# **SAPIEN 3** valve implantation in rheumatic aortic stenosis with a functioning mitral prosthesis: first case report from India



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## Introduction

Transcatheter aortic valve implantation (TAVI) is a rapidly evolving therapeutic option for patients with severe aortic stenosis who are high risk for surgery or for inoperable patients<sup>1</sup>. Indications for TAVI are evolving as it is being used as an option for intermediate-risk and low-risk patients. Data on the use of TAVI in rheumatic aortic stenosis are not widely available and have not been reported from India.

Pathology in rheumatic aortic stenosis differs from calcific severe aortic stenosis<sup>2</sup> and is characterised by commissural fusion with restricted opening and no calcification. We present a case report of TAVI in rheumatic aortic stenosis and prior mitral valve replacement with multiple comorbidities.

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## Description

A 70-year-old lady presented with a history of rheumatic heart disease and closed mitral valvotomy in 1978, mitral valve replacement with a prosthetic mechanical mitral valve (27 mm Medtronic-Hall prosthesis; Medtronic, Minneapolis, MN, USA) and De Vega's tricuspid annuloplasty in 2003. She had a past history of culture negative infective endocarditis in 2005 (treated with six weeks of antibiotic therapy), was a known diabetic, hypertensive, with severe bronchial asthma and had atrial fibrillation. She also had 90% right internal carotid artery stenosis and normal pressure hydrocephalus. She was cleared by the neurologist for TAVI. In view of high morbidity (48.153%) and mortality (14.249%) STS risk scores, she was rejected by cardiothoracic surgeons for surgical aortic valve replacement. An echocardiogram revealed a normally functioning mitral prosthesis (Figure 1), severe aortic stenosis with an aortic valve area of 0.5 cm<sup>2</sup> and a mean aortic pressure gradient of 45 mmHg, and normal left ventricular systolic function. The aortic valve was thickened with commissural fusion and had very minimal calcification. Computed tomography evaluation (Figure 2) showed tricuspid aortic leaflets with very minimal calcification, annulus diameter of 19.88 mm, and coronary height of 13.9 mm on the right side and 10 mm on the left side. Her epicardial coronaries were normal with adequately sized iliofemorals

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**Figure 1.** *Echocardiogram showing very minimal aortic valve calcification.* 



Figure 3. Final result with a 23 mm SAPIEN 3 valve.

and, after Heart Team discussion, she was considered for transfemoral TAVI. Although TAVI is usually indicated for degenerative aortic stenosis and not for rheumatic aortic stenosis, it was considered as an alternative in this case due to very high surgical risk.

Balloon aortic valvuloplasty and a simultaneous aortogram were carried out in order to assess annular size and also to look for coronary occlusion. A balloon-expandable SAPIEN 3 valve (Edwards Lifesciences, Irvine, CA, USA), oversized by 25%, was chosen to prevent valve embolisation and paravalvular leak. A 23 mm SAPIEN 3 valve was meticulously positioned, and



**Figure 2.** Computed tomography of the aortic valve showing very minimal aortic valve calcification.

slowly deployed during rapid ventricular pacing to achieve precise positioning. We achieved satisfactory haemodynamics and a final aortogram showed no paravalvular leak (Figure 3). She was discharged in a stable condition after a week. She has completed six months of clinical follow-up with an echocardiogram showing excellent valve function.

#### **Discussion and limitations**

The use of TAVI as a therapeutic strategy is considered a relative contraindication in rheumatic aortic stenosis<sup>3</sup>. The presence of annular/leaflet calcium is essential for performing TAVI as it helps to anchor the valve and prevent valve embolisation. Our case was unique with extreme high risk. The anticipated challenges were minimal calcification, low coronary height on the left side and the presence of a functioning mitral prosthesis, all of which increased the risk of valve embolisation and coronary occlusion.

Recent reports have shown that about one in 10 patients in the USA have TAVI for an off-label indication, especially aortic or mitral regurgitation and bicuspid aortic valves. In multivariate analysis, one-year mortality was no different in patients who had TAVI for an off-label condition relative to those who had TAVR for an on-label indication<sup>4</sup>. Apart from degenerative aortic stenosis, other expanded indications include (i) patients with patent coronary bypass grafts, especially functioning internal thoracic arteries, (ii) failed aortic bioprosthesis, at least 23 mm in size, avoiding resternotomies for cardiac reoperation, and (iii) patients with contraindications for sternotomy (e.g., retrosternal oesophageal conduits).

As a transcatheter valve requires annular/leaflet calcification to anchor it, in this case we chose to oversize the valve to prevent device embolisation. Moreover, an oversized valve and the annular symmetry of the patient's native valve might in fact favourably decrease the development of residual paravalvular leak. Despite the limited height of the coronary ostium, adequate sinus width and the absence of bulky leaflet calcification may also reduce the risks of coronary ostial occlusion. Regarding the choice of valve, both self-expanding and balloon-expandable were considered. The Medtronic Evolut<sup>™</sup> R valve (Medtronic) would have the advantage of repositioning up to 80% deployment, but has to be implanted in a deeper position relative to other valves and may not only interfere with the mitral prosthesis but could also potentially cause displacement towards the aorta and lead to inadequate positioning. The SAPIEN 3 valve was chosen considering the lesser possibility of its interference with the mitral prosthesis. Coronary occlusion was not a major concern due to the absence of bulky leaflet calcium and also visualisation of patent coronaries during the simultaneous aortogram carried out along with balloon valvuloplasty. One can also consider newly available fully repositionable and completely recapturable devices in this situation.

The SAPIEN 3 valve, in view of its non-repositionable characteristics, should be precisely positioned in the aortic annulus, with adequate pacing and slow deployment of the valve which is critical to assure stable implantation. Although device embolisation usually occurs early, it may occur later and hence a stringent follow-up is necessary.

Finally, this is a good beginning to start clinical trials for rheumatic aortic stenosis, especially in developing countries where we still see patients with rheumatic valvular heart disease.

#### Conclusion

TAVI can be performed in patients with rheumatic aortic stenosis who are not candidates for surgery after meticulous planning. The presence of minimal annular calcium and/or slight oversizing of the valve might help to anchor the valve. In the presence of a functioning mitral prosthesis, adequate pacing, meticulous positioning and slow deployment are crucial to ensure that the valve is not too deep in order to avoid mitral paravalvular leak.

# Impact on daily practice

The indications for TAVI may expand further, and proper planning and execution is vital in complex cases. It is time to start registries for TAVI in rheumatic aortic stenosis, particularly from developing countries.

#### **Conflict of interest statement**

The authors have no conflicts of interest to declare.

#### References

1. Kodali SK, Williams MR, Smith CR, Svensson LG, Webb JG, Makkar RR, Fontana GP, Dewey TM, Thourani VH, Pichard AD, Fischbein M, Szeto WY, Lim S, Greason KL, Teirstein PS, Malaisrie SC, Douglas PS, Hahn RT, Whisenant B, Zajarias A, Wang D, Akin JJ, Anderson WN, Leon MB; PARTNER Trial Investigators. Two-year outcomes after transcatheter or surgical aortic-valve replacement. *N Engl J Med.* 2012;366:1686-95.

2. Bilge M, Saatcı Yaşar A, Alemdar R, Ali S. Transcatheter aortic valve implantation with the CoreValve for the treatment of rheumatic aortic stenosis. *Anadolu Kardiyol Derg.* 2014;14:296-7.

3. Joint Task Force on the Management of Valvular Heart Disease of the European Society of Cardiology (ESC); European Association for Cardio-Thoracic Surgery (EACTS), Vahanian A, Alfieri O, Andreotti F, Antunes MJ, Barón-Esquivias G, Baumgartner H, Borger MA, Carrel TP, De Bonis M, Evangelista A, Falk V, Iung B, Lancellotti P, Pierard L, Price S, Schäfers HJ, Schuler G, Stepinska J, Swedberg K, Takkenberg J, Von Oppell UO, Windecker S, Zamorano JL, Zembala M. Guidelines on the management of valvular heart disease. *Eur Heart J.* 2012;33:2451-96.

4. Hira RS, Vemulapalli S, Li Z, McCabe JM, Rumsfeld JS, Kapadia SR, Alam M, Jneid H, Don C, Reisman M, Virani SS, Kleiman NS. Trends and Outcomes of Off-label Use of Transcatheter Aortic Valve Replacement: Insights from the NCDR STS/ACC TVT Registry. *JAMA Cardiol.* 2017;2:846-54.