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Editorial

Transcatheter tricuspid valve replacement: from innovation to real-world clinical integration

Reemplazo percutáneo de válvula tricúspide: de la innovación a la integración en la práctica clínica

Cristian Herrera-Flores,[a,b,c] Philip Lurz,[c] and Karl-Patrik Kresoja[c,*]

[a] *Servicio de Cardiología, Hospital Universitario de Salamanca, Instituto de Investigación Biomédica de Salamanca, Salamanca, Spain*
[b] *Centro de Investigación Biomédica en Red de Enfermedades Cardiovasculares (CIBERCV), Instituto de Salud Carlos III, Madrid, Spain*
[c] *Department of Cardiology, Zentrum für Kardiologie – Kardiologie I, University Medical Center, Johannes Gutenberg University, Mainz, Germany*

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Over the past 5 years, tricuspid valve has decisively entered the interventional spotlight. Driven by the growing recognition of the morbidity and mortality associated with tricuspid regurgitation (TR) across all severity grades, coupled with the limitations of both surgical and medical management, the field has been actively exploring less invasive, catheter-based solutions. To date, 2 transcatheter tricuspid valve edge-to-edge repair systems (PASCAL, Edwards Lifesciences, United States, and TriClip, Abbott, United States), have received both the CE mark and the approval from the U.S. Food and Drug Administration (FDA) for the treatment of patients with severe, symptomatic TR. Meanwhile, the TricValve system (P&F Products & Features, Austria), remains as the only CE-and FDA-approved transcatheter heterotopic device.

Despite recent advances, improvements in all-cause mortality and heart failure-related hospitalization have not been consistently demonstrated. Instead, the clearest benefit of transcatheter tricuspid procedures has been amelioration of health status and functional class. This has driven a paradigm shift in therapeutic goals from classic endpoints such as survival to a more patient-centered focus on quality-of-life metrics and patient-reported outcomes. One potential explanation for the limited impact on mortality is that current repair-based transcatheter therapies often leave behind residual TR. Persistent moderate or greater TR has been associated with worse clinical outcomes,[1] underscoring the need for more definitive solutions.

Transcatheter tricuspid valve replacement (TTVR) has the potential to completely abolish TR, representing a promising alternative for patients with complex anatomies unsuitable for edge-to-edge repair, including patients with baseline massive or torrential TR, severe leaflet tethering, large coaptation gaps or pacemaker-induced leaflet impingement. Among available TTVR devices,[2] the EVOQUE system (Edwards Lifesciences, United States) became the world's first dedicated transcatheter valve replacement device to receive regulatory approval (CE mark in 2023) for broader commercial use beyond clinical trials. The EVOQUE system features a self-expanding nitinol frame with bovine pericardial leaflets and an intra-annular sealing skirt, which is delivered through a 28-Fr transfemoral system with 3 planes of motion for precise positioning. The valve has a unique mechanism that uses the annulus, leaflets, and chords for stable, non-traumatic fixation through 9 ventricular anchors. It is currently available in 4 sizes (44 mm, 48 mm, 52 mm, and 56 mm) covering annular diameters from 37 mm to 58 mm and perimeters of up to 169 mm.

Two pivotal trials have demonstrated the technical feasibility and safety of the EVOQUE system, with substantial TR reduction and favorable short-term clinical outcomes as a standalone therapy (TRISCEND) or in combination with optimal medical therapy (TRISCEND II).[3] However, randomized clinical trials are not always representative of real-world practice. Observational data from non-trial settings are, therefore, essential to complement and contextualize findings from randomized clinical trials.

In a recent article published in *REC: Interventional Cardiology*, Pardo Sanz et al.[4] share their experience with the orthotopic EVOQUE valve implantation in a series of 10 consecutive patients, with outcomes assessed at 30 days. The mean age of the population (77 years) with high prevalence of comorbidities (including atrial fibrillation and 40% pacemaker prevalence) and symptom burden (all had New York Heart Association [NYHA] class ≥ 2 or recurrent hospitalizations) illustrate the frail and complex nature of this population, which mirrors that of the TRISCEND II trial and followed similar exclusion criteria (severely depressed right ventricular [RV] systolic function, unsuitable anatomies, life expectancy < 12 months). All patients had been considered ineligible for repair-based therapies due to complex tricuspid anatomy. Just a few years ago, these patients were often considered to have no treatment options.

The authors reported a 100% procedural success rate, a median procedural time of approximately 2 hours, consistent reduction of TR to mild or less in all cases, absence of major paravalvular leaks, and no in-hospital mortality. These results are highly encouraging and confirm the technical reproducibility of the EVOQUE system across centers and operators outside high-volume trial sites. Still, this procedure is resource-intensive, logistically complex, and requires multidisciplinary coordination, advanced peri-procedural imaging and available backup for cardiac surgery and emergent pacemaker implantation capabilities. In this series, 2 patients experienced transient RV failure, a severe complication. Abrupt

*** Corresponding author.**
E-mail address: kresojak@uni-mainz.de (K-P. Kresoja).

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elimination of torrential TR unequivocally leads to an acute rise in RV afterload. The RV, adapted to unloading into a low-pressure circuit, must suddenly adapt to a now-competent valve, an adjustment that some ventricles, particularly those with borderline or "pseudo-normalized" function, may not tolerate acutely. This scenario is similar to the afterload mismatch phenomenon in left-sided valve interventions. Additionally, one must consider the mechanical interaction between the prosthetic valve and the RV natural motion, which may further impair longitudinal function, the main determinant of RV systolic performance. Although managed successfully with inotropic support, these cases underscore the need for an exquisite RV assessment during pre-procedural planning. Future studies may benefit from integrating hemodynamic, load-independent data derived from pressure-volume loops along with multimodality imaging to more accurately characterize the RV and identify patients at risk of post-procedural decompensation.

Another relevant concern after TTVR is the risk of conduction disturbances.[2] One patient developed complete atrioventricular block, requiring permanent pacing. This was a patient with pre-existing right bundle branch block, a known predictor for the need of pacemaker implantation in other percutaneous transcatheter valve therapies. The anatomic proximity of the EVOQUE anchors to the conduction system, coupled with baseline conduction abnormalities, likely triggered this outcome. Optimal pacing strategies post-TTVR remain undefined, whether via transvalvular leads, coronary sinus pacing, leadless systems, or surgical epicardial leads. While technical refinements may eventually mitigate this risk, for now, comprehensive pre-implantation rhythm evaluation and prolonged postoperative telemetry monitoring are recommended.

Two patients were diagnosed with prosthetic valve thrombosis at the 1-month follow-up computed tomography despite adequate anticoagulation. Neither had symptoms or elevated transprosthetic gradients, raising, perhaps, the differential diagnosis of hypoattenuated leaflet thickening. This subclinical phenomenon has already been reported in up to 32% of cases in contemporary series.[5] Since transvalvular gradients remained low, it is unclear whether these subclinical thrombi would impact long-term valve durability or lead to embolic events. Nonetheless, the implications are significant. Should routine post-procedural computed tomography be performed? And what is the optimal antithrombotic regimen? In TRISCEND trials, oral anticoagulation (aiming International Normalized Ratio [INR] of 2.5-3.5) with adjuvant aspirin was recommend to all patients for the initial 6 months. This intensive antithrombotic regime may have explained, in part, the notable rate of severe bleeding events registered.[3] In contrast, the present cohort remained on previous anticoagulation strategies without antiplatelet therapy. As with transcatheter aortic valve replacement, we may need to rethink antithrombotic protocols specifically for the low-flow, low-pressure tricuspid bioprostheses —potentially balancing bleeding risks in an elderly population with thrombotic complications that may go unnoticed without advanced imaging.

Finally, a rare but instructive complication was reported, a case of severe functional mitral regurgitation occurring 5 days after the EVOQUE valve implantation, which resolved with diuretic and inodilator therapy. The mechanism may relate to the acute preload normalization after TR elimination and increase in forward stroke volume, which unmasked or exacerbated the preexisting mitral regurgitation.[6] Once again, intra and postoperative re-evaluation of coexisting valvular lesions is mandatory.

While the technical success and hemodynamic outcomes are commendable, the absence of formal assessment of quality-of-life and patient-reported outcomes is a limitation. In the TRISCEND II trial, improvements in Kansas City Cardiomyopathy Questionnaire (KCCQ) scores and NYHA class were key indicators of clinical benefit. Even when hard endpoints remain unchanged, post-procedure functional improvement (symptoms, activities of daily living, and independence) stands as a critical measure of clinical value, particularly in a patient population where survival may not reflect therapeutic success.

As TTVR moves from innovation to integration, 3 priorities emerge:

1. Long-term durability. What will the 5- and 10-year performance of the EVOQUE valve look like in terms of structural integrity, thrombotic risk, and reintervention rates?

2. Patient selection. Can we identify robust predictors (clinical, imaging or biomarker-based) to guide the choice between tricuspid valve repair and replacement?

3. Broader applicability. A 17% treatment rejection rate based on feasibility assessments was reported in the study, implying that there are still patients who are ineligible for this therapy. In fact, a 74% screening failure rate was documented in the first real-world TTVR registry.[7] Besides, should we scale this therapy beyond high-volume centers?

The tricuspid landscape is evolving rapidly. The study by Pardo Sanz et al.[4] exemplifies what is achievable when technological innovation meets clinical pragmatism. The EVOQUE valve stands at the frontier of transcatheter therapy, offering a lifeline to patients who previously had none. Yet, success demands meticulous patient selection, expert execution, and extended surveillance to guarantee long-term results. As we refine the art and science of tricuspid interventions, real-world experiences such as this one will remain essential to optimizing clinical practice and extending the evidence of novel transcatheter therapies.

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CONFLICTS OF INTEREST

None declared.

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