Catheterization and Cardiovascular Interventions

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CASE REPORT

Transcatheter Aortic Valve Replacement in Pure Native Valve Aortic Regurgitation Using a 35-mm Balloon-Expandable Myval XXL Valve and a 24-French Python BZ Smart Introducer Sheath

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ABSTRACT

Pure aortic regurgitation is the third most common valvular heart disease and is associated with significant morbidity and mortality. Surgical aortic valve replacement remains the standard treatment for symptomatic patients. Transcatheter aortic valve replacement (TAVR) is an alternative for those at high surgical risk; however, its use is limited by higher complication rates and the lack of suitable valve options. Previously, balloon-expandable valves were available only in sizes up to 32 mm, restricting their application in patients with larger aortic annuli. We report the first use of the 35 mm balloon-expandable Myval XXL valve with a long 24 French Python introducer sheath for TAVR in a patient with non-calcific aortic regurgitation and an annular area of 722 mm². This case highlights a potential advancement in TAVR technology, expanding treatment options for patients with non-calcific aortic regurgitation with large annuli previously considered ineligible for TAVR.

1 | Introduction

Aortic regurgitation is the third most common left-sided valvular heart disease affecting adults [1]. Severe non-calcific native valve aortic regurgitation (NCAR) is twice as common in males than females, more prevalent among the elderly, and carries significant morbidity and a mortality rate of up to 20% per year [2, 3]. Surgical management remains the mainstay of treatment for symptomatic NCAR in eligible patients [4, 5]. Transcatheter aortic valve replacement (TAVR) has been advocated for high surgical risk patients with severe NCAR. However, many patients with NCAR have large aortic annuli, and the availability of appropriate-sized transcatheter heart valves (THV) has remained a challenge for such patients. The 32 mm Myval XL with a nominal area of 840 mm^2 has been used successfully to treat many of these patients [6, 7].

We hereby describe the first use of a dedicated 35 mm Myval XXL THV for TAVR in a patient with pure native valve AR and a large aortic annulus.

2 | Case Report

An 80-year-old Indian male with severe symptomatic non-calcific NCAR caused by central non-coaptation, with left ventricular (LV) dilatation (LV end-systolic diameter of 55 mm) and LV ejection fraction of 50% was assessed for aortic valve replacement. The patient had obesity (BMI

Abbreviations: AR, aortic regurgitation; CDSCO, Central Drug Standard Control Organization; CT, computerized tomography; Fr, French; LV, left ventricular; LVOT, left ventricular outflow tract; NCAR, non-calcific aortic regurgitation; NYHA, New York Heart Association; PTFE, poly tetra fluro ethylene; STJ, sino-tubular junction; STS, Society of Thoracic Surgeons; TAVR, transcatheter aortic valve replacement; THV, transcatheter heart valves.

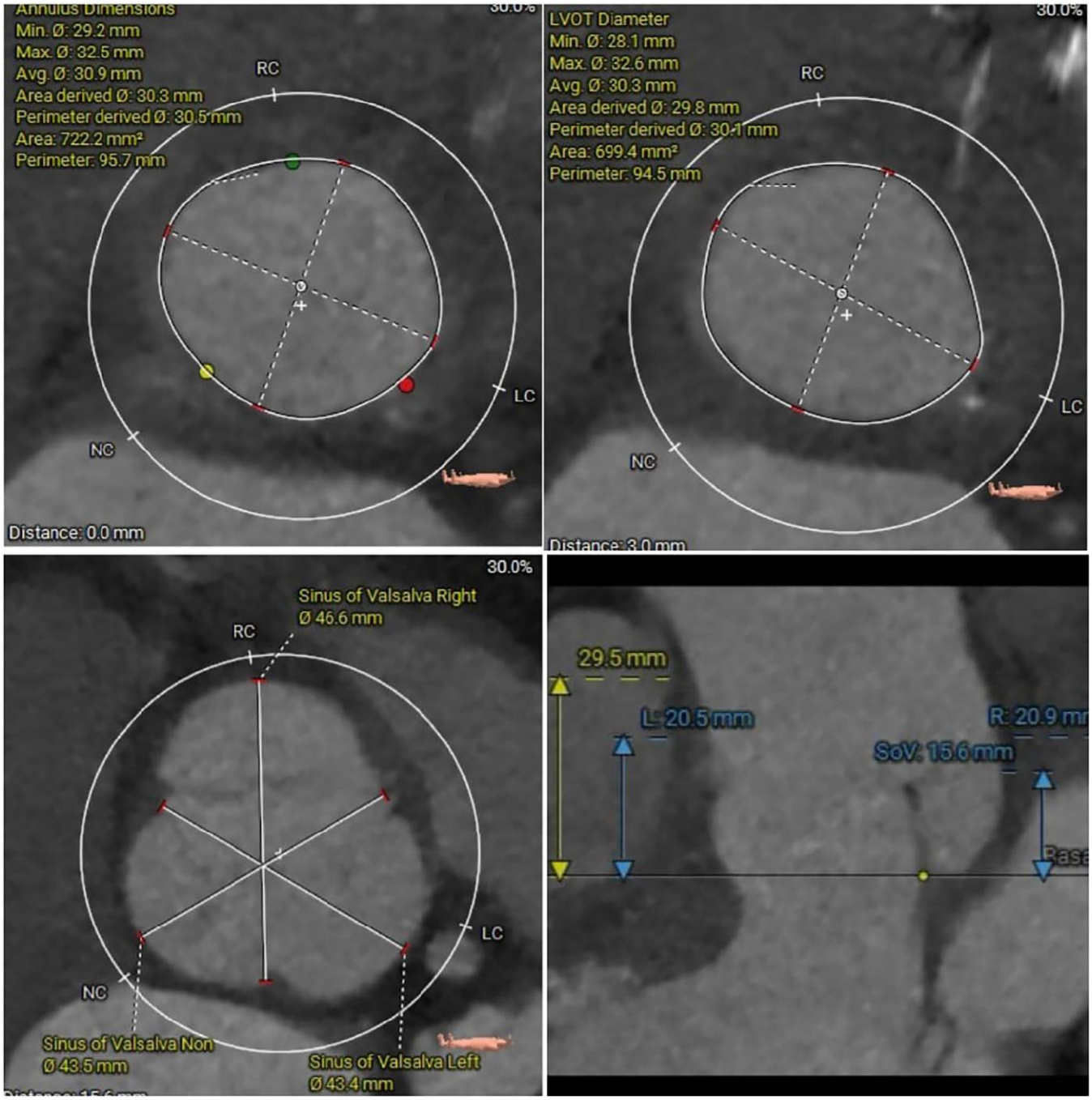

FIGURE 1 | Cardiac computed tomography (CT) scan showing measurements at the levels of the aortic annulus, sinotubular junction, and sinus of Valsalva. [Color figure can be viewed at wileyonlinelibrary.com]

35.3 kg/m²), chronic obstructive airway disease, diabetes mellitus, a creatinine clearance of 50 mL/min, paroxysmal atrial fibrillation, a stroke 5 years prior, and a history of permanent pacemaker implantation for complete atrioventricular block. Hence, the estimated Society of Thoracic Surgeons (STS) operative mortality score was 5.8%.

CT angiography revealed a non-calcific tri-leaflet aortic valve with an annulus area of 722 mm^2, area-derived diameter of 30.3 mm, perimeter of 97.5 mm, and perimeter-derived diameter of 30.5 mm. Aortic valve calcium score was 0, ascending aorta was dilated with a diameter of 41 mm, Sinotubular junction (STJ) diameter of 43 mm, LV outflow tract (LVOT) diameter of 30.3 mm, left coronary ostial height 20.5 mm, and right coronary ostial height 20.9 mm. Iliofemoral vessels were > 9 mm in size, but significant tortuosity was noted.

After a heart team discussion, and written informed consent, it was decided to proceed with TAVR using the balloon-expandable Myval THV (Meril Life Sciences, India). However, the 32 mm Myval valve, at its nominal volume, would only achieve an 11% oversizing and might require an additional 5 mL to exceed a 20% oversizing. Therefore, the 35 mm Myval valve, which would achieve approximately 30% oversizing, was selected.

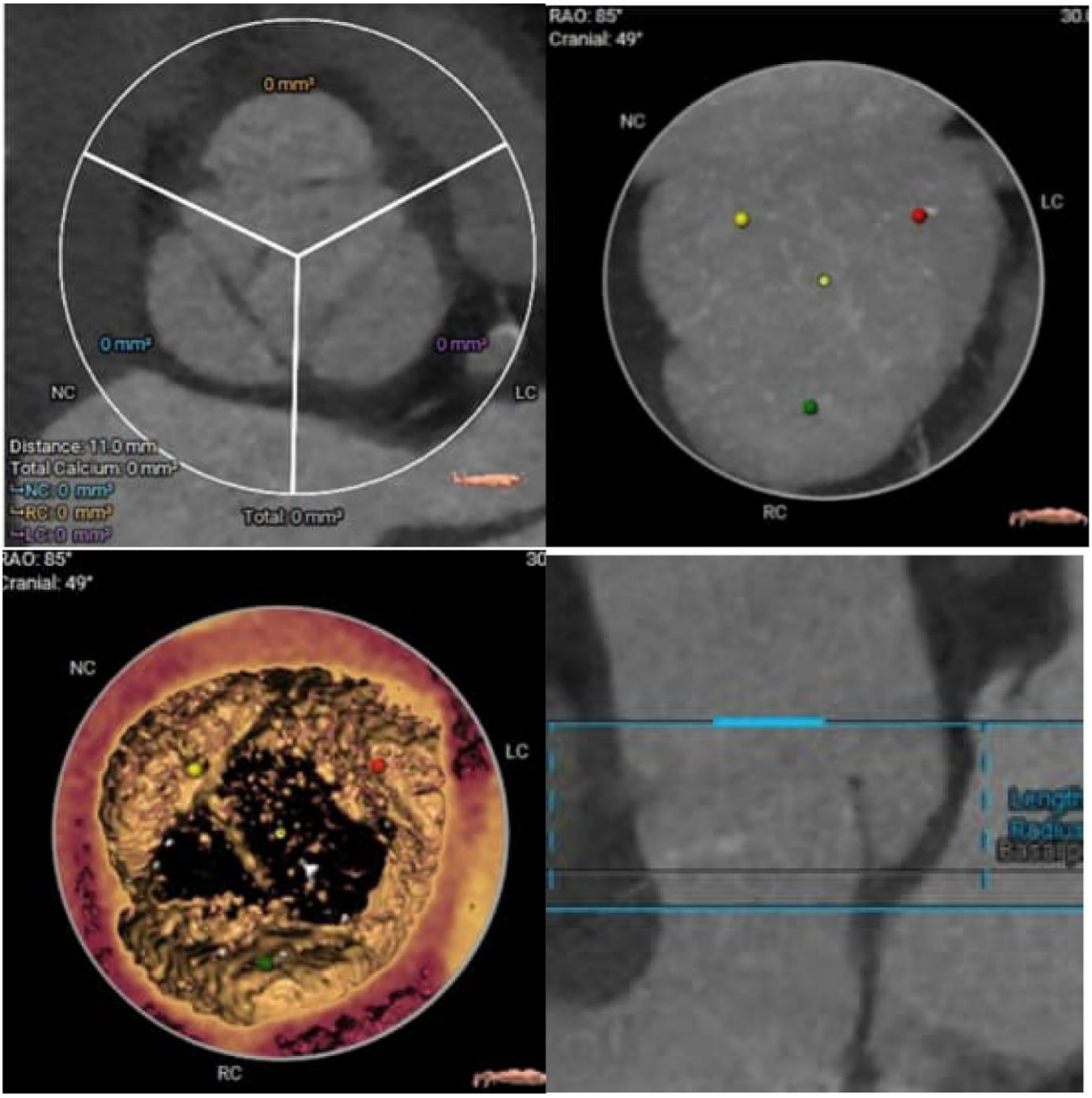

FIGURE 2 | Cardiac computed tomography (CT) scan images showing the absence of calcification in the aortic valve. [Color figure can be viewed at wileyonlinelibrary.com]

Right femoral artery access was obtained under ultrasound guidance, and Perclose Proglide (Abbott Vascular, USA) sutures were placed. The aortic valve was crossed using a 6 F pigtail catheter with a 0.035" J-tip PTFE guidewire, which was then exchanged for a Lunderquist wire (Cook Medical LLC, USA). A Python BZ Smart Introducer sheath (24 Fr/ 76.5 cm) (Meril Life Sciences Pvt. Ltd. Vapi, India) was introduced over the 0.035" Lunderquist wire and positioned with its distal tip in the aortic arch. The 35 mm Myval XXL THV, crimped onto a 35 mm Navigator THV balloon delivery system (Meril Life Sciences, India) with a nominal volume of 50 mL, was introduced and positioned across the aortic valve annulus. The valve was deployed with rapid right ventricular pacing at 190/min using slow inflation. During inflation, there was significant shortening at the aortic end of the valve, and a tendency to dive-in toward the left ventricle; fine adjustments could be made during inflation and the final overall annular position remained unchanged. Immediately post-procedure, the aortic valve gradient was 0, and an aortogram showed no paravalvular leak or coronary obstruction. The echo- cardiogram revealed no aortic regurgitation. After hemodynamic measurements, the Python BZ Smart introducer sheath was removed, and the femoral access site closed with the Proglide sutures. No hematoma or bleeding was observed.

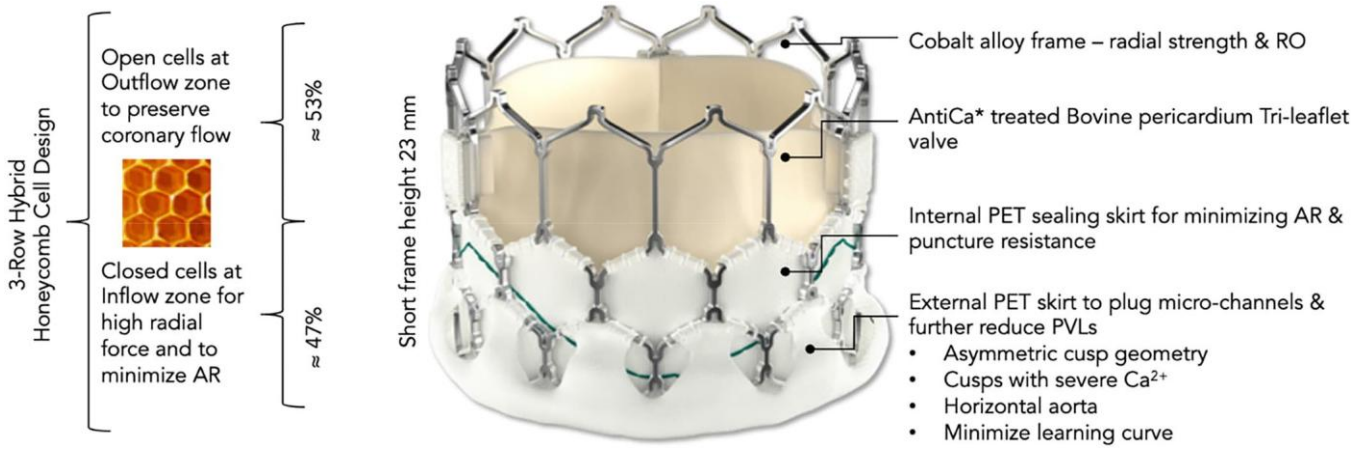

FIGURE 3 | Manufacturer-provided information on the 35-mm Myval transcatheter heart valve. The frame height of a nominally expanded Myval THV XXL 35 mm is 23 mm. [Color figure can be viewed at wileyonlinelibrary.com]

At the 30-day follow-up, the patient was in NYHA functional class I, and an echocardiogram showed no significant aortic gradient, regurgitation, or para-valvar leak (Figures 1–6).

3 | Discussion

TAVR in NCAR presents challenges due to various technical issues that increase complication rates: the absence of calcium to anchor the THV, leading to valve migration and embolization; the large annulus of the native aortic valve, which can cause para-valvular regurgitation; and the need for oversizing, which may damage the conduction system, increasing the likelihood of permanent pacing [8–10]. Excessive oversizing (more than 20%), and post dilatation are other factors that increase the risk of valve embolization. Overall TAVR in pure NCAR is associated with a lower device success rate, higher 30-day mortality, higher incidence of residual AR or para-valvar leak, higher need for permanent pacemaker implantation, and a significant need for conversion to open surgery [11–15].

Compared to other commercially available THVs, Myval is available in larger sizes—30.5 and 32 mm (Myval XL). The use of the 35 mm Myval XXL for transcatheter pulmonary valve replacement and calcific aortic stenosis has previously been reported [16, 17].

The 35 mm Myval XXL has a nominal area of 962 mm² and can be expanded up to 1000 mm² with additional volume. It is crimped onto a 35 mm Navigator balloon (Meril Life Sciences, India) with a nominal volume of 50 mL and has a crimped diameter of 8 mm and a crimped length of 31 mm. When fully expanded, this translates to a frame height of 23 mm [18]. At nominal inflation to 50 mL, the valve oversizing in our case was 15.5% by annulus diameter, 14.8% by perimeter, and 33% by annulus area.

The 24 French Python BZ Smart Introducer sheath (Meril Life Sciences, India) was chosen over the 14 F Python sheath (even though the latter could accommodate the 35 mm Myval) as there was difficulty navigating the thoracic aorta even with the pigtail catheter due to tortuosity; also, withdrawal of the THV back into the sheath, if required, would be easier with the larger sheath. The 24 French Python BZ smart sheath (Meril Life Sciences, India) has a length of 76.5 cm and a soft-tip dilator with three wire lumens. The use of this introducer sheath has been described previously [7].

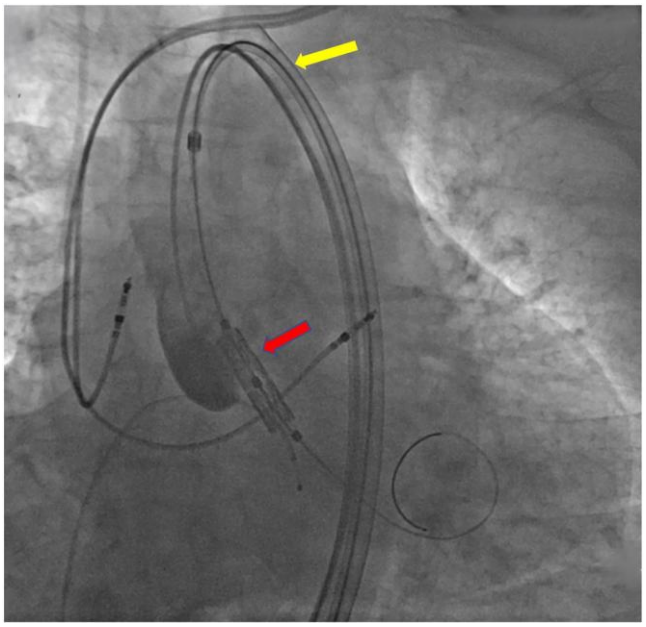

FIGURE 4 | Positioning of the transcatheter heart valve (red arrow) across the aortic annulus. The Python BZ Smart introducer sheath (yellow arrow) is visible in the descending aorta extending up to the aortic arch. [Color figure can be viewed at wileyonlinelibrary.com]

Artificial intelligence with structural and fluid computational modeling is increasingly used in TAVR planning. Dedicated software that has been trained on the hemodynamics and biomechanics of native and prosthetic aortic valves can be used to predict the risk of TAVR complications like annular rupture, coronary obstruction, paravalvular leak, patient-prosthesis mismatch, and need for permanent pacemaker implantation. Structural computational modeling with deep learning can

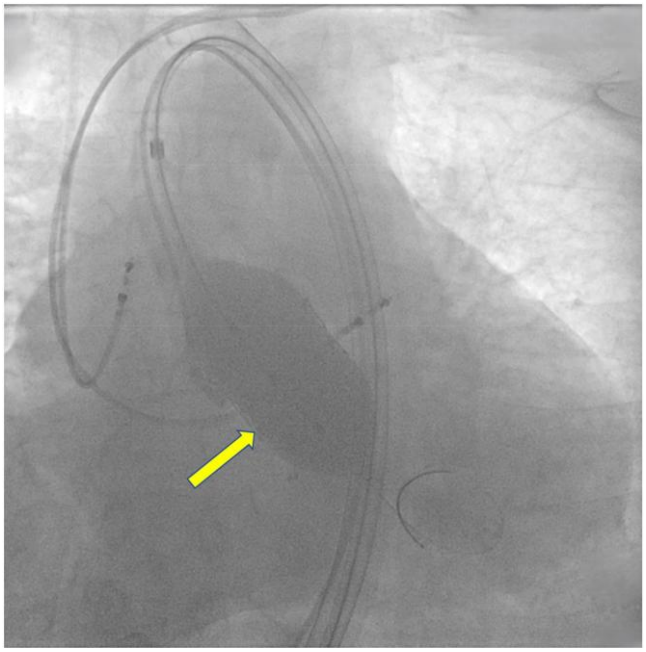

FIGURE 5 | The THV (yellow arrow) was gradually inflated to a final volume of 50 mL over 45 s, under rapid pacing at 190 beats per min. During the inflation process, the valve demonstrated a tendency to shift toward the left ventricle. However, fine adjustments were made in real-time to ensure optimal positioning of the valve throughout inflation. [Color figure can be viewed at wileyonlinelibrary.com]

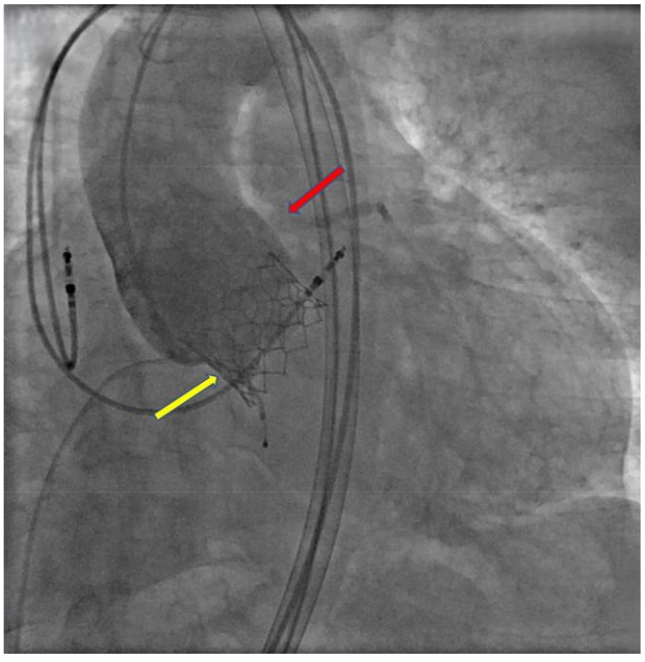

FIGURE 6 | The final position of the valve (yellow arrow) after deployment. No paravalvular leak or central aortic regurgitation was observed. The left coronary artery (red arrow) is visible above the transcatheter heart valve (THV) frame. [Color figure can be viewed at wileyonlinelibrary.com]

create patient-specific digital 3-dimensional replicas of the native aortic valve apparatus from CT images. Simulated deployment of different sizes of BEV or SEV in these patient-specific replicas can predict the interaction of the native aortic valve with the THV, throwing insights into potential complications, and helping the physician optimize treatment strategies [19–21].

This is the first successful use of the 35 mm Myval XXL THV for the treatment of non-calcific aortic regurgitation. Although the valve is available only under the special access program of the CDSCO in India, this device enables the treatment of NCAR with an aortic annulus area of 700 mm² or more, as well as calcific aortic stenosis with an annulus area as large as 1000 mm². This advancement could make TAVR accessible to nearly all patients with aortic valve disease who were previously excluded due to the unavailability of appropriately sized valves [6]. However, for the treatment of NCAR with TAVR, the high risk of THV embolization and migration remains a major challenge, while the need for permanent pacing and incidence of 30-day mortality are unacceptably high compared to TAVR for aortic stenosis. With the advent of newer, dedicated devices and further refinement in techniques, these challenges will be overcome soon.

Disclosure

AI assistants checked and edited the sentences and grammar, but they did not provide assistance with writing the scientific content.

Conflicts of Interest

The authors declare no conflicts of interest.

References

1. S. Noble and S. Mauler-Wittwer, "TAVR as an Alternative to SAVR for Pure Native Aortic Regurgitation," *Canadian Journal of Cardiology* 40, no. 2 (2024): 316–325, https://doi.org/10.1016/j.cjca.2023.11.023.

2. B. Iung, "A Prospective Survey of Patients With Valvular Heart Disease in Europe: The Euro Heart Survey on Valvular Heart Disease," *European Heart Journal* 24 (2003): 1231–1243.

3. P. Andell, X. Li, A. Martinsson, et al., "Epidemiology of Valvular Heart Disease in a Swedish Nationwide Hospital-Based Register Study," *Heart* 103 (2017): 1696–1703.

4. A. Vahanian, F. Beyersdorf, F. Praz, et al., "2021 ESC/EACTS Guidelines for the Management of Valvular Heart Disease," *European Heart Journal* 43 (2022): 561–632.

5. C. M. Otto, R. A. Nishimura, R. O. Bonow, et al., "2020 ACC/AHA Guideline for the Management of Patients With Valvular Heart Disease: Executive Summary: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines," *Circulation* 143 (2021): e35–e71.

6. A. Holzamer, F. Bedogni, P. van Wyk, et al., "Performance of the 32 mm Myval Transcatheter Heart Valve for Treatment of Aortic Stenosis in Patients With Extremely Large Aortic Annuli in Real-World Scenario: First Global, Multicenter Experience," *Catheterization and Cardiovascular Interventions* 102 (2023): 1364–1375, https://doi.org/10.1002/ccd.30820.

7. J. P. Sanchez-Luna, P. Martín, A. E. Dager, et al., "Clinical Outcomes of TAVI With the Myval Balloon-Expandable Valve for Non-Calcified Aortic Regurgitation," *EuroIntervention* 19, no. 7 (2023): 580–588, https://doi.org/10.4244/EIJ-D-23-00344.

8. M. Urena, D. Himbert, P. Ohlmann, et al., "Transcatheter Aortic Valve Replacement to Treat Pure Aortic Regurgitation on Noncalcified

Native Valves," *Journal of the American College of Cardiology* 68, no. 15 (2016): 1705–1706, https://doi.org/10.1016/j.jacc.2016.07.746.

9. S. A. Perez and A. Dager, "TAVR for Pure Native Valve Aortic Regurgitation." In *Mastering Structural Heart Disease*, eds. E. J. de Marchena and C. A. Gomez Gonzalez. (Wiley, 2023), https://doi.org/10.1002/9781119807841.ch11.

10. E. Poletti, O. De Backer, A. Scotti, et al., "Transcatheter Aortic Valve Replacement for Pure Native Aortic Valve Regurgitation," *JACC: Cardiovascular Interventions* 16, no. 16 (2023): 1974–1985, https://doi.org/10.1016/j.jcin.2023.07.026.

11. T. P. Vahl, V. H. Thourani, R. R. Makkar, et al., "Transcatheter Aortic Valve Implantation in Patients With High-Risk Symptomatic Native Aortic Regurgitation (ALIGN-AR): A Prospective, Multicentre, Single-Arm Study," *Lancet* 403, no. 10435 (2024): 1451–1459.

12. A. Elbadawi, S. Gilani, and H. Jneid, "Transcatheter Aortic Valve Replacement for Native Aortic Regurgitation," *JACC: Cardiovascular Interventions* 16, no. 16 (2023): 1961–1964, https://doi.org/10.1016/j.jcin.2023.07.018.

13. Y. Schneeberger, M. Seiffert, A. Schaefer, et al., "Tavi for Pure Non-Calcified Aortic Regurgitation Using a Self-Expandable Transcatheter Heart Valve," *Frontiers in Cardiovascular Medicine* 8 (2022): 743579, https://doi.org/10.3389/fcvm.2021.743579.

14. R. Markham, M. Ghodsian, and R. Sharma, "TAVR in Patients With Pure Aortic Regurgitation: Ready to Use?," *Current Cardiology Reports* 22 (2020): 98, https://doi.org/10.1007/s11886-020-01338-6.

15. S. Arora, S. Lahewala, Z. Zuzek, et al., "Transcatheter Aortic Valve Replacement in Aortic Regurgitation: The US Experience," *Catheterization and Cardiovascular Interventions* 98 (2021): E153–E162, https://doi.org/10.1002/ccd.29379.

16. S. Ramakrishnan, N. V. Faisal, L. Kadiyani, S. K. Gupta, and M. C. Sivaprakasam, "Transcatheter Pulmonary Valve Implantation With Custom-Made 35-mm Myval Transcatheter Heart Valve," *Annals of Pediatric Cardiology* 17, no. 4 (2024): 281–284, https://doi.org/10.4103/apc.apc_166_24.

17. J. Jose, P. V. George, S. U. Riyaz Mirza, P. G. Mathen, S. Selvaraj, and H. Raja, "Novel 35-mm Balloon-Expandable Transcatheter Aortic Valve Replacement," *JACC: Cardiovascular Interventions* 17, no. 8 (2024): 1057–1059.

18. Data on File With Meril Life Sciences, Vapi, India.

19. F. Esmailie, A. Razavi, B. Yeats, et al., "Biomechanics of Transcatheter Aortic Valve Replacement Complications and Computational Predictive Modeling," *Structural Heart* 6, no. 2 (June 2022): 100032.

20. A. Rouhollahi, J. N. Willi, S. Haltmeier, et al., "Cardiovision: A Fully Automated Deep Learning Package for Medical Image Segmentation and Reconstruction Generating Digital Twins for Patients With Aortic Stenosis," *Computerized Medical Imaging and Graphics* 109 (October 2023): 102289.

21. A. M. Tahir, O. Mutlu, F. Bensaali, et al., "Latest Developments in Adapting Deep Learning for Assessing TAVR Procedures and Outcomes," *Journal of Clinical Medicine* 12, no. 14 (July 2023): 4774.

Supporting Information

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