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Four years follow-up of leadless pacing system single center real life experience compared to data of the prospective trial

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Funding Acknowledgements: none

OnBehalf: Cologne Registry

Introduction: The Micra™ leadless intracardiac pacing system has been introduced and implemented into clinical routine more than three years ago. Feasibility, implantation safety and acute success have been proven in the setting of controlled studies. Additionally few real- life and post-implantation data exist. We aimed to report our single center follow-up (FU) data in comparison with the results of the prospective controlled Micra™- studie.

Methods: In 112 patients (69 men; age: 79 ± 10 y) successful Micra™ implantation was performed.Pacemaker interrogation was performed one to seven days after implantation and during FU (1; 3; 6, than every 6 month) up to 48 month. Data were assessed in a real-life setting and compared with existing data of the controlled prospectiv trial.

Results: The implantation was successful in all 112 attempts without procedure or device-related major complications. During Follow up there was one patient developing severe heart failure symptoms resulting in an implantation of a CRT-device and switching of the leadless pacemaker system.

The average acute thresholds, sensing and impedance after system release were: 0.63 ± 0.42V@0.24ms; 9,94 ± 3,61mV and 705 ± 166 Ohm. During follow up of up to 4 years neither, pacemaker failure, nor infections were reported. Measurements were reevaluated for long-term thresholds, sensing and impedance: 0.54 ± 0.16V @ 0.24 ms; 16,15 ±4,22 mV and 579 ± 133 Ohm. In the first three years no significant changes from acute to long-term measurements were detectable. In comparison to the data of the controlled trial the measurements of our real-life cohort was very similar.

Conclusion: In a real life setting the implantation of the leadless Micra™ system demonstrates high rate of implant success without major complications. Also shown were stable long-term system parameters in the clinical setting of up to two years of follow up. These data of every day clinical practice support the findings of the prospectiv trials.