MICRA NEWS

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Medtronic

We are very excited to launch our third 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.

THE MICRA JOURNEY:

TODAY
MICRA™ VR (VVIR)
- Ventricular pacing & sensing
- World's smallest pacemaker
- 1st transcatheter pacemaker FDA and CE Marked

2020
MICRA™ AV (VDD)
- Designed to provide AV synchrony
- Ventricular pacing & sensing
- Atrial sensing via mechanical accelerometer
- Pending CE Mark, currently not available for use in Europe, Middle East and Africa

FUTURE
MICRA™ DDD (DDDR)
- Modular design provides flexible implant
- In development stage, no CE Mark and not available for use

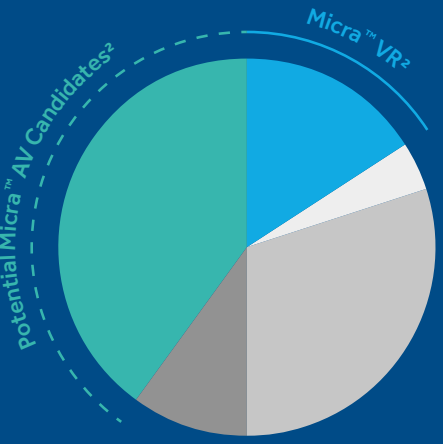
ON THE WAY TO A DUAL CHAMBER SOLUTION

Our first Micra™ (Micra™ VR) was commercially released in June 2015. We are about to celebrate the 5th anniversary of Micra™ in EMEA and we soon expect commercial launch of Micra™ AV (currently pending CE Mark and not available for use in EMEA). Micra™ AV has been designed to provide AV synchrony[1], allowing more patients to benefit from leadless pacing. We look forward to our continued partnership.

1. Medtronic Micra™ AV MC1AVR1 Reference Manual. January 2020.

Pacemaker Indications

- **AVB + AF**
- **Other**
- **SND only**
- **SND + AVB**
- **AVB only**



With Micra™ AV, more patients will be able to benefit from leadless pacing.

2. Lewis D, Whiting J. Bradycardia Indication Breakdown. January 2020. Medtronic data on file.

CLINICAL EVIDENCE

EVENT HIGHLIGHTS

REIMBURSEMENT LANDSCAPE

SPECIAL CASE

CLINICAL EVIDENCE

1 LEADLESS PACEMAKER IMPLANTATION: A FEASIBLE AND REASONABLE OPTION IN TRANSCATHETER HEART VALVE REPLACEMENT PATIENTS

The article "Leadless pacemaker implantation: A feasible and reasonable option in transcatheter heart valve replacement patients" by Sarah Moore, was published in PACE, May 2019.

This retrospective study compares the performance of leadless pacemakers with conventional transvenous pacemakers in patients after transcatheter valve replacement.

10 patients with leadless pacemakers were compared with 23 patients undergoing transvenous pacemaker implantations.

There were two post-operative complications in the conventional group: one pneumothorax and one pocket infection which required device removal. One patient in the leadless group developed a pseudoaneurysm which was treated with a covered stent. This happened early in the experience, before the use of ultrasound for femoral puncture became standard.

Leadless pacemakers perform as well as conventional pacemakers, have less tricuspid regurgitation and showed decreased blood loss during the procedure.

Therefore leadless pacemakers should be considered in this patient population.

LINK TO ABSTRACT >

2 QUALITY OF LIFE OF PATIENTS UNDERGOING CONVENTIONAL VS LEADLESS PACEMAKER IMPLANTATION: A MULTICENTER OBSERVATIONAL STUDY

The article "Quality of life of patients undergoing conventional vs leadless pacemaker implantation: A multicenter observational study" by Pilar Cabanas-Grandío was published in the Journal of Cardiovascular Electrophysiology in December 2019.

This observational study compares the quality of life of patients receiving a leadless pacemaker with those receiving a single chamber transvenous pacemaker.

The quality of life between 42 patients with a Micra™ was compared with 64 patients with a conventional pacemaker using the SF-36 questionnaire and 10 specific questions related to the implant procedure.

At baseline, quality of life of the two groups was the same statistically. 6 months after implantation, the Micra™ group had a significantly higher score for physical function, physical role and mental health, after adjusting for covariates. Also patient discomfort and physical restrictions were lower in the Micra™ group.

Leadless pacemakers are associated with a better quality of life in both physical and mental health.

LINK TO ABSTRACT >

3 STATE OF THE ART: LEADLESS VENTRICULAR PACING : A NATIONAL EXPERT CONSENSUS OF THE AUSTRIAN SOCIETY OF CARDIOLOGY

The article "State of the art: leadless ventricular pacing: A national expert consensus of the Austrian Society of Cardiology" by Clemens Steinwender, was published in the Journal of Interventional Cardiac Electrophysiology, in December 2019.

In part 1, the authors review the current literature of leadless pacing, summarizing the benefits as the prevention of long-term complications, especially lead- and pocket-related complications, and a reduction or elimination of the risk of device infection.

In part 2, the authors present a consensus statement about leadless pacing of the Austrian Society of Cardiology. The candidates for leadless pacing are described: good candidates are patients with challenging venous access, a history of device infection, and an elevated risk of complications, such as hemodialysis, advanced pulmonary disease, very low body mass index and frailty.

Possible candidates (i.e. majority of experts favor) are patients with two or more risk factors for device infection (diabetes, chronic kidney disease, corticosteroids, recurrent systemic infections and immunosuppressive therapy), transient sinus arrest or AV block with the need of backup pacing and very low anticipated ventricular pacing rate (less than 1-5% of beats), frequent sport activity stressing the shoulder (golf, hunting), age below 65 years, children and adolescents below 20 years.

In part 3, the authors provide recommendations concerning physician training, implant facilities and surgical management.

LINK TO ABSTRACT >

EVENT HIGHLIGHTS

THE FRENCH MICRA™ SYMPOSIUM

The French Micra™ symposium took place on January 16th in Paris.

Dr Serge Boveda from Clinique Pasteur (Toulouse), Prof. Eloi Marijon from HEGP (Paris) and Dr Philippe Ritter from CHU de Bordeaux, led the summit and engaged the audience which consisted of experienced Micra™ implanters from all throughout France.

Conclusions from the summit:

- The impact of the French reimbursement on the Micra™ practice has been very positive, despite the defined restricted sub groups.
- Higher volume center experience has shown stable electrical performance and procedure duration, as well as very low complications.
- The future of Micra™ is looking bright with Micra™ AV around the corner.

The symposium ended with a debate between the 3 physicians and the audience on patient selection. Given that Micra™ is reimbursed in defined sub groups, the discussion allowed physicians to exchange on their current practice.

NO LEADS PACING EVENT, VERONA, ITALY

The 'No Leads Pacing' training event took place at the end of 2019 in Verona, Italy and was led by Dr Morani from Ospedale Borgo Trento and Dr Gerdes from Aarhus University Hospital.

For the first time in Italy, physicians performed Micra™ implants and retrievals in a high tech cadaver lab.

This was a unique and very positive experience for the attendees. Attendees also got the chance to go in-depth on the Micra™ delivery catheter demo devices and the simulator and see two Micra™ live cases at the Ospedale Borgo Trento, led by Dr Morani.

The event was much appreciated as the hands-on experience throughout the training allowed physicians to become comfortable with the technology.

SWITZERLAND CREATES LEADLESS DRG

Leadless pacemakers have received their own DRG code from January 2020. This code is not linked to the product brand and is applicable for all leadless pacemakers.

Previously, Micra™ was grouped in the dual chamber DRG code for which the reimbursed amount was slightly lower than the new coding.

Micra™ is currently implanted in more than 20% of single chamber pacemaker patients in Switzerland which is a great achievement!

SPECIAL CASE

PERFORMANCE OF THE MICRA CARDIAC PACEMAKER IN NONAGENARIANS

Amine El Amrani, Bieito Campos, Concepción Alonso-Martín, José M. Guerra-Ramos, Enrique Rodríguez-Font, Zoraida Moreno-Weidmann, Óscar Alcalde-Rodríguez, Francisco J. Méndez-Zurita, Miguel Santaló, Hildemari Espinosa-Viamonte and Xavier Viñolas*

Introduction and objectives: The Micra™ transcatheter pacing system has shown high effectiveness and a lower complication rate than conventional transvenous pacemakers. However, the benefit of the device is unknown in the very old population (≥ 90 years). The aim of this study was to evaluate the safety and effectiveness of Micra™ in patients ≥ 90 years.

Methods: We present a prospective observational study with consecutive patients aged > 70 years who underwent implantation of a Micra™ pacemaker system. Patients were divided into 2 groups: ≥ 90 and < 90 years.

Results: The Micra™ system was implanted in 129 patients, of whom 41 were aged ≥ 90 years and 88 < 90 years.

The device was successfully implanted in 40 (97.6%) patients ≥ 90 years and in 87 (98.9%) patients < 90 years (P = .58). An adequate position was achieved with need for ≤ 2 repositions in 97.5% and 91.9% of patients, respectively (P = .32). Procedure time (26.1 ± 11.6 vs 30.3 ± 14.2 minutes; P = .11) and fluoroscopy time (6.4 ± 4.7 vs 7.2 ± 4.9 minutes; P = 0.41) were similar in the 2 groups.

There were 3 major complications (2.3%), all in the group aged < 90 years: 1 cardiac perforation, 1 femoral hematoma, and 1 femoral pseudoaneurysm. Thirteen patients aged ≥ 90 years (31.7%) and 16 patients aged < 90 years (18.2%) died during a mean follow-up of 230 ± 233 days and 394 ± 285 days, respectively.

There were no device-related deaths. No infection, dislocation or migration of Micra™ were observed. The electrical performance was optimal at follow-up.

Conclusion: The Micra™ leadless pacing system seems to be safe and effective in patients older than 90 years. It may be considered a reasonable alternative to conventional transvenous pacing in this population.

LINK TO ABSTRACT >

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