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Original Research Article

EARLY EXPERIENCE WITH TRANSCATHETER AORTIC VALVE REPLACEMENT (TAVR) WITH BIO-PROSTHETIC VALVE IN A TERTIARY CARE HOSPITAL IN SOUTH-INDIA

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Abstract:
Background: Transcatheter aortic valve replacement has revolutionized the treatment of patients with severe aortic stenosis, who are considered intermediate to high risk for surgical aortic valve replacement. However, the adoption of this treatment modality has been remarkably low in Asian population as compared to the western world, especially in India.
Aim: To describe the early experience of the TAVR program at our tertiary care hospital.
Materials and methods: Retrospective review of patients who underwent TAVR at Amrita Institute of Medical Sciences, Kochi between 01/03/ 2016 to 30/04/2021.
Results: There was a total of 19 patients who underwent TAVR (n=19), of which 5 (26 %) were females. 11 patients underwent TAVR with Medtronic self-expandable valves, and 8 patients with balloon expandable My Val Mean age of the patients was 75.93 +/- 9 years. (Mean □SD). Mean STS score was 8.34 +/- 9.5. Mean Euro score is 8.3 +/- 11.5. Implantation was successful in 18 patients, in one patient the device got dislodged the next day. Permanent pacemaker was implanted pre-procedure in two patients and post-procedure in two patients. There was significant coronary artery disease in 9 patients, and amongst them three underwent concomitant PCI along withTAVR. 1 patient had a left ventricular (LV apical clot) and TAVR was done with cerebral protection. The mean follow up was 24 +/-6 months. 3 patients developed mild paravalvular leak, and 2 patients had mortality: one patient died 5 months post-procedure due to pulmonary oedema secondary to LV dysfunction and associated CAD, second

developed pericardial effusion in hospital post operatively probably attributed to bleeding diathesis in the background of Polycythaemia Vera and CAD, and DIC.
Five patients could not be followed up.
Conclusion: TAVR procedure is feasible in severe aortic stenosis patients at intermediate to high operative risk for surgical AVR in the Indian context. With aging of the population, further reductions in cost, expanding indications and innovative technologies, TAVR adoption could certainly increase in India.

1. INTRODUCTION

The first transcatheter implantation of an aortic valve bio prosthesis was done by Dr Alan Cribier in 2002. Since then, TAVR technology has become a medical breakthrough of sorts. The technology has revolutionized the treatment of patients with symptomatic severe aortic stenosis (AS), who are deemed inoperable/high risk for SAVR. The last decade has seen an exponential increase in the usage of TAVR, especially in the developed western world. TAVR has been recognized as a reasonable alternative treatment strategy for symptomatic severe aortic stenosis patients who are at intermediate risk for SAVR.
Supported by positive results from numerous landmark randomized controlled trials and large national registries, more than 1,00,000 TAVR procedures have been performed[1-7]. Most of these cases have been performed in Europe and USA.
However, as compared to the western world, only about 10,000 TAVR cases have been performed in Asia. Most of these cases have been performed in Japan, followed by countries like China and Korea. Edward Sapien balloon expandable valves (Edwards Lifescience, Irvine, CA, USA) are by far the most commonly used TAVR valves in Asia, followed by the self-expandable Medtronic Core Valve (Medtronic Incorporation, Minneapolis, MN, USA)[8].

Asia has a population of 4.4 billion, in comparison to Europe's population of 741 million. This leaves a lot to be desired in the uptake of TAVR technology in Asia. Possible reasons for slow adoption rate of this technology include lack of government funding resulting in reimbursement challenges, high cost of TAVR devices, lack of screening and treatment infrastructure, lack of a Heart Team and structured training programme, relatively lower life expectancy and the presence of potentially challenging anatomical features[8]. In the Indian context, the adoption of the technology has been even slower, with cost of the device being the major hurdle in its widespread application. Barring the very first TAVR experience in India, there is a dearth of Indian literature on this treatment modality. In the background of absence of large/smallscale clinical series/registry data, we present our initial experience of 19 cases with self-expandable Medtronic CoreValve (Medtronic Incorporation, Minneapolis, MN, USA). And balloon expandable My Val.

2. RESULTS

Table 1: Baseline Characteristics

Baseline characteristics (n)	Value (n=19)
Age	75.93+/- 9.7 (Mean SD)
STS score	8.3 +/- 9.5
Euro II Score	8.3 +/- 11.5
AS gradient (ECHO)	41.4 20.32
LVEF	49.29 +/- 14.6
Comorbid conditions	
Diabetes mellitus	12
Systemic hypertension	8
Dyslipidemia	17
Chronic kidney disease	5
Chronic obstructive pulmonary disease	3
Obstructive sleep apnea	2
Prior stroke/TIA	3
Peripheral artery disease	2
CLD	2
H/O CAD	9
Previous arrhythmias	
Atrial fibrillation	1
Complete heart block	1
History of previous cardiac surgeries/procedures	
CABG	3
SAVR	3
PPI	2
Intracardiac clot	
LA/LAA clot	1
LV clot	1
NYHA Functional Class	
I	0
II	2
III	15
IV	2
Clinical Presentation	
Heart Failure	3

ACS (NSTEMI) with heart failure	2
Referral/outpatient	14

Table 2: Procedural characteristics

Procedural characteristics (n)	Value (n=19)
Transfemoral access	19
Non- transfemoral access	0
Vascular access complications	
Aortoiliac calcification	1
Other complications	
Cardiac arrest/CPR	2
Prophylactic PPI	1
Concomitant PCI	3
Valve-in-valve procedure	3
Cerebral protection	1
Femoral cutdown	2
Percutaneous device closure	17
Rapid pacing during TAVR implantation	19

Table 3: Clinical Outcomes of TAVR

Clinical Outcomes of TAVR (n)	**Value (n=5)**
Conversion to surgical AVR	1
Pericardial effusion	1
Myocardial infarction	0
Stroke	0
Endocarditis	0
Renal failure requiring dialysis	0
Paravalvular leak	
None	12
Trace	4
Mild	3
Moderate	0
Post-op arrhythmias	
Complete Heart Block	1
Atrial fibrillation	1
Patient prosthesis mismatch	1
Other complications	

Electrolyte disturbances	1
Post TAVR delirium	2
Readmission with heart failure	1
Death within 30 days	1
Death after 30 days	1

There was a total of 19 patients who underwent TAVR (n=19), of which 5 (26 %) were females. 11 patients underwent TAVR with Medtronic self-expandable valves, and 8 patients with balloon expandable My Val. Mean age of the patients was 75.93 +/- 9 years. (Mean □SD). The minimum age is 58 years and maximum 90 years. Mean STS score was 8.34 +/- 9.5. Mean Euro score is 8.3 +/- 11.5. Implantation was successful in 18 patients, in one patient the device got dislodged next day of procedure and was taken for emergency surgery. Permanent pacemaker was implanted pre-procedure in two patients and post-procedure in two patients. There was significant coronary artery disease in 9 patients, and amongst them three underwent concomitant PCI along with TAVR. 1 patient had a left ventricular (LV apical clot) and TAVR was done with cerebral protection. The mean follow up was 24 +/-6 months. 3 patients developed mild paravalvular leak, and 2 patients had mortality: one patient died 5 months post-procedure due to pulmonary oedema secondary to CAD and LV dysfunction, another developed pericardial effusion within 1 week post procedure secondary to bleeding diathesis and DIC in the background of JAK-2 mutation positive Polycythemia Vera. Five patients could not be followed up. One patient had complete heart block post procedure requiring dual chamber pacemaker. Associated comorbidities included diabetes mellitus 12 patients, hypertension in 8 patients, CKD in 5 patients, COPD and CVA in 3 patients each, PVD and CLD in 2 patients. The size of the valve varied from minimum 22 to maximum 34 mm.3 patients had valve in valve procedure. The mean LV- Aorta gradients was 49.2 +/- 14.6, and mean EF was 54.2 +/- 10.5. Two patient required femoral cut down due to difficult vascular access due to aortoiliac calcification. One patient required CPR during the procedure and was resuscitated. All procedures had intraoperative use of TEE.

3. DISCUSSION

The present study describes our early experience with self expandable aortic bio-prosthesis using Medtronic self-expanding aortic bio-prosthesis.

A total of 19 cases were performed in our institute from March 2016 to April 2021, of which 5 were females. The study population was elderly, and the mean age of the study population was 75.93 +/- 9.7. This age group was slightly higher as compared to similar reported studies of early TAVR experience[9-11].

The cases performed in our institute were significantly high risk for SAVR, considering that the mean STS score was 8.3 +/- 9.5. This was substantially higher as compared with other similar studies[11].

All the cases were discussed in a heart team meet, and underwent TAVR with self expandable aortic bio-prosthesis.

Significant CAD is often associated with severe AS, as evidenced by a large "real-world" experience from the Society of Thoracic Surgeons (STS) and American College of Cardiology (ACC) Transcatheter Valve Therapies Registry. The incidence of CAD in that registry among 12,182 patients treated with TAVR was 63%[12]. But the question as to whether concomitant PCI can be performed in the same setting as TAVR is unanswered, as is the time interval between the two treatment modalities, if they cannot be performed together. Some small scale studies[13] and recent meta-analysis[14] show that both modalities of treatment can be performed safely together. A recent larger study[15] also seems to show no difference between concomitant versus staged PCI and TAVR. However, other single centre studies suggest that incomplete coronary revascularization may be associated with worse outcomes in patients treated with TAVR and PCI [16,17]. Whether to revascularize CAD in TAVR candidates remains an area of uncertainty and ongoing clinical investigation, as there is lack of randomized clinical trials in this regard. The recently concluded ACTIVATION TRIAL [22] comparing a course of pre procedure PCI versus no PCI in patients undergoing TAVI with significant CAD found no difference in primary end points of death or re hospitalization at one year follow up between the two treatment strategies.
Our study had 3 patients who underwent concomitant PCI and TAVR, and one of them died after 5 months of procedure due to pulmonary edema.

Stroke is the most feared and devastating complication post TAVR. In the PARTNER trial, stroke risks were higher after TAVR than SAVR[18,19]. Hence, any intervention to minimize the incidence and the risks for stroke during TAVR is of utmost importance. The SENTINEL trial[20] showed that transcatheter cerebral embolic protection (TCEP) was safe, captured embolic debris in 99% of patients, and did not change neurocognitive function. But the reduction in new lesion volume on magnetic resonance scans was not statistically significant. However, SENTINEL device has been US-FDA approved for stroke prevention during TAVR, and many others are in the pipeline.
In our study, 1 patient underwent TAVR under cerebral protection with Spider device (distal embolic protection device) in both carotids, as he had an LV apical clot (which is also a relative contraindication to TAVR). He was on follow up for 3 years but lost to follow up since last 1 year.

Low flow low gradient (LF-LG) AS is a difficult subset of AS patients as there are considerable ‘gray zones’, both for diagnosis and optimal management of these patients. The most

counterintuitive type, however, is the so called 'Paradoxical' LF-LG severe AS subtype, or severe AS with normal EF.

The recent TOPAS TAVI registry concluded that TAVR was associated with good periprocedural outcomes in patients with LF-LG AS[21].

In our study, 5 of the 19 patients had LF-LG AS (4 Classical and 1 Paradoxical). 3 of them are doing well on follow up and 1 died after 5 months of procedure, and 1 is lost to follow up. On follow up, 2 patients had persistent LV systolic dysfunction and were admitted with heart failure, there was improvement in ejection fraction in one patient signifying LV dysfunction secondary to AS. A diagnosis of post-TAVI delirium was made in two of the patients.

Limitations

Due to this being an early experience with TAVR in South India, the modest sample size is the most obvious limitation of this study, based on which large scale conclusions are difficult to achieve.

But there is an opportunity to do large scale studies as the number of cases grow in this country, and with more patients and expertise in this context, there is always a scope for further large registries.

4. CONCLUSION

TAVR procedure is feasible in severe aortic stenosis patients at intermediate to high operative risk for surgical AVR in the Indian context, with acceptable results.

With aging of the population, further reductions in cost, expanding indications and innovative technologies, TAVR adoption could certainly increase in India.

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