring at least 30-days post-implant. Note the tracking index is defined as %AM-VP/%VP. The AV synchrony index is defined as the sum of %AM-VP, %AM-VS (ventricular senses preceded by atrial mechanical detection), and AV conduction mode switch percentage since last device interrogation session.

Figure 3: System or procedure related major complication rates during follow-up for the Micra AV PAR and historical transvenous dual-chamber cohort. Subdistributional hazard ratio based on data through 12-months post-implant as indicated by vertical dashed line. TV-DC = historical transvenous dual-chamber cohort.

Figure 4: **System revision rates for any cause through follow-up for the Micra AV PAR and historical transvenous dual-chamber cohort.** Subdistributional hazard ratio based on data through 12-months post-implant as indicated by the dashed vertical line. TV-DC = historical transvenous dual-chamber cohort.

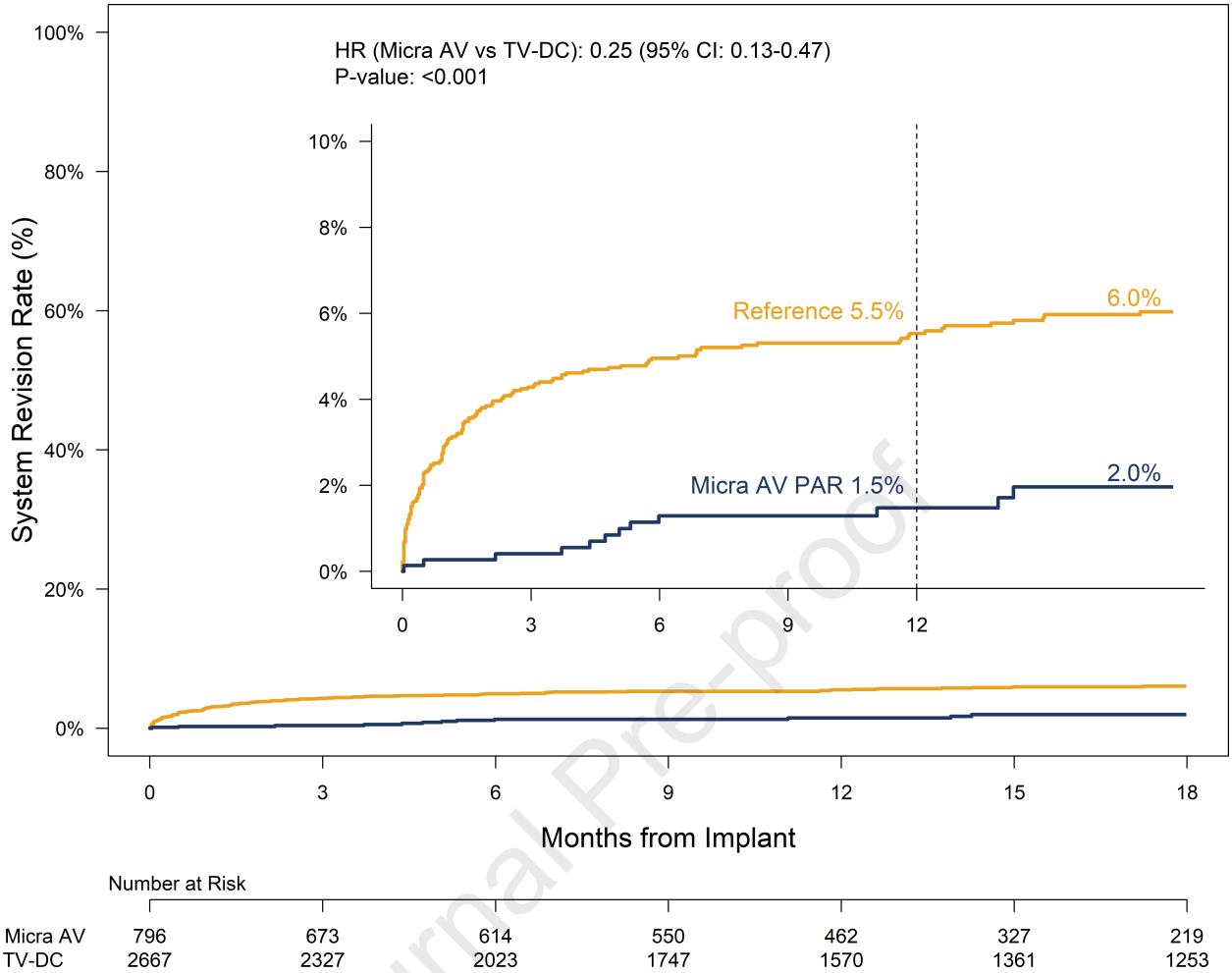






Number at Risk

Micra AV	801	658	602	537	452	317	213
TV-DC	2667	2230	1937	1671	1505	1301	1195



Number at Risk

Micra AV	796	673	614	550	462	327	219
TV-DC	2667	2327	2023	1747	1570	1361	1253

Supplement

Supplementary Statistical Methods

To account for differences in baseline and co-morbidities between Micra AV PAR patients and the 2,667 patients in historical dual-chamber transvenous cohort, propensity score overlap weights were used to derive adjusted hazard ratios for the comparison of major complications and system revisions between Micra AV patients and transvenous patients. To compute the propensity scores, a logistic regression model was used to model the likelihood of receiving Micra AV given the variables displayed in **Supplementary Table 1**. The resulting propensity scores were used to derive the overlap weight for each patient which could be used in weighted Fine-Gray models. Due to the presence of missing data, adjusted hazard ratios were computed across 100 imputed datasets using the fully conditional specification approach[1] and combined into a single estimate and 95% confidence interval using Rubin's rule.[2]

The Kruskal-Wallace test was used to compare the percentage of ventricular pacing and AV synchrony index by pacing indication.

Supplementary Table 1: **Baseline characteristics and co-morbidity comparison between Micra AV PAR and historical transvenous dual-chamber pacemaker cohort**

Patient Characteristics	Micra AV PAR (N = 801)	TV-DC cohort (N = 2667)	P-value
Age (years)			**< 0.0001**
Mean ± Standard Deviation	74.1 ± 15.1	71.1 ± 12.1	
Median	78.0	73.5	
25th Percentile - 75th Percentile	68 - 84	65 - 80	
Minimum - Maximum	16 - 96	9 - 100	
Number of Subjects with Measure Available (n, %)	797 (99.5%)	2667 (100.0%)	
Female (%)	**42.2% (338/801)**	**44.9% (1198/2667)**	**0.18**
Co-morbidities (%)			
AF	25.7% (206/801)	36.6% (977/2667)	< 0.0001
CAD	22.8% (183/801)	38.4% (1025/2667)	< 0.0001
CHF	9.9% (79/801)	15.0% (400/2667)	< 0.001
COPD	7.7% (62/801)	7.2% (53/735)	0.70
Diabetes	29.7% (238/801)	21.9% (395/1805)	< 0.0001
Hypertension	68.3% (547/801)	67.2% (1792/2667)	0.58
Renal disease	22.3% (179/801)	9.8% (26/266)	< 0.0001

Abbreviations: AF = atrial fibrillation; CAD = coronary artery disease; CHF = congestive heart failure; COPD = chronic obstructive pulmonary disease; TV-DC = historical transvenous dual-chamber cohort

Supplementary Table 2. Reasons for preclusion from transvenous pacemaker implant among Micra AV patients

Preclusion Reason[1]	**Micra Precluded (N = 250)**
Venous access issues (including thrombosis)[2]	60 (24.0%)
History of CIED infection/Bacteremia	88 (35.2%)
History of other/not-specified infection	7 (2.8%)
Cancer	50 (20.0%)
Prior complication with transvenous system	9 (3.6%)
Medical condition/high risk for complication	21 (8.4%)
Lifestyle	2 (0.8%)
Valve issues	18 (7.2%)
Other reason	14 (5.6%)

[1]A patient may have more than one reason for preclusion.
[2]Venous access issues include venous anatomy, occlussion, or need to preserve veins fo r hemodialysis.

Abbreviations: CIED = cardiac implantable electronic device

Supplementary Table 3: **Implant parameter characteristics**

Implant Characteristics	**Micra AV PAR (N = 801)**
Days Hospitalized Following Implant	
Mean ± Standard Deviation	3.2 ± 7.6
Median	1.0
25th Percentile - 75th Percentile	1 - 2
Number of Subjects with Measure Available (n, %)	792 (98.9%)
Procedure duration (min)	
Mean ± Standard Deviation	26.3 ± 18.2
Median	21.0
25th Percentile - 75th Percentile	15 - 32
Number of Subjects with Measure Available (n, %)	551 (68.8%)
Fluoroscopy duration (min)	
Mean ± Standard Deviation	7.0 ± 8.7
Median	5.0
25th Percentile - 75th Percentile	3 - 8
Number of Subjects with Measure Available (n, %)	721 (90.0%)
Implant Success	**99.4% (796/801)**
3 or Fewer Deployments (%)	**94.9% (636/670)**
Implant Location (%)	
Apex	8.5% (67/789)
Septum	87.6% (691/789)
RVOT	3.2% (25/789)
Other	0.8% (6/789)
Intra-procedure anticoagulation	
IV anticoagulation	79.8% (632/792)
Reversant use	4.6% (36/788)

Abbreviations: IV = intravascular; RVOT = right ventricular outflow tract

Supplementary Table 4: Summary of deaths during the follow-up period

Death Classification, No. Events (No. Patients, %)	Acute	Long-Term	Total
TOTAL DEATHS	**14 (1.75%)**	**85 (10.61%)**	**99 (12.36%)**
PROCEDURE/SYSTEM RELATED	1 (0.12%)	--	1 (0.12%)
SUDDEN CARDIAC DEATH	--	8 (1.00%)	8 (1.00%)
NON-SUDDEN CARDIAC DEATH	3 (0.37%)	12 (1.50%)	15 (1.87%)
NON-CARDIAC DEATH	7 (0.87%)	38 (4.74%)	45 (5.62%)
UNKNOWN CLASSIFICATION	3 (0.37%)	27 (3.37%)	30 (3.75%)

Acute follow-up period is from the day of implant attempt to 30-days post-implant. The long-term follow-up period includes the entire follow-up period beyond 30-days post-implant.

Supplementary Table 5: Percent Ventricular Pacing by Pacing Indication

Patient Characteristics	**Bradyarrhythmia with AF (N = 62)**	**SND (N = 66)**	**AV Block (N = 206)**	**Syncope (N = 71)**	**Other (N = 16)**	**P-value**
Condition that precludes use of TV-PPM	24.2% (15/62)	36.4% (24/66)	40.8% (84/206)	16.9% (12/71)	43.8% (7/16)	0.001
Pacing Mode						**< 0.0001**
VDD	46.8% (29/62)	75.8% (50/66)	86.4% (178/206)	76.1% (54/71)	93.8% (15/16)	
VVI/VVIR	53.2% (33/62)	24.2% (16/66)	13.6% (28/206)	23.9% (17/71)	6.3% (1/16)	
Pacing (%)						**< 0.0001**
Median	96.9	39.7	86.7	1.9	17.2	
25th Percentile - 75th Percentile	12 - 100	3 - 99	7 - 99	0 - 22	1 - 95	
<10%	24.2% (15/62)	34.8% (23/66)	26.2% (54/206)	66.2% (47/71)	50.0% (8/16)	
10% - 90%	21.0% (13/62)	31.8% (21/66)	27.7% (57/206)	12.7% (9/71)	18.8% (3/16)	
>90%	54.8% (34/62)	33.3% (22/66)	46.1% (95/206)	21.1% (15/71)	31.3% (5/16)	
AV Synchrony Index (%)						**< 0.0001**
Median	79.5	86.8	83.7	95.7	89.0	
25th Percentile - 75th Percentile	55 - 86	68 - 98	69 - 95	86 - 100	79 - 97	
Number of patients programmed to VDD (n, %)	29 (100.0%)	50 (100.0%)	178 (100.0%)	54 (100.0%)	15 (100.0%)	

Supplementary Table 6: System or procedure related major complications through 12-months post-implant by pacemaker system

No. Events (No. Patients, %)	Micra AV PAR (n=801)		Historical TV-DC Cohort (n=2667)	
Adverse Event Keyterm	**Acute[1]**	**12-Months[2]**	**Acute[1]**	**12-Months[2]**
TOTAL EVENTS	**25 (23, 2.9%)**	**30 (28, 3.7%)**	**217 (190, 7.1%)**	**271 (228, 8.8%)**
EMBOLISM AND THROMBOSIS	**1 (1, 0.1%)**	**1 (1, 0.1%)**	**6 (6, 0.2%)**	**7 (7, 0.3%)**
PULMONARY EMBOLISM	1 (1, 0.1%)	1 (1, 0.1%)	1 (1, 0.0%)	1 (1, 0.0%)
THROMBOSIS	--	--	0 (0, 0.0%)	1 (1, 0.0%)
VENOUS THROMBOSIS	--	--	5 (5, 0.2%)	5 (5, 0.2%)
ACCESS SITE	**8 (7, 0.9%)**	**8 (7, 0.9%)**	**38 (38, 1.4%)**	**40 (40, 1.5%)**
COMPLICATION OF DEVICE INSERTION	--	--	1 (1, 0.0%)	1 (1, 0.0%)
DEVICE EXTRUSION	--	--	0 (0, 0.0%)	1 (1, 0.0%)
IMPLANT SITE HAEMATOMA	--	--	5 (5, 0.2%)	5 (5, 0.2%)
INCISION SITE HAEMORRHAGE	1 (1, 0.1%)	1 (1, 0.1%)	--	--
INCISION SITE PAIN	1 (1, 0.1%)	1 (1, 0.1%)	--	--
MEDICAL DEVICE SITE REACTION	--	--	0 (0, 0.0%)	1 (1, 0.0%)
PNEUMOTHORAX	--	--	32 (32, 1.2%)	32 (32, 1.2%)
POST PROCEDURAL HAEMATOMA	3 (3, 0.4%)	3 (3, 0.4%)	--	--
POST PROCEDURAL HAEMORRHAGE	1 (1, 0.1%)	1 (1, 0.1%)	--	--
VASCULAR ACCESS SITE HAEMATOMA	1 (1, 0.1%)	1 (1, 0.1%)	--	--
VASCULAR PSEUDOANEURYSM	1 (1, 0.1%)	1 (1, 0.1%)	--	--
CARDIAC EFFUSION/PERFORATION	**10 (10, 1.2%)**	**10 (10, 1.2%)**	**27 (24, 0.9%)**	**30 (26, 1.0%)**
CARDIAC PERFORATION	1 (1, 0.1%)	1 (1, 0.1%)	11 (11, 0.4%)	12 (12, 0.5%)
CARDIAC TAMPONADE	6 (6, 0.7%)	6 (6, 0.7%)	4 (4, 0.1%)	4 (4, 0.1%)
PERICARDIAL EFFUSION	2 (2, 0.2%)	2 (2, 0.2%)	12 (11, 0.4%)	14 (13, 0.5%)
PERICARDIAL HAEMORRHAGE	1 (1, 0.1%)	1 (1, 0.1%)	--	--
PACING ISSUES	**1 (1, 0.1%)**	**3 (3, 0.4%)**	**78 (74, 2.8%)**	**110 (99, 3.8%)**
DEVICE CAPTURING ISSUE	1 (1, 0.1%)	2 (2, 0.3%)	9 (9, 0.3%)	11 (11, 0.4%)
DEVICE DISLOCATION	--	--	46 (44, 1.6%)	61 (58, 2.3%)
DEVICE PACING ISSUE	--	--	10 (10, 0.4%)	15 (14, 0.6%)
DEVICE SIGNAL DETECTION ISSUE	0 (0, 0.0%)	1 (1, 0.2%)	--	--
DEVICE STIMULATION ISSUE	--	--	3 (3, 0.1%)	5 (4, 0.2%)
LEAD DISLODGEMENT	--	--	7 (6, 0.2%)	14 (13, 0.5%)
OVERSENSING	--	--	0 (0, 0.0%)	1 (1, 0.0%)
UNDERSENSING	--	--	3 (3, 0.1%)	3 (3, 0.1%)
CARDIAC RHYTHM DISORDER	**0 (0, 0.0%)**	**1 (1, 0.1%)**	**16 (16, 0.6%)**	**19 (19, 0.7%)**
ATRIAL FIBRILLATION	--	--	14 (14, 0.5%)	16 (16, 0.6%)
ATRIAL FLUTTER	--	--	1 (1, 0.0%)	1 (1, 0.0%)
PACEMAKER GENERATED ARRHYTHMIA	--	--	0 (0, 0.0%)	1 (1, 0.0%)
SUPRAVENTRICULAR TACHYCARDIA	--	--	1 (1, 0.0%)	1 (1, 0.0%)
VENTRICULAR DYSSYNCHRONY	0 (0, 0.0%)	1 (1, 0.1%)	--	--
INFECTION	**--**	**--**	**4 (4, 0.1%)**	**7 (6, 0.2%)**
IMPLANT SITE INFECTION	--	--	3 (3, 0.1%)	5 (4, 0.2%)
INFECTION	--	--	1 (1, 0.0%)	2 (2, 0.1%)
MECHANICAL INTEGRITY	**--**	**--**	**4 (4, 0.1%)**	**5 (5, 0.2%)**
DEVICE CONNECTION ISSUE	--	--	4 (4, 0.1%)	4 (4, 0.2%)
DEVICE LEAD DAMAGE	--	--	0 (0, 0.0%)	1 (1, 0.0%)
OTHER	**5 (5, 0.6%)**	**7 (7, 0.9%)**	**44 (39, 1.5%)**	**53 (45, 1.8%)**
BASILAR MIGRAINE	--	--	1 (1, 0.0%)	1 (1, 0.0%)
CARDIAC FAILURE	0 (0, 0.0%)	0 (0, 0.0%)	0 (0, 0.0%)	1 (1, 0.1%)
CARDIAC FAILURE CONGESTIVE	--	--	8 (6, 0.2%)	11 (9, 0.4%)
CARDIOMYOPATHY	--	--	0 (0, 0.0%)	1 (1, 0.0%)
CEREBROVASCULAR ACCIDENT	1 (1, 0.1%)	1 (1, 0.1%)	--	--
CHEST DISCOMFORT	--	--	1 (1, 0.0%)	1 (1, 0.0%)
CHEST PAIN	--	--	2 (2, 0.1%)	3 (3, 0.1%)
CORONARY ARTERY DISEASE	--	--	5 (5, 0.2%)	5 (5, 0.2%)
DEVICE COMPUTER ISSUE	--	--	0 (0, 0.0%)	1 (1, 0.0%)
DEVICE PLACEMENT ISSUE	1 (1, 0.1%)	1 (1, 0.1%)	--	--
DRESSLER S SYNDROME	--	--	1 (1, 0.0%)	1 (1, 0.0%)
DYSPNOEA	1 (1, 0.1%)	1 (1, 0.1%)	--	--
FATIGUE	--	--	1 (1, 0.0%)	1 (1, 0.0%)
HYPERTENSION	--	--	1 (1, 0.0%)	1 (1, 0.0%)

No. Events (No. Patients, %)	Micra AV PAR (n=801)		Historical TV-DC Cohort (n=2667)	
Adverse Event Keyterm	**Acute[1]**	**12-Months[2]**	**Acute[1]**	**12-Months[2]**
LOSS OF CONSCIOUSNESS	--	--	1 (1, 0.0%)	1 (1, 0.0%)
MUSCULOSKELETAL PAIN	--	--	1 (1, 0.0%)	1 (1, 0.0%)
MYOCARDIAL INFARCTION	--	--	1 (1, 0.0%)	1 (1, 0.0%)
ORTHOSTATIC HYPOTENSION	--	--	1 (1, 0.0%)	1 (1, 0.0%)
PACEMAKER SYNDROME	1 (1, 0.1%)	3 (3, 0.4%)	--	--
PAIN IN EXTREMITY	--	--	1 (1, 0.0%)	1 (1, 0.0%)
PALPITATIONS	--	--	2 (2, 0.1%)	3 (3, 0.1%)
PERICARDITIS	--	--	4 (4, 0.1%)	4 (4, 0.2%)
PLEURAL EFFUSION	--	--	3 (3, 0.1%)	3 (3, 0.1%)
PNEUMONIA	1 (1, 0.1%)	1 (1, 0.1%)	2 (2, 0.1%)	2 (2, 0.1%)
PRESYNCOPE	--	--	1 (1, 0.0%)	1 (1, 0.0%)
PULMONARY OEDEMA	--	--	1 (1, 0.0%)	1 (1, 0.0%)
RENAL FAILURE	--	--	1 (1, 0.0%)	1 (1, 0.0%)
RESTLESSNESS	--	--	1 (1, 0.0%)	1 (1, 0.0%)
SYNCOPE	--	--	1 (1, 0.0%)	1 (1, 0.0%)
TRANSIENT ISCHAEMIC ATTACK	--	--	2 (2, 0.1%)	2 (2, 0.1%)
VASCULAR PSEUDOANEURYSM	--	--	0 (0, 0.0%)	1 (1, 0.0%)
VIRAL INFECTION	--	--	1 (1, 0.0%)	1 (1, 0.0%)

[1]Acute major complication rate computed as number of patients with event within 30-days of implant divided by number of patients with an implant attempt.
[2]12-month major complication rate based on the cumulative incidence function accounting for variable follow-up duration and a competing risk of death unrelated to the system or procedure.

Abbreviations: TV-DC = historical transvenous dual-chamber cohort

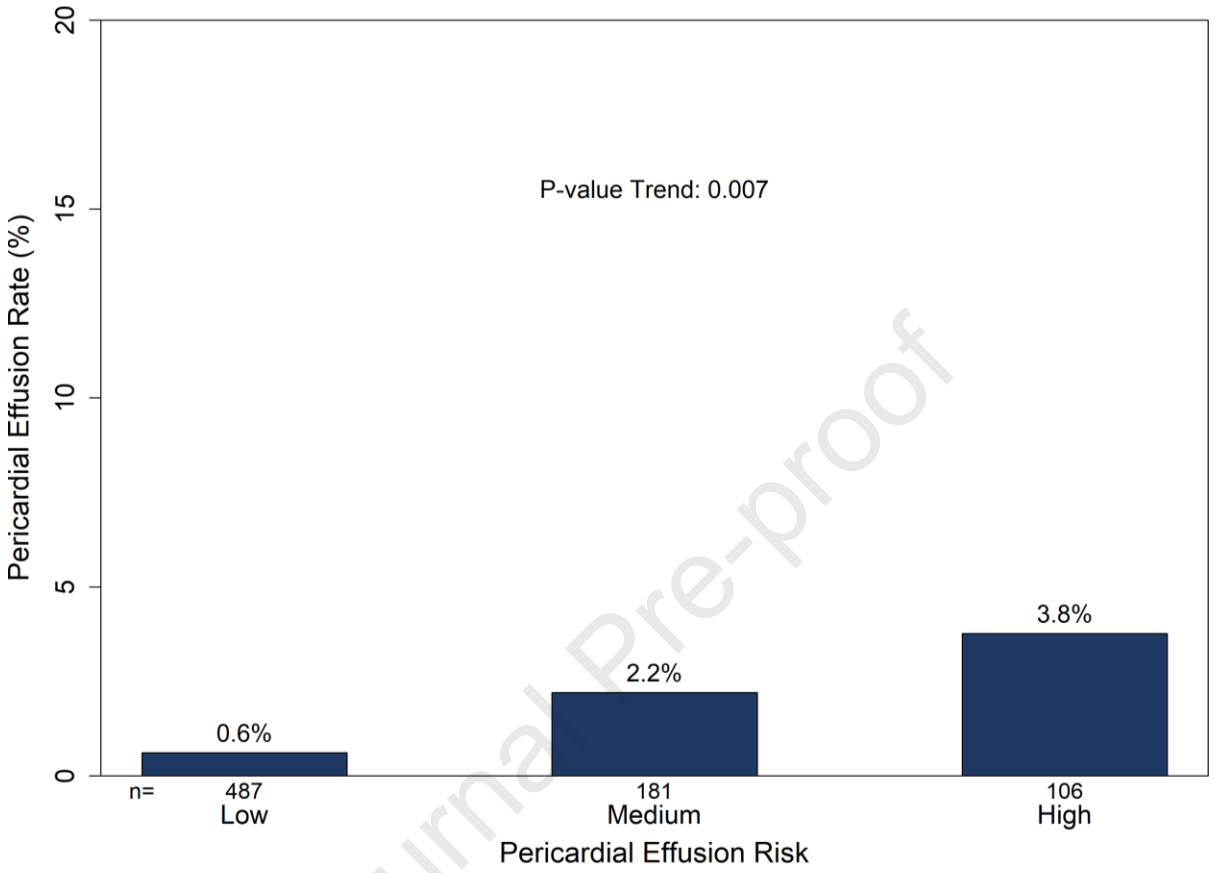
Supplementary Table 7: Summary of system revisions occurring within 12-months in the historical transvenous dual-chamber cohort.

	Revisions (Patients)
Total System Revisions	**148 (138)**
System Component Modified[1]	
Device	21 (21)
RA lead	71 (67)
RV lead	98 (94)
Reason for System Revision	
Cardiac perforation	7 (7)
Device migration	2 (2)
Device upgrade	4 (4)
High threshold	30 (29)
Infection	5 (5)
Lead dislodgement	70 (67)
Lead failure	1 (1)
Pacemaker syndrome	1 (1)
Extracardiac stimulation	7 (7)
Pocket site pain	2 (2)
Other	6 (6)
Not reported	12 (12)

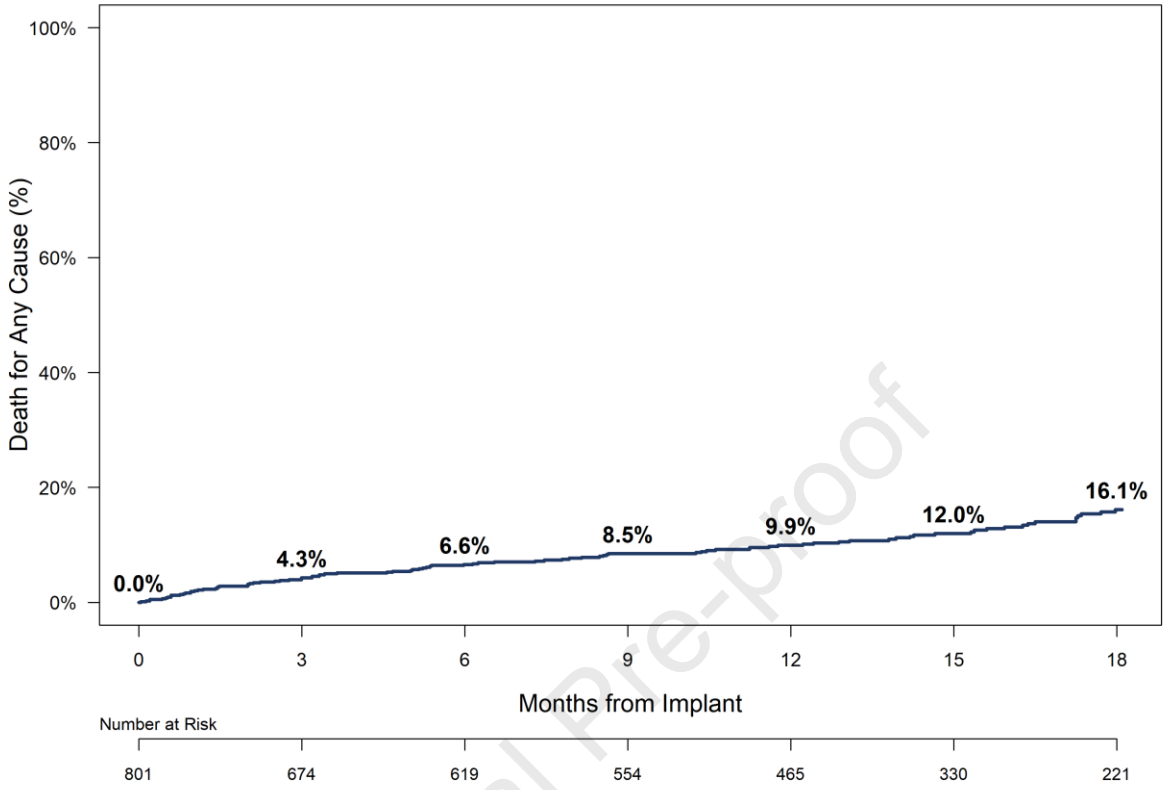
[1]More than one system component may have been modified.

Abbreviations: RA = right atrial; RV = right ventricular

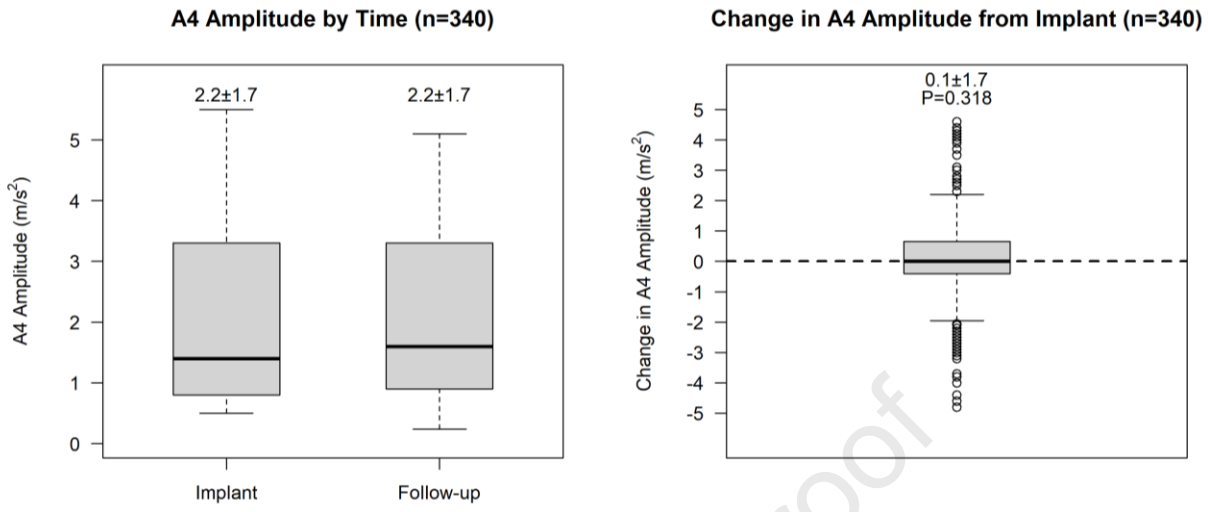
Supplementary Figure S1: Pericardial effusion rate by patient risk level. Baseline pericardial effusion risk based on Micra specific pericardial effusion risk scoring system.[3]



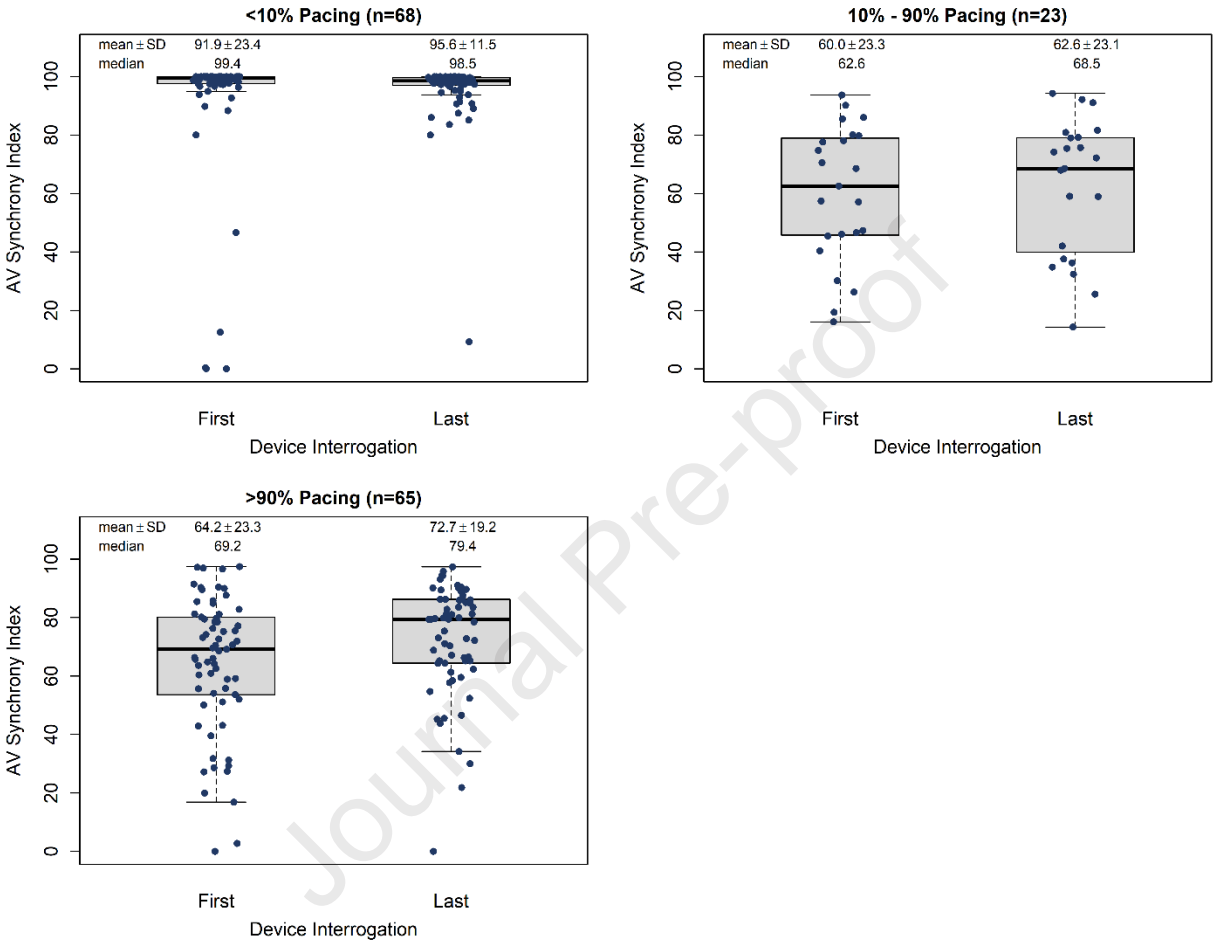
Supplementary Figure S2: All-cause mortality among Micra AV PAR patients



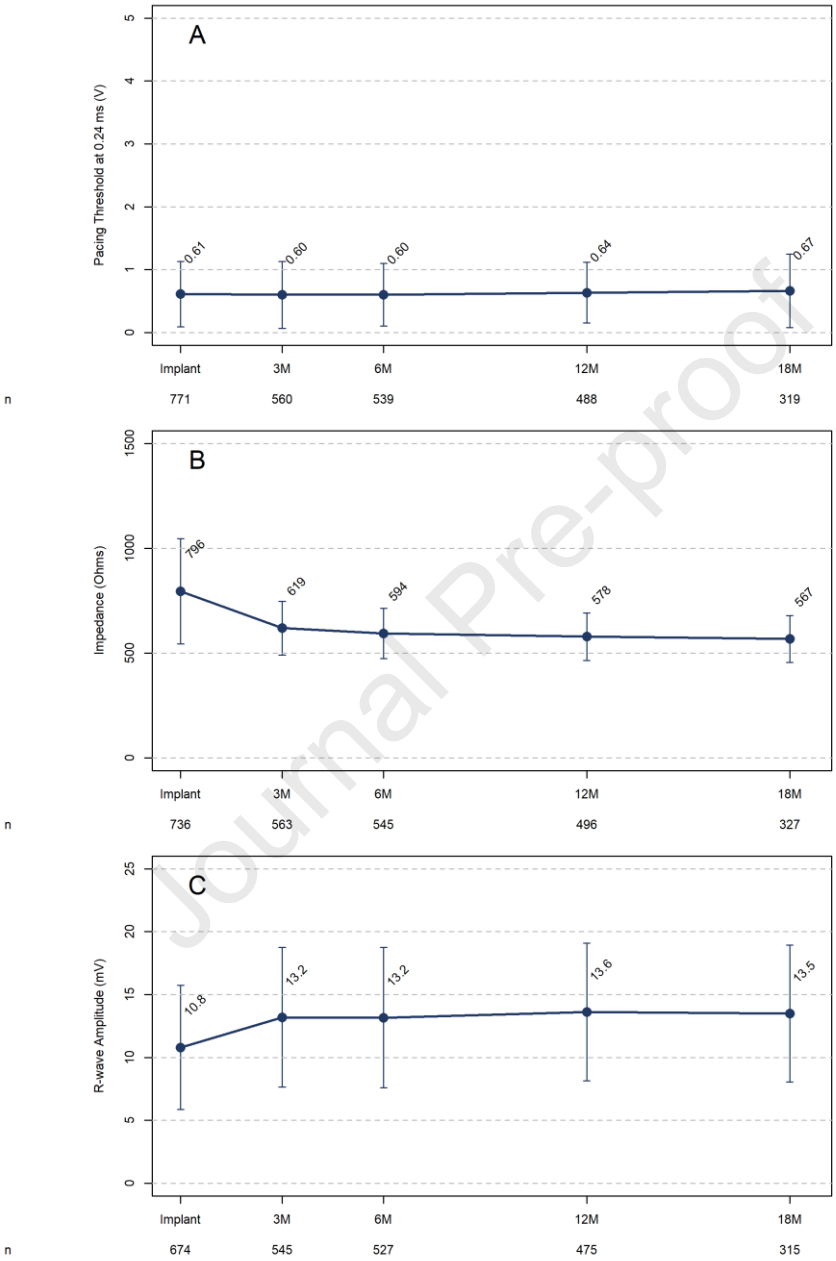
Supplementary Figure S3: **Change in A4 amplitude over time**



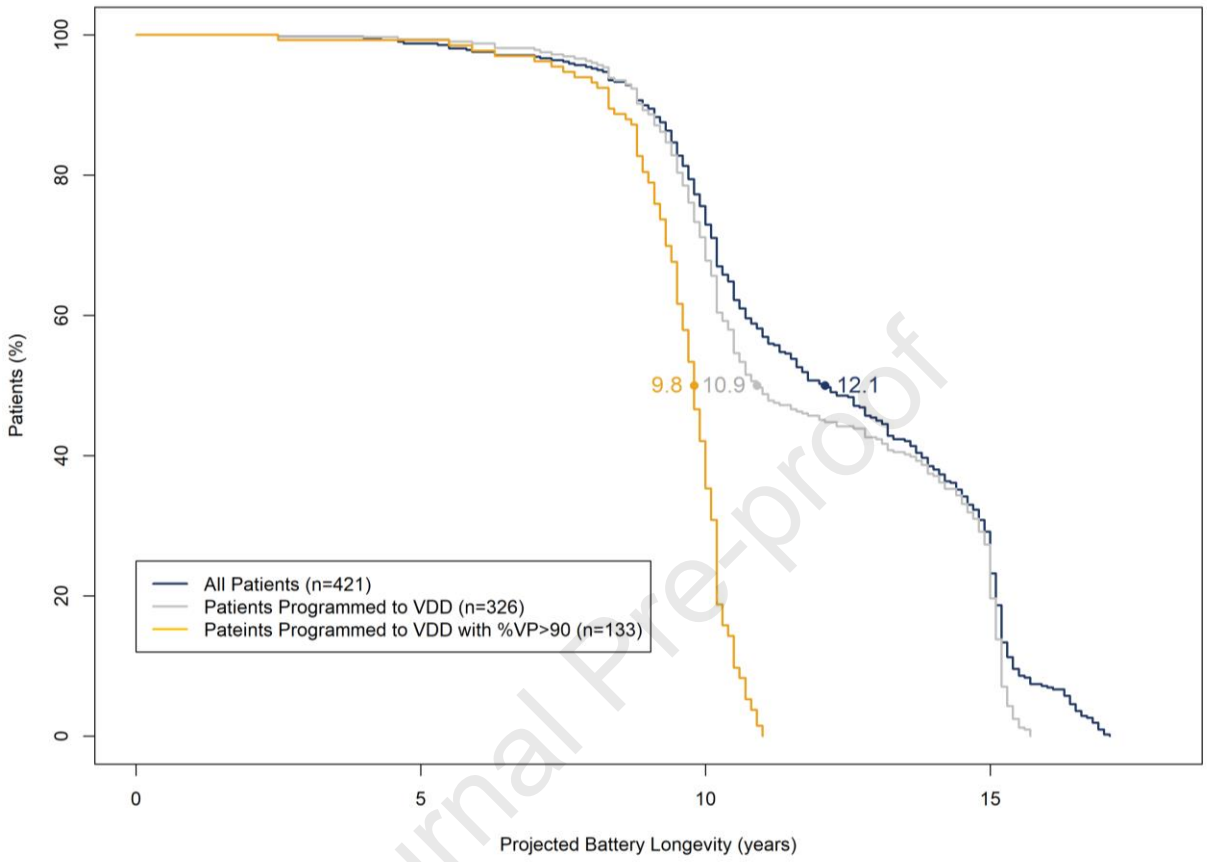
Supplementary Figure S4: Distribution of AV Synchrony Index by Ventricular Pacing Percentage over Time. The first device interrogation displays the AV synchrony index within 30-days post-implant. The last device interrogation displays the AV synchrony index at the patient's last device interrogation which occurred a median of 16.5 months (IQR: 8.7 – 22.9) post-implant. Note the n's represent the number of patients within each ventricular pacing category during both time periods.



Supplementary Figure S5: Electrical performance over time. Pacing capture threshold (A), impedance (B), and sensing amplitude (C). Error bars represent the mean ± standard deviation. n values indicate the number of patients with data available at each timepoint. n is the number of patients with an electrical value present within each visit window.



Supplementary Figure S6: Distribution of Projected Longevity by Pacing Mode and Ventricular Pacing Percentage. Closed circles indicate the median of the projected longevity distribution.



Supplementary References

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2. Rubin DB. Multiple imputation for nonresponse in surveys. Vol 81: John Wiley & Sons; 2004.

3. Piccini JP, Cunnane R, Steffel J, et al. Development and validation of a risk score for predicting pericardial effusion in patients undergoing leadless pacemaker implantation: experience with the Micra transcatheter pacemaker. Europace Jul 21 2022;24:1119-1126.