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 Disease (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 under went 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 labangiographically 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 atrioventricular 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.

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 trials. Previous randomized trials of TAVI with both balloon-expandable and self-expanding valves 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 TAVI. 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 globally. However, most patients with severe aortic stenosis are at low surgical risk, and there is now sufficient evidence regarding the comparison of TAVI with surgery in such patients also. 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 remaining 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 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 Lifesciences Irvine CA) was implanted in two patients and self-expandable Core Valve / Evolut R (by Medtronic Inc) in eighteen patients.

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

| Variables        | n (%)          |
|------------------|----------------|
| Age              | 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)        |
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 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 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 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%.

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 patient. 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 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.
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