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In-hospital outcome of Transcatheter Aortic Valve Implantation at Shahid Gangalal National Heart Centre, Kathmandu, Nepal

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ABSTRACT

Background: Transcatheter aortic valve implantation (TAVI) has emerged as a well-established treatment for severe aortic stenosis since its first application in humans in 2002. In Nepal, the inaugural TAVI procedure was performed in February 2022 at the Shahid Gangalal National Heart Centre. This study aims to share our initial experiences and outcomes of TAVI at our center.

Methods: We conducted a retrospective observational study involving all patients who underwent TAVI at our facility between February 2022 and February 2024. This report details patients' baseline clinical characteristics, procedural data, complications, and in-hospital outcomes.

Results: A total of 19 patients underwent TAVI during the study period. The age of patients ranged from 59 to 90 years, with a mean age of 75.2 ± 7.5 years; 10 patients (52.6%) were female. Four cases (21.1%) involved patients with bicuspid aortic stenosis. Baseline mean aortic valve area measured 0.8 ± 0.1 cm^2, and the pre-procedural mean pressure gradient was 52.2 ± 10.1 mmHg. Post-procedure, two patients (10.5%) required permanent pacemaker implantation. The balloon-expandable valve was utilized in 12 cases (63.2%), while the self-expandable valve was used in 7 cases (36.8%). The overall procedural success rate was 100%, and all patients were discharged following TAVI, with a mean hospital stay of 4.5 ± 1.8 days. A mild paravalvular leak occurred in one patient (5.3%). Post-TAVI, the mean aortic valve pressure gradient decreased to 8.1 ± 2.6 mmHg.

Conclusions: The outcomes of our initial TAVI procedures are promising, with in-hospital complication and mortality rates comparable to international standards, reinforcing the safety and efficacy of this intervention within our setting.

Keywords: Aortic Stenosis; balloon expandable valve; self-expandable valve; transcatheter aortic valve implantation.

INTRODUCTION

Transcatheter aortic valve implantation (TAVI) has evolved significantly since its first application in humans in 2002, establishing itself as a crucial intervention for patients with severe aortic stenosis. Initially developed for individuals at high or prohibitive surgical risk, the indications for TAVI have expanded to encompass intermediate and low-risk patients, demonstrating its growing acceptance within the clinical community.[1,2,3]

Following the European commercial approval in 2007, the uptake and proliferation of TAVI across Europe have been remarkable. [4] The procedure was introduced to Asia two years later, with the first TAVI performed in Singapore in February 2009 using the SAPIEN valve.[5] This advancement paved the way for further developments, including the commercial launch of the Core Valve in Malaysia in October 2009.[6] In South Asia, the first clinical experience with transcatheter aortic valve replacement (TAVR) was reported in India in 2011,[7] marking a significant progression for the region.

In Nepal, TAVI was first performed at Shahid Gangalal National Heart Centre in February 2022, heralding a new era in the management of aortic stenosis in the country.[8] This study aims to share our initial experiences and outcomes with TAVI, contributing to the growing body of knowledge in this field and highlighting its impact on patient care within Nepal.

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METHODS

This study was a retrospective, observational, single-center study. This study included all symptomatic severe aortic stenosis patient who underwent TAVI at our center between February 2022 and February 2024.The study was approved by the IRC of Shahid Gangalal National heart Centre, Kathmandu, Nepal. We retrospectively collected information about age, gender, cardiac CT details, comorbidities, TAVI valve type and size, aortic valve area, pre-TAVI-Aortic valve mean gradient, post TAVI aortic valve mean gradient, duration of hospital stay, complication and in-hospital outcomes from the catheterization laboratory and hospital data base. Severe Aortic stenosis was diagnosed with the echocardiogram. ECG-gated, contrast-enhanced cardiac CT report were reviewed for the measurements of the aortic annulus, root, sinuses, and vascular access.

All demographic, clinical, and technical data were collected using the "Data Collection Form' tabulated, and analyzed using SPSS (version 24). Continuous variables were summarized as mean ± standard deviation (SD), while categorical variables were summarized as frequency (proportion).

RESULTS

During two years we performed TAVI in 19 patients. Patients' age ranged from 59 years to 90 years with a mean of 75.2 ±7.5 years. Ten patients (52%) were females and nine patients (48%) were males. Two patients (10.5%) had pacemaker implantation before TAVI. Three patients (15.7%) had undergone percutaneous coronary intervention before TAVI. Four patients (21%) had bicuspid aortic valves.

Two (10.5%) cases were low flow low gradient severe aortic stenosis cases. Baseline characteristics are summarized in Table 1:

Severe calcification of the aortic valve was present in seven (36.8%) cases, Moderate in three (15.7%) cases, and Mild calcification in nine (48%) cases.

The Mean Aortic area was 0.8±0.1cm2. The aortic valve mean pressure gradient was 52.2± 10.1 mmHg before TAVI. All patients underwent TAVI through trans-femoral approach. In 18 (94.7%) cases conscious sedation was used for anesthesia. Three (15.7%) patients underwent Pre-dilation whereas two (10.5) patients underwent post dilatation.

Balloon-expandable valve was used in 12 (63.1%) cases and the self-expandable valve was used in 7 (36.8%) cases. Among the TAVI valves, Eleven (57.8%) were Myval, Five (26.3%) were Evolut Pro, One (5.2%) was Potrico, one (5.2%) was Navitor, and one (5.2%) was Sapien 3 valve as shown in Table.3.

Procedural success was achieved in all (100%) patients. All patients were discharged after TAVI. Post TAVI mean aortic valve pressure gradient was 8.1±2.6mmHg at the time of discharge. The Mean hospital stay was 4.5 ±1.8 days. Two (10.5%) patients needed permanent pacemakers after the TAVI. One (5.2%) patient had a mild paravalvular leak. One patient had a femoral artery pseudo aneurysm which was managed medically, another patient needed surgical repair due to Proglide failure as shown in table 4. Chimney Stent was used for coronary artery protection in one (5.2%) case as it was high-risk case for coronary artery occlusion.

Table 1 Baseline characteristics of patients.

Clinical characteristics	Mean ± (SD), n (%)
Age	75.2±7.5 years
Female	10 (52%)
Paced rhythm	Two (10.5%)
PCI	Three (15.7%)
Bicuspid Aortic valve	Four (21%)
Low flow low gradient	Two (10.5%)

Table 2. CT findings.

CT parameter	Mean (SD) /n(%)
Mean annular diameter (mm)	22.3+-2.1
Sinus of Valsalva (mm)	31.5+4.8
Sinotubular junction (mm)	29.1+4.
Left coronary height (mm)	13.3+2.7
Right coronary height (mm)	16.1+3.2
Annulus area (mm2)	385.5+73.4
Annulus perimeter (mm)	70+6.6

Table.3 Valve type.

Valve Type	n	%
Balloon Expandable	12	63.1
Myval	11	57.9
Sapien	1	5.2
Self Expandable	7	36.8
Evolut	5	26.4
Navitor	1	5.2
Potrico	1	5.2

Table 4. Outcomes and complications.	
Complications	N%
Vascular Site Complications	Two (10.5%)
Permanent Pacemaker	Two (10.5%)
PVL Mild	One
Major Bleeding	0
Stroke	0
Death	0

DISCUSSION

This is the first report to describe the clinical experience of TAVI in a tertiary referral hospital, which is also the first hospital in Nepal to introduce this technology and having the largest case volume in Nepal up until the end of 2024. It captures the real-world experience of TAVI in Nepal dealing with a new therapeutic modality that is both expensive and technically demanding. The clinical outcomes of our cohort show very promising results. Our TAVI experience reproduces the results reported by other well-known centers.[9-14] With proper patient selection and experienced proctor supervision we reached a 100% success rate with excellent procedural and clinical outcomes despite being in the beginning of our TAVI program.

Complication of TAVI in our cohort compared well with the landmark trials. Significant aortic regurgitation secondary to paravalvular leak (PVL) is a unique problem not uncommonly encountered following TAVI in contrast to patients who undergo SAVR in whom there is usually no residual leakage.[15,16] One study showed that even mild PVL after TAVI is associated with higher mortality rate at 2 years.[17] The rate of moderate or severe PVL in both the PARTNER 1B [9] and US Core Valve pivotal trial[18] was approximately 7%. No moderate or severe PVL was noted in our study, only one patient had mild PVL at discharge.

Stroke is one of the most disabling complications during TAVI. The major stroke rate in both the PARTNER and US CoreValve pivotal trial was approximately 5%. [9,18] Major stroke rates in one meta-analysis of more than 10 000 patients were 3.3%.[19] Our zero-stroke rate may be related to small sample size, but may also reflect careful patient selection and procedural planning. More cases of stroke would be expected if more patients were treated. The etiology of stroke after TAVI is multifactorial and includes embolism of valvular material during balloon valvuloplasty, device manipulation across an atheromatous aorta, and atrial fibrillation.[20] Multiple strategies to reduce periprocedural stroke have been attempted including direct stenting, avoidance of pre- or post-dilation, use of cerebral protection devices and different antithrombotic regimens.[21,22]

Conduction abnormality is another common complication following TAVI. The reported rate of permanent pacemaker implantation to treat high-grade heart block varies from 10% to 30% and it depends very much on type and implantation depth of the device.[23,24,25] The rate reported in the US CoreValve pivotal trial was 20% at 1 month and 22% at 1 year.[18] The permanent pacemaker implantation rate in our cohort was Two (10.5%) patients.

Major vascular complications occurred in approximately 6% of patients in the US CoreValve pivotal trial[18] and 11% in PARTNER 1 trial.[9] Rates of major vascular complications in different observational and randomized trials range from 5% to 17%.[19] The lower rate in the US CoreValve pivotal trial can be explained by the smaller size of the introducer sheath for CoreValve (18 Fr) compared with the much bigger 22-24 Fr sheath for the first-generation SAPIEN device in the PARTNER 1 trial.[9] For the same reason and the relative smaller size of peripheral vessels in an Asian population, higher rates of vascular complications are expect. Our complication rate of 10.4% is comparable to Hong Kong (8.9%) cohort which is compatible with the worldwide standard.[14]

Overall, the success of the procedure depends not only on the technical requirement in a very high-risk group of patients but also a comprehensive, multidisciplinary team approach. This 'heart team' approach is the cornerstone of the rapidly developing field of structural heart intervention and preferred strategies in dealing with anticipated complications.[26]

In this study, we evaluated the in-hospital outcomes of Transcatheter Aortic Valve Implantation (TAVI) at Shahid Gangalal National Heart Centre, Kathmandu, Nepal. Our findings, while in line with international data, reveal unique challenges and opportunities specific to our context.

The financial burden of TAVI procedures remains a significant concern in Nepal. Generally, these procedures are more expensive than surgical aortic valve replacements, which limits accessibility for many patients. Lack of governmental reimbursement have resulted in a slow and limited number of TAVI patients in Nepal. Healthcare systems need to consider models for subsidizing costs to improve patient access to this

lifesaving intervention.There is a also critical need for specialized training in TAVI procedures among our local cardiologists and surgeons. The relatively recent introduction of this technology necessitates ongoing education and practice to ensure that our healthcare providers are proficient in these advanced techniques.

Our early experience with TAVI at Shahid Gangalal National Heart Centre adds valuable insights to the existing literature. Specifically, we provide data that reflects the performance and safety outcomes in a South Asian context, demonstrating comparable results to those reported in higher-income countries. Importantly, we highlight the necessity of adapting TAVI practices to fit local healthcare environments, which can serve as a reference point for other countries with similar challenges. The outcomes observed in our center indicate that with the right training and resources, TAVI can be safely implemented and could become a viable alternative to surgical methods in resource-constrained settings. Observational study, single-Centre design, small sample size are the major limitations of this study.

CONCLUSIONS

Our initial results are promising, addressing the unique challenges highlighted will be crucial in optimizing TAVI delivery in Nepal and enhancing access for our patients. Continued research and collaboration within the region are essential to improve outcomes and establish best practices tailored to the local context.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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