Advancing Transcatheter Valve Replacement for Severe Aortic Regurgitation: Innovations in Devices and Multi-Modality Imaging

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April 15, 2024

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Word Count : 912 words

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For patients with severe symptomatic aortic regurgitation (AR) who are deemed at high surgical risk, off-label use of transcatheter aortic valve replacement (TAVR) is increasingly performed. However, the rate of complications is high in this subset, including migration, paravalvular regurgitation, pacemaker implantation, stroke, bleeding, vascular complication, acute renal failure, surgical conversion and mortality.(1)

In this issue of *Echocardiography* , Hu et al (ref) present their findings on 70 patients (56% of males, mean age=74±8 years) with severe symptomatic AR (all in NYHA functional class III or IV) on native or bioprosthetic valves who underwent a TAVR using the Vita-Flow valves (Microport), a novel self-expanding valve (Figure). The population was divided into two groups: group A consisted of 40 patients with aortic root dilatation or valve prolapse and no valvular calcifications, while group B comprised 30 patients with aortic valve degeneration and/or mild senile calcifications (Agatston score ranging from 0 to 100). All interventions were performed under general anesthesia, with procedural guidance provided by both fluoroscopy and real-time three-dimensional echocardiography. A comprehensive pre-procedural assessment of the anatomy was conducted using both transesophageal echocardiography (TEE) and computed tomography (MSCT) and dedicated software. The study focuses on the utility of echocardiography in the pre-procedural screening, intra-procedural monitoring, and 30-day post-procedural follow-up, while also identifying potential predictors for post-procedural complications.

The main results from the study can be summarized as follow:

- Multimodality imaging analysis demonstrated significant concordance between TEE and MSCT especially in the assessment of the annulus and aorta dimensions, as well as left and right coronary artery height, enabling accurate device sizing.

- The procedural success rate was high (96%) and there were no deaths at 30 days.
- Multiple underlying mechanisms of AR were successfully treated.
- Mild peri-valvular leakage was observed in 16% of cases but no moderate or greater peri-valvular leakage was reported.
- Incidence of significant complications was low, with 3% experiencing iliac artery dissection, 4% encountering stroke, and 3% developing acute renal insufficiency within 30 days post-procedure. No migration was reported.
- A noteworthy 22% of patients required new pacemaker implantation due to complete atrioventricular block, with a median implantation time of 6 days with right bundle branch block as the only independent predictor.
- Procedural success correlated with a positive left ventricular and atrial remodeling at 30 days (reductions in left atrial and left ventricular diameters, and improvement of the left ventricular ejection fraction).

The main limitations of this study include its retrospective single-center design, small sample size (although relatively large for a single center), mix of TAVR on native valves and valve-in-valve procedures, and a short follow-up period.

A significant proportion of patients with surgical indications for severe AR are not referred, often due to high surgical risk or comorbidities(2,3). Transcatheter treatment of AR is currently on the rise but is much more challenging than for aortic stenosis, notably due to the absence of calcifications.

TAVR is currently mostly performed using prostheses developed for aortic stenosis. A recent multicenter registry (PANTHEON) including 201 patients treated with commercially available devices (self-expandable and balloon expendable valves developed for AS) showed that with improvements in TAVR devices, in experienced centers and in selected patients, satisfactory outcomes can be achieved in a majority of patients, but that complications rates remained high (12% of embolization or migration at 1 month and 10% of moderate or greater residual leakage), regardless of prosthesis type. Critically, these complications were associated with high mortality or hospitalization for heart failure rates at 1 year (approximately 25%). Rates of permanent pacemaker implantation were also high (approximately 22%), often associated with device oversizing.(1)

Several devices designed for the management of AR are currently available or under evaluation. Presently, the JenaValve Trilogy system (JenaValve Technology) is the only dedicated device to have received Conformité Européenne (CE) mark approval for the transcatheter treatment of patients with AR. A recent multicenter registry, comprising 58 consecutive patients from 6 centers across Germany, demonstrated excellent outcomes with a 98% implantation success rate, the absence of moderate or severe paravalvular regurgitation, a 30-day mortality rate of 1.7%, and a 19.6% rate of new permanent pacemaker implantation.(4) The Jena-Valve ALIGN-AR Pivotal Trial (NCT04415047) included 177 patients with 91% of procedures performed under general anesthesia. The trial yielded a procedural success rate of 95%, with 3% of patients necessitating subsequent surgery. Only 0.6% experienced moderate or severe paravalvular regurgitation, and 30-day mortality rate was 2.2%. Additionally, 24% of patients received new pacemaker implantation, a rate that tended to decrease with experience, particularly with refined strategies for device sizing and positioning.

The J-Valve (JC Medical), specifically designed for the treatment of patients with AR, is another alternative. A recent study including 27 patients for compassionate use found a procedural success rate of 81% overall and 100% in the last 15 cases, with no patient having residual AR of moderate or greater degree at 30 days and a 13% rate of new pacemaker implantation.(5)

In conclusion, there is a genuine enthusiasm for transcatheter AR management, driven by both industry innovation and clinical demand. Dedicated devices seem to perform better than devices commercially used for aortic stenosis, but pacemaker implantation rate remains high. Multimodal imaging plays a pivotal role in patient and device selection, procedural guidance, and follow-up. Although echocardiography seems accurate, as for aortic stenosis, MSCT will remain the method of choice for pre-intervention procedural planning. As

the landscape rapidly evolves, refining patient selection, procedural techniques, and postprocedural care will be paramount to ensuring optimal outcomes in this challenging patient population.

DISCLOSURES

Julien Dreyfus has no relationships relevant to the contents of this paper to disclose.

David Messika-Zeitoun received unrestricted research grant from Edwards, outside the submitted work.

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FIGURE . Comparison of devices characteristics and outcomes after transcatheter aortic valve replacement for aortic regurgitation based on published studies.

AR: Aortic Regurgitation

	PANTHEON - Poletti et al. (N=201)	Garcia et al. (N=27)	Adam et al. (N=58)	Hu et al. (N=70)
Dedicated device for AR	No	Yes	Yes	Yes
Types of valves	- Evolut R and Pro - Accurate Neo and Neo2 - JenaValve - Navitor - Myval - Sapien 3 and Ultra	J-valve	JenaValve	Vita-Flow valve
CE marked	Yes	No	Yes	No
Device use	Off-label use of commercially available	Compassionate use	Commercially available	Commercially available
Self-expanding or balloon-expandable	Self-expanding and balloon-expandable	Self-expanding	Self-expanding	Self-expanding
Native valve or valve-in-valve procedures	Native valve	Native valve	Native valve	Native valve and valve-in-valve procedures
In-hospital/30 days				
- Procedural success	76%	81%	100%	96%
- Residual ≥ moderate AR	10%	0%	0%	0%
- Embolization/migration	12%	4%	0%	3%
- Permanent pacemaker implantation	22%	13%	20%	22%
- Major vascular complications	8%	19%	0%	3%
- Stroke	2%	4%	0%	4%
- Acute renal failure	11%	-	2%	3%
- Conversion to surgery	2%	7%	0%	1%
- Mortality	5%	4%	0%	0%

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