

First transcatheter aortic valve implantation for severe pure aortic regurgitation in Asia

Paul Toon-Lim Chiam¹, MBBS, FRCP, See Hooi Ewe¹, MBBS, MRCP, Yeow Leng Chua², MBBS, FRCS, Yean Teng Lim³, MBBS, FRCP

ABSTRACT Transcatheter aortic valve implantation (TAVI) has become the standard of care for inoperable patients with symptomatic severe aortic stenosis (AS), and an alternative to open aortic valve replacement for patients at high surgical risk. TAVI has also been performed in several groups of patients with off-label indications such as severe bicuspid AS, and as a valve-in-valve therapy for a degenerated surgical bioprosthesis. Although TAVI with CoreValve® prosthesis is technically challenging, and global experience in the procedure is limited, the procedure could be a treatment option for well-selected patients with severe pure aortic regurgitation (AR). Herein, we report Asia's first case of TAVI for severe pure AR in a patient who was at extreme surgical risk, with good clinical outcome at six months.

Keywords: aortic valve regurgitation, aortic valve stenosis, catheter, prosthesis, transcatheter aortic valve implantation

INTRODUCTION

Transcatheter aortic valve implantation (TAVI) was first performed in 2002.⁽¹⁾ It has become the standard of care for inoperable patients with symptomatic severe aortic stenosis (AS),^(2,3) and an alternative to open aortic valve replacement (AVR) for patients at high surgical risk.^(4,5) TAVI has also been performed in several groups of patients with off-label indications such as severe bicuspid AS,^(6,7) and as a valve-in-valve therapy for a degenerated surgical bioprosthesis.⁽⁸⁾ Although experience in the procedure is currently very limited, TAVI with CoreValve® prosthesis could be a treatment option for well-selected patients with severe pure aortic regurgitation (AR).⁽⁹⁾

CASE REPORT

A 43-year-old man presented with increasing dyspnoea on exertion (New York Heart Association [NYHA] class III). Past medical history included treated infective endocarditis (IE) six months prior to the current presentation, Child-Pugh class B–C liver cirrhosis complicated by thrombocytopenia (platelet count 60,000–70,000) and bleeding oesophageal varices that required banding, stable ischaemic heart disease with previous multivessel coronary angioplasty and stenting, thalassaemia minor, diabetes mellitus, hypertension and dyslipidaemia.

Echocardiography revealed severe AR due to a flail leaflet (noncoronary leaflet) (Fig. 1), likely as a result of IE. Left ventricular ejection fraction (LVEF) was mildly depressed at 45% and there was dilatation of the left ventricle. The aortic root dimensions, however, were within normal limits. Coronary angiography showed patent coronary stents and no new significant stenoses.

The patient was turned down for AVR at another public institution due to excessive risk (surgical mortality was estimated to be approximately 60%–70%); he was also subsequently

refused AVR at a private hospital due to the prohibitive surgical risk. He was then referred to our institution for consideration of TAVI. Computed tomography (CT) angiography showed an aortic annulus (diameter of 25 mm), normal aortic root dimensions, and adequate iliac and femoral artery size for the transfemoral approach. Based on the echocardiography and CT angiography findings, TAVI was deemed technically feasible. Although the prognosis of Child-Pugh class B–C liver cirrhosis is guarded with a survival of 2–5 years, the medical team, the patient, and the patient's family decided to proceed with TAVI for symptom relief and improvement in the patient's quality of life. Informed consent was obtained for extreme-risk, bail-out, open heart surgery, should complications that necessitate this occur during TAVI. As the patient was relatively young, and because we had no prior experience with the use of TAVI in such an off-label indication, approval was obtained from the ethics committee of the hospital.

The procedure was performed under general anaesthesia in a hybrid operating room. A 29-mm CoreValve® self-expandable transcatheter heart valve (Medtronic Inc, Fridley, MN, USA) was selected according to the manufacturer's recommendation, as the aortic root was not dilated and thus gross device oversizing was not necessary. The prosthesis was successfully deployed within the native aortic annulus via the transfemoral transarterial route (Fig. 2). In addition to the usual technique, a second pigtail catheter was placed at the aortic root to serve as an additional landmark of the native annulus (due to its lack of aortic valve calcification), and cardiac pacing at 120 bpm was employed during the release of the valve to reduce movement of the prosthesis. Intraprocedural transesophageal echocardiography showed good valve apposition with only trivial residual AR. Aortography revealed patent coronary

¹Department of Cardiology, ²Department of Cardiothoracic Surgery, National Heart Centre, ³Cardiology Associates, Mount Elizabeth Hospital, Singapore

Correspondence: Dr Paul TL Chiam, Senior Consultant, Department of Cardiology, National Heart Centre, 17 Third Hospital Avenue, Mistri Wing, Singapore 168752. paul.chiam.t.l@nhcs.com.sg

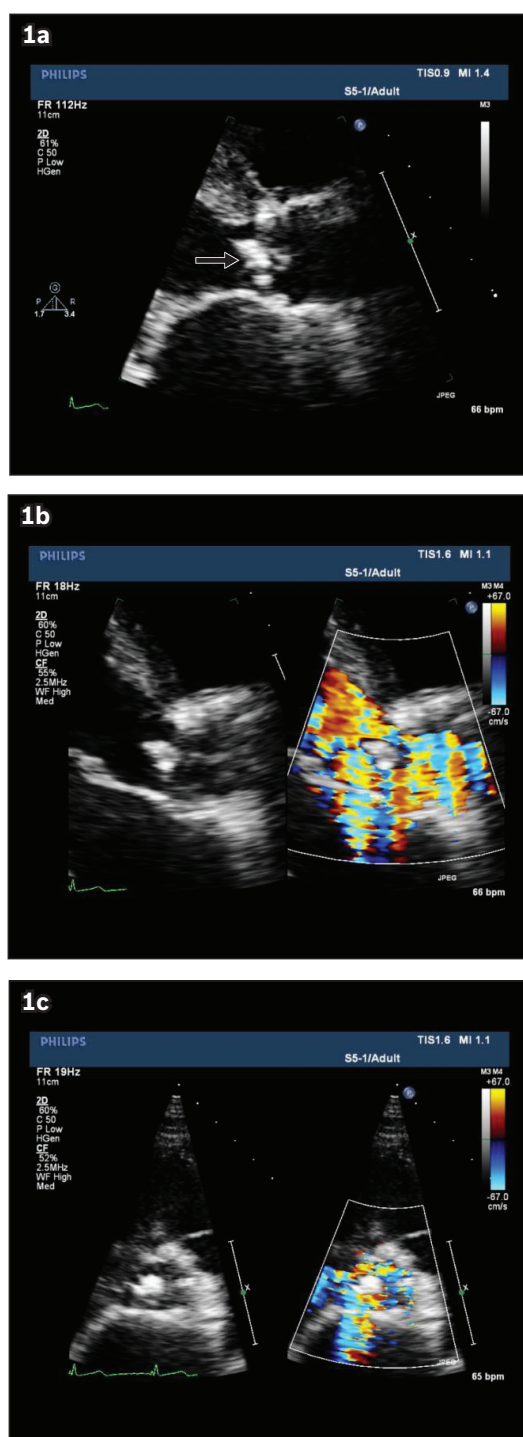


Fig. 1 Parasternal long axis transthoracic echocardiography images show (a) flail non-coronary aortic valve leaflet (arrow); and (b & c) severe AR (colour jets).

arteries and trivial AR. The patient made an uneventful recovery and was discharged after one week.

At 30 days post procedure, the patient reported significant symptomatic improvement and was recategorised as NYHA class I. Echocardiography showed an LVEF of 45%, a normally functioning aortic bioprosthesis with a mean pressure gradient of 12 mmHg, and only trivial AR. He has remained well with no detectable early diastolic murmur and good functional status at six months.

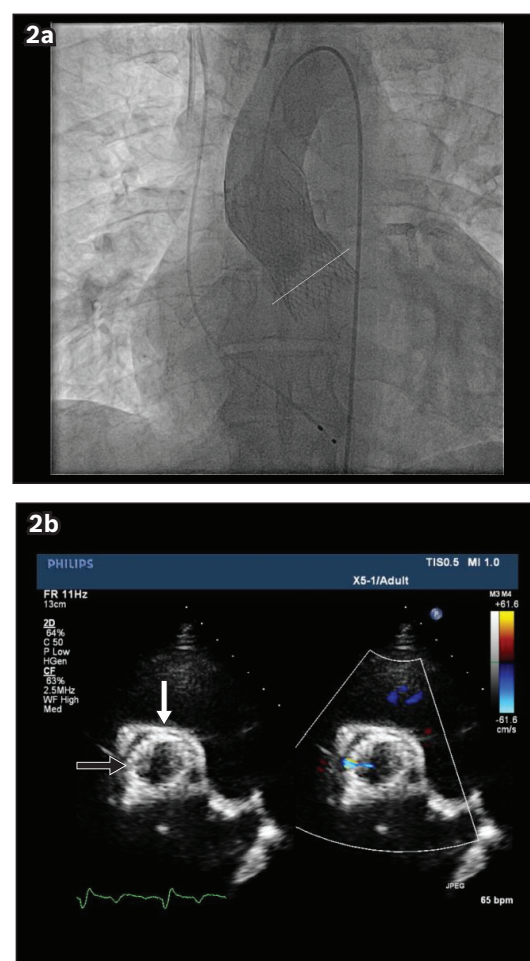


Fig. 2 (a) Fluoroscopic image of an aortogram shows the CoreValve® post deployment, with no leakage of dye toward the left ventricular cavity. The white line indicates the annular plane of the native aortic valve. (b) Parasternal short axis transthoracic echocardiography at one month shows a well-expanded valve (open arrow) within the native aortic annulus (white arrow).

DISCUSSION

With more than 90,000 patients having undergone TAVI, this procedure is now an established treatment option for inoperable and high surgical-risk patients with symptomatic severe AS. However, data for TAVI in severe pure AR has been sparse and limited to case reports, and only very recently, a small European registry.⁽⁹⁾ This is the first report of TAVI for severe pure AR in Asia.

In TAVI for severe AS, the calcified native leaflets that are not removed (they are instead 'crushed' against the aortic wall) serve to 'anchor' the transcatheter heart valve in the aortic annulus. In severe pure AR however, the leaflets are usually not calcified and the aortic root dimensions tend to be larger as compared to that in severe AS. Thus, the balloon-expandable Edwards SAPIEN valve (Edwards, Irvine, CA, USA), due to its short stent frame design (Fig. 3), may not be ideal for use in severe pure AR, despite the presence of robust randomised data of its use in severe AS.⁽²⁻⁵⁾ Conversely, the self-expandable CoreValve® (Fig. 4), due to its longer stent frame and hour-glass shape, may be more suitable for use in severe pure AR.



Fig. 3 Photograph shows an Edwards SAPIEN XT valve.



Fig. 4 Photograph shows a Medtronic CoreValve®.

Even so, it has been reported that the use of TAVI with CoreValve® in severe pure AR is associated with more complications, such as valve dislocation (due to the lack of native leaflet calcification), the need for two valves during the procedure (i.e. valve-in-valve), and also a higher likelihood of residual paravalvular leak after implantation.⁽⁹⁾ In the present case, we managed to avoid these potential complications by employing meticulous preprocedural imaging, and using certain techniques during the procedure to optimise valve stability during positioning and deployment. Once the CoreValve® is implanted at the correct anatomical position, the likelihood of CoreValve® embolisation is low even without native leaflet calcification to provide anchor support. Local tissue inflammation and scarring can then be expected to provide secure fixation of the valve within a few weeks.

One particular concern in the present case was the history of endocarditis and infected leaflet tissue in our patient. Although there are no reports regarding the long-term outcomes of TAVI in previous endocarditic valves, it can be expected that TAVI can be performed in the usual fashion if the endocarditis has completely healed without any biochemical markers of ongoing inflammation (i.e. 'sterile healed leaflets'), as was the case in our patient.

The haemodynamic performance of transcatheter valves is similar to that of surgical bioprostheses,⁽²⁻⁵⁾ although the long-term durability of transcatheter valves has not been demonstrated beyond ten years. In our patient, however, there was no other option, and any improvement in his quality of life would be highly significant since his longevity may already be severely limited by his other comorbidities. In fact, should his CoreValve® prosthesis degenerate in the future, a valve-in-valve procedure (i.e. putting another transcatheter heart valve within the CoreValve®) is a possible therapeutic option.⁽⁸⁾

In conclusion, TAVI has been performed in a limited number of patients who have severe pure AR and an excessive surgical risk. We report the first case of the use of TAVI in a patient with severe pure AR in Asia. A good haemodynamic and clinical outcome was achieved, with remarkable improvement in the patient's quality of life at six months post procedure.

REFERENCES

1. Cribier A, Eltchaninoff H, Bash A, et al. Percutaneous transcatheter implantation of an aortic valve prosthesis for calcific aortic stenosis: first human case description. *Circulation* 2002; 106:3006-8.
2. Leon MB, Smith CR, Mack M, et al. Transcatheter aortic-valve implantation for aortic stenosis in patients who cannot undergo surgery. *N Engl J Med* 2010; 363:1597-607.
3. Makkar RR, Fontana GP, Jilaihawi H, et al. Transcatheter aortic-valve replacement for inoperable severe aortic stenosis. *N Engl J Med* 2012; 366:1696-704.
4. Smith CR, Leon MB, Mack MJ, et al. Transcatheter versus surgical aortic-valve replacement in high-risk patients. *N Engl J Med* 2011; 364:2187-98.
5. Kodali SK, Williams MR, Smith CR, et al. Two-year outcomes after transcatheter or surgical aortic-valve replacement. *N Engl J Med* 2012; 366:1686-95.
6. Chiam PT, Chao VT, Tan SY, et al. Percutaneous transcatheter heart valve implantation in a bicuspid aortic valve. *JACC Cardiovasc Interv* 2010; 3:559-61.
7. Wijesinghe N, Ye J, Rodés-Cabau J, et al. Transcatheter aortic valve implantation in patients with bicuspid aortic valve stenosis. *JACC Cardiovascular Interv* 2010; 3:1122-5.
8. Dvir D, Webb J, Brecker S, et al. Transcatheter aortic valve replacement for degenerative bioprosthetic surgical valves: results from the global valve-in-valve registry. *Circulation* 2012; 126:2335-44.
9. Roy DA, Schaefer U, Guetta V, et al. Transcatheter aortic valve implantation for pure severe native aortic valve regurgitation. *J Am Coll Cardiol* 2013; 61:1577-84.