Device Therapy - Antibradycardia Pacing

A leadless pacemaker in the real-world setting: Patient profile and performance over time

Garweg C.[1]; Clementy N.[2]; Mondoloy P.[3]; Winter S.[4]; Bordachar P.[5]; Sharman D.[6]; Jung W.[7]; Eschalier R.[8]; Theis C.[9]; Defaye P.[10]; Anderson C.[11]; Pol A.[12]; Roberts PR.[13]

[1]University Hospitals (UZ) Leuven, Cardiology, Leuven, Belgium
[2]Centre Hospitalier Régional Universitaire de Tours, France, Tours, France
[3]Centre Hospitalier Universitaire de Toulouse, Toulouse, France
[4]St. Vinzenz Hospital (Köln), Cologne, Germany
[5]Centre Hospitalier Universitaire de Bordeaux, Bordeaux, France
[6]Northampton General Hospital (Cliftonville), Cliftonville, Northampton, United Kingdom of Great Britain & Northern Ireland
[7]Schwarzwald-Baar Hospital, Villingen-Schwenningen, Germany
[8]Centre Hospitalier Universitaire de Clermont-Ferrand, Clermont-Ferrand, France
[9]Robert Bosch Hospital, Stuttgart, Germany
[10]CHU Grenoble, Grenoble, France
[11]Medtronic, Mounds View, United States of America
[12]Bakken Research Center, Maastricht, Netherlands (The)
[13]University Hospital Southampton NHS Foundation Trust, Southampton, United Kingdom of Great Britain & Northern Ireland

Funding Acknowledgements: Type of funding sources: Private company. Main funding source(s): Medtronic, Inc.

OnBehalf: Micra Acute Performance EMEA Investigators

Background: The first in-man implant of the Micra leadless pacemaker occurred in December 2013. While prior trials demonstrated a high implant success rate and favorable safety and efficacy results; whether the patient population and outcomes have changed over time is not well studied.

Purpose: To characterize the evolution of patient profile and outcomes for patients receiving a leadless pacemaker through the pre-market and post-market environment.

Methods: Patients undergoing a Micra leadless pacemaker implant attempt from the initial Micra Investigational Device Exemption [IDE] and current Micra studies (Micra post-approval registry [PAR], Micra acute performance [MAP] study) were analyzed. Patient characteristics and pericardial effusions regardless of severity were summarized.

Results: The 3466 patients included in the analysis underwent a Micra implant attempt and were enrolled during consecutive timeframes: patients from the Micra IDE study (n = 726) underwent a Micra implant attempt from 2013-2015, patients from the PAR (n = 1814) from 2015-2018, and patients from Micra MAP cohort (n = 926) from 2018 – 2020. Implant success was >99.0% in all 3 studies. Median age ranged from 78 – 79 years among the 3 studies without significant difference. There were more patients requiring dialysis in the MAP cohort compared to the PAR or IDE cohorts (10.3%, 7.9%, and 3.9%, respectively; P < 0.001), but fewer patients with congestive heart failure (8.3%, 13.1%, and 18.0%; P < 0.001). Pacing indication was significantly different between the studies, with fewer patients in MAP having an indication of bradyarrhythmia associated with atrial fibrillation (AF) and more having an indication associated with atrioventricular block without AF (P < 0.001). The number of patients considered to be precluded for a transvenous pacemaker implant increased significantly from the initial IDE study to the PAR and MAP studies (6.2%, 23.9%, and 44.1%, respectively, P < 0.001). Implant site placement was mostly apical for the IDE but shifted to mostly septal placement in the PAR and MAP (septal placement: 33.3%, 64.0%, and 79.5%, respectively). The rate of pericardial effusion regardless of severity was 1.79% (n = 13) in the IDE, 0.83% (n = 15) in the PAR, and 0.97% (n = 9) in MAP (figure). Mean pacing thresholds among MAP EMEA patients were low (0.61 ± 0.40V) at implant and remained stable through 12 months (0.62 +/- 0.41V).

Conclusion: Despite patient differences over time, the Micra leadless pacemaker was implanted with a high success rate and a low perforation rate, in-line with prior reports.

Abstract Figure. Pericardial effusion rate by study