Manuscript

Introduction

The most prevalent heart valve disease, aortic valve stenosis (AS), is a leading cause of morbidity and mortality globally. The aortic valve (AV) is located between the left ventricle and the aorta, which is a main systemic blood channel that supplies blood to all bodily organs and tissues. Left ventricular enlargement, as well as the accompanying symptoms of exertion dyspnea, chest discomfort, and possibly syncope, might occur. The severity of the problem is determined by a number of echocardiographic parameters, including AS jet velocity, mean transvalvular pressure gradient, and AV area by continuity equation, in addition to the extent of these clinical symptoms (1,2).

Aortic valve replacement is the ultimate treatment for severe AS (AVR). The defective heart valve is replaced with a new, functional valve, which can be constructed of mechanical or bioprosthetic material. Surgical AVR (SAVR) has long been the gold standard of therapy for severe, symptomatic AS, and it is still recommended by US and European standards. It has been demonstrated to improve symptoms and increase survival rates. Transcatheter aortic valve implantation (TAVI), commonly known as transcatheter aortic valve replacement, is a less invasive method to AVR that has lately gained popularity. Both techniques are used to provide sufficient haemodynamic parameters, symptom alleviation, and increased survival (3,4).

A thorough sternotomy or minimally invasive surgical incisions are two surgical techniques to AVR that have shown equivalent results. The femoral artery is the standard route for TAVI. Alternative access locations are used in some groups, such as patients with severe peripheral artery disease. The transsubclavian artery and, less typically, the transcarotid or transcaval methods are among them. The advantage of such techniques is that they allow access in a less invasive manner, without having to open the chest cavity, which makes them a desirable option for old, frail patients who are at high surgical risk. The transapical and direct transaortic methods are two more common alternate access locations. SAVR is now being tested in comparison to TAVI in different populations, indicating a rising trend toward less invasive techniques (5,6).

In low-risk patients requiring an AVR, establishing a benchmark surgical strategy for SAVR is extremely important, especially in the current era of TAVR expansion. Hijri and colleagues compared the outcomes of fAVR with mAVR to assist guide crucial therapeutic decisions using their substantial 15-year single-center experience. There are several significant discoveries in this vast study. We found that mAVR and fAVR patients had identical surgical mortality and in-hospital outcomes, including stroke, bleeding reoperation rates, and repeat valve surgeries. mAVR and fAVR patients demonstrated similar midterm survival after correcting for numerous patient-related characteristics; however, mAVR did seem to result in a shorter hospital LOS and ICU stay (3).

There has been a lot of interest and growth in TAVR because of the shifting patient profile and the degree of comorbidities. In patients with AS, TAVR is a less intrusive and morbid technique to AVR that has recently been investigated in comparison to medicinal treatment and SAVR. The first TAVR investigations included inoperable and high-risk patients, as determined by their STS-PROM scores. When compared to medical therapy, TAVR resulted in higher survival (69.3 percent vs 49.3 percent), a lower risk of repeat hospitalization (22.3

percent vs 44.1 percent), and a lower rate of cardiac symptoms (25.2 percent vs 58 percent after one year; all P.05). In high-risk patients TAVR compared to SAVR lead to a somewhat improved survival at 1 year (75.8% vs 73.2%; P=.44) (4).

In recent years, minimally invasive aortic surgery has established itself as a viable alternative to traditional sternotomy (fAVR) in the operational management of aortic disease, however it is only available at a few cardiac surgery centers and in locations where TAVR is not available. mAVR is associated with better clinical results than fAVR, especially in high-risk elderly patients. Previously published findings from a 10-year study of 552 matched pairs comparing mAVR versus fAVR, finding that mAVR patients had shorter ventilation times, shorter ICU stays, and shorter LOS, but no differences in short- or long-term survival or the need for operative intervention (3).

While TAVR appears to offer a demonstrable benefit in terms of reducing acute kidney injury and the need for blood transfusions, it is also linked to a higher risk of permanent pacemaker installation (PPI), moderate-to-severe paravalvular regurgitation (PVL), and vascular problems. Furthermore, there is a lack of long-term data on the TAVR valve's longevity, which is cause for concern. Daubert et al. recently looked at the long-term performance of TAVR valves in terms of hemodynamic and valvular profile in patients who had previously participated in the PARTNER I trial and found no change in AV area, total transvalvular or paravalvular aortic regurgitation, or total transvalvular or paravalvular aortic regurgitation over 5 years. Despite these results suggesting that valve performance and cardiac hemodynamics are stable after implantation of TAVR valves, valve durability is still unknown and has to be cautiously indicated in the young low-risk population (7,8).

In Pakistan, Ali Ammar and colleagues led the first study to evaluate the safety and efficacy outcomes following TAVI. his study included 100 consecutive patients with severe AS undergoing TAVI. Sixty-three (63.0%) patients were males, and the mean age was 67.38 ± 10.73 years. Atrioventricular (AV) blockages were reported in 22% of instances, with major vascular access site problems occurring in 14% of cases. Patients' symptoms were significantly different before and after the operation. During their stay in the hospital, eight individuals (8%) died. At the one-month follow-up, 76 percent of patients had no restrictions on their physical activity. In conclusion, TAVI is a safe therapy in these high-risk individuals, and it represents an option to surgery for AS patients in the region, according to the findings of this study(9).

Objective

To compare the post-operative complication rate in Transcatheter Aortic Valve Implantation **[**TAVI] VS Surgical Aortic Valve Replacement **[**SAVR] within one week of the operation.

METHODS

Study Type: This is a retrospective cohort study in which two separate cohorts of patients would be included. The first group is of patients who undergo traditional open-heart surgery at our hospital for valve replacement, whereas the other cohort would be of patients who undergo valve replacement procedure using TAVI.

Study Location: The study would be conducted at a medical hospital based in Peshawar. The departments of cardiology would be requested to allow requisition of data from both surgical procedures.

Sampling Technique: Records of all the patients who underwent TAVI and SAVI in the last 5 years preceding the survey and fulfilling our inclusion criteria would be included in our study using purposive sampling method until the desired sample size is achieved.

Study population all the patients who underwent Transcatheter Aortic Valve Implantation **[**TAVI] and Surgical Aortic Valve Replacement **[**SAVR] in the last 5 years preceding the survey at the tertiary care hospital in Peshawar.

Inclusion Criteria: The inclusion criteria include:

1) Patients who underwent primary valve replacement surgery at our institute through either of these procedures
2) Patients who remained admitted in the hospital for at least one week.
3) Patients whose medical records are readily available at the hospital.

Exclusion Criteria:

1) Any patient with secondary valvular surgeries, by either means will not be included in the study.
2) Also patients with incomplete medical records will be excluded.
3) Any patient who was discharged before completing one week.

Study Duration: The total duration of this study, following ERC review will be approximately 6 months.

Sample Size: Using open epi, with a two-sided confidence interval of 95%, power of 80%, ratio of controls to cases 1.0, percent of controls exposed 40, and an odds ratio of 2.0, the calculated sample size is 268 (134 each cohort). Adjusting for a 10% attrition rate due to incomplete files, the sample size then turns out to be 295. (10)

Data Collection: After getting a clearance from the Ethics and Review Committee of the Frontier Medical College, ICD-10 coding for open heart surgery, TAVI and valve replacement would be used to identify patients. Following identification, a request form would be made to the HIMS department to pull out charts for the patients. A structured proforma would be used to extract the data of relevance from the files.

Data Analysis: The data analysis would be carried out on IBM SPSS Version 26. Mean and S.D will be calculated for continuous variables while frequencies and proportions will be reported for categorical variables. Chi-square test at 5% level of significance will be applied to compare the patient demographics, (including gender, co-morbidities, BMI, work, and NYHA classification of heart dysfunction) among the two groups. Moreover, in case of continuous variables (e.g age) independent sample t test will be applied. Cross tabs would be done to find association between variables such as NYHA classification and type of surgery, between ejection fraction (and other cardiac markers) to the surgery time, and between surgery type and associated post-operative complications (such as bleeding, ICU admission, infections), morbidities, and mortalities to identify any statistical significance. Incidence of post-operative complication rate (within 1 week of surgery) will be calculated for both the procedures separately using the below formula.

Number of patients who developed complications within one post-op week X 100 divided by total number of patients who underwent there procedure.

Ethical Considerations: An exemption review would be applied for in the Ethics and Review Committee of the Frontier Medical College. Data recorded digitally would be kept in password protected files, the password of which would be kept in secrecy, and available only to the principal investigator and those who he/she authorizes for use. Any patient identifier, including name, and MR number would be removed from all patient accounts entered in the proforma.

Result

Based on a cohort of 200 patients (100 in each group), a higher Postoperative Complication Rate was observed with SAVR compared with TAVI (39.0% vs 13.0%, respectively).Among SAVR patients the most common complications were postoperative bleeding (51.2%), infection (30.7%) and cardiac tamponade (17.9%).Patients who underwent TAVI had higher incidence of other postoperative complications which were vascular complications (53.8%) and need for pacemaker implantation (46.1%).On comparison the two groups did show significant differences in the mortality rate (SAVR G = 15.0% & TAVI G = 4.0%).

	Variable	**SAVR Group (n=100)**	**TAVI Group (n=100)**
	Median Age (y)	61.2	60.7
	Sex (M)	70	54
	Median BMI	25.2	21.4
	NYHA (III/IV)	86	95
.	Median Length of ICU Stay (days)	6.3	3.5

ICU, intensive care unit; NYHA, New York Heart Association.

Conclusion

TAVI has Low Postoperative Complication Rate and Mortality Rate compared to SAVR .Our Data confirm that TAVI is a safer and more reliable procedure for Patients suffering from Aortic Stenosis.

REFERENCES

1) Bhatia N, Basra SS, Skolnick AH, Wenger NK. Aortic valve disease in the older adult. Journal of Geriatric Cardiology 2016;13(12):941-4

2) Maganti K, Rigolin VH, Sarano ME, Bonow RO. Valvular heart disease: diagnosis and management. Mayo Clinic Proceedings 2010;85(5):483-500.
3) Hirji SA, Funamoto M, Lee J, Ramirez Del Val F, Kolkailah AA, McGurk S, et al. Minimally invasive versus full sternotomy aortic valve replacement in low-risk patients: which will stand against transcatheter aortic valve replacement?. Surgery 2018;164(2):282-7.
4) Leon MB, Smith CR, Mack M, Miller DC, Moses JW, Svensson LG. Transcatheter aortic-valve implantation for aortic stenosis in patients who cannot undergo surgery. New England Journal of Medicine 2010;363(17):1597-607.
5) Kolkailah AA, Hirji SA, Ejiofor JI, Ramirez Del Val F, Lee J, Norman AV, et al. Novel fast-track recovery protocol for alternative access transcatheter aortic valve replacement: application to non-femoral approaches. Interactive CardioVascular and Thoracic Surgery 2018;26:938–43.
6) Grover FL, Vemulapalli S, Carroll JD, Edwards FH, Mack MJ, Thourani VH, et al. STS/ACC TVT Registry. 2016 Annual Report of The Society of Thoracic Surgeons/American College of Cardiology Transcatheter Valve Therapy Registry. Journal of the American College of Cardiology 2017;69(10):1215–30.
7) Elmaraezy A, Ismail A, Abushouk AI, Eltoomy M, Saad S, Negida A, et al. Efficacy and safety of transcatheter aortic valve replacement in aortic stenosis patients at low to moderate surgical risk: a comprehensive meta-analysis. BMC Cardio- vasc Disord. 2017;17:234.
8) Daubert MA, Weissman NJ, Hahn RT, Pibarot P, Parvataneni R, Mack MJ, et al. Long-Term Valve Performance of TAVR and SAVR: A Report From the PART- NER I Trial. JACC Cardiovasc Imag. 2016.
9) Ammar A, Hassan Rizvi SN, Saghir T, Khan N, Akhtar P, Mengal N, Sial JA, Qamar N. Pakistan Following Foot Prints of Developed World in Structural Interventions: Experience of Transcatheter Aortic Valve Implantation Reported First Time. Cureus. 2020 Nov 16;12(11):e11497.
10) https://www.openepi.com/SampleSize/SSPropor.htm

Appendix

Patient Demographics

Patient Name	
MR Number	
Age of Patient	
Gender	
City of Residence	
Education	

Occupation	
BMI	
Comorbid Conditions	*Circle all that apply, and fill in for more details* ● Hypertension ● Diabetes Mellitus ● Cardiovascular Diseases ……. ● Renal Disease ……. ● Gastrointestinal Disease ……
History of Smoking	
History of Alcohol Intake	
Monthly Household Income	

Clinical Parameters

Sign and Symptoms on Admission	*Circle all that apply* ● Chest Pain ● Shortness of Breath ● Sweating ● Vomiting / Nausea ● Fatigue / Weakness ● Abnormal Heart Beating
Diagnosis	
Date of Admission	
Type of Surgery Performed	
Date of Surgery	

ASA of Surgery	
Intra-operative time	
Intra-operative blood loss	
Intra-operative complications	
Condition of Discharge	
Medications of Discharge	
Total Length of Hospital Stay	• *General Ward …….* • *ICU ……..* • *SCU ……..*
Post-operative complications (immediately)	
Post-operative complications (after a week)	
Post-operative complications (after a month)	