Percutaneous retrieval of an unanchored WiSE-CRT system left ventricular receiver electrode

Toshimasa Okabe, MD,* Ralph S. Augostini, MD, FHRS,* Michael K. Essandoh, MD,† John D. Hummel, MD, FHRS*

*From the *Department of Internal Medicine, Division of Cardiovascular Medicine, The Ohio State University Wexner Medical Center, Columbus, Ohio, and †Department of Anesthesiology, the Ohio State University Wexner Medical Center, Columbus, Ohio.*

Introduction

Leadless pacing technology is rapidly evolving. The WiSE CRT System (EBR Systems, Sunnyvale, CA) delivers ultrasonic energy to a left ventricular (LV) *endocardial* receiver electrode to achieve biventricular pacing and may be a solution for heart failure (HF) patients who fail conventional cardiac resynchronization therapy (CRT). By design, a percutaneously delivered LV endocardial electrode (ultrasound receiver and energy converter) delivers an ultrasound-based energy stimulus to the left ventricle that is synchronized to a right ventricular pacing output (Figure 1). Following premature detachment from the delivery system during implantation, an unanchored electrode may embolize in the left ventricle, necessitating percutaneous retrieval of the electrode. Percutaneous retrieval of an embolized electrode using the transseptal approach, however, has not been previously reported.

Case report

A 60-year-old female patient was initially treated with a dual-chamber pacemaker for complete heart block. She underwent upgrade to a cardiac resynchronization and defibrillator device owing to progressively declining LV ejection fraction and development of NYHA class III HF on guideline-directed medical therapy. Her ejection fraction and HF symptoms, however, did not improve substantially despite consistent LV pacing from the basal lateral LV lead location. Prior to further consideration of advanced mechanical HF therapies or consideration of cardiac transplantation, she was referred to the electrophysiology service and enrolled in the SOLVE-CRT trial (Stimulation Of the Left Ventricular Endocardium for Cardiac Resynchronization Therapy in Non-Responders and Previously Untreatable Patients) (WiSE-CRT, EBR Systems, Sunnyvale, CA. ClinicalTrials.gov Identifier: NCT02922036). An ultrasound transmitter/pulse generator was successfully placed on day 1 of the procedure. The following day, an LV endocardial electrode implantation was planned using a transseptal approach. The activated clotting time was maintained >300 seconds with intermittent heparin bolus. After standard transseptal puncture, a long transseptal sheath was exchanged to a large-bore steerable sheath (12F inner diameter, FlexCath Advance Steerable Sheath; Medtronic, Minneapolis, MN) over the guide wire. After mapping of LV endocardial activation times with an electroanatomical mapping system, a 12F WiSE delivery sheath (Model 2000; EBR Systems, Sunnyvale, CA) was advanced inside the FlexCath sheath. A balloon at the distal end of the delivery sheath was inflated with diluted contrast and the delivery sheath was carefully advanced to the site of latest LV endocardial activation and contrast was injected to ascertain adequate contact and alignment with the LV endocardial surface (Figure 2A). An 8F electrode catheter (Model 1000; EBR Systems) was

KEY TEACHING POINTS

- Embolization of left ventricular ultrasound electrode may occur during leadless cardiac resynchronization therapy pacemaker system implantation.
- It is feasible to approach electrode retrieval from the left ventricle using a transseptal approach.
- Real-time 3-dimensional transesophageal echocardiography can guide complex electrode retrieval using a snare.

KEYWORDS Cardiac resynchronization therapy; Device extraction; Embolization; Leadless pacemaker; Ultrasound; WiSE CRT system
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Address reprint requests and correspondence: Dr Toshimasa Okabe, Division of Cardiovascular Medicine, The Ohio State University Wexner Medical Center, 410 W 10th Ave, Columbus, OH 43210. E-mail address: Toshimasa.Okabe@osumc.edu.

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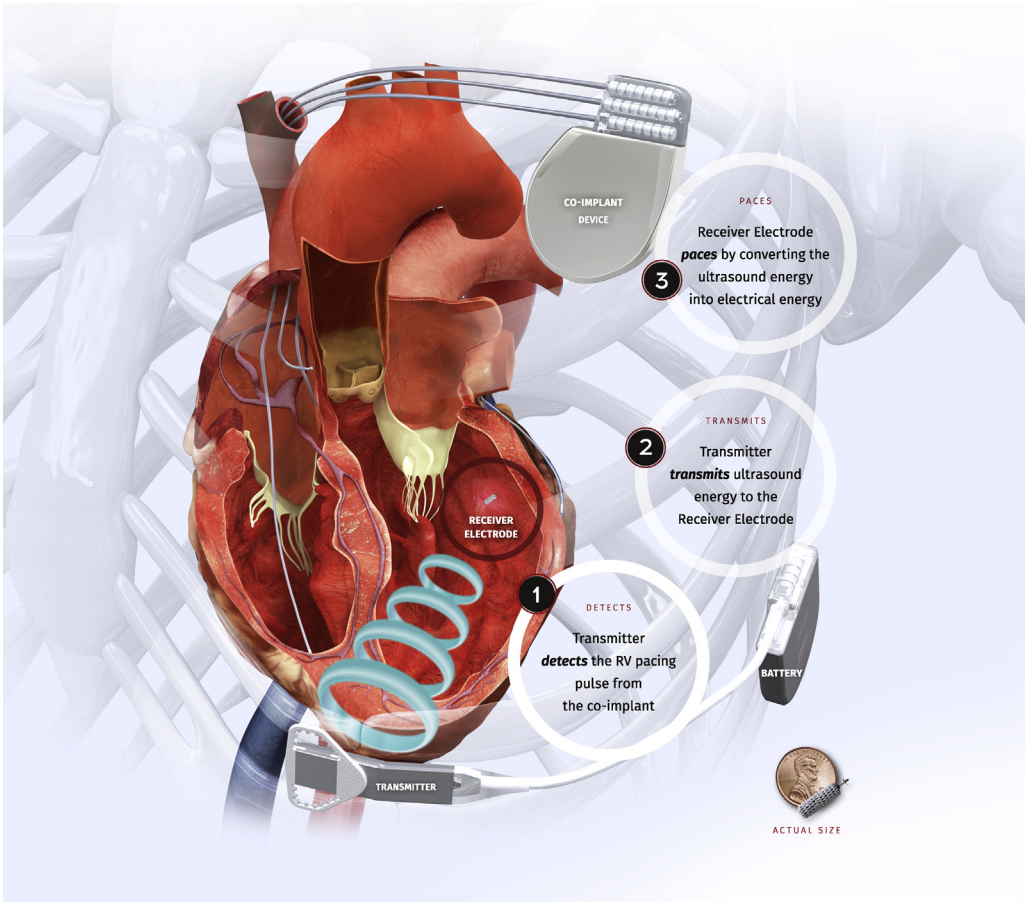

Figure 1 Schematic representation of the WiSE-CRT system (EBR Systems, Sunnyvale, CA). The electrode diameter, body length, and needle length are 2.7 mm, 9.1 mm, and 3.6 mm, respectively. (Not approved for use in the United States.)

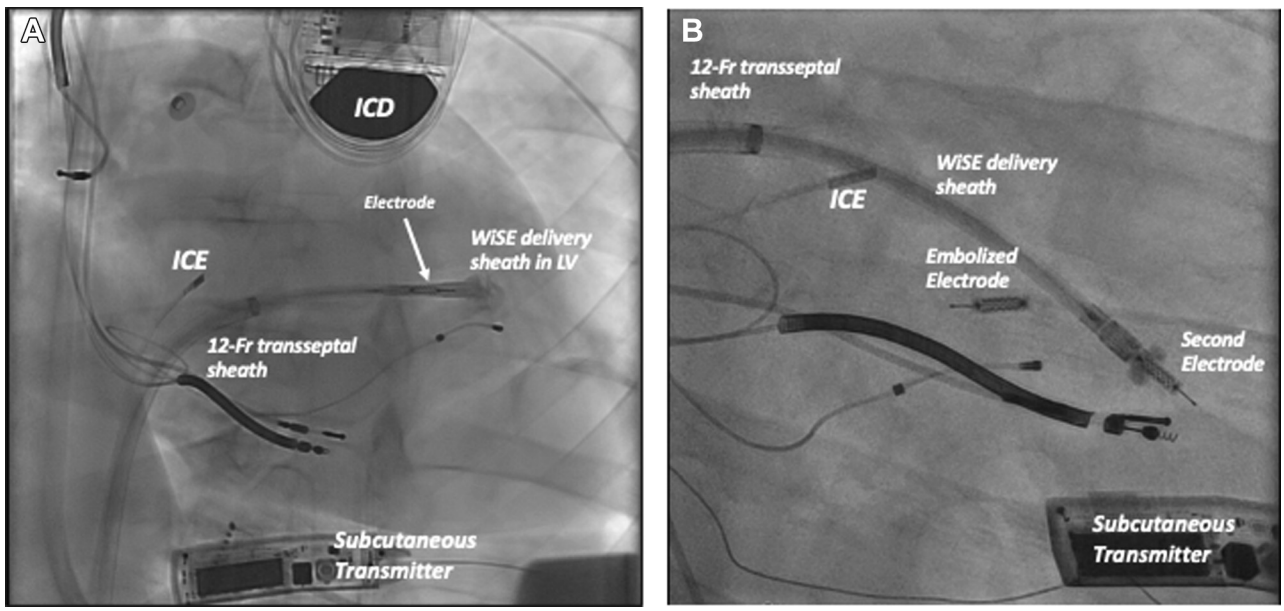

Figure 2 **A:** The electrode is advanced inside the WiSE delivery sheath (EBR Systems, Sunnyvale, CA), which is placed through a 12F transseptal sheath. **B:** After embolization of the first electrode, the second electrode was deployed in the anterolateral wall of the mid left ventricle (LV). ICD = implantable defibrillator; ICE = intracardiac echo.

slowly advanced until approximately 25% of the 9.1 mm electrode body was exposed outside the delivery sheath tip. The electrode anchor needle initially appeared to be inserted into the mid to basal inferolateral segment of the LV endocardial surface; however, an orthogonal cine image was not obtained to confirm complete electrode anchoring. Adequate pacing threshold (<2.5 V at the pulse width of 0.5 ms) and transmitter-electrode relation (distance <10 cm and angulation <30°) were confirmed; however, subsequent review of cine fluoroscopy revealed some residual contrast between the anchoring needle and the myocardium, thought at the time to be contrast wash within the trabeculae (Supplementary video 1). Given adequate electrical findings and desire to minimize the number of electrode deployment attempts in an area with thin myocardium, the operators deemed that there was adequate needle fixation and the electrode was detached under continuous fluoroscopic monitoring. The LV electrode, however, immediately moved from the original position and became wedged along the mitral valve (MV) apparatus (Supplementary video 2). The embolized LV electrode demonstrated no pacing capture at the maximum output. Percutaneous electrode removal was attempted unsuccessfully through the same 12F FlexCath sheath using an Amplatz GooseNeck snare (Medtronic, Minneapolis, MN) and a multi-loop EN Snare (Merit Medical, South Jordan, UT). These snares failed to reach behind the posterior MV leaflet on the LV side where the embolized electrode was entangled with the MV apparatus. Out of concern for incurring iatrogenic MV injury and apparent stability of the embolized electrode position, the decision was made to abandon it and place another electrode at a late activated LV location that was felt to be sufficiently distant from the embolized electrode to avoid simultaneous reception of the transmitted ultrasound signal. The second electrode was successfully deployed (Figure 2B) but it became immediately evident that the WiSE-CRT system could not selectively transmit ultrasonic energy to the intended second electrode, causing intermittent LV capture. Thus, removal of the embolized electrode became obligatory to allow consistent endocardial LV stimulation and for the safety of the patient.

On the following day (day 3), the patient was taken back to the lab for a repeat attempt at percutaneous transvenous extraction of the embolized electrode under general anesthesia. A 23F (27F outer diameter) Micra Introducer Sheath (Medtronic) was placed in the right atrium. After standard transseptal catheterization, the FlexCath sheath was advanced to the left atrium over the guide wire. A 15 mm Amplatz GooseNeck snare was advanced inside a 7F AR1 coronary diagnostic catheter in order to retroflex the snare to grasp the electrode behind the MV leaflet (Figure 3A, Supplementary video 3). Guided by fluoroscopy and 3-dimesional transesophageal echocardiography (TEE), the electrode was trapped inside the snare loop and successfully withdrawn to the FlexCath sheath, then to the Micra Introducer sheath (Figure 3B, Supplementary video 4). There was no significant MV regurgitation post retrieval, and the WiSE system demonstrated consistent LV capture at an adequate pacing capture threshold. Total procedure time and fluoroscopy time were 68 minutes and 30 minutes, respectively. There were no acute complications. The patient was discharged on dual antiplatelet therapy (total 3 months) as per the protocol.

Discussion

CRT is an established device treatment for eligible patients with drug-refractory systolic HF. CRT is generally delivered through *epicardial* LV lead placed via transvenous coronary sinus approach. CRT nonresponse is observed in 30%–50% of patients receiving a conventional CRT device. Additionally, 5%–15% of CRT-eligible patients are unable to receive a coronary sinus lead owing to anatomical variations, high

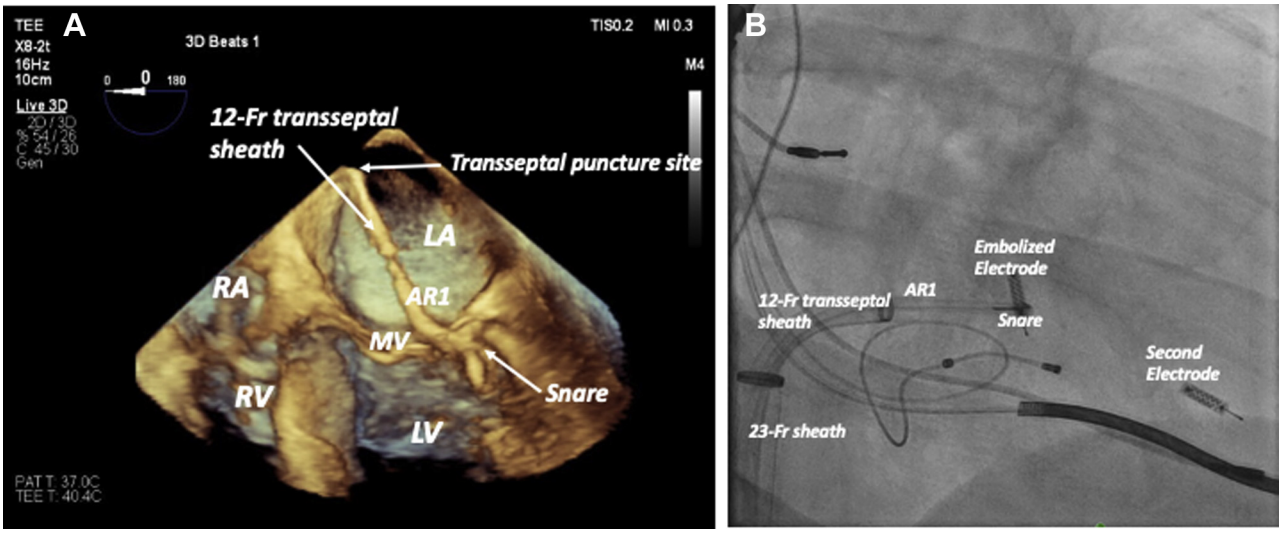

Figure 3 **A:** Three-dimensional transesophageal echocardiogram shows the angled coronary angiogram catheter (AR1) directed toward the basal anterolateral left ventricle (LV) where the embolized electrode is located. LA = left atrium; MV=mitral valve; RA = right atrium; RV = right ventricle. **B:** Right anterior oblique projection view of retrieval of the embolized electrode. The electrode was successfully snared and retrieved into the 12F transseptal sheath.

pacing threshold, or phrenic stimulation, and whether there is a salutary effect of endocardial vs epicardial LV pacing is unclear.[1]

Alternative CRT delivery methods include surgical LV lead and a transatrial, transseptal endocardial approach using a conventional transvenous active-fixation lead. The former approach has an inherently higher risk and may be technically difficult in patients with prior sternotomy. The latter approach has not been extensively evaluated and necessitates lifelong oral anticoagulation.[2]

The WiSE system provides LV *endocardial* pacing therapy without the need for permanent oral anticoagulation. The system consists of a co-implant right ventricular pacemaker/defibrillator, ultrasound transmitter/pulse generator, and LV endocardial receiver electrode. The device received European CE mark approval in 2015. Relatively small-scale case series and a postmarket surveillance registry of this emerging device are available to date.[3,4] It is currently undergoing a multicenter randomized trial for efficacy and safety (ClinicalTrials.gov Identifier: NCT02922036).

Electrode embolization was not reported in the International Registry, consisting of 90 patients. In this registry the most common acute (<30 days) complication (4/90 patients, 4.4%) was vascular complications related to femoral arterial access, while there was 1 death related to LV perforation, leading to an abundance of caution in deployment in thin regions of the left ventricle.[4]

Upon detailed review of the cine imaging post procedure, it was concluded that the electrode needle was not anchored, evidenced by the presence of contrast material between the anchoring needle and the myocardium (Supplementary video 1). At the time, this was felt by the operators to be contrast wash in trabeculae owing to fluoroscopic angulation. Although one must be cognizant of the risks of multiple deployments, it appears that if there is any question of contrast around the anchoring needle, adequate electrical parameters alone are not sufficient to support release and either further advancement or repositioning of the electrode must be pursued. Given that the embolized electrode was lodged behind the ventricular side of the MV leaflet and entangled with the MV apparatus, the angled coronary angiography catheter (AR1) was crucial to the procedural success via transseptal approach. Although a retrograde aortic approach would have led to a more advantageous angle from which to retrieve this embolized electrode, out of concern for dragging the electrode (with anchor needle) back through the aortic valve, the aorta, and major arteries, a transseptal approach was selected. Fortunately, when the electrode was snared and pulled back into the FlexCath sheath, its long axis became completely co-axial to the sheath lumen, and it was retrieved into the sheath without difficulty. In case the electrode's long axis was not aligned with the sheath tip, and the electrode body was caught obliquely in relation to the sheath tip, the large-bore Micra Introducer sheath (inner diameter 23F= 7.7 mm) was placed in the right atrium close to the interatrial septum to allow direct retrieval of the electrode into the large-bore sheath (with the option to repair any residual septal defect later).

Lastly, 3-dimensional TEE aided the retrieval by allowing a better understanding of the 3-dimensional relationship between the target electrode and the MV apparatus.

Leadless pacing technology and clinical application of such devices are rapidly evolving. However, experience with percutaneous retrieval of these leadless devices is currently limited, and it remains technically challenging.[5] For the routine usage of such devices in the future, concurrent advancement of retrieval techniques will be important.

Conclusion

Percutaneous retrieval of an embolized WiSE-CRT system electrode from the left ventricle via transseptal approach is feasible. The use of intraprocedural 3-dimesional TEE may improve procedural success.

Appendix

Supplementary data

Supplementary data associated with this article can be found in the online version at https://doi.org/10.1016/j.hrcr.2020.05.023.

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