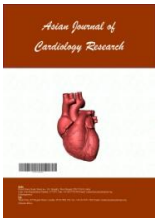

Asian Journal of Cardiology Research

3(2): 42-50, 2020; Article no.AJCR.65221

Aortic Valve Replacement: Transcutaneous Versus Surgical the Race is on

Navjyot Kaur[1], Shyam Thignam[2] and Manojkumar Rohit[1*]

[1]Department of Cardiology, PGIMER-Chandigarh, India.
[2]Department of Cardiothoracic Vascular Surgery, PGIMER-Chandigarh, India.

Authors' contributions

This work was carried out in collaboration among all authors. Author NK designed the study, did literature review, wrote the protocol, and produced first draft of manuscript. Author ST was involved in planning the study, in conceptualization and methodology. Author MR (ORCiD id: 0000-0001-5866-2742) was involved in planning the study, in conceptualization & methodology along with supervision, final review and editing. All authors read and approved the final manuscript.

Article Information

Editor(s):
(1) Dr. Sam Said, Hospital Group Twente, Netherlands.
Reviewers:
(1) Marco Gemelli, University of Padua, Italy.
(2) Godfrey Mutashambara Rwegerera, University of Botswana, Botswana.
(3) Nihad Abdul-Lateef Ali Kadhim, Al Qassim Green University, Iraq.
(4) Nassir Azimi, Midwestern University, USA.
Complete Peer review History: http://www.sdiarticle4.com/review-history/65221

Mini-review Article

Received 03 December 2020
Accepted 09 February 2021
Published 01 March 2021

ABSTRACT

Aortic valve replacement (AVR) is the only treatment proven to reduce mortality in severe symptomatic aortic stenosis (AS). Though the conventional surgical AVR (SAVR) with prosthetic valve remains the gold standard, the procedure has significant morbidity and mortality especially in elderly patients with multiple co-morbidities and hence could not be offered to almost one third of patients with severe AS. This has led to numerous technological advances in the field of AVR since last decade. The evolution of transcutaneous aortic valve replacement (TAVR) has made AVR possible in patients with prohibitive surgical risk and significantly improved the mortality. Sutureless aortic valve replacement (SuAVR) using minimally invasive access has shown some advantage over TAVR especially in intermediate surgical group patients. The encouraging results of aortic valve repair using glutaraldehyde treated autologous pericardium (Ozaki technique) have given a hope for freedom from prosthetic valve disease, especially in relatively young individuals. In this review we discuss the latest advancement in field of AVR, which now looks like a race between interventional cardiologist and cardiothoracic surgeon; much like the coronary artery disease management.

**Corresponding author: Email: cardiopgimerchd@gmail.com*

Keywords: Advancement; AVR; Neo-cusp formation; Ozaki technique; review; severe aortic stenosis; sutureless AVR (SuAVR); TAVR.

1. INTRODUCTION

Calcific degenerative aortic stenosis (AS) is the most frequent cause of severe symptomatic aortic valve disease worldwide, [1] followed by bicuspid aortic valve and rheumatic heart disease. Five-year survival rate of untreated symptomatic severe AS is lower than most of the metastatic malignancies [2] and aortic valve replacement (AVR) remains the only therapy proven to reduce the morbidity and mortality of this valvular heart disease [3]. Conventional surgical aortic valve replacement (SAVR) with prosthetic valve is the gold standard,but is associated with an operative mortality of 1-3% which increases exponentially with advanced age and co-morbidities [4]. Calcific degenerative AS is the disease of elderly and share the same risk factors as coronary artery disease (CAD), and more often the patients referred for AVR are elderly with multiple co-morbidities including CAD. Due to high procedural risk, nearly one third patients are denied surgery [5]. This led to the impetus on development of less invasive techniques like transcutaneous aortic valve replacement (TAVR) and surgical innovations like sutureless AVR (SuAVR) using minimally invasive approach. The AVR with prosthetic valve leaves the patients with another disease namely prosthetic valve disease marked by risk of valve thrombosis, anticoagulation related bleeding and structural valve deterioration (SVD). The neo-cuspid valve formation using glutaraldehyde treated autologous pericardium like Ozaki technique has given a hope to prosthetic material free durable and equally effective aortic valve repair.

TAVR: Where are we??

2. MAJOR TRIALS

Since its introduction in 2002, TAVR has become the standard of care for AS in patients with prohibitive procedural risk, while it can be a reasonable option in patients with high and intermediate surgical risk patients, especially in elderly population [6]. PARTNER 1B established the superiority of TAVR over conservative treatment in patients unfit for surgery [7]. Subsequently PARTNER 1A and US Pivotal Core Valve trial paved the way for TAVR in high surgical risk but operable patients [8,9]. While PARTNER II and SURTAVI established the non-inferiority of TAVR in intermediate risk group ,[10,11] PARTNER III and EVOLUT R trial showed comparable primary outcome of TAVR in low surgical risk group as well [12,13]. TAVR has been consistently associated with higher risk of vascular complications, paravalvular regurgitation (PVR), permanent pacemaker implantation (PPI); while significant bleeding, acute kidney injury and new onset atrial fibrillation are associated more commonly with SAVR [14,15]. Though the effective orifice area (EOA) and trans-valvular gradient obtained are lower with TAVR; there has been no difference between the symptom control in two modalities [15,16].

3. EVOLUTION OF TAVR

Since its inception two decades ago, TAVR has evolved enormously; improvement in stent designs, lower profile delivery systems, expandable sheaths and requirement of smaller vascular access have made the procedure safer. Standardized computed tomography (CT) imaging of access vessels, aorta, annular size and native valve morphology along with coronary-ostial height has allowed better pre-procedural planning. Not only does standardized imaging helps in deciding the vascular access and prosthetic valve size, but it also helps in predicting the possible complications. More and more TAVR are now being done under conscious sedation (CS) using transthoracic echocardiographic (TEE) guidance which further reduces the procedural time, recovery time and the total cost of procedure [16]. Recent review had revealed that this “minimalistic” approach under CS is not only associated with shorter hospital delays but also reduce the short term mortality [17]. However it reduces the use of TEE, which is associated with increased fluoroscopy time, contrast use and risk of PVR [16,18]. The use of TAVR for surgical valve failure has been shown to be safe, effective and has been associated with improved quality of life in high surgical risk patients [19]. In fact the new surgical bioprosthetic valves are being developed to be compatible with re-intervention with TAVR in case the valve fails in long run; given the higher mortality and morbidity with re-do surgery. As the operators gain experience and with advancement in hardware, the progressive decrease in mortality and complication rates have been observed in TAVR registries across

the world, [20-23] with number of TAVI exceeded the number of SAVR in Germany by the year 2014 [24].

4. ONGOING TRIALS AND EXPANDED INDICATIONS

Asymptomatic severe AS and moderate AS with impaired left ventricular (LV) function have been traditionally managed medically, given the higher morbidity of SAVR. Nonetheless these conditions are not totally benign. Even truly asymptomatic AS with negative stress test has an ongoing progression of disease, varying amounts of ventricular wall fibrosis and has considerable risk of sudden cardiac death [25,26]. Similarly patients with moderate AS and impaired LV function perform badly with recurrent heart failure hospitalizations. The current research aims to find out whether TAVR in such soft indications would improve the overall survival [27,28]. Though various registries are reporting constantly decreasing mortality and complication rate with TAVR, there are certain important concerns and answer is not a straightforward one. The long-term durability of TAVR valves remains un-established, while coronary intervene tions and redo procedures post TAVR are technically more challenging. Hence any expanded indication and wide spread use of TAVR in younger population requires high quality evidence. While ongoing trials, Early TAVR and EvoLVeD trial are evaluating TAVR in asymptomatic severe AS, TAVR UNLOAD trial is assessing the use of valve replacement in patients with moderate AS and LV dysfunction [27].

5. CHALLENGES

5.1 Structural Valve Deterioration (SVD) and Dysfunction

Valve design and age at time of implantation heavily influence the rate of SVD. Younger age at time of implantation and certain valve designs have been associated with rapid prosthetic valve dysfunction [29-31]. Though the five-year outcome from PARTNER 1 has been encouraging, [32] the evidence from surgical bioprosthetic valves reveals that SVD is rare before 10 years and hence we require longer follow up data. In pre-TAVR era, the most compelling indication for surgical bioprosthetic valve was need for avoidance of oral anticoagulation (OAC). Post TAVR, unless indicated for co-existing condition, long term OACs are not prescribed. However recent concern about subclinical valve thrombosis (SVT) on CT scan has put this recommendation to re-evaluation. Almost 10-15% TAVI valves were found to have SVT on CT scan; which were associated with increased transvalvular gradients and transient ischemic attacks [33]. Since OACs are associated with lower risk of SVT and are known to reverse the phenomenon, the results of ongoing trials like GALILEO, ATLANTIS and POPULAR TAVI for optimal antithrombotic therapy after TAVR are eagerly awaited.

5.2 Stroke

One of the most devastating complication of TAVR is stroke which is associated with 5-10% increase in short term mortality [34,35]. Though the incidence of clinical stroke has decreased in various TAVR registries and is comparable to SAVR, [15,27] diffusion weighted cerebral Magnetic Resonance Imaging (MRI) has shown new ischemic lesions in almost 75% of the patients [36]. Various embolic protection devices have shown a reduction in total infarct volume, none have decreased the risk of clinical stroke [37,38]. Furthermore the role of anticoagulation in addition to antiplatelets therapy to prevent stroke after TAVR is being actively studied.

5.3 Permanent Pacemaker Implantation (PPI)

TAVR commonly interferes with the conduction system and rate of PPI after TAVR is anywhere between 5-35% [39,40]. While few studies including TVT registry have documented higher mortality with PPM implantation, the same was not reciprocated in others [27,41]. Nonetheless, prolonged right ventricular pacing has detrimental effect on LV function and should best be avoided in younger individuals. While male sex, old age, preexisting conduction disturbance, smaller left ventricular outflow tract, calcified aortic and mitral annulus are important patient related risk factors; deeper valve deployment, balloon post dilatation and valve over sizing are procedure related risk factors associated with PPI after TAVR [42]. Besides valve design is also an important factor, with self-expanding valve being more associated with significant conductional blocks as compared to balloon expandable valves [43]. Further research into valve design and delivery is required to decrease the rate of PPI after TAVR.

5.4 Vascular Access Complications

With smaller profile delivery systems, expandable sheaths and sheathless approach,

transfemoral (TF) access is now possible in 90% of TAVR; with reported complication rate of 2% [27]. TF access, so far, has the best patient related outcomes; the other safer vascular access is subclavian artery [44]. Transcaval approach to aorta is feasible in 99% of patients, however it is associated with high rate retroperitoneal and life-threatening bleeds [45].

5.5 Infective Endocarditis (IE)

The incidence of IE ranges from 0.5-3% and is associated with high morbidity and mortality. Unlike SAVR, where most common organism implicated is staphylococcus, the infection post TAVR is more frequently caused by enterococcus species. The strict adherence to sterility protocols, use of antibiotic prophylaxis against gastrointestinal and genitourinary organisms and avoidance of mandatory urethral catheterization may reduce the incidence of IE [27]. Furthermore the use of bioabsorbable polymer scaffold and hybrid catheterization laboratory to reduce the IE are being actively investigated [46].

5.6 Bicuspid Aortic Valve (BAV)

BAV is one of the commonest causes of calcified AS. Since the BAV is associated with eccentric annulus, is highly calcified and has additional aortopathy, TAVR in the setting of bicuspid valve may be associated with higher complications like PVR and aortic wall injury, and has been traditionally excluded from most of the original TAVR trials. However, with newer valves like Sapien 3 associated with fewer complications and Bicuspid TAVR registry showing comparable outcomes in both Type 0 (without raphe) and Type 1 (with raphe) BAV, [47,48] further research into making the prosthesis and delivery mechanism safer in this challenging anatomy is required.

SAVR: Where are we??

Conventional SAVR remains the gold standard against which any other any other new treatment intervention for AS is compared to. However there have been multiple unmet needs and challenges which required addressal and included lesser invasive approach in elderly frail population with multiple co-morbidities, porcelain aorta, small aortic annulus and SAVR post chest radiation. Besides there has been a search for prosthetic material free aortic valve repair to decrease the morbidity associated with prosthetic valve thrombosis, OAC related bleeding and SVD. This has led to technological advancements like SuAVR using minimally invasive approach and the Ozaki technique.

SuAVR: This is a less invasive technique wherein the aortic valve is replaced surgically without using sutures or a maximum of four anchoring sutures [49]. The two SuAVR valves available in market are the self-expandable Perceval S (Sorin, Saluggia, Italy) and the balloon-expandableIntuity (Edwards Lifesciences) valve. They can be implanted both by the conventional median sternotomy or minimally invasive accesses such as ministernotomy and right anterior thoracotomy [50,51]. The minimally invasive accesses lead to reduced bleeding, blood transfusions, wound infection, atrial fibrillation, and ventilation times [49,50]. The SuAVR reduces the total ischemia, cardiopulmonary bypass (CPB) and aortic cross clamp time which have been consistently associated with higher morbidity and mortality, especially in high-risk patients with multiple co-morbidities. In fact SuAVR has been recommended to be first choice in high risk patients with multiple co-morbidities, who require concomitant procedures like dual valve replacement or coronary bypass graft as it reduces the total clamp time [52,53,54]. SuAVR is also the surgical procedure of choice in patients with small aortic annulus, aortopathy, porcelain aorta and in re-do surgeries [52,53,54]. The major concerns with SuAVR remain PVR and PPI, the incidence of which are reported to be 2.3% and 5.6 – 9.1% respectively [55,56,57]. The other reported adverse events after SuAVR include stroke, acute coronary syndromes, kidney injury and surgical site infections [58]. As far as the comparison between two types of SuAVR valves are concerned, the results have been comparable both in hemodynamic improvement and adverse events [59].

SuAVR versus TAVR: Where do we stand?

TAVR gives the most non-invasive way to manage the severe AS and with CS, the patient can be discharged the next day of procedure. With constant evolution of technology, the complications associated with TAVR like vascular access complications, PPI and PVR have decreased significantly over the years; however still remains a concern when compared with SAVR. SuAVR on the other hand allows direct visualization of aortic annulus, removal of calcium and deformed leaflets which reduce the

odds of complications like PVR, while allowing rapid deployment of valve. Though the use of minimally invasive access approach has made the SuAVR less invasive, there is mandatory requirement of general anaesthesia, CPB and aortic cross clamping which increase the risk of mortality and morbidity especially in high risk patients. Also, the risk of PVR and PPI still remains higher when compared to conventional SAVR. Though the meta-analyses comparing SuAVR and TAVR have revealed the reduction in perioperative mortality and PVR in SuAVR group, they have all been limited by extensive heterogenicity of original data [60,61]. Takagiet al. reported lower all-cause mortality in favour of SuAVR during direct comparison, however the results were non-significant when adjusted indirect-comparison was made [60]. Similarly Qureshi et al. could not demonstrate any difference in mortality, however the rate of PVR were lower with SuAVR [59].

Conventional SAVR versus Aortic valve neocuspidation using autologous pericardium (Ozaki Technique): Where are we?

Implantation of prosthetic valves is no cure; it gives the patient another disease. While SVD and repeat surgeries are the major shortcomings of bioprosthetic valves, the anticoagulation with its bleeding complications and valve thrombosis are the major concerns for mechanical prosthetic valves. The use of glutaraldehyde treated autologous pericardium to produce neo-cusps seems to overcome most of the shortcomings of prosthetic valves [62]. Being an autologous product, it is conceptually less likely to undergo SVD due to auto-immune reactions and treatment with glutaraldehyde makes the pericardium four times more resistant to degeneration than the native cusps [63]. No antithrombotics other than Aspirin for first 06 months post procedure are required [61]. It has been successfully used for AS, aortic regurgitation, native valve post infective endocarditis, prosthetic valve endocarditis and non-tricuspid anatomy. The results of immediate and midterm mortality and morbidity have favored the Ozaki over conventional SAVR [61,64] with added advantage of lower cost, better hemodynamic, lower peak & mean transvalvular gradients and lesser odds of re-do surgery. Midterm mean follow up of 54 months post Ozaki procedure has been encouraging with an infective endocarditis incidence of 0.3% per patient year which is much less than bioprosthetic valves (0.8%-1% per patient year) and only one patient out of 850 cases had SVD at midterm follow up; though long term results are awaited [63]. The procedure has a long learning curve, however the positive outcomes of Ozaki technique have been consistently reproduced by other centers as well [65,66]. The drawback of procedure is that it requires longer CPB and aortic cross clamp time [63] and may not be feasible if autologous pericardium is not available. Though midterm follow up of Ozaki procedure has not shown any significant SVD irrespective of age of implantation, longer follow up is eagerly awaited given the fact that most of bioprosthetic valves show significant deterioration after 10 years of age.

The Existing Guidelines and how do we choose??

The American and European guidelines recommend SAVR in low surgical risk patients, while TAVR remains the procedure of choice in prohibitive surgical risk group risk. Patients with high surgical risk may either be offered TAVR or SAVR, while SAVR is given class I recommendation over TAVR (class IIA) for intermediate surgical risk. The heart team and patient form the essence of decision taking and to choose one procedure over other requires a more personalized and tailored approach. The approach should be based on patient's co-morbidities, frailty, age, surgical risk, anatomy and above all the center's expertise. For instance, absence of a transfemoral access for TAVR in high surgical risk patient makes SAVR or SuAVR more desirable, while porcelain aorta or previous chest radiation will favor TAVR even in intermediate risk patient. In an experienced centre Ozaki can provide wonderful results in low and intermediate surgical risk patients, without any residual prosthetic valve disease.

6. CONCLUSION

AVR remains the only treatment of severe AS. Conventional SAVR has served as the gold standard for same, though it cannot be performed in large number of patients due to high morbidity and mortality. The last two decades have seen a tremendous technological advancement in field of AVR. TAVR produced a paradigm shift in management of patients with severe AS and has become the preferred procedure in high surgical risk patients. SuAVR using minimally invasive approach have reduced the CPB and cross clamp time in combined procedures with AVR like coronary bypass and dual valve replacement. It has special advantage in patients with fragile aortic wall and smaller

aortic annulus. New surgical techniques like Ozaki have given a new hope by all together replacing the prosthetic valves with neo-cusp formation using autologous pericardium. With advancement in technology and increased skill & experience, the complications associated with TAVR and SuAVR like PVR & PPI have declined and are likely to decrease further; but we need to keep an eye on long term structural integrity of these valves and certain new concerns like SVT with TAVR. Besides randomized trials comparing TAVR with SuAVR and Ozaki with conventional SAVR are required.

CONSENT

It is not applicable

ETHICAL APPROVAL

It is not applicable

COMPETING INTERESTS

Authors have declared that no competing interests exist.

REFERENCES

1. Osnabrugge RL, Mylotte D, Head SJ, Van Mieghem NM, Nkomo VT, LeReun CM, et al. Aortic stenosis in the elderly: disease prevalence and number of candidates for transcatheter aortic valve replacement: a meta-analysis and modeling study. J Am Coll Cardiol.2013;62:1002–1012.
2. Using constant hazard ratio. Data on file, Edwards Lifesciences LLC. Analysis courtesy of Murat Tuczu, MD, Cleveland Clinic; 2010.
3. Nishimura RA, Otto CM, Bonow RO, Carabello BA, Erwin JP, Guyton RA, et al. 2014 AHA/ACC guideline for the management of patients with valvular heart disease: executive summary: a report of the American College of Cardiology/ American Heart Association Task Force on Practice Guidelines. J Am Coll Cardiol. 2014;63(22):2438–2488.
4. Vahanian A, Otto CM. Risk stratification of patients with aortic stenosis. Eur Heart J. 2010;31(4):416–423.
5. Iung B, Baron G, Butchart EG, Delahaye F, Gohlke-Bärwolf C, LevangOW,et al. A prospective survey of patients with valvular heart disease in Europe: the Euro Heart Survey on Valvular Heart Disease. Eur Heart J. 2003;24(13):1231–1243.
6. Baumgartner H, Falk V, Bax JJ, De Bonis M, Hamm C, Holm PJ, et al. 2017 ESC/EACTS Guidelines for the management of valvular heart disease. Eur Heart J. 2017;38:2739–2791.
7. Kapadia SR, Leon MB, Makkar RR, Tuzcu EM, Svensson LG, Kodali S et al. 5-year outcomes of transcatheter aortic valve replacement compared with standard treatment for patients with inoperable aortic stenosis (PARTNER 1): a randomised controlled trial. Lancet 2015; 385(9986):2485-2491.
8. Mack MJ, Leon MB, Smith CR, Miller DC, Moses JW, Tuzcu EM, et al. 5-year outcomes of transcatheter aortic valve replacement or surgical aortic valve replacement for high surgical risk patients with aortic stenosis (PARTNER 1): A randomised controlled trial. The Lancet. 2015;385(9986):2477-2484.
9. Deeb GM, Reardon MJ, Chetcuti S, Patel HJ, Grossman PM, Yakubov SJ et al. 3-Year Outcomes in High-Risk Patients Who Underwent Surgical or Transcatheter Aortic Valve Replacement. J Am Coll Cardiol. 2016;67(22):2565-2574.
10. Leon MB, Smith CR, Mack MJ, Makkar RR, Svensson LG, Kodali SK, et al. Transcatheter or surgical aortic-valve replacement in intermediate-risk patients. N Engl J Med. 2016; 374:1609–1620.
11. Reardon MJ, Van Mieghem NM, Popma JJ, Kleiman NS, Søndergaard L, Mumtaz M, et al. Surgical or transcatheter aortic-valve replacement in intermediate-risk patients. N Engl J Med. 2017; 376:1321–1331.
12. Mack MJ, Leon MB, Thourani VH, Makkar R, Kodali SK, Russo M, et al. Transcatheter aortic-valve replacement with a balloon- expandable valve in low-risk patients. N Engl J Med. 2019; 380(18):1695–1705.
13. PopmaJJ, Deeb GM, Yakubov SJ, Mumtaz M, Gada H, Hair DO, et al. Transcatheter aortic-valve replacement with a self-expanding valve in low-risk patients. N Engl J Med. 2019;380(18): 1706-1715.
14. Gargiulo G, Sannino A, Capodanno D, Barbanti M, Buccheri S, Perrino C et al. Transcatheter aortic valve implantation versus surgical aortic valve replacement: a systematic review and meta-analysis. Ann Intern Med.2016;165: 334-344.

15. Siemieniuk R, Agoritsas T, Manja V, Devji T, Chang Y, Bala MM et al. al. Transcatheter versus surgical aortic valve replacement in patients with severe aortic stenosis at low and intermediate risk: systematic review and meta-analysis. BMJ.2016;354: i5130.
16. Oguri A, Yamamoto M, Mouillet G, Gilard M, Laskar M, Eltchaninoff H, et al. Clinical outcomes and safety of transfemoral aortic valve implantation under general versus local anesthesia. Circ Cardiovasc Interv. 2014;7:602.
17. Hyman MC, Vemulapalli S, Szeto WY, Stebbins A, Patel PA, Matsouaka RA, et al. Conscious sedation versus general anesthesia for transcatheter aortic valve replacement. Circulation. 2017;136: 2132.
18. de Brito FS, Carvalho LA, Sarmento-Leite R, Mangione JA, Lemos P, Siciliano A, et al.Brazilian TAVI Registry investigators. Outcomes and predictors of mortality after transcatheter aortic valve implant tation: results of the Brazilian registry. Catheter Cardiovasc Interv. 2015;85:E153–E162.
19. Deeb GM, Chetcuti SJ, Reardon MJ, Patel HJ, Grossman PM, Schreiber T, et al. 1-Year Results in Patients Undergoing Transcatheter aortic valve replacement with failed surgical bioprostheses. J A C C: Cardiovascular Interventions. 2017; 10(10):1034-1044.
20. Ludman P. Personal communication: Analysis of in-hospital mortality in UK TAVI dataset; 2018.
21. Walther T, Hamm CW, Schuler G, Berkowitsch A, Kotting J, Mangner N et al. Perioperative results and complications in 15,964 transcatheter aortic valve replacements: prospective data from the GARY registry. J Am Coll Cardiol. 2015; 65:2173–2180.
22. Carroll JD, Vemulapalli S, Dai D, Matsouaka R, Blackstone E, Edwards F, et al. Procedural experience for transcatheter aortic valve replacement and relation to outcomes. J Am Coll Cardiol.2017;70:29.
23. Auffret V, Lefevre T, Van BE, Eltchaninoff H, Iung B, Koning R, et al. Temporal trends in transcatheter aortic valve replacement in France: FRANCE 2 to FRANCE TAVI. J Am Coll Cardiol. 2017; 70:42–55.
24. Hamm CW, Arsalan M, Mack MJ. The future of transcatheter aortic valve implant tation. Eur Heart J.2016;37:803–810.
25. Lancellotti P, Magne J, Donal E, Davin L, O'Connor K, Rosca M, et al. Cinicaloutcome in asymptomatic severe aortic stenosis: insights from the new proposed aortic stenosis grading classification. J Am Coll Cardiol. 2012; 59:235–243.
26. Mare´ CS, Hachicha Z, Bellouin A, Dumesnil JG, Meimoun P, Pasquet A, et al. Usefulness of exercise-stress echocardiography for risk stratification of true asymptomatic patients with aortic valve stenosis. Eur Heart J. 2010; 31:1390–1397.
27. Van GL, Clavel MA, Vollema EM, Hahn RT, Spitzer E, Delgado V, et al. Prognostic implications of moderate aortic stenosis in patients with left ventricular systolic dysfunction. J Am Coll Cardiol. 2017;69:2383–2392.
28. Cahill TJ, Chen M, Hayashida K, Latib A, Modine T, Piazza N, et al. Transcatheter aortic valve implantation: Current status and future perspectives. European Heart Journal. 2018;39:2625–2634.
29. Bourguignon T, Bouquiaux-Stablo AL, Candolfi P, Mirza A, Loardi C, May MA, et al. Very long-term outcomes of the carpentier-edwardsperimount valve in aortic position. Ann Thorac Surg.2015;99:831–837.
30. David TE, Armstrong S, Maganti M. Hancock II bioprosthesis for aortic valve replacement: the gold standard of bioprosthetic valves durability? Ann Thorac Surg. 2010; 90: 775–781.
31. Arsalan M, Walther T. Durability of prostheses for transcatheter aortic valve implantation. Nat Rev Cardiol.2016;13:360.
32. Mack MJ, Leon MB, Smith CR, Miller DC, Moses JW, Tuzcu EM, et al. 5-Year outcomes of transcatheter aortic valve replacement or surgical aortic valve replacement for high surgical risk patients with aortic stenosis (PARTNER 1): A randomized controlled trial. Lancet. 2015;385: 2477–2484.
33. Chakravarty T, Sondergaard L, Friedman J, DeBacker O, Berman D, Kofoed KF, et al.Subclinical leaflet thrombosis in surgical and transcatheter bioprosthetic aortic valves: An observational study. Lancet. 2017;389:2383–2392.
34. Werner N, Zeymer U, Schneider S, Bauer T, Gerckens U, Linke A, et al. German Transcatheter Aortic Valve Interventions-

Registry Investigators. Incidence and clinical impact of stroke complicating transcatheter aortic valve implantation: results from the German TAVI Registry. Catheter Cardiovasc Interv. 2016;88:644–653.

35. Stortecky S, Windecker S, Pilgrim T, Heg D, Buellesfeld L, Khattab AA, et al. Cerebrovascular accidents complicating transcatheter aortic valve implantation: frequency, timing and impact on outcomes. EuroIntervention2012;8:62–70.
36. Daneault B, Kirtane AJ, Kodali SK, Williams MR, Genereux P, Reiss GR, et al. Stroke associated with surgical and transcatheter treatment of aortic stenosis: a comprehensive review. J Am Coll Cardiol.2011;58:2143–2150.
37. Haussig S, Mangner N, Dwyer MG, Lehmkuhl L, Lu¨cke C, Woitek F, et al. Effect of a cerebral protection device on brain lesions following transcatheter aortic valve implantation in patients with severe aortic stenosis: the clean-tavi randomized clinical trial. JAMA. 2016;316: 592–601.
38. Kapadia SR, Kodali S, Makkar R, Mehran R, Lazar RM, Zivadinov R, et al. Protection against cerebral embolism during transcatheter aortic valve replacement. J Am Coll Cardiol. 2017;69:367–377.
39. Ledwoch J, Franke J, Gerckens U, Kuck KH, Linke A, Nickenig G, et al. H; German Transcatheter Aortic Valve Interventions Registry Investigators. Incidence and predictors of permanent pacemaker implanttation following transcatheter aortic valve implantation: analysis from the german transcatheter aortic valve interventions registry. Catheter Cardiovasc Interv. 2013;82:E569–E577.
40. Fadahunsi OO, Olowoyeye A, Ukaigwe A, Li Z, Vora AN, Vemulapalli S, et al. Incidence, predictors, and outcomes of permanent pacemaker implantation following transcatheter aortic valve replacement: Analysis from the U.S. Society of Thoracic Surgeons/American College of Cardiology TVT Registry. JACC Cardiovasc Interv.2016;9:2189–2199
41. Nazif TM, Dizon JM, Hahn RT, Xu K, Babaliaros V, Douglas PS, et al. Predictors and clinical outcomes of permanent pacemaker implantation after transcatheter aortic valve replacement: the PARTNER (Placement of AoRticTraNscathetER Valves) trial and registry. JACC Cardiovasc Interv.2015;8:60–69.
42. Siontis GC, Juni P, Pilgrim T, Stortecky S, Bullesfeld L, Meier B, et al. Predictors of permanent pacemaker implantation in patients with severe aortic stenosis undergoing TAVR: a meta-analysis. J Am Coll Cardiol. 2014;64:129–140.
43. Webb J, Gerosa J, Lefevre T, Leipsic J, Spence M,Thomas M, et al. Multicenter evaluation of a next-generation balloon-expandable transcatheter aortic valve. J Am Coll Cardiol.2014;64: 2235–2243.
44. Frohlich GM, Baxter PD, Malkin CJ, Scott DJA, Moat NE, Hildick SD, et al. Comparative survival after transapical, direct aortic, and subclavian transcatheter aortic valve implantation (data from the UK TAVI Registry). Am J Cardiol. 2015;116:1555–1559.
45. Greenbaum AB, Neill WW, Paone G, Guerrero ME, Wyman JF, Cooper RL, et al. Caval-aortic access to allow transcatheter aortic valve replacement in otherwise ineligible patients. J Am Coll Cardiol.2014;63:2795.
46. Miyazaki Y, Soliman OII, Abdelghani M, Katsikis A, Naz C, Lopes S, et al. Acute performance of a novel restorative transcatheter aortic valve: preclinical results. EuroIntervention. 2017;13: e1410–e1417.
47. Yoon SH, Lefevre T, Ahn JM, Perlman GY, Dvir D, Latib A, et al. Transcatheter aortic valve replacement with early- and new-generation devices in bicuspid aortic valve stenosis. J Am Coll Cardiol. 2016; 68:1195–1205.
48. Yoon SH, Bleiziffer S, De Backer O, Delgado V, Arai T, Ziegelmueller J, et al. Outcomes in transcatheter aortic valve replacement for bicuspid versus tricuspid aortic valve stenosis. J Am Coll Cardiol.2017;69:2579–2589.
49. Di Eusanio M, Phan K: Sutureless aortic valve replacement. Ann Cardiothorac Surg. 2015;4(2): 123–130.
50. Miceli A, Murzi M, Gilmanov D, Fugà R, Ferrarini M, Solinas M, et al. Minimally invasive aortic valve replacement using right minithoracotomy is associated with better outcomes than ministernotomy. J Thorac Cardiovasc Surg. 2014;148(1):133–137.
51. Brown ML, McKellar SH, Sundt TM, Schaff HV, et al.: Ministernotomy versus conventional sternotomy for aortic valve

replacement: a systematic review and metaanalysis. J Thorac Cardiovasc Surg. 2009;137(3):670–679.

52. Hanedan MO, Yuruk MA, Parlar AI, Ziyrek U, Arslan AK, Sayar U,et al.Sutureless versus Conventional Aortic Valve Replacement: Outcomes in 70 High-Risk Patients Undergoing Concomitant Cardiac Procedures. Tex Heart Inst J. 2018;45(1):11–16.
53. Baran C, Durdu MS, Gumus F, Cakici M, Inan MB, Sirlak M, et al. Sutureless aortic valve replacement with concomitant valvular surgery. J Thorac Cardiovasc Surg. 2018;155(6):2414–2422.
54. Gersak B, Fischlein T, Folliguet TA, Meuris B, Teoh KH, Moten SC, et al.Sutureless, rapid deployment valves and stented bioprosthesis in aortic valve replacement: recommendations of an International Expert Consensus Panel. Eur J Cardiothorac Surg. 2016;49(3):709–718.
55. Kocher AA, Laufer G, Haverich A, Shrestha M, Walther T, Misfeld M, et al. One-year outcomes of the Surgical Treatment of Aortic Stenosis With a Next Generation Surgical Aortic Valve (TRITON) trial: a prospective multicenter study of rapid-deployment aortic valve replacement with the EDWARDS INTUITY valve system. J Thorac Cardiovasc Surg. 2013;145(1):110–116.
56. Hurley ET, O'Sullivan KE, Segurado R, Hurley JP. A meta-analysis examining differences in short-term outcomes between sutureless and conventional aortic valve prostheses. Innovations (Phila).2015;10(6):375–382.
57. Chandola R, Teoh K, Elhenawy A, Christakis G. Perceval sutureless valve – are sutureless valves here? CurrCardiol Rev. 2015;11(3):220–228.
58. Ensminger S, Fujita B, Bauer T, Möllmann H, Beckmann A, Bekeredjian R, et al. Rapid Deployment Versus Conventional Bioprosthetic Valve Replacement for Aortic Stenosis. J Am CollCardiol. 2018;71(13): 1417–1428.
59. D'Onofrio A, Salizzoni S, Filippini C, Tessari C, Bagozzi L, Messina A, et al. Surgical aortic valve replacement with new-generation bioprostheses: Sutureless versus rapid-deployment. J Thorac Cardiovasc Surg. 2020;159(2):432-442.
60. Takagi H, Ando T, Umemoto T. Direct and adjusted indirect comparisons of perioperative mortality after sutureless or rapid-deployment aortic valve replacement versus transcatheter aortic valve implant tation. Int J Cardiol. 2017;228:327–334.
61. Qureshi SH, Boulemden A, Szafranek A, Vohra H et al. Meta-analysis of sutureless technology versus standard aortic valve replacement and transcatheter aortic valve replacement. Eur J Cardiothorac Surg. 2018;53(2):463–471.
62. Ozaki S, Kawase I, Yamashita H, Uchida S, Nozawa Y, Matsuyama T, et al. Aortic valve reconstruction using self-developed aortic valve plasty system in aortic valve disease. Interact Cardiovasc Thorac Surg. 2011;12:550-553.
63. Yamashita H, Ozaki S, Iwasaki K, Kawase I, Nozawa Y, Umezu M. Tensile strength of human pericardium treated with glutaraldehyde. Ann Thorac Cardiovasc Surg. 2012;18:434-437.
64. Ozaki S, Kawase I, Yamashita H, Uchida S, Takatoh M, Kiyohara N. Midterm outcomes after aortic valve neocuspidization with glutaraldehyde-treated autologous pericardium. J Thoracic Cardiovasc Surg. 2018;s155(6):2379-2387.
65. Nguyen DH, Vo AT, Le KM, Vu TT, Nguyen TT, Vu TT, et al. minimally invasive ozaki procedure in aortic valve disease: The preliminary results, innovations (Phila). 2018;13(5):332-337.
66. Yamamoto Y, Iino K, Shintani Y, Kato H, Kimura K, Watanabe G, et al. Comparison of aortic annulus dimension after aortic valve neocuspidization with valve replacement and normal valve. Semin Thorac Cardiovasc Surg. 2017;29:143-149.

Peer-review history:
The peer review history for this paper can be accessed here:
http://www.sdiarticle4.com/review-history/65221