Development of a Leadless Conduction System Pacemaker – Mechanical Aspects

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Introduction

Previous research has shown the advantages of conduction system pacing compared with conventional right ventricular apical pacing (RVAP). Furthermore, leadless pacemakers (LLPMs) started to appear on the market in the last 5-10 years, overcoming the limitations of conventional systems. However, LLPMs can currently only perform RVAP. This project aimed to develop a prototype combining the advantages of the two technologies: a leadless conduction system pacemaker.

Materials and Methods

The chosen approach was to develop a 2-piece pacemaker. The batteries and the electronic circuit are located in the device body, implanted on the right ventricular apical septum. A needle electrode, connected with a small electrical cable, is then inserted on the mid-proximal septum to reach the left bundle branch (LBB) and provide conduction system pacing. The developed delivery catheter is based on an existing steerable catheter, which was modified by adding an external layer as well as customized handles for minimal invasive pacemaker placement.

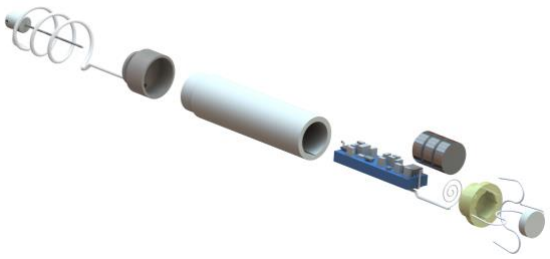

Fig. 1 Rendering of the developed leadless conduction system pacemaker represented in exploded view.

Results

The developed device could be tested in-vivo in a domestic pig. Because of the failure of a catheter part, the needle electrode could not be fully inserted in the septum to reach the LBB. Irrespective of that, cardiac pacing could be performed successfully. A post-operative analysis of the acquired data suggested a good placement of the distal catheter end near the desired location.

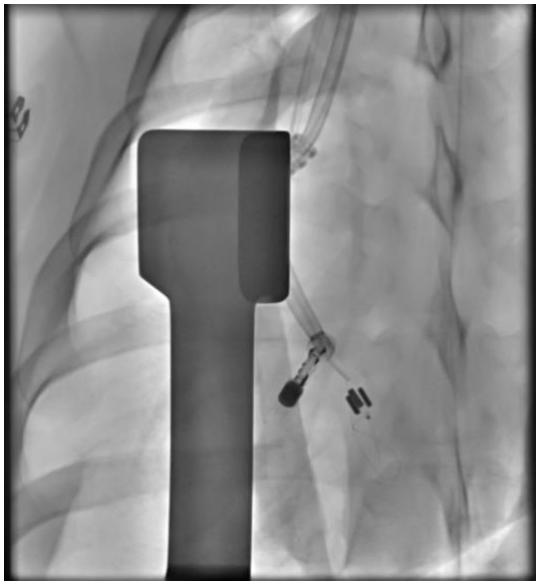

Fig. 2 RX of the in-vivo intervention showing the deployed PM body and the positioned electrode needle.

Discussion

The achieved results confirmed the validity of the chosen approach. The innovative approach to leadless pacing with a 2-piece device appeared to be a promising choice. However, given the minimally invasive implantation procedure, this approach results in a more complex catheter system and intraoperative procedure compared to available leadless pacemakers.

References

L. Bereuter et al., “Leadless cardiac resynchronization therapy: An in vivo proof-of-concept study of wireless pacemaker synchronization,” Heart Rhythm, vol. 16, no. 6, pp. 936–942, 2019.