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Research Article

General versus Local Anesthesia with Intravenous Sedation in Transcatheter Aortic Valve Implantation

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Background. Monitored anesthesia care (MAC) may offer better outcomes than general anesthesia (GA) in transcatheter aortic valve implantation (TAVI). We compared TAVI outcomes between patients who received MAC versus GA. *Methods*. We retrospectively reviewed data from all patients ($N = 659$), as well as 216 propensity-matched patients, who underwent TAVI at our institution during 2014–2019. *Results*. MAC and GA did not differ significantly in mortality (1.6% MAC vs. 4.2% GA, $p = 0.05$) or stroke (2.2% MAC vs. 2.4% GA, $p = 0.96$); however, median length of stay (LOS) was shorter in the MAC group (2 d MAC vs. 7 d GA, $p < 0.0001$). In propensity-matched patients, mortality (2.8% MAC vs. 4.6% GA, $p = 0.7$) and stroke (3.7% MAC vs. 1.9% GA, $p = 0.7$) did not differ significantly between groups. LOS remained shorter in the MAC group (2 d MAC vs. 7 d GA, $p < 0.0001$). *Conclusions*. In this large, single-center, retrospective study, MAC was associated with shorter hospital stay after TAVI.

1. Introduction

Initially developed as a method of intervention for patients with prohibitive operative risk who required aortic valve replacement [1–3], transcatheter aortic valve implantation (TAVI) has been subsequently studied in intermediate- [4, 5] and low-risk patients [6, 7]. As clinical indications for TAVI have expanded, the technology and deployment strategies have been refined to make TAVI even less invasive. Percutaneous femoral access has become standard, and this change has not increased vascular complication rates [8].

Initially, general anesthesia (GA) was the mainstay for TAVI procedures. However, monitored anesthesia care (MAC), the use of local anesthesia with conscious sedation in conjunction with a fast-track approach, offers the potential for better outcomes with a similar safety profile. Single-center studies [9, 10] have reviewed the use of MAC during TAVI [11, 12]. These studies have associated this strategy with lower rates of operative mortality and shorter intensive care unit and hospital lengths of stay (LOS) than GA [13]. These results have been further validated through meta-analyses [14] and analyses of the Transcatheter Valve Therapy Registry [15]. No significant differences between MAC and GA have been shown in complication rates [8], including rates of paravalvular leak and the need for permanent pacemaker (PPM) placement. However, these studies have shown rates of conversion from MAC to GA of up to 15% [16]. These findings have been validated with both currently available balloon-expandable and self-expanding valves [17]. The overall cost associated with TAVI has been preliminarily higher than that of its open surgical counterpart, at an additional $60,000 per year of life earned [17]. With this in mind, several groups have shown significant cost savings when MAC is used instead of GA [18].

In this study, we reviewed data from all patients who underwent TAVI at a single large institution. We compared outcomes in patients who underwent this procedure under GA versus MAC. These comparisons were further analyzed by propensity matching.

2. Patients and Methods

Data were obtained from our institution's prospectively maintained TAVI database as part of an ongoing quality improvement initiative. The project was conducted under Baylor College of Medicine institutional review board approval (#00009715) with a board-approved waiver of consent. We retrospectively reviewed data from all patients ($N = 659$; median age, 79 y; Table 1) who underwent TAVI at our institution from 2014 to 2019. Of these patients, 371 underwent TAVI under MAC and 288 underwent TAVI under GA. The procedures were performed in either a cardiac catheterization suite or a hybrid cardiovascular operating room. Patients who underwent TAVI in the catheterization suite recovered in their respective postanesthesia care unit, followed by the cardiac care unit and floor. Patients who underwent TAVI in the operating room recovered in the cardiovascular intensive care unit and then their respective floor. Cardiac anesthesia physician faculty was present for all cases, regardless of the anesthesia type used. The choice of MAC versus GA was left entirely to the providers' preference.

Both self-expanding and balloon-expandable valves were used (Table 2). Vascular access was obtained through bilateral common femoral arteries or by simultaneous unilateral femoral and radial arterial access. Access was obtained percutaneously or via open surgical femoral cutdown. Anesthesia type, procedure location, type of valve used, and access configuration were chosen at the discretion of the implanting team after preoperative multidisciplinary review and discussion.

Primary endpoints were mortality, stroke, and overall hospital LOS. Mortality was defined as occurring within 30 days of the procedure or during the index hospitalization. Secondary endpoints are the major postprocedural complications listed in Table 3. Respiratory failure was defined as requiring intubation more than 48 hours postprocedurally. Acute kidney injury was defined by Society of Thoracic Surgeons (STS) criteria as a serum creatinine level >4 mg/dL, an increase in serum creatinine level to three times baseline, an acute rise of at least 0.5 mg/dL, or a new requirement for postoperative dialysis. Propensity matching was based on several preoperative patient characteristics (Table 4): age, sex, diabetes, previous coronary artery bypass grafting (CABG), medically treated chronic kidney disease (CKD), preoperative end-stage renal disease necessitating dialysis, STS mortality risk score, Agatston calcium score, ejection fraction, preprocedural Kansas City Cardiomyopathy Questionnaire (KCCQ) score, and chronic obstructive pulmonary disease (COPD).

Statistical analyses were performed with SAS version 9.4 (SAS Institute, Cary, NC), Stata version 13 (StataCorp LLC, College Station, TX), and R version 3.4.0 (R Project for Statistical Computing, Vienna, Austria). Continuous variables are presented as mean ± standard deviation for normally distributed variables. Peak velocity was the only normally distributed continuous variable in the cohort. Non-normally distributed variables are reported as median ($Q1$–$Q3$). Categorical variables are presented as number and percentage. Univariable comparisons were performed with the Fisher exact test for any categorical variable with values of 5 or less in any cell; for all other categorical variables, the Pearson χ^2 test was used. For continuous variables, normality was tested with the Shapiro–Wilk test in all subcohorts. For continuous variables without normal distribution (usually because of small sample size), the nonparametric Wilcoxon test was performed. For all other continuous variables, a t-test was used.

One-to-one matching without replacement by propensity score was performed by using the nearest neighbor method with a caliper of 0.25 SD of the logit. Matching was conducted with the psmatch2 package in Stata version 14 (StataCorp LLC; Computing Resource Center, College Station, TX). Balance in the baseline covariates was examined by using standardized mean differences. We generated 108 propensity-matched pairs.

3. Results

Ejection fraction was largely preserved in the overall cohort, averaging 50%. Most patients were considered intermediate risk; the average STS mortality risk was 4.9% and did not differ significantly between groups ($p = 0.78$). Approximately, 19% of patients in both groups had a preoperative PPM in place ($p = 0.9$). Patients who underwent GA were more often female (36.4% MAC vs. 49.7% GA, $p = 0.0006$). In the overall cohort, MAC patients felt sicker at baseline according to their KCCQ scores (35 (26–45) MAC vs. 26.5 (21–37) GA, $p < 0.0001$). There was more pulmonary hypertension in the GA group (23.7% MAC vs. 39.6% GA, $p < 0.0001$). The median Agatston score for all patients was 2170 and did not differ significantly between the groups.

The cohort was divided nearly evenly between balloon-expandable valves (49.2% S3 and 4.9% Sapien) and self-expanding valves (46% CoreValve). Most balloon-expandable valves were placed under MAC, while most self-expanding valves were placed under GA.

Postoperative outcomes for the overall cohort are shown in Table 3. LOS significantly favored MAC over GA (2 (2-3) d MAC vs. 7 (4–13) d GA, $p < 0.0001$). There were no statistically significant differences between the groups in the

Table 1: Patient characteristics in overall cohort.

Patient variable	All patients ($N = 659$)	MAC ($n = 371$)	GA ($n = 288$)	P
Age (y)	79 (72–85)	80 (74–85)	78 (68–84)	0.0067
Height (cm)	170 (160.5–177)	170 (162–178)	167 (160–177)	0.0874
Weight (kg)	79 (69–93)	80 (69–93)	79 (68–96)	0.8689
Aortic valve area (cm^2)	0.8 (0.6–0.9)	0.8 (0.63–0.9)	0.77 (0.6–0.9)	0.2852
Peak velocity (m/s)	3.9 ± 0.7	3.9 ± 0.6	3.9 ± 0.7	0.2
Mean gradient (mmHg)	38 (30–45)	37 (29.3–45)	39 (30–46)	0.4428
Aortic annulus diameter (mm)	20 (20-21)	20 (20-21)	20.5 (19–21)	0.9410
Ejection fraction (%)	50 (50–60)	60 (55–60)	60 (44–60)	0.0058
STS operative mortality risk (%)	4.9 (3.43–7.18)	4.78 (3.41–7.14)	5 (3.56–7.3)	0.7860
Access-vessel size (mm)	6.3 (5.7–7.2)	6.35 (5.7–7.2)	6.3 (5.6–7.1)	0.7222
Agatston score	2170 (1505–3069)	2195 (1540–2994)	2056 (1363–3286)	0.9516
Valve-in-valve procedure	30 (4.6)	11 (3.0)	19 (6.6)	0.03
Preoperative KCCQ score	31 (24–42)	35 (26–45)	26.5 (21–37)	<0.0001
Female	278 (42.2)	135 (36.4)	143 (49.7)	0.0006
Previous CABG	129 (19.5)	81 (21.8)	48 (16.7)	0.095
Previous PCI	227 (34.4)	115 (31.0)	112 (38.9)	0.05
Preoperative CKD	286 (43.4)	153 (41.2)	133 (46.2)	0.005
Preoperative dialysis	37 (5.6)	13 (3.5)	24 (8.3)	0.005
Diabetes mellitus	256 (38.8)	128 (34.5)	128 (44.4)	0.009
Atrial fibrillation	197 (29.9)	103 (27.8)	94 (32.5)	0.2
Pulmonary hypertension	202 (30.7)	88 (23.7)	114 (39.6)	<0.0001
Peripheral vascular disease	317 (48.1)	180 (48.5)	137 (47.6)	0.8
COPD	258 (39.2)	132 (35.6)	126 (43.7)	0.03
Preoperative PPM	122 (18.5)	69 (18.6)	53 (18.4)	0.9
Previous chest radiation	25 (3.8)	13 (3.5)	12 (4.2)	0.7
Previous cancer	125 (19.0)	61 (16.4)	64 (22.2)	0.06
Preoperative tricuspid regurgitation	27 (4.1)	16 (4.3)	11 (3.8)	0.8

CABG, coronary artery bypass grafting; CKD, chronic kidney disease; COPD, chronic obstructive pulmonary disease; GA, general anesthesia; KCCQ, Kansas City Cardiomyopathy Questionnaire; MAC, monitored anesthesia care; PCI, percutaneous coronary intervention; PPM, permanent pacemaker; STS, society of thoracic surgeons.

Table 2: Device characteristics.

	Overall cohort				Propensity-matched groups		
	All patients	MAC	GA	P	MAC	GA	P
Device type				<0.0001			<0.001
CoreValve	303 (46.0)	47 (12.7)	256 (88.9)		12 (11.1)	97 (89.8)	
S3	324 (49.2)	301 (81.1)	23 (8.0)		91 (84.3)	9 (8.3)	
Sapien	32 (4.9)	23 (6.2)	9 (3.1)		5 (4.6)	2 (1.9)	
Valve size (mm)				0.7222			<0.001
All valves	26 (26–29)	26 (23–29)	29 (26–29)		26 (23–29)	29 (26–30)	
CoreValve	29 (26–29)	29 (26–30)	29 (26–29)		29 (26–34)	29 (29–34)	
S3	26 (23–29)	26 (23–29)	26 (23–29)		26 (23–26)	23 (23–26)	
Sapien	26 (26-26)	26 (26-26)	26 (26–27.5)		26 (26-26)	27.5 (26–29)	

GA, general anesthesia; MAC, monitored anesthesia care.

rates of mortality (1.6% MAC vs. 4.2% GA, $p = 0.05$) or stroke (2.2% MAC vs. 2.4% GA, $p = 0.96$). Transient ischemic attack was more frequent with GA (0 MAC vs. 1.4% GA, $p = 0.02$), but the number of these attacks overall was small: only 4 in the total cohort. Notable differences in secondary outcomes included higher rates of PPM placement (7.6% MAC vs. 14.6% GA, $p = 0.004$) and acute kidney injury (1.4% MAC vs. 3.8% GA, $p = 0.04$) with GA. Post-procedural respiratory failure requiring intubation for more than 48 hours was also more common with GA (1.1% MAC vs. 6.3% GA, $p = 0.001$). Only 5 patients (1.4%) in the MAC cohort underwent emergency conversion to GA. In the MAC group, 66.5% of patients did not have perivalvular leak and 57.1% in the GA group had no paravalvular leak ($p = 0.02$). No severe paravalvular leak was noted with MAC, and 3 cases were reported with GA. Unplanned vascular access repair was less often needed with MAC (2.7% MAC vs. 6.6% GA, $p = 0.02$). There were no data on how many patients began the case with open access versus percutaneous access. Only access complications were recorded in the database.

In the propensity-matched patients ($n = 216$; 108 matched pairs), LOS remained shorter in the MAC group (2 (2-3) d MAC vs. 7 (3–12) d GA, $p < 0.0001$). Similar to the overall

Table 3: Post-TAVI outcomes.

Outcome	Overall cohort				Propensity-matched groups		
	All patients	MAC	GA	P	MAC	GA	P
Death	18 (2.7)	6 (1.6)	12 (4.2)	0.05	3 (2.8)	5 (4.6)	0.7
Stroke	15 (2.3)	8 (2.2)	7 (2.4)	0.96	4 (3.7)	2 (1.9)	0.7
Postoperative length of stay (d)	3 (2–7)	2 (2-3)	7 (4–13)	<0.0001	2 (2-3)	7 (3–12)	<0.0001
Postoperative EF (%)	60 (55–60)	60 (60–60)	60 (49–60)	<0.0001	60 (60-60)	60 (55–60)	0.04
Postoperative KCCQ score	60 (55–63)	61 (56–63)	60 (53–62)	0.0216	60 (56–62)	59.5 (53–63)	0.07
Paravalvular leak				0.02			0.02
None	404 (62.4)	240 (66.5)	164 (57.1)		80 (75.5)	59 (54.6)	
Trace	109 (16.8)	60 (16.6)	49 (17.1)		15 (14.2)	24 (22.2)	
Mild	107 (16.5)	52 (14.4)	55 (19.2)		9 (8.5)	20 (18.5)	
Moderate	25 (3.9)	9 (2.5)	16 (5.6)		2 (1.9)	3 (2.8)	
Severe	3 (0.5)	0	3 (1.1)		0	2 (1.9)	
Readmission	64 (9.7)	32 (8.7)	32 (11.1)	0.3	7 (6.5)	13 (12.0)	0.2
Emergency conversion to GA	N/A	5 (1.4)	N/A	N/A	3 (2.7)	N/A	N/A
Transient ischemic attack	4 (0.6)	0	4 (1.4)	0.02	0	1 (0.9)	>0.99
Postoperative PPM	70 (11.0)	28 (7.6)	42 (14.6)	0.004	7 (6.5)	16 (14.8)	0.05
Acute kidney injury	16 (2.4)	5 (1.4)	11 (3.8)	0.04	2 (1.9)	3 (2.8)	>0.99
Respiratory failure	22 (3.2)	4 (1.1)	18 (6.3)	0.001	2 (1.9)	9 (8.3)	0.03
Ventricular fibrillation	12 (1.8)	4 (1.1)	8 (2.8)	0.1	0	4 (3.7)	0.1
Vascular access complication requiring intervention	29 (4.4)	10 (2.7)	19 (6.6)	0.02	4 (3.7)	7 (6.5)	0.5
Sepsis	21 (3.2)	8 (2.2)	13 (4.5)	0.09	4 (3.7)	5 (4.6)	>0.99
GI bleeding	15 (2.3)	8 (2.2)	7 (2.4)	0.8	4 (3.7)	1 (0.9)	0.4
Periprocedural support							0.09
CPB	9 (1.4)	0 (0)	9 (3.1)	0.0004	0 (0)	4 (3.7)	
Cannulation only	4 (0.6)	1 (0.3)	3 (1.0)	—	1 (0.9)	0 (0)	
IABP	3 (0.5)	0	3 (1.0)	—	0	2 (1.6)	
Impella	1 (0.2)	0	1 (0.3)	—	0	0	
TandemHeart	3 (0.5)	0	3 (1.0)	—	0	1 (0.9)	

CPB, cardiopulmonary bypass; EF, ejection fraction; GA, general anesthesia; GI, gastrointestinal; IABP, intra-aortic balloon pump; KCCQ, Kansas City Cardiomyopathy Questionnaire; MAC, monitored anesthesia care; PPM, permanent pacemaker. — indicates that the number of procedures was too small for an accurate p value to be calculated.

Table 4: Preoperative variables in propensity-matched groups.

	MAC ($n = 108$)	GA ($n = 108$)	Std mean difference
Age (y)	79 (73–84.5)	81 (74–86)	0.097
Ejection fraction (%)	55.5 (50–60)	60 (49.5–60)	0.069
STS operative mortality risk (%)	4.74 (3.55–6.84)	4.35 (3.3–6.73)	0.011
Agatston score	2337 (1682–3055)	2151 (1291–3306)	0.028
Preoperative KCCQ score	28.5 (22.5–36.5)	27 (22.5–37)	0.040
Female	45 (41.7)	47 (43.5)	0.038
Previous CABG	22 (20.4)	20 (18.5)	0.046
Preoperative CKD	55 (50.9)	52 (48.1)	0.019
Preoperative dialysis	4 (3.7)	6 (5.6)	0.078
Diabetes mellitus	49 (45.4)	45 (41.7)	0.076
COPD	43 (40.0)	46 (42.6)	0.057

CABG, coronary artery bypass grafting; CKD, chronic kidney disease; COPD, chronic obstructive pulmonary disease; GA, general anesthesia; KCCQ, Kansas City Cardiomyopathy Questionnaire; MAC, monitored anesthesia care; STS, Society of Thoracic Surgeons.

cohort, mortality (2.8% MAC vs. 4.6% GA, $p = 0.7$) and stroke rates (3.7% MAC vs. 1.9% GA, $p = 0.7$) did not differ significantly between the propensity-matched MAC and GA patients. The difference in the rate of transient ischemic attack lost statistical significance once patients were matched (0% MAC vs. 0.9% GA, $p > 0.9$). There were no significant differences in the rates of PPM placement (6.5% MAC vs. 14.8% GA, $p = 0.05$) or AKI (1.9% MAC vs. 2.8% GA, $p > 0.99$). Prolonged respiratory failure remained significantly more frequent in the propensity-matched group in patients who underwent GA (1.9% MAC vs. 8.3% GA, $p = 0.03$).

4. Discussion

Once approved only for high-risk patients [3], TAVI use has now expanded into moderate- and low-risk patient groups [4–7] for the treatment of advanced aortic valve stenosis. As experience with the procedure has grown, the technique has become less and less invasive, with MAC being used extensively. Our database study confirms the safety of these techniques, with MAC patients having significantly shorter length of stay than their propensity-matched GA counterparts, and no difference in mortality or stroke.

In our large, single-center cohort, the average STS risk of mortality for all patients was moderate. Ejection fraction was largely preserved, but there were notable comorbidities in the cohort. One fifth of patients had pacemakers previously implanted. A significant proportion of patients had CKD, pulmonary hypertension, and COPD. Native aortic valve characteristics were similar in both groups, with high calcium burdens noted.

Our data, like those from other institutions, suggest that MAC is safe and effective in TAVI patients [9, 10]. Mortality in both cohorts was low, with no significant differences in either the overall cohort or the propensity-matched patients. Stroke rates did not differ significantly between anesthesia methods; of note, cerebral protection is not routinely used for device implantation at our institution.

One of the most important findings in our study is the extremely low rate of conversion from MAC to GA: only 5/371 patients or less than 5% for the total cohort. Although percutaneous access was the preferred approach in most cases, open conversion and vascular repair were needed more frequently with GA. There seems to be no correlation between the rate of conversion from MAC to GA and the need for vascular repair, as the rate of intraoperative intubation was also very low. However, we have no way to know how many of the intubations in the GA group were planned, being related to preoperative access concerns or planned open access.

The frequency of PPM implantation was significantly greater after GA than after MAC in the overall cohort. While the overall number of balloon-expandable and self-expanding valves used in the cohort was nearly equal, the distribution of implantation for the 2 types was not. Most balloon-expandable valves were placed under MAC, whereas the majority of self-expanding valves were placed under GA. There was no difference in PPM placement in propensity-matched patients although the small number of PPM recipients resulted in this analysis being underpowered.

Very few patients in the MAC cohort required emergency intubation, further confirming the safety of MAC for most patients. We acknowledge that there may always be a clinical selection bias, with patients who are perceived to be sicker migrating to the general anesthetic cohort. For instance, while the prevalence of COPD was similar between groups, a substantial proportion of patients in the GA group (6.2%) remained intubated for more than 48 hours postoperatively. It is possible that these patients had more severe illness that was not reflected quantifiably by their preoperative comorbidities. There was also a significantly greater incidence of pulmonary hypertension in the GA group; these patients may represent an identifiable segment of the TAVI population that could benefit if transitioned to MAC rather than undergoing positive-pressure ventilation and assuming the inherent risk of prolonged intubation. Mechanical circulatory support was rarely used in any form within the cohort. This may suggest that the GA group did not include enough outlier patients with a prolonged LOS due to acute illness to significantly affect the cohort's overall LOS.

We acknowledge that our study has certain limitations. It is a single-center study with a retrospective design. Also, as noted previously, the distribution of valve types was not the same in the GA and MAC groups. We were unfortunately not able to capture intensive care unit LOS, which may have been useful in comparing the severity of illness between the cohorts. Recovery pathways were also not standardized between patients who underwent procedures in the cath lab versus in the operating room, which may have also influenced LOS. In addition, we do not have exact data regarding the use of inotropes in the two groups. Furthermore, access methods were not standardized within the cohort; patients underwent bilateral femoral access or unilateral femoral and radial access at the discretion of the provider.

5. Conclusion

In this large, single-center, retrospective study, using MAC for TAVI was associated with shorter length of stay than using GA. MAC was also associated with lower rates of postoperative respiratory failure and, especially, periprocedural intubation. These results confirm previous findings suggesting that MAC can be used safely and have several advantages over GA when adopted as standard therapy.

Data Availability

All patient data have been deidentified and are currently held in repository through the Baylor TAVR database. With regard to access of data, all inquiries may be made to the corresponding author.

Conflicts of Interest

Dr. Preventza discloses a financial relationship with W.L. Gore & Associates and Terumo Aortic; Dr. LeMaire with Terumo Aortic, Cerus, and CytoSorbents; and Dr. Coselli with Terumo Aortic, Medtronic, W.L. Gore & Associates, CytoSorbents, and Abbott Laboratories. Dr. Krajcer has presented at events supported by Medtronic. The other authors have nothing to disclose.

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