

TAVR: General Anesthesia or Moderate Conscious Sedation?

A report of findings from registries and large cohorts.

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With transcatheter aortic valve replacement (TAVR) now an acceptable treatment option in high- and intermediate-risk populations—and possibly low-risk patients as well—there is a focus on optimizing procedural techniques and perioperative management.¹⁻⁴ The choice of anesthesia has been one such subject of interest. Although early experience almost exclusively utilized general anesthesia, moderate conscious sedation has recently gained popularity.^{5,6} The utilization of moderate conscious sedation increased from 2% in 2012 to 17% in 2015, with some centers now utilizing moderate conscious sedation in nearly two-thirds of cases.^{5,7,8} There is, however, significant practice-level variation when it comes to the choice of anesthesia.⁹ In this article, we examine studies comparing moderate conscious sedation with general anesthesia (Table 1). This article is not meant to be exhaustive but rather to highlight representative studies.

WHAT IS MODERATE CONSCIOUS SEDATION?

Although specifics may vary, moderate conscious sedation involves local infiltration of 2% lidocaine at the site of cannulation. In addition, the patient receives small doses of sedatives, such as fentanyl and propofol, with or without intravenous midazolam. In contrast to general anesthesia, patients under moderate conscious sedation are frequently awake during the procedure and able to communicate with the proceduralists.

ADVANTAGES AND DISADVANTAGES OF MODERATE CONSCIOUS SEDATION

Utilization of moderate conscious sedation has recently gained popularity because it negates challenges such as difficult airway, ventilation in patients

with chronic lung disease, myocardial depressant effects of anesthetics that necessitate inotropic support, and delayed awakening from anesthesia.¹⁰ It also allows assessment of an awake patient's responses that can be used to monitor cerebral perfusion and is associated with lower costs compared to general anesthesia.¹¹ However, many anesthesiologists and proceduralists prefer general anesthesia because it allows for more definite control of the airway and ventilation with minimal patient movement, easier management of hemodynamic challenges, and more effective attenuation of stress response during the procedure, while also providing more time for the proceduralists performing TAVR.¹⁰ General anesthesia is also preferred in patients with claustrophobia, back pain, or severe sleep apnea, or those who are unable to lay in the supine position for a prolonged period of time.

LITERATURE REVIEW

In our search, we found two randomized clinical trials that compared moderate conscious sedation with general anesthesia.^{12,13} The study by Mayr et al examined cerebral desaturation during the procedure but did not report clinical outcomes.¹² SOLVE-TAVI is the only randomized controlled trial to directly compare clinical outcomes between general anesthesia and moderate conscious sedation in patients undergoing TAVR.¹³ Most data, however, are derived from large registries, retrospective studies, and meta-analyses that compare safety and outcomes.

SOLVE-TAVI Clinical Trial

Theile compared clinical outcomes between general anesthesia (n = 220) and moderate conscious sedation (n = 218) in patients undergoing TAVR.¹³ The study

TABLE 1. STUDIES COMPARING MODERATE CONSCIOUS SEDATION WITH GENERAL ANESTHESIA IN PATIENTS UNDERGOING TAVR

Study	Number of Participants (N)	Design	Population	Outcomes (MCS vs GA)
SOLVE-TAVI ¹³	438 (GA, n = 220; MCS, n = 218)	RCT	Patients randomized 1:1 to receive MCS or GA	• Mortality: 2.3% vs 2.8%; $P = .77$ • Stroke: 2.8% vs 2.4%; $P > .99$ • Moderate to severe PVL: 1.9% vs 1.4% $P = 0.72$ • Inotrope use: 97.3% vs 62.8%; $P < .001$ • Hospital LOS: 9 vs 9 d; $P = .74$ • ICU LOS: 47 vs 51 h; $P = .59$
Attizzani et al ¹⁴	11,006 (GA, n = 8,239; MCS, n = 2,767)	Propensity-matched retrospective cohort	Patients in the TVT registry who underwent transfemoral TAVR between January 2014 through June 2016 with a self-expanding bioprosthesis	• Device success: 94.6% vs 94.5%; $P = .905$ • In-hospital mortality: 1.1% vs 2.7%; $P < .001$ • In-hospital stroke: 2.7% vs 2.3%; $P = .413$ • Paravalvular regurgitation grade: $P = .113$ • ICU LOS: 40.1 ± 58.4 vs 50.9 ± 72.1 h; $P < .001$ • Postprocedure LOS: 4.1 ± 3.6 vs 5 ± 4.5 d; $P < .001$
Hyman et al ⁶	10,997 (GA, n = 9,260; MCS, n = 1,737)	Propensity-matched retrospective analysis	Patients in the TVT registry who underwent transfemoral TAVR between April 2014 through June 2015	• Procedural success: 97.9% vs 98.6%; $P < .001$ • In-hospital mortality: 1.5% vs 2.4%; $P < .001$ • Procedural inotrope requirement: 29.3% vs 43.7%; $P < .001$ • Hospital LOS: 6 ± 7.1 vs 6.5 ± 5.5 d; $P < .001$
OBSERVANT ¹⁵	1,494 (GA, n = 357; MCS, n = 1,137)	Propensity-matched retrospective analysis	Patients enrolled in the OBSERVANT study undergoing TAVR between December 2010 and June 2012	• 30-d mortality: 3.9% vs 4.8%; $P = .564$ • Stroke: 1.3% vs 0.7%; $P = .414$ • Paravalvular regurgitation $\geq$ mild: 49.5% vs 57%; $P = .858$ • ICU LOS: 3.5 vs 2.9 d; $P = .086$
German Aortic Valve registry ¹⁶	16,543 (GA, n = 8,422; MCS, n = 8,121)	Propensity-matched retrospective analysis	Patients in the German Aortic Valve Registry who underwent TAVR between 2011 through 2014	• Procedural success: 97.8% vs 97.8%; $P = .999$ • In-hospital mortality: 2.4% vs 3.8%; $P = .003$ • Stroke: 1% vs 1.4%; $P = .10$ • PVL (II+): 3.9% vs 4.9%; $P = .13$ • ICU LOS: 2 vs 2 d; $P = .001$ • Hospital LOS: 9 vs 9 d; $P = .11$
Villablanca et al ¹⁷	10,572	Meta-analysis	Patients in randomized and non-randomized studies that directly compared outcomes of MCS and GA among patients undergoing TAVR	• Procedural success: 95.4% vs 98.2%; $P = .37$ • 30-d mortality: 4.5% vs 6.2%; $P = .01$ • PVL: 8.9% vs 8%; $P = .94$ • Use of inotropic/vasopressor drugs: 5.8% vs 7.3%; $P < .001$ • ICU LOS: 1.3 vs 1.5 d; $P = .01$ • Hospital LOS: 7.2% vs 9.3%; $P < .001$
Ehret et al ¹⁸	4,263	Meta-analysis	Patients in RCTs and observational studies published between January 2006 and June 2016 that compared LAS to GA in a population undergoing TAVR	• 30-d mortality: 5.6% vs 5.9%; $P = .48$ • PVL: 3.9% vs 3.5%; $P = .41$ • Use of inotropic/vasopressor drugs: 31% vs 65%; $P < .001$ • ICU LOS: mean difference, -0.47 d; $P = .002$ • Hospital LOS: mean difference, -1.49 d, $P = .002$
Bianco et al ¹⁹	MCS, N = 282	Retrospective analysis	Patients from a prospectively recorded database undergoing transfemoral TAVR with open surgical cutdown under MAC between 2015 and 2017	• In-hospital mortality: 2.1% • In-hospital stroke: 4.6% • Paravalvular regurgitation (moderate): 4.6% • ICU LOS: 9.2 ± 16.7 h • Postprocedure LOS: 3.6 ± 2.5 d
Debry et al ²⁰	174 (GA, n = 122; MCS, n = 52)	Retrospective cross-sectional analysis	Patients unsuitable for transfemoral TAVR due to severe peripheral vascular disease who underwent transcatheter TAVR at two French centers between 2009 and 2014	• Device success: 88.4% vs 93.4%; $P = .26$ • 30-d mortality: 7.3% vs 7.3%; $P = .94$ • In-hospital stroke: 0% vs 8.1%; $P < .001$ • Paravalvular regurgitation grade (≥ 2): 9.6% vs 8.1%; $P = .76$ • Hospital LOS: 6 ± 3.3 vs 11.3 ± 8.8 d; $P < .001$

Abbreviations: GA, general anesthesia; ICU, intensive care unit; LAS, local anesthesia with (optional mild to moderate) sedation; LOS, length of stay; MAC, monitored anesthesia care; MCS, moderate conscious sedation; PVL, paravalvular leak; RCT, randomized controlled trial; TAVR, transcatheter aortic valve replacement; TVT, Transcatheter Valve Therapy.

found no differences between general anesthesia and moderate conscious sedation in terms of mortality rate (2.8% vs 2.3%; $P = .77$), stroke (2.4% vs 2.8%; $P > .99$), myocardial infarction (0.5% vs 0.5%; $P = .99$), or moderate to severe paravalvular leak (1.4% vs 1.9%; $P = .72$). Mean length of hospital stay (9 vs 9 days; $P = .74$) and mean length of intensive care unit (ICU) stay (51 vs 47 hours; $P = .59$) were also similar in both groups. Catecholamine use, however, was less frequent with moderate conscious sedation compared to general anesthesia (62.8% vs 97.3%, respectively; $P < .001$).

Findings From Large Registries and Cohorts

In a recent analysis, Attizzani et al analyzed 11,006 patients (general anesthesia group, $n = 8,239$; moderate conscious sedation group, $n = 2,767$) from the TVT registry.¹⁴ These were patients who underwent TAVR with a self-expanding bioprosthesis in the United States between January 2014 and June 2016. The study found no differences in terms of stroke (2.7% in the general anesthesia group vs 2.3% in the moderate conscious sedation group; $P = .413$) or grade of paravalvular leak. Major vascular complications (0.7% vs 1.4%; $P = .026$), length of ICU stay (40.1 ± 58.4 vs 50.9 ± 72.1 hours; $P < .001$), and length of postprocedural hospital stay (4.1 ± 3.6 vs 5.0 ± 4.5 days; $P < .001$) were significantly lower with moderate conscious sedation. In addition, in-hospital (1.1% vs 2.7%; $P < .001$) and 30-day all-cause mortality (2.1% vs 3.9%; $P = .001$) were also lower in the moderate conscious sedation group.

An earlier study by Hyman et al also analyzed safety and outcomes of patients from the TVT registry with an overlapping time period (April 2014 through June 2015); however, this study was not limited to self-expanding valves alone.⁶ Of the 10,997 patients included in the study, 1,737 (15.8%) patients received moderate conscious sedation, while 9,260 (84.2%) patients received general anesthesia. The study found no differences in intraprocedural success with moderate conscious sedation (98.5% in the general anesthesia group vs 98.2% in the moderate conscious sedation group; $P = .31$). Similar to the study by Attizzani et al, use of moderate conscious sedation was associated with lower in-hospital (1.6% vs 2.5%; $P = .03$) and 30-day (4.1% vs 2.9%; $P = .03$) mortality, length of ICU and hospital stay (6.0 vs 6.5 days; $P < .001$), and combined 30-day death/stroke rates (4.8% vs 6.4%; $P < .001$).

One of the earlier studies that compared moderate conscious sedation with general anesthesia in patients undergoing TAVR was a subset analysis from the OBSERVANT study.¹⁵ Of the 1,494 patients enrolled in the study, 1,137 (76.1%) patients received

moderate conscious sedation whereas 357 (23.9%) patients underwent general anesthesia. After propensity matching, the study reported no differences between the two groups in terms of 30-day mortality (3.9% in the moderate conscious sedation group vs 4.8% in the general anesthesia group; $P = .564$), stroke (1.3% vs 0.7%; $P = .414$), mean length of ICU stay (2.9 ± 4.7 vs 3.5 ± 4.5 days; $P = .086$), paravalvular leak $\geq$ mild severity (8.2% vs 11.3%; $P = .858$), or major vascular injury (8.6% vs 7.9%).

The largest analysis comparing moderate conscious sedation with general anesthesia comes from the German Aortic Valve registry.¹⁶ The study included 16,543 patients (moderate conscious sedation, $n = 8,121$; general anesthesia, $n = 8,422$) undergoing elective or urgent transfemoral TAVR in Germany between 2011 and 2014. After propensity matching, procedural success (97.8% in moderate conscious sedation vs 97.6% in general anesthesia) and paravalvular leak (5% vs 4.9%) were similar in the two groups. Stroke was also similar (1.5% vs 1.4%) in the two groups, although major vascular complications were more frequent in the general anesthesia group (10.9% vs 9.3%; $P < .001$). After matched analysis, length of ICU stay (proportion of cases with ≤ 1 day: 38.2% vs 34.5%; $P = .003$) was shorter with moderate conscious sedation, but there was no difference in the length of hospital stay. Thirty-day mortality was significantly lower in patients undergoing TAVR with moderate conscious sedation compared with general anesthesia in the matched population (2.8% vs 4.6%; hazard ratio [HR], 0.60; 95% confidence interval [CI], 0.45–0.80; $P < .001$). At 1 year, the difference in mortality was not significant (14.1% vs 15.5%; HR, 0.90; 95% CI, 0.78–1.03; $P = .130$).

Systematic Reviews and Meta-Analyses

In a meta-analysis of 26 studies that included 10,572 patients, Villablanca et al found that moderate conscious sedation for TAVR was associated with lower overall 30-day mortality (4.5% vs 6.2%; risk ratio [RR], 0.73; 95% CI, 0.57–0.93; $P = .01$), use of inotropic/vasopressor drugs (5.8% vs 7.3%; RR, 0.45; 95% CI, 0.28–0.72; $P < .001$), hospital length of stay (7.2 vs 9.3 days; $P < .001$), ICU length of stay (1.3 vs 1.5 days; $P = .01$), procedural duration (97 vs 124 min; $P < .001$), and fluoroscopy time (101 vs 124 min; $P = .02$).¹⁷ Procedural success was 95.4% in the moderate conscious sedation group versus 98.2% in the general anesthesia group (RR, 1.40; 95% CI, 0.67–2.96; $P = .37$). Vascular complications (7.7% in the moderate conscious sedation group vs 6.4% in the general anesthesia group) and major bleeding (6.1% vs 4.7%) were also similar in the two groups.

Ehret et al included one randomized clinical trial and 19 observational studies in their meta-analysis (4,263 patients) and found no differences between the two groups in terms of conversion to open heart surgery (2.5% in moderate conscious sedation group vs 2.9% in the general anesthesia group; RR, 0.89, 95% CI, 0.51–1.56; $P = .68$), major vascular complications (5.8% vs 4.6%; RR, 0.95, 95% CI, 0.69–1.31; $P = .75$), and moderate to severe aortic regurgitation (3.9% vs 3.5%; RR, 0.85, 95% CI, 0.57–1.26; $P = .41$).¹⁸ Moreover, the study found that moderate conscious sedation was associated with a lower incidence of need for catecholamines (31% in the moderate conscious sedation group vs 65% in the general anesthesia group; RR, 0.47, 95% CI, 0.32–0.70; $P = .0002$), a shorter hospital stay (mean difference, –1.49 days, 95% CI, 2.45 to –0.53 days; $P = .002$), and a shorter ICU stay (mean difference, –0.47, 95% CI, –0.83 to –0.11; $P = .01$).

Other Studies

Although studies on patients with transfemoral access without surgical cutdown appear to be in favor of moderate conscious sedation, data on choice of anesthesia with alternate access or open surgical technique are more scarce. In a recent study, Bianco et al studied patients in the TVT registry who underwent transfemoral open surgical access for TAVR.¹⁹ Of 282 patients, 11 (3.9%) required conversion to general anesthesia. Major vascular complications occurred in only two (0.7%) patients, whereas there was in-hospital mortality in six (2.1%) patients.

Debry et al compared the use of moderate conscious sedation with general anesthesia in 174 patients undergoing transcatheter TAVR at two French centers.²⁰ Moderate conscious sedation was used in 52 (29.8%) patients, while 122 (70.2%) underwent general anesthesia. Successful carotid access was achieved in all cases and there were no differences in major vascular complications (13.9% in the general anesthesia group vs 5.7% in the moderate conscious sedation group; $P = .12$), 30-day mortality (7.3% vs 7.6%; $P = .94$), and 1-year mortality (13.9% vs 9.6%; $P = .43$). General anesthesia was associated with a higher number of cerebrovascular accidents when compared with moderate conscious sedation (8.1%, $n = 10$ vs 0%, $n = 0$; $P < .001$).

COST

In 2017, Toppen et al compared the cost of moderate conscious sedation to general anesthesia in 225 patients undergoing TAVR.¹¹ After propensity matching, the study concluded that the total direct cost of TAVR with moderate conscious sedation was 71.5% of the cost

when general anesthesia was used. The ICU direct cost (45.3%), anesthesia direct cost (47.1%), operating room recovery cost (42.6%), pharmacy direct cost (42.1%), and room direct cost (45.5%) were also lower in patients receiving moderate conscious sedation.

DISCUSSION

These data suggest that moderate conscious sedation in TAVR is both feasible and safe in certain populations. It is associated with a shorter-duration ICU and hospital stay, reduced requirement for intraprocedural inotropic support, and lower costs with comparable procedural success. Certain caveats, however, need to be considered while making any definite conclusions. First, these results are derived from observational studies on select populations, subjecting these findings to significant selection bias. General anesthesia is often chosen for patients who are considered “more complex,” whereas moderate conscious sedation is reserved for “less complex” patients, which is not reflected in these studies. Second, the trend toward more frequent use of moderate conscious sedation overlaps with an overall improvement in outcomes with TAVR.^{5,7,15} This would suggest that improved outcomes reported with moderate conscious sedation may be related to overall improved outcomes with TAVR, rather than less frequent use of general anesthesia. Finally, although we have presented data largely from meta-analyses and large registries and cohorts, studies with smaller sample sizes have had variable results. While these studies have often not been powered to deduce statistically significant results, they may be an indication of patient populations or practice experiences that need to be considered when deciding on the choice of anesthesia.

CONCLUSION

Although general anesthesia has traditionally been used for TAVR, there is now a shift toward higher utilization of moderate conscious sedation. Existing data, mostly from large registries and meta-analyses, support this shift by demonstrating reduced costs and length of stay, with comparable procedural success and complication rates in patients undergoing moderate conscious sedation. However, these findings are limited to select groups and more randomized clinical trials are needed to make more definite conclusions. ■

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