ARCHIVES OF THE TURKISH SOCIETY OF CARDIOLOGY

Official journal of the TURKISH SOCIETY OF CARDIOLOGY

The Effect of Anesthesia Type Applied in Transcatheter Aortic Valve Implantation

Transkateter Aort Kapak İmplantasyonunda Uygulanan Anestezi Tipinin Etkisi

ABSTRACT

Objective: Different results have been obtained in studies on the effect of anesthesia type applied during transcatheter aortic valve implantation on in-hospital outcomes. In this study, we aimed to investigate the association of the type of anesthesia with the lenght of stay in the intensive care unit and the need for inotropes in patients undergoing transcatheter aortic valve implantation.

Methods: A total of 140 patients who underwent transcatheter aortic valve implantation between January 2016 and January 2022 were retrospectively analyzed. The patients were divided into 2 groups as deep sedation and general anesthesia according to the type of anesthesia.

Results: The mean age of all patients was 78.5 ± 8.6 years, and 69 of the patients (49.3%) were female. Length of stay in intensive care unit, midazolam dosage, use of inotropic agents, and procedural hypotension were significantly lower in the deep sedation group than in the general anesthesia group [(1[1-2] vs. 1[1-2.5] days, $P=0.03$), (2.1 ± 0.4 mg/kg vs. 2.3 ± 05, $P=0.02$), (39 (37.9%) vs. 22 (59.5%), $P=0.02$), (41 (39.8%) vs. 25 (67.6%), $P=0.004$)]. General anesthesia was associated with increased use of inotropic agents during transcatheter aortic valve implantation compared to deep sedation (odds ratio=2.93 95% CI=1.18-7.30, $P=0.02$).

Conclusion: The use of inotropes is less in transcatheter aortic valve implantation procedures performed under deep sedation and length of stay in intensive care unit is shorter.

Keywords: Deep sedation, general anesthesia, inotrope requirement, intensive care stay, transcatheter aortic valve implantation

ÖZET

Amaç: Transkateter aort kapak implantasyonu (TAKİ) sırasında uygulanan anestezi tipinin hastane içi sonlanımlar üzerine etkisi ile ilgili yapılan çalışmalarda farklı sonuçlar elde edilmiştir. Biz bu çalışmada TAKİ yapılan hastalarda kullandığımız anestezi tipinin yoğun bakım yatış süresi (YBYS) ve inotrop ihtiyacı ile ilişkisini araştırmayı amaçladık.

Yöntem: Çalışmamızda Ocak 2016 ile Ocak 2022 tarihleri arasında kardiyoloji kliniğimizde TAKİ uygulanan toplam 140 hasta retrospektif olarak incelendi. Hastalar, uygulanan anestezi tipine göre derin sedasyon (DS) ve genel anestezi (GA) olmak üzere 2 gruba ayrıldı.

Bulgular: Tüm hastaların ortalama yaşı 78,5 ± 8,6 idi ve hastaların 69'u (%49,3) kadındı. YBYS, midazolam dozu, inotropik ajan kullanımı ve işlemle ilişkili hipotansiyon; DS grubunda GA grubuna göre anlamlı olarak daha düşüktü [(1[1-2] 'e karşı 1[1-2,5] gün, $P=0,03$), (2,1 ± 0.4 mg/kg'a karşı 2.3 ± 0,5, $P=0,02$), (39 (%37,9) 'a karşı 22 (%59,5), $P=0,02$), (41 (%39,8) 'e karşı 25 (%67,6), $P=0,004$)]. GA, DS'ye göre TAKİ işlemi sırasında inotropik ajan kullanımında artış ile ilişkiliydi (odds ratio = 2,93, %95 güven aralığı = 1,18-7,30, $P=0,02$).

Sonuç: DS altında yapılan TAKİ işlemlerinde inotrop kullanımı daha azdır veYBYS daha kısadır.

Anahtar Kelimeler: Derin sedasyon, genel anestezi, inotrop ihtiyacı, yoğun bakım yatış süresi, transkateter aort kapak implantasyonu

Although transcatheter aortic valve implantation (TAVI) has emerged as the only treatment option in the treatment of patients with severe aortic stenosis who are at high surgical risk and cannot be operated on, it is increasingly applicable to patients

ORIGINAL ARTICLE
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Received: January 30, 2023
Accepted: April 10, 2023

Cite this article as: Yılmaz Ş, Zeren G, Avcı İl, et al. The effect of anesthesia type applied in transcatheter aortic valve implantation. *Turk Kardiyol Dern Ars.* 2023;51(6):394-398.

DOI:10.5543/tkda.2023.38920

with moderate and recently low surgical risk.[1-5] Increasing experience and technological developments and the increasingly minimally invasive orientation of the procedure have led to the revision of anesthesia protocols. While general anesthesia (GA) was used in high and very high-risk patients in the first randomized clinical trials of TAVI, recent studies have shown that deep sedation (DS) is becoming more common.[6] Both methods have advantages and disadvantages. Very different results have been obtained in studies on the comparison of anesthetic applications in TAVI. While it has been reported that DS use reduces the length of stay (LOS) in intensive care unit (ICU) and total hospital stay, other studies found no difference.[7-10] In some studies, GA has been reported to increase the need for inotropes.[10]

In this study, we investigated whether the type of anesthesia used during TAVI was related to ICU LOS and inotrope requirement.

Materials and Methods

A total of 140 patients who applied to our cardiology clinic between January 2016 and January 2022 and were found suitable for TAVI by our cardiac team were retrospectively analyzed. Informed consent was obtained from all patients before the procedure and the ethics committee approval was obtained from the Haydarpaşa Numune Training and Research Hospital Ethics Committee (Approval Number: HNEAH-KAEK 2021/313, Date: 13.12.2021). According to the type of anesthesia administered during TAVI, the patients were divided into 2 groups as DS and GA. Clinical and laboratory characteristics of all patients were examined and in-hospital outcomes were recorded.

Anesthesia Administration

The DS group received an IV bolus of 1 mg/kg propofol, 0.02 mg/kg midazolam, and an infusion of 0.7-1.8 mcg/kg/h dexmedetomidine, along with a subcutaneous administration of 10 mL of 2% prilocaine for local anesthesia in the inguinal region. For GA, an IV bolus of 0.6 mg/kg rocuronium, 0.6 mcg/kg fentanyl, 1 mg/kg propofol, and a continuous infusion of 0.5 mg/kg/h propofol and 0.03 mg/kg/h midazolam were administered. Both groups underwent intraprocedural monitoring with continuous invasive measurement of arterial blood pressure through a radial artery catheter. A blood pressure of less than 90/60 mmHg during the procedure was considered procedural hypotension. Pulse oximetry was also used for continuous ECG monitoring and transcutaneous arterial oxygen saturation. The anesthesia protocol was determined by an anesthesiologist in accordance with the current guidelines. After the procedure, all patients were monitored in the ICU until they woke up and achieved hemodynamic stability.[11]

ABBREVIATIONS

ACA	Anterior cerebral arteries
DS	Deep sedation
EMR	Electromagnetic radiation
GA	General anesthesia
ICU	Intensive care unit
IQR	Interquartile range
LOS	Length of stay
MCA	Middle cerebral arteries
MI	Myocardial infarction
NIRS	Near-infrared spectroscopy
rSO2	regional cerebral oxygen saturation
SBP	Systolic blood pressure
TAVI	Transcatheter aortic valve implantation

Definition

Near-Infrared Spectroscopy

Near-infrared spectroscopy (NIRS) is a non-invasive method that uses the absorption of infrared light by chromophores to estimate the venous-weighted regional cerebral oxygen saturation (rSO_2). Near-infrared spectroscopy devices emit electromagnetic radiation (EMR) in the near-infrared range (700-1000 nm), which is absorbed by the cerebral parenchyma or detected by receptors after passing through underlying tissue in a parabolic arch. The proximal sensor detects photons from the extracerebral tissue, while the distal sensor detects photons from deeper tissue, typically near the junction of the anterior (ACA) and middle cerebral (MCA) arteries. The device uses the modified Beer–Lambert law to provide a measurement of regional cerebral oxygen saturation (rSO_2) expressed as a percentage of the proportion of measured oxyhemoglobin (at 920 nm) to total hemoglobin (760 nm). The frontal cortex is often the region monitored, as it is suitably accessible and exposed and has clinical importance as a watershed area.[12]

American Society of Anesthesiologists Physical Status Classification

This is a classification system that is a simple and useful method used to quickly evaluate preoperative patients. According to this classification, patients are classified from 1 to 6. Class 1 describes a normal healthy person, while class 6 describes a patient who has suffered brain death.[13]

Statistical Analysis

Continuous variables are presented as median, interquartile range (IQR) (25^{th}-75^{th}), or mean and SDs. Categorical variables were expressed as absolute numbers and percentages. The chi-square test or Fisher's exact test was used to compare categorical variables between groups. Continuous variables, *t*-test, or Mann–Whitney *U* tests were compared according to distributions.

Response Variable: Use of Inotropes during TAVI Procedure

The logistic regression method was used to investigate the relationship between predictive variables and inotropic use. The effects of individual predictors were reported using odds ratio and 95% CI. The *P* values of <0.05 were considered statistically significant.

All statistical analyses were performed with R studio version 4.2 (R Project, Austria) using the "rms" and "Hmisc" packages.

Results

General anesthesia was performed in 37 (26.4%) of the 140 patients included in the study, and DS was performed in 103 (73.6%) patients. The mean age of all patients was 78.5 ± 8.6 years, and 69 of the patients (49.3%) were women. One hundred ten patients (78.6%) had hypertension, 55 (39%) had diabetes mellitus (DM), and 89 (63.6%) had coronary artery disease (CAD). Body mass index (BMI), logistic Euroscore, and left ventricular ejection fraction were similar in both groups. Other demographic and clinical characteristics are given in Table 1.

Table 1. Pre-Procedural Clinical and Demographic Variables by Type of Anesthesia

Variables	Deep Sedation (n=103)	General Anesthesia (n=37)	All Patients	P
Age (years)	78.9 ± 8.3	77.3 ± 9.3	78.5 ± 8.6	0.35
Female (n, %)	44 (42.7)	25 (67.6)	69 (49.3)	0.01
BMI (kg/m²)	27.5 ± 3.8	28.2 ± 3.6	27.7 ± 3.8	0.37
Logistic EuroSCORE	24.3 ± 10.9	24.7 ± 11.6	24.4 ± 11	0.85
CAD (n, %)	68 (66)	21 (56.8)	89 (63.6)	0.31
Hypertension (n, %)	83 (80.6)	27 (73)	110 (78.6)	0.33
DM (n, %)	35 (34)	20 (54.1)	55 (39)	0.03
EF (n, %)	50.5 ± 11.5	48.9 ± 11.2	50.1 ± 11.1	0.45
Pre-procedural SBP (mmHg)	141.7 ± 29.2	143.6 ± 26	142.2 ± 28.3	0.72
Pre-procedural DBP (mmHg)	59 ± 11.9	61.9 ± 12.2	59.8 ± 12	0.21
HR (bpm)	64 ± 9.4	64 ± 9.1	64.3 ± 9.3	0.82
NIRS (%)	63.4 ± 10.3	59 ± 9.5	62.2 ± 10.3	0.02

BMI, body mass index; bpm, beat per minute; CAD, coronary artery disease; DBP, diastolic blood pressure; DM, diabetes mellitus; EF, ejection fraction; HR, heart rate; NIRS, near-infrared spectroscopy; SBP, systolic blood pressure.

Dexmethadomine use and NIRS were significantly higher in the DS group than in the GA group [(1.4 ± 0.3 vs. 0.60 ± .4, $P < 0.001$) (63 ± 9.3% vs. 59.31 ± 0.4%, $P=0.04$), respectively]. Intensive care unit length of stay, midazolam, inotropic agent use, and procedural hypotension were significantly lower in the DS group than in the GA [(1[1-2] vs. 1[1-2.5] days, $P:=0.03$), (2.1 ± 0.4 vs. 2.3 ± 0.5 mg/kg, $P=0.02$), (39 (37.9%) vs. 22 (59.5%), $P=0.02$), (41 (39.8%) vs. 25 (67.6%), $P=0.004$)]. Other process specifications are given in Table 2. The histogram of intensive care durations according to anesthesia types is given in Figure 1.

Multivariate logistic regression analysis revealed that increased systolic blood pressure (SBP) was inversely associated with increased inotropic agent use during TAVI procedure (odds ratio=0.97 CI 95%, 0.96-0.99 $P=<0.001$). In addition, GA was associated with an increased use of inotropic agents during TAVI compared to DS (odds ratio=2.93, 95% CI 1.18-7.30, $P=0.02$). Other parameters in the model were not associated with the use of inotropic agents during TAVI (Table 3).

Discussion

In this study, we showed that the inotrope requirement is less, and the ICU LOS is shorter in TAVI procedures performed under DS. We also determined that one of the predictors of inotropic use during the procedure was baseline systolic blood pressure.

The first randomized studies on TAVI were conducted in high-risk and very high-risk patients, and general anesthesia was used during the procedure.[6] Improvements have been made in anesthetic applications, as the experience of the operators has

Table 2. Procedural Clinical Features by Type of Anesthesia

Variables	Deep Sedation	General Anesthesia	All Patients	P
Procedural SBP (mmHg)	120.6 ± 17.5	118.6 ± 17.6	120.1 ± 17.5	0.55
Procedural DBP (mmHg)	52.6 ± 9.5	54 ± 8.7	53 ± 9.3	0.44
HR (bpm)	72.1 ± 11.3	71.7 ± 11.8	72 ± 10.7	0.83
Midazolam (mg/kg)	2.1 ± 0.4	2.3 ± 0.5	2.2 ± 0.4	0.02
Dexmethadomine (mcg/kg/h)	1.4 ± 0.3	0.6 ± 0.4	1.2 ± 0.5	<0.001
NIRS (%)	63 ± 9.3	59.3 ± 10.4	62 ± 9.7	0.04
Inotropic agent use (n, %)	39 (37.9)	22 (59.5)	61 (43.6)	0.02
Hypotension (n, %)	41 (39.8)	25 (67.6)	66 (47.1)	0.004
Procedure duration (minute)	65.5 ± 15.5	68.8±16	66.4±15.7	0.28
ICU LOS (day)	1 [1-2]	1 [1-2.5]	1 [1-2.3]	0.03
ASA class (n, %)				
2	7 (6.8)	4 (10.8)	11 (7.9)	0.54
3	95 (92.2)	32 (86.5)	127 (90.7)	
4	1 (1)	1 (2.7)	2 (1.4)	

ASA, The American Society of Anesthesiologists; bpm, beat per minute; DBP, diastolic blood pressure; HR, heart rate; ICU LOS, intensive care unit length of stay; NIRS, near-infrared spectroscopy; SBP, systolic blood pressure.

increased, device profiles have decreased, percutaneous vascular closure systems have been used, and the procedure has been performed on patients with increasingly lower risk. It is seen that the application of DS in TAVI procedures is increasing rapidly.[8] In recent studies comparing low-risk TAVI and conventional surgery, it was found that DS was used at a rate of 65.1% and 43.1%, respectively.[4,5] In our study, the rate of DS was quite high (73.6%), and our patients were in the high/very high-risk group.

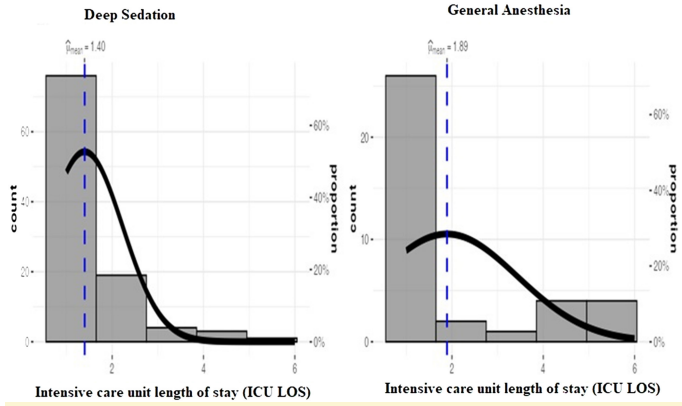

Figure 1. Histogram of intensive care unit length of stay (ICU LOS) by anesthesia types.

Table 3. Multivariable Logistic Regression for Prediction of Intra-procedural Inotropic Agent Use

Variables	Odds Ratio	Confidence Interval %95	*P*
Logistic EuroSCORE	0.99	0.97-1.03	0.96
Pre-procedural SBP (mmHg)	0.97	0.96-0.99	<0.001
Anesthesia type (GA vs. DS)	2.93	1.18-7.30	0.02
Gender (reference : female)	0.89	0.42-1.89	0.76
DM, yes/no	1.25	0.58-2.70	0.56
Midazolam (mg/kg)	0.53	9.19-1.50	0.23

DM, diabetes mellitus; DS, deep sedation; GA, general anesthesia; SBP, systolic blood pressure.±

Most of the studies comparing DS to GA in TAVI are registry studies, and randomized studies are limited. In these registry studies, it is reported that the use of conscious sedation leads to a decrease in operating room times, ICU LOS, total hospital stay, and costs.[8,14-16] In a registry study involving 10 997 patients, less procedural inotrope use with DS was associated with shorter ICU LOS and total hospital stay, as well as lower in-hospital and 30-day mortality.[9] In a recent meta-analysis, the mean hospital stay was 7.2 days in DS and 9.3 days in GA, with a significant difference in favor of DS.[8] Although these comparative studies using observational data cannot definitively establish the superiority of one technique over the other, these results demonstrate the safety of conscious sedation in this population. In our study, similar to these studies, the ICU LOS was shorter in the DS group, and the need for inotropes was less. Furthermore, our study suggests that baseline systolic blood pressure is one of the predictors of intraprocedural inotropic use. Some studies also show that DS has no effect on the length of hospital stay. In the randomized controlled trial of SOLVE–TAVI, DS led to similar outcomes for the primary efficacy endpoint of all-cause mortality, stroke, myocardial infarction (MI), infection requiring antibiotics, and acute kidney injury, compared to GA. However, GA led to a higher requirement for catecholamines without affecting procedure or device times, ICU length of stay, delirium rates, or overall hospital stay. The duration of hospital stay was the same in both groups, with an average of 9 days.[10] There are several factors that explain the reason for these differences in studies. More work was done in the early years of TAVI, so many reports may reflect the TAVI learning curve when moving from GA to DS and not the anesthetic strategy itself. Additionally, most registries are prone to patient selection bias, and the high, very high, and moderate risk diversity in the patient population may preclude a complete comparison of the 2 anesthetic applications. Furthermore, the length of hospital stay can be affected by many factors, such as the availability of rehabilitation centers after discharge, which can vary among different centers and countries. Moreover, reimbursment and healthcare policy can also have an impact on the length of hospital stay. Therefore, considering all these reasons, randomized studies are needed in this area.

Limitations

One of the main limitations of our study is that it is a retrospective study. The possibility that the general anesthesia procedure was performed in the more fragile patient group may have led to patient selection bias. The lack of data on the amount of procedural bleeding may have an effect on hypotension and inotrope requirements during the procedure. The limited data on other parameters that determine patients' inotropic requirements (peripheral complications, and medications taken prior to the procedure) also constitute a limitation.

Conclusion

Deep sedation during TAVI reduces the need for inotropes, shortens ICU LOS, and appears to be safe.

Ethics Committee Approval: The study is approved by the Haydarpaşa Numune Training and Research Hospital Ethics Committee (Approval Number: HNEAH-KAEK 2021/313, Date: 13.12.2021).

Informed Consent: Patients' informed consent was obtained.

Peer-review: Externally peer-reviewed.

Author Contributions: Concept – C.Y.K., Ş.Y.; Design – C.Y.K., G.Z., Ş.Y.; Supervision – C.Y.K., İ.İ.A., M.A.S.; Resource – M.A.S., İ.İ.A., F.C.; Materials – B.Ş., F.C., O.T., M.F.Y.; Data Collection and/or Processing – B.Ş., O.T., F.C.; Analysis and/or Interpretation – G.Z., Ş.Y., F.C.; Literature Review – B.Ş., F.C., M.F.Y.; Critical Review – C.Y.K., İ.İ.A., M.F.Y.

Declaration of Interests: The authors have no conflict of interest to declare.

Funding: The authors declared that this study has received no financial support.

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