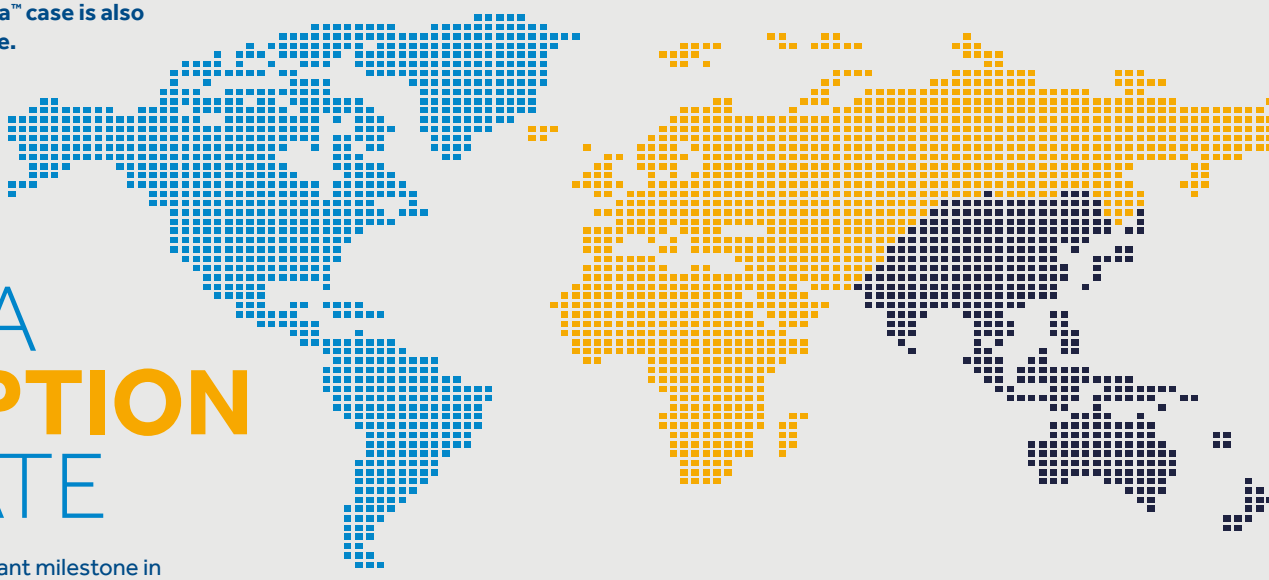
MICRA NEWS

ISSUE 2 DECEMBER 2019

Medtronic

We are very excited to launch our second Micra™ newsletter for the Europe, Middle East and Africa (EMEA) Region. The newsletter is being issued quarterly and includes content about Micra™ adoption, latest clinical evidence, reimbursement milestones, and highlights from recent events. A special Micra™ case is also featured in every issue.

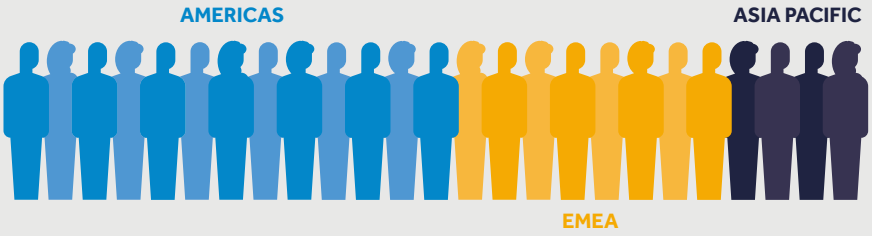
>50,000 PATIENTS TREATED WORLDWIDE



MICRA ADOPTION UPDATE

We reached an important milestone in November: **>50,000 patients have been treated with Micra™ worldwide!** Congratulations to all of you for being a part of the Micra™ family and having contributed.

Another important news is that our **Marvel 2** feasibility study data was presented at the American Heart Association's congress on November 16th in Philadelphia. You will find more information in the Clinical Evidence section.



CLINICAL EVIDENCE

REIMBURSEMENT LANDSCAPE

SPECIAL CASE

EVENT HIGHLIGHTS

CLINICAL EVIDENCE

1 LEADLESS PACEMAKER IMPLANTATION IN HEMODIALYSIS PATIENTS

The article "*Leadless pacemaker implantation in hemodialysis patients*" by Mikhael El-Chami, was published in JACC Clinical Electrophysiology, February 2019.

Leadless pacemakers may offer an attractive alternative to transvenous pacing in hemodialysis patients by preserving veins for hemodialysis while reducing the infection risk. 201 patients received a Micra™ while being on hemodialysis. In 72%, the physician felt that the patient had a condition that precluded the use of a transvenous pacemaker. Main reasons were 1. Preserve venous access (79%), 2. Prior infection (20%) and 3. Venous occlusion (17%).

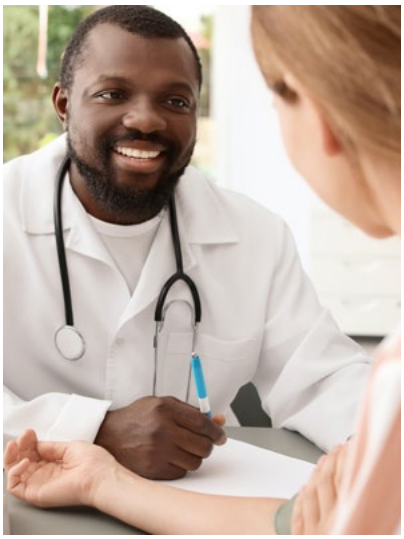
Compared to patients not on hemodialysis, the group was younger, had a higher BMI, more often CHF, CAD, cardiomyopathy, hypertension and diabetes.

Implant success rate was 98%, pacing threshold and sensing were excellent and stable. There were 3 major complications resulting in death: one patient developed a pericardial effusion requiring surgery and subsequently died on the same day; a second patient had a perforation requiring pericardiocentesis but developed sepsis 2 weeks later and died 3 weeks after implant due to septic shock; a third patient developed severe acidosis after prolonged Micra™ implant and concomitant AV node ablation and died during hospitalization. Kaplan-Meier estimated major complication rate at 12 months was 4.9% compared to 3.2% for the non-dialysis group; the hazard ratio of 1.8 however was not statistically significant.

In conclusion, Micra™ is an effective pacing option in this challenging patient population with several co-morbidities. The risk of infection is low, the upper venous circulation is spared, and the safety profile is acceptable.

LINK TO ABSTRACT >

2 ATRIOVENTRICULAR SYNCHRONOUS PACING USING A LEADLESS VENTRICULAR PACEMAKER: RESULTS FROM THE MARVEL 2 STUDY



The article *"Atrioventricular synchronous pacing using a leadless ventricular pacemaker: Results from the MARVEL 2 study"* by Clemens Steinwender was published in JACC Clinical Electrophysiology, November 2019.

Currently leadless pacemakers are only capable of single-chamber ventricular pacing. An automated, enhanced accelerometer-based algorithm to provide AV synchronous pacing, was downloaded in patients implanted with a Micra™ pacemaker and evaluated.

The primary efficacy objective, percentage AV synchronous pacing >70%, was evaluated in 40 AV block patients and was significantly higher during algorithm activation (i.e. VDD mode): 0% during VVI-50 pacing and 95% in VDD mode.

The percentage AV synchrony increased from 27% in VVI-50 to a mean of 89% and median of 94% in VDD mode. During VDD pacing, the left ventricular outflow tract velocity time interval increased by 8.8%.

In the 75 patients who received the algorithm download, no pauses or episodes of pacing-induced tachycardia were reported during VDD pacing.

In conclusion, accelerometer-based atrial sensing with an automated, enhanced algorithm significantly improved AV synchrony in patients with sinus rhythm and AV block implanted with a leadless ventricular pacemaker.

LINK TO ABSTRACT >

The use of this algorithm is currently only in the feasibility stage and is not available for commercial use in any geography.

EVENT HIGHLIGHTS

MICRA™ EMEA 5TH IMPLANTER SUMMIT

This year's implanter summit took place in Amsterdam and gathered more than 60 Micra™ implanters from 20 countries across the EMEA region. The topics below were presented by experienced Micra™ implanters.

Latest clinical data
presented by Dr P. Roberts (UK)

- Micra™ Acute Performance data shows very promising results in terms of implant success rate and major complication rate

Key procedure insights since launch
presented by Dr A. Breitenstein (CH), Dr S. Boveda (FR) and Dr K. Abozguia (UK)

- Predictable implantation time
- Electrical profile stable over time
- Same day discharge is an option in the majority of patients when using ultrasound for femoral access, septal placement and implantation early in the morning

You can access the presentations through the following:

LINK TO PRESENTATIONS >

Debate 1 on Micra™ after infection, *led by Prof. Bongiorni (IT) and Dr Breitenstein (CH)*

Conclusions:

- Micra™ is a very good option in patients after device explantation and lead extraction for infection

Micra™ in renal failure and hemodialysis
presented by Dr C. Garweg (BE)

- Micra™ preserves venous access for the future in hemodialysis/renal disease patients

Reimbursement landscape
presented by Benedict Brown (Medtronic), Dr P. Roberts (UK), Dr S. Boveda (FR), Prof. C. Steinwender (AT) and Prof. W. Jung (DE)

- Reimbursement in US/Japan is leading to single chamber penetration rates of >50%
- EMEA is advancing 'slowly but surely', with a now dedicated DRG in Switzerland, Germany and France

Debate 2 on Micra™ for vasovagal syncope (VVS) patients, *led by Prof. W. Jung (DE) and Dr P. Roberts (UK)*

Conclusions:

- Micra™ can be a suitable option for VVS patients
- Micra™ in young patients suffering from regular arrhythmia related VVS to be used as last resort
- Delay use of transvenous leads. At replacement, evaluate if VVS is still prevalent
- Using hysteresis and back-up pacing as alternative for RDR in dual chamber pacemakers

MICRA RECEIVES DRG IN GERMANY

The German DRG authority has recently published that Micra™ will receive a dedicated DRG! This is great news for Micra™ patients.

Micra™ implanting centers no longer need to apply for the innovation budget (NUB).

- The DRG covers all leadless pacemakers
- Funding is expected for renal failure, previous infections, thrombosis, cancer patients, compromised venous access, previous lead complication, risk of pneumothorax, tricuspid valve disease

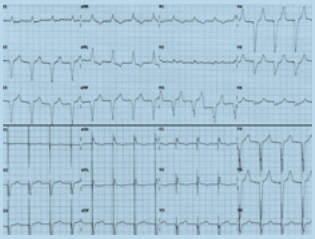
SPECIAL CASE 1

HOW TO UPGRADE A LEADLESS PACEMAKER TO CARDIAC RESYNCHRONIZATION THERAPY

Thibaud Lacour MD, Arnaud Bisson MD, Anne Bernard MD, PhD, Laurent Fauchier MD, PhD, Dominique Babuty MD, PhD, Nicolas Clementy MD

Introduction: We sought to develop an efficient method to upgrade pacing-induced cardiomyopathy (PICM) patients from a leadless pacemaker (LPM) to cardiac resynchronization therapy.

Methods and Results: Three consecutive patients with chronic atrial fibrillation, implanted with an LPM, with permanent right ventricular pacing, and who developed left ventricular systolic dysfunction due to PICM, were included. A conventional biventricular pacemaker with two different coronary sinus leads, one used for left lateral ventricular pacing, one for early right ventricular sensing, was implanted. It was then synchronized with the LPM working as the right ventricular pacing lead to provide biventricular pacing. The upgrading technique was feasible in all cases, without any perioperative complication. All patients had an improved clinical status during follow-up.



Twelve-lead ECG before (top panel) and after (low panel) the upgrading procedure in patient #2, showing significant QRS narrowing. ECG, electrocardiogram

Conclusion: This new upgrading technique allows efficient cardiac resynchronization therapy in LPM patients while preventing tricuspid valve crossing and providing an increased battery longevity.

LINK TO ABSTRACT >

SPECIAL CASE 2

EXTRACTION OF A LEADLESS PACEMAKER **23 MONTHS AFTER IMPLANTATION**

Alexander Breitenstein, Daniel Hofer, Ardan M. Saguner and Jan Steffel

A 78-year-old man suffering from symptomatic bradycardic permanent atrial fibrillation with syncope in the setting of amyloid-associated cardiomyopathy underwent uncomplicated implantation of a leadless pacemaker [Micra™ Transcatheter Pacing System (TPS)]. Although successful in the end, slightly elevated pacing thresholds were observed in several regions of the right ventricle. Ultimately, a mid-septal position with a threshold of 1.13V @ 0.24ms was accepted. After an initial stable course, pacing thresholds steadily increased over time and the battery depleted after 23 months. We decided to extract the existing Micra™ pacemaker and replace it with a conventional transvenous VVI pacemaker.

A Micra™ delivery sheath (23 Fr) was advanced to the right atrium via a right femoral access. A steerable large-curl 8.5-Fr sheath was advanced to the right ventricle via the Micra™ delivery sheath. A 6-Fr Amplatz Goose Neck Snare (25mm) was placed over the body of the Micra™ pacemaker. From there, the loop was closed and pulled back to engage the proximal retrieval feature of the device. The device could be removed safely from the right ventricular wall by gentle manual traction and pulled back into the right atrium, and removed from the body. A thorough inspection of the extracted device demonstrated nearly no adhesions surrounding the pacemaker including the nitinol tines.

LINK TO ABSTRACT >

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