Transcatheter Aortic-Valve Implantation

ORIGINAL ARTICLES

TRANSCATHETER AORTIC - VALVE IMPLANTATION (TAVI) - AN EXPERIENCE AT ARMED FORCES INSTITUTE OF CARDIOLOGY

Abdul Hameed Siddiqui, Sohail Aziz, Ghulam Rasool Maken, Ali Nawaz Khan, Farhan Tuyyab, Mohsin Saif, Tahir Iqbal, Javeria Kamran, Anam Fatima Janjua, Imran Ahmed*

Armed Forces Institute of Cardiology/National Institute of Heart Disease (AFIC/NIHD)/National University of Medical Sciences (NUMS) Rawalpindi Pakistan, *Ahad Rofeda General Hospital, Ahad Rafidah, Saudi Arabia

ABSTRACT

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

Study Design: A retrospective cross sectional study.

Place and Duration of Study: Armed Forces Institute of Cardiology/National Institute of Heart Diseases (AFIC/NIHD) Rawalpindi, from Mar 2015 to Aug 2019.

Methodology: Sixteen patients have undergone transcatheter aortic valve implantation since 2015 in the institute. Base line blood chemistry including creatinine clearance, ultrasonography abdomen, carotid Doppler, CXR, HRCT chest was done in all cases as part of the protocol. All patients under went procedure through transfemoral route. Valve structure and peripheral vasculature for suitability of the procedure was assessed by computerized coronary tomographic angiography (CCTA) with TAVI protocol. Procedure was carried out under general anesthesia in all patients except one.

Results: Sixteen patients underwent the procedure successfully with reduction of the mean gradients immediately after valve implantation to less than 15mmHg recorded in the cath lab angiographically subsequently complemented by echocardiography. There were 2 deaths during the index hospitalization. Both occurred in the cath lab, one death was due to development of severe acute aortic regurgitation and second was due to acute coronary obstruction. Four 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 atrioventricular (AV) block post procedure.

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

Keywords: Computerized coronary tomographic angiography (CCTA), Transcatheter aortic-valve implantation (TAVI).

This is an Open Access article distributed under the terms of the Creative Commons Attribution License (http://creativecommons.org/licenses/by/4.0), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited.

INTRODUCTION

The role of transcatheter aortic-valve implantation TAVI in the treatment of patients with severe, symptomatic aortic stenosis has evolved on the basis of evidence from clinical trials¹⁻⁵. Previous randomized trials of TAVI with both balloon-expandable and self expanding valves⁶⁻¹⁰. showed that, in patients who were at intermediate or high risk for death with surgery, TAVI was either superior or non-inferior to standard the rapies, including surgical aortic valve replacement. These results led to an expansion of guideline recommendations for TAVI¹¹⁻¹⁴. Moreover, technological enhancements and procedural simplification have contributed to increased use of TAVI, Such that more patients now undergo TAVI than isolated surgery for aortic valve replacement globally¹⁴. However, most patients with severe aortic stenosis are at low surgical risk¹⁵, and there is now sufficient evidence regarding the comparison of TAVI with surgery in such patients also^{16,17}. 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 inter-

Correspondence: Dr Abdul Hameed Siddiqui, Department of Cardiology, AFIC/NIHD, Rawalpindi Pakistan *Email: drahsahs@gmail.com*

mediate to high risk patients based upon Society of Thoracic Surgeons (STS) and (euro-II) scoring systems.

METHODOLOGY

Sixteen patients so far have undergone transcatheter 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 anaesthetist, a clinical cardiologist and an interventional cardiologist.

Baseline transthoracic echocardiography was recorded in all patients and transoesophageal in selected cases. Base line blood chemistry including creatinine clearance, ultrasonography abdomen, and carotid doppler, CXR, HRCT chest (in selected cases) was done in all cases as part of the protocol. Mean age of the patients was 72.4 \pm 8.53 years. There were fourteen males (87.5%) and two females (12.5%). All patients under went procedure through transfemoral 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. In nine patients aortic valve was trileaflet (56.2%) and in remaining seven it was bicuspid (43.8%). Mean gradient across the valve was 58.8 ± 13.30. As far as symptomtology was concerned 9 patients (56.3%) 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 patients 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 Life-sciences Irvine CA) was implanted in two patients and

self-expandable core valve/Evolut R (by Medtronic Inc) in fourteen 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.

RESULTS

From Mar 2015 through Aug 2019, 16 patients underwent procedure. Mean age of the patients was 72.4 ± 8.53 years. There were

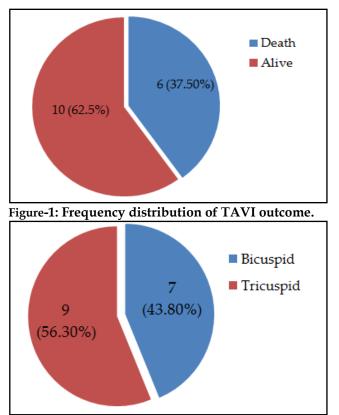


Figure-2: Frequency distribution of types of valves involved.

fourteen males (87.5%) and two females (12.5%). All patients under went procedure through transfemoral 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. In nine patients aortic valve was trileaflet (56.2%) and in remaining seven it was bicuspid (43.8%).

Mean gradient across the valve was 58.8 \pm

| Table-I: | Demographic | parameters | of | patients | |
|----------------------------------|-------------|------------|----|----------|--|
| underwent TAVI procedure (n=16). | | | | | |

| Variables | Frequency | Percentages | | |
|-------------------|---------------------------------|-------------|--|--|
| Age Mean ± SD | $72.437 \pm 8.53 \text{ years}$ | | | |
| Gender | 72.407 ± 0 | .co years | | |
| Male | 142 | 87.5 | | |
| Female | | 12.5 | | |
| Age group | | 12.5 | | |
| <60 years | 2 | 13.4 | | |
| 5 | | 26.7 | | |
| 60-69 years | 4 | | | |
| 70-79 years | 8 | 53.3 | | |
| 80-89 years | 2 | 13.3 | | |
| NYHA Class | | | | |
| II | 1 | 6.7 | | |
| III | 5 | 33.3 | | |
| IV | 1 | 6.7 | | |
| Hypertension | 4 | 26.7 | | |
| Diabetes Mellitus | 2 | 13.3 | | |
| Syncope | 4 | 26.7 | | |
| Angina | 9 | 56.3 | | |
| Heart Failure | 1 | 6.3 | | |
| | | | | |

Table-II:EchocardiogramandcomputedtomographicAngiography findingsduring thepost processing done before (TAVI).

| | / | | |
|------------------------------------|-----------------------|--|--|
| Parameters | Values (Mean ± SD) | | |
| Av-annular size | 22.52 ± 4.02 | | |
| AV mean gradient | 55.34 ± 7.02 | | |
| Av peak gradient mmHg (highest) | 89 ± 14.7 | | |
| Aortic_Annulus_Average | 24.03 ± 2.53 | | |
| Aortic_Annulus_Perimeter | 78.7 ± 9.09 | | |
| Aortic_Annulus_Area | 418.78 ± 123.11 | | |
| LVOT_average | 23.76 ± 2.46 | | |
| Sinotubular_junction_average | 25.14 ± 2.61 | | |
| Ascending_Aorta_avg | 30.83 ± 6.36 | | |
| Angles_Annular | 47.57 ± 12.9 | | |
| Angles_Aortic_Arc | 62.56 ± 4.35 | | |
| MV gradient | 58.87±13.30 | | |

13.30 (table-II). As far as symptomtology was concerned 9 patients (56.3%) 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. There were 2 deaths during the index hospitalization. One death was due to development of severe acute aortic regurgitation and second was due to acute coronary obstruction. Four patients died in next three months during follow up (fig-1). Mean gradient across the valve after the procedure was lessthan 15mm.

Hg recorded Echocardiographically. One patient required permanent pacemaker because of development of left bundle branch block post procedure. Nine patients are in follow up with significant improvement in symptoms.

DISCUSSION

Valve replacement is the only effective treatment for adults with severe, symptomatic aortic stenosis. 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 lifetime. This goal is about to be achieved, as evidenced by sequential randomized clinical trials of transcatheter 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 $4\%^{14}$.

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 contraindicated or declined by the patient¹⁴⁻¹⁶. 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. 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 not yet available, so caution is needed in

selecting valve for young patients. Aorticvalve hemodynamics were sub-stantially 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 study¹⁷⁻²⁰.

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 disturbace.

CONFLICT OF INTEREST

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

REFERENCES

- Mack MJ, Leon MB, Thourani VH, Makkar R, Kodali SK, Russo M, et al. Transcatheter aortic-valve implantation with balloon expandible valve in low-riskpatients. N Engl J Med 2019; 380(18): 1695-705.
- 2. Popma JJ,Deeb GM,Yakubov SJ, Mumtaz M, Gada H. Transcatheter aortic-valve replacement with a self-expanding valve in low risk patients. N Engl J Med 2019; 380(18): 1706-15.
- 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, Svensson LG, et al. Transcatheter versus surgical aortic-valve replacement in high-risk patients. N Engl J Med 2011; 364(23): 2187-98.
- Leon MB, Smith CR, Mack MJ, Makkar RR, Svensson LG, Kodali SK, et al. Transcatheter or surgical aortic-valve re-placement in intermediate-risk patients. N Engl J Med 2016; 374(17): 1609-20.
- 6. 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 aor- tic stenosis (PARTNER 1): a randomised controlled trial. Lancet 2015; 385(1): 2485-91.
- 7. 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 ran-domised controlled trial. Lancet 2015; 385(1): 2477-84.

- 8. Webb JG, Doshi D, Mack MJ. A randomized evaluation of the SAPIEN XT transcatheter heart valve system in pa- tients with aortic stenosis who are not can- didates for surgery. JACC Cardiovasc In- terv 2015; 8(14): 1797-806.
- 9. Thourani VH, Kodali S, Makkar RR, Herrmann HC, Williams M, Babaliaros V, et al. Transcatheter aortic valve replace- ment versus surgical valve replacement in intermediate-risk patients: a propensity score analysis. Lancet 2016; 3879(10034): 2218-25.
- 10. Popma JJ, Adams DH, Reardon MJ, Yakubov SJ, Kleiman NS, Heimansohn D, et al. Transcatheter aortic valve replacement using a self-expanding bioprosthesis in patients with severe aortic stenosis at ex- treme risk for surgery. J Am CollCardiol 2014; 63(19): 1972-81.
- 11. Adams DH, Popma JJ, Reardon MJ, Yakubov SJ, Coselli JS, Deeb GM, et al. Transcatheter aortic-valve replacement with a self-expanding prosthesis. N Engl J Med 2014; 370(19): 1790-8.
- 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(14): 1321-31.
- 13. Gleason TG, Reardon MJ, Popma JJ, Deeb GM, Yakubov SJ, Lee JS, et al. 5-Year outcomes of self-expanding transcatheter versus surgical aortic valve replacement in high-risk patients. J Am CollCardiol 2018; 72(22): 2687-96.
- 14. Nishimura RA, Otto CM, Carabello BA, Fleisher LA, Bonow RO, et al. 2017 AHA/ACC focused update of the 2014 AHA/ACC guideline for the man- agement 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 CollCardiol 2017; 135(25): 1159-95.
- Baumgartner H, Falk V, Bax JJ, De Bonis M, Hamm C, Holm PJ, et al. 2017 ESC/EACTS guidelines for the man- agement of valvular heart disease. Eur Heart J 2017; 38(36): 2739-91.
- Rick A, Patrick T, Joseph E, Ralph G, John D, Clifford J, et al. Savr tavr volumes. Presented at a meeting of the Society of Thoracic Sur geons American College of Cardiology TVT Registry Stakeholder Advisory Group, Washington, DC Med 2019; 73(20): 2609-35.
- Thourani VH, Suri RM, Gunter RL, Sheng S, O'Brien SM, Ailawadi G, et al. Contemporary real-world outcomes of surgical aortic valve replacement in 141, 905 low-risk, intermediaterisk, and high-risk patients. Ann Thorac Surg: 2015; 99(1): 55-61.
- 18. Holmes Jr., DR, Nishimura RA, Grover FL. Annual outcomes with transcatheter valve therapy: from the STS/ACC TVT registry. J Am Coll Cardiol. 2015; 66: 2813-23.
- 19. Deeb GM, Reardon MJ, Chetcuti S. 3-Year outcomes in highrisk patients who underwent surgical or transcatheter aortic valve replacement. J Am Coll Cardiol 2016; 67(5): 2565-74.
- 20. Siontis GC, Praz F, Pilgrim T. Transcatheter aortic valve implantation vs. surgical aortic valve replacement for treatment of severe aortic stenosis: a meta-analysis of randomized trials. Eur Heart J 2016; 37(5): 3503-12.

.....