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Off-Label Indications for Transcatheter Aortic Valve Replacement: A Worrying Trend

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Abstract

Some influencing articles are showing similar survival rates at one-year follow-up between transcatheter and surgical aortic valve replacement. This makes that some patients are being treated with transcatheter procedures by off-label indications. However, these same articles are showing in the transcatheter group higher rates of complications with lifelong repercussions. Moreover, recently some works suggest shorter durability of transcatheter prostheses compared with surgical valves.

Keywords: Transcatheter aortic valve replacement; Severe aortic stenosis

Surgical aortic valve replacement (SAVR) is the gold-standard treatment for severe aortic stenosis. However, a new procedure based on transcatheter techniques, transcatheter aortic valve replacement (TAVR) has shown similar survival rates in high surgical risk patients at two years follow-up [1].

Recently, Tamburino et al. [2] showed, using rigorous statistical methods, similar survival rates between surgical aortic valve replacement (SAVR) and transcatheter aortic valve replacement (TAVR) at one year follow up.

However, in this Italian study which represents a real world setting, they observed that the existence of complications with repercussion usually for life like paravalvular aortic regurgitation or permanent pacemaker was five times higher after TAVR [2].

Cardiac surgeons and cardiologists are observing that off-label indications for TAVR are rapidly increasing. So, TAVR is increasingly offered not only to inoperable or high-risk patients, as recommended by clinical practice guidelines, but also to those with few or relative contraindications to surgery. If so, in view of the excellent short- and long-term results of SAVR in low-risk patients and the lack of evidence on very long-term durability of TAVR, this should be a worrying trend [2].

A worrying trend because it has been shown that even mild paravalvular aortic regurgitation is associated with impaired survival rate at two years follow up so long-term follow up probably favors surgical approach [1].

A worrying trend because permanent pacemakers and even new conduction defects (with no need of pacemaker) have shown to result in an impaired recovery of left ventricular ejection fraction (LVEF) after the procedure [3]. We know that better post-procedural recovery of LVEF after aortic valve replacementis associated with better improvement in functional status and better late survival. So we can conclude again that surgical alternative is probably better for the long-term [3].

And a worrying trend because there is a lack of long-term durability of TAVR. We have learned from surgical experience that there are great differences in long-term durability between types of bioprostheses. Materials, manufacturing process and, finally, the design are the three most important factors on which depends durability. So, the actuarial freedom from structural valve degeneration of some stented bioprostheses is 80% at 15 years [4]. With no suture ring, valves for TAVR are morphologically quite similar to some stentless surgical valves that have shown less durability than usual stented bioprostheses [5]. Recently, a fatigue simulation study has confirmed that, under identical loading conditions and with identical leaflet tissue properties, the transcatheter valve leaflets sustained higher stresses, strains, and fatigue damage compared to the surgical prosthesis leaflets. The simulation results suggest that the durability of transcathter prostheses may be significantly reduced compared to surgical valves to about 7.8 years [6].

Compared with the surgical approach, transcatheter techniques have shown similar survival rates in high-risk surgical patients. Nobody can doubt that transcatheter procedures are an extraordinary tool to treat patients with severe aortic stenosis. From my point of view, these new techniques have the potential to become the gold-standard treatment for these patients in the future. However, survival rate and functional status at 5, 10 and 15 years need to be assessed before indications may be extended. Moreover, the awaited results of the randomised PARTNER II trial with the Edwards XT valve and of the SURTAVI trial with the Medtronic Core Valve will bring an evidence-based comparison of TAVR versus SAVR in lower risk patients [7].

Therefore, until further data are available, guidelines recommendations should be followed so TAVR should be only used for inoperable or high-risk surgical patients [8].

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