## Title

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Original Article

# The Incidence of Dysphagia Among Patients Undergoing TAVR With Either General Anesthesia or Moderate Sedation

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*Objectives:* To determine the incidence of dysphagia and aspiration pneumonia following transcatheter aortic valve replacement (TAVR) performed with either general anesthesia (GA) or moderate sedation (MS).

*Design:* Retrospective study.

*Setting:* Tertiary care university hospital.

*Participants:* One hundred ninety-seven patients undergoing TAVR from 2012 to 2016

*Interventions:* After Institutional Review Board approval, 197 consecutive patients undergoing TAVR from 2012 to 2016 at the authors' institution were identified for analysis and placed into groups depending on method of anesthesia received (GA: n = 139 *v* MS: n = 58). Groups then were compared with respect to baseline characteristics, operative details, primary outcome variables (dysphagia, pneumonia), and secondary outcome variables.

*Measurement and Main Results:* Any patient who failed the institution's postprocedure bedside swallow test subsequently underwent a fiberoptic endoscopic evaluation of swallowing test, confirming the diagnosis of dysphagia. GA patients were significantly more likely to develop dysphagia, which occurred in 10 GA patients and no MS patients ($p = 0.04$). MS patients also were found to have significantly reduced operative durations and spent less time in the intensive care unit and hospital ($p < 0.001$).

*Conclusions:* Patients who underwent TAVR with moderate sedation were less likely to develop dysphagia. Use of MS may be particularly suitable in patients predisposed to swallowing dysfunction.



*Key Words:* transcatheter aortic valve replacement; conscious sedation; anesthesia; dysphagia; pneumonia; outcomes

THE NORMAL SWALLOWING MECHANISM involves a precise interplay between oropharyngeal sensation, central nervous system integration, and execution by oral and esophageal muscles. It allows for delivery of oral contents to the esophagus while protecting the airway from inadvertent aspiration.[1] Although dysphagia is a common complication of cerebrovascular accidents, it also occurs in a subset of cardiac surgical patients, with an incidence of 3% to 51% depending on method of diagnosis.[2-5] It is well established that postoperative dysphagia is associated with complications such as pneumonia and increased costs of care.[5-7] Patients with dysphagia also exhibit delayed return of oral intake, increased utilization

**Author Contributions**

Study concept: S.S., A. Mendelsohn, P.B.
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Data collection: L.M., R.K.,
Data analysis: L.M., R.K., A. Mantha, P.B.
Data interpretation: L.M., R.K., A. Mantha, P.B.
Article drafting: L.M., R.K., A. Mantha, P.B.
Critical revisions: L.M., S.S., A. Mendelsohn, P.B.

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of feeding tubes, and cardiovascular complications including postoperative arrhythmias, low cardiac output, and need for inotropic and mechanical support.[8-9] Indeed, development of dysphagia delays hospital discharge and increases resource utilization in both medical and surgical patient populations.[10-14]

Although reliable methods for the early detection of postoperative dysphagia are lacking, prior investigations have identified several factors associated with this complication. Given the higher incidence of stroke in patients with dysphagia, it has been suggested previously that this condition is related to cerebral injury.[15,16] Preoperative characteristics including older age; history of congestive heart failure; diabetes mellitus; and perioperative characteristics such as operative duration, use of cardiopulmonary bypass, and use of endotracheal intubation have been associated with dysphagia.[7,13,17] Moreover, based on the increasing incidence of dysphagia in modern series of cardiac surgery patients, some have implicated the nearly universal use of transesophageal echocardiography (TEE) as the cause.[18] Nonetheless, postoperative dysphagia following cardiac surgery has garnered more attention in the past decade.

More recently, transcatheter aortic valve replacement (TAVR) has emerged as the preferred therapy for severe aortic stenosis in patients at intermediate or high surgical risk for open aortic valve replacement (AVR).[19] Although the majority of such valve replacements are performed as open surgical procedures, TAVR now is applied increasingly to patients with frailty and other comorbid conditions not accounted for by the Society of Thoracic Surgeons (STS) risk calculator.[20-23] Although previously commonly performed using general anesthesia (GA) and transesophageal echocardiography (TEE),[24-27] TAVR now is performed more routinely under moderate sedation (MS) and transthoracic echocardiography (TTE), also termed "minimalist TAVR."[24-28] TAVR with moderate sedation has been shown to reduce procedure duration, shorten hospital length of stay, and lower the risk of nosocomial infections.[25-28] However, the impact of TAVR (with GA or MS) on postoperative dysphagia remains unknown. The present study was performed to evaluate the incidence of postoperative dysphagia in TAVR patients. The authors further hypothesized that using a MS and TTE protocol would reduce rates of postoperative dysphagia and pneumonia.

## Methods

All consecutive adult patients undergoing isolated transfemoral TAVR at Ronald Reagan-UCLA Medical Center from October 2012 to May 2016 were identified retrospectively using the authors' institutional STS database and American College of Cardiology Transcatheter Valve Therapy Registry. Patients with preoperative/postoperative tracheostomies and those with preoperative swallowing dysfunction were excluded from the analysis (Fig 1). The study was approved by the Institutional Review Board at the University of California, Los Angeles.

Patients were stratified into 2 groups: those who underwent TAVR with MS, and those who underwent TAVR with GA. All GA patients underwent intubation and TEE. No MS patients underwent intubation. All MS patients underwent TTE. Use of MS versus GA was determined on an individual basis by a treatment team composed of cardiologists, cardiac surgeons, and an anesthesiologist. Moderate sedation was defined as a "drug induced depression of moderate degree during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. No intervention is required to maintain a patent airway, and spontaneous ventilation is adequate." (American Society of Anesthesiologists) General anesthesia was defined as "drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function." (American Society of Anesthesiologists).

Candidates for TAVR received a coronary angiogram as part of their routine preoperative evaluation. All TAVR procedures were performed in a cardiac catheterization suite. TEE was used for TAVR with GA and TTE with MS.

Postoperatively, all subjects undergoing cardiac surgery or TAVR at the authors' institution are assessed routinely via a targeted bedside swallowing screen. This test has been described elsewhere and appears to be highly sensitive for detecting dysphagia.[29] Any patient who failed the bedside swallow test subsequently underwent a fiberoptic endoscopic evaluation of swallowing (FEES) test, confirming the diagnosis of dysphagia. Primary outcome variables included dysphagia and pneumonia, while several secondary outcomes were considered, including postoperative stroke, procedure time, intensive care unit (ICU), and hospital length of stay. Pneumonia was diagnosed based on chest radiographic plain films, which were obtained daily postoperatively and documented in the electronic medical record. Endotracheal tube size was defined as the internal diameter of the tube in millimeters. Definitions of variables were based on the STS Adult Cardiac Database Specifications version 2.81.[30]

Categorical variables were analyzed using Fisher's exact test; independent sample t-tests were used to assess continuous variables. A p value $<0.05$ was considered statistically significant. All data analysis was performed using Stata 13.0 (StataCorp, College Station, TX).

## Results

After application of exclusion criteria, 197 patients remained in the study (58 in the MS group and 139 in GA). No patient in the MS group required conversion to GA. All patients received Edwards SAPIEN valves (Edwards Lifesciences, Irvine CA).

Baseline patient characteristics are presented in Table 1. Although not statistically significant, MS patients were more likely to be designated as New York Heart Association Class

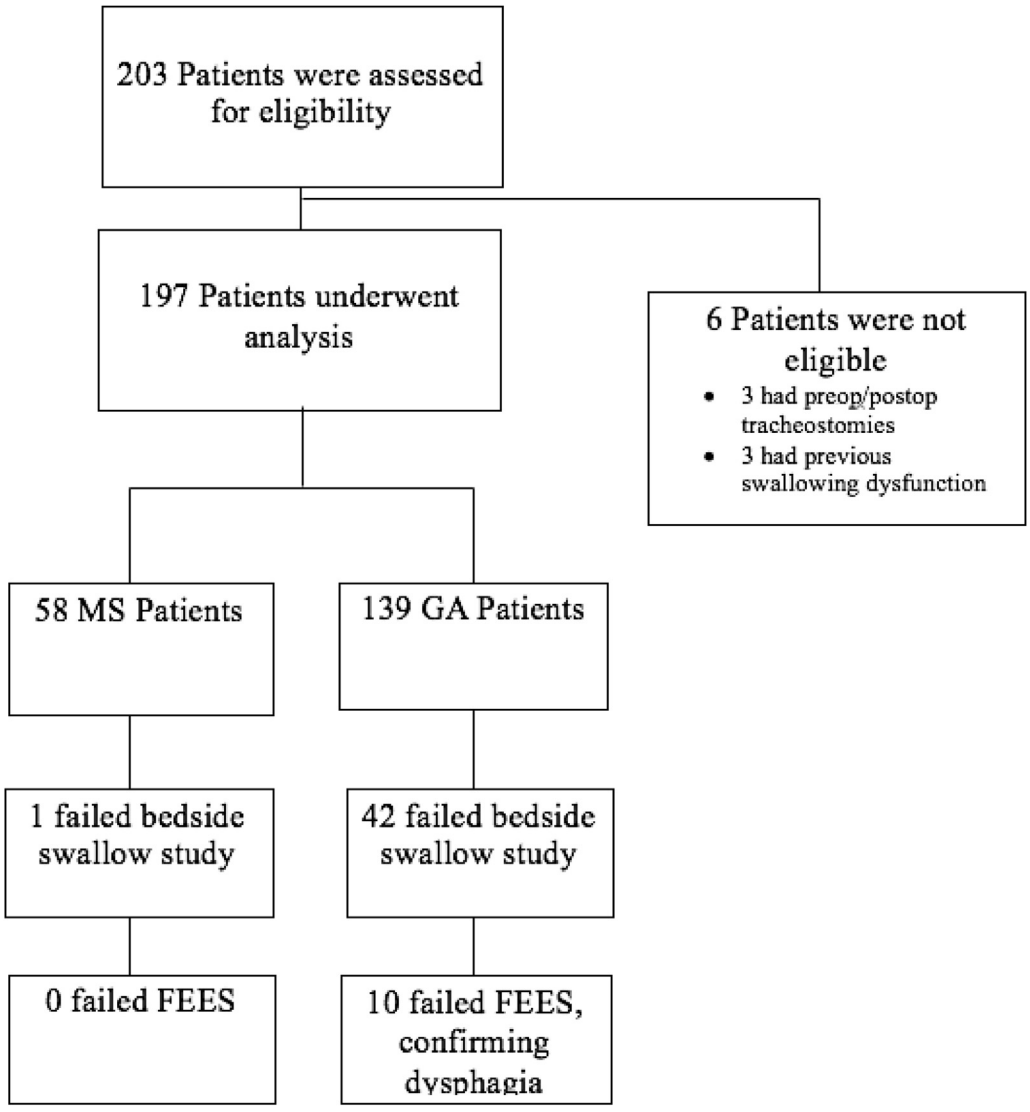


Fig 1. Screening, enrollment, and follow-up of patients undergoing TAVR.

Table 1
Baseline Characteristics

| Patient Characteristic | General Anesthesia n = 139 | Moderate Sedation n = 58 | All Patients n = 197 | p Value |
|---|---|---|---|---|
| Age, (mean ± SD) | 82.2 ± 12.4 | 83.8 ± 9.2 | 82.7 ± 11.5 | 0.40 |
| Female, % | 49.6 | 48.3 | 49.2 | 0.87 |
| Hypertension, % | 79.9 | 79.3 | 79.7 | 1.00 |
| BMI, kg/m$^2$ (mean ± SD) | 26.5 ± 6.2 | 27.3 ± 5.3 | 26.7 ± 5.9 | 0.37 |
| Diabetes, % | 34.5 | 24.1 | 31.5 | 0.18 |
| Dialysis, % | 3.6 | 5.2 | 4.1 | 0.70 |
| Elevated creatinine, % | 25.2 | 25.9 | 25.4 | 1.00 |
| Chronic lung disease, % | 32.4 | 32.8 | 32.5 | 1.00 |
| Smoking history, % | 2.9 | 6.9 | 4.1 | 0.24 |
| Previous stroke, % | 12.9 | 12.1 | 12.7 | 1.00 |
| STS risk score, (mean ± SD) | 7.5 ± 4.2 | 7.2 ± 5.2 | 7.4 ± 4.6 | 0.68 |
| NYHA class | | | | |
| Class I, % | 10.8 | 7.0 | 9.7 | 0.60 |
| Class II, % | 36.0 | 31.6 | 34.7 | 0.62 |
| Class III, % | 41.0 | 57.9 | 45.9 | 0.06 |
| Class IV, % | 12.2 | 3.5 | 9.7 | 0.07 |

Abbreviations: BMI, body mass index; NYHA, New York Heart Association; SD, standard deviation; STS, Society of Thoracic Surgeons.

Table 2
Operative Outcomes

| Variable | General Anesthesia n = 139 | Moderate Sedation n = 58 | All Patients n = 197 | p Value |
|---|---|---|---|---|
| Operative Time, min (mean ± SD) | 149.5 ± 108.0 | 95.0 ± 44.6 | 133.4 ± 97.0 | <0.001 |
| ICU Time, h (mean ± SD) | 87.1 ± 109.3 | 27.4 ± 32.1 | 69.5 ± 97.3 | <0.001 |
| Hospital time, d (mean ± SD) | 6.7 ± 6.3 | 2.6 ± 2.1 | 5.5 ± 5.8 | <0.001 |
| Postoperative stroke, n (%) | 1 (0.7) | 2 (3.5) | 3 (1.5) | 0.21 |
| Aspiration pneumonia, n (%) | 4 (3.0) | 0 (0.0) | 4 (2.1) | 0.32 |
| Dysphagia, n (%) | 10 (7.2) | 0 (0.0) | 10 (5.1) | 0.04 |

Abbreviations: ICU, intensive care unit; SD, standard deviation.

Table 3
Intubation Characteristics

| Variable | No Dysphagia n = 129 | Dysphagia n = 10 | All GA Patients n = 139 | p Value |
|---|---|---|---|---|
| Intubation time, h (mean ± SD) | 7.9 ± 17.2 | 26.1 ± 52.7 | 9.3 ± 22.0 | 0.01 |
| ETT size, mm (mean ± SD) | 7.3 ± 0.4 | 7.3 ± 0.5 | 7.3 ± 0.4 | 0.78 |

Abbreviations: ETT, endotracheal tube; GA, general anesthesia; SD, standard deviation.

III and less likely as Class IV. The proportion of patients with a previous stroke was nearly identical between groups.

Of the 197 patients, 42 (21.3%) failed the bedside swallow study and received an FEES. Of these, 10 subsequently were diagnosed with dysphagia, all in the GA group ($p = 0.04$, Table 2). One MS patient failed the bedside swallow study but exhibited normal deglutition on FEES. Four patients, all of whom received GA, developed postoperative pneumonia; this trend was not statistically significant.

Two patients in the GA cohort suffered a postoperative ischemic stroke, one of whom subsequently developed dysarthria and dysphagia. One patient in the MS group had an ischemic stroke but, despite presenting with dysarthria and aphasia, did not experience any swallowing abnormalities.

On average, patients receiving GA had significantly longer procedure times and ICU or hospital lengths of stay as shown in Table 2 ($p < 0.001$). Data for intubation time and endotracheal tube size are shown in Table 3. Patients who developed dysphagia were intubated for a significantly longer duration (26.1 *v* 7.9 hours, $p = 0.01$). No relationship between endotracheal tube size and postoperative dysphagia was observed ($p = 0.78$).

A logistic regression model was used to identify independent predictors of postoperative dysphagia, based on risk factors previously described in the literature (Table 4). Length of intubation was found to be the only statistically significant variable ($p = 0.04$, odds ratio = 1.02). A positive association with female sex also was observed ($p = 0.05$, odds ratio = 5.60). The authors also evaluated the relationship of body mass index and endotracheal tube size to dysphagia in the multivariable model while accounting for the potential interaction with sex. Neither the individual terms (body mass index and endotracheal tube) nor the interaction terms with sex were significant at the $a = 0.05$ level. Furthermore, a likelihood ratio test was performed to evaluate whether a significant difference in the explanatory power of the current model and the model with these terms exists which demonstrated no improvement (likelihood ratio test chi-squared: 7.92, $p = 0.09$).

## Discussion

The reported incidence of postoperative swallowing dysfunction following cardiac surgery is highly variable and can range from 3% to 51% of all patients.[2-5] This is likely an underdiagnosed complication of cardiac surgery and is associated with pneumonia and excess resource utilization.[11] Initially thought to be related to occult neurologic injury, development of dysphagia appears to be multifactorial and may be related to advanced age, frailty, operative complexity, and direct laryngeal trauma secondary to endotracheal intubation and TEE use.[13,17-18] Given the relative safety and rapidity of TAVR, the authors sought to establish the incidence of dysphagia in this patient population and further evaluate the impact of GA and MS on this complication. The authors found a 7% incidence of dysphagia among patients who received TAVR with GA and a 0% incidence among those having MS.

Table 4
Multivariate Analysis of Predictors of Dysphagia

| Variable | Odds Ratio | p Value | 95% CI |
|---|---|---|---|
| Age | 0.99 | 0.75 | 0.94-1.05 |
| Female sex | 5.60 | 0.05 | 0.97-32.43 |
| Hypertension | 2.37 | 0.43 | 0.27-20.45 |
| NYHA class | 1.56 | 0.31 | 0.66-3.67 |
| Intubation time (h) | 1.02 | 0.04 | 1.00-1.04 |
| Operative time (min) | 1.00 | 0.51 | 1.00-1.00 |

Abbreviations: CI, confidence interval; NYHA, New York Heart Association.

The authors are unaware of prior studies describing the incidence of dysphagia following TAVR. It may be expected that this complication would occur at higher rates in comparison to open AVR. First, TAVR usually is offered to patients who may not tolerate an open surgical procedure, due to advanced age and multiple comorbidities. Second, ischemic stroke is a common and feared complication of TAVR, occurring at an average rate of 4.1%.[16,31] Roughly one-half of these patients subsequently develop swallowing dysfunction.[16,31] In the current series, the authors observed postoperative dysphagia in 5.1% of the study population, similar to estimates in patients undergoing general cardiac surgery.[4] The authors also observed an ischemic stroke rate of 1.6%, which is lower than expected and may be a product of institutional experience.

Although neurologic events and patient demographics may be associated with dysphagia, prior investigations have found endotracheal intubation to be perhaps the most powerful predictor of dysphagia.[17] The presence of an endotracheal tube leads to mucosal irritation, causing loss of architecture and a subsequent inflammatory cascade.[32] Direct laryngeal injury and inflammation also can trigger vocal cord paralysis.[33] Indeed, others have demonstrated that dysphagia is particularly likely when patients are intubated for prolonged periods. Barker observed a 51% incidence of dysphagia among patients undergoing coronary artery bypass grafting and intubated for at least 48 hours.[5] As such, it is not surprising that length of intubation is correlated directly with dysphagia.[17,32] There is also evidence suggesting a relationship between endotracheal tube caliber and dysphagia, although the authors' data did not corroborate this hypothesis.[34]

In the present study, dysphagia occurred exclusively in patients receiving GA. The varying incidence of dysphagia between groups is likely attributable to 2 processes. First, TAVR with MS does not require endotracheal intubation, mitigating a potent risk factor for dysphagia. As expected, patients who developed dysphagia also were intubated for significantly longer than those who did not. In addition, the logistic regression identified intubation time as an independent predictor of dysphagia. Second, TAVR with MS is performed with TTE rather than TEE. TEE, although generally considered a safe procedure, may trigger dysphagia, possibly due to trauma caused by insertion of the probe or compression of pharyngoesophageal tissues.[18,35] Studies differ in methodology, sample sizes, and conclusions.[17,18, 36, 37] Ultimately, the GA protocol used in the current study incorporated both endotracheal intubation and TEE, meaning the authors were unable to analyze the independent contribution of TEE toward dysphagia. Although it is likely that TEE will continue to be used routinely in modern cardiac operations, the impact of limiting its duration of use deserves further investigation.

The body of literature on choice of anesthesia in TAVR is limited but growing.[25-28] In general, patients of advanced age or those with significant comorbidities may be better suited for minimalist TAVR.[25-28] The authors found that patients in the MS cohort spent significantly less time in the ICU, operating room, and hospital. These findings are consistent with prior analyses of the risks and benefits of MS TAVR.[23,25]

The present study represents the first to assess the relationship between anesthetic method and dysphagia in TAVR patients. A major cause of death after cardiac and thoracic operations, pulmonary complications require progressive efforts to avoid to improve quality of care.[12] The authors' analysis suggests that TAVR with MS minimizes the risk of these complications. As such, minimalist TAVR may be appropriate at least in patients with preoperative risk factors for swallowing dysfunction, such as advanced age, congestive heart failure, and history of stroke.[13]

This study has several limitations, including those inherent to its retrospective nature. Secondly, the findings represent experience at a single institution, limiting their generalization. The marked reduction of dysphagia with MS did not lead to a statistically significant reduction in the incidence of pneumonia. This may be due to the overall low burden of this complication in the present cohort, and may be a function of small sample size. Nonetheless, the relationship between dysphagia and aspiration pneumonia has been established in previous cohorts.[4] Postoperative magnetic resonance imaging screenings were limited to patients with stroke symptoms (eg, dysarthria, dysphagia, limb weakness), and therefore the authors may have missed clinically silent strokes.

## Conclusion

In summary, TAVR performed with moderate sedation may reduce the risk of postoperative dysphagia. When considering anesthetic technique, moderate sedation may be appropriate for candidates predisposed to swallowing dysfunction. Large-scale randomized controlled trials are warranted to evaluate further the relationship between moderate sedation and dysphagia in TAVR patients

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