Implantation of a leadless pacemaker in patients with a mechanical tricuspid valve

Jongmin Hwang, MD, Seongwook Han, MD, Hyoung-Seob Park, MD, Cheol Hyun Lee, MD, In-Cheol Kim, MD, Woo Sung Jang, MD

PII: S2214-0271(22)00010-0
DOI: https://doi.org/10.1016/j.hrcr.2022.01.010
Reference: HRCR 1267

To appear in: HeartRhythm Case Reports

Received Date: 30 October 2021
Revised Date: 16 December 2021
Accepted Date: 19 January 2022


This is a PDF file of an article that has undergone enhancements after acceptance, such as the addition of a cover page and metadata, and formatting for readability, but it is not yet the definitive version of record. This version will undergo additional copyediting, typesetting and review before it is published in its final form, but we are providing this version to give early visibility of the article. Please note that, during the production process, errors may be discovered which could affect the content, and all legal disclaimers that apply to the journal pertain.

© 2022 Published by Elsevier Inc. on behalf of Heart Rhythm Society.
Implantation of a leadless pacemaker in patients with a mechanical tricuspid valve

Short title: Leadless pacemaker implantations through a mechanical TV

Jongmin Hwang, MD¹, Seongwook Han, MD¹, Hyoung-Seob Park, MD¹, Cheol Hyun Lee, MD¹, In-Cheol Kim, MD¹, Woo Sung Jang, MD²

¹Division of Cardiology, Department of Internal Medicine, Keimyung University Dongsan Hospital, Keimyung University School of Medicine, Daegu, Republic of Korea
²Department of Thoracic and Cardiovascular Surgery, Keimyung University Dongsan Hospital, Keimyung University School of Medicine

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Address for correspondence:
Jongmin Hwang, MD, PhD, CCDS, CEPS-A
1035 Dalgubeol-daero Dalseo-gu Daegu 42601, Republic of Korea
E-mail: dsmcdevice@kmu.ac.kr, dsmcep@gmail.com

Keywords: pacemaker; leadless pacemaker; mechanical tricuspid valve; Epstein anomaly; atrioventricular block, sinus node dysfunction

Total word count: 2044 words.
Introduction
The leadless pacemaker (LPM) has become an effective alternative to the traditional single-chamber ventricular transvenous pacemaker (PM) in selected patient populations. The LPM does not require a subcutaneous pocket or use of a transvenous lead, potentially mitigating many of the short- and long-term risks inherent to transvenous PMs, including infections, lead fractures, and venous occlusions.

In patients who have a prosthetic tricuspid valve (TV), five options can be considered for the PM ventricular lead implantation: implant epicardial leads; implant a standard right ventricular (RV) transvenous lead; implant a para-Hisian lead; or implant a coronary sinus (CS) lead for left ventricular (LV) pacing only; and implant an LPM. However, only two options are available in patients with a mechanical TV: implantation of an epicardial lead or implantation of a CS lead for left ventricular pacing. Further, currently, implanting an LPM through a mechanical TV is not considered as an alternative option yet. Therefore, we report the experience of an LPM implantation in an Epstein anomaly patient with a mechanical TV as a last resort.

Case report
A 34-year-old man diagnosed with an Epstein anomaly at age 5 and underwent a mechanical TV replacement surgery (TVR) at age 7 was referred to a cardiac implantable electronic device clinic for recurrent dizziness and near syncope. He was diagnosed with paroxysmal atrial flutter and tachycardia-bradycardia syndrome 6 years prior, and, at that time, a mechanical TV thrombosis and valve malfunction were also noted. Hence, he a redo-TVR with a mechanical valve and epicardial PM implantation were performed simultaneously. After the operation, the epicardial PM system became infected. Despite continuous antibiotic treatment, 6 minor debridement surgeries, and 2 advancement flap surgeries, the infection was not controlled. He
had no choice but to remove the total epicardial PM system (third open-heart surgery). Fortunately, he was in a stable state without the PM for several years, but dizziness recently occurred again, and the Holter monitoring documented paroxysmal atrial flutter followed by a 3.5-second-long atrial pause accompanied with symptoms (Supplementary Figure 1).

One of the two options, including implanting a CS lead or redo-epicardial PM, was considered. However, a preoperative computed tomography scan showed that the CS ostium was below the mechanical valve (Figure 1). Therefore, only two alternative options were available: an AAI-type transvenous PM or redo-epicardial PM. An electrophysiologic (EP) study was performed to evaluate the atroventricular (AV) conduction and status of the right atrial scar. Right atrial pacing was possible but 2:1 AV block occurred at an atrial pacing cycle length of 700 msec, suggesting a poor AV node function. The patient was awake during EP study, and considering his age and the circumstances of the EP lab, we assumed that a hypervagotonia would not affect the AV node function during the EP study. Detailed EP study around His bundle area was impossible due to his distorted anatomy (CS ostium under mechanical TV). Further, his baseline ECG exhibited complete right bundle branch block (Supplementary figure 2) and he had a redo TVR, which could not exclude the possibility of any damage to the AV node during the surgery. In addition, his average heart rate was around 60 bpm and maximal heart rate around 100 bpm during atrial tachycardia without any AV nodal blocking agent on the Holter monitoring and 12-lead ECG (Supplementary Figures 3 and 4). For the above reasons, we concluded that implanting only an AAI type pacemaker was not the safest pacemaker option for this patient. Thus, a redo-epicardial PM implantation was recommended. It would be the fourth open-heart surgery for the patient. However, the thoracic surgeon was worried about difficulty in finding a portion of the ventricle with an acceptable pacing threshold due to the prior surgery. We had an in-depth discussion with the patient about the possible options and, finally, we decided to try a Micra (Micra transcatheter pacing system, Medtronic, Minneapolis,
MN) implantation, however, it was currently not recommended.

Before the procedure, we simulated whether the Micra device could freely move in and out through the mechanical valve (Supplementary Video 1., using a dummy model of a St. Jude Mechanical Heart Valve 27mm and Micra device). In this simulation, the Micra device could freely pass through the fully opened leaflet of the mechanical heart valve. The patient's TV valve was an St. Jude Mechanical Heart Valve 31mm model, and the diameter of the Micra device was 6.7mm. Therefore, we assured that the implantation of the Micra through a mechanical tricuspid valve would be possible.

Then the procedure was performed. After puncturing the right femoral vein with an 8Fr short sheath, a sequential dilation of the entry site was done until the 27Fr Micra introducer sheath was inserted. After introducing the delivery catheter with the Micra device into the right atrium, the mechanical valve was crossed with the Micra delivery sheath (Supplementary Video 2A, 2B). Some resistance was felt because the distal end of the delivery catheter, which contained the Micra device, was slightly bigger than the other parts of the delivery catheter. This resistance was overcome by gently pushing the catheter. Since the diameter of the main body of the delivery catheter was much smaller than that of the fully opened valve leaflet, no resistance was felt during subsequent manipulation of the delivery catheter. The typical apical septal location was not suitable to apply enough tip pressure because the RV was markedly enlarged, and there was a limitation of movement of the delivery system due to the mechanical valve. After several attempts, we were able to successfully deploy the Micra device in the RV outflow tract (Figure 2).

The pull and hold test revealed that 3 tines were engaged, and the electrical measurements were within the recommended values: R-wave: > 20 V, impedance: 1010 Ohms, threshold: 0.5 V @ 0.24 ms. The electrical parameters were stable after the pull and hold tests; we cut and removed the entire tether. The withdrawal of the delivery catheter was relatively easy, and no resistance
was felt during withdrawal of the delivery system (Supplementary Video 3). Subsequent fluoroscopy and echocardiography did not show any abnormal movement of the mechanical valve. The total procedural and fluoroscopy times were 60 min and 16.5 min, respectively. The peri-procedural anticoagulation strategy was as follows: The day before the procedure, the patient’s INR was 2.63. The nighttime warfarin dosing for the day before the procedure was skipped and the INR of the procedure day was 2.42. Although he was in the therapeutic range of the INR, we administered a bolus of 3000 international units of unfractionated heparin for the complexity of the procedure. A heparinized saline drip through the introducer was also maintained during the procedure. Hemostasis was successfully achieved with a figure-of-8-suture and there were no complications during the hospitalization. The patient was discharged after a week. Now he visits our hospital regularly, without any further symptoms. Figure 3 shows post-procedure chest radiography image.

Discussion

TV surgery carries a significant risk of conduction disorders requiring an implantable electronic device. The implantation rate of PMs has tended to decrease over the decades, but rates as high as 27% have recently been described after a TV replacement. However, implanting cardiac electronic devices in patients who had a TV surgery is a challenging procedure. Especially, as described above, there are only two options to implant a ventricular lead of PM in patients with a mechanical tricuspid valve: (1) LV only pacing through the CS like cerclage pacing, (2) epicardial pacemaker. And considering the degenerative nature of conduction system disorders, implanting an only AAI-type pacemaker is not a reliable solution for this type of patients.

In this report, the mechanical TV was unintentionally placed over the CS ostium, therefore there was no option other than an epicardial pacemaker implantation. Since the patient had
already undergone three-open heart surgeries, it was expected that finding epicardial sites with an acceptable pacing threshold would be difficult. Furthermore, his AV conduction was not good for atrial pacing only. The patient was a young 34-year-old who strongly wanted an alternative method other than the fourth open-heart surgery. So, we decided to try to implant the LPM through the mechanical TV as a last resort.

The following points should be considered when deciding whether to perform the procedure as in this case. Above all, the size of the implanted mechanical TV is most important. The diameter of the Micra device is 6.7mm, and the delivery catheter is 23Fr (about 7.7mm). Hence, the diameter of one-side of the fully opened mechanical TV should be greater than 23Fr. After passing through the mechanical TV, manipulation of the delivery catheter was not difficult due to the main body of the delivery catheter being smaller than the Micra device. Since the TV is firmly fixed, it is not necessary to focus on a typical apical septal location to apply adequate tip pressure and a good reverse curve of the delivery catheter. Needless to say, preprocedural imaging for the planning and guidance of the procedure is mandatory. Especially, a thoughtful discussion is required about the trajectory of the device/delivery catheter through imaging. The right internal jugular vein has been demonstrated as a safe alternative for LPM implantations in adults and pediatric patients, a superior approach may be appropriate depending on the case to avoid any significant catheter tip deflection after going across the mechanical TV. After deploying the device and performing the Pull and Hold test, the recapture cone should remain within the RV so that the tether does not get caught on the mechanical TV. Despite the lower catheter profile of the delivery catheter without an Micra device, there is at least a theoretical concern of an oblique withdrawal across the valve resulting in catheter entrapment along the edge of the coaptation line where a pincer entrapment is possible. To avoid this situation, the use of adenosine may be considered prior to the catheter withdrawal to temporarily suspend the valvular motion. This has been conventionally taught as a technique to mitigate catheter
entanglement risk if a mechanical mitral valve is inadvertently crossed during an LA ablation procedure. Finally, in order to minimize any damage to the mechanical TV, it is recommended to shorten the procedure time as much as possible.

Conclusion

In this case, we performed an implantation of an LPM through a mechanical TV as a last resort. Although our procedure was successful, more studies and discussion are needed to determine whether the LPM could be a reasonable alternative option for patients with mechanical TVs requiring a PM.

Acknowledgements

We thank Ms. Jae-Hee Kim from Medtronic Korea for her assistance and Mr. John Martin for his linguistic assistance.

References


dependence following tricuspid valve surgery: a multicentre analysis. Europace Dec 1


Figure legends

Figure 1. Computed tomography image of the patient’s heart showed the coronary sinus ostium under the mechanical tricuspid valve. TV, tricuspid valve; CS, coronary sinus.

Figure 2. Fluoroscopy image of the final position and Reverse curve of the Micra delivery catheter. (A) Right anterior oblique (20 degree) fluoroscopy image. (B) Left anterior oblique (35 degree) fluoroscopy image.

Figure 3. Chest radiography after the procedure. (A) Posteroanterior view. (B) Lateral view.
Figure 2. (A)
Figure 2. (B)
Figure 3. (B)
Key teaching points

- Leadless pacemaker (PM) implantation (Micra, Medtronic, Minneapolis, MN) through the mechanical tricuspid valve (TV) can be done.

- The size of the implanted mechanical TV should be considered first. The diameter of the Micra device is 6.7mm, and the delivery catheter is 23Fr (about 7.7mm).

- Although our procedure was successful, more studies and discussions are needed to determine whether leadless PM could be a reasonable alternative option for the patients with the mechanical TV requiring PM.