Case Report

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Transcatheter Aortic Valve Implantation: First Case in Nepal

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Abstract

Surgical aortic valve replacement has remained the gold standard therapy for symptomatic severe aortic stenosis patients for decades. However, in the past decade transcatheter aortic valve implantation has been an alternative to surgical aortic valve replacement in patients with symptomatic severe aortic stenosis who are not suitable for open-heart surgery. We report the first case of transcatheter aortic valve implantation in Nepal, an 80-year-old female with symptomatic severe Aortic valve Stenosis who underwent successful aortic valve implantation and had good functional and hemodynamic results at a one-month follow-up.

Keywords: Aortic valve stenosis; Surgical aortic valve replacement; Transcatheter aortic valve implantation

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Introduction

Prevalence of degenerative aortic valve stenosis (AS) is growing due to an increase in general life expectancy.[1] Once symptomatic and left untreated, it results in repeated hospitalization and confers a mortality risk of 50% at two years.[2] Surgical aortic valve replacement (AVR) remains the gold standard therapy for symptomatic severe AS patients.[3] However, for elderly patients with symptomatic severe AS and who have significant comorbidities, conventional AVR with cardiopulmonary bypass is associated with unacceptably high morbidity and mortality. A significant proportion of patients are denied AVR due to high surgical risk. Euro Heart survey found that up to one-third of symptomatic severe AS patients were denied surgery primarily based on age and left ventricular systolic impairment over and above validated cardiovascular comorbidities.[4] Transcatheter aortic valve implantation (TAVI) was first reported in men by Cribier et al. in 2002[5] Evolving experience suggests that TAVI offers improved survival compared to medical or valvuloplasty treatment for inoperable patients[6,7] and comparable results to high-risk surgical AVR patients.[8,9] TAVI procedures offer advantages by avoiding cardiopulmonary bypass and open chest access. We describe the first successful TAVI in Nepal.

Case Report

An 80-yr-old female with severe degenerative aortic stenosis visited our hospital for chest heaviness and dyspnea on exertion (NYHA functional class III). ECG showed Sinus Rhythm with Left Ventricular hypertrophy. Transthoracic echocardiography revealed severe degenerative tricuspid aortic valve with severe stenosis. There was concentric left ventricular hypertrophy. The calculated aortic valve area was 0.85 cm2, the peak velocity was 4.01m/s, the peak gradient across the aortic valve was 64mmHg, and the mean pressure gradient was 46 mmHg as shown in Fig. 1. The aortic annulus diameter was 20.2 mm and the left ventricular ejection fraction was 65%. Coronary Angiogram revealed non-critical lesions.

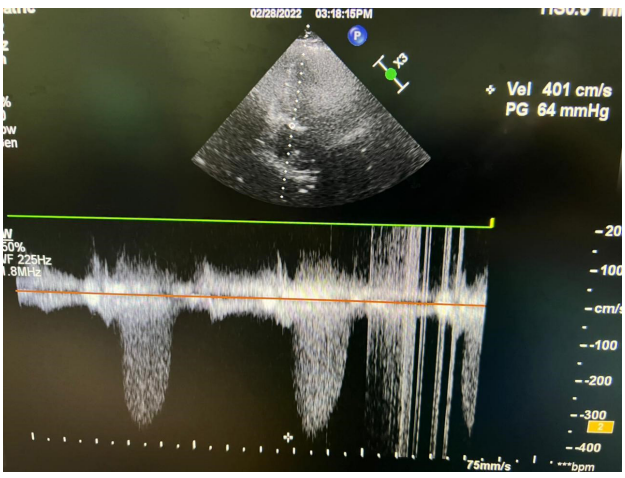

Fig.1.*Echocardiogram. Pressure gradient across aortic valve before TAVI*

CT revealed Mean Annulus Diameter 19.9mm, Annulus Perimeter 62.6mm, Sinus of Valsalva Mean Diameter (Mean) 26.6mm, Mean Sinus of Valsalva height 20.6mm. Annulus Area 308.1mm2. Height of Right coronary ostia was 9.6mm and the height of left coronary ostia was 15.6mm. Average right common iliac, external iliac and femoral artery diameter were 6.8mm,

5.8mm and 6.3mm respectively. Average left common iliac external iliac and femoral artery diameter were 7.7 mm, 6.4 mm and 6.1 mm respectively. Based on CT analysis 23mm Core valve Evolut PRO(Medtronic) was the suitable. The patient was recommended to undergo TAVI due to old age.

Informed consent was obtained from the patient and his family. TAVI was performed in the cardiac catheterization lab. All the prerequisites of procedures were pre-checked by an anesthesiologist, cardiologists and cardiac surgeons. An operation theatre was kept prepared in case of emergency. The team consisted of two cardiac anesthesiologists, five cardiologists, one cardiac surgeon, one interventional radiology technician, and three Cath lab nurses. The procedure was done under general anesthesia. Transesophageal echocardiography (TEE) was performed to provide imaging during the procedure. Right radial artery, right femoral artery, left femoral artery and right internal jugular vein were cannulated. Continuous arterial pressure monitoring was done through the right radial artery. Right Internal jugular access was used to place a temporary pacemaker in the right ventricle. Left femoral artery was used to introduce 6-Fr graduated pigtail catheter through a 6-Fr sheath into the noncoronary sinus as a marker for valve placement and to allow arteriography during the TAVI valve placement for positioning. The Right Femoral artery was used to deliver the TAVI valve. Once all arterial and venous accesses were achieved, intravenous unfractionated heparin was administered to achieve a recommended activated clotting time of >250 s.

A soft, J-tipped 0.035-mm wire was placed into the descending thoracic aorta (DTA) through the right femoral artery, Preclosure with two suture-mediated closure devices (Perclose ProGlide®, Abbott Laboratories, Abbott Park, IL) was deployed at 2 and 10 o'clock positions, with maintenance of arterial access with the J-tipped guidewire. A 6-Fr AL-1 catheter was passed through the valve delivery sheath over a 145-150 cm, 0.035-inch J- tipped guidewire and exchanged for a straight-tip wire to cross the valve. Once across, the straight-tip wire was exchanged for a 300-cm J-tipped wire. The AL-1 catheter was then removed and exchanged for a 6-Fr angled pigtail catheter. A preshaped stiff guidewire (ConfidaTM Brecker, Medtronic, Inc., Minneapolis, MN;) was then placed through the angled pigtail catheter into the left ventricle, with the transition point of the guidewire held above the apex, and pointing away from the ventricular wall. A16-F equivalent catheter EnVeo DCS InLine Sheath (Medtronic) mounted with the Evolut Pro valve, was then advanced "sheathless" into the patient and implanted at the annulus as shown in Fig 2.

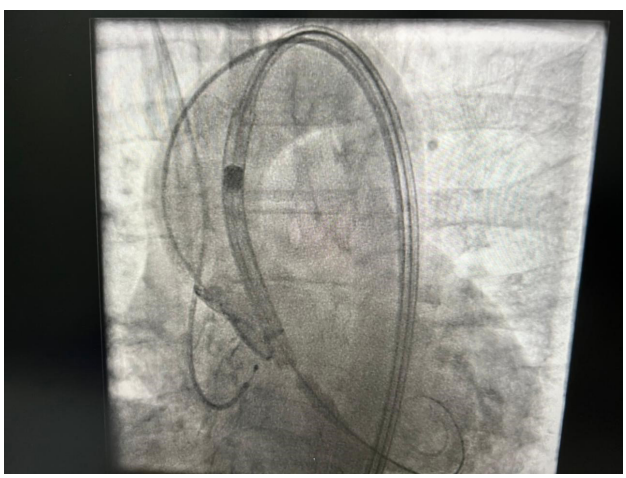

Fig. 2 *Evolut Pro valve across aortic valve before deployment*

Core valve Evolut PRO (Medtronic USA) was deployed under a pacing of 180 beats/min. The position of the valve was checked with a root aortogram using a pigtail catheter before and after deployment. We positioned 5mm below the native annulus. The root aortogram and coronary angiography revealed the optimal position of the bioprosthesis and normal coronary perfusion as shown in Fig 3.

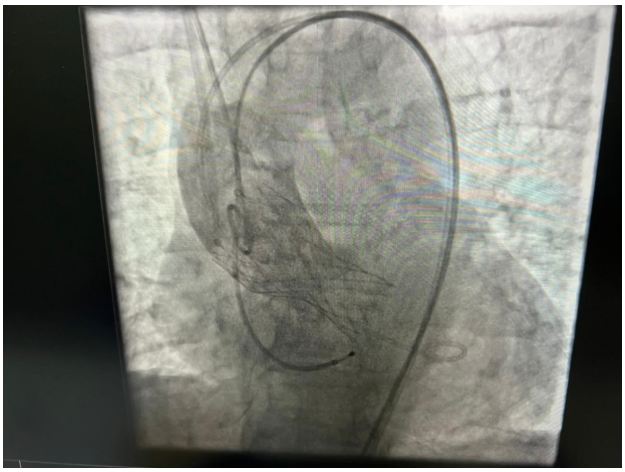

Fig.3 *Fluoroscopic image of the deployed Evolut Pro valve*

The immediate post-deployment transesophageal echocardiography showed a good position, normal leaflet motion, no paravalvular leakage, and a mean pressure gradient of 11 mmHg. Following successful valve implantation, EnVeo DCS was removed, and while maintaining wire position, the ProGlide® deployed, and protamine was administered. Anesthesia was reversed and the patient was extubated before being moved to the cardiac intensive care unit. Recovery was uneventful and she was discharged on a postoperative Day 5. The postoperative echocardiography before the discharge showed good prosthetic valve function with a mean aortic gradient of 13 mmHg without residual paravalvular leak and good left ventricular ejection fraction. The patient was well at the 30 follow-up days and she had an improved functional status of NYHA class I.

Discussion

AVR is the gold standard treatment for symptomatic severe AS and has shown to improve outcome and survival. This procedure consists of median sternotomy, placing patient 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%.[10] However, in elderly patients with multiple comorbidities, the mortality can be 5-10 times higher.[11] Balloon valvuloplasty could temporarily relieve the symptoms but does not alter the prognosis for these patients[12]. Percutaneous transcatheter replacement of aortic valve has emerged as an alternative for patients who are not suitable for surgical AVR.[13]

There are two representative devices for TAVI. Two competing systems with MHRA, CE- and FDA approval from Edwards Lifesciences (Sapien series) and Medtronic (CoreValve) have been evaluated in trials. The two devices differ in terms of leaflet and stent material, annulus sizing, and deployment method and can be delivered via transapical, transfemoral, subclavian, or axillary access. The CoreValve system has an advantage over Sapien THV as it is fully retrievable as long as the introducer catheter is not released from the valve. There were several reports that showed good early results with the CoreValve.[14] However, the incidence of having to place a permanent pacemaker was increased with using the CoreValve.[15] Godin et al. recently reported that the Sapien THV revealed a low incidence of heart block.[16]

The Evolut PRO transcatheter aortic valve (Medtronic) represents the next-generation self-expanding valve in the CoreValve Evolut family. The Evolut PRO valve is a repositionable, self-expanding nitinol frame with supra-annular porcine pericardial leaflets transcatheter aortic valve. The principal design modification is an external porcine pericardial wrap that has been added to cover the first 1.5 cells (~12 mm) with the aim to enhance annular sealing and minimize the paravalvular leak. It maintains the benefits of a low-profile, self-expanding valve with supra-annular function like the Evolut R valve. The Evolut PRO valve can be recaptured or repositioned to assist in optimal positioning at the level of the aortic annulus.[17] The Medtronic TAVR 2.0 US Clinical Study; evaluated the safety and efficacy Evolute PRO system. This study supports the use of the Evolut PRO System for the treatment of severe symptomatic AS in patients who are at increased surgical risk and results in excellent hemodynamics and minimal paravalvular leak.

Our patient had a high surgical risk due to her advanced age and TAVI was offered as an alternative procedure. The procedure was successfully performed without any complications. Even though 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. The patient's clinical improvement and hemodynamic findings at 30 days are consistent with the reported literature. [18, 19]

TAVI has emerged as an alternative technique to treat aortic stenosis patients with high surgical risk. Careful preprocedural planning is required for a successful TAVI procedure. The goals of preprocedural planning are to assess the optimal method of access; define anatomic relationships between the aortic valve, root, left ventricle, and coronary ostia; choose the optimal device size; and, lastly, contribute to the procedural plan.[20]

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 Nepal, 80 years old patient with symptomatic severe AS was successfully treated, with good clinical outcome and satisfactory hemodynamics at one-month follow-up. Complete equipment, a team approach, and preparation for unwanted fatal complications were required to achieve a successful result.

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Conflicts of Interest

The authors declare no conflicts of interest.

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