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

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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 published 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 TAVR trials.

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

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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.\textsuperscript{12,13}

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 transosophageal echocardiogram, and percutaneous femoral approach.

TAVR specific diagnostic workup included electrocardiogram (ECG)-gated, contrast-multidetector computed tomography (MDCT) of heart, aorta, and ilio-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 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 cm\(^2\), 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. Intraprocedural 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. Intraprocedural 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 aortogrammand 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 cm\(^2\)). 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 TAVR PROTOCOL | POST TAVR |
|--------------------------|-----------|
| PRE TAVR                 | POST TAVR |
| ECHO                     | ICU (OVERNIGHT) |
| PFT                      | Q x 15 for 4 h |
| HEMATOLOGY               | Q x 30 min for 6 h |
| URINE ROUTINE & CULTURE  | Q 4 h for 12 h |
| CHEST X-RAY              | ECG, CBC, Chest X-Ray |
| HBA1C/TSH                | Medications (loading with antiplatelets if required, IV antibiotics, Anticoagulation from next day if indicated). |
| CHEST                    | POST OP DAY 1 |
| PHYSIOTHERAPY            | Radial and central line removal. Mobilization in ICU. ECG, CBC, RFT and Echo. |
| INCENTIVE                | Transfer to the room |
| SPIROMETRY               | DAY 2 till discharge. |
| PRE-ANAESTHETIC CHECK UP | Rehabilitation |
| PHYSICIAN PRBC IN RESERVE| Patient Education |
| ECHO                      | Medication optimization |
| RADIAL LINE              | 24-h Holter in selected patients before discharge |
| CENTRAL LINE             |                     |
| CONDOM CATHETER FOR MALES|                     |
| LOCAL ANAESTHESIA (LIDOCAINE + BUPIVACAINE) |                     |
| CONSCIOUS SEDATION (DEXMEDETOMIDINE INFUSION) |                     |
| BIS MONITOR              |                     |
| CEREBRAL OXYMETER        |                     |
| NASAL CPAP               |                     |
| PERCUITNEOUS ACCESS      |                     |
| NO PA CATHETER           |                     |
| TPM REMOVED IN CATH-LAB FOR MAJORITY OF CASES |                     |
| PMI IMPLANTED FOR PATIENTS WITH BASELINE TRIFASCULAR AV |                     |
| BLOCK CONCOMITANT WITH TAVR |                     |
| TTE                      |                     |
| NEUROLOGICAL ASSESSMENT |                     |
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 population was 73 years. 63% were males. The average STS score was 3.99 ± 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, 31% received balloon-expandable Sapien 3 valve, and 28.5% received balloon-expandable MyVal™. Two patients had hemodynamic 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 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 ± 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 anaesthesia-minimalistic approach to general anaesthesia-TEE approach. With increasing experience, TAVR is performed under conscious sedation.

### Table 2

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

| Variable, n (%) | n = 105 |
|----------------|---------|
| Age, Years Mean ± SD | 72.93 ± 9.25 |
| Gender, n (%) | | |
| Female | 36 (36.54) |
| Male | 64 (63.46) |
| BMI, Mean ± SD | 26.85 ± 5.29 |
| BSA | 1.76 ± 0.24 |
| Society of thoracic surgeons score, Mean ± SD | 3.99 ± 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 ± SD | 59.11 ± 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 | 0.29mm² |
| Mean Pulmonary artery systolic pressure | 35 mmHg |
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 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 3

| Procedural Characteristics | Conscious Sedation | Intubation |
|----------------------------|--------------------|------------|
| Mean Procedural Fluoroscopy Time | 24 ± 25 min | 72 ± 28.9 min |
| Mean Procedure time | 90 ± 46 ml | 57 (54.2%) |
| Pre-dilation | 29 (27.6%) | 0 |
| Post-dilation | 105 | 0 |
| Percutaneous femoral access closure (Proglide) | 33 (31%) | 30 (28.5%) |
| Surgical cutdown for femoral access (pre and post) | 0 | 0 |
| Procedural success | 104 (99%) | 0 |
| Intra-procedural death | 0 | 0 |
| Annulus Rupture | 0 | 0 |
| Aortic Dissection | 0 | 0 |
| Conversion to General anaesthesia | 0 | 0 |
| Ventricular Perforation | 0 | 0 |
| In-hospital TAVR to SAVR conversion | 1 | 0 |
| In-hospital SAVR conversion mortality | 1 | 0 |
| Coronary Obstruction | 0 | 0 |

Table 4

| Procedural Outcomes (in-hospital and 30-day) | 30 Days |
|---------------------------------------------|---------|
| All Cause Mortality | (0.9%) |
| Procedural mortality | (0.9%) |
| Stroke | (1.9%) |
| Disabling Stroke | (0.9%) |
| Non-Disabling stroke | (0.9%) |
| New Pacemaker Implantation | (5.7%) |
| Paravalvular Leak (PVL) | (5.7%) |
| Severe | (0.9%) |
| Moderate | (1.9%) |
| Mild | (2.8%) |
| Trivial | (6.6%) |
| No PVL | (92.7%) |
| Average ICU stay | (94.8%) |
| Average Hospital Stay | (94.8%) |
| Average Post procedural Mean Gradient | 8.48 mmHg |
| Average post Procedural peak gradient | 15.33 mmHg |
| Reintervention | 0 |
| Acute Kidney injury | 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). |
|---------------------------------------------------------------------------------------------------------------------------------|---------|
| 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           | Sapien 3   | 23         | 3rd Day             |
| 4. | 82  | Trifasicular AV Block | Sapien 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               |
The incidence of pulmonary arterial hypertension is up to 50% in the TAVR population. 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, while another showing reduced survival and increased hospitalization. Asymptomatic LBB, post-TAVR, is a predictor for post TAVR PPM was right bundle branch block (RBBB) and left anterior hemiblock. 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. 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 (AVB) or severe bradycardia on 24 h continuous ECG monitoring done before the procedure. 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. 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. 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.

The paravalvular leak of any degree remains an important challenge in TAVR patients. The incidence of more than mild PVL in 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. 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.

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 transesophageal 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.

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-endothelized valve stent struts and dead space behind the TAVR valve, which may present as a thrombogenic surface.

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.

Table 6

| 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%          |

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.

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