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Authors

Lum, Matthew Y

Wang, Sue X

Wisneski, Andrew D

et al.

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# Development of the Minimalist Approach for Transcatheter Aortic Valve Replacement at a Veterans Affairs Medical Center

**Matthew YKT Lum, MD**[1], **Sue X Wang, MD**[1], **Andrew D. Wisneski, MD**[1], **Norah Liang, MD**[1], **Jeffrey D. Zimmet, MD, PhD**[2], **Kendrick A Shunk, MD, PhD**[2], **Martin Stechert, MD**[3], **Martin J London, MD**[3], **Liang Ge, PhD**[1], **Elaine E Tseng, MD**[1]

[1]Division of Cardiothoracic Surgery, University of California San Francisco and San Francisco Veterans Affairs (VA) Medical Centers, San Francisco, CA,

[2]Division of Cardiology, University of California San Francisco and San Francisco VA Medical Centers, San Francisco, CA,

[3]Department of Anesthesia, University of California San Francisco and San Francisco VA Medical Center.

## Abstract

**Objectives—**While a minimalist transcatheter aortic valve replacement (TAVR) approach has shown safety and efficacy at civilian hospitals, limited data exist regarding developing this approach at Veterans Affairs (VA) medical centers (VAMC). We implemented TAVR minimalist approach using conscious sedation (CS) with transthoracic echocardiography (TTE) and compared safety and outcomes with general anesthesia (GA) with transesophageal echocardiography (TEE) at a university-affiliated VAMC.

**Methods—**258 patients underwent transfemoral TAVR at a VAMC between November 2013 and October 2019. 93 patients underwent general anesthesia/TEE, and 165 patients underwent conscious sedation/TTE (minimalist approach, MA) with dexmedetomidine (Precedex) and remifentanil. Propensity score matching with nearest neighbor matching was used to account for baseline differences, yielding 227 participants (81 GA, 146 CS).

**Results—**Minimalist TAVR approach had no effect on 30-day mortality or paravalvular leakage. No differences were found in permanent pacemaker implantation, major vascular complications, and post-operative hemodynamics. In this population, minimalist TAVR approach did not reduce procedural time, nor hospital or intensive care unit length of stay.

**Conclusions—**Unlike civilian hospitals, the minimalist approach with conscious sedation/TTE did not reduce overall length of stay in the veteran population; however, it was safe and effective for transfemoral TAVR without impacting clinical outcomes of mortality, major vascular complications, and paravalvular leakage.

Corresponding Author: Elaine E. Tseng, MD, Division of Cardiothoracic Surgery, University of California San Francisco and San Francisco VA Medical Center, 500 Parnassus Ave, Ste 405W, Box 0118, San Francisco, CA 94143. Office: 415-221-4810 ext 23452, Fax: 415-750-2181, elaine.tseng@ucsf.edu.

**Keywords**

TAVR; MAC; general anesthesia

## Introduction

Transcatheter aortic valve replacement (TAVR) has rapidly become an accepted alternative to surgery for the treatment of aortic stenosis in intermediate, high, and prohibitive-risk patients.[1,2] The results from the recently published Placement of AoRTic TraNscathetER Valve (PARTNER) 3 Trial[3] and Evolut Low Risk Trial[4] demonstrated superiority of balloon-expandable TAVR and noninferiority of self-expanding TAVR over surgical aortic valve replacement in low-risk patients, respectively, cementing the path for TAVR's expansion to an even greater patient population.[1,5]

As TAVR becomes more widely used, studies have examined the use of a minimalist approach (MA) with conscious sedation (CS) and transthoracic echocardiography (TTE) versus the use of general anesthesia (GA) and transesophageal echocardiography (TEE) for TAVR cases. These studies, often performed at high-volume TAVR centers, suggest the safety and efficacy of a minimalist approach for TAVR.[6–8] The definition of a minimalist approach varies but typically encompasses minimizing procedural elements and implementing post-procedure protocolized pathways to achieve early discharge. CS in TAVR has been associated with shortened length of stay, decreased procedure time, and decreased costs without impacting incidence of procedural mortality or major complications compared to GA.[9–11] In our minimalist approach, we opted to use conscious sedation and intraprocedural transthoracic echocardiography as opposed to general anesthesia and intraprocedural transesophageal echocardiography, and gradually minimized adjunctive procedures by selective use of central venous access, minimizing Foley catheter usage, but maintaining admission to intensive care unit post-procedure. Outcomes of TAVR patients in federal system have recently been reported,[12] demonstrating excellent short-term results. However, the minimalist approach has not been uniformly adopted at Veterans Affairs (VA) medical centers. Thus, outcomes for the safety and efficacy of such a minimalist approach remain largely unknown since VA data are not captured by the Society of Thoracic Surgeons/American College of Cardiology (STS/ACC) Transcatheter Valve Therapies (TVT) Registry. VA outcomes are separately reported to national VA databases for benchmarking and quality improvement purposes, but there is value in reporting these data publicly for transparency given an overall high comorbidity burden in this population as well as for patient preference with regards to choice of health care facility.

Since the first VA TAVR program was established in 2011, several centers have emerged across the country, including our VAMC, one of the first five VA-approved TAVR sites.[13] The perioperative outcomes at our VAMC have previously been described.[12,14] This study expands upon the previously reported results and investigates procedural outcomes of our TAVR program as a minimalist approach was adopted.

## Materials and Methods

We retrospectively reviewed 289 patients at a VA medical center undergoing TAVR between November 2013 and October 2019. Patients undergoing TAVR with concomitant percutaneous coronary intervention (PCI) and cases of elective valve-in-valve procedures for surgical bioprosthetic valve degeneration were excluded, with 258 patients remaining. At our VAMC, TAVR was initially performed using GA and TEE with a gradual transition to the use of CS and TTE as the program transitioned to nearly uniform use of MA. Our MA program involved using CS with dexmedetomidine (Precedex) and remifentanil titrated such that the patient is only purposefully responsive to verbal or tactile stimulation while maintaining adequate spontaneous ventilation. It also used TTE rather than TEE, preferential use of condom instead of Foley catheters, and a selective insertion of internal jugular lines based on preoperative parameters. In contrast, the traditional approach used GA, TEE, central lines, and Foley catheters. All post-TAVR patients automatically were admitted to ICU, with subsequent transfer to a step-down, telemetry unit, or discharge depending upon clinical stability and bed availability.

The VA Computerized Patient Record System (CPRS) records was used to investigate TAVR outcomes. 93 patients underwent TAVR with GA, while 165 patients underwent MA with CS. Data were collected based on STS Cardiac Surgery guidelines.[15] In the analysis of our data, patients were propensity score matched to account for differences in baseline characteristics.[16,17] Propensity scores were estimated using a logistic regression model based on factors found to be significantly different at baseline, including STS mortality score, age, prior MI, prior CABG, prior PCI, chronic lung disease, and aortic valve area (Fig. 1).[18] Propensity score matching using a nearest neighbor algorithm with one neighbor yielded 227 patients whose data were supported by the algorithm, comprised of 81 patients who underwent TAVR with GA and 146 patients who underwent TAVR with CS. Statistical analyses were performed using Stata version 16 (StataCorp LLC, College Station, TX), with $p<0.05$ considered statistically significant.

## Results

### Baseline patient characteristics

Between November 2013 and October 2019, 258 TAVR procedures were performed at the SFVAMC. Sixty-four percent (n=165/258) were performed under MA with CS/TTE and 36.0% (n=93/258) were performed under GA/TEE. The procedure was converted from CS to GA in 1.55% (n=4/258) of cases for hypotension and apnea, and in two cases, vascular complications. Preoperative demographics and comorbidities are summarized in Table 1. 95.7% (n=89/93) of the GA patients and 98.8% (n=163/165) of the MA patients were male (p=0.114). Mean age was 80.2 years old for GA patients and 77.5 years old for MA patients (p=0.022). GA patients had higher surgical risk with 4.89% STS predicted risk of mortality (PROM) vs. 3.03% STS-PROM risk for MA (p<0.001). Preoperative ejection fraction (p=0.811), smoking status (p=0.058), diabetes (p=0.343), and hypertension (p=0.657) were not significantly different between GA and MA patients. GA patients were more likely to have a history of myocardial infarction (MI) (p<0.001), coronary artery bypass grafting (CABG) (p=0.003), percutaneous coronary intervention (PCI) (p=0.010), and chronic lung

disease (p<0.001). Prior stroke (p=0.385) was not statistically significant between GA and MA patients. New York Heart Association Class was not significantly different between GA and MA patients (p=0.156). Differences in aortic valve area were statistically though not clinically significant, with GA group at 0.714 $cm^2$ compared to 0.776 $cm^2$ for MA (p=0.007). Preoperative aortic valve mean pressure gradient was not significantly different between GA 44.0mmHg and MA 42.2mmHg (p=0.209). After propensity score matching was implemented, 227 patients remained, including 81 patients who underwent TAVR with GA/TEE and 146 patients who underwent TAVR with MA with CS/TTE.

## Procedural Characteristics

Table 2 shows procedural characteristics in the GA and MA groups. Of the 93 GA patients, 17 were treated with Sapien, 28 with Sapien XT, 19 with Sapien 3, 17 with Medtronic CoreValve, 10 with Medtronic CoreValve Evolut R, and 2 with Medtronic CoreValve Evolut Pro. Of the 165 CS patients, 2 were treated with Sapien XT, 132 with Sapien 3, 19 with Medtronic CoreValve Evolut R, and 12 with Medtronic CoreValve Evolut Pro. Central lines were used in 97.8% of cases under GA compared to 83.0% of cases under MA (p<0.001). Foley catheters were used in 96.8% of cases under GA versus 16.4% of cases under MA (p<0.001). Redo TAVR-in-TAVR procedures were later performed in 5 patients, 4 under GA and 1 under CS, due to worsening paravalvular leak or device migration associated with patient-specific anatomy. The repeat procedures were performed under GA. Among the propensity matched groups, no patients required cardiac surgical intervention for any complication during the index TAVR admission.

## Procedural Outcomes

Table 3 describes perioperative characteristics and outcomes. Our minimalist approach with CS was associated with shorter procedure time of 93.1 vs. 132.1 minutes with GA, although the difference was not statistically significant after propensity score matching (p=0.198). CS was associated with a decrease in contrast use with 125.5mL under MA compared to 155.4mL under GA (p=0.0075) and a decrease in fluoroscopy time with 17.0min under MA compared to 26.1min under GA (p=0.0080). Post-procedure hospital length of stay, defined as the number of days from TAVR procedure until hospital discharge (p=0.460), and ICU stay (p=0.536) were similar between the two groups. 30-day post-operative mortality was 1.23% in the GA group and 1.37% in the MA group (p=0.417). The difference in the need for blood transfusion between GA patients (13.6%) and MA patients (2.74%) was statistically significant (p = 0.025). Post-operative stroke was 3.70% in the GA group and 2.05% in the MA group (p=0.074). Rates of permanent pacemaker (p=0.242), atrial fibrillation (p=0.573), and cardiac arrest (p=0.247) were not significantly different for MA vs. GA. The rate of major vascular complications as defined by the VARC-2 criteria,[19] was not significantly different between the two groups (p=0.466). The need for a repeat valve procedure (p=0.567) due to worsening paravalvular leak or device migration was not significantly different for MA vs. GA. Post-operative paravalvular leak was also not significantly different between MA and GA groups (p=0.071). Similarly, post-operative aortic valve mean pressure gradient was not significantly different between MA and GA groups (p=0.913). Mild paravalvular leak rates were 12.3% for MA vs. 19.8% for GA, and moderate paravalvular leak rates were 0% for MA vs. 4.94% for GA. No paravalvular leak

exceeding moderate degree occurred in either group. Post-operative ejection fraction was not statistically significant between patients receiving MA vs. GA (p=0.0850).

## Discussion

TAVR under MA in civilian populations has been shown to improve clinical outcomes and quality of life while lowering costs.[9] However, the limited data reported regarding TAVR outcomes at federal institutions[12] did not examine a minimalist approach which has not been uniformly adopted, and national TAVR registries do not capture VA outcomes. This retrospective review examined the outcomes of 258 patients at a single VAMC as the TAVR program transitioned to nearly uniform use of MA with CS/TTE from GA/TEE. Propensity score matching using a nearest neighbor algorithm yielded analyses of 227 patients, 88.0% of the original 258 patients. Our data showed that the adoption of MA did not impact 30-mortality or paravalvular leakage rates. Differences in procedural time were not significantly different once propensity score matching was employed. Our results demonstrate that the adoption of MA did not compromise outcomes in the VA patient population, while procedural benefits were conferred to patients.

In a smaller study of VA TAVR, MA for TAVR was associated with decreased procedural times, fluoroscopy times, and contrast use.[20] Our much larger study of 258 patients also showed decreased fluoroscopy time and contrast use but not procedural times, and we accounted for baseline population differences with propensity score matching. We also described MA development for our VAMC TAVR program with avoiding Foley insertion and reducing central venous line placement in addition to conversion from GA/TEE to conscious sedation and TTE. We found no significant differences in post-operative mean pressure gradient or post-operative ejection fraction using MA vs. GA/TEE. No significant differences were seen in 30-day mortality, stroke, new onset atrial fibrillation, cardiac arrest, and major vascular complications between MA and GA/TEE. There was no significant difference in the rates of post-TAVR permanent pacemaker implantation in MA and GA/TEE. Similarly, no significant difference was found for rates of repeat valve procedures between MA and GA/TEE. Four of the five cases requiring repeat valve procedures took place under GA/TEE, suggesting that that MA does not lead to increased rates of device malposition. The most likely explanation for these repeat procedures is the learning curve associated with the TAVR procedure itself. Overall, the results suggest that these outcomes are comparable between TAVR performed with MA and TAVR performed under GA.

Unlike the civilian population, our data found no significant difference in post-procedure hospital length of stay, and in post-procedure ICU length of stay. Civilian population studies have shown an association between MA techniques and early discharge. The Vancouver TAVR clinical pathway showed significant differences in the use of local anesthesia/CS and avoidance of a urinary catheter when comparing early discharge at 1 day versus standard discharge at 3 days.[21,22] In contrast, our data showed no association, with 19.8% of GA patients discharged before 3 days compared to 19.2% of MA patients (p=0.841). Literature suggests that lengths of stay greater than 5 days is an independent predictor of 30-day readmission.[23] When examined by stays shorter than 5 days, our data showed that 60.4% of

GA patients were discharged by day 5 compared to 75.3% of MA patients (p=0.030) (Fig. 2). These results suggest that our transition to MA was done safely.

The inability to reduce hospital length of stay is unique to our VA population. Most patients are referred from as far as Los Angeles to the south and Eureka to the north. As such, length of stay disposition in the hospital is frequently longer to arrange transportation. Many of our patients rely on VA shuttles which are not available on the weekends, limiting our ability to offer early discharge at the end of the work week. Similarly, during our study, the ICU length of stay did not change because the telemetry floors were unable to accommodate patients who might be at risk of requiring a temporary pacemaker or at risk of vascular complications. As such, TAVR patients were kept in the ICU for 48 hours of monitoring. Interestingly, with the advent of COVID-19 and limitations in ICU beds after this study was completed, ICU bed utilization has decreased to less than 48 hours to accommodate sicker hospital patients. Our policy has evolved to include monitoring in the post-anesthesia care unit for patients not requiring a pacemaker and without bleeding rather than sending these patients directly to the ICU, given our resource limitations in the setting of COVID-19.

Our structural heart team determined the use of TAVR versus surgical aortic valve replacement informed by concurrent guidelines, which changed over the course of the study period as high, intermediate, and low risk trials extended the use of TAVR to more patients.[3] For the TAVR cases, the decision to use GA/TEE vs. MA with CS/TTE involved the collaboration of the anesthesia and structural heart teams. Contraindications to CS include patient preference for GA, which was rare, the inability to lie flat and or still, the inability to cooperate under sedation, difficult airway in a setting where conversion to GA was more likely from a cardiac standpoint. Since 2016, CS has become preferred over GA in the absence of these contraindications because of its theoretical benefits.

Our data showed that, compared to MA patients, GA patients had higher STS mortality scores, were older, were more likely to have had a prior MI, were more likely to have a prior CABG or prior PCI, and were more likely to have chronic lung disease. These demographic differences are consistent with findings at other institutions, which showed that patients receiving CS had lower STS mortality scores than patients receiving GA.[24] These differences are likely related to the necessity of using GA in patients with more severe cardiac and pulmonary disease as well as the presence of other comorbidities. For instance, severe congestive heart failure affects a patient's ability to lie flat, and dementia affects a patient's ability to lie still. In these settings, a patient may not be a candidate for MA with CS/TTE. Propensity matching enabled us to account for some of these differences, with reductions in standardized percent bias in all significantly different categories (Table 1). Yet, given that patient characteristics were used in the determination of the anesthetic used, heart team judgment is necessary to appropriately administer MA with CS/TTE in patients undergoing TAVR.

The findings in this study are consistent with data from the literature comparing GA and MA. In recent meta-analyses comparing TAVR under GA and MA, no significant difference was found in rates of stroke, major vascular complication, or the need for a permanent pacemaker.[25,26] Interestingly, data from national registries and some meta-analyses showed

that the use of CS was associated with lower 30-day mortality, suggesting that CS may be superior to GA.[11,25] This finding is encouraging, although 30-day mortality data remain mixed, with our data and the results from other studies showing no significant difference.[26] Nonetheless, given the non-inferiority of TAVR performed under MA and the potential advantages of cost saving, MA should be considered as the primary option for appropriately selected patients undergoing TAVR.

Cases under GA allow use of transesophageal echocardiography (TEE) while our defined minimalist approach uses CS with intraprocedural transthoracic echocardiography (TTE). Theoretical concerns have existed with the move from GA to MA including concerns that complications such as annular rupture or cardiac tamponade would be diagnosed late. As we adopted MA, TTE immediately after valve deployment became our protocol and enabled us to quickly evaluate for tamponade or aortic dissection. We found no differences in post-procedural paravalvular leak, similar to literature comparing the use of TTE and TEE.[27] Similarly, no difference has been shown for post-procedural aortic regurgitation or tamponade when comparing the use of TEE and angiography to angiography alone.[28] Furthermore, our data showed no significant difference in major vascular complications for patients undergoing MA vs. GA.

This study was limited by its retrospective and single-center design. The patient population studied is representative of the VA TAVR program, which is predominantly male with age affected by service years. Due to inherent differences in baseline characteristics of the GA/TEE vs. MA cohorts, propensity score matching was implemented. Another study limitation is that the learning curves for TAVR and development of MA occurred together which makes it difficult to tease out the impact of learning curve for TAVR from the effects of MA. Nonetheless, our study suggests that our TAVR program was able to safely transition from GA and TEE to a minimalist approach, which offers procedural benefits without compromising TAVR outcomes.

## Conclusions

As one of the first 5 VA centers approved to perform TAVR, we showed that a federal facility was able to safely transition from general anesthesia with TEE to a minimalist approach using conscious sedation with TTE for TAVR procedures. Furthermore, our results showed reduction in contrast use and fluoroscopy time as the MA program developed. These data are not captured by the STS/ACC registry and demonstrates transparency of TAVR outcomes at federal facilities. Our results suggest that the use of MA for TAVR can be extended to other federal facilities with the possibility of reducing cost without compromising quality of care. These findings become increasingly important as TAVR becomes more widely used to treat aortic stenosis.

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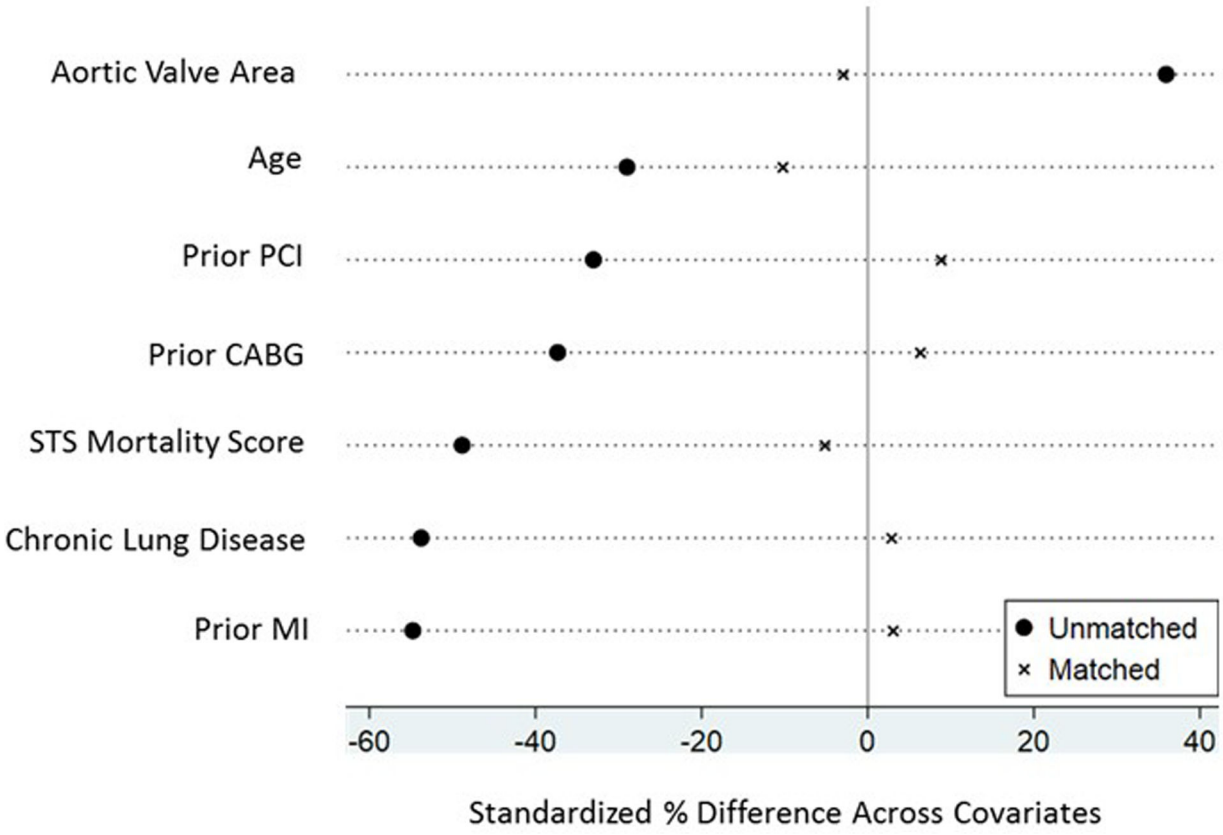


**Figure 1.**
Standardized percent difference across covariates before and after propensity score matching

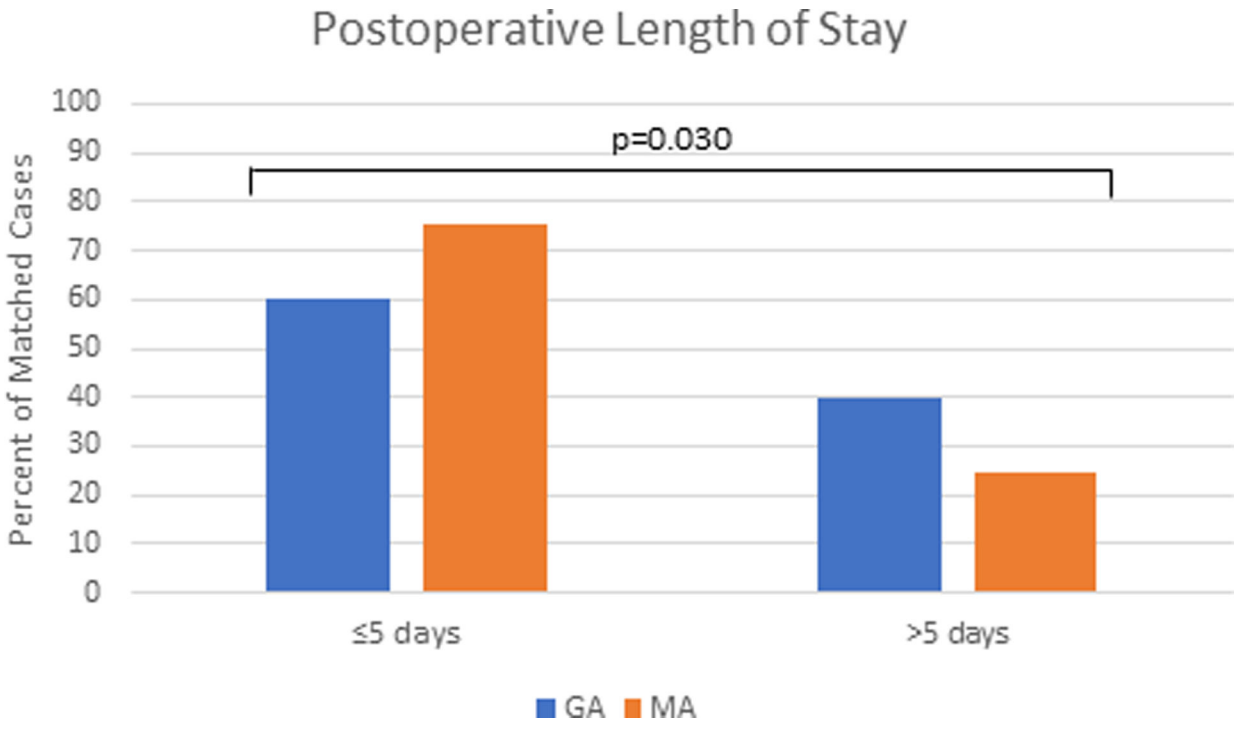


**Figure 2.**
Postoperative length of stay in days based upon percentage of propensity matched cases by approach.

**Table 1.**

Unmatched Preoperative Demographics & Comorbidities

| | General Anesthesia | Minimalist Approach | p-value |
|---|---|---|---|
| **Patients, n** | 93 | 165 | |
| **STS Mortality Score (%), mean (SD)** | 4.89 (4.13) | 3.03 (3.47) | <0.001* |
| **Age (y), mean (SD)** | 80.2 (10.3) | 77.5 (8.44) | 0.022* |
| **Male Gender, n (%)** | 89 (95.7) | 163 (98.8) | 0.114 |
| **Ejection Fraction (%), mean (SD)** | 55.6 (15.0) | 55.2 (12.4) | 0.811 |
| **Smoking Status** | | | |
| Current Smoker, n (%) | 5 (5.38) | 20 (12.1) | 0.058 |
| Prior Smoker, n (%) | 67 (72.0) | 96 (58.2) | |
| **Diabetes, n (%)** | 44 (47.3) | 68 (41.2) | 0.343 |
| **Hypertension, n (%)** | 85 (91.4) | 148 (89.7) | 0.657 |
| **Prior MI, n (%)** | 41 (44.1) | 32 (19.4) | <0.001* |
| **Prior CABG, n (%)** | 32 (34.4) | 30 (18.2) | 0.003* |
| **Prior PCI, n (%)** | 38 (40.9) | 42 (25.5) | 0.010* |
| **Prior Stroke, n (%)** | 9 (9.68) | 11 (6.67) | 0.385 |
| **Chronic Lung Disease, n (%)** | 54 (58.1) | 53 (32.1) | <0.001* |
| **New York Heart Association Class** | | | |
| Class I, n (%) | 0 (0) | 1 (0.61) | 0.156 |
| Class II, n (%) | 5 (5.38) | 17 (10.3) | |
| Class III, n (%) | 78 (83.9) | 139 (84.2) | |
| Class IV, n (%) | 10 (10.8) | 8 (4.85) | |
| **Aortic Valve Area (cm), mean (SD)** | 0.714 (0.160) | 0.776 (0.183) | 0.007* |
| **Mean Pressure Gradient (mmHg), mean (SD)** | 44.0 (9.48) | 42.2 (11.6) | 0.209 |

*
**p<0.05,** determined using 2-tailed t-test or chi-squared tests.

**Table 2.**

Procedural Characteristics

| | General Anesthesia | Minimalist Approach | Total |
|---|---|---|---|
| **Patients, n** | 93 | 165 | 258 |
| **Valve Platform** | | | |
| Sapien | 17 | 0 | 17 |
| Sapien XT | 28 | 2 | 30 |
| Sapien S3 | 19 | 132 | 151 |
| CoreValve | 17 | 0 | 17 |
| CoreValve Evolut R | 10 | 19 | 29 |
| CoreValve Evolut Pro | 2 | 12 | 14 |
| **Central Venous Access, n (%)** | 91 (97.8) | 137 (83.0) | $p<0.001$ * |
| **Foley Catheter Usage, n (%)** | 90 (96.8) | 27 (16.4) | $p<0.001$ * |

* **$p<0.05$,** determined using chi-squared test.

**Table 3.**

Perioperative Characteristics & Outcomes

| | General Anesthesia | Minimalist Approach | p-value matched |
|---|---|---|---|
| **Operative Time (min), mean (SEM)** | 132.1 (7.41) | 93.1 (3.39) | 0.198 |
| **Volume of Contrast Used (mL), mean (SEM)** | 155.4 (8.42) | 125.5 (3.97) | 0.008* |
| **Fluoroscopy Time (min), mean (SEM)** | 26.1 (1.23) | 17.0 (0.668) | 0.008* |
| **Post-procedure Hospital Length of Stay (days), mean (SEM)** | 5.31 (0.433) | 5.14 (0.449) | 0.460 |
| **Post-procedure ICU Length of Stay (days), median (SEM)** | 3.69 (0.307) | 4.11 (0.278) | 0.536 |
| **30-Day Mortality, n (%)** | 1 (1.23) | 2 (1.37) | 0.417 |
| **Received transfusion, n (%)** | 11 (13.6) | 4 (2.74) | 0.025* |
| **Stroke, n (%)** | 3 (3.70) | 3 (2.05) | 0.074 |
| **Permanent Pacemaker, n (%)** | 11 (13.6) | 21 (14.4) | 0.242 |
| **Atrial Fibrillation, n (%)** | 7 (8.64) | 8 (5.48) | 0.573 |
| **Cardiac Arrest, n (%)** | 0 (0) | 1 (0.685) | 0.247 |
| **Major Vascular Complication, n (%)** | 4 (4.94) | 8 (5.48) | 0.466 |
| **Repeat Valve Procedure, n (%)** | 3 (3.70) | 1 (0.685) | 0.567 |
| **Paravalvular Leak** | | | |
| None, n (%) | 30 (37.0) | 62 (42.5) | |
| Trace, n (%) | 31 (38.3) | 66 (45.2) | |
| Mild, n (%) | 16 (19.8) | 18 (12.3) | |
| Moderate, n (%) | 4 (4.94) | 0 (0) | 0.071 |
| **Post-operative Mean Pressure Gradient (mmHg), mean (SEM)** | 8.30 (0.511) | 9.88 (0.411) | 0.913 |
| **Post-operative Ejection Fraction** | 59.8 (1.18) | 58.5 (1.00) | 0.0850 |

* **p<0.05,** calculated using nearest-neighbor propensity score matching. Mean values and percentages were calculated based on unmatched data.