TAVI in Patients Unsuitable for Surgery A Prognostic Benefit for All?*

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Since Alain Cribier performed the first human transcatheter aortic valve implantation (TAVI) in 2002 (1), the procedure has evolved into a reproducible and safe technique with >100,000 procedures performed worldwide. Early experience with new devices and techniques in Europe led to advanced procedural techniques, and large commercial and national registries provided real-world outcome data (2–4). Nevertheless, despite excellent results, various studies also demonstrated that although TAVI is a promising alternative treatment option for patients at high risk for surgical aortic valve replacement (SAVR), there is a group of patients who, despite successful prosthetic valve implantation, do not benefit from the procedure. It became clear that for the benefit of these patients, as well as to improve the economic strength and future viability of TAVI, treatment of this futile cohort should be avoided. Therefore, major attempts have been made to develop a clear understanding of the characteristics of this patient group; so far, there has not been much success.

The US PARTNER (Placement of Aortic Transcatheter Valve) trial is the first prospective randomized trial of TAVI. It is a noteworthy project not only because it has been jointly designed and executed by a heart team of interventional cardiologists and cardiac surgeons, but also because it provides robust data to answer specific questions on the treatment of aortic stenosis (AS) by using conventional and transcatheter techniques. A variety of information, mainly on the effectiveness and safety of TAVI compared with SAVR, has been published in recent years. The outcome of 2 key publications (5,6) resulted in US Food and Drug Administration approval for transfemoral and transapical TAVI by using the Edwards Sapien transcatheter heart valve (Edwards Lifesciences Corporation, Irvine, California) in patients with symptomatic AS who are at high risk or unsuitable for SAVR.

In this issue of the Journal, Makkar et al. (7) present a subanalysis of cohort B, a group of patients from PARTNER in whom the heart team of interventional cardiologists and cardiac surgeons estimated the perioperative mortality after SAVR to be ≥50% and who were therefore considered unsuitable for open heart surgery. This group is particularly interesting because it contains additional patient characteristics previously not used in TAVI studies, which allow a specific analysis of the reasons why certain patients were classified as inoperable for SAVR, the gold standard treatment at the time. In addition, because cohort B is supposed to be the highest risk group in PARTNER, it can potentially be used to identify patients in whom TAVI may be futile. The authors divided cohort B into those patients who were turned down for surgery due to surgical/technical reasons and those individuals who face high-risk SAVR due to their general condition and comorbidities. This grouping is useful; it has previously been demonstrated that long-term prognosis after TAVI is mainly affected by noncardiac comorbidities and the patient’s general condition at the time of TAVI (2–4).

This analysis also provides new information, as there has been a lack of understanding why patients with symptomatic AS are denied SAVR, a fact well documented by the European Heart Survey (8). For that reason, it is of interest for the cardiac community, and particularly TAVI heart teams, to understand the reasons why patients in cohort B were classified as unsuitable for surgery by the interventional cardiologist and surgeon. This is of even more importance, as current risk scores for SAVR have been developed by using only data from surgical cohorts. This resulted in a selection bias because patients with certain risk factors (e.g., severe liver disease, severe respiratory disease, severe frailty) may never have been accepted for surgery and therefore did not enter those risk model calculations. Even the PARTNER trial provides a good example of their weakness to classify high-risk patients for SAVR. Although cohort B patients have a Society of Thoracic Surgeons’ score similar to patients in cohort A (11.2% vs. 11.8%), cohort B was classified as inoperable (estimated mortality ≥50%) and cohort A only high-risk for SAVR (estimated mortality ≥15% but <50%). There are obviously risk factors identified by the heart team that are not captured by currently used risk score algorithms.

The new data presented also provide helpful information to identify patients in whom TAVI is potentially futile. Makkar et al. (7) demonstrate that in patients in whom
SAVR would be challenging due to surgical/technical reasons such as porcelain aorta, previous radiation of the chest, midline crossing right internal thoracic artery grafts, or challenging access to the heart, TAVI results in excellent outcomes. In contrast, patients who are inoperable because of their general condition—and in this respect, immobilization and frailty as well as severe respiratory and renal disease play an important role—face a grim future even with TAVI. They not only have a higher mortality 2 years after the procedure, but they also experience increased repeat hospitalizations and reduced quality of life. Nevertheless, these patients still do better compared with patients who receive standard medical treatment. Those patients with a Society of Thoracic Surgeons’ score of ≥15% faced the worst prognosis, with a 1-year mortality of 43%, which rose to 53% at 2 years, and could therefore potentially be seen as the patient group in whom TAVI is most likely to be futile.

The excellent outcomes in patients, who for surgical/technical reasons have been considered inoperable, make it most likely that patients with a combination of symptomatic AS and these surgical/technical characteristics, even if they are younger and otherwise carry a low risk for SAVR, would benefit from TAVI treatment. Therefore, for the future, TAVI could be considered more liberally in patients who face technical/surgical challenges for SAVR. In these patients, a transfemoral procedure (as in cohort B) should be considered, but with respect to the excellent European experience (9), appropriate patients should also be offered transapical TAVI.

In terms of the morbidity and mortality of cohort B, it is important to mention that in PARTNER, the first generation of the Edwards Sapien balloon-expandable, transcatheter heart valve was used. This use (and the fact that for cohort B only transfemoral access was available in this trial) may explain why the vascular complication rates are relatively high compared with the most recent outcomes using the smaller, second generation of the Edwards Sapien devices (Sapien XT, Edwards Lifesciences Corporation) presented at this year’s EuroPCR meeting (10). Development of treatment strategies for vascular complications and the future availability of even-smaller devices will further reduce the risk of vascular complications.

It is also worth mentioning that a significant number of patients in this trial (7), as well as in other previous TAVI investigations (2–4), experienced paravalvular leakage. Knowing the impact on survival even in the early years after TAVI (11), one would expect that patient outcome will further improve if the incidence of paravalvular leakage could be reduced with the next generation of transcatheter heart valves.

These developments would further support a more liberal indication of TAVI in younger and in general, lower-risk patients who suffer from surgical/technical risk factors for SAVR. How a reduction of device-related morbidity during implantation and long-term follow-up would improve the survival of frail patients with severe clinical comorbidities in the long term remains to be seen.

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