DEVICE-TO-DEVICE COMMUNICATION FOR A NOVEL DUAL-CHAMBER LEADLESS PACEMAKER SYSTEM: RELIABILITY OF MAINTAINING ATRIOVENTRICULAR SYNCHRONY IN AN OVINE MODEL OF AV CONDUCTION BLOCK

Vivek Y. Reddy MD; Reinoud Knops MD, PhD; Daniel J. Cantillon MD, FHRS; Petr Neuzil MD; Alok Gambhir MD, FHRS; Rahul N. Doshi MD, FHRS; Daniel Booth MSE; Weigun Yang MS, MSBME; Aditya Goil; Nima Badie PhD; David Ligon BS, MSBME, MSBME and Matthew G. Fishler PhD

Background: For leadless pacemaker (LP) therapy to expand beyond single chamber right ventricular (RV) pacing to dual-chamber pacing, discrete right atrial (RA) and RV LPs must achieve true atrioventricular (AV) synchrony—which in turn requires the paired LPs to wirelessly communicate beat-by-beat at each paced or sensed event.

Objective: To assess a novel, bidirectional, beat-by-beat, implant-to-implant communication (i2i™) protocol in a chronic ovine model of atrioventricular block.

Methods: After femoral venous access, RA and RV LPs (Aveir™ DR system; Abbott, IL) were implanted (Figure 1) and paired in 4 sheep, with radiofrequency ablation of the AV node occurring after the RV but before the RA LP implant. At 9 weeks post-implant, 12 days of data were collected (using the Merlin programmer) during the sheep’s natural variations of heart rate, posture and body movement. i2i success was the metric to indicate reliable AV synchrony, and synchrony was defined by an AV interval of ≤ 300ms. The longest programmed AV delay was 200ms.

Results: RA and RV LPs were successfully implanted in all sheep. Sensed amplitudes, impedances and pacing capture thresholds for RA and RV were 3.0 ± 0.9mV and N/A, 262 ± 45 and 478 ± 71ohm, and 1.1 ± 0.6 and 0.4 ± 0.2V at 0.4ms respectively. The heart rates were 64 ± 18bpm (range 40-170bpm) with 3.6 ± 0.8% at or above 110bpm. Atrial pacing and sensing occurred in 32 ± 7% and 68 ± 7% of beats, with RV pacing at each beat. i2i success was 98.9 ± 1.8% RA-to-RV, 99.4 ± 0.6% RV-to-RA, and 99.2 ± 1.0% overall. In instances of i2i loss, 98.5% of these episodes were of < 6 sec duration. During i2i loss from RV-to-RA, RA-to-RV, or bidirectionally, the LP system effectively switches from DDD to VDD, DDI, or VDI, respectively; this ensures RV pacing while maximizing RA pacing/tracking when possible. Figure 2 shows that despite RV-to-RA i2i loss (A) or RA-to-RV loss (B), AV synchrony can still be maintained in certain instances—depending on subject condition. For bidirectional i2i loss (C), the AV interval was extended for 1 beat, but AV synchrony returned the following beat.