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Journal Title: Journal of atrial fibrillation
Volume: Volume 12, Number 1
Publisher: Cardiofront | 2019-06, Pages 2153-2153
Type of Work: Article | Final Publisher PDF
Publisher DOI: 10.4022/jafib.2153
Permanent URL: https://pid.emory.edu/ark:/25593/v30j8

Final published version: http://dx.doi.org/10.4022/jafib.2153

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Original Research
Journal of Atrial Fibrillation

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Abstract

Background : Data suggests that same day discharge after implantation of trans-venous pacemakers is safe and feasible. We sought to determine whether same day discharge was feasible and safe following implantation of Medtronic MICRA leadless pacemakers.

Methods : We retrospectively identified all patients undergoing MICRA placement at our institution between April 2014 to August 2018 (n=167). Patients were stratified into two groups: those discharged on the same day as their procedure (SD, n=25), and those observed for at least one night in the hospital (HD, n=142). The primary endpoint included a composite of major complications including: access site complications, new pericardial effusion, device dislodgement, and need for device revision up to approximately 45 days of follow up.

Results : SD and HD had similar age (75±13 vs. 75±13 years, p=0.923), prevalence of male sex (49 vs. 44%, p=0.669), and frequency of high-grade heart block as an indication for pacing (38 vs. 32%, p=0.596). There were more Caucasians in the SD group (72 vs. 66%, p=0.038). The rate of the composite endpoint was statistically non-significantly higher in the HD group (3.5% vs. 0.0%, p=1.00). The rates of each individual components comprising the composite endpoint were similar between groups.

Conclusions : Our data suggest that in appropriately selected patients, same day discharge can occur safely following Micra leadless pacemaker implantation.

Introduction

Currently over one million cardiac pacemakers are implanted each year, with 200,000 of those placed in the United States[1,2]. A relatively novel development in pacemaker technology is the advent of leadless pacemakers, designed to avoid long-term complications associated with traditional transvenous systems[3,4]. The Medtronic MIRCA transcatheter pacing system (TPS) is a single chamber ventricular pacemaker with functionality similar to traditional transvenous pacing systems[5-7]. It is, however, 93% smaller than traditional transvenous systems[7]. The device is implanted directly into the right ventricle via percutaneous femoral venous access and is affixed to the myocardium with 4 nitinol tines[5]. The MICRA TPS[6] has enjoyed a high rate of procedural success[5,7]. However, consensus on optimal strategies for post-implantation management for the MICRA system are yet to be established.

Same-day discharge after cardiac implantable electronic device procedures is often considered routine[8,9]. While the transvenous access required for placement of the MICRA system is large (27 French outer diameter sheath)[6], the procedural stress of implantation of leadless pacemaker devices is, in principle, similar to other transcatheter cardiovascular procedures. Longer hospital stay is typically associated with higher cost to the patient and health care system[8] and can expose patients to hospital acquired complications. Thus, elucidating the shortest time required to safely monitor patients after MICRA TPS is desirable. We sought to investigate the safety and feasibility of same-day discharge after MICRA TPS implantation.

Key Words

MICRA, Pacemaker, Discharge.

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Methods

Patient Selection

We retrospectively evaluated all patients who underwent placement of the Medtronic MICRA leadless pacemaker system from April of 2014 to May of 2018 at three hospitals within our institution (Emory University Hospital, Emory University Hospital Midtown and Emory Saint Joseph's Hospital). This study was approved by our institutional review board.

Data collection and Endpoints

We evaluated all routine medical history and pre-procedure medication information and procedural characteristics including time to discharge. We also evaluated metrics relevant to the procedure including indications for pacing, continuation of active anticoagulation during the periprocedural period, mode of sedation, fluoroscopy time (as a surrogate for difficulty of device placement), the method of hemostasis including the use of a superficial soft tissue "figure of eight" hemostatic suture[11], as each of these could potentially influence the need for further inpatient observation. We also included information regarding the status and performance of the leadless pacemaker and procedure-related complications following the procedure and during routine post-procedural follow up (typically 4-6 weeks after implantation).

Device performance at implant/discharge and up to routine first post-implant follow up were characterized. Device malfunction was defined according to the criteria used in the MICRA investigational device exemption (IDE) study[6]. Complications were grouped into 1) procedure-related major complications (death, permanent loss of device function, need for system revision or replacement with a transvenous pacing system), and 2) groin access site related complications (hematoma, retroperitoneal bleeding, pseudoaneurysm, arteriovenous fistula, infection) which were characterized as "major" for any complication that required direct intervention including medical therapy or percutaneous or operative intervention) and "minor" if they were only observed and did not require direct clinical intervention. The primary endpoint of the study was a composite of all major groin access and procedure related complications. Each individual endpoint was secondarily evaluated individually.

Statistical Analysis

Patients were categorized into two groups for analysis: those discharged on the same day as their procedure (same day discharge) and those observed at least overnight (or longer) in the hospital (hospital admission group). Among the hospital admission (HD) group, a subgroup analysis was done by stratifying the group between those admitted after placement of the MICRA TPS (n=73) and those that were admitted for other primary indications and underwent MICRA TPS during the course of their hospital stay (n=69). Among those for whom quantitative metrics from follow up device interrogations were not available, there was a subset (n=24) for whom qualitative results (i.e. "normal function" vs. "device malfunction") were available and were included in the final analysis for device malfunction. Normality of distribution of continuous variables was tested using the Kolmogorov–Smirnov test. Comparisons of continuous baseline variables across groups were performed using the Student's t-, and Mann-Whitney U tests, for normally and non-normally distributed data, respectively. The mean differences between initial and final values included those pertaining to the function of the pacemaker device: impedance (in Ohms), pacing capture threshold (in Volts), and sensing amplitude (in millivolts) were evaluated using the paired-t test for normally distributed variables, or Wilcoxon signed rank test for variables found to have non-normal distributions. Comparison of categorical variables was performed using Chi-squared and Fisher's Exact tests for binary categorical variables where appropriate, and Mann-Whitney U test for ranked ordinal level variables. All analyses was performed using IBM SPSS ver. 25 (2017; IBM SPSS Statistics for Macintosh, Version 25.0. Armonk, NY: IBM Corp).

Results

Baseline and Procedure Related Characteristics

We identified 167 patients that underwent MICRA TPS implantation during the study period. Patients in the same-day discharge (SD) group (n=25) were more often white and Hispanic compared to the HD group. The HD group had a statistically non-significant higher burden of comorbidities [Table 1] including coronary artery disease (42.2% vs. 28%), congestive heart failure (44.4% vs. 24.0%), peripheral vascular disease (20.4% vs. 8.0%), end stage renal disease (17/6% vs. 4.0%), bacteremia (8.5% vs. 0.0%), and endocarditis (5.6% vs. 0.0%).

Table 1: Baseline Clinical Characteristics

	HD (n=142)	SD (n=25)	P-level
Age (years)	75 (±13)	75 (±13)	0.923
Sex (Male)	49.3%	44.0%	0.669
Race			0.038
White	66.2%	72.0%	
African American	33.1%	20.0%	
Hispanic	0.7%	8.0%	
Other	0.0%	0.0%	
Hypertension	81.7%	80.0%	1.000
Diabetes	33.8%	36.0%	1.000
Hyperlipidemia	62.0%	64.0%	1.000
Coronary Artery Disease	42.3%	28.0%	0.194
Congestive Heart Failure			0.204
Systolic	9.9%	4.0%	
Diastolic	34.5%	20.0%	
Stroke	12.0%	12.0%	1.000
Peripheral Vascular Disease	20.4%	8.0%	0.172
Tobacco Abuse	20.4%	20.0%	1.000
COPD	16.9%	16.0%	1.000
CKD			0.238
Stage I	4.4%	16.0%	
Stage II	3.7%	0.0%	
Stage III	11.8%	8.0%	
Stage IV	5.9%	0.0%	
Stage V	4.4%	0.0%	
End Stage Renal Disease	17.6%	4.0%	0.131
Type of Renal Replacement			0.365
Hemodialysis	16.2%	4.0%	
Peritoneal Dialysis	1.4%	0.0%	
Other	0.7%	0.0%	
History of Bacteremia	8.5%	0.0%	0.217
History of Endocarditis	5.6%	0.0%	0.283
History of Syncope	26.1%	24.0%	1.000
EKG Metrics			
PR interval (ms)	199 (±82)	200 (±200)	0.620

QRSd (ms)	115 (±42)	111 (±111)	0.846
Bundle Branch Block Type			0.472
Right Bundle	19.3%	20.8%	
Left Bundle	9.3%	12.5%	
IVCD	7.1%	4.2%	
QTc (ms)	458 (±50)	456 (±41)	0.242
INR	1.61 (±0.65)	1.85 (±0.57)	0.674
Aspirin Therapy	43.3%	32.0%	0.380
Other Antiplatelet Agents	12.1%	0.0%	0.059
Statin Therapy	49.3%	56.0%	0.665
Beta Blocker	44.0%	44.0%	1.000
Calcium Channel Blocker	33.3%	36.0%	0.821
ACE/ARB Therapy	35.5%	36.0%	1.000
Aldactone	2.8%	12.0%	0.070
Antiarrhythmic Therapy	9.4%	8.0%	1.000
Warfarin	35.2%	48.0%	0.264
DOAC	26.1%	24.0%	1.000

Baseline Characteristics at the time of MICRA TPS implantation. ACE =Angiotensinogen Converting Enzyme Inhibitor; ARB=Angiotensin Receptor Blocker; CKD=Chronic Kidney Disease; COPD=Chronic Obstructive Pulmonary Disease; ; DOAC=Direct Oral Anticoagulant; EKG=Electrocardiogram; ms=milliseconds; INR=International Normalize Ratio; IVCD=(nonspecific) Interventricular Conduction Delay; QTc=Corrected QT interval.

Both groups otherwise had similar baseline characteristics including ECG characteristics and active medications [Table 1]. There was a similar distribution of indications for pacing between groups [Table 2].

There were no significant differences in procedural characteristics between groups [Table 2]. The procedure was primarily performed under moderate sedation in both groups (96.0% vs. 97.7%, p=1.00). The length of fluoroscopy time was similar between the SD and HD groups (4.1 vs. 5.3 minutes, p=0.206), as was utilization of a "figure of eight" hemostatic suture (80.0% vs. 70.4%, p=0.47). Similarly, there was no significant difference in the proportion of patients in SD and HD that underwent the procedure while on therapeutic anticoagulation (18.0% vs. 12.1%, p=1.00).

All patients had follow-up sufficient to assess groin and procedure related complications. Follow up device interrogations were available in 74% (125/167) of patients. In total, 33 patients did not have quantitative follow up interrogation data (two in the SD group and thirty-one in the HD group). These patients were either lost to follow up to the device clinic (n=26), had their device revised (n=1), or died (n=6) prior to their follow up interrogations. Interrogation data from both the time of implantation and at follow up was available in 76% (19/25) of patients in the same day discharge group and 69% (97/142) of patients in the HD group. However, after including patients for whom qualitative results were available (see Methods), follow up device function was available in 89% (149/167) of patients.

Procedural Outcomes

Baseline and follow up metrics of device function were similar between groups [Table 3].

Table 2: Procedure Related Characteristics

	HD (n=142)	SD (n=25)	P-level
Anticoagulation Interrupted	78.9%	72.0%	1.000
Indication for Pacing			0.792
Sinus Node Dysfunction	32.4%	32.0%	
AV Block	40.1%	40.0%	
His Ablation	22.5%	20.0%	
Symptomatic Bradycardia	1.4%	1.4%	
Other Indication NOS	3.5%	4.0%	
Fluoroscopy Time (minutes)	5.34 (±4.69)	4.09 (±2.89)	0.206
Anesthesia type			1.000
Moderate Sedation	97.7%	96.0%	
General Anesthesia	1.5%	4.0%	
Figure of Eight Suture Used	70.4%	80.0%	0.470
Length of Stay, Median (IQR)	0 (0)	1 (1)	N/A

Procedure related characteristics among SD and HD groups. AV=Atrioventricular; IQR=Interquartile Range; NOS=Not Otherwise Specified.

Table 3: Device Performance Metrics at Implantation and Follow up

	HD	SD	P-level
At Implantation	(N=132)	(N=22)	
Final Pacing Impedance (Ohms)	699 (±196)	768 (±177)	0.127
Final Pacing Capture Threshold (Volts)	0.631 (±0.469)	0.685 (±0.434)	0.620
Pulse Width (milliseconds)	0.329 (±0.216)	0.317 (±0.109)	0.816
Final Sensing Amplitude (in mV)	10.753 (±5.408)	10.996 (±5.554)	0.846
Lower Rate (BPM)	62 (±12)	60 (±12)	0.515
At Follow Up	(N=103)	(N=22)	
Follow up Pacing Impedance (Ohms)	614 (±123)	624 (±107)	0.729
Follow up Pacing Capture Threshold (Volts)	0.633 (±0.601)	0.768 (±0.495)	0.328
Pulse Width (milliseconds)	0.31 (±0.09)	0.3 (±0.08)	0.699
Follow up sensing amplitude (mV)	12.625 (±5.778)	13.532 (±7.12)	0.598
Follow Up Lower Rate	62 (±11)	60 (±10)	0.462
Changes from Implantation to Follow Up	(N=98)	(N=19)	
Change in Impedance (Ohms)	-98 (±171)	-155 (±100)	0.166
Change in Capture Threshold (Volts)	0.014 (±0.570)	0.016 (±0.227)	0.992
Change in Pulse Width (milliseconds)	-0.018 (±0.263)	-0.015 (±0.127)	0.965
Change in Sensing Amplitude (mV)	2.28 (±4.88)	2.59 (±4.68)	0.802
Change in Impedance (%)	-16.88 (±29.25)	-23.63(±15.06)	0.331
Change in Capture Threshold (%)	-17.78 (±73.69)	-4.98 (±35.93)	0.255
Change in Pulse Width (%)	-15.65 (±105.48)	-10.49 (±44.98)	0.844
Change in Sensing Amplitude (%)	4.59 (±89.11)	2.56 (±69.07)	0.928

Device Performance metrics from interrogations from those in whom quantitative interrogations were available. BPM=beats per minute; mV=millivolts.

Table 4: Procedure Related Complications

	HD (n=142)	SD (n=25)	P-level
Major Groin Complication	1.4% (2/142)	0% (0/25)	1.000
Hematoma	0% (0/2)	0%	
Pseudoaneurysm	50% (1/2)	0%	
Retroperitoneal Bleed	0% (0/2)	0%	
Other (including infection)	50 (1/2)%	0%	
Minor Groin Complication	2.8% (4/142)	8.0% (2/25)	0.223
Hematoma	75% (3/4)	50% (1/2)	
Pseudoaneurysm	0% (0/4)	0% (0/2)	
Retroperitoneal Bleed	0% (0/4)	0% (0/2)	
Other (including infection)	25% (1/4)	50% (1/2)	
Procedural Complications			
Pericardial Effusion	0.7% (1/142)	0% (0/25)	1.000
Any Dislodgment*	2.4% (3/125)	0%	0.226
Need for Revision of System	1.4% (2/142)	0%	1.000
Transvenous Pacemaker after MICRA	1.4% (2/142)	0%	1.000

Procedure Related Complications over total follow up time. *Among those that had follow up interrogations with quantitative or qualitative data available.

The rate of the composite endpoint was statistically non-significantly higher in the HD group (3.5% vs. 0.0%, p=1.00). There was a similar rate of major and minor groin complications between groups [Table 4].

Similarly, there was no significant difference in the rate of procedure-related compilations between either group [Table 4]. The mean length of stay for the HD group was 2.5 ± 3.5 days. The mean length of stay for those admitted after MICRA TPS was 1.4 ± 1.4 days, whereas it was 3.8 ± 4.5 days among those admitted for other reasons that underwent MICRA TPS during the course of their hospitalization (p<0.001).

Mean time to initial follow up after MICRA TPS was shorter for the SD compared to HD groups (58 ± 52 vs. 119 ± 172 days, p=0.003). However, total follow up time for the study was similar between the SD and HD groups (477 ± 429 vs. 507 ± 450 days, p=0.760).

Major Procedure Related Complications

In the HD group, two (2/140) patients developed major groin complications. One patient developed a small pseudoaneurysm and associated hematoma which resolved with observation alone and a superficial groin site infection (considered minor) treated conservatively with oral antibiotics with good result. The second developed an acute right iliac and femoral vein DVT on post-procedure day 2, in the setting of having oral anticoagulation held. Oral anticoagulation was resumed without further incident. There were no major groin complications in the same day discharge group (0/25).

Two patients in the HD group had procedure related complications. The first patient had a micro-dislodgement with significant rise in capture thresholds and required upgrade to a transvenous system approximately 6 weeks after implantation. The second had a difficult implantation with subsequent pericardial effusion and tamponade requiring drainage. The patient did eventually require upgrade to a transvenous system, but this was approximately 10 months after the procedure. There were no major procedure related complications in the same day discharge group.

Discussion

Optimal strategies for post-procedural management of MICRA TPS placement have not been described. In this small single center study, same-day discharge after MICRA TPS placement appears to be safe and feasible. We did not identify any difference in major complications, including problems with device function, procedural and access complications, between those discharged on the day of procedure compared to HD.

The goal of this study was primarily to demonstrate feasibility of early discharge among patients undergoing MICRA TPS. The goal of early discharge is this setting is to facilitate early mobility and decrease unnecessary utilization of medical resources. A wide range of lengths of stays have been previously reported for leadless pacemaker systems[13,14]. However, to the best of our knowledge, no report to date has described same day discharge among patients undergoing MICRA TPS, nor outcomes after early compared to late discharge. Ritter et al. reported that time to discharge varied widely geographically among those undergoing MICRA TPS[13]. Among those not discharged on the day of procedure, the length of stay in our study was similar to previously reported data[13].

Importantly, there were notable differences between the SD and HD groups. Patients in the HD group had a higher, albeit statistically non-significant incidence of end-stage renal disease, bacteremia and endocarditis compared to those in the SD group. The HD group was also, in part, comprised of patients admitted for other acute or decompensated illness who received a MICRA TPS as part of their overall care. Given this, the SD group represents a cohort of patients who were likely less sick and had fewer co-morbidities than the HD group. Taken together, our data suggest that same day discharge, while not appropriate for all patients, is indeed safe and feasible among properly selected patients at the discretion of the treatment team.

Our study has several limitations. Same day versus overnight observation after MICRA implantation was not randomly allocated and it's likely that selection bias played a role in identifying those felt most suitable for same day discharge. As such, it is likely that the patients that were discharged on the same day were those of lowest clinical risk. In addition, the practice of same day discharge was embraced after the investigators acquired ample experience with this procedure. However, this would still argue that, in properly selected patients and in the hands of experienced operators, same-day discharge is feasible in patients after TPS. Moreover, baseline and pre-procedural characteristics, as well as indications for pacing, were similar between groups. Second, our sample size, especially the same day discharge group, was small. As such, our ability to detect differences in rare complications was limited. Our study also suffered

from a high rate of loss to follow up in terms of quantitative device interrogations (15.6%). Furthermore, the rate of loss to follow up in this regard was higher in the hospital admission group compared to the SD group (17% vs. 8%). However, our complication rates were consistent with prior studies[5]. Likewise, the metrics of device function at implantation and on follow up that were available were consistent with prior reports[6].

Conclusion

Our data suggest that in appropriately selected individuals, same -day discharge after MICRA TPS is feasible and safe.

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