Supraglottic airway versus endotracheal tube for transesophageal echocardiography guided watchman procedures

Sridhar Reddy Musuku, Isha Doshi, Dmitriy Yukhvid, Christopher A. Di Capua, Alexander D. Shapeton
Albany Medical Center, 43 New Scotland Avenue, Albany-United States

ABSTRACT
Context: Atrial fibrillation (AF) is the most common arrhythmia in adults. For over 90% of non-valvular AF patients, the left atrial appendage is the primary site of thrombus formation. Left atrial appendage occlusion using the FDA-approved Watchman™ device has been shown to have better clinical outcomes with minimal post-procedural complications when compared to warfarin therapy for patients with contraindications to anticoagulation. Traditionally, this procedure requires an endotracheal tube (ETT) to facilitate transesophageal echocardiography (TEE) guidance. However, recently supraglottic airway (SGA) has emerged as a feasible, non-inferior alternative to ETT for procedures requiring TEE. Aims: Compare outcomes between TEE guided Watchman™ procedures performed with a SGA versus ETT. Settings and Design: A single tertiary care academic medical center. Methods and Materials: Retrospective Observational Study comparing SGA and ETT patients. Statistical Analysis Used: 1:4 propensity score matching of SGA and ETT patients. Results: 42 SGA patients were matched with 155 ETT patients. All patients underwent procedure with TEE. SGA patients had shorter operating room time (11 min difference, \( P = 0.00001 \)) and considerably shorter PACU length of stays (45 min difference, \( P = 0.024 \)). Statistically significant, but clinically trivial differences were seen in procedure times (\( P = 0.015 \)) and fluoroscopy times (\( P = 0.017 \)). Patients in the SGA group received lower fentanyl (\( P < 0.00001 \)) dosages. No significant differences were observed in postoperative complications, organ-specific morbidity or 30-day mortality. Conclusions: General anesthesia with SGA is likely a safe, feasible alternative to ETT in Watchman™ procedures requiring TEE guidance. Use of SGA was associated with significant reductions in operating room time and PACU length of stay, potentially offering advantages in terms of resource utilization.

Keywords: Atrial fibrillation, echocardiography, Supraglottic airway, TEE, Watchman™ procedure

INTRODUCTION
Atrial fibrillation (AF) is the most common arrhythmia in adults; responsible for half of all cardio-embolic strokes,[1] and predicted to affect 6–12 million people in the United States by 2050 and 17.9 million in Europe by 2060.[2,3] Nonvalvular AF in older patients is an independent risk factor for the incidence of stroke.[4] Patients with non-valvular AF have an approximately 5-fold increase in risk of stroke,[4] and for more than 90%

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of these patients, the left atrial appendage (LAA) is the primary site of thrombus formation. These AF related cardioembolic events are associated with high morbidity and mortality. Over the last decade, LAA occlusion has become an attractive alternative for non-valvular AF patients to prevent thromboembolism when long-term oral anticoagulation is hazardous or otherwise unsuitable.

The only Food and Drug Administration (FDA) approved endovascular device for stroke prevention is the Watchman™ LAA device (Boston Scientific Corporation, St Paul, MN). This device has been shown to effectively seal the LAA and decrease the incidence of thromboembolic stroke, long-term bleeding, and mortality in AF patients with contraindications to oral anticoagulation, when compared to warfarin therapy. Performed as a one-time procedure, the Watchman™ device is an implant that fits directly in the LAA through a catheter-based delivery system, via trans-septal puncture from the right-to-left atrium. The device permanently seals the LAA and thereby prevents blood clots from escaping. Transesophageal echocardiography (TEE) or intracardiac echo (ICE) are routinely used peri-procedurally to identify the morphology, size, and depth of the LAA. Additionally, these imaging modalities allow clinicians to determine the number and location of lobes relative to LAA ostium, as well as guide for proper positioning of the device. Fluoroscopy and contrast are also used to further assist with this procedural guidance.

Since TEE is often instrumental in guiding device implantation, traditionally, general anesthesia (GA) with airway maintenance via an endotracheal tube (ETT) has been the standard of care. However, in recent years the use of GA with supraglottic airway (SGA) has been gaining traction as an effective alternative to ETT in a variety of cardiovascular procedures to improve hemodynamic stability and reduce anesthetic requirements. SGA use has also shown to decrease airway complications, and postoperative nausea/vomiting. Multiple studies have compared the use of SGA-TEE versus ETT-TEE for catheter ablation in AF patients, demonstrating that SGA is a safe, feasible, and non-inferior approach in terms of TEE use, as well as procedural and postoperative complications. However, no prior studies have directly compared ETT and SGA in the context of the Watchman™ LAA occlusion procedure.

The aim of this study was to compare outcomes of Watchman™ procedures performed with TEE guidance, at a single institution, using GA with an ETT versus SGA for airway maintenance. Given existing literature, operating room (OR) time served as the primary outcome in this study. Procedure time, post-anesthesia care unit (PACU) length of stay (LOS), hospital LOS, administration of fentanyl and rocuronium, intraprocedural complications, and post-procedural morbidity and mortality served as secondary outcomes. The authors hypothesized that SGA is feasible, safe and effective alternative to ETT with comparable primary and secondary outcomes in patients undergoing Watchman™ procedures.

SUBJECTS AND METHODS

This study was approved by the appropriate institutional review board, and requirement for written informed consent was waived. This study was a retrospective observational analysis of patients who underwent Watchman™ LAA occlusion procedures under (i) general anesthesia with an ETT and (ii) general anesthesia with an SGA. All patients with non-valvular AF referred to a single large tertiary academic medical center between September 2017 and May 2019 for an elective Watchman™ procedure were evaluated. All patients underwent the procedure with TEE. A total of 197 consecutive patients were reviewed, including 155 ETT patients and 42 SGA patients.

Data gathering

Data was gathered retrospectively from patient medical records and the Watchman™ patient registry. Post-operative complications, morbidity and 30-day mortality data were also collected from the patient records and the cardiology clinic data.

Procedural screening and computed tomography (CT) imaging were reviewed prior to the procedure by the structural heart to determine if the LAA anatomy was suitable for intervention. The anesthetic technique was chosen at the discretion of the cardiac anesthesiologist, based on factors like BMI, oropharyngeal anatomy and history of GERD. All procedures were conducted in cardiac catheterization laboratories. Standard American Society of Anesthesiology (ASA) monitors were used in all procedures.

Placement technique Supraglottic airway

Preoxygenation and a combination of inhalational agent, sevoflurane, and IV propofol (0.5-1.5 mg/kg) were used for induction of anesthesia in SGA patients. An i-gel SGA (Intersurgical, East Syracuse, NY), size 4 or 5 depending on patient body weight, was then inserted and secured after ensuring adequate chest expansion and positive ETCO₂. Then a lubricated TEE probe (GE Vivid, GE healthcare, CA, USA) was introduced and positioned at the left corner of mouth. SGA was secured in the center of the mouth.
or slightly to the right. Fentanyl (0.5–2 μg/kg) was titrated as needed to assist with appropriate anesthetic depth, and to a respiratory rate of 12-16 per minute. A small dose of rocuronium (5 mg) was occasionally administered to decrease patient movement and thus facilitate the procedure. The level of inhalational anesthetic (sevoflurane or isoflurane) was titrated to approximately 1.0–1.8 MAC as needed to maintain appropriate depth of anesthesia. SGA patients who had spontaneous efforts were supported using pressure support ventilation (PSV) to achieve a tidal volume of 5–7 mL/kg, and patients without effort were supported using a synchronous volume-controlled mode and switched later to the PSV mode.

**Placement technique ETT**
For ETT placement, standard intravenous induction agents (propofol 0.5-2 mg/kg or etomidate, 0.2-0.3 mg/kg) and fentanyl (0.5-2 μg/kg) were used. Neuromuscular blockade with rocuronium (0.5 mg/kg) was administered prior to direct laryngoscopy and ETT placement. Sevoflurane or isoflurane was used as a maintenance agent. A size 7 mm ETT was used in female patients and size 8 mm ETT was used in male patients. All ETT patients were supported using lung protective, weight-based, volume-controlled ventilation. A lubricated TEE probe was inserted using standard approach.

**TEE use and procedural technique for Watchman™ LAA occlusion**
A procedure-specific TEE exam was performed on each patient to assess the LAA morphology, inspect for thrombus and to guide the procedure. Heparin was administered to achieve an activated clotting time (ACT) of >280 seconds after the trans-septal puncture. Once the procedure was completed, protamine was used to reverse the heparin, and the TEE probe was then removed. The SGA was removed when the patient was awake. For the ETT group, neuromuscular blockade was reversed with neostigmine and glycopyrrolate or sugammadex, and the ETT was removed when standard extubation criteria were met. Both groups of patients were transferred to the PACU and later to the floor.

**Statistical analysis**
Statistical analysis was performed using R Version 3.6.3 (R Foundation for Statistical Computing, Vienna, Austria) and Microsoft Excel. Patients who received an ETT were placed in the control group, while those who received an SGA were in the treatment group. Results were considered statistically significant where \( P < 0.05 \). Due to the very limited literature surrounding SGA use in Watchman™ procedures, no power analysis was conducted.

### Baseline demographic variables
An initial analysis of baseline variables between the two groups was conducted using Wilcoxon Rank sum tests for continuous variables, Chi-square test of independence for categorical variables with counts ≥10 in either group, and Fisher’s exact test for categorical variables with counts <10 in either group. Continuous variables included age, BMI, and CHA2DS2-VASc scores. Categorical variables with counts ≥10 included gender, history of chronic heart failure (CHF), hypertension (HTN), stroke, coronary artery disease (CAD), chronic obstructive pulmonary disease (COPD), and previous surgery. Categorical variables with counts <10 included history of left ventricular (LV) dysfunction, diabetes (DM), transient ischemic attack (TIA), deep venous thrombosis (DVT), renal dysfunction, pulmonary HTN, obstructive sleep apnea (OSA), myocardial infarction (MI), prior procedures and continuous positive airway pressure (CPAP) use.

### Propensity score matching
Propensity score matching (PSM) aims to equate treatment groups with respect to measured baseline covariates to

| Table 1: Pre-propensity matching assessment of baseline characteristics |
|-----------------------------|-----------------|-----------------|---------|
| Variable                    | Treatment Group | \( P \) value* |
| Age (years)                 | ETT (79%)       | 0.29            |
| BMI (kg/m²)                 | ETT (29%)       | 0.15            |
| CHA2DS2-VASc Score          | ETT (54%)       | 0.77            |
| Gender (M)                  | ETT (91%)       | 0.84            |
| CHF                         | ETT (77%)       | 0.74            |
| LV Dysfunction              | ETT (21%)       | 0.42            |
| HTN                         | ETT (149%)      | 0.40            |
| DM                          | ETT (63%)       | 0.29            |
| Stroke                      | ETT (28%)       | 0.11            |
| TIA                         | ETT (19%)       | 0.79            |
| DVT                         | ETT (16%)       | 0.037           |
| Renal Dysfunction           | ETT (45%)       | 0.44            |
| CAD                         | ETT (95%)       | 0.56            |
| COPD                        | ETT (84%)       | 0.26            |
| Pulmonary HTN               | ETT (6%)        | 0.99            |
| OSA                         | ETT (12%)       | 0.48            |
| MI                          | ETT (33%)       | 0.99            |
| CPAP Use                    | ETT (13)        | 0.76            |
| Previous Surgery            | ETT (68)        | 0.83            |

*Statistical tests performed: Wilcoxon rank-sum test; chi-square test of independence; Fisher’s exact test. BMI: Body Mass Index; CAD: Coronary Artery Disease; CHA2DS2-VASc: Congestive heart failure, Hypertension, Age, Diabetes, previous Stroke/transient ischemic attack, Vascular disease, Sex; CHF: Chronic Heart Failure; COPD: Chronic Obstructive Pulmonary Disease; CPAP: Continuous Positive Airway Pressure; DM: Diabetes; DVT: Deep Venous Thrombosis; HTN: Hypertension; LV: Left Ventricular; MI: Myocardial Infarction; OSA: Obstructive Sleep Apnea; TIA: Transient Ischemic Attack
achieve a comparison with reduced selection bias. The propensity score was estimated using a multivariate logistic regression model that reflected the probability of a patient receiving ETT or SGA. Any confounding variables were tested as covariates and were entered as the dependent outcome variable. PSM variables used in analysis can be seen in Table 2. The histograms of propensity score distributions for each treatment group demonstrate that there was a sufficient region of commonality. ETT patients were then matched to SGA patients in a 4:1 ratio, through nearest neighbor matching with replacement.

### Statistical tests of outcome variables

An analysis of outcome variables between the two groups was conducted using Wilcoxon Rank Sum tests for continuous variables, Chi-square test of independence for categorical variables with counts $\geq 10$ in either group, and Fisher’s exact test for categorical variables with counts $< 10$ in either group. Continuous variables included OR time, procedure time, fluoroscopy time, contrast volume, PACU LOS, hospital LOS, and fentanyl, and rocuronium dosage. Categorical variables with counts $< 10$ included pericardial effusion, events of postoperative mechanical ventilation, postoperative MI, postoperative nausea vomiting (PONV), postoperative sore throat, postoperative sepsis, admission to ICU, readmission, 30-day mortality, and hospital mortality.

### RESULTS

#### Baseline demographic variables

Non-parametric tests of significance on the baseline variables demonstrated relatively similar characteristics in the SGA and ETT groups [Table 1]. Despite this similarity, there remained the potential for selection bias due to unobserved, or otherwise unrecorded variables. Therefore, PSM analysis was conducted to reduce the risk of treatment selection bias.

#### Propensity score matching

The following variables were chosen to represent the baseline health of the population being examined: age, BMI, CHA2DS2-Vasc scores, gender, history of: CHF, LV dysfunction, HTN, DM, stroke, TIA, DVT, renal dysfunction, CAD, pulmonary COPD, pulmonary HTN, OSA, MI, CPAP use, prior surgeries, the interaction between LV dysfunction and CAD, and the interaction between BMI and OSA. The results of the regression model can be seen in Table 2, and the ROC curve can be seen in Figure 1a. The baseline characteristics (demographic and clinical) had no significant difference between the two groups, signifying well matched and comparable cohorts. The overlap in the distributions of propensity scores [Figure 1b] fulfils the common support assumption required for PSM. After matching, there was good alignment between the treatment groups [Figure 1c and d].

**Primary outcome** [Table 3 and Figure 2]: Compared to the SGA group, OR time in ETT patients was significantly longer [median (IQR) ETT: 50 (40, 65) minutes; SGA: 39 (34, 48) minutes; $P = 0.00001$]. Boxplots [Figure 2] show the numerical difference.

**Secondary outcomes** [Table 3 and Figure 2]: The ETT group had slightly longer procedure times [median (IQR); ETT: 32 (25, 44) minutes; SGA: 28 (22, 39) minutes $P = 0.015$] and fluoroscopy times [median (IQR) ETT: 11 (8, 16) minutes; SGA: 10 (6, 13) minutes $P = 0.017$] when compared to the SGA group. The SGA group, however, did have significantly shorter PACU LOS [median (IQR) ETT: 246 (182, 309) minutes; SGA: 201 (153, 260) minutes; $P = 0.024$]. Hospital LOS was similar between the two groups ($P = 0.99$).

The SGA group patients received lower fentanyl dosages [median (IQR); ETT: 100 (100, 100) µg; SGA:
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Figure 1: Propensity score matching. Treatment: Supraglottic airway (SGA); Control: endotracheal tube (ETT); (a) ROC curve of regression analysis. (b) Overlapping histogram of propensity scores. (c) Distribution of propensity scores of matched and unmatched units. (d) Histograms of propensity score distribution before and after propensity matching

Table 3: Significance of primary and secondary outcomes after propensity score matching

| Continuous Parameters                  | ETT            | SGA            | \( P \) value* |
|----------------------------------------|----------------|----------------|----------------|
| OR Time (min)                          | 50 (40, 65)    | 39 (34, 48)    | 0.00001        |
| Procedure Time (min)                   | 32 (25, 44)    | 28 (22, 39)    | 0.015          |
| Fluoroscopy Time (min)                 | 11 (8, 16)     | 10 (6, 13)     | 0.017          |
| Fentanyl (\( \mu g \))                 | 100 (100, 100) | 100 (75, 100)  | 0.00001        |
| Rocuronium (mg)                        | 50 (50, 50)    | 0 (0, 5)       | 0.00001        |
| Hospital LOS (days)                    | 1.00 (1.00, 1.00) | 1.00 (1.00, 1.00) | 0.99          |
| PACU Stay (min)                        | 246 (182, 309) | 201 (153, 260) | 0.024          |

| Categorical Parameters                 | Number of patients (%) |
|----------------------------------------|------------------------|
| Pericardial Effusion                   | 3 (1.9%)               | 0 (0%)          | 0.99          |
| Postop Mechanical Ventilation          | 3 (1.9%)               | 0 (0%)          | 0.99          |
| Postop MI                              | 0 (0%)                 | 1 (2.4%)        | 0.21          |
| Postop Nausea Vomiting                 | 7 (4.5%)               | 0 (0%)          | 0.35          |
| Postop Sore Throat                     | 3 (1.9%)               | 0 (0%)          | 0.99          |
| Postop Sepsis                          | 1 (0.6%)               | 0 (0%)          | 0.99          |
| Admission to ICU                       | 2 (1.3%)               | 1 (2.4%)        | 0.99          |
| Readmission                            | 3 (1.9%)               | 1 (2.4%)        | 0.99          |
| 30-day Mortality                       | 0 (0%)                 | 0 (0%)          | --            |
| Hospital Mortality                     | 0 (0%)                 | 0 (0%)          | --            |

*Statistical tests performed: Wilcoxon rank-sum test; chi-square test of independence; Fisher’s exact test

1ICU: Intensive care unit; LOS: Length of stay; MAC: minimum alveolar concentration; MI: Myocardial Infarction; OR: Operating Room; PACU: Post-anesthesia care unit; Postop: Post-operative

100 (75,100) \( \mu g \); \( P < 0.00001 \) and lower rocuronium dosages [median (IQR); ETT: 50 (50, 50) mg; SGA: 0 (0, 5) mg; \( P < 0.00001 \)] than ETT patients. [Figure 2].

Two ETT patients were admitted to the ICU. Three ETT patients and one SGA patient were readmitted to the hospital. For both outcomes, no statistical difference was seen (\( P > 0.99, P > 0.99 \) respectively). No patients in either group expired within 30 days or during their hospital stay.

There were no statistical differences in any postoperative complications including mechanical ventilation (\( P > 0.99 \)), MI (\( P = 0.21 \)), PONV (\( P = 0.35 \)), sore throat (\( P > 0.99 \)), and sepsis (\( P > 0.99 \)). Cardiac arrest, pericardial tamponade,
postoperative acute kidney injury and stroke were eliminated from the analysis because no patients experienced these complications.

**DISCUSSION**

When conducting Watchman™ LAA occlusion procedures, assessment of the size and anatomy of the LAA and confirmation of optimal positioning of the LAA occlusion device requires TEE or ICE guidance. Typically these procedures are done under GA to optimize procedural safety and efficacy. While the current consensus is to conduct general anesthesia using an ETT, this study demonstrates that the use of an SGA with TEE is a safe and feasible alternative in patients undergoing Watchman™ LAA procedures. Compared to the ETT group, SGA patients displayed shorter OR times and considerably shorter PACU LOS, as well as decreased fentanyl and rocuronium dosages. Notably, morbidity and mortality were similar in both groups.

Reduced OR time improves efficiency, reduces cost, enhances provider and patient satisfaction and may offer improved patient safety. Consistent with previous studies comparing OR times between SGA and ETT use, our findings also demonstrate shorter OR times (11 minute (22%) median difference) in the SGA group. This may be in part attributable to faster airway management and emergence with SGA, which does not require laryngoscopy and neuromuscular blockade. The differences in fluoroscopy and procedure time were clinically minor, although statistically significant.

The PACU is a resource-intensive environment as it provides continuous evaluation of post-surgical patients and specialized care. The total expense associated with staffing a 2-hour PACU stay has previously been estimated as roughly equivalent to a 24-hour admission in a hospital ward, with many hospitals aiming to discharge patients from the PACU within 2 hours. As such, shorter PACU stays facilitate workflow and likely reduce overall cost of the hospital stay. In our study, the PACU LOS stay was significantly shorter (45 minute (18%) median difference) for the SGA group as compared to the ETT group, representing the potential for considerable reductions in costs and resource utilization.

Administered opioid burden was higher in the ETT group, in agreement with prior studies that highlighted decreased anesthetic requirements when using an SGA. Lower intraoperative opioid administration has been associated with shorter recovery times and lower risk of PONV. In a recent meta-analysis, Patki confirmed lower anesthetic requirements for SGA patients when compared with ETT, as well as identifying an association with decreased procedure duration. In the present study, ETT patients...
received rocuronium more frequently and at a higher dosage, compared to SGA patients. The administration of higher dosages of rocuronium paired with Sugammadex, necessary in ETT patients, carries significant allergic potential[26] and potential for side effects.[27] Additionally, lowering NMBD use for this patient population may reduce the risk of residual postoperative neuromuscular blockade.[28]

Intraprocedural TEE use in SGA patients did not adversely affect the positioning of SGA, and all required TEE views were successfully obtained in all patients. There were no adverse airway complications or aspiration events in patients managed with an SGA, a finding that is consistent with the previously established robust safety profile of these devices.[15,17,29‑32] In the present study, all SGA patients had successful Watchman™ device implantation. TEE use in conjunction with SGA has been gaining momentum as more studies present data suggesting the practice to be safe and effective. A randomized trial in pediatric patients demonstrated that SGA in conjunction with TEE was safe, and reported minimal airway related complications.[33] SGA-TEE has been safely used during atrial ablation procedures,[18] as well as being successfully utilized as a first-line rescue tool during desaturation episodes during TEE performed under sedation.[33] Though not specifically studied here, SGA may also be helpful in special populations where intubation is often avoided, like for professional singers.[34] Although there is a commonly held concern among anesthesiologists that performing TEE with SGA may lead to dislodgement, and potential aspiration risk, multiple studies have demonstrated that this technique does not meaningfully interfere with safe airway management.[13,15,33] Our findings add to the growing body of literature supporting the safety and efficacy of TEE use with SGA.[13,15,17,31,33] Though ETTS remains the standard of care, we propose that SGA is a safe and feasible alternative to ETT in Watchman™ LAA procedures requiring TEE, and may in fact offer potential benefits in terms of cost and resource utilization.

This study is subject to a few limitations. The primary limitation to this study is its retrospective design. Though PSM may significantly reduce selection bias, without a randomized controlled trial this cannot be eliminated. Furthermore, due to maintenance with inhaled anesthetics and limitations of retrospective data gathering, we were not able to assess and compare depth of anesthesia between groups. We did not collect pain scores, or patient and proceduralist satisfaction, and these may offer future research avenues. Our study is also limited by the relatively small number of patients in the SGA arm. Though we did not identify any airway complications or aspiration events in the SGA group, the safety of this technique has only been demonstrated in retrospective trials, and no randomized trial for SGA with TEE has yet been published.

CONCLUSION

General anesthesia with a supraglottic airway is a feasible alternative to endotracheal tube during Watchman™ LAA occlusion procedures requiring TEE. Supraglottic airway use was associated with reduced OR time, considerably reduced PACU length of stay, as well as lower administered fentanyl dosages, without an increased risk of post-operative complications, morbidity or mortality.

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Conflicts of interest

There are no conflicts of interest.

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