

ORIGINAL ARTICLES

TRANS-CATHETER AORTIC VALVE IMPLANTATION (TAVI)-A CASE SERIES AT AFIC/NIHD

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ABSTRACT

Objective: To share our experience of percutaneous trans-catheter aortic valve implantation in patients with severe symptomatic aortic stenosis.

Study Design: A retrospective cross sectional study.

Place and Duration of Study: The study was conducted at Armed Forces Institute of Cardiology/National Institute of Heart Diseases (AFIC/NIHD) Rawalpindi, from Mar 2015 to Feb 2020.

Methodology: Retrospective analysis of all consecutive patients who underwent percutaneous trans-catheter aortic valve implantation was done to assess its immediate, short and long term outcome and safety. Twenty patients have undergone trans-catheter aortic valve implantation since 2015 in the institute. Base line blood chemistry including creatinine clearance, ultra-sonography abdomen, carotid Doppler, chest X-ray, High-Resolution Computed Tomography chest was done in all cases as part of the protocol. Mean age of the patients was 73 ± 7.91 . There were sixteen males (80.0%) and four females (20.0%). All patients underwent procedure through transfemoral route. Valve structure and peripheral vasculature for suitability of the procedure was assessed by computerized coronary tomographic angiography with TAVI protocol. In eleven patients aortic valve was trileaflet (55.0%) and in remaining nine it was bicuspid (45.0%). Mean gradient across the valve pre-procedure was 56.37 ± 9.14 . Thirteen patients (65.0%) presented with angina/dysnoea NYHA III, 6 patients with syncope (30.0%) and one (5.0%) had heart failure. Two patients had undergone previous coronary artery bypass surgery. Procedure was carried out under general anesthesia in all patients except one. Balloon expandable Edwards Sapien valve was implanted in two patients and self-expandable Core Valve/Evolut R in eighteen patients.

Results: Seventeen patients underwent the procedure successfully with reduction of the mean gradients immediately after valve implantation to less than 15 mmHg recorded in the cath lab angiographically subsequently complemented by transthoracic echocardiography. There were 3 deaths during the index hospitalization. Two occurred in the catheterization laboratory, one death was due to development of severe acute aortic regurgitation and second was due to acute coronary obstruction. Third death occurred due to acute kidney injury after seven days. Five patients died in next three months during follow up. One patient required permanent pacemaker because of development of left bundle branch block and second degree atrio-ventricular block post procedure.

Conclusion: Transcatheter aortic valve implantation in patients with severe symptomatic aortic stenosis is a very effective and procedurally safe option and reasonable alternative to surgical valve replacement in high operative risk individuals.

Keywords: Atrio-ventricular, Trans-catheter aortic valve implantation.

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INTRODUCTION

The role of trans-catheter aortic-valve implantation (TAVI) in the treatment of patients with severe, symptomatic aortic stenosis has evolved on the basis of evidence from clinical trials¹. Previous randomized trials of TAVI with both

balloon-expandable and self-expanding valves² showed that, in patients who were at intermediate or high risk for death with surgery, TAVI was either superior or non-inferior to standard therapies, including surgical aortic-valve replacement; these results led to an expansion of guideline recommendations for TAVI³. Moreover, technological enhancements and procedural

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simplification have contributed to increased use of TAVI, such that more patients now undergo TAVI than isolated surgery for aortic-valve replacement globally⁴. However, most patients with severe aortic stenosis are at low surgical risk⁵, and there is now sufficient evidence regarding the comparison of TAVI with surgery in such patients also⁶. In the study, We present data of our patients who have undergone this procedure in Armed Forces Institute of Cardiology in last three years. The patients included low to intermediate to high risk patients based upon Society of Thoracic Surgeons (STS) and Euro II scoring systems.

METHODOLOGY

Twenty patients so far have undergone trans-catheter aortic valve implantation since 2015 in this institute. Before proceeding with the procedure, informed consent was obtained along with Heart Team discussion which included cardiothoracic surgeon, cardiac anesthetist, a clinical cardiologist and an interventional cardiologist. Baseline transthoracic echocardiography was recorded in all patients and trans-oesophageal in selected cases. Base line blood chemistry including creatinine clearance, ultra-sonography abdomen, carotid doppler, CXR, HRCT chest (in selected cases) was done in all cases as part of the protocol. All patients underwent procedure through trans-femoral route. Risk scoring used was based on Society of Thoracic surgeons (STS) and Euro II scoring system widely used internationally in all centers with high volume of this procedure. Valve structure and peripheral vasculature for suitability of the procedure was assessed by computerized coronary tomographic angiography (CCTA) with TAVI protocol.

RESULTS

From March 2015 through Feb 2020, twenty patients underwent trans-catheter aortic valve implantation procedure. Mean age of the patients was 73.10 ± 7.91 years. There were sixteen males (80.0%) and four females (20.0%) and age distribution is illustrated in figure. In eleven patients aortic valve was trileaflet (65.0%) and in remain-

ing nine it was bicuspid (45.0%). Mean gradient across the valve was 56.37 ± 9.14. As far as symptomatology was concerned, 13 patients (45.0%) presented with angina/dysnoea NYHA III, 6 patients with syncope (37.5%) and one (6.3%) had heart failure that was stabilized first before the procedure. Two patients had undergone previous coronary artery bypass surgery. Procedure was carried out under general anesthesia in all pati-

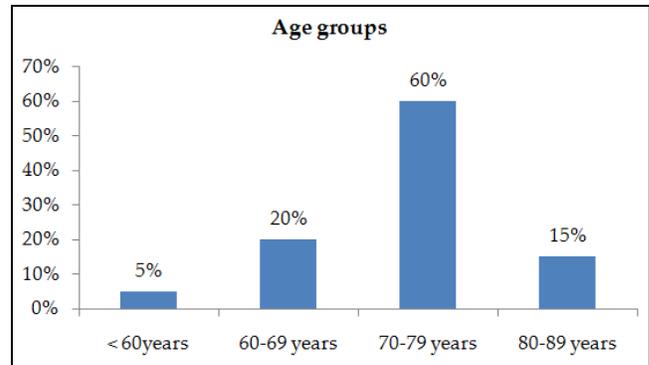


Figure: Age group distribution of TAVI patients (March 2015 to February 2019).

ents except one in whom conscious sedation was used because of severe chronic obstructive pulmonary disease. Three patients underwent coronary revascularization before valve implantation. Balloon expandable Edwards Sapien valve (by Edwards Lifesciences Irvine CA) was implanted

Table-I: Demographic parameters of patients underwent TAVI procedure (n=20).

Variables	n (%)
Age	
Mean ± SD	73.10 ± 7.913 years
Gender	
Male	16 (80.0)
Female	4 (20.0)
NYHA Class	
II	4 (20.0)
III	6 (30.0)
IV	1 (5.0)
Hypertension	8 (40.0)
Diabetes Mellitus	5 (25.0)
Syncope	7 (35.0)
Angina	9(56.3)
Heart Failure	1 (6.3)

in two patients and self-expandable Core Valve / Evolut R (by Medtronic Inc) in eighteen patients.

Femoral access was obtained through direct ultrasound and angiographic guidance and Proglide was used as sealing device after implantation of the valve for vascular closure along with manual compression.

There were 3 deaths during the index hospitalization. One death was due to development of severe acute aortic regurgitation and second was

Table-II: Echocardiogram and computed tomographic angiography findings during the post processing done before TAVI (n=20).

Parameters	Values (Mean \pm SD)
Av-Annular Size	24.76 \pm 3.42
AV Mean Gradient	56.37 \pm 9.14
Av Peak Gradient mmHg (Highest)	80.87 \pm 24.30
Aortic_Annulus_Average	23.61 \pm 2.91
Aortic_Annulus_Perimeter	77.23 \pm 9.28
Aortic_Annulus_Area	433.98 \pm 117.08
LVOT_Average	23.89 \pm 3.48
Sinotubular_Junction_Average	26.72 \pm 3.94
Ascending_Aorta_Avg	32.45 \pm 6.81
Angles_Annular	52.03 \pm 11.14
Angles_Aortic_Arc	56.52 \pm 16.18
MV Gradient	58.87 \pm 13.30

due to acute coronary obstruction. Third patient died due to acute kidney injury on seventh day after the procedure. Five patients died in next three months during follow up. Mean gradient across the valve after the procedure was less than 15 mmHg recorded by transthoracic echocardiography. One patient required permanent pacemaker because of development of left bundle branch block post procedure. Twelve patients are in follow up with significant improvement in symptoms.

DISCUSSION

Valve replacement is the only effective treatment for adults with severe, symptomatic aortic stenosis⁷. The ideal prosthetic valve would be associated with minimal risk and discomfort at implantation with hemodynamics similar to those of a normal valve, not requiring anticoagulation and durable for the patient's lifetime⁸⁻¹³. This goal

is about to be achieved, as evidenced by sequential randomized clinical trials of trans-catheter aortic-valve implantation (TAVI), initially in patients at prohibitive or high estimated risk for death with surgical aortic-valve replacement, then in patients at intermediate risk, and now in patients at low risk, defined as a risk of less than 3 to 4%¹⁴⁻¹⁶.

Because of these considerations, current guidelines recommend the use of a mechanical valve in adults younger than 50 years of age, unless long-term anticoagulation is contra-indicated or declined by the patient¹⁷⁻¹⁹. Among adults 50 to 70 years of age, long-term outcomes are similar with mechanical and biologic valves; the risk of bleeding and thrombosis associated with mechanical valves is balanced against the risk of valve deterioration and reintervention associated with bioprosthetic valves.²⁰⁻²⁵ In most patients older than 70 years of age, the use of a bioprosthetic valve is appropriate; in this group of patients, TAVI is likely to become the preferred option over surgery. Robust data as regards durability of the transcatheter bioprosthetic valve beyond 5 years are going to be available soon but caution is still needed in selecting valve for younger patients. Aortic-valve hemodynamics were substantially improved in both the TAVI group and the surgery group and probably contributed to the reduction in symptoms and improvement in health-related outcomes that was observed in randomized trials. Similar findings were observed in our case series though the numbers are small which a limitation in our study.

CONCLUSION

Transcatheter aortic valve implantation in patients with severe symptomatic aortic stenosis is a reasonable alternative to surgical replacement with almost similar outcome when compared in terms of symptomatic improvement, long term survival, stroke incidence, bleeding complications and rhythm disturbance.

CONFLICT OF INTEREST

This study has no conflict of interest to be declared by any author.

REFERENCES

1. Mack MJ, Leon MB, Thourani VH, Makkar R, Kodali SK, Russo M, et al. Transcatheter aortic-valve implantation with balloon expandible valve in low-risk patients. *N Engl J Med* 2019; 380(18): 1695-705.
2. Popma JJ, Deeb GM, Yakubov SJ, Mumtaz M, Gada H, O'Hair D, et al. Transcatheter aortic-valve replacement with a self-expanding valve in low risk patients. *N Engl J Med* 2019; 380(18): 1706-15.
3. Leon MB, Smith CR, Mack M, Miller DC, Moses JW, Svensson LG, et al. Transcatheter aortic-valve implantation for aortic stenosis in patients who cannot undergo surgery. *N Engl J Med* 2010; 363(17): 1597-607.
4. Smith CR, Leon MB, Mack MJ, Miller DC, Moses JW, Lars G, et al. Transcatheter versus surgical aortic-valve replacement in high-risk patients. *N Engl J Med* 2011; 364(23): 2187-98.
5. 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(17): 1609-20.
6. Kapadia SR, Leon MB, Makkar RR. 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: 2485-91.
7. Mack MJ, Leon MB, Smith CR. 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. *Lancet* 2015; 385: 2477-84.
8. Webb JG, Doshi D, Mack MJ. A randomized evaluation of the SAPIEN XT transcatheter heart valve system in patients with aortic stenosis who are not candidates for surgery. *JACC Cardiovasc Interv* 2015; 8: 1797-806.
9. Thourani VH, Kodali S, Makkar RR. Transcatheter aortic valve replacement versus surgical valve replacement in intermediate-risk patients: a propensity score analysis. *Lancet* 2016; 387(1): 2218-25.
10. Popma JJ, Adams DH, Reardon MJ. Transcatheter aortic valve replacement using a self-expanding bioprosthesis in patients with severe aortic stenosis at extreme risk for surgery. *J Am Coll Cardiol* 2014; 63: 1972-81.
11. Adams DH, Popma JJ, Reardon MJ. Transcatheter aortic-valve replacement with a self-expanding prosthesis. *N Engl J Med* 2014; 370: 1790-8.
12. Reardon MJ, Van Mieghem NM, Popma JJ. Surgical or transcatheter aortic-valve replacement in intermediate-risk patients. *N Engl J Med* 2017; 376: 1321-31.
13. Gleason TG, Reardon MJ, Popma JJ. 5-Year outcomes of self-expanding transcatheter versus surgical aortic valve replacement in high-risk patients. *J Am Coll Cardiol* 2018; 72: 2687-96.
14. Nishimura RA, Otto CM, Bonow RO. AHA/ACC focused update of the 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 clinical practice guidelines. *J Am Coll Cardiol* 2017; 70: 252-89.
15. Baumgartner H, Falk V, Bax JJ. 2017 ESC/EACTS guidelines for the management of valvular heart disease. *Eur Heart J* 2017; 38(1): 2739-91.
16. SAVR TAVR volumes. Presented at a meeting of the society of thoracic surgeons-american college of cardiology tvT registry stakeholder advisory group, Washington, DC, March 4, 2019.
17. Thourani VH, Suri RM, Gunter RL. Contemporary real-world outcomes of surgical aortic valve replacement in 141,905 low risk, intermediate risk, and high risk patients. *Ann Thorac Surg* 2015; 99: 55-61.
18. Søndergaard L, Ihlemann N, Capodanno D. Durability of transcatheter and surgical bioprosthetic aortic valves in patients at lower surgical risk. *J Am Coll Cardiol* 2019; 73: 546-53.
19. Waksman R, Rogers T, Torguson R. Transcatheter aortic valve replacement in low-risk patients with symptomatic severe aortic stenosis. *J Am Coll Cardiol* 2018; 72: 2095-105.
20. Kodali S, Thourani VH, White J. Early clinical and echocardiographic outcomes after SAPIEN 3 transcatheter aortic valve replacement in inoperable, high-risk and intermediate-risk patients with aortic stenosis. *Eur Heart J* 2016; 37: 2252-62.
21. Pocock SJ, Ariti CA, Collier TJ, Wang D. The win ratio: a new approach to the analysis of composite endpoints in clinical trials based on clinical priorities. *Eur Heart J* 2012; 33: 176-82.
22. Vandvik PO, Otto CM, Siemieniuk RA. Transcatheter or surgical aortic valve replacement for patients with severe, symptomatic, aortic stenosis at low to intermediate surgical risk: a clinical practice guideline. *Bio Med J* 2016; 354: i5085.
23. Otto CM, Kumbhani DJ, Alexander KP. ACC expert consensus decision pathway for transcatheter aortic valve replacement in the management of adults with aortic stenosis: a report of the American College of Cardiology Task Force on Clinical Expert Consensus Documents. *J Am Coll Cardiol* 2017; 69: 1313-46.
24. Schymik G, Heimeshoff M, Bramlage P. A comparison of transcatheter aortic valve implantation and surgical aortic valve replacement in 1,141 patients with severe symptomatic aortic stenosis and less than high risk. *Catheter Cardiovasc Interv* 2015; 86: 738-44.
25. Rosato S, Santini F, Barbanti M. Transcatheter aortic valve implantation compared with surgical aortic valve replacement in low-risk patients. *Circ Cardiovasc Interv* 2016; 9(5): e003326.