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EDITORIAL

Transcatheter aortic valve replacement in low-risk young population: A double edge sword?

Sukhdeep Bhogal, Akash Batta

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Abstract

Since the advent of transcatheter aortic valve replacement (TAVR) in 2002, it has now become the default interventional strategy for symptomatic patients presenting with severe aortic stenosis, particularly in intermediate to high-surgical risk patients. In 2019, the United States Food and Drug Administration approved TAVR in low-risk patients based on two randomized trials. However, these breakthrough trials excluded patients with certain unfavorable anatomies and odd profiles. While currently there is no randomized study of TAVR in young patients, it may be preferred by the young population given the benefits of early discharge, shorter hospital stay, and expedite recovery. Nonetheless, it is important to ruminate various factors including lifetime expectancy, risk of pacemaker implantation, and the need for future valve or coronary interventions in young cohorts before considering TAVR in these patients. Furthermore, the data on long-term durability (> 10 years) of TAVR is still unknown given most of the procedures were initially performed in the high or prohibitive surgical risk population. Thus, this editorial aims to highlight the importance of considering an individualized approach in young patients with consideration of various factors including lifetime expectancy while choosing TAVR against surgical aortic valve replacement.

Key Words: Transcatheter aortic valve replacement; Surgical aortic valve replacement; Pacemaker implantation; Coronary re-access; Structural deterioration

Core Tip: In 2019, the United States Food and Drug Administration approved transcatheter aortic valve replacement (TAVR) in low-risk patients based on the two large randomized trials. However, patients with certain unfavorable anatomies and clinical profiles were excluded from these trials. Despite the lack of clear evidence in young patients (< 65 years), it may be preferred by this population given the benefits of early discharge, shorter hospital stay, and expedite recovery. Nonetheless, it is important to ruminate various factors including lifetime expectancy, risk of pacemaker implantation, and the need for future valve or coronary interventions in young cohorts before considering TAVR in these patients.

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INTRODUCTION

Transcatheter aortic valve replacement (TAVR) has now revolutionized the treatment of symptomatic severe AS and has now become the standard of care across all risk categories. The first transcatheter heart valve (THV) designed by Cribier *et al*[1] was a stainless-steel stent (23 mm in diameter and 17 mm in height) containing a trileaflet valve made of bovine pericardium, compatible with a 24-French introducer sheath and was implanted using antegrade transeptal approach. Since then, there has been a huge refinement in the design of both THVs and delivery systems, transforming challenging interventions into a standardized, streamlined procedure. It has emerged as a less invasive alternative therapy to conventional surgical aortic valve replacement (SAVR) with either superior or comparable outcomes. As it has been two decades since the first implant in April 2002, the use of TAVR expanded rapidly with randomized data showing the safety and efficacy of TAVR initially in inoperable-risk, followed by high, intermediate, and most recently low-risk patients. However, the landmark trials investigating TAVR excluded patients with unfavorable anatomy such as bicuspid aortic valve, associated aortopathy, short or large annulus diameters, concomitant severe valvular disease, and young populations < 65 years of age. Certain concerns emerge when TAVR is contemplated for younger population with expected survival > 10 years.

CONSIDERATIONS AND RISK IN YOUNGER PATIENTS UNDERGOING TAVR

The key trepidations during or following TAVR include the risk of conduction abnormalities, coronary artery obstruction, and future coronary re-access. Studies have shown longer hospital stays[2] and a higher risk of all-cause death with pacemaker implantation at 1-year post-TAVR[3]. Though factors such as implantation depth are operator-dependent, the presence of conduction abnormalities such as baseline right bundle branch block is a known predictor of increased risk of pacemaker implantation[4]. TAVR has demonstrated higher rates of pacemaker implantation compared to SAVR, even in low-risk patients[5]. The deleterious effects of right ventricular pacing on cardiac hemodynamics are established and include increased bi-ventricular volumes and dysfunction in the long run along with predisposition to the development of cardiac arrhythmia, particularly atrial fibrillation. Additionally, younger patients with a pacemaker would require multiple generator changes given longer life expectancy which further adds to the morbidity. While the cusp overlap technique showed promise in reducing the rates of pacemaker implantation with self-expanding valves, it remains a valid concern, particularly in the young population[6].

Furthermore, coronary artery obstruction is rare, but a life-threatening complication associated with a very high periprocedural and late mortality[7]. Also, with the extension of TAVR in low-risk young patients, interventional cardiologists are likely to face challenges in re-accessing coronaries in these patients, due to progressive coronary artery disease given the similar baseline risk factors. Thus, the preprocedural planning in young patients before considering TAVR or SAVR should include an evaluation of all these factors plus an assessment of congenital valve abnormalities (bicuspid or unicuspid), unfavorable anatomies such as short or large annulus diameter, presence of peripheral artery disease and concomitant severe valvular disease or significant coronary artery disease. Similarly, the coronary height and choice of THV become important when considering TAVR in this group of patients. Yet, when these abnormalities or conditions are present, they should be considered comprehensively based on individual risk profiles before decision-making.

For patients with symptomatic or asymptomatic severe AS, the current valvular guidelines endorse (class I recommendation) the use of TAVR for patients > 80 years or younger patients with life expectancy < 10 years over SAVR [8]. In contrast, for patients < 65 years of age or have life expectancy > 20 years, SAVR is recommended over TAVR[8]. Lastly, for patients between age of 65 and 80 years of age, the guidelines endorse the use of either TAVR or SAVR based on the heart team approach[8]. The fundamental limitation of THV is that they are prone to degeneration, which constraint their long-term durability. This is important, particularly in young patients, who have long life expectancy and are, therefore, more likely to need repeat valve interventions. The initial studies of TAVR were conducted in inoperable and high-risk octogenarians, which limited the identification of late valve degeneration as these subjects died from other causes before the commencement of valve dysfunction[9]. The latest evidence shows promising durability of TAVR

valves beyond 5 years and freedom from structural valve deterioration between 6 and 9 years of duration[10-12]. However, the data on the durability of these valves beyond 10 years is currently unavailable. Moreover, a specific risk prediction tool for THV is not available. For younger patients < 50 years of age, SAVR with a mechanical valve prosthesis appears to be a reasonable option provided no contraindication to anticoagulation with patients' willing to consider long-term vitamin K antagonist therapy while avoiding the risk of reoperation[8]. Additionally, for young patients with atrial fibrillation, or unprovoked venous thromboembolism, or hypercoagulable states demanding long-term anticoagulation, a mechanical valve appears a reasonable consideration. Evidence on the latest-generation mechanical bi-leaflet prosthesis valves is encouraging in terms of the need for relatively lower levels of international normalized ratio maintained between 1.5 to 2.0, which is associated with reduced risk of major and minor bleeding events[13]. Otherwise, if anticoagulation is undesirable or contraindicated, consideration of Ross procedure that involves replacement of the aortic valve with the patient's own pulmonic valve, and the pulmonic valve with a homograft is currently recommended in young patients[14].

The debate among 50-69 years of age remains ongoing, given multiple observational studies showing similar survival rates with either mechanical or bioprosthetic THV[15-17]. Some studies in patients aged < 65 years, demonstrated increased rates of valve deterioration, reoperation, and mortality with surgical bioprosthetic valves, however, with lower rates of stroke and hemorrhage over mechanical valves[18-20]. Therefore, it is imperative to consider the tradeoffs including bleeding, reoperation, and life expectancy in these patients. Lastly, there is no precise risk tool to predict the deterioration rate of THV, which is inevitable in current bioprosthetic valves.

CONCLUSION

In conclusion, while TAVR in young patients seems a reasonable alternative given the desirable benefits of early discharge and expedited recovery, it does not appear to be a straightforward answer for all patients when considering various individual risk profiles and weighing future options. With this uncertainty, debate continues in the field of structural cardiology as to which option (SAVR *vs* TAVR) and or valve (mechanical *vs* bioprosthetic) is the best optimal strategy for low-risk young patients. Therefore, although there is no good answer yet while awaiting further research and new valve refinements, shared decision-making is recommended regarding the choice of the prosthetic valve by considering individualized patient factors including age, values, and preferences including anticoagulation and lifetime strategies such as predictability of reoperation and future valves[8].

FOOTNOTES

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