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Original Article

Comparison of Deep Sedation and General Anesthesia With an Endotracheal Tube for Transcaval Transcatheter Aortic Valve Replacement: A Pioneering Institution's Experience

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Objectives: Transcaval transcatheter aortic valve replacement (TC-TAVR) is an alternative approach to transcatheter aortic valve replacement involving deployment of the bioprosthetic valve via a conduit created from the inferior vena cava to the descending aorta in patients for whom the traditional transfemoral approach is not feasible. By analyzing the largest known cohort of TC-TAVR patients, the authors wished to compare hospital length of stay and post-procedure outcomes between patients who underwent the procedure under deep sedation (DS) and patients who underwent general anesthesia with an endotracheal tube.

Design: Retrospective, single-center study.

Setting: Henry Ford Hospital in Detroit, MI.

Participants: Patients undergoing TC-TAVR from 2015 to 2018.

Measurements and Main Results: Seventy-nine patients were included in the analysis, which consisted of 38 under general anesthesia with an endotracheal tube and 41 under DS. The sample was divided into a general anesthesia (GA) group and DS group. There were no significant differences in implant success rate or post-procedure outcomes, including in-hospital mortality ($p = 0.999$) and major vascular complication rate ($p = 0.481$), between the two groups. Patients in the GA group stayed a median of 24 hours longer in the intensive care unit (ICU) ($p < 0.001$) and one day longer in the hospital ($p = 0.046$) after the procedure compared to patients in the DS group. The median procedure time was significantly lower (135 minutes) in the DS group compared to the GA group (167 minutes, $p < 0.001$).

Conclusions: Patients undergoing TC-TAVR under DS had similar postoperative outcomes and shorter post-procedure hospital and ICU lengths of stay compared to general anesthesia. In the authors' experience, DS is the preferred anesthetic technique for TC-TAVR.

Key Words: transcaval transcatheter aortic valve replacement; transcatheter aortic valve replacement; deep sedation; general anesthesia; aortic stenosis

TRANSCATHETER AORTIC valve replacement (TAVR) is a minimally invasive procedure performed to replace the aortic valve in aortic stenosis. The traditional approach for TAVR is to obtain arterial access via the femoral artery; that is, transfemoral TAVR. However, there is a subgroup of patients who are not candidates for traditional transfemoral transcatheter aortic valve replacement (TF-TAVR) due to small or otherwise inaccessible femoral arteries. Studies have shown that this subgroup of patients may be as high as 15% of the population and are often women with small iliofemoral

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arteries or those with peripheral arterial disease.[1,2] In addition, use of large arterial sheaths poses a risk for major vascular complications including hemorrhage and rupture.[3] Alternative therapies that also may pose a risk for major vascular complications include transcaval, transaortic, transcarotid, subclavian, and transapical approaches.

Transcaval aortic valve replacement (TC-TAVR) first was attempted in humans in 2013 at the authors' institution and, subsequently, has become an alternative approach for patients who cannot receive the traditional TAVR.[4,5] TC-TAVR has been shown to be as safe as transcarotid or TF-TAVR.[6] The principle of TC-TAVR is that the retroperitoneal interstitial hydrostatic pressure exceeds venous pressure, forcing blood exiting the aorta to return to venous circulation via the aortocaval communication into the inferior vena cava (IVC).[4,5]

At the authors' institution, anesthetic management for transfemoral TAVR is achieved using deep sedation (DS). This approach avoids endotracheal intubation, and employs DS using various intravenous anesthetics such as propofol, remifentanil, and dexmedetomidine. There are many studies that show potential benefits of this approach, such as decreased intensive care unit (ICU) stay, decreased costs, and decreased time in the hospital.[7,8] For TC-TAVR, there are no published guidelines for optimal anesthetic management. At the authors' institution, patients have received general anesthesia (GA) with an endotracheal tube as well as DS.

By examining the largest known single-institution cohort of TC-TAVR patients, the authors hypothesized that DS was similar to GA with respect to post-procedure outcomes including implant success, in-hospital mortality, and rates of major vascular complications, and, potentially, is associated with shorter post-procedure hospital and ICU length of stay.

Methods

The study presented herein was a retrospective, single-center, cohort study performed at Henry Ford Hospital's main campus after approval from the institutional review board. Electronic health record data from patients receiving TC-TAVR at Henry Ford Hospital from 2015 to 2018 were obtained for review via the Epic electronic medical record and the Society of Thoracic Surgeons (STS)/American College of Cardiology Transcatheter Valve Therapy Registry. Patients selected for TC-TAVR included patients with severe, symptomatic aortic valvular heart disease deemed as high or prohibitive surgical risk. A multidisciplinary team of surgeons, cardiologists, and anesthesiologists had reached a consensus that these patients likely would benefit from TAVR but would not be suitable for transfemoral approach due to small or diseased iliofemoral vessels as identified by computed tomography angiography. A balloon-expandable transcatheter heart valve (Edwards, Irvine, CA) or a self-expandable transcatheter heart valve (Medtronic, Fridley, MN) was used for TC-TAVR. The size and choice of valve was decided at a multidisciplinary meeting. The authors' approximate distribution for all TAVRs was 80% balloon expandable and 20% self-expandable.

TC-TAVR involves gaining arterial access by initially obtaining venous access followed by crossing the retroperitoneal interstitial space by creating an opening between the IVC and the abdominal aorta. The valve then is deployed through the IVC aortic conduit up into the aortic valve position. After deployment, the hole subsequently is closed using a nitinol occluder device similar to that used in atrial septal defect closure. A preprocedural contrast computed tomography identifies an appropriate caval-aortic crossing trajectory, and is achieved by means of simultaneous aortography and venography during the procedure. Unlike the transcarotid approach, the TC-TAVR is fully percutaneous and has favorable ergonomics.[9]

The TC-TAVR patient sample was divided into two cohorts: GA and DS. The GA group was defined as patients who underwent endotracheal intubation with muscle relaxation. The DS group of patients underwent sedation with spontaneous ventilation. An anesthesiologist was involved in the intraprocedural care of all TC-TAVR patients.

Via retrospective chart review, it was identified that there were no specific selection criteria to select the technique of anesthesia; that is, DS versus GA defined as intubated with an endotracheal tube. The anesthetic technique was at the discretion of the attending anesthesiologist managing the patient. The anesthesia technique used was ascertained by chart review of the preoperative assessment and the intraoperative record. Patients who underwent DS and then had to be intubated intraprocedurally were excluded from the data analysis.

Patients in the GA group were induced with propofol and rocuronium and underwent endotracheal intubation followed by maintenance with isoflurane. Patients were reversed with sugammadex or neostigmine/glycopyrrolate at the completion of the procedure and were attempted to be extubated in the procedure room based on standard extubation criteria at the discretion of the cardiothoracic anesthesiologist (procedural success, patient awake, following commands, and hemodynamically stable). Patients in the DS group were sedated with a combination of propofol, dexmedetomidine, and/or remifentanil to maintain spontaneous ventilation. Patients typically are unconscious, maintaining spontaneous ventilation via simple facemask with purposeful response to only painful or repeated stimuli (DS). Patients from both groups who had hemodynamic instability after the procedure requiring pressor/inotrope support or those who could not be extubated successfully were admitted to the ICU.

Patient demographic characteristics and data on coexisting medical comorbidities, including hypertension, diabetes mellitus, chronic lung disease, prior cerebrovascular accidents, prior myocardial infarctions, prior percutaneous coronary interventions, and prior cardiac surgeries, were collected for each group. Before the procedure, risk stratification was performed using the STS risk score. Procedure-specific characteristics that were analyzed included procedure duration, fluoroscopy time and dose, and hospital and ICU durations of stay.

Patients were followed up from date of hospital admission up to hospital discharge. The primary outcomes were hospital and ICU length, of stay after the procedure. Secondary

outcomes included procedure duration and rates of implant success, cardiac arrest, in-hospital ischemic stroke, major vascular complications, and death. Per the STS/American College of Cardiology Transcatheter Valve Therapy Registry database definitions, the procedure duration was defined as the time from initial vascular access attempt to the time that the patient leaves the room. Implant success was defined as (1) successful vascular access, delivery, and deployment of the device and successful retrieval of the delivery system; (2) correct position of the device in the proper anatomic location; (3) intended performance of the prosthetic heart valve (aortic valve area >1.2 cm^2 and mean aortic valve gradient <20 mmHg or peak velocity <3 m/s, without moderate or severe prosthetic valve aortic regurgitation); and (4) only one valve implanted in the proper anatomic location. Major vascular complications were defined by aortic dissection or rupture, access-related vascular injury leading to life-threatening bleeding, or distal embolization resulting in irreversible end-organ damage.

Continuous variables were summarized in mean and standard deviation, or median and interquartile range, and compared by using Student *t* test or Mann-Whitney test. Categorical variables were summarized in frequency and proportion and compared by using Pearson chi-square test or Fisher exact test if the expected value in any cell was <5. A p value < 0.05 was considered to be statistically significant. All statistical analysis was performed use R software version 3.5.2 (R Foundation for Statistical Computing, Vienna, Austria; https://www.R-project.org/).

Results

A total of 83 patients underwent TC-TAVR at Henry Ford Hospital between 2015 and 2018. Thirty-eight belonged to the general GA group and 41 belonged to the DS group. Four patients converted from DS to GA during the procedure and were excluded from the study.

There was a considerable variation in proportion of cases over the years, reflective of procedural experience and learning curve. In 2015, 25% of the cases were performed under DS; this increased to 33% in 2016, 75% in 2017, and 100% in 2018.

Patient demographics, including age and sex, were comparable between the GA and DS groups (Table 1). There was no significant difference in median body mass index between the GA and DS groups. Prevalence of medical comorbidities, including diabetes mellitus, hypertension, and chronic lung disease, were not significantly different between the groups. Rates of prior myocardial infarction, stroke, and history of percutaneous coronary intervention or coronary artery bypass graft were similar between the GA and DS groups (Table 1).

The overall median STS risk score was 5.58, indicating an intermediate–high-risk patient population. There were no statistical differences in STS risk scores, ejection fraction, or aortic valve parameters (peak velocity, valve area, and gradient) between the GA and DS groups (Table 1).

Patients undergoing GA had significantly longer procedure durations (167 minutes *v* 135 minutes, $p = 0.003$). However, there were no significant differences in median fluoroscopy time ($p = 0.566$), fluoroscopy dose ($p = 0.084$), or contrast volume ($p = 0.462$; Table 2).

Table 1
Patient Characteristics*

Characteristic	GA (n = 38)	DS (n = 41)	p Value
Age	81 (74-86)	80 (73-86)	0.476
Male sex	14 (36.8)	22 (53.7)	0.203
BMI	25.8 (22.9-30.4)	24.7 (21.2-27.8)	0.261
Diabetes	16 (42.1)	20 (48.8)	0.712
Hypertension	36 (94.7)	35 (85.4%)	0.314
Chronic lung disease	9 (23.7)	10 (24.4)	0.513
Previous MI	14 (36.8)	12 (29.3)	0.634
Previous stroke	2 (5.3)	7 (17.1)	0.195
Previous PCI	15 (39.5)	22 (53.7)	0.300
Previous CABG	16 (42.1)	10 (24.4)	0.151
STS risk score	7.1 (4.3-10.4)	4.7 (3.1-7.9)	0.053
Ejection fraction	58 (42, 63)	60 (55, 67)	0.056
Aortic valve area	0.7 (0.6-0.84)	0.69 (0.53-0.82)	0.690
Aortic peak velocity	3.8 (3.25, 4.32)	3.9 (3.6, 4.4)	0.402
Aortic peak gradient	56 (42.5-76.5)	64 (54.5-78)	0.198
Aortic mean gradient	38.5 (24.5-47.5)	40 (30.5-45.5)	0.345

Abbreviations: BMI, body mass index; CABG, coronary artery bypass graft; DS, deep sedation; GA, general anesthesia; MI, myocardial infarction; PCI, percutaneous coronary intervention; STS, Society of Thoracic Surgeons.

* Normally distributed data shown as mean ± standard deviation, non-normally distributed data as median (25th-75th percentile), and categorical data as n (% of group).

The overall implant success rate was 97.5%, with no significant differences in success rates between the GA and DS groups (97.4% *v* 97.6%, respectively, $p = 0.999$). Patient follow-up after the procedure revealed significantly longer ICU and hospital lengths of stay in the GA group. On average, patients who underwent GA stayed one day longer in the hospital and 24 hours longer in the ICU than patients who underwent DS ($p = 0.046$ and $p < 0.001$, respectively). There were no significant differences in rates of complications including cardiac arrest, ischemic stroke, or major vascular complications between the GA and DS groups after the procedure (Table 3).

The in-hospital mortality rate in patients who underwent the TC-TAVR procedure was 1.3% (one patient of 79). There was

Table 2
Procedural Data*

Procedural Data	GA (n = 38)	DS (n = 41)	p Value
Implant success	37 (97.4)	40 (97.6)	0.999
Fluoroscopy time (s)	42 (39-50)	41 (36-50)	0.566
Fluoroscopy dose kerma	805 (605-1106)	728 (468-951)	0.084
Contrast volume	127 (91-149)	131 (101-160)	0.462
Procedure time (min)	167 (144-200)	135 (114-164)	0.003‡

Abbreviations: DS, deep sedation; GA, general anesthesia.

* Normally distributed data shown as mean ± standard deviation, non-normally distributed data as median (25th-75th percentile), and categorical data as n (% of group)

‡ $p < 0.01$.

Table 3
Outcomes*

Outcome	GA (n = 38)	DS (n = 41)	p Value
Major vascular complication	1 (2.6)	0 (0)	0.481
Cardiac arrest	3 (7.9)	1 (2.4)	0.347
Ischemic stroke	0 (0)	1 (2.4)	0.999
Length of stay ICU (h)	24 (18-42)	0 (0-16)	< 0.001‡
Length of stay hospital (d)	5 (4-6)	4 (3-6)	0.046†
In-hospital mortality	0 (0)	1 (2.4)	0.999

Abbreviations: DS, deep sedation; GA, general anesthesia; ICU, intensive care unit.

*Normally distributed data shown as mean ± standard deviation, non-normally distributed data as median (25th-75th percentile), and categorical data as n (% of group).

†$p < 0.05$.

‡$p < 0.01$.

no significant difference in in-hospital mortality between the two groups ($p = 0.999$; Table 3).

Although not part of the study analysis, four patients converted from DS to GA. Reasons for conversion were obtained from chart review. One of the patients was intubated due to worsening hypercapnia and one was difficult to sedate due to altered mental status in the setting of acute liver failure. The other two patients required conversion to GA due to procedure-related concerns including need to perform a transesophageal echocardiogram and due to the cardiologist's preference.

Discussion

The authors' institution's experience suggests that DS could be a viable option in patients undergoing transcaval TAVR. In this study, patients receiving DS for TC-TAVR had similar rates of implant success and postoperative outcomes to patients receiving GA with an endotracheal tube. The authors found that ICU length of stay and hospital length of stay were significantly lower in the DS group compared to the GA group. The length of the procedure was also significantly lower in the DS group compared to the GA group. This study suggested that use of DS may provide a more efficient use of hospital and ICU time in centers performing TC-TAVR.

The first TC-TAVR procedure was performed at Henry Ford Hospital in 2013 and published in 2014.[4] Due to the novel nature of the procedure and learning curve, all the initial TC-TAVRs were performed at the authors' institution using GA with an endotracheal tube. The decision to secure the airway was based on lack of experience with caval-aortic puncture and anticipation of hemodynamic instability. Initially, nearly all patients were admitted to the ICU after the procedure for possible risk of major vascular complication. However, by the end of 2014, due to improving operator experience, high implant success rates (>95%), and low rates of major vascular complications, the authors' institution started performing these procedures under DS. As more cardiac anesthesiologists became familiar with the procedure, a higher proportion of cases were being performed under DS. By 2018, nearly 100% of TC-TAVRs at the authors' institution were being performed under DS. To date, there is a lack of literature guiding anesthetic technique for transcaval TAVRs. To provide more objective data, the authors decided to perform this study and analyze data from 2015 to 2018 to help provide evidence to select the mode of anesthesia for these procedures.

Based on the authors' analysis, the median procedure duration was 32 minutes longer in the GA group than the DS group, and this was statistically significant ($p = 0.003$). Although this duration did not include time for induction/intubation or time for reaching appropriate depth of sedation, this duration did include time taken for emergence and attempt at extubation. There was no significant difference in overall median procedure durations on a year-to-year basis (2015, 2016, 2017, and 2018). This likely suggests that the role of learning curve and operator experience in procedure duration after 2015 was not significant. The authors believe that the significant difference in procedure duration between the groups probably can be explained by the time taken for emergence from GA, including muscle relaxant reversal and time taken for extubation assessment and, finally, the extubation attempt, if possible. The median patient age being 80 likely accounted for longer durations of emergence and role of multiple comorbidities including chronic lung disease. The authors' center uses a combination of propofol, dexmedetomidine, and/or remifentanil for DS for TC-TAVRs. By using these agents with a relatively low context-sensitive half-time, the time for emergence from sedation is considerably lower compared to agents such as midazolam and fentanyl.[10]

The median ICU duration of the GA group was 24 hours longer than that of the DS group ($p < 0.001$), and the median hospital length of stay in the GA group was one day longer ($p = 0.046$). This significant result was because 33 of 38 GA patients required an ICU stay, whereas only 14 of 41 DS patients were admitted to the ICU. Intubation rather than sedation in this frail population requiring TC-TAVRs is associated with greater hemodynamic instability leading to ICU stay. An observational study by Dehédin et al. in patients undergoing TF-TAVR found that patients receiving GA had greater hemodynamic instability and intraoperative requirement of catecholamines.[11] In addition, 23.7% of these patients had chronic lung disease (Table 1), which is associated with extubation failure,[12] leading to prolonged ICU and hospital length of stay. A retrospective observational cohort study by Abawi et al. found that use of GA in the nontransfemoral TAVR group was associated with prolonged in-hospital stay, which could be related to increased rates of postoperative delirium.[13] Although there are numerous published reports comparing sedation with GA for transfemoral TAVRs, the type of anesthetic often is defined poorly using terms such as *monitored anesthesia care, conscious sedation*, or *moderate sedation* without a clear definition. Going forward, it is critical to define the level of sedation as clearly as possible as the role of anesthesiologists for TAVR is continually evolving.[14] The largest observational study to date by Hyman et al. compared conscious sedation versus GA for transfemoral TAVR and found

statistically significantly shorter lengths of stay and lower mortality in the conscious sedation group compared to the GA group.[7] This study was observational and suggested the relative safety of conscious sedation, but better-designed studies are needed to show the superiority of conscious sedation.

The femoral arterial access is still the preferred approach for TAVR worldwide. However, in the unique high-risk population of patients who are not candidates for femoral access, the authors have seen that the transcaval approach is a viable alternative, with an overall implant success rate of 97.5% and in-hospital mortality of 1.3%, which were not significantly different between the GA and DS groups. Paone et al. performed a retrospective review to compare transfemoral, transcarotid, and transcaval access for TAVR. The authors found no difference in 30-day/in-hospital and one-year survival.[6]

Of the four patients who converted from DS to GA, two patients converted secondary to patient-related factors including worsening hypercapnia in a patient with chronic obstructive pulmonary disease and obstructive sleep apnea, and altered mental status in a patient with acute liver failure and hepatic encephalopathy, which made it difficult to make any conclusions. Larger studies with a more substantial cohort of patients should examine if certain patient characteristics could predict the need for GA, but this may not be possible as TC-TAVR is a very uncommon procedure. Although not specific for DS, there is evidence that a multidisciplinary team and review of baseline patient characteristics can help with deciding on minimalist versus GA pathways.[15] However, there also is evidence that baseline patient characteristics for patients undergoing TF-TAVR with the minimalist technique are not predictive of intraoperative morbidity, which likely applies to TC-TAVR as well.[16] Therefore, the group believes that despite evidence TAVR can be done without an anesthesiologist, there should always be an anesthesiologist present for any TAVR, especially TC-TAVR, as procedural complications can occur.[17,18]

Conversion at the cardiologist's request and need for transesophageal echocardiography (TEE) were procedure-related factors responsible for conversion in the remaining two patients. Hahn et al. explained that although TEE can be valuable in intraprocedural confirmation of landing zone morphology and valve positioning, reports from experienced, high-volume sites stated that intraprocedural TEE imaging may not be necessary for safe placement of a transcatheter heart valve.[19] In a review of imaging in TAVR procedures, Bleakley et al. stated that the shift away from general anesthesia has led to fewer patients having TEE-guided TAVR, but this did not have any impact on outcomes.[20]

It is important to interpret this study in the context of the limitations. Despite being the largest cohort of patients receiving TC-TAVR, this was only a single-center study. Being a retrospective review, selection criteria for GA versus DS is typically anesthesia provider–dependent and preference for DS has evolved over time and experience. Although there was no significant difference in body mass index between the groups, only 20% of the sample population was obese. The authors understand that centers with a high proportion of patients who are obese may prefer GA due to greater risk of airway obstruction and difficult airway. In addition, although it was clear that all patients in DS group did not undergo endotracheal intubation and all patients in the GA group underwent endotracheal intubation, the precise anesthetic depth of each patient in the DS group was not standardized. Multiple cardiac anesthesiologists have been involved in these procedures, and no protocol/guidelines have been used for anesthetizing these patients prior to this study.

In conclusion, this single-center retrospective study suggested that DS had similar postoperative outcomes and shorter hospital and ICU lengths of stay after the procedure compared to general anesthesia. The authors strongly believe that DS should be used whenever possible, since quicker time to hospital discharge translates to more efficient use of ICU and hospital time and resources. However, the decision to use sedation for TC-TAVRs should be based on operator and institutional experience. Perhaps a minimalist approach; that is, conscious sedation, is possible for TC-TAVR, but this is yet to be proven. The authors believe a strong multidisciplinary approach (surgeon, cardiologist, and cardiac anesthesiologist present) is paramount for delivering a safe anesthetic and achieving positive results in this challenging patient population.

Conflict of Interest

D. Wang is a consultant for Edwards Lifesciences. W. O'Neill is a consultant for Abbott and Boston Scientific.

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