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The Risk is Small: Implant Complications of Leadless Pacemakers are Related to Body Size

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Leadless cardiac pacemakers (LPM) are increasingly used for permanent pacing. Compared to transvenous pacemakers (TVP) with conventional pacing leads, LPM have been shown to provide effective ventricular demand pacing (VVI) with or without rate adaptation (VVI/IR). LPM avoid the acute and long-term risks related to the leads and pacemaker pockets [1]. Efficacy and electrical performance is comparable to TVP. However, implant complications remained significant, especially life-threatening pericardial effusion and tamponade. In carefully conducted clinical studies such as the Investigational Device Exemption (IDE) study [2] and post approval registry (PAR) [3], pericardial tamponade/effusion occurred in 1.79% and 0.77% respectively. A recent report [4] found that LPM to be increasingly used in older patients between 2017 and 2019 in the United States of America compared to TVP, the implant complication rate was lower (8.6% vs 11.2%), but mortality was higher (5.2% vs 1.3%, p < 0.001), driven mainly by pericardial effusion/tamponade.

In this issue of the Journal of Hong Kong College of Cardiology, Tam et al. [5] addressed the safety and efficacy of LPM in 147 patients implanted in a territory referral center between 2015 and 2018. Their cohort was 80.5 ± 8.7 years old, with high prevalence of co-morbidities (except for chronic lung disease), as expected for this age group who required permanent pacing. Their procedural efficacy and safety were 95.2% and 97.3%, respectively. These results compared well to those published by IDE study [2] and the PAR [3], and testify to the proficiency of their centre. Nevertheless, pericardial tamponade/effusion remained a significant issue (2%), most of them requiring pericardial drainage.

Based on the clinical characteristics of their cohort, the authors identified only small body mass index (BMI) to be significantly related to failure to achieve successful composite efficacy and safety outcome on univariate risk prediction (BMI 22.12 vs 23.86 kg/m², p = 0.001; body weight 53.18 ± 5.66 vs 59.15 ± 11.33 kg, p = 0.07). In a secondary analysis based on the median body weight, the BMI group that was below the median had more implants at mid- or high septal region of the right ventricle (RV), implant attempts, need for recapture and longer procedure time compared to those above median weight. Need for more implantation attempts obviously increased the risk of trauma to the RV and perforation. A small BMI was most likely associated with a smaller RV size and increased the risk. An international series [6] identified 32/2817 patients (1.1%) with pericardial effusion/tamponade after LPM, and they also found univariate predictors for this complication to be related to small BMI (25.7 ± 6 vs 27.8 ± 5.7 kg/m²), in addition to advanced age (≥85 yrs), chronic lung disease, and a history of atrial fibrillation. Small BMI that was significantly related to this complications occurred in those with 25.7 ± 6.0 kg/m², and the risk was 4 times higher for BMI below 20 kg/m².

What are the implications of these findings? While risk factors for pericardial effusion/tamponade may differ from the patient demographics and difference in implant technique, a common denominator for complications in these different international cohorts appeared to be due to small body build. While
it remained to be tested, small body build in these series probably translated to smaller RV size and increased the risk of perforations. Whether a smaller RV also increased repositioning rate and a higher final implant position remained possibility to be tested. As the standard 27F delivery sheath for Micra™ (Medtronic Inc) and the same LPM were used for all patients, appropriate sizing and improvement in delivery strategy/equipment may be warranted. At present, caution and preparation for pericardial effusion therapy are warranted to address this issue, particularly in those with low body weight.

The study results should be taken with some limitations. Being a cohort study, there was no control on the implant protocol and follow up may not be uniform. As the study spanned over a 3 year period, experience and knowledge of the relevant site of RV pacing to avoid complications such as the mid-septal RV would be useful to see a time related trend [7]. A measurement of RV size such as using echocardiography would be helpful rather than a crude BMI measurement.

In summary, implantation of LPM can be achieved in a high percentage of patients and LPM are safe and effective. Implant risks were small, but a small body weight was riskier.

Ethics information
Not applicable.

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Conflict of interest
None declared.

References