



Single-center experience of 105-minimalistic transfemoral transcatheter aortic valve replacement and its outcome



Ravinder Singh Rao ^{a, *}, Samin Sharma ^b, Navneet Mehta ^c, Ajeet Bana ^d, Hemant Chaturvedi ^e, Rajeev Gupta ^f, Prashant Varshney ^c, Kailash Gadhwal ^g, DharamPrakash Saran ^g, Prashant Diwedi ^g

^a Structural Heart Disease and TAVR Program, Interventional Cardiology, Eternal Hospital, Jaipur, India

^b Eternal Hospital Jaipur, International Clinical Affiliations, Clinical and Interventional Cardiology, Mount Sinai Hospital, New York, USA

^c Department of Cardiac Anesthesia, Eternal Hospital, Jaipur, India

^d Department of Cardiothoracic Surgery, Eternal Hospital, Jaipur, India

^e Department of Non-Invasive Cardiology, Eternal Hospital, Jaipur, India

^f Department of Internal Medicine, Eternal Hospital, Jaipur, India

^g Cardiology, Eternal Hospital, Jaipur, India

ARTICLE INFO

Article history:

Received in revised form

11 December 2020

Accepted 29 January 2021

Available online 3 February 2021

Keywords:

Transcatheter aortic valve replacement

Aortic stenosis

Conscious sedation

Transfemoral

Minimalist

ABSTRACT

Introduction: Transcatheter aortic valve replacement (TAVR) increases worldwide, and indications expand from high-risk aortic stenosis patients to low-risk aortic stenosis. Studies have shown that minimalistic TAVR done under conscious sedation is safe and effective. We report single-operator, the single-center outcome of 105 minimalist transfemoral, conscious sedation TAVR patients, analyzed retrospectively.

Methods: All patients underwent TAVR in cardiac catheterization lab via percutaneous transfemoral, conscious sedation approach. A dedicated cardiac anesthetist team delivered the conscious sedation with a standard protocol described in the main text. The outcomes were analyzed as per VARC-2 criteria and compared with the latest low-risk TAVR trials.

Results: A total of 105 patients underwent transcatheter aortic valve replacement between July 2016 to February 2020. The mean age of the population was 73 years, and the mean STS score was 3.99 ± 2.59 . All patients underwent a percutaneous transfemoral approach. Self-expanding valve was used in 40% of cases and balloon-expandable valve in 60% (Sapien3™ in 31% and MyVal™ in 29%) of cases. One patient required conversion to surgical aortic valve replacement. The success rate was 99 percent. The outcomes were: all-cause mortality: 0.9%, stroke rate 1.9%, New pacemaker rate 5.7%, 87.6% had no paravalvular leak. The mild and moderate paravalvular leak was seen in 2.8% and 1.9%, respectively. The mean gradient decreased from 47.5 mmHg to 9 mmHg. The average ICU stay was 26.4 h, and the average hospital stay was 5.4 days. Our outcomes are comparable with the latest published low-risk trial.

Conclusion: Minimalist, conscious sedation, transfemoral transcatheter aortic valve replacement when done following a standard protocol is safe and effective.

© 2021 Published by Elsevier B.V. on behalf of Cardiological Society of India. This is an open access article under the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>).

1. Introduction

Transcatheter aortic valve replacement (TAVR) has become a standard of care for patients with severe aortic stenosis at high-risk for surgery. In severe aortic stenosis patients, who are at low risk for

surgery, TAVR was non-inferior to surgical aortic valve replacement (SAVR).^{1,2} In the PARTNER II trial sub-analysis, 88% of patients underwent transfemoral TAVR, and the results were superior to surgical aortic valve replacement (SAVR). The alternative access approach has a higher complication rate like bleeding, stroke, prolonged hospitalstay, and peri-procedural myocardial infarction than transfemoral TAVR.³ In the published reports with first-generation TAVR valves, minimalistic TAVR was done in selected cases. However, minimalistic TAVR under conscious sedation can be

* Corresponding author. Director TAVR and Structural Heart Disease Eternal Hospital, 3A Jagatpura Road, Jaipur, India.

E-mail address: rsrao.sn@gmail.com (R.S. Rao).

done with the present generation valves in all comers. Use of conscious sedation TAVR has been shown to shorten ICU and hospital stay and decrease mortality.^{4,5}

We report our single-center, single-operator experience of 105 TAVR cases done as a minimalist approach: percutaneous transfemoral, conscious sedation instead of general anesthesia, and transthoracic echocardiogram and its outcomes.

2. Methods

2.1. Minimalist TAVR

We describe minimalistic TAVR, which was done in the cardiac catheterization laboratory, under conscious sedation, no transesophageal echocardiogram, and percutaneous femoral approach.

TAVR specific diagnostic workup included electrocardiogram (ECG)-gated, contrast-multidetector computed tomography (MDCT) of heart, aorta, and ileo-femoral vessels. A pre-anesthetic check-up by a dedicated cardiac anesthetist for conscious sedation was done before TAVR.

All patients except one underwent ECG gated contrast MDCT angiography with the use of 120 ml of contrast. The study was ECG gated with 0.6 mm of slice thickness for the annulus assessment and 1 mm slice thickness for aortogram. The annulus assessment was done in 35%–45% RR interval. The access vessels were assessed from ascending aorta to descending aorta and pelvic vessels from iliac to the femoral bifurcation. The valve was selected based on the patient’s anatomy and access vessel size to do all procedures transfemoral. The self-expanding valve was sized based on the perimeter, and the balloon-expandable valve was sized based on the annulus area.

2.2. Inclusion and exclusion criteria

The retrospective data of patients who underwent transcatheter aortic valve replacement at our institution from January 2016 to March 2020 was analyzed after obtaining local ethics committee approval. Inclusion Criteria: Patients with severe aortic stenosis based on Echo aortic valve area less than 1 cm², mean gradient more than 40 mmHg or aortic valve velocity more than 4 m/s and life expectancy of more than two years and after heart team

evaluation, underwent transcatheter aortic valve replacement. Exclusion criteria: Patients whose anatomy was not amenable to TAVR, like large annulus and life expectancy less than one year, were excluded.

2.3. Conscious sedation protocol

Eutectic mixture of local anesthetic (EMLA) was applied 2 h before the procedure at both the groins, radials, and sides of the neck. Central line and radial line were placed on the day of the procedure in all patients. Intraoperative continuous cerebral oximetry was used in all the patients. IV dexmedetomidine infusion was used for sedation. A mixture of 2% Lidocaine and 0.5% Bupivacaine was used for local site administration. Bispectral index (BIS) monitor was used for all patients to monitor the depth of anesthesia during the procedure, and the score was maintained between 50 and 75. Intraoperative nasal CPAP was used in all patients. The infusion was stopped immediately on completion of the procedure. The patient was shifted out of the cath lab after a neurological examination and ruling out a stroke.

2.4. Minimalist procedure protocol

The standard protocol was followed for all patients. TAVR was performed in a catheterization laboratory. The radial line and central line were inserted. Conscious sedation protocol was followed as described above. Percutaneous femoral access was obtained either under fluoroscopy guidance or by ultrasound guidance. Two Perclose Proglide (Abbott, Santa Clara, California) was used in the majority (number 100) of the cases, and one ProGlide and one Angio-seal were used (Terumo, New Jersey, USA) in a few (number 5). A 5 F pigtail catheter was used to obtain an aortogram and identify the annular plane view. The aortic valve was crossed using a 0.035 straight tip wire with Amplatz Left-2 catheter in most cases. The balloon-tipped temporary pacemaker was placed from the groin. Pre-dilatation was done in all bicuspid cases, horizontal annulus, and in very severe aortic stenosis (mean gradient more than 60 mmHg and aortic valve area less than 0.4 cm²). Post dilatation was done if there was more than trivial aortic regurgitation or mean gradient more than 10 mmHg after valve deployment. Post-procedure transthoracic echocardiogram

Table 1
Minimalist transcatheter aortic valve replacement protocol.

MINIMALIST TAVR PROTOCOL		
PRE TAVR	PERI-TAVR	POST TAVR
<ul style="list-style-type: none"> • ECHO • PFT • HEMATOLOGY • URINE ROUTINE & CULTURE • CHEST X-RAY • HbA1C/TSH • CHEST PHYSIOTHERAPY • INCENTIVE SPIROMETERY • PRE-ANAESTHETIC CHECK UP • 2 UNITS PRBC IN RESERVE 	<ul style="list-style-type: none"> • RADIAL LINE • CENTRAL LINE • CONDOM CATHETER FOR MALES • LOCAL ANAESTHESIA (LIDOCAINE + BUPIVACAINE) • CONSCIOUS SEDATION (DEXMEDETOMIDINE INFUSION) • BIS MONITOR • CEREBRAL OXYMETER • NASAL CPAP • PERCUATNEOUS ACCESS • NO PA CATHETER • TPM REMOVED IN CATH-LAB FOR MAJORITY OF CASES • PPM IMPLANTED FOR PATIENTS WITH BASELINE TRIFASCULAR AV BLOCK CONCOMITANT WITH TAVR • TTE • NEUROLOGICAL ASSESSMENT 	<p>ICU (OVERNIGHT)</p> <ul style="list-style-type: none"> • MONITORING OF VITALS AND ACCESS SITE • Q x15 for 4 h • Q x 30 min for 6 h • Q 4 h for 12 h • ECG, CBC, Chest X -Ray • Medications (Loading with antiplatelets if required, IV antibiotics, Anticoagulation from next day if indicated). <p>POST OP DAY 1</p> <ul style="list-style-type: none"> • Radial and central line removal. Mobilization in ICU. ECG, CBC, RFT and Echo. • Transfer to the room <p>DAY 2 till discharge.</p> <ul style="list-style-type: none"> • Rehabilitation • Patient Education • Medication optimization • 24-h Holter in selected patients before discharge

was done in the cath lab. The sheath was removed. The vascular closure device was deployed, and hemostasis was confirmed by doing a digital subtraction angiogram of the pelvic and femoral vessels. Neurological examination was performed in the cath lab, and then the six French arterial access sheath was removed. The temporary pacemaker was removed in the majority of the cases. It was left in high-grade AV block post procedures and shifted to the neckline from the femoral vein. The monitoring was as per the protocol in Table 1. The patient was shifted out of the ICU on the second day and then discharged.

3. Results

3.1. Patient characteristics

A total of 105 patients underwent transcatheter aortic valve replacement (TAVR) between July 2016 to February 2020. Baseline characteristics are shown in Table 2. The mean age of the

Table 2
Baseline characteristics of the patients undergoing minimalist transcatheter aortic valve replacement.

Variable, n (%)	n = 105
Age, Years Mean \pm SD	72.93 \pm 9.25
Gender, n (%)	
Female	36 (36.54)
Male	64 (63.46)
BMI, Mean \pm SD	26.85 \pm 5.29
BSA	1.76 \pm 0.24
Society of thoracic surgeons score, Mean \pm SD	3.99 \pm 2.79
NYHA	
I	00
II	14 (12.50)
III	82 (78.85)
IV	9 (8.65)
Medical History, n (%)	
Angina	28 (26.92)
Syncope	10 (9.62)
Diabetes mellitus	26 (25.00)
Hypertension	71 (68.27)
Coronary artery disease	46 (44.23)
PTCA	17 (16.35)
CABG	18 (17.14%)
Peripheral or cerebral vascular disease, or history of stroke	11 (10.58)
COPD	29 (27.88)
Cirrhosis	2 (1.92)
Chronic kidney disease	21 (20.19)
End stage renal disease	3 (2.88)
eGFR, Mean \pm SD	59.11 \pm 22.13
Neoplasia	5 (4.81)
Hyperthyroid	00
Hypothyroid	25 (24.04)
Smoking	19 (18.27)
Previous non-cardiac Surgery	27 (25.96)
Allergy	18 (17.31)
ECG Admission	
AF	4 (2.88)
LBBB	6 (4.81)
PACED	3 (0.96)
RBBB	5 (4.81)
RBBB + LAHB	2 (0.96)
RBBB + LAHB + 1 DEGREE AV BLOCK	2 (1.92)
SR	78 (70.19)
Valve Characteristics and Echo characteristics	
Bicuspid Aortic Valve	33 (31%)
Average aortic Velocity	4.34 m/s
Mean Aortic valve Mean Gradient	47.5 mmHg
Mean Aortic Valve Peak Gradient	75.7 mmHg
Mean indexed aortic valve area	0.29mm ²
Mean Pulmonary artery systolic pressure	35 mmHg

population was 73 years. 63% were males. The average STS score was 3.99 \pm 2.79. All patients were symptomatic. CKD was present in 20% of patients, and three patients were on hemodialysis. Coronary artery disease (CAD) was present in 44% of patients, and 18 patients had a previous CABG history. 31% of patients had bicuspid aortic valve.

3.2. Procedural characteristics

Procedural characteristics are shown in Table 3. TAVR was performed under conscious sedation in 99.6% of patients. We devised a minimalistic TAVR protocol suitable for Indian practice where the single-center TAVR numbers remain low, and safety and outcomes is an important concern. All procedures were performed via percutaneous transfemoral approach. Mean fluoroscopy time and procedural time was 24 min and 61 min, respectively. The average contrast volume used was 82 ml. Pre-dilatation was done in 54% of cases, and post dilatation was one in 27.6% of cases. The procedure success was seen in 99% of cases with zero intraprocedural deaths. 40% of patients received self-expanding Evolut R and Corevalve valve, 31% received balloon-expandable Sapien 3 valve, and 28.5% received balloon-expandable MyVal™. Two patients had femoral complications: one required balloon angioplasty and another stenting.

3.3. Outcomes: in-hospital and 30-days

The outcomes data is shown in Table 4. The procedural mortality was zero percent, and the all-cause mortality was one (0.9%). One patient underwent SAVR and died due to sepsis. The above outcomes remained the same at 30 days. Two patients developed stroke, one had a transient ischemic stroke, and one had a disabling stroke. New pacemaker implantation was seen in 6 (5.7%) cases. The baseline characteristics of patients receiving pacemakers are shown in Table 5. Three patients had baseline trifascicular atrioventricular conduction block, two had atrial fibrillation, and one had left bundle branch block with first-degree atrioventricular block. Of patients requiring a pacemaker, three patients received a self-expanding valve, and three received balloon-expandable valves (two received Sapien 3 valve and one patient received MyVal). 87% of patients had no para-valvular leak, which had increased to 89% at 30-days. Mild PVL was seen in 2.8% of cases, trivial PVL in 6.6%, moderate PVL in 1.9%, and severe PVL in 0.9% (Table 4). The average ICU stay was 26.4 h, and the average hospital stay was 5.4 days. The average mean gradient of the cohort had decreased from 47.5 mmHg to 9 mmHg (Table 4).

4. Discussion

We report our outcome of 105-minimalist conscious sedation TAVR, done in the cardiac catheterization lab and via the percutaneous femoral approach. All outcomes were assessed as per the VARC-2 definition. The average risk of the cohort was low risk with an STS score of 3.99 \pm 2.79. All patients underwent conscious sedation, percutaneous TAVR. The procedure success was seen in 99% percent of the cases. One patient needed emergency surgery for an embolized valve and the left main occlusion. The average ICU stay was one day, and the average hospital stay was five days. The comparison of results with recently published low-risk trials is shown in Table 6.

With positive outcomes in the low-risk TAVR trials, more and more aortic stenosis patients are treated with TAVR. There is variation in the TAVR practice varying from local anesthesia-minimalistic approach to general anaesthesia-TEE approach. With increasing experience, TAVR is performed under conscious sedation

Table 3
Procedural characteristics.

Procedural Characteristics	
Conscious Sedation	104
Intubation	1
Mean Procedural Fluoroscopy Time	24 ± 25 min
Mean Procedure time	72 ± 28.9 min
Mean Contrast Volume	90 ± 46 ml
Pre-dilatation	57 (54.2%)
Post-dilatation	29 (27.6%)
Percutaneous femoral access closure (Proglide)	105
Surgical cutdown for femoral access (pre and post)	0
Procedural success	104 (99%)
Intraprocedural death	0
Annulus Rupture	0
Aortic Dissection	0
Conversion to General anaesthesia	0
Ventricular Perforation	0
In-hospital TAVR to SAVR conversion	1
In-hospital SAVR conversion mortality	1
Coronary Obstruction	0
Valve used	42 (40%)
Self-Expanding (Corevalve and Evolut R)	33 (31%)
Balloon Expandable- Sapein 3 Valve	30 (28.5%)
Balloon Expandable -MyVal	
Valve Sizes	
20 mm Valve	4 (3.8%)
21.5 mm Valve	2 (1.9%)
23 mm Valve	35 (33.3%)
24.5 mm Valve	3 (2.8%)
26 mm Valve	32 (28.5%)
27.5 mm Valve	1 (0.9%)
29 mm Valve	22 (20.9%)
31/34mmValve	6 (5.7%)
Femoral Stenosis Requiring Stenting or Ballooning	2 (1.9%)

Table 4
Procedural outcomes (in-hospital and 30-day).

Procedural Outcomes	30 Days	
All Cause Mortality	1 (0.9%)	1 (0.9%)
Procedural mortality	0 (0%)	0 (0%)
Stroke	2 (1.9%)	2 (1.9%)
Disabling Stroke	1 ((0.9%))	1 ((0.9%))
Non-Disabling stroke	1 (0.9%)	1 (0.9%)
New Pacemaker Implantation	6 (5.7%)	6 (5.7%)
Paravalvular Leak (PVL)		
Severe	1 (0.9%)	0
Moderate	2 (1.9%)	1 (0.9%)
Mild	3 (2.8%)	5 (4.7%)
Trivial	7 (6.6%)	5 (4.7%)
No PVL	92 (87.6%)	94 (89.5%)
Average ICU stay	26.4 Hours	
Average Hospital Stay	5.4 Days	
Average Post procedural Mean Gradient	8.48 mmHg	9 mmHg
Average post Procedural peak gradient	15.33 mmHg	16 mmHg
Reintervention	0	0
Acute Kidney injury	2	0
Infective Endocarditis		0
Valve Thrombosis		0

Table 5
Baseline Characteristics Of Patients Receiving Pacemaker (AF: Atrial Fibrillation, LBBB: Left bundle branch block, AV: Atrial Ventricular).

S No	Age	Baseline ECG	Valve Type	Valve size	Day of Implantation
1.	84	AF	CoreValve	31 mm	3rd Day
2.	81	LBBB with 1st Degree AV Block	Evolut R	29 mm	2nd Day
3.	70	AF	Sapient 3	23	3rd Day
4	82	Trifasicular AV Block	Sapient 3	29 mm	Day 0
5.	82	Trifasicular AV Block	MyVal	21.5 mm	2nd Day
6.	82	Trifasicular AV Block	Evolut R	26 mm	Day 0

compared to general anesthesia. In Transcatheter Valve Therapy Registry, USA, conscious sedation TAVR group had lesser in-hospital death (1.6% versus 2.5%, $p=0.03$), shorter length of ICU and hospital stay (6 days versus 6.5 days), and lesser combined 30-day stroke and death rate (4.8% versus 6.4%) when compared to general anesthesia.⁶

In a recent meta-analysis, TAVR under conscious sedation with a minimalistic approach was associated with lower 30-day mortality, decreased ICU and hospital stay, shorter procedural time, and reduced inotrope support.⁷ A minimalistic TAVR is associated with improved procedural efficiency and reduced length of stay without compromising success and safety.⁸ A small retrospective study showed that performing TAVR without an anesthesiologist's attendance did not change hospital outcomes.⁹ However, procedural sedation related adverse events and hypoxia can occur in 21% of cases performed by physicians with no formal training. Hypotonia of hypopharyngeal muscles and increased incidence of obstructive sleep apnoea is seen in up to 75% of elderly patients.¹⁰ All sedatives affect respiration and also reduce pharyngeal muscle tone. This may impact coordination in swallowing and may cause aspiration.¹¹

Table 6
Comparison Of Outcomes With Recently Published Low Risk Randomized Trials (PPM: Permanent Pacemaker Implantation, PVL: Paravalvular leak).

COMPARISON WITH LATEST LOW RISK TRIALS				
	PARTNER 3	EVOLUT-R LOW RISK	NOTION	STUDY OUTCOMES
STS SCORE	1.9 + 0.7	1.9 + 0.7	2.9 + 1.6	3.9 + 2.79
PPI	6.6%	17%	34%	5.7%
MORTALITY	0.2	0.5	2.1	0.9
STROKE	0.6	3.4	1.4	1.8
PVL				
MILD	39.6	37.6	61	2.8%
MOD-SEVERE	0.8%	3.5%	15.3%	1.9%

The incidence of pulmonary arterial hypertension is upto 50% in the TAVR population.¹² Sedation-related respiratory depression can further lead to increased PAH and right ventricular failure, affecting the outcomes. The above challenges were overcome by the presence of a cardiac anesthetist in our experience. A cardiac anesthetist would do a pre-anesthetic check-up at the time of admission in all patients. The use of nasal BiPAP avoided hypoxia due to sedation if any. BIS monitor was used in all cases to assess the depth of sedation and cerebral oximeter for assessment of cerebral perfusion. The need for vasopressor agents in conscious sedation TAVR is less compared to general anesthesia.

The permanent pacemaker (PPM) implantation remains an important barrier as TAVR moves to the low-risk patients and younger age groups. The impact of pacemaker implantation in post TAVR patients is controversial, showing no difference in mortality or heart failure,¹³ while another showing reduced survival and increased hospitalization.¹⁴ Asymptomatic LBB, post-TAVR, increases PPM risk at follow up and adversely affects the left ventricle recovery. In PARTNER trial patients' analysis, the strongest ECG predictor for post TAVR PPM was right bundle branch block (RBBB) and left anterior hemiblock.¹⁴ Similarly, in our six patients who received PPM, 4 had baseline RBBB. Short Length of the membranous septum and deeper valve implantation is a strong predictor of increased PPM rates after TAVR.¹⁵ The pacemaker implantation rates in the latest low-risk trials were 6.6% in the PARTNER 3 trial, 17% in Evolut R low-risk trial, and 34% in the NOTION trial. The self-expandable valve was used in the low-risk Evolut trial and Notion trial. The right bundle branch block is consistently associated with increased risk of a permanent pacemaker in SAVR and TAVR patients, the rate of 10–20% in SAVR and more than 25% in TAVR patients. TAVR patients might have concealed conduction abnormalities, which manifests post-procedure as shown by Urena et al, that one-third of patients requiring PPM post-TAVR had episodes of complete heart block (CHB) or high degree atrioventricular block (HAVB) or severe bradycardia on 24 h continuous ECG monitoring done before the procedure.¹⁶ Valve and procedural characteristics associated with increased risk of CHB are implantations deeper than 5–7 mm and a higher degree of valve oversizing.

With the current generation TAVR valves, more than 90% of procedures are performed via percutaneous femoral approach. Transfemoral TAVR has shown superior clinical outcomes compared to surgical aortic valve replacement.¹⁷ In a propensity-matched comparison of the percutaneous femoral approach and surgical cutdown by Kawashima et al, the percutaneous approach was associated with fewer bleeding complications, fewer blood transfusions, and fewer AKI incidence, and shorter hospital stay to surgical cutdown.¹⁸ In our experience, all patients were done via a percutaneous approach. There was no access-femoral site complication requiring surgical repair. Percutaneous TAVR decreases ICU stay, allows early ambulation, rehabilitation, and discharge to home rather than nursing or rehabilitation facilities. Henry et al showed

that patients discharged to skilled nursing homes had 2.5 times the mortality than those discharged home.¹⁹

The paravalvular leak of any degree remains an important challenge in TAVR patients. The incidence of more than mild PVL in low-risk PARTNER 3 and EVOLUT R trial was 0.8% and 3.5%, respectively. However, mild PVL was seen in 39.6% in PARTNER 3 TAVR patients and 37.6% in Evolut *r* low-risk trial. Severe PVL is rarely seen using a current-generation valve and CT scan sizing of the annulus. Moderate to severe PVL is associated with poor outcomes and increased all-cause mortality.²⁰ The PVL outcome is also dependent on the STS score. PVL did not affect the outcome in patients with STS score greater than 8. However, in intermediate and low-risk patients, even mild PVL is associated with increase one-year-mortality and rehospitalization compared to noPVL.²¹

In our cohort, with the use of the latest generations valve in most cases, moderate to severe paravalvular leak was seen in only 2% of patients. 93 percent of patients had no or trivial PVL. Similarly, the role of transoesophageal echocardiography to decrease the risk of the paravalvular leak remains debated. In recently published clinical trials of low surgical risk patients, the preferred use of conscious sedation for TAVR in 65.1% was not associated with higher moderate or severe paravalvular regurgitation.¹

The peri-procedural stroke can be identified immediately during or after the procedure, in a conscious sedation TAVR. When recognized in the cardiac catheterization lab, the stroke can be immediately treated with interventional neuroradiology. Hence the golden period is not lost in such a situation. The disabling stroke rate in the low-risk partner 3 trial was 0.6%, and in our cohort, it is 0.9%. Stroke during TAVR can result from emboli from the arch, ascending aorta, crossing the valve, pre-dilatation, and post-dilatation. The risk of stroke persists for the first seven days. However, it is maximum in the first 24 h. The late presentation of the stroke within 24 h could be due to thrombus formation on the embolised small particles once the heparin effect wears off. The delayed stroke can also be due to the non-endothelialized valve stent struts and dead space behind the TAVR valve, which may present as a thrombogenic surface.²²

There was no very early valve structural degeneration or infective endocarditis, or peri-valvular regurgitation. In our cohort, the mean gradient decreased from 47.5 to 9 mmHg. The mean gradient of TAVR patients at baseline in PARTNER3 and Evolut R low-risk trial was 49.4 ± 12.8 mmHg and 47.2 ± 12.3 mmHg, respectively, and decreased to 13.6 mmHg in the PARTNER 3 and 8.6 mmHg in EVOLUT R low-risk trial.²³

5. Conclusion

The outcomes of minimalist TAVR performed under conscious sedation are in line with low-risk randomized control TAVR trials. The minimalistic TAVR can be adopted in India effectively and without compromising the patients' safety and outcomes.

6. Limitation

The above findings are the largest reported from the single center-single operator cohort in India. However, the major limitation is that it is a retrospective analysis and not a randomized study.

References

- Mack MJ, Leon MB, Thourani VH, et al. Transcatheter aortic-valve replacement with a balloon-expandable valve in low-risk patients. *N Engl J Med*. 2019;380:1695–1705. Med.
- Poppma JJ, Deb M, Yakubov S, Mum, taz M, et al. Transcatheter aortic-valve replacement with a self-expanding valve in low risk patients. *N Engl J Med*. 2019 Jun;31(6):171–175.
- Stamou SC, Lin N, James T, Rothenberg M. Alternative access versus transfemoral transcatheter aortic valve replacement in nonagenarians. *J Invasive Cardiol*. 2019 Jun;31(6):171–175.
- Wood DA. Could a "simplified" transcatheter aortic valve replacement procedure eliminate post-operative delirium? *JACC Cardiovasc Interv*. 2016;9:169–170.
- Prasitlumkum N, Mekritthikrai R, Kewcharoen J, Kanitsoraphan C, Mao MA, Cheungpasitporn W. Delirium is associated with higher mortality in transcatheter aortic valve replacement: systemic review and meta-analysis. *Cardiovasc Interv The*. 2019. Jun. 1.
- Hyman MC, Vemulapalli S, Szeto WY, et al. Conscious sedation versus general anaesthesia for transcatheter aortic valve replacement: insights from the National Cardiovascular data registry society of thoracic surgeons/American college of cardiology Transcatheter valve therapy registry. *Circulation*. 2017;136:2132–2140.
- Villablanca PA, Mohananey D, Nikolic K, et al. Comparison of local versus general anesthesia in patients undergoing transcatheter aortic valve replacement: a meta-analysis. *Cathet Cardiovasc Interv*. 2018;91:330–342.
- Gurevich S, Oestreich B, Kelly RF, et al. Outcomes of transcatheter aortic valve replacement using a minimalist approach. *Cardiovasc Revascularization Med*. 2018;19:192–195.
- Konigstein M, Ben-Shoshan J, Zahler D, et al. Outcome of patients undergoing TAVR with and without the attendance of an anesthesiologist. *Int J Cardiol*. 2017;241:124–127.
- Weaver CS, Hauter WE, Brizendine EJ, et al. Emergency department procedural sedation with propofol: is it safe? *J Emerg Med*. 2007;33:355–361.
- D'Angelo OM, Diaz-Gil D, Nunn D, et al. Anesthesia and increased hypercarbic drive impair the coordination between breathing and swallowing. *Anesthesiology*. 2014;121:1175–1183.
- Ben-Dor I, Goldstein SA, Pichard AD, et al. Clinical profile, prognostic implication, and response to treatment of pulmonary hypertension in patients with severe aortic stenosis. *Am J Cardiol*. 2011;107:1046–1051.
- Urena M, Webb JG, Tamburino C, et al. Permanent pacemaker implantation after transcatheter aortic valve implantation: impact on late clinical outcomes and left ventricular function. *Circulation*. 2014;129:1233–1243.
- Nazif TM, Dizon JM, Hahn RT, et al. Predictors and clinical outcomes of permanent pacemaker implantation after transcatheter aortic valve replacement: the PARTNER (Placement of Aortic Transcatheter Valves) trial and registry. *JACC Cardiovasc Interv*;8:60-69.
- Hamdan A, Guetta V, Klempfner R, et al. Inverse relationship between membranous septal length and the risk of atrioventricular block in patients undergoing transcatheter aortic valve implantation. *JACC Cardiovasc Interv*. 2015;8:1218–1228.
- Urena M, Hayek S, Cheema AN et al. Arrhythmia burden in elderly patients with severe aortic stenosis as determined by continuous electrocardiographic recording. Toward a better understanding of arrhythmic events after transcatheter aortic valve replacement. *Circulation* 131:469-477.
- Siontis GC, Praz F, Pigrim T, Mavridis D, Verma s, et al. Transcatheter aortic valve implantation vs surgical aortic valve replacement for treatment of severe aortic stenosis: a meta-analysis of randomized trials. *Eur Heart J*. 2016;37:3503–3512.
- Kawashima H, Watanabe Y, Kozuma K, et al. Propensity-matched comparison of percutaneous and surgical cutdown approaches in transfemoral transcatheter aortic valve implantation using a balloon-expandable valve. *Euro-intervention*. 2017;12:1954–1961.
- Henry L, Halpin L, Hunt S, Holmes SD, Ad N. Patient disposition and long-term outcomes after valve surgery in octogenarians. *Ann Thorac Surg*. 2012;94:744–750.
- Athappan G, Patvardhan e, TuzcuEM SvenssonLG, et al. Incidence, predictors, and outcomes of aortic regurgitation after transcatheter aortic valve replacement: meta-analysis and systematic review of literature. *J Am Coll Cardiol*. 2013;(61):1585–1595.
- Kodali S, Pibarot P, Douglas PS, et al. Paravalvular regurgitation after transcatheter aortic valve replacement with the Edwards Sapien valve in the PARTNER trial: characterizing patients and impact on outcomes. *Eur Heart J*. 2015;36:449–456.
- Tay EL, Gurvitch R, Wijesinghe N, et al. A high-risk period for cerebrovascular events exists after transcatheter aortic valve implantation. *JACC Cardiovasc Interv*. 2011;4:1290–1297. <https://doi.org/10.1016/j.jcin.2011.08.012>.
- Braghiroli J, Kapoor K, Thielhelm TP, Ferreira T, Cohen MG. Transcatheter aortic valve replacement in low risk patients: a review of PARTNER 3 and Evolut low risk trials. *Cardiovasc Diagn Ther*. 2020;10(1):59–71.