Percutaneous transcatheter aortic valve replacement: first transapical implant in Asia

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ABSTRACT

Percutaneous transcatheter implantation of the aortic valve has been demonstrated as an alternative to open heart surgery in high-risk patients with symptomatic severe aortic stenosis (AS) who are not suitable for open surgery. The majority of these new devices are delivered via the transfemoral approach. However, due to the current size of delivery sheaths, the small and tortuous iliofemoral anatomy makes this approach challenging. The transapical approach provides a viable option for this patient subgroup. The first-in-Asia transcatheter aortic valve implantation via the transapical route is described. A 79-year-old Chinese woman with symptomatic severe AS and peripheral arterial disease, who was at high surgical risk, was successfully treated, and had good functional and haemodynamic results at the three-month follow-up.

Keywords: aortic valve stenosis, bioprosthesis, heart valve prosthesis, transcatheter aortic valve implantation, transapical

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INTRODUCTION

For patients with symptomatic severe aortic stenosis (AS), surgical aortic valve replacement (AVR) provides relief of symptoms and improves survival.[1] Transcatheter heart valve therapy is emerging as an alternative for patients with symptomatic severe AS who are not suitable for open surgery.[2] This technology has evolved tremendously since the first-in-man implantation in 2002,[3] and transfemoral device delivery has shown encouraging results.[2] However, limitations remain due to the existing delivery sheath profiles, especially in patients with small, diseased or tortuous access vessels.[2] We describe the first transapical transcatheter aortic valve implantation for symptomatic severe AS in Asia.

CASE REPORT

A 79-year- old Chinese woman with known AS presented with progressive shortness of breath on exertion and a worsening functional status (New York Heart Association [NYHA] Class 3) over a two-year period. Additional medical history included ischaemic heart disease with prior percutaneous coronary interventions (bare metal stents) to the circumflex artery in the year 2000 and the distal right coronary artery in 2004, peripheral vascular disease with percutaneous intervention (stenting) to the distal abdominal aorta extending into the left common iliac artery in 2000, hypertension, insulin-dependent diabetes mellitus and dyslipidaemia.

Echocardiographic assessment showed severe AS with an aortic valve area (AVA) of 0.8 cm^2 and a mean pressure gradient of 36 mmHg across the aortic valve. The aortic annulus measured 23 mm in diameter. The left ventricular ejection fraction (LVEF) was 60%. Moderate septal hypertrophy was noted; however, there was no left ventricular outflow tract obstruction. Cardiac catheterisation showed the stents to the circumflex and distal right coronary arteries to be patent. The mean pressure gradient was 64 mmHg, with a calculated AVA of 0.6 cm^2. Abdominal aortogram showed the stent to be patent (crossing the origin of the right common iliac artery, and extending into the left common iliac artery), but the left external iliac artery was diseased, with a minimum diameter of 5 mm.

The logistic EuroScore was 13.5% and the Society of Thoracic Surgeons (STS) score was 4.6%. Chest radiograph (Fig. 1) and computerised tomographic angiogram revealed extensive ascending aorta and arch calcification (porcelain aorta). Due to this reason and her advanced age and comorbidities, she was deemed to be unsuitable for open AVR by two senior cardiothoracic surgeons. In view of the peripheral vascular disease and the resultant small iliofemoral vessels, the patient was offered transapical transcatheter aortic valve implantation.

Informed consent was obtained from the patient and her family. The procedure was performed in the cardiac

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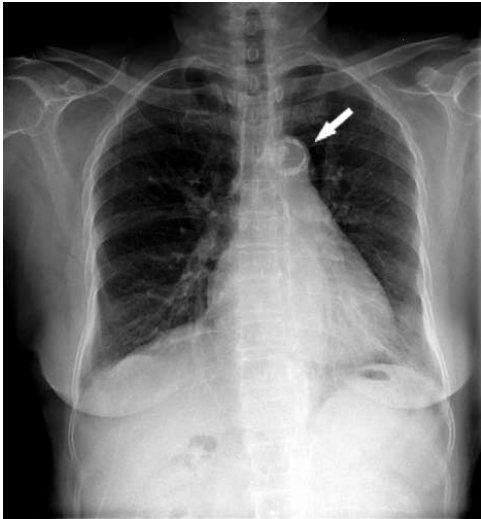Fax: (65) 6224 3632
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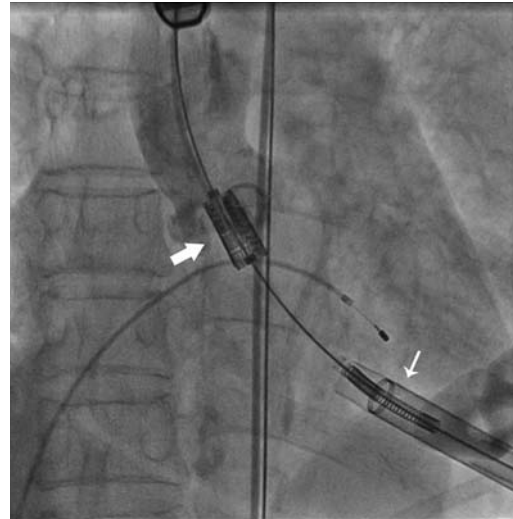**Fig. 1** Chest radiograph shows aortic calcification (arrow).

Fig. 2 Aortogram shows the Sapien THV (thick arrow) in position at the aortic annulus. The thin arrow shows the tip of the introducer sheath within the left ventricle.

catheterisation laboratory, which was modified to adapt to the procedure. The patient was put under general anaesthesia. A cannula was placed in the right radial artery for continuous blood pressure (BP) monitoring, and a Swan-Ganz catheter was placed in the right internal jugular vein for central venous pressure monitoring. Transoesophageal echocardiography (TEE) was performed to confirm aortic annulus dimension and to provide imaging during the procedure. Left groin venous and arterial access was obtained for the placement of a pacing wire in the right ventricular apex and a pigtail catheter in the aortic root.

A left anterior mini-thoracotomy was performed, the pericardium incised, and the left ventricular apex exposed. Pledgeted mattress purse-string sutures were placed on the apex, which was punctured, and a soft-tip 0.035-inch wire was used to cross the aortic valve antegradely. This was exchanged for a stiff 0.035-inch exchange length wire, which was placed across the aortic arch and the tip positioned in the abdominal aorta. A 14-Fr sheath was introduced into the apex, and balloon aortic valvuloplasty (20 mm × 3 cm balloon) was performed under rapid ventricular pacing.

Throughout the procedure, adequate perfusion pressures were ensured by maintaining the systolic BP above 100 mmHg, using vasoconstrictors as needed. A 26-Fr introducer sheath was subsequently introduced into the apex, and a 26-mm Sapien transcatheter heart valve (THV) (Edwards Lifesciences, Irvine, CA, USA) was then manually crimped onto a 26 mm × 3 cm balloon and advanced into the aortic annulus. Optimal device position was assessed with fluoroscopy (Fig. 2) and TEE, and the THV was then deployed under rapid

pacing by inflating the balloon (Fig. 3).

Immediate post-deployment TEE showed a stable THV position, a mean pressure gradient of 11 mmHg and a trivial paravalvular leak. Root aortogram revealed minimal aortic regurgitation and patent coronary arteries (Fig. 4). Anaesthesia was reversed, and the patient was extubated on-table. Recovery was uneventful except for wound pain, which was controlled with oral analgesia, and she was discharged on postoperative Day 9. The patient was well at the 90-day follow-up and reported a marked improvement in the functional status to NYHA Class 1. Echocardiographic assessment showed a LVEF of 74%, a mean pressure gradient of 7 mmHg across the aortic valve and the disappearance of the aortic paravalvular leak.

DISCUSSION

Surgical aortic valve replacement remains the gold standard therapy for patients with symptomatic severe AS. However, a significant proportion of patients are assessed to be unfit and thus not offered this treatment.[4] Balloon valvuloplasty did not alter the prognosis for these patients.[5] Percutaneous transcatheter has emerged as an alternative for patients who are not suitable for surgical AVR.[2]

The Sapien THV consists of three bovine pericardial leaflets mounted within a stainless steel frame. It can be deployed either via the transfemoral or transapical approach using proprietary delivery systems. The transapical technique was developed in order to avoid and overcome some of the transfemoral limitations, mostly related to small or tortuous access femoral vessels. Walter et al reported a procedural success rate of
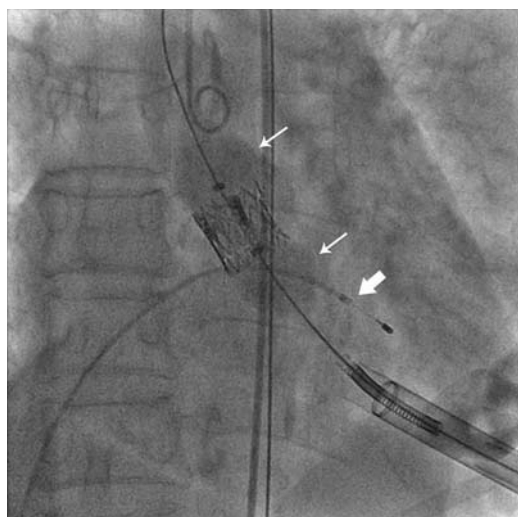
Fig. 3 Deployment of the Sapien THV by balloon inflation (thin arrows). The thick arrow shows the pacing wire.
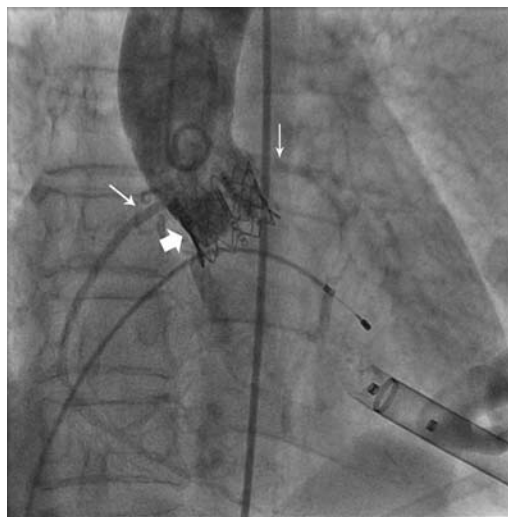

Fig. 4 Root aortogram shows patent coronary arteries (thin arrows). The thick arrow shows the expanded THV.

94%, and a 30-day mortality of 8% in a high-risk group of 50 patients (mean logistic EuroSCORE 27.6 +/– 12.2; mean STS score 5.8 +/– 9.1).[6]

The Sapien THV has obtained the European CE mark, and is currently in use in many centres in Europe and in Canada; it is also undergoing a FDA-sanctioned clinical trial in North America. This case is the first transapical implant in Asia, following on the first Asian transfemoral implant at our centre.[7] This is a relatively new technology with promising short to mid-term results.[2] In comparison with current surgical bioprosthetic aortic valves, however, long-term durability data is still lacking. In view of this, patients considered for this therapy must be deemed to be at high surgical risk, and not suitable for conventional AVR. The relative contraindications for surgical AVR include irradiated chest and porcelain aorta.[8]

Risk assessment of open surgery is performed using either the logistic EuroSCORE[9] or the STS score.[10] These risk stratification scores were developed to predict operative risk for open heart surgery in Europe and in the United States, respectively. A EuroSCORE > 20, or a STS score > 10 is considered high risk. Our patient had a logistic EuroSCORE of 13.5% and a STS score of 4.6%, but her surgical-risk was assessed to be high in view of her age, comorbidities and heavily calcified (porcelain) aorta, for which she had been denied open AVR for more than a year.

In the workup to the procedure, the authors had considered the potential procedural risks of transcatheter heart valve therapy, including coronary artery occlusion (a rare complication), which may necessitate stenting of the occluded coronary[11] and device embolisation, which may require transcatheter or even open surgical retrieval. The risk of embolisation was minimised by meticulous positioning of the device under rapid pacing prior to deployment. Another concern was the risk of pneumonia,[2] which may result from wound pain, prolonged immobilisation or general debility of the patient. Measures, such as the judicious use of oral analgesia, on-table extubation and early mobilisation, resulted in the patient being discharged home on Day 9. Additional measures, including smaller incisions, the usage of special soft tissue retractors and intercostal blocks, have since resulted in discharges as early as Day 6. The patient's post-procedural clinical and haemodynamic results were consistent with the reported data. Her mean pressure gradient of 7 mmHg compared favourably with the reported figures of 10–20 mmHg, and her trivial paravalvular leak disappeared with time.[12]

In conclusion, percutaneous transcatheter aortic valve implantation is a viable alternative for selected patients with symptomatic severe AS who are at high surgical risk and not suitable for open surgery. In this first-in-Asia transapical implantation of a transcatheter heart valve, a patient with symptomatic severe AS, porcelain aorta and arterial access limitations was successfully treated, with good clinical outcome and satisfactory haemodynamics at 90-day follow-up.

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