# Tricuspid valve-in-valve implantation for failing bioprosthetic valves: an evolving standard of care

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**Abstract:** Redo surgery for bioprosthetic tricuspid valve failure is associated with high morbidity and mortality. In recent years, transcatheter tricuspid valve-in-valve (VIV) therapy utilizing ballon-expandable transcatheter valves has become available. The tricuspid Valve-in-Valve International Data (VIVID) registry initial results represent the largest experience with tricuspid VIV therapy, demonstrating high procedural success rates with low 30 days mortality and excellent survival free of repeat tricuspid intervention in 1 year. Although longer clinic and hemodynamic follow-up will be needed to fully understand the role of this therapy, these data support the safety, feasibility and beneficial effects of tricuspid VIV therapy. For patients with bioprosthetic tricuspid valve failure, tricuspid VIV is likely to become a first-line treatment option.

**Keywords:** Transcatheter valve-in-valve; tricuspid valve; bioprosthetic valves

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Many patients undergoing surgery for tricuspid valve disease have anatomic features unsuitable for repair, often necessitating valve replacement. Bioprosthetic heart valves (BHV) are often preferred over mechanical valves for various reasons, including avoiding the need for high-level systemic anti-coagulation and attendant bleeding risks, and higher rates of prosthetic valve thrombosis observed in the tricuspid position (1). Despite improvements in BHV technology including better leaflet design, hemodynamic profile and anti-calcification agents, BHV structural failure is inevitable in the long term primarily due to leaflet degeneration and calcification, and less commonly due to endocarditis, pannus or thrombus formation. The longevity of BHV at tricuspid location might be shorter than those in systemic circulation with a reoperation rate of 10–22% at 9 years and freedom from re-intervention of <60% at 15 years (2-4). Rizzoli *et al.* in a meta-analysis of 11 studies reported a bioprosthetic tricuspid valve deterioration rate of 1.7% patient/year (5).

Tricuspid valve replacement in acquired valve disease carries a reported surgical mortality of 7–22% and as high as 37% in patients undergoing valve replacement after prior tricuspid repair (4,6,7). Patients with tricuspid valve disease are often complex, with multiple co-morbidities and poly-valvular involvement, which contributes to the high observed mortality rate (8). Redo surgery in patients with prior tricuspid valve replacement carries a higher risk compared to the index procedure given advanced age in many patients, multiple co-morbidities including renal dysfunction, pulmonary disease and reduced functional class with an in-hospital mortality rate of greater than 13% (9). Additionally, the presence of adhesions from prior surgery as well risk of damage to vital structures like bypass grafts makes redo surgery technically challenging.

The increased use of BHV has coincided with the development and expansion of transcatheter heart valve technology thus offering an opportunity to harness these for failing BHV. Valve-in-valve (VIV) therapy first demonstrated in a human by Wenaweser *et al.* using a CoreValve (Medtronic, Minneapolis, MN, USA) in a failing Mitroflow (Medtronic, Minneapolis, MN, USA) aortic bioprosthesis (10) has now been utilized in successfully other heart valve positions (11). The US Food and Drug Administration (FDA) approval for aortic VIV therapy first

came on March 30, 2015 for the use of CoreValve system for high-risk patients with failed surgical BHV (12). This was based on a prospective US registry of 143 patients with 30-day and 6-month survival rates without major stroke of 95.8% and 89.3%, respectively. Subsequently, the SAPIEN XT (Edwards Lifesciences, Irvine, CA, USA) valve also received US FDA approval for aortic VIV on October 15, 2015 based on high overall 1-year survival rates of 86.6% and low overall stroke rate of 3.7% (13). These were derived from independently adjudicated data from the Placement of Aortic Transcatheter Valves (PARTNER) II trials: PARTNER II VIV study (n=197 patients).

The multicenter Valve-in-Valve International Data (VIVID) registry by McElhinney *et al.* involving 156 patients from 53 centers represents the largest retrospective data collection of tricuspid VIV procedures to date. In this study, the Melody valve (Medtronic, Minneapolis, MN, USA) was used in 94 and SAPIEN valve in 58 patients. There was no difference in outcomes according to the valve type although Melody THV were more likely to be placed in younger patients, those with congenital native valve disease and in smaller surgical bioprosthesis. The cases were collected over a period of 7 years and the majority of centers where these were performed had experience of one to three cases, reflective of the rarity of this procedure. Indeed, prior literature in tricuspid VIV procedure has been limited to smaller reports and case series (11,14-17). A majority of the patients in the tricuspid VIVID registry were relatively young (median age of 40 years) with congenital disease responsible for the index tricuspid valve replacement in 56% of the patients. Endocarditis and rheumatic heart disease accounted for a majority of the remaining cases.

The procedure itself had a high technical success rate with successful results achieved in 150 of the 152 attempted tricuspid VIV implantations across multiple centers internationally, despite low average levels of experience. There were significant improvements in tricuspid valve inflow gradients and regurgitation grades as well as right atrial pressure hemodynamics. Furthermore, the short and mid-term follow-up results of the study were encouraging over a median follow-up duration of 13.3 months. Importantly, 30-day mortality was 3.3% and estimated survival from tricuspid re-intervention at 1-year was achieved in 83% of the patients. There was also significant symptomatic improvement in patients with only 14% of those with available data in NYHA class III or IV following tricuspid THV implant compared to 71% of the patients prior to VIV therapy. Important predictors of poor outcome included patients with more advanced heart failure (NYHA class IV symptoms) and those acutely ill requiring hospitalization prior to VIV, suggesting that this group requires further study to better identify in which patients this therapy may be beneficial or futile.

The use of transcatheter heart valves for VIV procedure has certain advantages over use in native valve disease like known true internal diameter of the prosthetic valve, easy visualization of landmarks and anchoring provided by the stent and the sewing ring (18). The tricuspid valve is a low flow valve with a large effective orifice area and generally requires large caliber valves. Forty-seven percent (n=74) of the patients in the study by McElhinney *et al.* had a labeled size of tricuspid valve bioprosthesis of >29 mm, thus allowing for a larger effective orifice area after VIV therapy. This avoids the pitfalls that may be associated with post-VIV patient-prosthesis mismatch, for example the impaired survival observed in the aortic VIVID registry noted for patients with smaller surgical (<21 mm) bioprosthesis (19). Moreover, the tricuspid VIV procedure can be performed using a transvenous approach further limiting large-bore vascular access challenges and complications. Sixty-nine percent of the patients in the study by McElhinney *et al.* received tricuspid VIV via femoral venous approach, 28% via internal jugular vein while only 3% (5/152) were performed using direct right atrial access.

Careful procedural planning is essential for VIV therapy. The selected VIV implant should have an external diameter that best matches the true internal diameter of failing surgical bioprosthesis to ensure secure anchoring of the THV (20). Valve sizing should also take into consideration the amount of leaflet thickening, calcification and pannus formation that may further reduce the prosthesis internal diameter. Careful fluoroscopic positioning of the THV is essential to avoid malposition and embolization of the THV, using the sewing ring as the most reliable anchor. In only 2 out of 152 attempted tricuspid VIV patients in the VIVID registry, the deployed valve embolized acutely to the right atrium or ventricle and was successfully retrieved in both cases, highlighting the simplicity and feasibility of the tricuspid VIV procedure.

The study by McElhinney *et al.* provides encouraging results regarding the safety and efficacy of tricuspid VIV therapy with results that were reproducible across multiple centers internationally in patients of all age groups and multiple valve sizes, despite varying levels of experience with the procedure. The data was however self-reported, with no pre-specified protocols for hemodynamic

 

monitoring/collection and no core laboratories or auditing of data. Longer follow-up of these patients will be required to provide insight into longevity of the VIV procedures and to compare outcomes according to THV type. Given the infrequency of tricuspid valve replacement, registry data, particularly those conducted prospectively with international adjudication, will be essential to better understand the role of VIV therapy. Based on the available evidence to date, tricuspid VIV therapy appears to be a safe, feasible and effective alternative to redo surgery that likely should be a first line treatment option for patients with symptomatic severe tricuspid BHV dysfunction who otherwise have a reasonable life expectancy and are expected to benefit from the procedure.

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