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Implantation of the Micra transcatheter pacing system: A single center North India experience

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ABSTRACT

Background: The leadless pacemaking transcatheter system, Micra, is a miniaturized, single-chamber pacemaker system. We report herein our experience with implantation of the Micra TPS system.
Objective: The current study was conducted to evaluate the safety and efficacy of the leadless Micra Transcatheter Pacemaker System (Medtronic).
Research design and methods: This was a prospective single centre nonrandomized study without controls. A transcatheter pacemaker was implanted in patients who had guideline based indications for ventricular pacing. 28 subjects were screened based on the selection criteria. Mica TPS was implanted. Parameters assessed were: duration of procedure (from femoral vein puncture to venous access closure), fluoroscopy time, number of device repositions, periprocedural electrical measurements (sensing, threshold and impedance) and in-hospital, intermediate to long term adverse events related to procedure.
Result and conclusion: s: The device was successfully implanted in 28 subjects. The mean intraoperative sensing value was 9.04 ± 1.5 mV and the impedance was 766.89 ± 213.9 Ω. At discharge from hospital, those values were 13.2 ± 15.83 mV and 855 ± 111.7, respectively. The recommended pacing threshold value as achieved in all subjects was 0.78 V, i.e. ≤ 1 V at 0.24 ms. There was no adverse event or complications reported for any of the subjects. Mean time from hospitalization to discharge was 1.5 days. Implantation of leadless pacemakers is feasible, safe and provides advantages over the conventional system.

1. Background

Cardiac pacemakers are implanted, in approximately over a million of patients every year [1]. The number of patients globally undergoing pacemaker implantation has increased steadily up [2]. The first epicardial pacing system was implanted almost 50 years ago. Ever since significant advancements in pacemaker technology has undertaken, thereby evolving of highly sophisticated, transvenous pacing systems. These high-performance devices undoubtedly contributed to the improvement of both prognosis and the quality of life of patients with bradyarrhythmias resulting from Sick Sinus Syndrome and high degree atrioventricular (AV) block [3,4]. Improvisation in the technological achievements in the field of pacing, in relation to longevity of battery and miniaturization of the device, software programme, lead performance, implantation techniques have evolved pacing as an option that is safe and reliable.

1.1. Complications of traditional pacemakers

Conventional pacemakers are associated with a significant risk of complications. Short term transvenous pacemaker-related complication rates have been reported in 9.5%–12.6% of patients [5]. Complications are related to the pocket or lead. Frequently

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encountered are the lead related problems which include pneumothorax, cardiac perforation, lead dislodgement, venous thrombosis, obstruction of branches of superior cava, regurgitation of the tricuspid valve and infections. Pocket-related complications include hematomas, skin erosion, or life-threatening pocket infections requiring extraction of the pacemaker systems [6,7]. Studies have shown that long-term complications are primarily related to lead failure, identifying it as the weakest component of the current pacing system [5,6]. Early recognition of these complications triggered the researchers to conceptualize the leadless pacemaker system in the 1970's. and successfully implanted in dogs using a mercury battery powered capsule [8]. Ever since there has been gradual development in the technology. In 2016 CE and FDA approved single-chamber right ventricular leadless cardiac pacemaker was introduced as Micra Transcatheter Pacing System (TPS; Medtronic).

1.2. Advancements in pacing technology

1) advances in component design including miniaturization and low power utilization advancements, (2) improvements in battery technology to allow adequate pacemaker longevity despite its low profile and overall size, (3) communication protocols to also minimize power utilization, 4) practical catheter-based delivery tools to negotiate the vasculature and cardiac anatomy and permit safe affixation to the myocardial wall.

1.3. Micra TPS characteristics

Table 1 depicts characteristics of Micra Pacing system [9,10,23,24]. (Fig. 1)The cathode is steroid eluting to reduce inflammation, and situated on the distal end of the pacemaker. The device is fixated by nitinol tines.The unique feature of nitinol tine design is to pulls the micra cathode into contact and constantly seeks to return to its original form.

1.4. Objective of the study

This is a prospective non randomized without control single centre study presenting an early experience with Micra leadless pacemaker placement.

2. Research Design and methods

The study was conducted in accordance with the ethical standards as laid down in the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards. Ethics approval was obtained from the Institutional Ethical Committee at Max Super Specialty Hospital, New Delhi, India. Based on the selection criteria subjects were enrolled for the study.

Table 1
Characteristic of MICRA pacing system.

CHARACTERISTICS	
Length (mm)	25.9
Volume (cm3)	0.8
Weight (grams)	2
Fixation Mechanism	Nitinol tines
Pacing Mode	VVI/R
Sensor	Accelerometer
Battery Longevity (Years)	4.7 (2.5 V @ 0.4 ms)* 10 (1.5 V @ 0.24 ms)

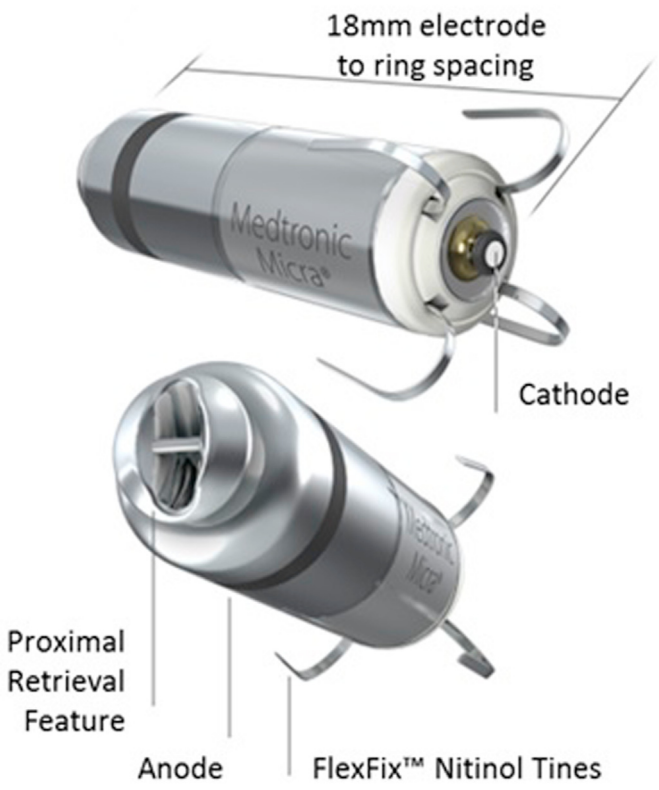


Fig. 1. Micra TPS system.

2.1. Study criteria

Inclusion criteria	Exclusion criteria
individual ≥18 years of age	pacemaker syndrome
chronic and/or permanent atrial fibrillation associated with complete heart block	retrograde ventriculoarterial (VA) conduction
sick sinus syndrome (SSS)	drop in arterial blood pressure with the onset of ventricular pacing
complete heart block (CHB)	pre-existing endocardial defibrillation with current implantation of: either conventional or subcutaneous implantable cardioverter defibrillator or cardiac resynchronization therapy
ECG findings suggestive of significant conditions and disorder	implanted vena cava filter
	evidence of thrombosis in one of the veins used for access during the procedure
	previous implanted leadless cardiac pacemaker
	Cardiovascular or peripheral vascular surgery within 30 days of enrolment

28 subjects were enrolled for this study. Written informed consent, briefing the characteristics of the new system indications and potential complications, was obtained prior from the enrolled subjects Parameters assessed were: duration of procedure (from femoral vein puncture to venous access closure), fluoroscopy time, number of device repositions, periprocedural electrical measurements (sensing, threshold and impedance) and in-hospital, intermediate to long term adverse events related to procedure. Post implantation of the device subject underwent chest radiography

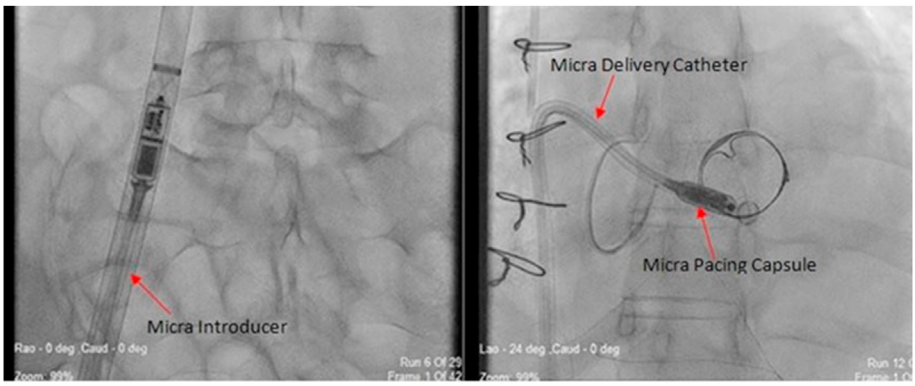


Figure: A: Percutaneous delivery MICRA B: placement of MICRA in Right Ventricle

Fig. 2. A: Percutaneous delivery MICRA B: placement of MICRA in Right Ventricle.

and standard ECG before hospital discharge. Follow-up assessments were done at 1 week, 1-3-6 months up to 3 years.

2.2. Device implantation

The Micra TPS is a single chamber ventricular pacemaker. The device was attached to a steerable catheter delivery system with catheter and inserted through a femoral vein with the use of a 23-French (outer diameter 27 F) introducer sheath. The delivery system was advanced into the right ventricle (RV), and the device was affixed to the myocardium with four electrically inactive nitinol tines located at the distal end of the device (Fig. 2).The optimal electrical measurement results were checked. In the event the electric measurement are not achieved, the system is fully repositionable while the device is still connected to the delivery system. The optimal location of device placement in the right ventricle was determined by injecting radiographic contrast. After electrical threshold testing and determining stability with a positive tug test, the device was released from the delivery system (Fig. 3, Fig. 4, Fig. 5).Vascular access site was closed with subcutaneous absorbable double 'figure-of-eight' suture followed by 4 h bandage compression used for the access site in the groin [11].

3. Results

Micra pacemaker was implanted in 28 subjects. The device were implanted through the femoral vein to the right ventricle septum.The mean age group of the subjects was 71.71 ± 8.44 years, 20 males (71%) 8 females (28%). Pacemaker indications included: Atrial Fibrillation (50%), complete heart block (25%), brady-tachycardia syndrome (7%), sinus arrest with infrequent pauses or syncope (7%), sick sinus syndrome & Morgagani Adams Stokes Syndrome (35.71%), Sick sinus syndrome (35%). Concomitant comorbidities were diabetes mellitus (39.28%) coronary artery disease (46.4%), hypertension (78.5%) chronic kidney disease (17.8%) COPD (7.1%) (Table 2). 8 subjects had infections related to the previous placement of conventional pacemakers. Mean procedure time was 1.05 ± 0.07 h. Mean fluoroscopy duration was 3.29 ± 5.34 min.

(minimum 3′1″- maximum 5′1″). Repositioning of the system and the position of the device was changed 14 patients, among them 10 patients underwent 1 time only while 2 times only in 4 subjects due to suboptimal pacing threshold or sensing value. The mean intraoperative sensing value was 9.04 ± 1.5 mV and the

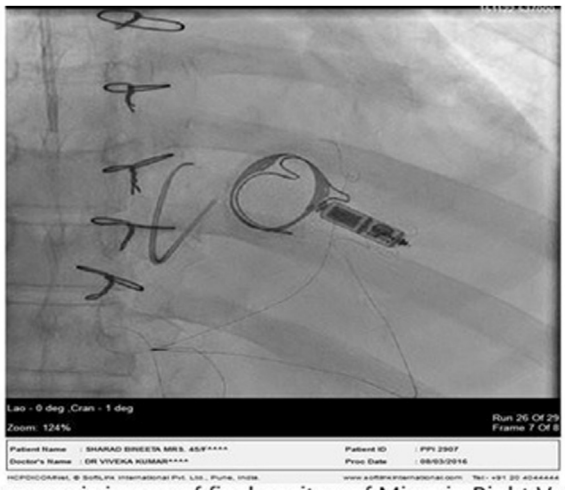


Fig. 3. Flouroscopic Image of final Position of MICRA in Right Ventricle.

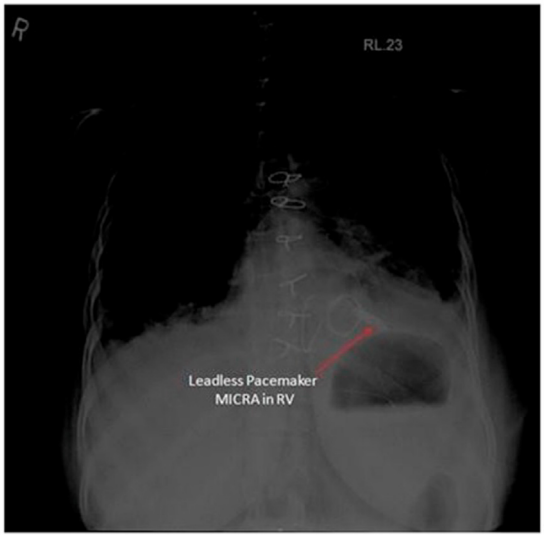
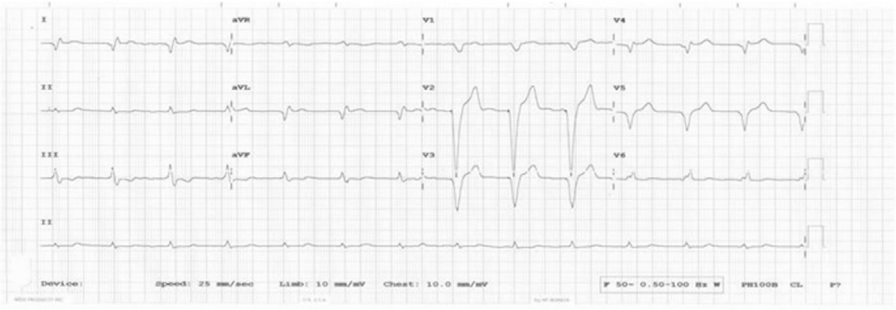


Fig. 4. PA View X- Ray chest showing position of MICRA in Right Ventricle.



ECG Showing Paced rhythm (VP) after implantation of Micra

Fig. 5. ECG Showing Paced rhythm (VP) after implantation of Micra.

Table 2
Baseline characteristics of the subjects.

Characteristics (n = 28)	Mean ± SD	N (%)
Gender		
Male	–	20 (71)
Female	–	8 (28)
Age (Years)	71.71 ± 8.4	
Comorbidity		
CAD	–	7 (39.28)
Diabetes	–	12 (465.40
Hypertension	–	19 (78.5)
CKD	–	4 (17.8)
COPD	–	2 (7.1)
LVEF	52.85 ± 4.17	–
Indication for Pacemaker – Micra		
AV block 2	–	7 (25.0)
SA with syncope	–	3 (10.7)
Bradytachy Syndrome	–	2 (7.0)
SSS-MASS	–	10 (35.7)
AV block 3	–	6 (21.4)
Average number of days in hospital	1.5 days (*hospitalization to discharge)	–
Contraindication for traditional pacemaker		
Post PPI + PI	–	8 (28.5)
Bilateral lymphoedema	–	2 (7.1)
AV Fistula thrombosis	–	2 (7.1)
NONE	–	16 (57.1)
Basal Rhythm		
AF	–	8 (28.5)
NSR paroxysmal AF	–	14 (50.0)
NSR	–	6 (21.4)

CAD = coronary artery disease, AF = atrial fibrillation, LVEF = left ventricular ejection fraction, CHB- complete heart block, SA = sinus arrest, SSS = sick sinus syndrome, MAS = morgagni adams stokes syndrome, COPD = chronic obstructive pulmonary disease, CKD = chronic kidney disease, AV = atrioventricular, NSR = normal sinus rhythm, PI = pocket infection, PPI = permanent pacemaker implantation.

impedance was 766.89 ± 213.9 Ω. At discharge from hospital, those values were 13.2 ± 15.83 mV and 855 ± 111.7 Ω, respectively. The recommended pacing threshold value as achieved in all subjects was 0.78 V, i.e. ≤ 1 V at 0.24 ms. There was no adverse event or complications reported for any of the subjects. Mean time from hospitalization to discharge was 1.5 days (Table 2, Table 3). Subjects were followed up to 3 years.

4. Discussion

Introduction of leadless pacemakers have presented advantages over conventional transvenous systems. Predominant complications are related to lead and pocket in transvenous cardiac pacing system [12]. Pacing leads and the pacemaker serve as a potential foreign body source for infections [13]. The small size, reduced surface area, and lack of lead exposed to the bloodstream appear to substantially mitigate the risk of early device infection in Micra pacemakers. Micra implantations have reported high procedural success rate of varying results: 97% [14], 95.8% [15], 99.2% success rate was reported in a full cohort of 719 patients. 6 months of follow-up, efficacy and safety of the device were evaluated against performance goals that were based on data from recipients of conventional transvenous pacemakers study [16]. A recent report from the Micra study compared matched cohorts of transvenous pacemakers, demonstrating 48% lower complications and 47% less hospitalizations at one year, driven by an 82% decrease in pacemaker revision procedures in the Micra group [17].The interim report from Micra TPS post-approval registry also showed high procedural efficacy with 99.6% successful implantations [18]. In our study the pacing devices were successfully implanted in all 28 subjects to the RV Septum confirmed by the LAO projection with contrast medium injection. The septal positioning of the pacemaker system have been reported with benefits in terms of avoiding pericardial effusion and tamponade. In the literature a trend toward

Table 3
Characteristic of the pacing procedure.

PROCEDURE CHARACTERISTICS (N = 28)		Mean ± SD	N (%)
Duration of Implantation (hours)		1.05 ± 0.07	
Duration of Fluoroscopy (Mins)		3.29 ± 5.34	–
Number of Systems Reposition			
None		–	14 (50.0)
1		–	11 (39.2)
2		–	3 (10.71)
Intraoperative electric parameters			
Sensing (mv)		9.04 ± 01.5	
Impedence (ohm)		766.89 ± 213.9	
Threshold at 024 ms (v)		0.7107 ± 0.20	
Electric parameters at discharge	**hospital**		
Sensing (mv)*		13.2 ± 15.83	
impedence (ohm)**		855 ± 111.7	
Threshold at 024 ms (v)**		0.70 ± 0.16	
Final device position ventricle	**in right**		
Apical Septum		–	5 (17.86)
Midseptum		–	15 (53.57)
High Septum		–	6 (21.42)

*V = volt, **MV = millivolt, **MS = millisecond.

more frequent septal implantations could be observed. 65.9% apical implantations in one of study compared to 39.3% in post-approval registry [19,20]. The electric parameters were maintained in all the subjects above the defined thresholds of the sensing values during the procedure and time of discharge. This is in accordance with the previous published studies [20–22]. In comparison to the traditional pacing systems, few procedural and long-term complications are reduced with leadless pacemaker but it also brings new problems i.e. vascular complications at the groin puncture site. In the IDE study arteriovenous fistula or pseudoaneurysm occurred in 5 (0.7%) patients [19]. A similar rate of vascular complications was observed in post-approval registry. Among total 0.75% of access site complications, there were 2 hematomas (0.25% of patients) [20]. The possible complications with Micra are: cardiac perforation, cardiac tamponade, large haematoma needing blood transfusion, Micra embolization. None of these complications were reported in our study during the sequence of followups.

5. Conclusion

This study was carried out at a single cardiology centre. It showed that the leadless cardiac pacemaker was capable of providing effective and safe pacemaker function in a varied group of patients who had indications for long-term pacing therapy. Leadless pacemakers have shown both safety and efficacy in the short term and long term follow-up (3 years) as an alternative to transvenous pacemakers. Our study suggests multicentre randomized controlled clinical trials of Micra TPS with long term follow up.

CRediT authorship contribution statement

Viveka Kumar: Conceptualization, Methodology, Investigation, Supervision, Formal analysis, Validation, Resources. **Rajendra Agarwal:** Methodology, Investigation, Validation, Writing - review & editing. **Mitendra Singh Yadav:** Investigation, Project administration. **Sangeeta Dhir:** Writing - original draft, Writing - review & editing. **Vivek Kumar:** Supervision, Writing - original draft.

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