Editorial

Pitfalls of transcatheter tricuspid valve replacement: lessons from a decade of experience

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Over the last decade, transcatheter tricuspid valve replacement (TTVR) has emerged as a therapeutic option for patients with tricuspid regurgitation (TR) who are not candidates for surgical tricuspid valve (TV) treatment due to high operative risk, or for transcatheter edge-to-edge repair (TEER) owing to unfavorable anatomy. A large septolateral coaptation gap, jet location extending into the anteroseptal segment, star-shaped en face TR jet morphology, and limited image quality have been associated with lower procedural success rates, and the presence of multiple such features favors TTVR over TEER (1). Initially performed for compassionate use (2), TTVR has progressed through single-arm feasibility studies (3) and a randomized trial (4), demonstrating excellent efficacy with improved quality of life, leading to commercial approval of the EVOQUE valve (Edwards Lifesciences, Irvine, CA) in the EU and North America. Several other TTVR systems are currently under clinical investigation, each incorporating different anchoring mechanisms, including subannular anchors engaging the leaflets, annular anchoring with radial force and leaflet tines, septal fixation combined with two lateral leaflet anchors, and radial force with outflow tract anchoring, all of which may influence TR reduction, right ventricular (RV) function, conduction disturbances, and intraprocedural imaging requirements (5). However, despite rapid progress, many unknowns remain.

To date, TTVR has been performed mainly in elderly, highly symptomatic patients with predominantly secondary TR associated with atrial fibrillation (AF) and high surgical risk [mean age ~80 years; New York Heart Association (NYHA) II/III >70%; mean Society of Thoracic Surgeons Predicted Risk of Mortality (STS-PROM) 8–10%] (2-4). Renal insufficiency was present in more than half of the patients, and hepatic dysfunction with ascites was observed in 20–50%, suggesting advanced right heart failure (HF). In patients undergoing TV surgery, delayed operative intervention in patients with RV dysfunction and end-organ damage including renal and hepatic dysfunction negatively impacts perioperative outcomes (6). However, predictors of prognosis in patients undergoing TTVR remain to be defined. The recent real-world European commercial EVOQUE registry demonstrated that preoperative RV dysfunction was associated not only with adverse short-term outcomes including in-hospital mortality but also with reduced clinical improvement at follow-up (7). This would suggest that TTVR is best avoided in patients with advanced RV dysfunction, with likely preference for tricuspid transcatheter edge-to-edge repair (TEER) given it rarely abolishes TR. In addition, invasive hemodynamic assessment to exclude precapillary pulmonary hypertension and/or pulmonary vascular resistance >5 WU is important to avoid post-TTVR afterload mismatch and RV failure. The pulmonary artery (PA) to RV coupling index, assessed either non-invasively measured as PA systolic pressure divided by tricuspid annular plane systolic excursion (TAPSE) (≤0.406) (8) or invasively measured as PA systolic pressure/TAPSE ratio (<0.303) (9), has been linked to worse outcomes in patients undergoing TEER, and likely also

holds true for patients undergoing TTVR.

Although RV function is usually assessed by echocardiography, accurate evaluation remains challenging given the complex anatomy and geometry of the RV. Computed tomography (CT) derived RV ejection fraction (EF) ≤45% has been shown to be associated with worse clinical outcomes in patients undergoing transcatheter TV repair (10). Similarly, RV end-diastolic volume ≥150 mL/m^2 and RVEF <50% as assessed by cardiac magnetic resonance imaging were associated with higher risk for adverse clinical outcomes in patients with TR (11). In addition, three-dimensional echocardiography derived RV-PA coupling, defined as RV forward stroke volume/RV end-systolic volume <0.40 was associated with worse clinical outcomes (12). These parameters potentially allow better risk stratification and earlier identification of appropriate candidates for intervention.

Acute RV failure can occur after TTVR through several mechanisms, including an abrupt increase in RV afterload in the presence of precapillary and/or postcapillary pulmonary hypertension, and an increase in myocardial oxygen consumption in the setting of RV ischemia (13). Careful monitoring of hemodynamics and RV function is essential for early identification of hemodynamic instability. Optimization of volume status and rhythm disturbances, prompt initiation of vasopressor and/or inotropes, as well as the targeted treatment of underlying pulmonary hypertension or ischemia, are key management strategies.

Initially, TTVR demonstrated improvements in quality of life rather than reduction in HF hospitalization or mortality compared to medical therapy at 1-year follow-up (4). TTVR with EVOQUE resulted in an improvement of at least one NYHA functional class in 79% of patients, an increase of ≥10 points in the Kansas City Cardiomyopathy Questionnaire (KCCQ) score in 66%, and an improvement of ≥30 m in 6-minute walk distance in 48%. However, a recent TRISCEND II post hoc analysis stratified by TR severity indicated that TTVR reduced HF hospitalization by 40% [number needed to treat (NNT) 6.6] and combined all-cause mortality and HF hospitalization by 30% (NNT 7.1) in patients with baseline massive/torrential TR compared to medical therapy at 18 months follow-up, while no significant difference was observed in patients with severe TR (14). Patients with massive/torrential TR have a higher risk profile with more advanced RV remodeling, putting them at higher risk of HF and death. Unlike TEER, TTVR consistently reduces TR to less or equal to mild regardless of baseline TR severity, likely making it the preferred intervention in such patients.

Although TTVR has superior efficacy, it may come at a cost of decreased safety due to complications such as high-grade atrioventricular (AV) block requiring permanent pacemaker (PPM) implantation, major bleeding, and valve malposition requiring surgical or percutaneous reintervention. The incidence of conduction disturbances requiring PPM has been reported between 12% in the TRIPLACE registry (15) and 25% in the TRISCEND II randomized trial and are device-specific (4). A recent report from the TRIPLACE registry identified baseline left bundle branch block and anterior/posterior fascicular block as risk factors (8); in our clinical experience, patients with slow AF are also at increased risk. Although the majority of high-grade AV block occurs within 72 hours after TTVR, a substantial proportion develops within the first week and may be sudden and unpredictable. In addition, although rare, such events have been reported up to 30 days post-procedure. Future device iterations that avoid subvalvular anchors or excessive radial force near the membranous septum may help reduce the risk of conduction disturbances. In a real-world registry, the majority of patients requiring PPM following TTVR were treated with leadless pacemakers (46%) or coronary sinus leads (27%) (15), which minimize interference with the implanted bioprosthesis, and are thus considered preferred options. The high bleeding risk in patients undergoing TTVR is related to advanced age, renal or hepatic insufficiency, and the use of a large-bore sheath. Bleeding complications can be reduced by temporary discontinuation of anticoagulation, avoidance of periprocedural heparin bridging, and careful postprocedural hemostasis before resuming anticoagulation, preferably with direct oral anticoagulants (DOACs) (16). Although uncommon, paravalvular leak (PVL) can result in significant residual TR, and may necessitate transcatheter PVL closure (17,18). Adequate preoperative management of volume status with intravenous loop diuretics, aimed at achieving an euvolemic state, can reduce tricuspid annular size, thereby facilitating appropriate oversizing of the TTVR device and thereby minimizing PVL and valve malposition (11).

Patients with pre-existing cardiac implantable electronic devices (CIEDs) are common in the TTVR population and require special consideration. Jailing of CIED leads has been associated with minimal lead function changes in short-term follow-up, with low rates of lead revision (19). However, jailing of CIED leads may preclude subsequent lead extraction in the event of CIED-related infection. Conversely, pre-procedural lead extraction carries inherent procedural risks and may

result in leaflet or subvalvular apparatus injury, potentially precluding treatment with TTVR systems that rely on subvalvular anchoring. Careful case-by-case discussion with electrophysiology (EP) specialists is warranted, particularly in patients with pacemaker dependency, active implantable cardioverter-defibrillator (ICD) leads, a high risk of CIED infection, or limited lead slack with anticipated high lead tension after jailing.

Data on the long-term valve durability after TTVR are currently lacking. Although mechanical stress is lower in the right heart due to reduced pressures, the lower opening and closing forces and larger valve size may predispose to valve thrombosis, thereby accelerating degeneration. Indeed, in a 2-year follow-up of EVOQUE patients, hypo-attenuated leaflet thickening (HALT) was identified in 36% of patients with available CT imaging despite anticoagulation, while clinically relevant valve thrombosis was uncommon (20). A systematic review and meta-analysis has reported a significant incidence of valve thrombosis following TTVR, with the incidence rates of clinical and subclinical valve thrombosis of 8.5 and 14.0 events per 100 patient-years, respectively, despite the extensive use of anticoagulants (21). In a study with planned four-dimensional (4D) CT after TTVR, among 12 patients with HALT, two were switched from DOACs to warfarin, seven continued DOAC therapy with or without dose intensification, and three remained on warfarin with intensification of the therapeutic range, with improvement in HALT observed irrespective of the anticoagulation strategy (22). While the optimal anticoagulation strategy is still uncertain, in patients with clinical valve thrombosis and a significant transvalvular pressure gradient, intensification of DOAC dosing, switching to warfarin or targeting a higher INR, are reasonable options, balancing the risk of bleeding. Further studies are needed to clarify the impact of HALT on long-term valve performance and patient outcomes.

The 5-year follow-up of the first-in-human EVOQUE case was recently reported, with only mild intravalvular TR (23). According to reports on surgical tricuspid valve replacement (TVR), bioprosthetic valves were associated with higher reoperation rates compared with mechanical valves, beginning seven years after the index surgery (24). Further long-term follow-up data on valve durability, as well as evidence regarding feasibility, safety, and durability of valve-in-valve implantation using balloon-expandable valve for failed TTVR are eagerly awaited. Such data will be essential when considering TTVR as first-line therapy.

Although several pitfalls remain for TTVR, the superior and predictable reduction in TR is clearly associated with better improvement in symptoms and quality of life when compared to TEER, with reductions in HF hospitalization in patients with massive/torrential TR. TTVR uptake is expected to increase with further device evolution to minimize high-grade AV block, device malposition, and PVL. As safety improves, one may anticipate randomized trials comparing TTVR and TEER in patients that are eligible for both therapies, further refining our understanding of patient and device selection for transcatheter TV intervention.

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