

Case Report

Transcatheter Aortic Valve Implantation (TAVI): First Case in Thailand

Pranya Sakiyalak MD*, Worawong Slisatkorn MD*,
Suwatchai Pornratanarangsi MD**, Nattawut Wongpraparut MD**,
Decho Jakrapanichakul MD**, Kasana Raksamani MD***,
Ungkab Prakanrattana MD***, Pansak Laksanabunsong MD*

*Division of Cardiovascular and Thoracic Surgery, Department of Surgery, Faculty of Medicine Siriraj Hospital,
Mahidol University, Bangkok, Thailand

** Division of Cardiology, Department of Medicine, Faculty of Medicine Siriraj Hospital,
Mahidol University, Bangkok, Thailand

***Department of Anesthesiology, Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok, Thailand

Aortic valve replacement (AVR) is the standard treatment for patients with symptomatic severe aortic stenosis (AS). However, many patients are not offered surgery due to high surgical risk for open AVR. Transcatheter aortic valve implantation has been an alternative to open heart surgery in patients with symptomatic severe aortic stenosis (AS) who are not suitable for open surgery. The first transcatheter aortic valve implantation in Thailand via the transapical route is described. An 87-year-old woman with symptomatic severe AS, calcified aorta and peripheral arterial disease, who was at high surgical risk, was successfully treated, and had good functional and haemodynamic results at six-months follow-up.

Keywords: Aortic valve stenosis, Bioprostheses, Cardiothoracic surgery, Heart valve prosthesis implantation, Percutaneous prosthesis implantation, Percutaneous transcatheter aortic valve implantation

J Med Assoc Thai 2012; 95 (1): 124-8

Full text. e-Journal: <http://www.jmat.mat.or.th>

For patients with symptomatic severe aortic stenosis (AS), surgical aortic valve replacement (AVR) provides relief of symptoms and improves survival⁽¹⁾. Since the first-in-man implantation in 2002⁽²⁾, transcatheter aortic valve is emerging as an alternative for patients with symptomatic severe AS who are not suitable for open surgery⁽³⁾. There are currently two implantation techniques, transapical and transfemoral approaches. The authors describe the first transapical transcatheter aortic valve implantation for symptomatic severe AS in Thailand.

Case Report

An 87-year-old woman with known AS presented with progressive shortness of breath on exertion and a worsening functional status (New York Heart Association [NYHA] Class 3). She

was admitted at an outside hospital with acute pulmonary edema and was turned down for surgery by the cardiac surgeon. Additional medical history included coronary artery disease, peripheral vascular disease, hypertension, non-insulin-dependent and diabetes mellitus. Echocardiographic assessment showed severe calcified AS with an aortic valve area (AVA) of 0.74 cm² and a mean pressure gradient of 42 mmHg across the aortic valve. The aortic annulus measured 21 mm in diameter. The left ventricular ejection fraction (LVEF) was 67%. Calcified mitral valve annulus was also noted. A coronary angiogram revealed single-vessel coronary artery disease with severe stenosis of left anterior descending artery (LAD). She had undergone percutaneous coronary intervention for LAD lesion with bare metal stent 1 month earlier. Her subsequent cardiac catheterization including thoracic and abdominal aortography with iliofemoral runoffs revealed patent left anterior descending artery stent. Her left and right iliac artery diameters were 6.5 cm and 6 cm respectively with heavily calcification. The mean pressure gradient across the aortic valve was 43 mmHg, with a calculated

Correspondence to:

Sakiyalak P, Division of Cardiovascular and Thoracic Surgery,
Department of Surgery, Faculty of Medicine, Siriraj Hospital,
Mahidol University, Bangkok 10700, Thailand.
Phone: 0-2419-7998, Fax: 0-2411-0260
E-mail: sipy@mahidol.ac.th

AVA of 0.7 cm^2 . The logistic Euro Score was 12%. Due to her advanced age and comorbidities, she was offered transcatheter aortic valve implantation as an alternative to conventional surgery. In view of the peripheral vascular disease and small iliofemoral vessels, transapical approach was chosen. Informed consent was obtained from the patient and her family. The procedure was performed in the cardiac catheterization suite. The procedure was done under general anaesthesia. Transesophageal echocardiography (TEE) was performed to confirm aortic annulus dimension and to provide imaging during the procedure. Right groin venous and arterial accesses were obtained for the placement of a pacing wire in the right ventricular apex and a pigtail catheter in the aortic root. Apex of the heart was identified with fluoroscopy then left anterior mini-thoracotomy was performed, the pericardium incised and the left ventricular apex exposed (Fig. 1). Pledgedget mattress purse-string sutures were placed just lateral to the apex. Pacingwire was sutured on the epicardium directly. Apex was then punctured and a softtip wire was inserted across the aortic valve antegradely. This was exchanged for a stiff 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 was performed under rapid ventricular pacing. During the procedure, adequate perfusion pressures were ensured by maintaining the systolic BP above 100 mmHg, using vasoconstrictors. An introducer sheath was exchanged to a 24-Fr sheath and a 23-mm Sapien transcatheter heart valve (THV) (Edwards Lifesciences, Irvine, CA, USA) was manually crimped onto a 23 mm x 3 cm balloon (Fig. 2) and advanced into the aortic annulus. Optimal device position was assessed with fluoroscopy (Fig. 3) and TEE and the THV was then deployed under rapid pacing by inflating the balloon (Fig. 4). Immediate post-deployment TEE showed a stable THV position, a mean pressure gradient of 11 mmHg and a mild paravalvular leak. TEE and root aortogram revealed minimal aortic regurgitation (Fig. 5). Anaesthesia was reversed and the patient was extubated before being moved to the cardiac intensive care unit. Recovery was uneventful and she was discharged on postoperative Day 4. The patient reported a marked improvement in the functional status to NYHA Class 1 at the 1, 3 and 6 months follow-up. Echocardiographic assessment 1 month follow-up showed a LVEF of 77%, a mean pressure gradient of 19 mmHg across the aortic valve and a mild to moderate amount of the aortic

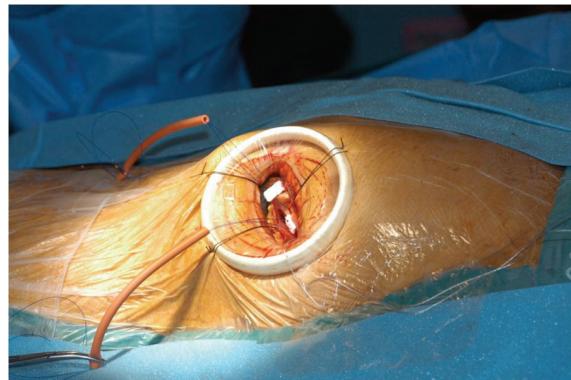


Fig. 1 Left anterior mini thoracotomy using fluoroscopy guided for the location of apex



Fig. 2 Photograph shows the Sapien THV crimped onto a balloon

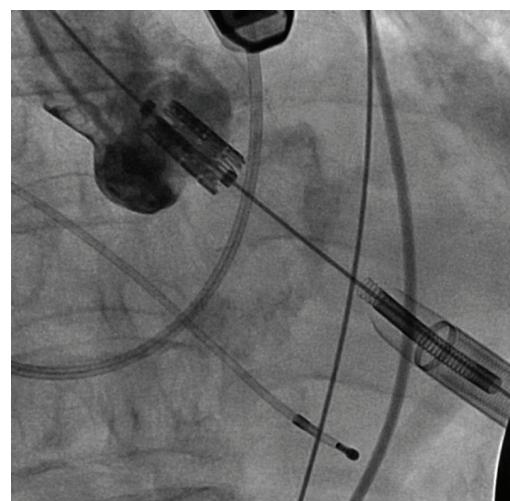


Fig. 3 Aortogram shows the Sapien THV in position at the aortic annulus

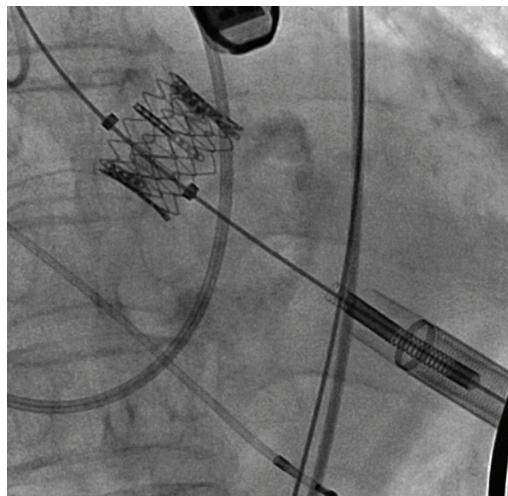


Fig. 4 Fluoroscopic image shows deployment of the Sapien THV

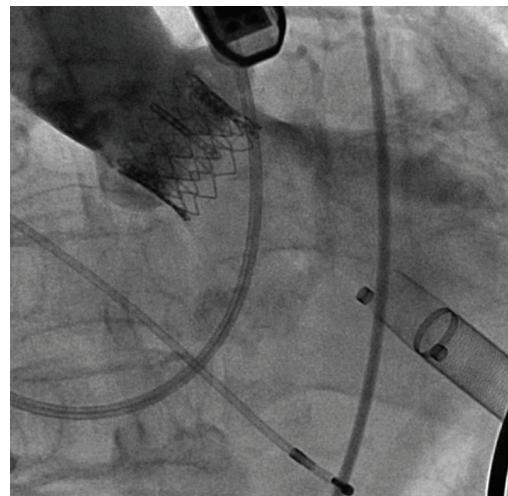


Fig. 5 Root aortogram revealed THV in good position with minimal aortic regurgitation

paravalvular leak. She remained well at 6 months follow-up.

Discussion

Aortic valve replacement (AVR) is the gold standard treatment for symptomatic aortic stenosis, shown to improve outcome and survival. This procedure consists of median sternotomy, placing under cardiopulmonary bypass, arresting the heart and manually excising the valve leaflet and suturing a prosthetic valve on to the aortic annulus. As an isolated procedure, AVR carries an average 30-day mortality of 1-3%. However, in elderly patients with multiple comorbidities, the mortality can be 5-10 times higher⁽⁴⁾. Balloon valvuloplasty could temporarily relieve the symptoms but 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 (Fig. 5). 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. The Sapien THV has obtained the European CE mark and is currently in use in many centers in Europe and in Canada. Recently, Sapien THV is being evaluated in the PARTNER (Placement of AoRTictraNscathetER valves) pivotal trial for US Food and Drug Administration

(FDA) approval. The trial compared patients with severe aortic stenosis who were not suitable candidates for surgery, who were randomized between TAVI using the Sapien THV valve, compared with the standard therapy of medical therapy including balloon aortic valvuloplasty. The PARTNER trial showed a significantly reduced rate (54 percent) of death from all causes and rehospitalization using TAVI⁽⁶⁾. The present study suggests TAVI is an effective treatment option for severe aortic stenosis in patients who cannot have surgery. TAVI is a relatively new technology with promising short to mid-term results⁽³⁾. In comparison with current surgical bioprosthetic aortic valves, however, long-term durability data is still lacking. Therefore, patients considered for TAVI should have high surgical risk and not suitable for conventional AVR. The relative contraindications for surgical AVR include reoperation after coronary artery bypass grafting (CABG) and porcelain aorta⁽⁷⁾.

The presented patient had high surgical risk due to her advanced age and comorbidities and TAVI was offered as an alternative procedure. The procedure was successfully performed without any complication. The patient's clinical improvement and hemodynamic findings at 30 days are consistent with the reported literature. Despite the fact that the native leaflets are not removed, valve areas of 1.5-1.6 cm² have been consistently achieved with mean pressure gradients around the range of 10-20 mmHg^(8,9). The mild-moderate paravalvular leak in the presented patient is not expected to pose any significant problem in the future

as most studies show that these leaks either disappear or remain stable, and that mild-moderate paravalvular leaks are well tolerated⁽¹⁰⁾.

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 TAVI case in Thailand, a patient with symptomatic severe AS, high surgical risk and arterial access limitations was successfully treated, with good clinical outcome and satisfactory hemodynamics at 6 month follow-up.

Acknowledgement

The authors wish to thank Dr Anson Cheung from St Paul's Hospital, Vancouver, British Columbia, Canada, for his technical assistance during the procedure.

Potential conflicts of interest

None.

References

1. Kvidal P, Bergstrom R, Horte LG, Stahle E. Observed and relative survival after aortic valve replacement. *J Am Coll Cardiol* 2000; 35: 747-56.
2. Cribier A, Eltchaninoff H, Bash A, Borenstein N, Tron C, Bauer F, et al. Percutaneous transcatheter implantation of an aortic valve prosthesis for calcific aortic stenosis: first human case description. *Circulation* 2002; 106: 3006-8.
3. Webb JG, Altwegg L, Boone RH, Cheung A, Ye J, Lichtenstein S, et al. Transcatheter aortic valve implantation: impact on clinical and valve-related outcomes. *Circulation* 2009; 119: 3009-16.
4. Gehlot A, Mullany CJ, Ilstrup D, Schaff HV, Orzulak TA, Morris JJ, et al. Aortic valve replacement in patients aged eighty years and older: early and long-term results. *J Thorac Cardiovasc Surg* 1996; 111: 1026-36.
5. Otto CM, Mickel MC, Kennedy JW, Alderman EL, Bashore TM, Block PC, et al. Three-year outcome after balloon aortic valvuloplasty. Insights into prognosis of valvular aortic stenosis. *Circulation* 1994; 89: 642-50.
6. Leon MB, Smith CR, Mack M, Miller DC, Moses JW, Svensson LG, et al. Transcatheter aortic-valve implantation for aortic stenosis in patients who cannot undergo surgery. *N Engl J Med* 2010; 363: 1597-607.
7. Chiam PT, Ruiz CE. Percutaneous transcatheter aortic valve implantation: assessing results, judging outcomes, and planning trials: the interventionalist perspective. *JACC Cardiovasc Interv* 2008; 1: 341-50.
8. Cribier A, Eltchaninoff H, Tron C, Bauer F, Agatiello C, Nercolini D, et al. Treatment of calcific aortic stenosis with the percutaneous heart valve: mid-term follow-up from the initial feasibility studies: the French experience. *J Am Coll Cardiol* 2006; 47: 1214-23.
9. Webb JG, Pasupati S, Humphries K, Thompson C, Altwegg L, Moss R, et al. Percutaneous transarterial aortic valve replacement in selected high-risk patients with aortic stenosis. *Circulation* 2007; 116: 755-63.
10. Rajani R, Kakad M, Khawaja MZ, Lee L, James R, Saha M, et al. Paravalvular regurgitation one year after transcatheter aortic valve implantation. *Catheter Cardiovasc Interv* 2010; 75: 868-72.

รายงานผู้ป่วยผ่าตัดใส่ลิ้นหัวใจ aortic ผ่านสายสวนรายแรกของประเทศไทย

ปรัชญา สาคิยลักษณ์, วงศ์ ศลิปภูรรักษ์, สุวัชช์ พรัตตันธัศรี, ณัฐวุฒิ วงศ์ประภาตัน, เดชา จกรพานิชกุล,
กษณา รักษาณี, อังกาน ปราการรัตน์, พันธุ์ศักดิ์ ลักษณบุญส่ง

การผ่าตัดเปลี่ยนลิ้นหัวใจ aortic เป็นการรักษามาตราฐานในผู้ป่วยลิ้นหัวใจ aortic ตีบที่มีอาการในผู้ป่วยที่มีความเสี่ยงสูงต่อการผ่าตัดเปลี่ยนลิ้นหัวใจมักจะถูกปฏิเสธการรักษา การผ่าตัดใส่ลิ้น aortic ผ่านสายสวนเป็นทางเลือกใหม่สำหรับผู้ป่วยที่มีความเสี่ยงสูงในการรักษาโรคลิ้นหัวใจ aortic ตีบมาก ผู้นิพนธ์รายงานผู้ป่วยหนงสูงไทย อายุ 87 ปี ที่มีโรคลิ้นหัวใจตีบมาก มีหินปูนจับหลอดเลือด aorta และมีโรคหลอดเลือดแดงส่วนปลายตีบ ซึ่งส่งผลให้มีความเสี่ยงสูงต่อการผ่าตัดเปลี่ยนลิ้นหัวใจ aortic ผู้ป่วยรายนี้ได้รับการผ่าตัดใส่ลิ้นหัวใจ aortic ผ่านสายสวนเป็นรายแรกของประเทศไทย ผลการรักษาเป็นที่พอกใจจากการติดตามการรักษาเป็นระยะเวลา 6 เดือน