EuroIntervention
2026;22:e419-e421
published online e-edition April 2026
DOI: 10.4244/EIJ-D-25-01191

VIEWPOINT

Aortic regurgitation: can transcatheter therapies deliver what we need?

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Aortic regurgitation (AR) is a common problem, particularly in the elderly, and untreated symptomatic severe AR has a poor prognosis. Based on the ACC/AHA 2020 Guidelines[1], surgical aortic valve replacement (SAVR) remains the only recommended treatment for AR, leaving an unmet need for high surgical risk patients. For this reason, out of necessity, clinicians have used off-label commercial transcatheter aortic valve implantation (TAVI) devices, originally developed for the treatment of aortic stenosis (AS), for years in AR patients, but the outcomes are inadequate. However, in Europe, a dedicated TAVI device, JenaValve Trilogy (JenaValve Technology). has obtained European Conformity (CE) mark approval. The recently updated European Society of Cardiology/European Association for Cardio-Thoracic Surgery (ESC/EACTS) 2025 Guidelines[2] have recognised improvements in transcatheter technologies for AR patients with a Class IIb recommendation for TAVI in patients who are ineligible for surgery.

TAVI has become a leading therapy for AS with excellent procedural outcomes. In contrast, when the same commercial TAVI devices have been utilised for patients with AR, the procedural results have been hampered by high rates of valve migration and embolisation, need for a second device, residual paravalvular leak (PVL) and pacemaker implantation. In the PANTHEON (Performance of Currently Available Transcatheter Aortic Valve Platforms in Inoperable Patients With Pure Aortic Regurgitation of a Native Valve) registry, 201 patients with native AR were studied. Overall device success at 30 days with off-label TAVI devices was 76.1%, with valve embolisation or migration occurring in 12.4% of patients. Importantly, valve embolisation or migration was associated with a higher incidence of the composite endpoint of mortality and heart failure hospitalisation at 1 year as well as all-cause mortality. Consistent with previous studies, there was a high rate of moderate or greater PVL (9.5%) and new permanent pacemaker implantation was required in 22.3% of patients[3].

A recent meta-analysis of 34 studies including 2,162 patients with pure AR demonstrated better outcomes with the two dedicated TAVI devices, JenaValve Trilogy and J-Valve (JC Medical), compared with off-label TAVI using commercial devices. In this study, 1,193 AR patients treated with dedicated TAVI devices were compared with 969 patients who received off-label TAVI. The 30-day event rates of residual greater than moderate AR, transcatheter heart valve (THV) migration or embolisation, reintervention, and permanent pacemaker implantation were significantly lower in the dedicated device group[4]. This may be the reason why the patients in the dedicated THV group also experienced a lower one-year mortality. On the other hand, patients in the dedicated device group were implanted under active research protocols which may have led to a selection bias where extreme surgical-risk patients were only offered off-label devices.

Thus, a dedicated device for AR that is safe, effective, and durable is a necessity. Of the dedicated devices evaluated thus far, the JenaValve Trilogy has the greatest number of implants worldwide, with over 750 patients treated in the United States and almost 1,000 patients in Europe. This device has been CE-mark approved in Europe since 2021. The Trilogy valve has a nitinol-based self-expanding frame with porcine pericardial leaflets and three locators that clip onto the native aortic leaflets. This device was formally studied in the United States in the ALIGN-AR Pivotal Trial, which included 180 high-risk surgical patients with ≥3+ AR. The

SUBMITTED ON 29/10/2025 - REVISION RECEIVED ON 04/12/2025 - ACCEPTED ON 04/12/2025

technical success rate was high, achieved in 95% of patients. The primary safety and efficacy endpoints were compared for non-inferiority with prespecified performance goals. The 30-day primary safety endpoint was a composite of all-cause mortality, any stroke, major vascular complication, life threatening or major bleeding, new pacemaker, acute kidney injury, valve dysfunction, and surgery or intervention related to the device; it achieved non-inferiority (27%). While only 2% all-cause mortality and 1% disabling strokes were observed at 30 days, the new pacemaker rate was 24%. The primary efficacy endpoint was 1-year all-cause mortality and met non-inferiority with an event rate of 7.8%. The study demonstrated excellent valve haemodynamics with low mean gradients at 30 days and 1 year (3.9 mmHg and 4.3 mmHg, respectively) and no or trace paravalvular leak in 92% of patients at 1 year. JenaValve Trilogy TAVI in these patients resulted in significant functional improvement. Comparatively, while 68% of patients had New York Heart Association (NYHA) Class III/IV symptoms at baseline, only 7% had NYHA Class III symptoms at 1 year. Reverse left ventricular (LV) remodelling was observed post-TAVI with a significant decline in LV mass and LV end-systolic dimension at 1 year[5]. These results support the safety and efficacy of the first dedicated transfemoral TAVI device for treating symptomatic AR patients. Since the publication of the ALIGN-AR Pivotal Trial, these results have been replicated in a larger cohort of patients treated through the continued access registry. At ACC 2025, an analysis of 320 patients treated as part of the continued access registry compared with the 180 patients treated in the pivotal trial demonstrated that 30-day all-cause mortality decreased to 0.9% from 2.2%, but otherwise the primary safety endpoints were very similar[6]. These promising results in a high surgical risk cohort have fuelled interest in expanding this technology to a low/intermediate surgical risk cohort of patients. The ARTIST trial is the first randomised controlled study of any TAVI device in AR patients (ClinicalTrials.gov: NCT06608823). The study is currently enrolling and aims to evaluate 1,016 patients with symptomatic ≥3+ AR. Patients enrolled must be deemed suitable for both SAVR and TAVI and will be followed for 10 years. The primary non-inferiority endpoint at 12 months includes death, symptomatic stroke and urgent cardiac rehospitalisation.

J-Valve is another dedicated TAVI system for AR. It is a self-expanding valve with bovine pericardial leaflets and has 3 nitinol anchor rings that capture the native leaflets. It has been mostly studied within China where it is currently approved for AS and AR.

Initial data with this transfemoral system were published from a multicentre, North American registry in which 27 patients were treated with J-Valve under a compassionate use protocol. The access was transfemoral in 78% of the patients, and there was an 81% procedural success rate overall (n=22/27) and 100% after valve modification (n=15/15)[7]. More recently, an early feasibility study enrolled AR patients in the US and reported promising results in 15 patients[8]. Procedural success was 93.5%, and all patients had none or trace residual AR. Currently, J-Valve is enrolling patients in the JOURNEY pivotal trial (ClinicalTrials.gov: NCT06455787), a high surgical risk, single-arm, prospective registry.

The evidence base for dedicated TAVI in patients with pure AR has grown substantially over the past several years. Currently, the JenaValve Trilogy device is CE-mark approved in Europe and is awaiting commercial approval in the United States following the completion of the ALIGN-AR trial. The J-Valve system is an approved device in China; enrolment has been initiated in the US for its use in the JOURNEY pivotal trial studying high surgical risk patients. Based on the encouraging results of the ALIGN-AR trial, the JenaValve Trilogy device is now being investigated in the ARTIST trial to expand TAVI for AR to low and intermediate surgical risk patients. With two dedicated TAVI devices for AR on the horizon, we are hopeful to provide reliable transcatheter therapies to high surgical risk AR patients.

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Conflict of interest statement

T.P. Vahl reports institutional funding to Columbia University Irving Medical Center from Abbott, Boston Scientific, Edwards Lifesciences, JenaValve, and Medtronic; and has personally received consulting fees from 4C Medical, InnovHeart, and Philips. L.S. Ranard reports institutional funding to Columbia University from Boston Scientific and JenaValve; and consulting fees from Philips, InnovHeart, and 4C Medical.

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