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Editorial

The Journey of TAVR

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Eighteen years ago, Alain Cribier, MD, and colleagues performed the first transcatheter aortic valve replacement in the year 2002 at Charles Nicolle University Hospital, University of Rouen, France [1]. In the intervening years, Transcatheter Aortic Valve Replacement (TAVR) has completely revolutionize the landscape of Cardiovascular medicine and brought a new spotlight in a treatment previously reign by Surgeons.

TAVR was born at the beginning with a mission to answer an unmet need. Before the development of transcatheter prosthesis, options were limited for many patients with severe aortic stenosis. Surgical Aortic Valve Replacement (AVR) was considered the gold standard, but a large subset of patients were considered too high risk for surgery. The alternative less invasive treatment, balloon valvuloplasty worked in some patients, but the results generally were not durable.

The initial experience was dominated by multiple challenges, including significant paravalvular regurgitation (PVL), aortic root injury, malapposition, device embolization, conduction disturbances, and access-related complications. Bail-out measures such as conversion to conventional surgery or implantation of a second valve were frequently required.

Among numerous factors that contributed to improved outcomes, there are a few milestones of TAVR therapy that should be highlighted. These are, the use of computed tomography-based annular sizing that helped decrease Paravalvular leak; the promotion of transfemoral access by low-profile delivery systems, with new data discouraging alternative access in the light of worst outcomes, and the use of pre-shaped stiff wires that substantially reduced the risk of left ventricle perforation among others.

TAVR has now been fully integrated into the therapeutic armamentarium for managing Aortic Stenosis in patients who are at every level of risk for conventional surgery, with >300,000 procedures having been performed in > 80 countries. One of the things that made this massive expansion possible, is another hallmark of TAVR and is that it has been relentlessly researched. We have multiple Randomize Clinical Trials assessing all surgical risk Aortic Valve Replacement candidates with comparable results to surgery and even excelling conventional Surgery in the low risk population [1,2]. We also have registries with greater than 90,000 consecutive U.S. commercial patients with the Transcatheter Valve Therapy Registry [3].

The TAVR field is constantly evolving and is far from having plateau, with many out of the box ideas that might see the light in the coming years. As an example, the Leaflex™ Catheter System (Pi-Cardia, Rehovot, Israel) [4] is a percutaneous device allowing delivery of controlled mechanical impacts to the aortic valve leaflets. These impacts are intended to fracture calcium deposits embedded within the leaflets focally, thereby restoring leaflet flexibility and mobility, achieving an increase in valve opening area. This means potentially treating the valve without the need of replacing it with a prothesis or improving the results in heavily calcified TAVRs. Similar to these technologies there is the electro-hydraulic lithotripsy in a balloon, that might as well break calcium bridges on the valve and improve its mobility hence, its stenosis. Another game changer in the future could be the development of polymer-based valve leaflets materials with reduce thrombogenicity and improved long term durability, something that will come as a focus later on these editorial.

The overwhelming sense is that TAVR may soon replace surgical AVR as the treatment of choice for patients with symptomatic severe aortic stenosis or even conquering, in a near future, oligo- or asymptomatic patients, and other current off-label conditions including pure aortic regurgitation and bicuspid valves.

We have managed to improve and decrease most of the complications encountered with the first-generation devices. For example, PVL that was identified as an important prognostic determinant after TAVR in itself, is no longer a critical issue.

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With the use of modern devices, rates of more-than-mild PVL have decreased to below 5%, and some new-generation devices like the *Lotus™ device, Boston Scientific* have reached the performance level of surgical bioprostheses. The frequency of vascular access-related complications has been reduced by means of CT imaging, use of closure devices and decreasing profiles of delivery systems. It was even possible to reduce the rate of major stroke to approximately 3%, which is in the range of that observed for surgical valve replacement or even introduce concomitant cerebral embolic protection devices, where we still need more data on hard outcomes before adding it to every TAVR procedure.

However, the most crucial aspects of TAVR`s outcome, now that we entered in a new population with lower risk and younger patients, is long-term performance and durability. It is important to point out, that these will not only involve the different principles of prosthesis deployment (balloon expandable vs. self/mechanically expanding), but may also be affected by the material and position of the leaflets, pre- and post-dilatation, over- or undersizing, positioning, and the degree of device landing zone calcification. Therefore, we must acknowledge there is a need to accumulate more data on the outcome of TAVR in patients who are younger and have lower risk.

As a result of the previous statement, we can admit it is time for a paradigm shift in how we approach decisions about valve treatment in patients with single aortic stenosis and no aortic root disease or infectious complication of the valve. Estimated surgical risk no longer dictates the choice between surgery and TAVR; instead, the primary considerations are life expectancy and valve durability, both of which are related to the patient's age [5,6]. We know surgical bioprosthesis have lower durability in younger patients and that is the reason current guidelines recommend the use of a mechanical valve in adults younger than 50 years of age, unless long-term anticoagulation is contraindicated or declined by the patient. On the other hand, in most patients older than 70 years of age, the use of a bioprosthetic valve is appropriate; in this group of patients, TAVR is likely to become the preferred option over surgery. Even so, caution is needed, because robust data regarding the durability of the transcatheter bioprosthetic valve beyond 5 years are not yet available. Last but not least, the female gender is also something to consider when indicating a valve in a low risk population as women have longer life expectancy than men and were undermine in clinical trials where 65 to 70% were males with a mean age of approximately 74 years. Nevertheless, results are comparable in both sexes [7].

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