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Editorial

Transcatheter mitral valve replacement: there is no one-size-fits-all solution

Recambio mitral transcatéter: la talla única no existe

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Mitral regurgitation (MR) is the most prevalent form of valve disease in developed countries[1] and its prevalence increases with age affecting ∼10% of people > 75 years.[2] MR is a very heterogenous disease that damages not only the mitral valve apparatus but also its surrounding structures. In primary MR, mitral valve surgery is the therapy of choice in symptomatic patients or asymptomatic patients with left ventricular dysfunction. Surgical repair is generally preferred over replacement if technically feasible.[3,4] In secondary MR, the surgical approach is still under discussion[5] and it is spared for patients with indications for other surgical cardiac procedures (ie, coronary artery bypass graft).[3,4]

Several studies suggest that a large proportion of MR patients are never treated due their high surgical risk[6] and that such a conservative approach results in high re-hospitalization (∼90%) and mortality rates (50%) within 5 years following the initial diagnosis.[7] This population has become a clear unmet need and a target for the development of less invasive therapeutic approaches. Several transcatheter mitral valve repair (TMVR) technologies inspired by well-established surgical techniques have been developed and have already been approved for clinical use. The most commonly used, the MitraClip device (Abbott Vascular, United States) has reached more than 100 000 implants and demonstrated safety and efficacy in several MR subsets.[8-10] Although clinical adoption continues to increase, edge-to-edge repair does not fully resolve MR and has some anatomical limitations too (ie, calcified leaflets) that prevent a wider use. Transcatheter mitral valve replacement (TMVR) offers a more universal concept for the management of mitral valve disease with a more predictable abolition of MR severity in a procedure that could be less invasive compared to current surgical techniques.[11]

Important lessons have been learned from ongoing TMVR clinical studies. First, the patients screened for these trials, considered of high or prohibitive surgical risk display more complex anatomical substrates than originally thought that lead to very high rejection rates. Imaging sizing algorithms used to confirm patient eligibility are patient- and valve-design specific, but have not been standardized in all valve programs. The availability of different device sizes has also limited the wider adoption of this technology.

One of the biggest earliest technical concerns was the ability to achieve valve stability in the absence of sutures. To tackle this issue, several anchoring mechanisms have been developed resulting in high periprocedural success and low early dislodgment rates.[12] The potential for left ventricular outflow tract obstruction is still the biggest Achilles' heel of this technology. Several factors including[13] aorto-mitral-annular angle, degree of septal hypertrophy, the left ventricle size, and device protrusion into the cavity may contribute to left ventricular outflow tract obstruction. The short and mid-term valve leaflet performance has not been an issue to this day. Mean transvalvular gradients and paravalvular leaks have been similar to those obtained after surgical mitral valve replacement.

The rate of periprocedural complications varies based on the valve program we are dealing with. The mean 30-day all-cause mortality reported is ∼13.6%.[14] Approximately 4.6% of periprocedural death rate mainly due to unsuccessful TMVR deployment that ends up leading to conversion to open heart surgery. Also, issues with the management of access site are responsible for some deaths mainly associated with myocardial tears. The remaining deaths occur following the TMVR procedure. Transapical access has been associated with a higher rate of periprocedural complications (particularly bleeding) and mortality in TMVR procedures.[14] The negative effects of thoracotomy in frail populations and the higher degree of myocardial injury associated with the transapical approach may be particularly deleterious in patients with reduced left ventricular ejection fraction.[14] Finally, acute hemodymamic changes due to valve implantation in patients with severely depressed left ventricular ejection fraction (< 30%) is a very well-known phenomenon in the surgical field that worsens the prognosis of these patients.

Long-term data in a large cohort of patients is still lacking. In the largest series reported so far, no cases of structural valve degeneration, new occurrence of paravalvular leaks or valve dislocation requiring reintervention have been reported.[14] However, a more systematic clinical and echocardiography follow-up of patients undergoing TMVR is crucial to provide consistent data on valve durability and structural valve failure in the future. Data on the risk of long-term thrombosis is scarce too. No episodes of clinically relevant valve thrombosis have been reported with other TMVR devices. Three-month anticoagulation therapy is currently recommended although no long-term data on the real thrombogenic profile of these devices has been reported yet.[3,4,15]

TMVR is evolving to become a new alternative for treating patients with severe MR of very high or prohibitive surgical risk. The complexity of the mitral valve apparatus and the heterogeneity of

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the disease have limited the wide adoption of these technologies. Several devices are under clinical evaluation and the early experience gained with some of them proves the feasibility of their implantation. Larger studies including a larger number of patients are still needed to test the clinical performance of these technologies. Emerging transseptal TMVR systems have the potential to overcome some of the limitations of current transapical devices. However, technical and anatomical challenges will remain the same. The TMVR field is rapidly evolving, what is somehow clear now is that it will benefit a specific population subset and that there is no such thing as a one-size-fits-all solution.

CONFLICTS OF INTEREST

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