

EDITORIAL COMMENT

# The “Big Five” Complications After Transcatheter Aortic Valve Replacement



## Do We Still Have to Be Afraid of Them?\*

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Since 2002, the treatment of severe aortic valve stenosis has been revolutionized by introducing transcatheter aortic valve replacement (TAVR) as a complementary technique to surgical aortic valve replacement (SAVR). During this time, TAVR has become the standard of care for patients with severe aortic stenosis at increased surgical risk (1). The year 2016 was a breakthrough for this technology, because this was the first time when overall in-hospital mortality after transvascular TAVR was numerically lower than after isolated SAVR in Germany. Despite the fact that the patient cohorts were completely different and SAVR patients were at a numerically lower surgical risk, as indicated by the German aortic valve score, similar in-hospital survival was only found in the low-risk group, whereas TAVR was superior in patients at intermediate, high, and very high risk (2).

Surgical risk scores cannot be translated to the typical TAVR patients and often seem to overestimate the procedural risk (3,4). Nonetheless, we have learned over the years that 5 periprocedural complications may occur that impact survival after TAVR more or less significantly: moderate/severe paravalvular leakage (PVL) (5,6); major vascular and bleeding complications (7,8); disabling stroke (9); acute kidney injury (AKI) (10); and conduction

abnormalities, such as high-degree atrioventricular block (11) with the necessity for permanent pacemaker implantation.

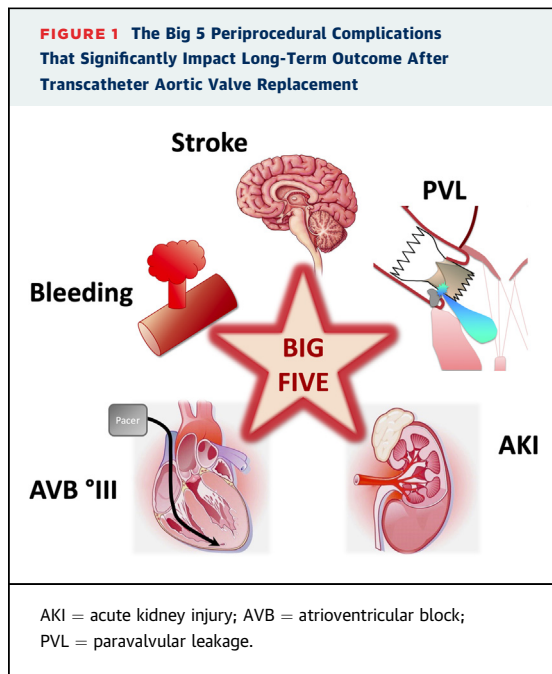
Not surprisingly, an “event-free” TAVR procedure, without the occurrence of any of the “Big 5” complications, has the lowest morbidity and mortality. Actually, the term “Big 5” was coined by big-game hunters in the southern parts of Africa and refers to the 5 most-feared animals that are dangerous to encounter on foot. In a figurative sense, this means that the “sighting” (occurrence) of the “Big 5 of TAVR complications” (Figure 1) has to be prevented by all means during the procedure.

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In this issue of *JACC: Cardiovascular Interventions*, Arnold et al. (12) assessed the impact of these 5 periprocedural complications on mortality and quality-of-life after TAVR among 3,763 patients at intermediate or high surgical risk from the PARTNER 2 studies. The authors used multivariable models that included complications and baseline clinical factors to examine the independent association of each complication with the outcomes. Although major stroke and stage-3 AKI were associated with a markedly increased 1-year mortality risk and poorer quality-of-life among survivors, other complications, such as moderate/severe PVL, major or life-threatening bleeding, and conduction disturbances with the need for pacemaker implantation, were each associated with a more modest increase in mortality and decrement of quality-of-life. After adjusting for baseline characteristics and patient factors (the so-called “surgical risk” of the patient), the strongest independent predictors of short-term mortality and impaired quality-of-life following the procedure continued to be major stroke, major bleeding events, and stage 3 AKI.

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In the early years of the TAVR procedure, occurrence of the “Big 5” during or shortly after completion of the procedure was not uncommon. Over the past decade, device modifications in combination with increased operator experience, better patient selection, and optimized pre-procedural planning by using routine computed tomography sizing have led to a substantial reduction in most of the procedure-related issues. The former “Achilles’ heel” for the procedure, PVL, has been addressed by the introduction of next-generation transcatheter heart valves that have external sealing skirts covering the peri-prosthetic space. These devices lead to a lower rate of PVL than their predecessors in real-world clinical practice and are at least in part repositionable to correct a suboptimal initial positioning (13,14). The occurrence of major vascular and bleeding complications can also be reduced by decreasing the profile of the sheaths and deployment catheters used for these so-called next-generation transcatheter heart valves (13,14). Addressing these 2 issues has helped to prevent hypotensive phases during the procedure and guarantees a more stable hemodynamic situation after the procedure, along with a lower rate of AKI after TAVR. However, 2 peri-procedural issues still remain: conduction abnormalities and embolic stroke.

A debate is still ongoing whether conduction disturbances, such as a new-onset left bundle branch block or an intermittent high-degree atrioventricular block, pose a potential threat for the patient and may explain sudden cardiac death during follow-up. The common consensus is that a trade-off exists between oversizing of the prosthesis with less PVL on one hand and the occurrence of conduction abnormalities on the other hand. In this large-scale analysis, Arnold et al. (12) showed that besides the effect on length of hospital stay and costs, this post-procedural issue had only a small effect on survival or quality-of-life after adjustment for other pre- and peri-procedural characteristics.

Undisputedly, post-procedural stroke remains the most-dreaded complication following TAVR. Experiencing a major (disabling) stroke is more feared than death itself by many of the elderly patients undergoing TAVR. However, as there are 2 sides to every coin, we must differentiate the peri-procedural (probably embolic) stroke risk during the first 48 h, which accounts for only one-half of the TAVR-related strokes, from the later risk that may be associated with occult atrial fibrillation or subclinical valve thrombosis. Fortunately, the TAVR-related stroke risk is lower than that found for SAVR patients, and major stroke occurs in <2% of TAVR procedures (13,14). Ongoing trials are working to address whether cerebral protection during the procedure, better intraprocedural pharmacological protection, or increased use of anticoagulants after TAVR (at the same time exposing patients to a higher risk of post-procedural bleeding) will be helpful to further mitigate stroke risk.

The group of authors are congratulated on this substantial analysis that brings together the pieces of the puzzle: occurrence of the “Big 5” complications seems to have a more substantial impact on outcome and quality-of-life than the individual comorbidity burden as indicated by surgical risk scores. Therefore, an “event-free” TAVR procedure has to be the ultimate goal for the well-being of patients.

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