



## Short Communication

## Early and late outcomes after transcatheter aortic valve implantation in Indian subpopulation



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Degenerative Aortic stenosis (AS) is one of the most common valvular heart disease in elderly, which if left untreated has very low 5 year survival rate of 18%.<sup>1</sup> Number of trials led to the initial approval of TAVR for high risk and inoperable patients, which has further expanded to include low surgical risk cases.

Present study included a total of 23 patients, who underwent TAVR between year 2017 until October 2020, and were subsequently followed up over a period of one year. Patients' pre-procedural, procedural and post procedural characteristics were obtained including the symptomatic status, electrocardiogram, Echocardiography parameters, CT parameters, hemodynamic data and coronary angiogram.

Age of presentation ranged from 60 to 88 years. 88.7% of patients had either STS or Euroscore2 score of >4%. Mean AS gradient obtained on echocardiography was  $46 \pm 19.8$  mm Hg, while as per hemodynamic data peak to peak gradient was  $49.2 \pm 31$  mm Hg and mean pressure gradient was  $46.3 \pm 28$  mm Hg. Severe Aortic regurgitation (AR) was seen in 4 (17.4%) patients. 3 (13%) patients had bicuspid aortic valve, 1 (4.3%) had native valve pure aortic regurgitation, 3 (13%) had degenerated aortic bioprosthesis and 1 (4.3%) had low flow low gradient severe AS (Tables 1 and 2).

16 (69.9%) patients underwent TAVR using self-expanding 3rd generation Evolute R, while balloon expandable valve was used in rest, including Edward Sapien 3 in 2 (8.7%) and MyVal in 5 (21.7%). All cases were done in general anesthesia using femoral access. None of the patient had significant gradient or aortic regurgitation post valve implantation. Post TAVR mean AR index was 0.43. Post TAVR complete heart block (CHB) developed in 2 (8.7%) patients, both with baseline right bundle branch block, and subsequently underwent permanent pacemaker implantation during the initial hospital stay. Access site complications were seen in 6 (26.6%), of which 2 (8.7%) patients needed surgical intervention. Stroke was seen in 3 (13%) patients during the initial hospital stay, but had only transient symptoms with no residual weakness (Tables 3 and 4).

At the end of one year there was no mortality. 4 (17.3%) patients had re-hospitalization due to heart failure. Other complications included prosthetic valve mismatch in 2 (8.6%) and prosthetic valve leaflet thrombosis in 2 (8.6%). One (4.3%) patient during follow-up had holter documented long sinus pause of 6.8 s for which pacemaker implantation was done. 1 (4.3%) patient with low flow low gradient AS, severe left ventricular dysfunction and documented tachy-brady syndrome underwent left bundle branch optimized CRT. By end of one year the cumulative MACE, which included mortality or heart failure hospitalization or ACS or CVA, was seen in 30% (Figs. 1 and 2).

The principal finding in our study was no mortality upto 1 year followup. This was in contrast to 13.9% observed from US TAVI registry<sup>2</sup> and corresponding Indian study with all cause mortality of 8%.<sup>3</sup> Present study showed stroke rate of 13% which was quite high compared to other major studies as data from TVT registry report stroke rate of 2.5% at 30 days and 4.1% at 1 year and zero case from the Indian study.<sup>3,4</sup>

In this study TAVR was found to be an effective alternative for severe AS patients with no mortality up to 1 year follow-up. The MACE events were mainly contributed by increased heart failure hospitalization and stroke rate.

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**Table 1**  
Baseline demographics.

AGE (YEARS)	60-88 (74)
Gender	Male- 16 (69%) Female – 7 (30.4%)
Body mass index BMI (kg/m <sup>2</sup> )	25.5 ( ± 3.96)
Frailty	6 (26.1%)
Diabetes	8 (34.8%)
Hypertension	18 (78.3%)
Dyslipidemia	12 (52.1%)
Chronic obstructive airway disease	10 (43.5%)
Stroke	1 (4.3%)
Peripheral arterial disease	4 (17.4%)
Chronic kidney disease	2 (8.7%)
Porcelain aorta	2 (8.7%)
Previous myocardial infarction	6 (26.1%)
Previous PCI	3 (13%)
Previous CABG	7 (30.4%)
Previous balloon aortic vavuloplasty	0%
Previous aortic vavle replacement	3 (13%)
Previous mitral valve replacement	1 (4.3%)
Previous radiation	1 (4.3%)
Syncope/Presyncope	3 (13%)
Nyha	IV- 9 (39.1%) III- 9 (39.1%) II- 5 (21.7%)
Hemoglobin (GM/DL)	12.45 (9.8–15.9)
Creatinine (MG/DL)	1.1 (0.54–1.55)
NT PROBNP (PG/ML)	3050 (342–20000)
Euro score 2	7.6 ± 5.24 (2.5–19.59)
STS Score	5.5 ± 1.88 (3–9.65)

PCI- Percutaneous coronary intervention; CABG- Coronary artery bypass graft.

**Table 2**  
Hemodynamic data at baseline.

Left ventricle systolic pressure (mm Hg)	170 ± 31 (120–220)
Left ventricle end diastolic pressure (mm Hg)	19.8 ± 9.6 (6–48)
Aortic systolic pressure (mm Hg)	119.3 ± 22.36 (90–164)
Aortic diastolic pressure (mm Hg)	49.1 ± 15.5 (30–70)
Peak to peak pressure gradient (mm Hg)	49.2 ± 31 (0–139)
Mean pressure gradient (mm Hg)	46.3 ± 28 (0–120)
Aortic regurgitation	
None	9 (39.2%)
Mild	7 (30.4%)
Moderate	3 (13.0%)
Severe	4 (17.4%)

**Table 3**  
Procedural characteristics and post TAVR outcomes.

Anaesthesia	General: 23 (100%)
Access	Femoral:23 (100%)
Valve	Balloon expandable: Myval-5 (21.7%) Edward Sapien 3–2 (8.7%) Self expandable Corevalve- 16 (69.9%)
Valve size	
21	2 (8.7%)
23	8 (34.8%)
26	6 (26.1%)
29	6 (26.1%)
34	1 (4.3%)
Predilation	18 (78.3%)
Post dilation	6 (26.1%)
Post implantation mean gradient	5 mm hg
Post procedure need for pacemaker	2 (8.7%)
Access site complication	6 (26.6%)
Post TAVR- trop t (pg/ml)	33.5 (230–0)
Post TAVR- Nt ProBNP (pg/ml)	2075 ± 1900 (278–8000)
Length of hospital stay (days)	7 (5–16)
Symptom worsening	0%
Post TAVR- Acute coronary event	0%
Post TAVR mortality	0%
Post TAVR Cerebrovascular accident	3 (13%)
TIA (transient ischemic attack)	1 (4.3%)
Stroke	2 (8.7%)
Renal dysfunction	1 (4.3%)
Prolonged ventilation (>24 h)	1 (4.3%)
Blood transfusion	6 (26.1%)
Tachy-arrhythmia	0%
Emergency surgery	0%

TAVR- Transcatheter aortic valve replacement.

**Table 4**  
Post TAVR outcomes during followup.

Characteristics	1 month followup	1 year followup
Nyha		
I	14 (60.9%)	11 (47.8%)
II	8 (34.8%)	9 (39.1%)
III	0	0
IV	1 (4.3%)	3 (13%)
Ejection fraction(%)	58.56 ± 11 (30–73)	60.3 ± 10 (32–80)
Prosthetic valve gradient (mmHg)	6.6 (0–45)	9.5 (0–37)
Aortic regurgitation		
None	10 (43.5%)	11 (47.8%)
Trivial	10 (43.5%)	9 (39.1%)
Mild	3 (13%)	3 (13%)
Moderate	0	0
Acute coronary event	0	0
Cerebro vasular accident	0	0
Patient prosthesis mismatch	2 (8.7%)	0
Valve leaflet thrombosis	0	2 (8.7%)
Arrhythmia		
Sick sinus syndrome	0	2 (8.7%)
Heart failure admission	1 (4.3%)	3 (13%)
Other complications		
Foot gangrene-limb amputation	0	1 (4.3%)
Mortality	0	0
Drug compliance	23 (100%)	21 (91.3%)

TAVR- Transcatheter aortic valve replacement.

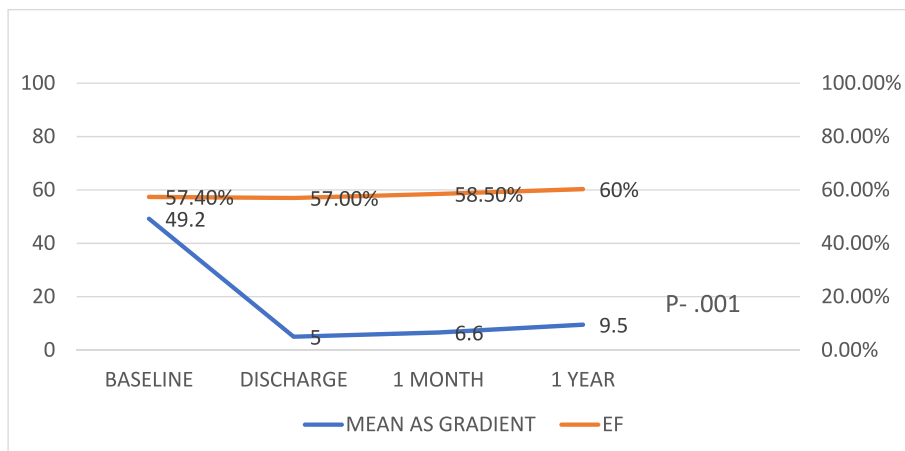


Fig. 1. Followup aortic valve gradients and Left ventricular function (AS- Aortic stenosis; EF- Ejection fraction).

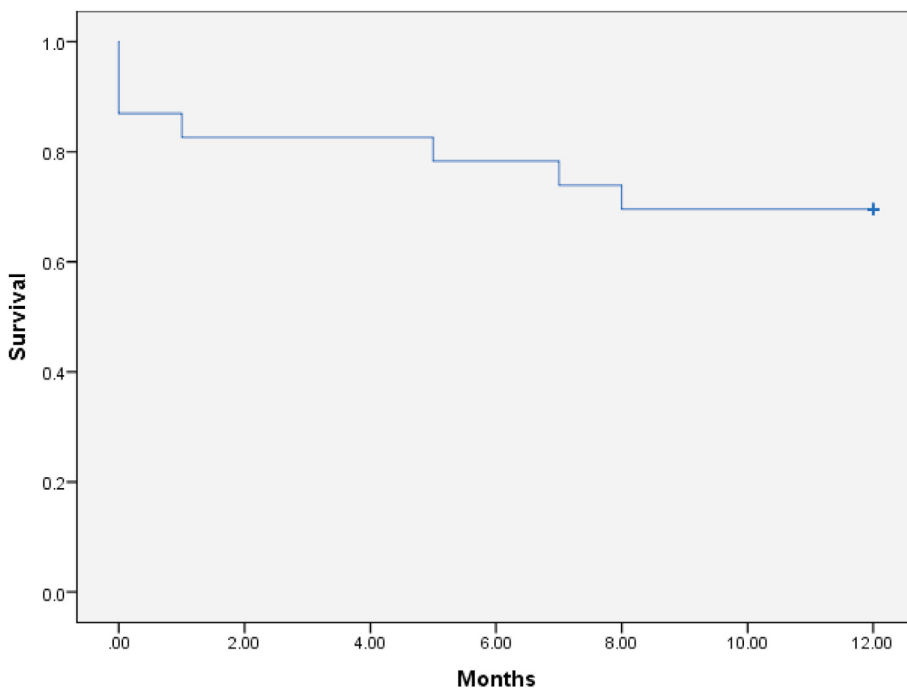


Fig. 2. Kaplan Meier survival analysis showing event free survival.

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**Declaration of competing interest**

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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**Abbreviations**

- TAVR/TAVI: transcatheter aortic valve replacement
- CT: computed tomography
- AS: aortic stenosis
- CHB: Complete heart block
- CRT: Cardiac resynchronisation therapy
- ACS: Acute coronary event
- CVA: Cerebrovascular accident