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COMMENTARY

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Transcatheter aortic valve replacement for native and prosthetic aortic regurgitation: Two birds with one stone

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Over the course of the last decade transcatheter aortic valve replacement (TAVR) has been extensively performed and investigated for the treatment of patients with symptomatic severe aortic stenosis (AS) and is currently considered an alternative to surgical aortic valve replacement, even in younger, lower surgical risk patients. In addition, technological advancements and growing operators' experience, have brought TAVR to the treatment of bioprosthetic valve failure (BVF)[1] and, more rarely, pure aortic regurgitation (AR).[2–4] Although randomized clinical trials (RCTs) are lacking, the efficacy of the transcatheter aortic valve-in-valve (VIV) implantation in patients with BVF has emerged from large real-world registries.[1] In these studies, isolated severe regurgitation was the cause of BVF in almost one-third of cases and was associated with a better survival rate than BVF due to restenosis.[1] Nevertheless, increased risk for postprocedural elevated transvalvular pressure gradients (≥20 mmHg), particularly in patients with small bioprostheses implanted (diameter ≤ 21 mm), remains well-known, possibly hampering the hemodynamic improvements and long-term efficacy of VIV implantation.[3]

On the contrary, the available data on the use of TAVR for the treatment of severe native AR (NVAR) are scanter and, actually, NVAR remains an off-label indication for TAVR. The lack of annular/leaflet calcification, the irregular and large orifice geometry, and the frequent association of ascending aorta pathology make the TAVR procedure much riskier compared to the AS setting, due to the higher risk of complications like device embolization, second valve implantation, and significant residual postprocedure paravalvular leak. Nonetheless, previous studies on this topic have shown TAVR feasibility and safety in patients deemed at high surgical risk or inoperable. In the largest study published on NVAR in high surgical risk patients, TAVR ($n = 912$) outcome was similar to surgically treated patients ($n = 13{,}808$) in terms of in-hospital mortality both in unmatched and propensity-matched cohorts.[4] A favorable outcome of TAVR in pure NVAR was found also by others with the use of the oversized self-expandable ACURATE neo device at the cost of a slightly higher need for permanent pacemaker implantation.[2]

Sawaya et al., comparing the outcome of TAVR for the treatment of isolated AR due to BVF or native valve (NV) disease, found that safety and efficacy were superior in the former group of patients. Furthermore, they highlighted the lower rate of moderate-to-severe residual AR after TAVR with new generation transcatheter heart valves (THV) compared to old generation devices.[3]

Similarly, the current study of Paraggio et al.[5] explored the hemodynamic impact of new generation TAVR devices in patients with isolated AR, trying to find whether there is a significant interaction between AR in BVF versus NV disease patients. The Authors presented a retrospective evaluation of 28 patients who underwent successful TAVR with both invasive and noninvasive hemodynamic assessment by means of left ventricle (LV) catheterization before and after TAVR and echocardiography before, after (24–72 h) and at follow-up (3–12 months).

Regarding procedural data, both groups were treated with new-generation devices (comprising Evolut PRO, Evolut R, SAPIEN 3, and

Portico) in the majority of cases (only one case in the NV group implanted with CoreValve); self-expandable devices were the preferred option for treatment, with Evolut R being the most frequently implanted in both groups. The size of implanted prothesis was significantly different between the BVF group (25 mm mean) and the NV group (33 mm mean). The rate of THV oversizing has not been reported by the authors. The results were reassuring with a procedural success rate of 96.4% and no cases of moderate or severe post-TAVR AR. In the BVF group, there were no cases of severe residual mean gradient (reported mean gradient 14 mmHg), while in the NV group, bail-out implantation of a second prothesis was needed only in one case, and the need for new permanent pacemaker implantation rates was 25%.

When compared to BVF patients, patients with NVAR were younger, had significantly larger LV end-systolic diameter, and more impaired diastolic function, suggesting a longer period of chronic volume overload in this group. Notwithstanding, TAVR resulted in a similar hemodynamic improvement and reverse LV remodeling in both groups with a significant reduction of the LV end-diastolic volume, at the price of an initial decrease in LV ejection fraction that recovered at later follow up.

The results of this study complement those of the study by Sawaya et al., providing encouraging preliminary data on the hemodynamic changes that occur in AR patients in the first year after the TAVR procedure. Moreover, despite a significantly lower sample size, this study seems to confirm the high rates of device success and lower rates of moderate-to-severe residual AR achieved in this setting with new generation THVs.

Even though limited by a small number of studied patients, the absence of an evaluation of clinical endpoints and of independent core-lab validation of hemodynamic data, the present study adds another piece of information related to the hemodynamic benefits of TAVR in the setting of AR either due to BVF or native valve disease. Notwithstanding, as also stated by the authors, the results obtained in this study cannot easily be translated to less experienced centers. As such, as pointed out in current ESC guidelines for the treatment of valvular heart disease, TAVR for the treatment of severe isolated AR should be undertaken only in selected high-risk patients in experienced centers.

Further larger studies and RCTs are needed to assess if similar outcomes are achievable in different highly experienced centers and translate into a significant improvement of major clinical endpoints.

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CONFLICTS OF INTEREST

The authors declare no conflicts of interest.

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