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Perspective

Is it the time to reconsider the choice of valves for cardiac surgery: mechanical or bioprosthetic?

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Valvular heart disease is a pathologic process involving one or more of the four valves (aortic, pulmonary, mitral and tricuspid) of the heart typified by stenosis or regurgitation and leading to patient symptoms. The most common causes are tissue degeneration, rheumatic fever and congenital heart diseases. Aortic valve replacement (AVR) using either mechanical or bioprosthetic (tissue) valves *via* open-heart surgical AVR (SAVR) is the most widely accepted standard treatment. The choice of which valve type to be used depends on patient age, disease nature and other comorbidities. A study conducted by Khan and colleagues compared outcomes of mechanical and tissue cardiac valves and found that tissue and mechanical valve recipients have similar survival over 20 years of follow-up[1]. However, differences were found: there is an increased risk of hemorrhage in patients receiving mechanical valve replacements and an increased risk of late reoperation in all patients receiving tissue valve replacements. Randomized trials show more midterm morbidity with mechanical valves when compared to bioprosthetic valves (***Table 1***). The major argument against the use of bioprosthetic valves in young and middle aged patients is the inevitability of reintervention for structural valve failure. On the other hand, mechanical valves are heralded as a life-long solution. Current literature suggests that most patients receiving tissue valves do not have a reoperation. This is supported by life-table analysis of large data sets which suggest that the average life-expectancy of a 60 year-old after AVR is about 12 years[2]. Because most bioprosthetic valves are free from structural deterioration for 12–15 years, many patients will die before the valves degenerate. The risk of tissue valve reoperation increases progressively with time, especially in younger patients. The American College of Cardiology/American Heart Association (ACC/AHA) recommends that a bioprosthetic valve be indicated for in patients of any age for whom anticoagulant therapy is contraindicated, cannot be managed appropriately, or is not desired and a mechanical prosthesis is reasonable for AVR or mitral valve replacement (MVR) in patients less than 60 years of age who do not have a contraindication to anticoagulation[3]. Up to now, clinical practice has largely followed this recommendation. During the last two decades, there has been an increasing trend for surgeons to implant a bioprosthetic as opposed to a mechanical valve. This trend has greatly accelerated in the last few years with the approval and broad adoption of transcatheter aortic valves. As a result, an increasing incidence of patients requiring reoperation for failing bioprosthetic valves is to be expected.

While the current guidelines are clear that patient choice and willingness to take anticoagulation are critical driving factors in valve choice, the fact is that presently older patients preferentially receive bioprosthetic valves while younger patients receive mechanical valves. We believe that there is considerable evidence

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Table 1 **Major differences between bioprosthetic and mechanical valves**

Long-term survival rate	Equivalent
Mid-term morbidity rate	Worse with mechanical valves
Reoperation rates	Low with biological valves and are not insignificant with mechanical valves
Redo AVR morbidity rate	Reoperative AVR has similar mortality to primary valve replacement
Complication rate	Complications of mechanical prosthesis are more devastating than those of biological valves
Quality of life	Mechanical valves can have substantial negative impact on daily quality of life

for consideration of bioprosthetic valves as a preferential choice for valve replacement in patients below 60 years of age[4].

Reoperative cardiac valve replacement is a more complex procedure involving repeat sternotomy and removal of the previous prosthesis that potentially presents higher mortality and morbidity rates. In one study, results in 3,380 patients who underwent elective, isolated reoperative AVR were compared with those in 54,183 patients who underwent isolated primary AVR during the same period. The authors concluded that reoperative SAVR was associated with higher operative mortality (4.6% *vs.* 2.2%, $P<0.0001$) and higher composite operative mortality and major morbidity (21.6% *vs.* 11.8%, $P<0.0001$) including stroke, vascular complications, and postoperative aortic insufficiency[5]. Another consideration is that complications specific to mechanical valves are more devastating than complications specific to bioprosthetic valves. Structural valve failure in tissue valves is rarely an acute emergency. This is in contrast to complications of mechanical valves for which structural failure is an acute emergency, and the permanent neurological sequelae of embolic or hemorrhagic stroke which can result in catastrophic changes in a young person's life. The negative impact of mechanical valves on day to day quality of life, especially for young active individuals is significant but certainly understated.

Technological progress has resulted in the availability of transcatheter aortic valve replacement/implantation (TAVR/TAVI) using implantable bioprosthetic valves for patients with severe aortic valve disease. TAVR has been demonstrated to be a valuable alternative since its first clinical use in 2002 for aortic stenosis (AS) in a selected high-risk surgical patient population and, when successful, results in marked hemodynamic and clinical improvement[5–7]. The indications for TAVR have been expanded from the initial high surgical risk patients to currently include intermediate surgical risk patients[8–10] and clinical trials are underway to determine the feasibility, safety and effectiveness of TAVR in low surgical risk patients with AS as well as in patients with isolated aortic regurgitation[11–13]. TAVR with the Edwards SAPIEN 3 valve in intermediate-risk patients with severe AS is associated with low mortality, strokes, and regurgitation at 1 year[10]. In another study, at the end of a 2-year follow-up, the rate of all-cause mortality or disabling stroke was 19.3% in the TAVR group and 21.1% in the SAVR group ($P=0.25$), demonstrating the non-inferiority of TAVR[9]. In a transfemoral approach cohort, TAVR resulted in a lower rate of mortality or disabling stroke than surgery, whereas in the transthoracic access cohort, outcomes were similar in the two groups. It must also be noted that TAVR resulted in larger aortic valve areas than did surgery and also resulted in lower rates of acute kidney injury and severe bleeding whereas surgery resulted in fewer major vascular complications and less paravalvular aortic regurgitation (PVR). This study demonstrated that both mild and moderate/severe PVR predicted higher 1-year mortality[14]. Permanent pacemaker (PPM) requirement is another complication of TAVR. PPM was required in 8.8% of patients without prior PPM who underwent TAVR with a balloon-expandable valve in the PARTNER trial and registry. For self-expandable valves the incidence was found to be even higher (22.6%) [15]. It is not clear at this time exactly what effect this will have on morbidity and mortality when compared with TAVR and SAVR patients who did not require post procedure PPM. At the current time, the most widely used transcatheter prosthetic valves are Edwards SAPIEN (XT)/SAPIEN3 and Medtronic CoreValve or CoreValve Evolut R valves, with other valves in development.

As the population ages, cardiac surgeons and cardiologists are faced with an increasing number of elderly patients who have structural valve degeneration of previously placed surgical bioprosthetic heart valves. Transcatheter valve-in-valve (ViV) implantation is emerging as a treatment option for patients with deteriorated bioprostheses. It has been demonstrated that a number of patients undergoing ViV procedures exibit high postprocedural gradients. This incidence is higher in patients that had smaller (21 mm) bioprosthetic valves implanted at their original surgery[16].

Coronary obstruction and thrombosis could potentially limit its use. ViV has been used in aortic, mitral, tricuspid and pulmonary valve positions. There are different types of transcatheter valves used for ViV. In one study, there were 6 types of transcatheter heart valves implanted in degenerated bioprostheses through different anatomic access sites[17]. ViV is reserved to replace a failed bioprosthetic heart valve (***Fig. 1***). However, transcatheter mitral valve replacement was successfully performed after surgically explanting a mechanical mitral valve prosthesis[18].

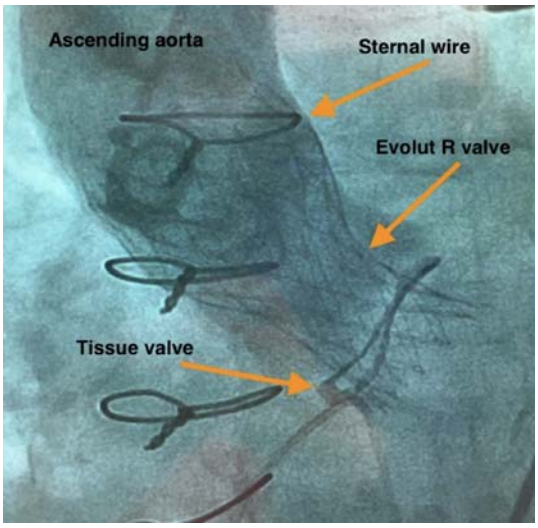

Fig. 1 **Representative imaging of valve in valve (ViV) placement in a degenerated bioprosthetic aortic valve using Medtronic CoreValve Evolut R.**

As with every transformative technology, it remains imperative to evaluate the short- and long-term outcomes of a minimally invasive technique when compared with the standard open surgical technique. The heart team must make these decisions in conjunction with the patient not only for the primary valve but also for the ViV procedure. For elderly, high-risk patients with structural valve degeneration, transcatheter options almost certainly provide reasonably comparable outcomes.

In summary, it has been suggested that there is no difference in long-term (20 years) outcomes between aortic bioprosthetic and mechanical valves[19–21]. Mid-term morbidity is worse with mechanical valves. While reoperation rates are low with bioloprosthetic valves, the requirement for reoperation in patients with mechanical valves is not insignificant. Reoperative cardiac valve surgery has much higher mortality and morbidity compared to initial SAVR, especially in elderly patients that have multiple comorbidities. In elderly and other high-risk patients requiring reoperation for bioprosthetic structural valve failure, transcatheter ViV implantation has been proved to be a viable treatment option and appears to have shorter ICU stay, shorter hospital stay and lower surgical risk in short-term studies[16,22]. Given similar 20 year outcomes for SAVR with mechanical and bioprosthetic valves, and the availability of ViV replacement for failed bioprosthetic valves, it may be reasonable to consider bioprosthetic cardiac valve as the first choice for patients who require heart valve replacement even in younger patient populations. However, long-term outcome studies on ViV replacements are necessary.

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References

[1] Khan SS, Trento A, DeRobertis M, et al. Twenty-year comparison of tissue and mechanical valve replacement[J]. *J Thorac Cardiovasc Surg*, 2001, 122(2): 257–269.

[2] van Geldorp MW, Eric Jamieson WR, Kappetein AP, et al. Patient outcome after aortic valve replacement with a mechanical or biological prosthesis: weighing lifetime anticoagulant-related event risk against reoperation risk[J]. *J Thorac Cardiovasc Surg*, 2009, 137(4): 881–886., e1–e5.

[3] Nishimura RA, Otto CM, Bonow RO, et al. 2014 AHA/ACC guideline for the management of patients with valvular heart disease: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines [J]. *J Thorac Cardiovasc Surg*, 2014, 148(1): e1–e132.

[4] Anyanwu A. Surgical aortic valve replacement: biologic valves are better even in the young patient. http://www.acc.org/latest-in-cardiology/articles/2015/03/03/09/28/surgical-aortic-valve-replacement-biologic-valves-are-better-even-in-the-young-patient accessed on May 16, 2017

[5] Kaneko T, Vassileva CM, Englum B, et al. Contemporary outcomes of repeat aortic valve replacement: a benchmark for transcatheter valve-in-valve procedures[J]. *Ann Thorac Surg*, 2015, 100(4): 1298–1304, discussion 1304.

[6] Durand E, Borz B, Godin M, et al. Transfemoral aortic valve replacement with the Edwards SAPIEN and Edwards SAPIEN XT prosthesis using exclusively local anesthesia and fluoroscopic guidance: feasibility and 30-day outcomes[J]. *JACC Cardiovasc Interv*, 2012, 5(5): 461–467.

[7] Bartel T, Bonaros N, Müller L, et al. Intracardiac echocardiography: a new guiding tool for transcatheter aortic valve replacement[J]. *J Am Soc Echocardiogr*, 2011, 24(9): 966–975.

[8] Holmes DR Jr, Mack MJ, Kaul S, et al. 2012 ACCF/AATS/SCAI/STS expert consensus document on transcatheter aortic valve replacement: developed in collabration with the American Heart Association, American Society of Echocardiogra-

phy, European Association for Cardio-Thoracic Surgery, Heart Failure Society of America, Mended Hearts, Society of Cardiovascular Anesthesiologists, Society of Cardiovascular Computed Tomography, and Society for Cardiovascular Magnetic Resonance[J]. *J Thorac Cardiovasc Surg*, 2012, 144(3): e29–e84.

[9] Leon MB, Smith CR, Mack MJ, et al. Transcatheter or surgical aortic-valve replacement in intermediate-risk patients[J]. *N Engl J Med*, 2016, 374(17): 1609–1620.

[10] Thourani VH, Kodali S, Makkar RR, et al. Transcatheter aortic valve replacement versus surgical valve replacement in intermediate-risk patients: a propensity score analysis[J]. *Lancet*, 2016, 387(10034): 2218–2225.

[11] Rosato S, Santini F, Barbanti M, et al. Transcatheter aortic valve implantation compared with surgical aortic valve replacement in low-risk patients[J]. *Circ Cardiovasc Interv*, 2016, 9(5): e003326.

[12] Saji M, Lim DS. Transcatheter aortic valve replacement in lower surgical risk patients: review of major trials and future perspectives[J]. *Curr Cardiol Rep*, 2016, 18(10): 103.

[13] Franzone A, Piccolo R, Siontis GC, et al. Transcatheter aortic valve replacement for the treatment of pure native aortic valve regurgitation: a systematic review[J]. *JACC Cardiovasc Interv*, 2016, 9(22): 2308–2317.

[14] Kodali S, Pibarot P, Douglas PS, et al. Paravalvular regurgitation after transcatheter aortic valve replacement with the Edwards sapien valve in the PARTNER trial: characterizing patients and impact on outcomes[J]. *Eur Heart J*, 2015, 36(7): 449–456.

[15] Wijeysundera HC, Qiu F, Koh M, et al. Comparison of outcomes of balloon-expandable versus self-expandable transcatheter heart valves for severe aortic stenosis[J]. *Am J Cardiol*, 2017, pii: S0002–9149(16)32016–1.

[16] Dvir D, Webb JG, Bleiziffer S, et al. , and the Valve-in-Valve International Data Registry Investigators. Transcatheter aortic valve implantation in failed bioprosthetic surgical valves[J]. *JAMA*, 2014, 312(2): 162–170.

[17] Conradi L, Silaschi M, Seiffert M, et al. Transcatheter valve-in-valve therapy using 6 different devices in 4 anatomic positions: Clinical outcomes and technical considerations[J]. *J Thorac Cardiovasc Surg*, 2015, 150(6): 1557–1565., 1567.e1–e3., discussion 1565–1567.

[18] Murphy M, Austin C, Bapat V, et al. Use of an Edwards Sapien S3 valve to replace a dysfunctional mechanical mitral valve in an 11-year old boy: another small step for surgical and interventional collaboration[J]. *Eur J Cardiothorac Surg*, 2016, 50(3): 577–579.

[19] McClure RS, McGurk S, Cevasco M, et al. Late outcomes comparison of nonelderly patients with stented bioprosthetic and mechanical valves in the aortic position: a propensity-matched analysis[J]. *J Thorac Cardiovasc Surg*, 2014, 148(5): 1931–1939.

[20] Wang Y, Chen S, Shi J, et al. Mid- to long-term outcome comparison of the Medtronic Hancock II and bi-leaflet mechanical aortic valve replacement in patients younger than 60 years of age: a propensity-matched analysis[J]. *Interact Cardiovasc Thorac Surg*, 2016, 22(3): 280–286.

[21] Zhao DF, Seco M, Wu JJ, et al. Mechanical versus bioprosthetic aortic valve replacement in middle-aged adults: a systematic review and meta-analysis[J]. *Ann Thorac Surg*, 2016, 102(1): 315–327.

[22] Tourmousoglou C, Raob V, Lalosc S, et al. What is the best approach in a patient with a failed aortic bioprosthetic valve: transcatheter aortic valve replacement or redo aortic valve replacement?[J]. *Interact Cardiovasc Thorac Surg*, 2015, 20(6): 837–843.