TAVR vs SAVR: Rising Expectations and Changing Indications for Surgery in Response to PARTNER II

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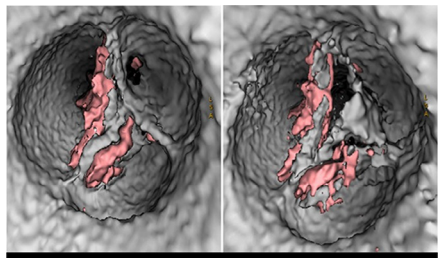
Despite the criticisms and concerns raised on the data published in the PARTNER II trial and related analyses, we are undeniably witnessing a revolution in the management of aortic valve disease, in which conventional full sternotomy surgical aortic valve replacement (SAVR), with all related complications and clinical burden, will soon become a nonviable option. Several of the findings described in the PARTNER II trial, although considerable as points of incongruence and study biases in comparison with SAVR, could be taken as lessons to found a new course in SAVR and redesign the respective roles of surgery and interventional procedures in aortic disease. In particular, the results of these trials can actually be considered as a stimulus to invest more effort to improve the current surgical practice that should embrace alternative solutions and least invasive approaches to provide a competitive advantage over percutaneous procedures. An analysis of these points in light of the more recent findings on transcatheter valve durability, thrombosis, and postprocedural complications is provided. Considerations on the parallel progress of SAVR and on the need for a behavioral change in the surgical community are discussed.



Annular and leaflet calcification with ventricular extension. To "implant" or "replace"?

Central Message

SAVR vs TAVR: Time is short for surgeons to truly embrace alternative solutions and least invasive approaches to SAVR as a realistic alternative to TAVR expansion.

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INTRODUCTION

The results of the most recent clinical trials and international registries pertaining to transcatheter aortic valve replacement (TAVR) recommend extension of TAVR into lower risk patient groups.[1] These studies support the safety and effectiveness of the technology in intermediate-low-risk patients and by implication anticipate similar clinical advantages in lower risk groups.

The outcomes presented in these studies appear to dispel a lot of the doubts and discouraging considerations on the applicability of TAVR to lower risk patients regarding the risk of severely impairing complications, unclear survival advantage, and cost inefficiency, which have recently been proposed.[2] However, the claimed non-inferiority of TAVR and the results of these studies have been challenged in several aspects.

TAVR VS SAVR

As sharply pointed out by Shofer in a comment on the results of a propensity matched analysis comparing the SAPIEN 3 device and surgical aortic valve replacement (SAVR), a patient selection bias can be observed analyzing the TAVR and surgical populations with an imbalance in the inclusion criteria that greatly disfavors the surgical group.[3] Additionally, the interesting and potentially important findings of the study are severely undermined by the lack of definition of actual treatment in the surgical group, resulting in extreme heterogeneity in this arm of the study. There was a statistically significant higher presence of moderate-to-severe mitral disease as well as a lower left ventricular function in the surgical

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group, which clearly might affect the outcomes of these patients.[3] As per the study protocol, the trial accepted as inclusion criterion redo cases. This clearly entails a significant increase in the perioperative risks in the surgical group only, as requiring notoriously more dangerous chest re-entry procedures. Similarly, there was a significantly higher presence of patients with concomitant coronary disease, which has not been addressed in the PARTNER II manuscripts for the TAVR group, but presumably would have undergone concomitant coronary artery bypass graft procedure during the actual trial in the surgical group, therefore resulting in a combined and higher risk operation. These are hardly comparable treatments whatever preintervention matching criteria are applied. Conversely, analyzing the exclusion criteria, aortic annuli <18 mm or >27 mm, which can easily be served surgically but not percutaneously, have been ruled out, as well as pure aortic incompetence, once again easily addressed by SAVR.

Beside the scientific biases and cited criticisms, we are undeniably witnessing a revolution in the management of aortic valve disease in which conventional full sternotomy SAVR, with all related complications and burden on length of stay, perioperative blood loss, and chest discomfort, will soon become a nonviable option.[4] Entrenching behind unconstructive critiques and dogmatically believing in the traditional full sternotomy approach are a blind attitude in the face of the overwhelming enthusiasm for TAVR from cardiologists and patients. Conversely, several of the findings described, despite the studies' selection biases, could be taken as lessons in finding a new course for SAVR and in redesigning the respective roles of surgery and interventional procedures in aortic disease.

First, an interesting finding of PARTNER II regards the alleged hemodynamic superiority of TAVR over SAVR in respect to gradient and effective orifice area. The authors attributed the superiority of TAVR in this context to valve-sizing differences and the possibility of transcatheter valves to expand to the anatomical annulus size, which is unlikely with a fixed-size surgical sewing ring. This point is largely undermined by the lack of definitions in the surgical group. Indeed, a subanalysis including the actual baseline annular diameter (size range between 18 and 25 mm) and the type and size of bioprostheses implanted in the surgical group is missing and should be taken into consideration to ensure comparability of the 2 groups. In view of the large spectrum of profiles and hemodynamic characteristics of bioprostheses currently on the market and the use of latest generation TAVR devices in this study, a head-to-head comparison between similar generation prostheses would have been of extreme interest to clarify the point if an "implantation" without "replacement" of the native valve (ie, surgical decalcification) is the best strategy. However, if confirmed, these results might trigger an important behavioral change in the surgical attitude toward aortic valve replacement (AVR), pushing surgeons to implant larger prostheses or to move toward superior-performing bioprosthetic technology, such as sutureless or stentless valves, to offer patients forward-flow hemodynamics comparable with TAVR in the virtual absence of paravalvular regurgitation, one of the complications of TAVR often requiring redo procedures.[5]

Although it might be argued that sutureless valves are also affected by paravalvular leakages and that new-generation TAVR devices are significantly less hobbled by this drawback, the hemodynamic concerns initially reported by Del Trigo et al regarding the rapid onset of valve degeneration within just 2 years (minimum follow-up of 6 months) after implantation[6] presaged the recent alarming news given by Dr Dvir and colleagues as a late-breaking trial presentation at the EuroPCR meeting. These authors showed only a 40% freedom from transcatheter heart valve deterioration by year 8 after implantation and a survival of 0.52% (2 patients out of 387) at 10 years. Despite newer generation devices might show improved performance and the mortality rate might have been related to the advanced age of the patients involved, the short life span of these prostheses clearly shed some shadows on the prospect of the extension of TAVR on younger low-risk subjects, remarking the idea that durability is the Achilles heel of this procedure at the moment.

To this extent, analyzing the most recent report on TAVR by the Society of Thoracic Surgeons and the American College of Cardiology, a particularly striking feature is the apparent discordance between the 30-day mortality and 1-year mortality rates (4.6% vs 21.6% in 2015), indicating a rapid worsening of the clinical conditions of these patients.[7] Although the modalities of death are not reported, one might question if this subset of patients enjoyed good health post procedure in their last few months of life, or experienced a worsening of their New York Heart Association class or quality of life as they struggled to reach the 30-day reporting watershed? This group alone accounted for 17% of the total TAVR dataset, a not insignificant proportion of patients. Understanding this phenomenon is of very real importance if TAVR is to make the transition from an end-of-life procedure to the preferred mode of aortic valve intervention for all age or risk groups.

Another important finding arising from the recent literature is equipoise in the occurrence of stroke between the TAVR and the surgical groups, with the former showing even better outcomes than the latter. Interestingly, as per study protocol, TAVR patients were administered with dual antiplatelet regimen, which is normally not used after SAVR, and this was maintained for a minimum of 1 month.[1] One presumes that