Brazilian Journal of Anesthesiology 2022;72(4): 539—541

Sociedade Brasileira de Anestesiologia

Brazilian Journal of ANESTHESIOLOGY

SHORT COMMUNICATION

Conscious sedation versus general anesthesia for transcatheter aortic valve implantation: a retrospective study

Manuela Téllez-Alarcón [a], Felix Ramón Montes [b,*], Pedro Hurtado [b], Laura P. Gutiérrez [b], Jaime R. Cabrales [c], Jaime Camacho [d], Darío Echeverri [c]

[a] *Fundación CardioInfantil - Instituto de Cardiología, Investigation Department, Laboratory of Vascular Function, Bogotá, Colombia*
[b] *Fundación CardioInfantil - Instituto de Cardiología, Department of Anesthesiology, Bogotá, Colombia*
[c] *Fundación CardioInfantil — Instituto de Cardiología, Department of Interventional Cardiology, Bogotá, Colombia*
[d] *Fundación CardioInfantil — Instituto de Cardiología, Department of Cardiovascular Surgery, Bogotá, Colombia*

Received 26 April 2021; accepted 23 November 2021
Available online 17 December 2021

Transcatheter Aortic Valve Implantation (TAVI) is recommended in severe aortic stenosis with prohibitive and high surgical risk, and as an alternative in intermediate and low risk patients.[1] Despite the growth in the number of procedures, the optimal anesthetic management has not been established. Initially, TAVI was performed almost exclusively under General Anesthesia (GA), but developments in technology, and increase in experience promoted changes in anesthetic technique.

At our institution, TAVI was conventionally performed under GA until December 2017, when a Conscious Sedation (CS) protocol was implemented. This protocol became the first line of anesthetic management, unless the patient had considerations to avoid it (difficult airway, poor baseline respiratory status or inability to lie flat, right heart failure, severe pulmonary hypertension, or anticipated vascular access challenges). The objective of this study was to compare the post-interventional outcomes of CS with those of GA in patients undergoing transfemoral TAVI.

We conducted a retrospective, single-center, before-after study in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement. All consecutive patients who underwent transfemoral TAVI from January 1, 2016 through March 30, 2020 were divided as they received GA (before December 31, 2017) or sedation (after January 1, 2018).

GA was induced with etomidate, fentanyl or remifentanil, and rocuronium followed by maintenance with sevoflurane (0.8—1.0 MAC) supplemented with a continuous infusion of remifentanil or bolus of fentanyl. In all cases, a radial arterial catheter and Transesophageal Echocardiography (TEE) probe was used. A central venous catheter or pulmonary artery catheter was inserted, depending on the patient's characteristics and the anesthesiologist's criteria. At the end of the procedure, paralysis was reversed and extubation was attempted. In the CS group, after insertion of a radial artery catheter, patients underwent moderate to deep sedation (American Society of Anesthesiologists [ASA] definition) with continuous infusion of remifentanil supplemented with dexmedetomidine or propofol. Oxygen by a face mask was administered, and respiratory activity was monitored by capnography. Transthoracic echocardiography was conducted at the end of the procedure for a minority of cases.

All patients received bilateral infiltration of 0.5% bupivacaine in the groin. Femoral arterial access was obtained by percutaneous puncture, and routinely the femoral vein was cannulated to place a temporary pacing lead in the right ventricle. Balloon aortic valvuloplasty and implantation of balloon-expandable prostheses or self-expandable prostheses

* Corresponding author.
E-mail: montes.felix@hotmail.com (F.R. Montes).

https://doi.org/10.1016/j.bjane.2021.11.009

were performed using rapid ventricular pacing (140 −180 beats per minute). X-Ray fluoroscopy and TEE (the latter in the GA group) were used to evaluate the position of the prosthetic valve. For all types of prostheses, the temporary pacing lead was removed at the end of the procedure and was only kept in patients with atrioventricular block, previous right bundle branch block, or new left bundle branch block with grade 1 atrioventricular block. Patients were reassessed 24 hours after to define a permanent pacemaker implantation.

Hypotension (systolic arterial pressure < 90 mmHg) was treated with a single 4 μg intravenous norepinephrine bolus. A continuous norepinephrine infusion was started when multiple boluses were needed. Bispectral index and/or cerebral oxygen saturation were not standardized, and they were used according to the anesthesiologist's preference. All patients were admitted to the Intensive Care Unit (ICU) after the intervention.

The primary endpoints were ICU and total postoperative Length Of Stay (LOS). Secondary endpoints included all causes of 30-day mortality, immediate procedural mortality, and the incidence of major postoperative complications according to the Valve Academic Research Consortium-2 criteria.[2] Type of intraoperative monitoring, incidence of vasopressor/vasodilator use, procedural time, and anesthesia time were registered. Data were analyzed by unpaired *t*-test with Welch's correction, Fisher's exact test or Chi-Square as appropriate. A *p*-value < 0.05 was considered statistically significant. All patients were analyzed in their original group.

Our analysis included 158 patients who underwent transfemoral TAVI, of whom 76 were scheduled for GA and 82 for CS. History of arterial hypertension was noted

Table 1 Demographic characteristics and endpoints.

	Conscious sedation n = 82	General anesthesia n = 76	*p*-value
Demographic characteristics			
Age, years (mean, 95% CI)	80.4 (78.9−81.9)	78.1 (75.8−80.4)	0.10
Sex (% male)	48.8% (40/82)	55.6% (42/76)	0.43
EuroSCORE II (mean, 95% CI)	4.0 (3.08−4.82)	4.9 (4.07−5.82)	0.11
STS risk score (mean, 95% CI)	4.1 (3.29−4.94)	5.1(4.34−5.90)	0.08
Body Mass Index (mean, 95% CI)	25.0 (23.98−25.95)	26.2 (25.18−27.25)	0.08
Coronary artery disease	40.2% (33/82)	40.8% (31/76)	1
Previous myocardial infarction	19.5% (16/82)	17.1% (13/76)	0.83
NYHA III or IV	47.6% (39)	56.6% (43)	0.26
History of cerebrovascular disease	10.9% (9/82)	7.9% (6/76)	0.59
Arterial hypertension	86.6% (71/82)	53.9% (41/76)	<0.0001
Diabetes	22.0% (18/82)	19.7% (15/76)	0.85
Creatinine > 2 mg.dL^{-1}	4.9% (4/82)	5.3% (4/76)	0.99
COPD	24.4% (20/82)	23.7% (18/76)	0.99
Prior open-heart surgery	6.1% (5/77)	14.4% (11/76)	0.11
History of congestive heart failure	31.7% (26/82)	40.8% (31/76)	0.25
Ejection fraction (mean, 95% CI)	50.8% (48.0−53.6)	48.2% (45.2−51.3)	0.21
Intraoperative, primary and secondary endpoints			
Anesthesia time, min (mean, 95% CI)	134.0 (121.1−146.8)	169.7 (160.0−179.4)	<0.0001
Procedural time, min (mean, 95% CI)	74.5 (60.7−88.3)	88.4 (79.8−96.9)	0.09
Vasopressor administration, n (%)	55 (67.1%)	67 (88.2%)	0.0021
Vasodilatadors administration, n (%)	32 (39.0%)	38 (50.0%)	0.20
Cardiopulmonary bypass salvage, n (%)	1 (1.2%)	1 (1.3%)	1
ICU LOS (days)	1.68 (1.4−1.9)	2.37 (2.0−2.7)	0.002
Days in regular floor after TAVI	1.68 (1.3−2.0)	2.0 (1.6−2.4)	0.24
Total postoperative LOS (days)	3.37 (2.9−3.8)	4.38 (3.8−5.0)	0.009
In-hospital mortality, n (%)	1 (1.22%)	3 (3.94%)	0.35
Global mortality, n (%)	2 (2.38%)	5 (6.17%)	0.27
Need for POP mechanical ventilation, n (%)	0 (0%)	3 (3.94%)	0.10
Disabling stroke, n (%)	1 (1.22%)	1 (1.31%)	1
Major bleeding, n (%)	2 (2.43%)	3 (3.94%)	0.67
Major vascular complications, n (%)	1 (1.22%)	2 (2.63%)	0.20
Acute kidney injury, n (%)	3 (3.66%)	4 (5.26%)	0.71
New onset atrial fibrillation, n (%)	3 (3.66%)	2 (2.63%)	1
New pacemaker, n (%)	5 (6.10%)	6 (7.90%)	0.76
Device success, n (%)	70 (85.37%)	65 (85.53%)	1

Data is provided as mean (95% Confidence Interval) or incidence (percentage).
CI, Confidence Interval; STS, Society of Thoracic Surgery; NYHA, New York Heart Association; COPD, Chronic Obstructive Pulmonary Disease; LOS, Length of Stay; TAVI, Transcatheter Aortic Valve Implantation; ICU, Intensive Care Unit; POP, Postoperative.

to be higher in the CS group ($p < 0.001$), with no other difference in baseline characteristics. Seven patients (8.5%) in the CS group required conversion to GA due to hemodynamic instability for arrhythmia after the guidance step (n = 2), peripheral vascular injury requiring vascular exploration (n = 2), aortic lesion requiring cardiopulmonary bypass, deep sedation with oxygen desaturation, and an uncooperative patient who moved during the procedure.

The mean anesthesia time was significantly shorter in the CS group compared with the GA group (134 [121—146] minutes vs. 170 [160—179] minutes, $p < 0,0001$). No difference was found in the mean procedural time. ICU and total postoperative LOS were significantly higher in the GA group than in the sedation group, whereas postoperative-exclusive of ICU LOS was the same for both groups. No difference was found in any secondary endpoints (Table 1).

In this study, the implementation of a sedation protocol in patients undergoing transfemoral TAVI was associated with a significant decrease in total postoperative and ICU LOS. The improvement in these variables was achieved without a measurable increase in the incidence of intraoperative or postoperative complications.

The election of the anesthesia management for patients undergoing TAVI is dependent on medical and "cultural" practices. European registries show variations by country between 0 and 100% in the adoption of sedation as the main technique,[3] while in the United States, GA continues to be the principal method of anesthesia.[4] However, in recent years, there has been a worldwide growing trend towards the choice of sedation or regional techniques as opposed to GA.

Supporters of the use of sedation to perform TAVI base their decision on several of the findings observed in the present study. Frequently, avoiding the induction, orotracheal intubation, and positive pressure ventilation during GA are cited, leading to better hemodynamic stability and less use of vasopressors and inotropes. The supporters of GA base their decision on the no need for collaboration of critically ill patients, immediate establishment of a fully controlled environment in case of complications, and the possibility of routine monitoring with TEE.

For us, the finding of a decrease in ICU and hospital LOS is an important result. In our country, TAVI is considered an expensive procedure usually restricted to very high-risk patients, so any reduction in costs resulting from resource optimization is always welcome. ICU and hospital LOS are associated with higher costs, and although it was not directly measured, reduced stays have been shown to effectively reduce costs.[5]

In our study, the rate of conversion to GA (8.5%) was comparable to previous studies (which range between 3—17%), and reasons for conversion were similar. This finding highlights the fact that unplanned conversion to GA occurs relatively frequently, and the anesthesiology team must be prepared to ensure a smooth and safe change between anesthetic techniques. In our experience, the conversion to general anesthesia was performed without negatively impacting the outcome of the patients. However, this report does not have the power to identify differences in this regard.

Data on TAVI outcomes has largely been obtained from large centers in industrialized countries. Unlike them, the present study describes the findings obtained in patients belonging to a low-volume center located in a middle-income country in which there is scarce information.

In conclusion, the implementation of a CS protocol for transfemoral TAVI was associated with improved ICU and hospital LOS. The clinical endpoints were not affected by the anesthesia technique.

Funding

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Conflicts of interest

The authors declare no conflicts of interest.

References

1. Mack MJ, Leon MB, Thourani VH, et al. Transcatheter aortic-valve replacement with a balloon-expandable valve in low-risk patients. N Engl J Med. 2019;380:1695—705.
2. Kapptein AP, Head SJ, Généreux P, et al. Updated standardized endpoint definitions for transcatheter aortic valve implantation: The Valve Academic Research Consortium-2 consensus document. J Thorac Cardiovasc Surg. 2013;45:6—23.
3. Neumann FJ, Redwood S, Abdel-Wahab M, et al. General anesthesia or conscious sedation for transfemoral aortic valve replacement with the SAPIEN 3 Transcatheter Heart Valve. Int Heart J. 2020;61:713—9.
4. Hyman MC, Vemulapalli S, Szeto WY, et al. Conscious sedation versus general anesthesia for transcatheter aortic valve replacement. Insights from the National Cardiovascular Data Registry Society of Thoracic Surgeons/American College of Cardiology transcatheter valve therapy registry. Circulation. 2017;105:2132—40.
5. Toppen W, Johansen D, Sareh S, et al. Improved costs and outcomes with conscious sedation vs. general anesthesia in TAVR patients: Time to wake up? PLoS One. 2017;12:1—12.