

# Monitored Anesthesia Care vs. General Anesthesia for Trans Catheter Aortic Valve Implantation (TAVI): Our Initial Experience

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Received date: June 01, 2019; Accepted date: June 21, 2019; Published date: June 28, 2019

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## Abstract

**Background:** The game changer in the field of treatment for Aortic Stenosis in patients with high operative risk for surgical aortic valve replacement is Trans catheter Aortic Valve Implantation (TAVI). Most TAVI have been done under General Anesthesia (GA) with Trans Esophageal Echocardiography (TEE). GA in this patient group is hazardous and is associated with significant complications. The aim of the present study was to study and compare the outcome of patients among those who underwent TAVI with general anesthesia against those who underwent TAVI with Monitored Anesthesia Care (MAC).

**Materials and methods:** After institutional ethics committee approval and obtaining written informed consent, 31 patients undergoing Trans catheter aortic valve implantation (TAVI) were registered. First 21 (n=21) (Group A) patients who underwent TAVI at our center received general anesthesia. Subsequent 10 (n=10) (Group B) patients who were scheduled for the procedure received sedation with dexmedetomidine. Patient selection for TAVI was based on various risk calculators which attempts to ascertain surgical risks. The study was carried out at a tertiary care hospital in western Maharashtra between November 2017 and March 2019.

**Results:** No statistically significant difference regarding pre-operative patient characteristics, comorbidity and procedural characteristics. i.e the duration of procedure, stay in ICU, days to discharge from procedure and duration of stay in hospital. However there are trends in favor of monitored anesthesia case in terms of reduction in procedural time and hospital stay.

**Conclusion:** TAVI can be performed in majority of cases, under dexmedetomidine based sedation. Our initial experience suggests that this should result in a shorter implant procedure time, reduced stay in intensive care unit and shorter time to hospital discharge.

**Keywords:** Trans catheter aortic valve implantation; Monitored anesthesia care; Dexmedetomidine

**Abbreviations:** TAVI: Trans Catheter Aortic Valve Implantation; SAVR: Surgical Aortic Valve Replacement; BAV: Balloon Aortic Valvuloplasty; TEE: Trans Esophageal Echocardiography; MAC: Monitored Anesthesia Care; RV: Right Ventricular Pacing.

## Introduction

The most common valvular heart disease in elderly patients is aortic valve stenosis and it is a major cause of mortality and morbidity. The gold standard treatment for adult patients with severe symptomatic Aortic Stenosis still remains surgical aortic valve replacement (SAVR) (ACC/AHA class I recommendation) [1]. The advantage of SAVR is it improves symptoms and prolongs the survival in suitable patients and has a mortality rate of 4-8% in patients who are more than 70 years of age [2]. Other options which were available earlier included Balloon Aortic Valvuloplasty (BAV) which had a complication rate of >10% and did not show any improvement in survival rate [3,4] and now the game changer in the field of treatment for Aortic Stenosis in patients

with high operative risk for surgical aortic valve replacement is Trans catheter Aortic Valve Implantation (TAVI) [5]. Recent advances which has made TAVI a safe and simple procedure is the excellent designing of the valve which reduces perivalvular leak, use of smaller size of sheath, lesser need for rapid Right Ventricular (RV) pacing and decreased need for Intraoperative Trans Esophageal Echocardiography (TEE) guidance. General anesthesia with Trans Esophageal Echocardiography was a standard of care for TAVI. But patients with respiratory illness and other co morbidity conditions who are at high risk for surgical AVR tolerate general anesthesia very poorly [6]. Now with the decreased use of TEE and with increasing use of fluoroscopic aortic calcification coupled with multiple small volume aortogram which provides an excellent anatomical positioning of the implant these procedures can be carried out under Monitored Anesthesia Care (MAC). The aim of the present study was to study and compare the outcome of patients among those who underwent TAVI with general anesthesia against those who underwent TAVI with monitored anesthesia care.

## Methods

After institutional ethics committee approval and obtaining written informed consent, 31 patients undergoing Trans catheter aortic valve implantation (TAVI) were registered. The first 21 patients who underwent TAVI at our center received general anesthesia. After the procedure patients were transferred to cardiac ICU and then were extubated within 1 to 2 hours after fulfilling the extubation criteria. Two patients developed respiratory complications post extubation and required reintubation and were ventilated for a day. Both the patients were shifted out of ICU and were discharged from hospital after 5 to 7 days. We reassessed our approach because of these experience and in subsequent 10 patients who were scheduled for the procedure received sedation with dexmedetomidine. The study was carried out at a tertiary care hospital in western Maharashtra between November 2017 and March 2019. Patient selection for TAVI was based on various risk calculators which attempts to ascertain surgical risks. A proforma for selection of patients for TAVI vs. SAVR was prepared by the heart team of the hospital, which included European system for cardiac operative risk evaluation (Euro SCORE), the Society of Thoracic Surgeons Predicted Risk of Mortality (STS-PROM) score. A STS/Euro score II of  $\leq 4$  (logistic Euro score I  $\leq 10\%$ ) was in favor of SAVR and a STS/Euro score II of  $\geq 4$  (Logistic Euro score I  $\geq 10\%$ ) was in favor of TAVI. Other aspects which were considered for the selection of patients for TAVI vs SAVR included clinical characteristics of the patients like age, presence of severe co-morbidity, previous cardiac surgery, frailty, restricted mobility and suspicion of endocarditis. Anatomical and technical aspects which were considered for selection of patients included access for trans femoral TAVI, sequelae of chest radiation, porcelain aorta, presence of intact coronary bypass grafts at risk when sternotomy is performed, expected PPM, chest deformities, distance between coronary Ostia and aortic valve annulus, size of aortic valve annulus, presence of thrombi in aorta/LV, Morphology of aortic valve and aortic root. Other cardiac conditions that were considered for selection of patients included severe coronary artery disease, severe primary mitral, tricuspid valve disease, aneurysm of ascending aorta and septal hypertrophy requiring myectomy.

**Anesthesia Technique:** In both the group patients were taken to the cath lab were under local anesthesia and strict aseptic precaution a wide bore peripheral IV cannulae, right radial artery cannulation, right internal jugular venous cannulation for insertion of 7 French triple lumen catheter and a pacing sheath was introduced.

Group A patients were induced with Inj Etomidate (0.2 mg/kg) Inj Fentanyl (0.5  $\mu\text{g}/\text{kg}$ ) and Inj Rocuronium (0.8-1 mg/kg) and anesthesia was maintained with 50% air and oxygen and Inj atracurium (0.5 mg/kg). No inhalation agents were used. At the end of the procedure patients were shifted to medical ICU and extubated within an hour.

In Group B patients 1% lignocaine was used subcutaneously at the arterial and venous access sites. Sedation was started with injection dexmedetomidine infusion @ 0.5-1  $\mu\text{g}/\text{kg}/\text{min}$  and was titrated according to response. In some patients Inj midazolam not more than 1-2 mg was used.

**Monitoring:** - Both the group patients were continuously monitored for heart rate, invasive blood pressure, pulse oximetry, urine output, activated clotting time (after heparinization) and arterial blood gases including serum lactate.

Aim during anesthesia in both groups was to:

Maintain sinus rhythm to achieve optimal LV filling from atrial kick.

Avoiding tachycardia to maintain adequate coronary perfusion during diastole.

To maintain systemic vascular resistance-which decreases after anesthetic induction

During rapid ventricular pacing (RVP) myocardial ischemia was Prevent by:-

Maintaining a SBP of at least 120 mmHg/MAP of  $>75$  mmHg

Limiting RVP to 10-12 sec

Allowing BP to recover before further RVP

Minimizing the number of episodes of RVP

Following valve deployment

Vasopressor infusion was reduced/stopped to prevent hypertension.

During decannulation, hypertension was avoided to prevent vascular injury and to reduce blood loss. When required NTG (Nitroglycerin) infusion/SNP (Sodium nitropruside) infusion was started.

## Results

A total of 31 patients underwent TAVI group A (n=21) group B (n=10) during the period Nov 2017 to Feb 2019. There was no statistically significant difference regarding pre-operative patient characteristics like age, aortic stenosis max gradient (mm of hg), logistic euro SCORE% (Table 1).

Sl. No.	Characteristics	GA (n=21)	MAC (n=10)	p-value
		Median range	Median range	
1	Age (Years)	73 (71-74)	70 (64-77)	T=0.28
		Mean=71.57	Mean=71.20	p value=0.78
		SD 3.35	SD 3.64	
2	AS max gradient (mmhg)	90 (90-102)	94 (63-141)	T=-1.118
		Mean=98.25	Mean=100	p value=0.273
		SD 4.31	SD 3.39	
3	Logistic Euroscore%	22.9 (22-27)	21.8 (11-50)	0.25

**Table 1:** Patient characteristics.

There was no statistically significant difference between the groups with regards to patient's sex, previous CABG, COPD, renal failure, cerebro vascular disease and peripheral vascular disease (Table 2).

Sl. No.	Characteristics	GA (n=21)	MAC(n=10)	p
		% No of case	% No of case	
1	Male	67 (14)	67 (7)	1.00
2	Previous CABG	33 (7)	67 (7)	1.52
3	COPD	33 (7)	33 (7)	1.00

4	Renal Failure (Creatinine>220 mmol/l)	0 (0)	11 (1)	1.00
5	Cerebrovascular disease	33 (7)	11 (1)	0.45
6	Peripheral vascular disease	33 (7)	22 (2)	1.00

**Table 2:** Patient characteristics.

With regards to procedural characteristics. i.e. the duration of procedure, stay in ICU, days to discharge from procedure to discharge and duration of stay in hospital, there was no statistically significant difference (Table 3). This probably may be because of small number of patients involved in the study. However there are trends in favor of monitored anesthesia case in terms of reduction in procedural time and hospital stay.

Sl. No.	Characteristics	GA (n=21)	MAC (n=10)	p-value
		Median range	Median range	
1	Procedure, duration minutes	135 (85-205)	105 (95-130)	0.46
2	ICU stay, Days	1 (0-1)	0 (0-0)	0.25
3	Days from procedure to discharge	4 (3-6)	3 (2-8)	0.23
4	Hospital stay, Days	5 (3-7)	3 (2-8)	0.23

**Table 3:** Procedural characteristics.

Complication: One patient whose aortic annulus was more than the acceptable upper limit, developed grade two aortic regurgitation. Following the procedure two patients required permanent pacemaker, either prophylactically (long PR Interval and LBBB n=1) or because of complete heart block (n=1). One patient developed right femoral artery laceration during percutaneous suture closure necessitating surgical repair.

One patient had acute coronary occlusion following prosthetic deployment and developed cardiac arrest. Airway was secured and standard advanced cardiac life support protocols were followed and was planned for CPB and emergent sternotomy but patient could not be revived.

### Statistical analysis

Data were statistically described in terms of percentage using a fisher exact test. Continuous variables such a median and range were compared by Mann-Whitney test. A p value of <0.05 were considered to be statistically significant.

### Discussion

The results of our study show that there is no statistically significant difference between the groups with regard to procedural characteristics. Although the number of patients in our study is small, there is a favorable outcome with regards to MAC in terms of shorter procedural time, time to extubation, stay in ICU and overall hospital stay.

Patients who undergo TAVI are usually elderly patients with significant associated comorbidities and who are at high risk for SAVR. The main risk in these kinds of patients includes respiratory complications, hypotension with renal dysfunction which is further aggravated by use of contrast media. Therefore when these procedures are carried out under MAC it offers the patient a greater chance of recovery as early mobilization is important in these patients.

Dexmedetomidine is a highly selective, shorter-acting intravenous  $\alpha$ -2 agonist with a  $\alpha$ -2 to  $\alpha$ -1 selectivity ratio of 1600:1 [7]. Studies evaluating the hemodynamic stabilizing and sympatholytic effects have shown that  $\alpha$ -2 agonists can potentially reduce postoperative cardiovascular complications. Multiple studies have reported that Dexmedetomidine has a protective effect on specific organs, including the heart, brain, kidney, and lungs [8]. In addition, Dexmedetomidine has been shown to have anti-inflammatory properties, decreasing mortality and attenuating plasma cytokine concentrations in laboratory animals exposed to endotoxin in a dose-dependent fashion [9].

Many centers use Trans esophageal echocardiography (TEE) to guide implantation of valve prosthesis [10]. But the disadvantage of TEE is that it necessitates general anesthesia. Advantage of TEE is that there is direct visualization of positioning of the distal aspect of the valve apparatus in the outflow tract of the left ventricle in relation to the anterior leaflet of mitral valve. Alternatively this can also be done by using fluoroscopic landmarks of aortic valve calcification and intermittent aortogram thereby avoiding the use of TEE and therefore the need for general anesthesia.

Under monitored anesthesia care once the implant is being deployed successfully the patient can go directly to coronary care unit rather than being ventilated in surgical ICU. Advantage of MAC being patient is in control of his/her own airway rather than being intubated. GA patients usually are extubated 2-3 hours after the procedure and this translates to one extra day of overall hospital day.

### Conclusion

TAVI as a procedure is being developed to treat severe symptomatic AS patients in whom SAVR is of high risk. A multi-disciplinary approach and an effective communication are key to successful programme. As our TAVI programme matures with improved results and shorter procedural times, anesthesia management may shift from GA to MAC.

From the anesthetist perspective he must always be prepared for any potential acute and catastrophic complications, and also must be aware of the current technology and must be willing to contribute to the preoperative management of these patients who are usually elderly, frail and have multiple co-morbidities, so as to get a favorable outcome.

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