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Dual-Chamber Leadless Pacemakers Maintain Synchrony with Beat-to-Beat Wireless Communication

Alok Gambhir, Rahul Doshi, Nima Badie, Daniel Booth, Weiqun Yang, Peter Nee,
Matthew Fishler, Dave Ligon, Petr Neuzil, Daniel Cantillon, Reinoud Knops

Abstract— **Leadless pacemakers are self-contained devices implanted entirely within the target heart chamber for single-chamber pacing. This feasibility study demonstrates leadless dual-chamber pacing using wireless, bidirectional communication between paired leadless pacemakers implanted in the right atrium and right ventricle.**

Clinical Relevance— **Leadless pacemakers can mitigate complications associated with transvenous, single-chamber devices. Using a novel wireless communication modality, true dual-chamber leadless pacing is now possible.**

I. Introduction

Despite decades of clinical experience, 1 in 6 conventional pacemaker patients experience complications in the first 3 years, mostly attributed to transvenous leads and the subcutaneous pocket [1]. The leadless pacemaker (LP), implanted entirely within the target chamber, was designed to mitigate some of those complications, while simplifying the implant procedure.

The majority of implanted pacemakers are dual-chamber. Although single-chamber pacing with one LP has been well-established, expanding the application to multi-chamber pacing requires continual, bidirectional communication across multiple devices. This preclinical study demonstrates the performance of a novel, proprietary implant-to-implant (i2i) communication modality that achieves synchronous, true dual-chamber pacing by two leadless pacemakers implanted in the right atrium (RA) and right ventricle (RV).

II. Methods

The i2i communication uses subthreshold electrical pulses transmitted/received through blood and tissue using the existing pacing/sensing electrodes. Each i2i transmission contains up to 32 bits of information encoded into a series of short, biphasic pulses, with "1" encoded as a triplet of pulses, and "0" as a lack thereof.

The i2i transmissions occur beat-by-beat at every paced or sensed event. For each paced event, the pacing LP transmits immediately before delivering the pacing pulse; for each sensed event, the sensing LP transmits immediately after detecting the intrinsic event. Thus, the receiving LP can initiate the corresponding blanking periods and pacing intervals. Transmissions may also include additional content, such as updated pacing rates or mode switches. If i2i communication fails from RA-to-RV, RV-to-RA, or in both directions, the DDD mode switches to DDI, VDD, or VDI modes, respectively. These safeguards guarantee RV pacing, while maintaining RA tracking and pacing whenever possible.

A preclinical feasibility study was performed to evaluate *in vivo* i2i performance during natural variations in heart rate, posture, and body movement. RA and RV Aveir™ LPs (Abbott, Abbott Park, IL) were implanted in 3 ovine subjects percutaneously via femoral vein per standard procedures. Eight months post-implant, the Merlin programmer was used to collect counts of i2i transmissions sent and received by each LP in the previous week, and transmission success rates were calculated. Values are reported as mean ± standard deviation.

III. Results

RA and RV LPs were successfully implanted and paired in all 3 ovine subjects without adverse events. At 8 months post-implant, 3766±306 RA-to-RV and 4031±635 RV-to-RA transmissions/hour were sent (7797±918 total/hour), with receipt success rates of 97.7±2.3% and 96.7±2.1% (97.2±1.8% overall), respectively (Table 1).

All LP systems demonstrated successful DDD pacing. Of all instances when i2i communication was lost, 95.3±4.9% of RA-to-RV and 98.2±1.4% of RV-to-RA communication loss durations were shorter than 0.1 min in duration (97.9±1.5% overall). No instances of communication loss were longer than 5 min.

TABLE I. Wireless Transmission Performance

i2i Transmission Metric	*RA-to-RV*	*RV-to-RA*	*Total*
Transmissions per Hour (#)	3766 ± 306	4031 ± 635	7797 ± 918
Success Rate (%)	97.7±2.3	96.7±2.1	97.2±1.8

IV. Discussion & Conclusions

This preclinical study demonstrated the efficacy of a true dual-chamber, DDD leadless pacemaker system. Atrio-ventricular synchrony was maintained using wireless, bidirectional communication at every beat, with an overall transmission success rate of 97%. Expanding leadless pacemakers to dual-chamber pacing may help mitigate some transvenous pacemaker complications.

References

[1] D. J. Cantillon *et al.*, "Complications and Health Care Costs Associated With Transvenous Cardiac Pacemakers in a Nationwide Assessment," *JACC Clin. Electrophysiol.*, 2017, doi: 10.1016/j.jacep.2017.05.007.

*Research supported by Abbott. DB, NB, WY, PN, MF, and DL are Abbott employees. Alok Gambhir, 1150 Hammond Dr Suite 520, Atlanta, GA 30328; phone: (404) 962-6000; e-mail: alok.gambhir@gmail.com