Eight year follow-up data on a leadless pacing system real life experience in comparison to data of the prospective trial

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Introduction: The Micra™ leadless intracardiac pacing system has been introduced and implemented into clinical routine in 2015, with its next generation MICRA AV™ in 2020. Feasibility, implantation safety, and acute success have been proven in the setting of controlled studies. Even apart from controlled studies, this new technology was beneficial for the individual patient. We aimed to report our single center follow-up (FU) data with a follow-up of up to six years.

Methods: In 272 patients (136 men; age: 81±5.7 y), Micra™ implantation was performed.

Pacemaker interrogation was performed one to seven days after implantation and during FU (1; 3; 6, then every 6 month) up to 84 months. Data were assessed in a real-life setting and compared with existing data of a controlled prospective trial.

Results: The implantation was successful in all 272 attempts with only one pericardial effusion as major complication. During follow up there were two patients 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: 0.57±0.34V@0.24ms; 10.02±3.96mV and 752±1201Ohm. During follow up of up to 7 years neither, pacemaker failure, nor infections were reported. Measurements were reevaluated for long-term thresholds, sensing and impedance: 0.75 ± 0.38V @ 0.24 ms; 18.38 ± 2.75 mV and 525 ± 102 Ohm. During seven years, no significant changes from acute to long-term measurements were detectable. In comparison to the controlled trial, our measurements of this real-life cohort were very similar.

Conclusion: In a real-life setting, the implantation of the leadless Micra™ system demonstrates a high rate of implantation success without major complications. We were also able to show stable long-term system parameters in the clinical setting of up to seven years of follow up with a very good battery longevity of about 12.3 years.