Acute Performance of the Micra Transcatheter Pacemaker in Chinese Patients

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Introduction: Previous results from the global Micra clinical trials demonstrated a high implant success rate and excellent safety and efficacy. However, performance in the Chinese population has not previously been reported. We report acute performance results from the China Micra Transcatheter Pacing Study.

Methods: The purpose of the prospective, multi-site, single arm China Micra Transcatheter Pacing Study is to confirm the safety and efficacy of the Micra Transcatheter Pacing System for human use in Chinese patients. Patient baseline characteristics, procedural information, and acute safety and electrical performance through 1 month were summarized.

Result: Micra was successfully implanted in 81 (98.8%) of 82 patients recruited from 7 participating centers in China. Patients were on average 68.6 ± 11.8 years of age, with an average BMI of 23.7 ± 3.8 kg/m², 50.6% were female, and patients had multiple co-morbidities, including chronic lung disease (24.7%) and diabetes (25.9%) (see Table). The most commonly reported primary indication for pacing was bradyarrhythmia with atrial fibrillation (44.4%) followed by sinus node dysfunction (40.7%). Devices were mostly implanted in the RV septum/mid-septum (92.6%), with a median number of 2 deployments for successful implants. Through 30 days post-implant there were 2 major complications reported (2.4%); 1 arteriovenous fistula event and 1 pyrexia event. There were no perforation/effusion events reported and no deaths reported through 30 days. Mean pacing capture thresholds at implant were 0.52 ± 0.29 V @ 0.24ms and remained stable through 1 month (0.50 ± 0.57 V).

Conclusion: Performance of the Micra Transcatheter Pacemaker in the Chinese population demonstrates a high 98.8% implant success rate and low rate of major complications through 30 days post-implant, reinforcing the positive results observed in the global trials.