Case Report

Nepalese Heart Journal 2024; Vol 21(2), 43-46

Transcatheter aortic valve implantation using balloon-expandable Myval transcatheter heart valve in a patient with bicuspid aortic valve with low-flow, low-gradient severe aortic stenosis

Chandra Mani Adhikari[1], Amrit Bogati[1], Birat Krishna Timalsena[1], Md. Sajjad Safi[1], Sushant Kharel[1], Pratik Thapa[1], Vijay Ghimire[1], Rahul Yadav[1], Barkadin Khan[1], Dipanker Prajapati[1]

[1] Department of Cardiology, Shahid Gangalal National Heart Centre, Kathmandu, Nepal

Corresponding Author:
Chandra Mani Adhikari
Department of Cardiology
Shahid Gangalal National Heart Centre
Kathmandu, Nepal
Contact: 9851212111
Email: topjhap@gmail.com
ORCID ID NO: https://orcid.org/0000-0001-5811-9977

Cite this article as: Adhikari, C. M., Bogati, A., Timalsena, B., Safi, S., Kharel, S., Thapa, P., Ghimire, V., Yadav, R., Khan, B., & Prajapati, D. Transcatheter aortic valve implantation using balloon-expandable Myval transcatheter heart valve in a patient with bicuspid aortic valve with low-flow, low-gradient severe aortic stenosis. Nepalese Heart Journal, 21(2), 43-46.

Submission Date: March 21, 2024
Accepted Date: October 14, 2024

Submitted using Care checklist

Abstract

Transcatheter aortic valve implantation is the preferred treatment for aortic stenosis in elderly patients at high surgical risk. This is one of the complex Transcatheter aortic valve implantation cases done in Shahid Gangalal National Heart Centre. This case is complex as it involves a Bicuspid Aortic valve with low-flow, low-gradient severe aortic stenosis, annular calcification extending up to the left ventricular outflow tract, and horizontal aorta. We share this case which was successfully performed using a balloon-expandable Myval transcatheter heart valve.

Keyword: Bicuspid aortic Stenosis, Low-flow, low-gradient aortic valve stenosis, Transcatheter aortic valve implantation

DOI: http://doi.org/10.3126/nhj.v21i2.70779

Introduction

Transcatheter aortic valve implantation (TAVI) is a well-established treatment option in patients with severe symptomatic aortic stenosis (AS) with a high risk for surgical aortic valve replacement (SAVR). However, this recommendation was based on clinical trials that excluded bicuspid aortic valve (BAV) patients.[1] BAV is a common cardiac anomaly that is present in 0.5-2% of the general population.[2] Patients with BAV have larger annular dimensions, calcified, bulky, and irregular aortic valve leaflets, altered aortic geometry, and may have variable coronary anatomy.[3] These differences can complicate the device delivery and apposition of the prosthetic TAVI valve.[4] BAV has several anatomic features that could increase the risk of TAVI complications and can cause TAVI failure.[5] However, outcomes of TAVI in patients with BAV using new-generation valves are promising compared to early-generation valves.[6]

As Per the 2020 ACC/AHA guidelines, severe symptomatic low-flow, low-gradient (LFLG) severe AS is characterized as the presence of severe leaflet calcification with reduced leaflet motion, with stroke volume index below 35 mL/ m^2 and aortic valve area ≤1.0 cm^2 with resting maximum aortic jet velocity below 4 m/s or mean pressure gradient ≤40 mmHg.[7]

In this case report, we share our experience with CE-marked, balloon-expandable (BE) Myval Transcatheter Heart Valve (THV) from Meril Life Sciences Pvt. Ltd., India, in a patient diagnosed with a bicuspid aortic valve with low-flow, low-gradient severe aortic stenosis, and annular calcification extending up to the left ventricular outflow tract and horizontal aorta.

Case Report

A 74-year-old man presented in the outpatient department with a complaint of shortness of breath. ECG showed a normal sinus rhythm. The echocardiography revealed a type 1A BAV with low-flow (peak aortic velocity = 3.7m/s) and low-gradient (peak pressure gradient ≈56 mmHg and mean pressure gradient = 30 mmHg) (Fig 1) with a calculated aortic valve area of 0.5cm^2. The patient had global hypokinesia of the left ventricle with reduced left ventricular ejection fraction (LVEF =30%).

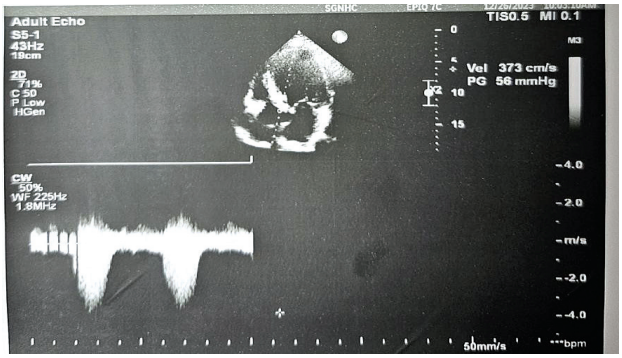

Figure 1: Echocardiogram: Continious doppler Signal of Aortic valve

A dobutamine stress echocardiogram revealed LFLG Severe AS with contractile reserve. A coronary angiogram revealed non-critical coronary artery disease.

On multi-slice computed tomography (MSCT), the mean aortic annulus diameter was 25.6 mm, the annulus perimeter was 81.4 mm, the sinus of Valsalva's mean diameter was 42.2 mm, and the annulus area was 504.1 mm2. The right and left coronary ostial heights were 14 mm and 20.8 mm, respectively. The MSCT also revealed a Bicuspid Type 1a Aortic Valve, Severe Aortic Valve Calcification, Annular Calcification extending into LVOT from RCC & LCC as shown in Fig 2 and the horizontal aorta (Aortic Angle of 74°) as shown in Fig. 3.

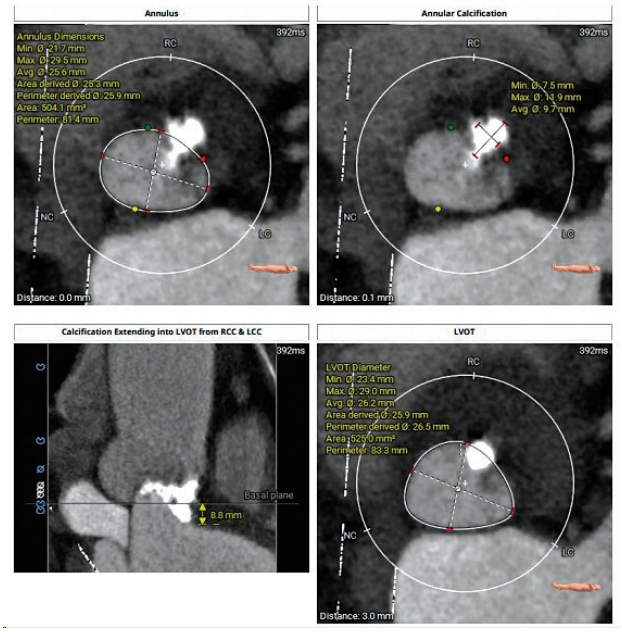

Figure 2: MSCT Annular calcification extending into LVOT

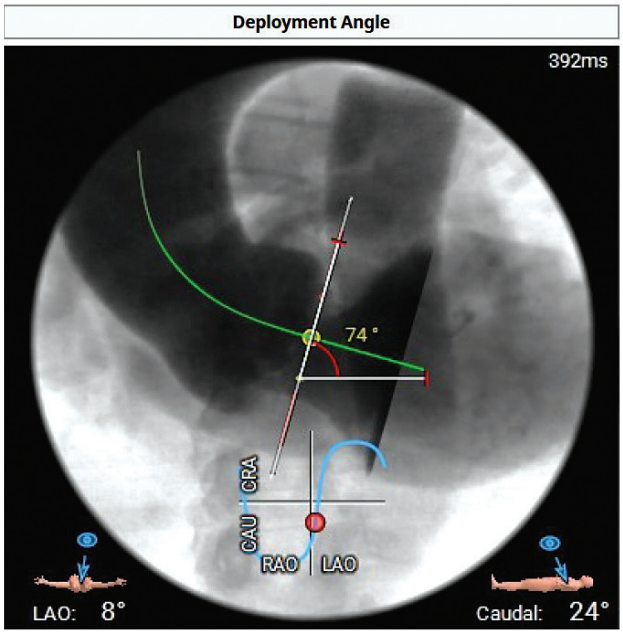

Figure 3: Aortic angle

The average diameters of the right common iliac (9.9 mm), external iliac (7.6 mm), and femoral (7.9 mm) arteries were observed to be normal.

The choice of treatment options and their benefits was discussed with the patient, but the patient opted for TAVI. Written informed consent was obtained from both the patient and the family. A thorough assessment by a comprehensive heart team, which consists of a cardiac surgeon, anesthesiologist, and cardiologist, ensured that all necessary conditions for the intervention were met. The patient underwent TAVI under local anesthesia and intraoperative transthoracic echocardiography (TTE) imaging guidance. The right and left femoral arteries and left femoral vein were cannulated. A temporary pacemaker was inserted into the right ventricle through the left femoral vein. To guide valve placement and allow arteriography for positioning, a 6Fr pigtail catheter was introduced through a 6Fr sheath into the noncoronary sinus using the left femoral artery. The THV was delivered through the right femoral artery. After achieving all necessary arterial and venous accesses, intravenous unfractionated heparin was administered to maintain an activated clotting time of over 250 seconds. Using the right femoral artery access, a J-tipped, soft 0.035 mm wire was advanced into the descending thoracic aorta. Following the procedure, a single suture-mediated closure device (Perclose ProGlide, Abbott Cardiovascular, Abbott Park, IL, USA) was deployed for pre-closure while keeping arterial access through the J-tipped guidewire. Subsequently, a 14Fr Python expandable introducer sheath (Meril Life Sciences Pvt. Ltd., India) was advanced into the femoral artery. A 6Fr AL-1 catheter was threaded through the valve delivery sheath using a 145–150 cm 0.035-inch J-tipped guidewire. It was then switched to a straight-tip wire to navigate through the valve. After crossing the valve, the straight-tip wire was exchanged for a 300 cm J-tipped wire. The AL-1 catheter was replaced with a 6Fr angled pigtail catheter. A reshaped stiff guidewire, SAFARI 2™ (Boston Scientific, Marlborough, MA, USA), was advanced through the pigtail catheter into the left ventricle, positioning the guidewire's transition point above the apex, pointing away from the ventricular wall. The septum was pre-dilatated with an 18X40mm Mammoth balloon. A 26 mm BE Myval

THV was implanted under pacing at 180 beats/min. The placement was verified through a root aortogram using a pigtail catheter before and after deployment. The BE Myval THV was positioned in the native annulus Figure 4.

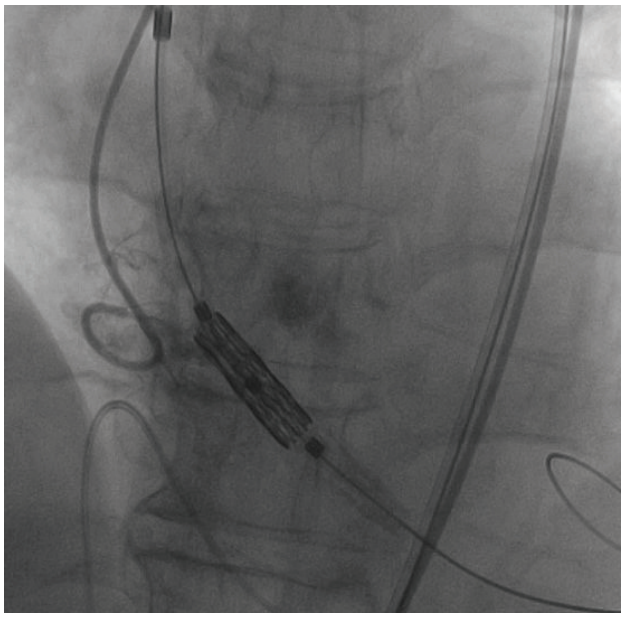

Figure 4: Positioning the Myval THV inside the aortic annulus

The root aortogram confirmed the optimal positioning of the bioprosthesis.

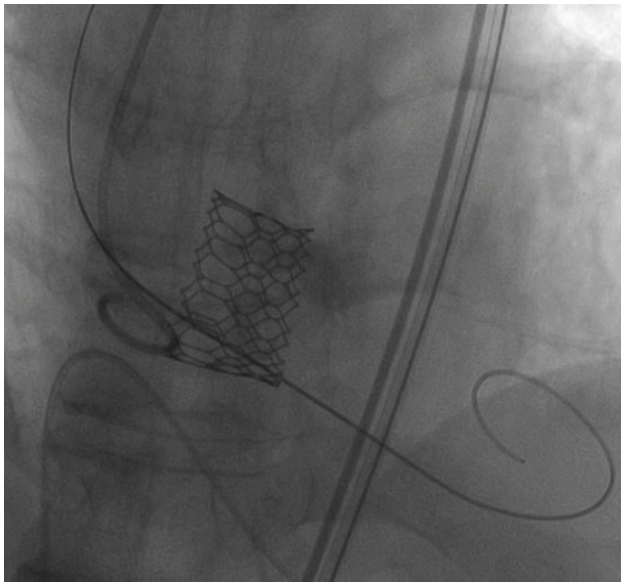

Figure 5: Fluoroscopic image showed the optimal deployment of the Myval THV

Immediate post-deployment TTE demonstrated a well-placed valve with normal leaflet motion, no paravalvular leakage, and a mean pressure gradient of 3 mmHg. After successful valve implantation, the introducer sheath, catheter, and guidewires were removed, and the patient was transferred to the cardiac intensive care unit. The postoperative recovery period was uneventful, and echocardiography before discharge showed normally functioning prosthetic valve function with a mean aortic gradient of 3 mmHg and no paravalvular leak. The patient was discharged on the fourth day in stable condition.

Discussion

In recent years, TAVI has emerged as an excellent alternative for patients with symptomatic severe AS who are either unsuitable for SAVR or at high surgical risk.[8] However, TAVI in patients with BAV is not as well studied, and the latest guidelines do not currently endorse TAVI for BAV patients.[9,10]

A meta-analysis and trial sequential analysis by Chan et al.[11] compared outcomes between TAVI in BAV and tricuspid aortic valve (TAV) stenosis. This analysis included eight studies with 917 BAV patients and 3,079 TAV patients. It reveals no significant differences in primary and secondary outcomes such as acute renal failure, permanent pacemaker (PPM) implantation rates, stroke, and 30-day mortality. Furthermore, 30-day and 1-year mortality, as well as PPM implantation rates, were not significantly different between the two groups. However, a significantly higher rate of postoperative aortic regurgitation was observed in BAV patients (P=0.002).[11]

TAVI in BAV patients poses several challenges due to the asymmetrical and heavily calcified valve anatomy, the presence of a raphe, and a horizontal aorta, which can complicate guidewire crossing.[5] The risk of coronary obstruction is also elevated. In cases where the risk of coronary occlusion is high, the use of chimney stents or leaflet laceration with an electrified guidewire has been proposed to prevent coronary obstruction and improve prosthesis expansion.[12,13] Pre-dilation of the native valve is more frequently performed in BAV patients than in TAV cases to facilitate the crossing of the delivery system and ensure appropriate THV expansion. This approach also aids in assessing the supra-annular anatomy's response.[14] The balloon used for valvuloplasty should be sized according to the minor axis of the aortic valve complex, as the appearance of a waist may indicate a calcified or resistant raphe, increasing the risk of THV under-expansion or annular injury. This consideration influences the choice of THV type and valve size. For balloon-expandable valves (BEV), a low grade of oversizing (<10%) is recommended to minimize the risk of annulus rupture.[5]

Post-dilation is often required in BAV cases due to the raphe and calcification burden, which can lead to valve under-expansion and insufficient sealing in the pericommissural region. This is particularly important with self-expanding (SE) valves, which have a lower radial force.[15] These technical and anatomical challenges may contribute to the higher risk of stroke and new ischemic lesions observed in BAV patients.[16]

In our case, pre-dilation was performed to facilitate the crossing of the delivery system, ensure appropriate THV expansion, and assess the response of the supra-annular anatomy. The balloon used for valvuloplasty was sized according to the minor axis of the aortic valve complex. With an annular area of 504.1 mm², a 26 mm Myval was selected. It results in a 5.3% oversize, consistent with the recommendation to limit oversizing to less than 10% in BEV implantation to reduce the risk of annular rupture.

Recent meta-analyses have shown that both SAVR and TAVI are associated with significant reductions in all-cause mortality compared to conservative management in all subclasses of LFLG AS.[17] However, findings from the TOPAS-TAVI registry indicate that approximately one-third of LFLG-AS patients may die within two years of TAVI.[18] A meta-analysis by Ueyama et al. compared

outcomes between SAVR and TAVI in LFLG patients reveals that both interventions reduce all-cause mortality but the extent of the reduction with TAVI is not superior to that with SAVR.[19] The less invasive nature of TAVI offers the potential to improve outcomes in patients with LFLG severe symptomatic AS.

Careful preprocedural planning is essential for a successful TAVI procedure. The primary goals of preprocedural planning include assessing the optimal method of access, defining anatomic relationships between the aortic valve, root, left ventricle, and coronary ostia, and selecting the ideal device type and size. The choice between BE and SE valves depends not only on patient characteristics but also on operator experience.

Conclusion:

The case report demonstrates the successful completion of a Transcatheter Aortic Valve Implantation procedure with a Balloon-Expandable Myval Transcatheter Heart Valve in a patient with Bicuspid Aortic Valve and Low-Flow Low-Gradient severe Aortic Stenosis, complicated by a horizontal aorta and annular calcification extending up to the Left Ventricular Outflow Tract.

References

1. Leon MB, Smith CR, Mack M, Miller DC, Moses JW, et al. Transcatheter aortic-valve implantation for aortic stenosis in patients who cannot undergo surgery. N Engl J Med. 2010;363(17):1597-607. doi:10.1056/NEJMoa1008232.
2. Michelena HI, Desjardins VA, Avierinos JF, Russo A, Nkomo VT, et al. Natural history of asymptomatic patients with normally functioning or minimally dysfunctional bicuspid aortic valve in the community. Circulation. 2008;117(21):2776-84. doi:10.1161/ CIRCULATIONAHA.107.740878.
3. Watanabe Y, Chevalier B, Hayashida K, Leong T, Bouvier E, Arai T, et al. Comparison of multislice computed tomography findings between bicuspid and tricuspid aortic valves before and after transcatheter aortic valve implantation. Catheter Cardiovasc Interv. 2015;86(2):323- 30. doi:10.1002/ccd.25830.
4. Zegdi R, Lecuyer L, Achouh P, Didier B, Lafont A, et al. Increased radial force improves stent deployment in tricuspid but not in bicuspid stenotic native aortic valves. Ann Thorac Surg. 2010;89(3):768- 72. doi:10.1016/j.athoracsur.2009.12.022.
5. Flavien Vincent, Julien Ternacle, Tom Denimal, Mylène Shen, Bjorn Redfors, et al. Transcatheter Aortic Valve Replacement in Bicuspid Aortic Valve Stenosis.Circulation. 2021; 143: 1043–1061. doi: 10.1161/CIRCULATIONAHA.120.048048
6. Yoon SH, Lefèvre T, Ahn JM, Perlman GY, Dvir D, et al. Transcatheter aortic valve replacement with early- and new-generation devices in bicuspid aortic valve stenosis. J Am Coll Cardiol. 2016;68(11):1195-205. doi:10.1016/j.jacc.2016.06.041.
7. Catherine M Otto, Rick A Nishimura, Robert O Bonow, Blase A Carabello, John P Erwin 3rd, et al. 2020 ACC/ AHA Guideline for the Management of Patients With Valvular Heart Disease. J Am Coll Cardiol 2021;77(4):e25-e197. doi:10.1016/j.jacc.2020.11.018.
8. Webb JG, Altwegg L, Boone RH, Cheung A, Ye J, et al. Transcatheter aortic valve implantation: impact on clinical and valve-related outcomes. Circulation 2009; 119: 3009-16. doi:10.1161/CIRCULATIONAHA.108.837807
9. A. Baumgartner H, Falk V, Bax JJ, De Bonis M, Hamm C, et al. 2017 ESC/EACTS guidelines for the management of valvular heart disease. Eur Heart J. 2017;38(36):2739-91. doi:10.1093/eurheartj/ehx391.
10. B. Nishimura RA, Otto CM, Bonow RO, Carabello BA, Erwin JP 3rd, et al. 2017 AHA/ACC focused update of the 2014 AHA/ACC guideline for the management of patients with valvular heart disease: a report of the American college of cardiology/American heart association task force on clinical practice guidelines. Circulation. 2017;135(25):e1159-95. doi:10.1161/CIR.0000000000000503.
11. Jeffrey Shi Kai Chan, Sukhdeep Singh, Peter Eriksen, Lok Him Tsui, Amer Harky, for the Cardiovascular Evidence Review Collaboration (CvERC). Transcatheter Aortic Valve Implantation in Bicuspid Aortic Valve with Aortic Stenosis: a Meta-Analysis and Trial Sequential Analysis.Braz J Cardiovasc Surg 2022;37(1)88-98. doi: 10.21470/1678-9741-2020-0146
12. E. Komatsu I, Mackensen GB, Aldea GS, Reisman M, Dvir D. Bioprosthetic or native aortic scallop intentional laceration to prevent iatrogenic coronary artery obstruction. Part 1: how to evaluate patients for BASILICA. EuroIntervention. 2019;15:47–54. doi: 10.4244/EIJ-D-19-00057
13. Liu X, He Y, Zhu Q, Gao F, He W, et al. Supraannular structure assessment for self-expanding transcatheter heart valve selection in patients with bicuspid aortic valve. Catheter Cardiovasc Interv. 2018;91:986–994. doi: 10.1002/ccd.27467
14. Mangieri A, Tchetch. D, Kim WK, Pagnesi M, Sinning J-M,et al. Balloon versus self-expandable valve for the treatment of bicuspid aortic valve stenosis. Circ Cardiovasc Interv. 2020;13:e008714. doi: 10.1161/CIRCINTERVENTIONS.119.008714
15. J. Seeger J, Kapadia SR, Kodali S, Linke A, W.hrle J, et al. Rate of peri-procedural stroke observed with cerebral embolic protection during transcatheter aortic valve replacement: a patient-level propensity-matched analysis. Eur Heart J.2019; 40: 1334–1340. doi: 10.1093/eurheartj/ehy847
16. K. Fan J, Fang X, Liu C, Zhu G, Hou CR, et al. Brain Injury After Transcatheter Replacement of Bicuspid Versus Tricuspid Aortic Valves. J Am Coll Cardiol. 2020;76: 2579–2590. doi:10.1016/j.jacc.2020.09.605
17. Christophe Tribouilloy, Franck Lévy, Dan Rusinaru, Pascal Guéret, Hélène Petit-Eisenmann, et al. Outcome after aortic valve replacement for low-flow/low-gradient aortic stenosis without contractile reserve on dobutamine stress echocardiography. J Am Coll Cardiol. 2009;53(20):1865-1873. Doi:10.1016/j.jacc.2009.02.026
18. Henrique Barbosa Ribeiro, Stamatios Lerakis , Martine Gilard, João L Cavalcante, Raj Makkar et al. Transcatheter Aortic Valve Replacement in Patients With Low-Flow, Low-Gradient Aortic Stenosis. J Am Coll Cardiol 2018;71(12):1297–1308. Doi:10.1016/j.jacc.2018.01.054
19. Hiroki Ueyama, Toshiki Kuno, Matthew Harrington, Hisato Takagi, Parasuram Krishnamoorthy. et al. Impact of Surgical and Transcatheter Aortic Valve Replacement in Low-Gradient Aortic Stenosis: A Meta-Analysis. J Am Coll Cardiol Intv. 2021;14(13):1481–1492.doi:https://doi.org/10.1016/j.jcin.2021.04.038