



Self-expandable transcatheter aortic valve for surgical prosthetic aortic valve dysfunction

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As the prevalence of surgical bioprosthetic aortic valve replacement (SVAR) increases (1), more patients will likely suffer from structural valvular deterioration (SVD). Repeat SAVR (R-SAVR) has been the standard of care and has several advantages, including the ability to replace a bioprosthetic valve with any other valve required, the ability to enlarge the annulus if needed and the ability to directly confirm coronary clearance. Likewise, valve-in-valve transcatheter aortic valve replacement (ViV-TAVR) has advantages, including the avoidance of repeat sternotomy, which has risks of mortality and complications, and shorter hospitalization. However, ViV-TAVR is associated with the risk of coronary obstruction and unknown valve durability. Taken together, there are short-term considerations such as safety, coronary obstruction, stroke, procedural success without para-valvular leak and freedom from coronary obstruction for ViV-TAVR. Long-term considerations include long-term survival, hemodynamics, durability and the facility of future valvular interventions. There is no direct randomized data which compares R-SAVR to ViV-TAVR. However, several meta-analyses have shed light on both short-term and longer-term issues.

Survival

Pompeu *et al.* recently published a meta-analysis of twelve studies including a combined 16,207 patients undergoing R-SAVR or ViV-TAVR (2). This and other studies (3) suggest that thirty-day mortality is lower with ViV-TAVR than R-SAVR. This mirrors the findings of transcatheter

versus surgical trials, where less invasive procedures have lower early mortality. Again, mirroring native valve studies, this early advantage is diminished over time, with one-year mortality being no different in the latest meta-analysis (2). Patients in these studies tend to be in their late-seventies, with up to 25% mortality at three years for ViV-TAVR patients. Future studies must examine long-term mortality, especially if they include, or intend to be used to guide treatment in younger patients with longer life expectancy.

ViV-TAVR appeared to be associated with a lower rate of complications compared to R-SAVR, including a lower rate of major bleeding and shorter hospitalization (2). Stroke rate appeared to be equivalent between both modalities (2), or occurred too infrequently to be compared (3). Coronary occlusion is a particularly feared complication of ViV-TAVR; the rates of coronary occlusion appeared to be similar between balloon and self-expandable TAVR.

Patient prosthesis mismatch

Patient prosthesis mismatch (PPM) appeared to be one of the major limitations of ViV-TAVR, especially when there is a small bioprosthesis (2). Up to 35% of ViV-TAVR patients suffered severe PPM (4). In a study of over 1,000 ViV-TAVRs, small prostheses were associated with late mortality at eight years (5). The rate of severe PPM appeared to be significantly increased after ViV-TAVR compared to R-SAVR (2), which has been associated with late mortality (6). PPM after ViV-TAVR is less of an issue with larger bioprostheses, and may be partially alleviated by

valve fracture or the use of prostheses designed for TAVR implantation with expandable sewing rings. Valve fracture involves inflation of a high-pressure balloon across the rigid annuloplasty ring until the “waist” in the balloon disappears, often heralded by an audible cracking noise. This results in significant improvement in valve gradients and allows implantation of a larger TAVR valve (7). Self-expanding valves sit in the supra-annular position and are therefore not constrained by the annulus. In general, we favor self-expandable supra-annular valves with valve fracture as needed for small bioprostheses.

Durability

Available data suggests that ViV-TAVR durability may be limited, with 10% of valves suffering SVD at three years (4,5). In particular, balloon-expandable valves appeared to be associated with higher incidence of post ViV-TAVR re-intervention (5). As experience grows, the nuances of which TAVR valve is most suitable to implant and in which specific bioprosthesis will mature. Data from ex-vivo experiments show that the optimal implantation height associated with the best hemodynamic profile varies for each valve and TAVR combination (8). Using a physiologic left heart simulator, this group demonstrated that self-expandable valves had optimal hemodynamics at the normal implantation depth, whereas balloon expandable valves had their best hemodynamic profile at a +6 supra-annular position, when tested in a Perimount prosthesis (8). Indeed, self-expandable valves had better ViV performance than balloon-expandable valves under these conditions. The impact of this on durability is a matter of active investigation.

Decision-making

Repeat valve interventions require careful decision-making, with input from surgeons and cardiologists together as a heart team. The center of this team must be the patient, whose individual anatomy, clinical status and values will inform a shared decision-making process. This approach is rightly associated with a class I recommendation in valvular heart disease management guidelines (9). The same set of factors which determine pre-procedural decisions also dominate our response to residual gradients and leaks, with a high bar for well-functioning patients with an extended life expectancy. Although the concept of a SAVR followed by a TAVR has gained traction, we must be careful to

caution patients about the unknown impact of this strategy on valve durability and survival, as data is still accumulating. Valve performance is another important concept for these patients, whose active lifestyles may be better served by a Ross operation, or in some limited cases, by mechanical valve implantation.

Conclusions

Most studies have shown largely equivalent outcomes between ViV-TAVR and R-SAVR, especially with respect to early mortality (2,5,10). On the one hand, this is an impressive result for ViV-TAVR since this cohort is typically higher risk than patients undergoing R-SAVR. On the other hand, these data are the result of optimized patient selection for either modality. It is clear that a randomized trial is needed and will occur in the near future. These trials must clarify several important questions. First, are short term outcomes equivalent between ViV-TAVR and R-SAVR, and how do these compare in the medium and long-term? Second, what is the long-term durability of ViV-TAVR? Third, which patient cohorts benefit from each therapy as a primary strategy, and with which TAVR valves and in which bioprostheses? Fourth, what are the serial hemodynamic performance profiles of these valves? Until randomized data is available, we should continue to select patients who stand to benefit from either therapy based on their individual characteristics and alongside their predicted risk profiles and life expectancy.

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Footnote

Conflicts of Interest: PF: Edwards Lifesciences: Investigator, speaker; Medtronic: Investigator, speaker. WYS: Edwards Lifesciences: investigator, advisory board, speaker; Medtronic: investigator, advisory board, speaker. The other authors have no conflicts of interest to declare.

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