Rapid Deployment Aortic Valve Replacement via Right Lateral Mini-Thoracotomy — First Clinical Experience in Japan —

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**Background:** Rapid deployment aortic valve replacement has been developed to shorten procedural times and to facilitate minimally invasive cardiovascular surgery.

**Methods and Results:** As a representative rapid-deployment valve, the balloon-expanding INTUITY Elite (the 2nd-generation Edwards INTUITY Valve System) was uneventfully implanted via a right lateral mini-thoracotomy in 2 patients with severe aortic valve stenosis. Both of them recovered quickly and were discharged from hospital without significant adverse events.

**Conclusions:** Implantation of the INTUITY Elite valve via right mini-thoracotomy is feasible and safe.

**Key Words:** Minimally invasive cardiac surgery; Minithoracotomy; Rapid deployment aortic valve replacement

Aortic valve replacement (AVR) using conventional bioprostheses is still the gold standard surgical treatment for severe aortic valve stenosis (AS), but transcatheter aortic valve replacement (TAVR) and surgical AVR using rapid-deployment valves (RDVs) have been introduced as effective alternatives in certain patients. Rapid-deployment aortic valve replacement (RDAVR) was developed to shorten the duration of myocardial ischemia and cardiopulmonary bypass (CPB) in response to the value proposition of beating-heart TAVR and to facilitate minimally invasive cardiovascular surgery (MICS). The INTUITY Valve (Edwards Life Sciences, Irvine, CA, USA), one of the commonly used RDVs, consists of a Carpentier-Edwards PERIMOUNT Magna Ease Pericardial Aortic Bioprosthesis and a pre-crimped, cloth-covered, balloon-expandable stainless-steel frame. Early and long-term European studies demonstrated acceptable safety and excellent hemodynamic performance of the 1st-generation INTUITY, which was certified with CE marking in 2011, as was the 2nd-generation INTUITY Elite Valve System in 2014. In the USA, a prospective, nonrandomized, multicenter, single-arm clinical trial showed outcomes similar to those reported in Europe, resulting in the INTUITY Elite Valve System being widely used. In Japan, however, the INTUITY Valve System is not yet commercially available, but because MICS is now commonly applied, it is expected that the INTUITY Valve System will soon be in great demand. We report our experience with MICS-AVR using the INTUITY Elite Valve System (the first clinical usage in Japan) and offer some operative tips.

**Methods**

We undertook the first 2 cases of RDAVR via median full sternotomy, but in June and August 2018, 2 patients with symptomatic severe AS underwent RDAVR using the INTUITY Elite via right lateral minithoracotomy. This series of RDAVR was approved (as “Highly Difficult New Medical Technology”) by Osaka University, and written informed consent was given by the patients.

**Case 1**

A 76-year-old woman presented with shortness of breath. Detailed examination revealed severe AS with a type I bicuspid valve. Because she had suitable anatomy, MICS-AVR was indicated. An 8-cm skin incision was made below the edge of the pectoralis major muscle, and a right lateral minithoracotomy was performed through the 3rd intercostal space. Because she had severe atherosclerotic disease in the descending aorta, CPB was established via a vascular graft in the right axillary artery and a drainage cannula from the right femoral vein. The opened pericardium was sufficiently pulled up and the...
aortic root lifted such that we could tie sutures directly without a knot pusher.\textsuperscript{11} Under antegrade-cardioplegic arrest, calcified aortic cusps were carefully removed, and a 25-mm metal bougie was passed through the annulus. A 23-mm INTUITY Elite valve was placed on the annulus using 3 equidistant guiding sutures (non-pledgeted 2-0 braided polyester suture). After secure valve seating was confirmed, the balloon was appropriately inflated and the guiding sutures directly tied (Figure 2).

Case 2
A 77-year-old woman with severe AS underwent MICS-RDAVR with a 21-mm INTUITY Elite valve. Her aortic annular size was 24 mm. Different from the first case, we started partial CPB via the femoral artery (FA) and vein to depress the heart. Retrograde arterial perfusion was maintained within 2 L/min to avoid the risk of neurological complications. Next, a 14Fr cannula was inserted into the ascending aorta to maintain antegrade cerebral perfusion. Otherwise, the operative procedure was the same as in case 1.

Results
Supplementary Table shows the detailed operative data. Both patients recovered promptly without severe complications. Although the first patient presented with paroxysmal atrial fibrillation and the second patient transiently developed complete atrioventricular block, regular sinus rhythm spontaneously recovered in each case. Postoperative transthoracic echocardiography revealed no perivalvular leakage and acceptable aortic gradient and valve area (Supplementary Table). Both patients were sent home without heart failure symptoms.

Figure 1. Minimally invasive aortic valve replacement performed via a right lateral minithoracotomy approach, which might be cosmetically superior to conventional right anterior minithoracotomy.

Figure 2. (A) The Edwards INTUITY Elite Valve System consists of an INTUITY Elite valve, a delivery system, and an inflation device. (B) The 3 equidistant guiding sutures (*) were placed through the native annulus. There are also 3 commissure sutures to provide a good visual field. (C) Aortic valve replacement using the INTUITY Elite Valve System was safe and uneventful.
Discussion

RDAVR can not only shorten the cross-clamp time but also facilitate MICS-AVR. In their prospective multicenter randomized trial, Borger et al showed that MICS-RDAVR using the Edwards INTUITY Valve System was associated with significantly reduced cross-clamp time and better valvular hemodynamic function than conventional AVR through a full sternotomy. Further investigations are mandatory to elucidate the potential benefits of MICS-RDAVR using the INTUITY Elite Valve System for the first time in a clinical setting in Japan. Its use was suitable and reasonable for MICS-AVR using the Edwards INTUITY Valve System greatly facilitates guiding sutures and commissures to confirm proper seating to avoid conduction disturbance. We also visualize the 3 subvalvular tissues.

There are several technical tips for MICS-RDAVR using the INTUITY Elite. First, never oversize the valve. In the case of “in-between” size, we choose the smaller size to avoid conduction disturbance. We also visualize the 3 guiding sutures and commissures to confirm proper seating of the valve.

As for surgical complications of RDAVR, a relatively high incidence of de novo pacemaker implantation (PMI) has been reported. Although the rate seems higher than after conventional surgical AVR using other bioprostheses, the PMI rate after RDAVR has been decreasing over time (from 17.2% (2007–2008) to 5.4% (2016)) and is not inferior to that with TAVR (14.7% vs. 9.8% in RDAVR). Both of our patients had atherosclerotic disease in the peripheral artery and/or descending aorta. In case 1, axillary artery graft cannulation was selected, but was time-consuming. Therefore, in case 2 we directly cannulated both the ascending aorta and the FA, maintaining antegrade cerebral perfusion to avoid neurological complications. Murzi et al reported that central aortic cannulation could avoid complications associated with retrograde perfusion and thus extended the suitability of MICS to those who have an absolute contraindication for FA cannulation. We believe antegrade perfusion alone or combined with low-flow retrograde perfusion is feasible, safe, and beneficial during MICS-AVR.

In conclusion, RDAVR via right minithoracotomy was performed safely and successfully using the INTUITY Elite Valve System for the first time in a clinical setting in Japan. Its use was suitable and reasonable for MICS-AVR. Because we are still on the learning curve, further investigations are mandatory to elucidate the potential benefits of MICS-RDAVR using the INTUITY Elite Valve System via a right lateral minithoracotomy.

Disclosure

The authors declare no conflicts of interest.

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None.

References


Supplementary Files

Please find supplementary file(s):