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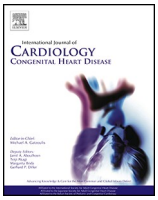

Reflections on transfemoral TAVI in dextrocardia with severe aortic regurgitation: Navigating anatomical complexity, off-label innovation, and future directions

Pandula Athauda arachchi [a,b,*], Sulakkana De Silva [b]

[a] General Sir John Kotelawala Defence University, Ratmalana, Sri Lanka
[b] Durdans Heart Centre, Colombo, Sri Lanka

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ABSTRACT

This reflective article explores the first reported case in literature of a transfemoral transcatheter aortic valve implantation (TAVI) in a dextrocardiac patient with severe aortic regurgitation (AR), left-sided superior vena cava (LSVC), and prohibitive surgical risk. It provides an overview of off-label TAVI for pure AR, aortic regurgitation without annular calcification, and in patients with rare congenital anomalies such as dextrocardia. The article discusses the technical, ethical, and procedural challenges, including device oversizing, the use of new-generation valves, and the risk of paravalvular leaks. The review also highlights recent advances in TAVI devices, procedural planning, and outcomes from multicenter studies and registries. The case underscores the importance of innovation, multidisciplinary collaboration, and the evolution of ethical frameworks to guide the safe expansion of TAVI into complex scenarios.

1. Introduction

Transcatheter aortic valve implantation (TAVI) has revolutionized the treatment of aortic stenosis, but its use in pure aortic regurgitation (AR) remains off-label [1,2]. It refers to the deployment of transcatheter valves in situations outside approved indications, such as treating severe native AR without annular calcification or performing TAVI in patients with rare congenital anomalies, such as dextrocardia [2]. These cases often involve high-risk or inoperable patients who are poor candidates for surgery. This overview summarizes global evidence on off-label TAVI for AR, including registry data, observational studies, and emerging trials [1,3,4]. The goal is to support the use of innovative off-label TAVI in complex scenarios when conventional options are limited, such as in a patient with dextrocardia and severe AR.

2. Index procedure and outcomes

A 70-year-old male with dextrocardia, severe AR [(EROA) of 0.45 cm^2, LVEF 53 %], and LSVC, with worsening dyspnoea (NYHA III), had a failed attempt at SAVR, 2 years earlier ("inability to access from incision"). Subsequently, he sustained an ischemic stroke requiring thrombolysis, with neurological deficits, and has extreme vascular tortuosity of iliac arteries, atrial fibrillation with heart block, and wass on anticoagulation. The MDT discussion centered on high-risk of redo surgery due to frailty and STS-ACSD score of 28.3 %. Transfemoral TAVI was performed after procedural planning involving anatomical assessments on CT, coronary angiogram, and upper limb venogram. (See Fig. 1) A 30.5 mm Myval (Meril Lifesciences) BE-TAVI device (30 % oversized to a valve area of 541 mm^2) with 50:50 % deployment and post-dilatation achieved stability despite zero calcification, followed by trans-LVSC septal pacing. (See Fig. 2). No complications were noted over a period of one year.

3. Challenges of TAVI in pure AR (non-calcified annuli)

Unlike aortic stenosis, pure AR presents the challenge of large annuli with minimal or no calcification, which makes secure anchoring a transcatheter valve difficult [1,3]. Early-generation TAVI devices performed poorly in AR cases, with higher risks of valve embolization, migration, and paravalvular leaks (PVL) [1]. Operators often oversize valves significantly (15–18 % larger than the annulus) to improve stability [1]. In one study, 92 % of cases required extra balloon volume during deployment to achieve a secure fit [1]. Early studies reported

* Corresponding author. General Sir John Kotelawala Defence University, Ratmalana, Sri Lanka.
E-mail addresses: athaudaarachchipm@kdu.ac.lk, athudaarachchipm@kdu.ac.lk (P. Athauda arachchi).

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Abbreviations

TAVI	Transcatheter Aortic Valve Implantation
AR	Aortic Regurgitation
LSVC	Left-sided Superior Vena Cava
AF	Atrial Fibrillation
EROA	Effective Regurgitant Orifice Area
LVEF	Left Ventricular Ejection Fraction
NYHA	New York Heart Association
SAVR	Surgical Aortic Valve Replacement
CT	Computerized Tomography
MDT	Multidisciplinary Team
STS-ACSD	Society of Thoracic Surgeons- Adult Cardiac Surgery Database

improving to 85 % with new-generation valves. Yoon et al. [3] (n = 331) demonstrated improved device success (61 % vs. 81 %, $p < 0.001$) and reduced residual AR (18.8 % vs. 4.2 %) with newer devices. The U.S. STS/TVT Registry [4] (n = 230) reported 81.7 % device success, though 30-day mortality remained 13.3 %.

5. Dedicated AR devices vs off-label TAVI

Specialized devices like the JenaValve Trilogy [5] and J-Valve show superior outcomes compared to off-label TAVI [6]. A 2024 meta-analysis [6] found lower 30-day mortality (3 % vs. 11 %) and PVL (1 % vs. 8 %) with dedicated AR devices. The Myval registry [7] reported 94.7 % technical success in 113 AR patients, with 30-day mortality of 5.3 %.

6. TAVI in dextrocardia and other complex anatomies

Dextrocardia requires procedural adaptations, including fluoroscopic mirroring and catheter rotation [2]. A review of 11 dextrocardia TAVI cases (2012–2019) reported successful implantation with no acute deaths [2]. Combined challenges (e.g., dextrocardia + AR) highlight the feasibility of TAVI in anatomically complex patients [2].

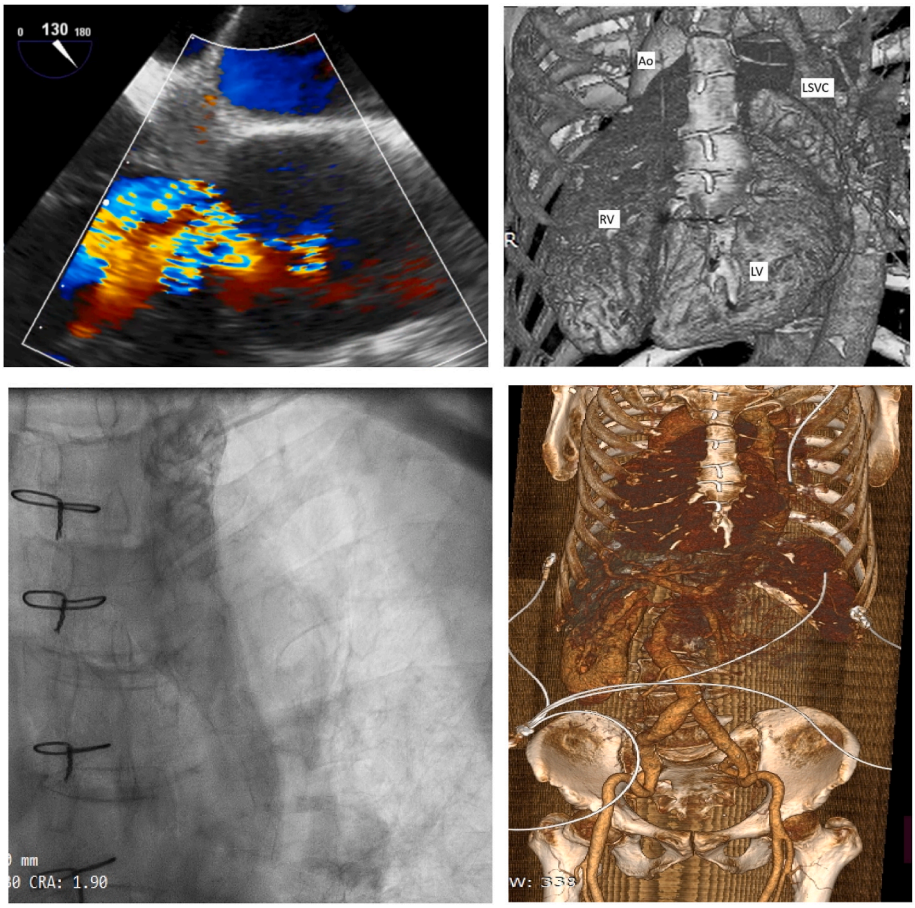

Fig. 1. Imaging of severe AR, dextrocardia, LSVC, and tortuous iliac arteries.
Top left: TTE demonstration of severe AR. *Top right*:3D-reconstruction of dextrocardiac heart with chambers and connection of great vessels. *Bottom left*: Left arm venogram confirmation of flow in LSVC into coronary sinus. *Bottom right*: tortuous left and right femoral and ilac arteries on both sides.

second-valve implantation in 19–24 % of AR cases with first-generation devices; newer series show reduced rates (8–9 %) [3]. Residual moderate AR after TAVI was associated with a 3-fold higher 1-year mortality [4].

4. Outcomes from multicenter studies and registries

Early Multicenter Registries (2017): Initial data from Sawaya et al. [1] (n = 146), reported device success rates of 72 % in native AR,

7. Regulatory and guideline perspectives on off-label TAVI

As of 2025, no TAVI device is approved in the US for native AR. In Europe, the JenaValve Trilogy received CE Mark approval in 2021 for

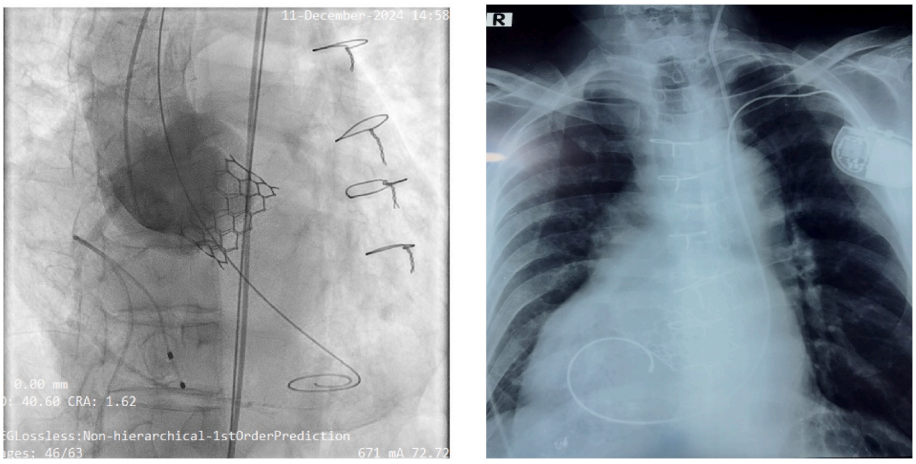

Fig. 2. Post-TAVI deployment and CXR illustrating valve position in dextrocardia.
Left: Post-TAVI deployment, absence of AR. Right:CXR illustration of position of dextrocardiac heart, TAVI valve and pacemaker lead via LSVC.

AR, supported by the ALIGN-AR trial [8]. The ongoing ARTIST trial [9] will compare TAVR versus surgery for AR. Current guidelines classify TAVI for AR as experimental, emphasizing MDT-driven decisions.

8. Conclusion

Off-label TAVI in complex patients, such as those with severe AR and dextrocardia, is increasingly supported by clinical evidence and technological innovation [1,3–9]. Whilst pharmacotherapy is still limited in aortic valve disease [10,11], Continued advancements in valve device design, multidisciplinary collaboration, and ethical frameworks will need to expand TAVI's leading role in high-risk scenarios and complex anatomies. Vacular anomalies in congential disease may pose challenges of unintended sheath and device failures, and proper evaluation and reporting of complications must be encouraged [11,12].

CRediT authorship contribution statement

Pandula Athauda arachchi: Writing – review & editing, Writing – original draft, Visualization, Resources, Methodology, Investigation, Funding acquisition, Formal analysis, Data curation, Conceptualization. **Sulakkana De Silva:** Visualization, Investigation, Data curation.

Declaration of competing interest

The authors declare no conflicts of interest.

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References

[1] Sawaya FJ, Deutsch MA, Seiffert M, et al. Safety and efficacy of transcatheter aortic valve replacement in the treatment of pure aortic regurgitation in native valves and failing surgical bioprostheses. JACC Cardiovasc Interv 2017;10(10):1048–56.
[2] Chen CC, Hsu RB, Chu PH. Transcatheter aortic valve implantation in dextrocardia: a case report. Acta Cardiol Sin 2021;37(6):683–6.
[3] Yoon SH, Schmidt T, Bleiziffer S, et al. Transcatheter aortic valve replacement in pure native aortic valve regurgitation. J Am Coll Cardiol 2017;70(22):2752–64.
[4] Anwaruddin S, Desai ND, Bavishi C, et al. Transcatheter aortic valve replacement in patients with pure native aortic regurgitation. Am J Cardiol 2019;124(5):781–8.
[5] TCTMD.com. JenaValve Trilogy CE Mark approval. 2021.
[6] Le Ruz R, Dumonteil N, Marcheix B, et al. Transcatheter aortic valve implantation with new devices in patients with pure native aortic regurgitation. EuroIntervention 2024;20(17):e1076–85.
[7] Sanchez-Luna JP, Munoz-Garcia AJ, Jimenez-Navarro MF, et al. Transcatheter aortic valve implantation with the myval system in non-calcific aortic regurgitation. EuroIntervention 2023;19(7):580–8.
[8] TCTMD News. ALIGN-AR at 2 Years – Trilogy in aortic regurgitation. October 2024.
[9] ARTIST Trial Investigators. Transcatheter versus surgical aortic valve replacement in severe aortic regurgitation: the ARTIST randomized trial. J Am Coll Cardiol 2025;75(15):1801–10.
[10] Athauda-Arachchi P, Lang C. Metabolic antianginal agent ranolazine offers good symptom relief in a patient with inoperable severe aortic stenosis. Cardiovasc Therapeut 2012;30(4):e210–1. https://doi.org/10.1111/j.1755-5922.2011.00273.x.
[11] Morselli F, McNally R, Nesti L, Liu B, Khan H, Thomson RJ, Stevenson A, Banerjee A, Ahmad M, Hanif M, Steeds R, Khan M. Pharmacological interventions for the treatment of aortic root and heart valve disease. Cochrane Database Syst Rev 2021;2021(12):CD014767. https://doi.org/10.1002/14651858.CD014767.
[12] Athauda-Arachchi P, Dorman S. Retention and fracture of a hydrophilic radial artery sheath due to severe spasm. Intervent Cardiol 2012;4(1):57.