

The Courage to Take the Journey to a New World: The Challenges in Developing a Valve Team

El valor de viajar hacia un nuevo mundo: los desafíos de desarrollar un equipo valvular

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Few areas of medicine evolve as quickly as cardiovascular medicine and surgery. The rapid development and proliferation of sophisticated diagnostic and therapeutic tools have resulted in substantial improvements in both quantity and quality of life, worldwide. Among the countless developments aimed at reducing the burden of cardiovascular disease, few have had such a rapid implementation, acceptance, and profound impact on patients' lives as transcatheter valve therapies – (TAVR: Transcatheter aortic valve replacement). Within a few short years, the proliferation of TAVR has evolved into the preferred and, in many areas of the world, the most commonly used therapy for the treatment of symptomatic aortic stenosis. The publication of the now landmark PARTNER trials has established the foundation for the use of TAVR in patients otherwise deemed to be at either prohibitive, extreme, high, or even intermediate risk for traditional valve surgery (SAVR: Surgical aortic valve replacement). However, as with any new therapy – especially one that is not only invasive but aimed at a complex, sick, and high-risk patient population, there are learning curves, incremental improvements in technology, an evolving understanding of the nuances of patient selection, and probably most importantly a recognition of the true benefits and clinical realities that often must be separated from the hype. The fact that TAVR therapies are also expensive and perceived by many –healthcare providers as well as patients– as being a much more desirable option compared to the invasiveness of traditional open-heart surgery, also contributes to the myth that TAVR, in any form and implementation, is the “silver bullet” that will cure symptomatic aortic valve disease, and always, inherently, “better” than SAVR. Nevertheless, without a doubt, many patients –especially those who would have been turned down for SAVR or who might have experienced less than ideal outcomes as a function of their poor functional status, co-morbidities,

and risks- have been able to enjoy a substantial and objective improvement in their symptoms and life expectancy.

The accompanying manuscript in this Journal by Raleigh and colleagues – “Transapical and Transfemoral Aortic Valve Implantation. Impact and General Considerations of both Approaches” (1) highlights many of the issues that Heart Teams worldwide face as they develop their structural valve disease programs. While some might be critical of their outcomes in terms of survival, length of stay, incidence of stroke, and procedural associated complications – particularly as they compare their early experiences with a transfemoral versus a transapical approach – it is important to realize the impressive successes of this developing Team and recognize that such criticisms might be short-sighted. Taken in the context of the evolving understanding of this “disruptive” therapy and how it can be best applied, the Team at this Argentinian community hospital clearly needs recognition not only for their accomplishments but also for the courage to present their outcomes – specifically contributing to the growing body of literature that helps separate the reality from the myth of TAVR and TAVR programs and outcomes.

Much like Christopher Columbus sailing to the New World to find a better route, Valve Teams and Programs have embarked on a journey to determine the optimal therapies for patients with aortic valve disease. Such a Journey is not without risks along the way –together with the courage to be the first to adopt a new route- in terms of working with new and evolving technologies (some of which might make the journey better, faster, and safer, and some of which might not), optimizing patient selection, deciding on the best technical approach, and solidifying the structure and function of a multi-disciplinary Team. Succeeding in such a Journey –specifically identifying the destination and then reaching it (or at least getting slowly

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closer to the final goal) is not easy in medicine. The target is always moving, the technologies are evolving (and not always for the best in the long run), the patients are getting sicker, and the expectations for better outcomes grow all in the context of the desire to help patients –and especially those who otherwise would have no other options.

An important finding of Raleigh's paper is the recognition that not all TAVR's are created equal – much like the Journey to the New World had several paths. Specifically addressed in their paper is the realization that a transfemoral approach is associated with a significantly different risk/benefit profile than the transapical approach. In fact, their findings are consistent with the growing literature that has suggested that the risks of a transapical approach are much higher than those of a transfemoral approach, and that many programs have all but abandoned this approach in favor of other alternative access approaches such as axillary artery, trans-caval, direct access, or trans-carotid –or even acknowledging that maybe traditional SAVR is potentially the best option. Recognizing that each patient needs to be individualized in terms not just of the specific therapy – i.e. TAVR vs SAVR – but just as importantly, the technical nuances of how each therapy can and should be performed in the context of the patient, available technology, co-morbidities, and Team experiences (both successes and failures) is extremely important. These points are the essence of a truly high-level functional Heart Team. It is not just a matter of individuals deciding “which” therapy to offer, but how that therapy is going to be implemented that is crucial for programmatic success. Success that is often a function of learning and understanding over time what works and what does not.

Probably most importantly in reporting their outcomes for the different approaches is demonstrating that TAVR is not a perfect procedure. As illustrated in their patient profiles, demographics, STS and EuroSCORES, this group faced the difficult challenge of trying to help a very sick patient population. Evolving guidelines for the management of aortic stenosis in the “TAVR era” –especially in the context of publicly reporting of clinical outcomes- address the specific issue of outcomes. These guidelines have introduced the well-known concept that outcomes that are viewed as being too good to be true, often are. The point is not that programs are intentionally “lying” but rather there is the concern that if programs report morbidity and/or mortality rates that are considered too low, then there is the risk that potentially high-risk patients might not be offered the benefit of a “life-saving” therapy because of concerns that a less than ideal outcome might ruin a program's reputation or

publicly reported metrics. Furthermore, outcomes that might be perceived as being “too good” might also imply that low-risk patients are getting TAVR –a therapy that has only been approved and validated in selected intermediate and high-risk patients– and that such patients might, for various reasons, not be offered or considered for standard of care SAVR. This is not to imply that Teams and programs should not continuously review and even subject their outcomes to peer-review with the goal of striving for perfection, but rather recognize the necessary balance that must occur with such therapies. The balance is not only selecting those patients who a program feels will benefit most from TAVR but, as importantly, to have the courage to offer very high-risk or prohibitive risk patients the chance to benefit from TAVR even though there is a recognition that some of these patients might experience a complication and even not survive. Clearly, there must be a middle ground and it is up to each program to determine what that middle ground is and how they approach the inherently conflicting goals of perfect outcomes to try and help as many patients as possible.

Fundamentally, for TAVR to succeed as a viable therapy it is critical to understand which patients will benefit and which patients will not. It is not just a matter of TAVR vs SAVR –but, more importantly, understanding the risks, benefits, advantages and disadvantages of the different technologies as they evolve, as well as the different technical aspects of the procedure itself. Just as importantly is the recognition that some patients, despite being at intermediate or higher risk, might actually be better served with surgery. However, above all, for true long-term program success there must be the courage to recognize the reality from the myth and to be willing to present outcomes and experiences in a manner so that all can benefit from this ever evolving learning curve. As such, Raleigh and the entire Team must be congratulated and praised for their accomplishments by demonstrating the many challenges that Valve Teams worldwide are facing as they strive for success in the setting of what will always be, by definition, less than perfect outcomes..

CONFLICTS OF INTEREST

None declared.

(See authors' conflicts of interest forms on the website/Supplementary material).

REFERENCES

1. Valle Raleigh J, Agatiello C, Romeo F, Oberti P, Falconi M, Battellini R, et al. Transapical and Transfemoral Aortic Valve Implantation. Impact and General Considerations of both Approaches. *Rev Argent Cardiol* 2018;86:171-6.