

The effect of anesthesia management on mortality and morbidity in patients who underwent transcatheter aortic valve implantation

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Abstract

Objectives: We aimed at investigating the effects of two different anesthesia techniques in our patients who underwent transcatheter aortic valve implantation (TAVI).

Material and methods: The effects of two different anesthetic methods were retrospectively evaluated in 100 patients who underwent TAVI between January 2010 and October 2020. Patients were divided into a general anesthesia (GA) group and a sedation-local anesthesia (S-LA) group according to the anesthetic methods used.

Results: Of 100 patients who underwent transcatheter aortic valve implantation, 20 (20%) received GA, and 80 (80%) received S-LA. The mean ages of the patient groups undergoing GA and S-LA were 76.20 ± 7.22 and 75 ± 8.44 years, respectively. The duration of the procedure and anesthesia was significantly longer in the GA patient group than in the S-LA patient group. With the exception of the logistic European Society of Cardiac Operative Risk Assessment, the demographic and preoperative data of the two groups were similar. The most common comorbidity in both groups was hypertension. When comparing complications between groups, the incidence of intraoperative hemodynamic instability, ephedrine use, inotropic drug use, intra-aortic balloon pump placement, postoperative infection and cardiac tamponade was significantly higher in the GA group. The length of intensive care and hospital stay was similar between the groups, but the 30-day and 3-month mortality rates were significantly higher in the GA group than in the S-LA group.

Conclusion: S-LA provided more stable hemodynamics, shorter operative and anesthetic times, fewer intraoperative and postoperative complications, and reduced mortality. S-LA application during the TAVI procedure is a more reliable alternative to GA.

Key words: general anesthesia, sedation, aortic valve stenosis, transcatheter aortic valve implantation

Introduction

Aortic stenosis (AS) is the most common heart valve pathology in developed countries. Its prevalence is reported to increase with age, reaching 9.8% between 80 and 89 years of age [1-3]. Left untreated, symptomatic AS has a poor prognosis and leads to increased mortality [4,5]. Transcatheter aortic valve implantation (TAVI) is an interventional treatment modality that provides a non-surgical replacement of the aortic valve [6]. With increasing worldwide attention, this new technology has revolutionized the treatment of AS. Although many studies have demonstrated the effectiveness of TAVI in

AS, there is no consensus on the most appropriate type of anesthesia to support TAVI [7]. While TAVI was originally performed under general anesthesia (GA), technological advances in catheters and other devices, and the increasing experience of anesthesiologists and surgeons, allowed TAVI to be performed under sedation-local anesthesia (S-LA) [8,9]. In our study, we aimed to investigate retrospectively the application examines the success of two different anesthetic methods, their impact on complications, and 1-, 3-, and 6-month mortality rates in patients undergoing TAVI.

Material and methods

Local Ethics Committee approval (2011-KAEK-25 2020/10-16) was obtained for this study, which was conducted to evaluate patients who underwent TAVI between January 2010 and October 2020. The study was conducted in accordance with the principles of the Helsinki Declaration and included patients over 18 years of age undergoing TAVI under GA or S-LA. Patients who had pre-procedure cardiac arrest required open-heart surgery during and after TAVI, and patients under 18 years of age with missing data were excluded from the study. Data were collected retrospectively from patient charts, hospital automation systems, and anesthesia follow-up charts. The patients were divided into two groups GA and S-LA groups according to the anesthetic method used. Patient demographics, comorbidities, American Society of Anesthesiologists (ASA) Physical Status Classification, European Society of Cardiac Operative Risk Assessment (EuroSCORE) or Society of Thoracic Surgeons (STS) scores, ejection fraction (EF), anesthesia method, anesthesia and operative time, type of aortic valve used, site of catheterization, hemodynamic data, need for inotropic drugs, length of intensive care unite (ICU) and hospital stay, the incidence of complications, and mortality rates were recorded. Data on 1-, 3-, and 6-month mortality rates were obtained from hospital records, telephone contacts, and civil registration offices. Since all data were collected retrospectively and managed anonymously, patient consent was not required.

At our hospital, the TAVI procedure is approved by a committee consisting of a cardiologist, a cardiac surgeon, and an anesthetist. The severity of aortic stenosis is determined by transthoracic echocardiography. In the preoperative anesthesia assessment, detailed medical history, comorbidity, physical examination, laboratory and consultation results, ASA, logistics EuroSCORE and STS score results are evaluated.

The TAVI procedure is performed in our hospital's angiography unit under sterile conditions and accompanied by fluoroscopy. The type of anesthesia to be performed is decided based on the evaluation of the GA or S-LA, the general condition of the patient, and the details of the procedure. For GA applications, the anesthetic agent may change. Generally, midazolam, fentanyl, propofol and ketamine hydrochloride in induction; Rocuronium is also preferred as a muscle relaxant. Sedation is with fentanyl and midazolam. An intraoperative reduction in systolic blood pressure greater than 25% from baseline or less than 90 mmHg was considered hypotension. Fluid therapy is used for low blood pressure. If there is no response, infusions of ephedrine, norepinephrine, and dobutamine are scheduled according to the patient's hemodynamic status. The transfemoral approach is preferred in most patients. Subclavian/axillary, transaortic, and transapical approaches are alternative approaches in patients unsuitable for the transfemoral approach. The most common valves are the Edwards family (Edwards Lifesciences, Irvine, USA), the Medtronic family (Medtronic, Minnesota, USA), and the Portico valve (St. Jude Medical Inc., USA). At the end of the procedure, all patients are transferred to the ICU.

Statistical analysis

The statistical analyses of the study were carried out using the SPSS 21 (IBM Corp. Released 2012. IBM SPSS Statistics for Windows, Version 21.0. Armonk, NY: IBM Corp.). Data with and without normal distribution were presented with, respectively, the mean \pm standard deviation and the median (25-75%). Categorical variables were presented with numbers and

percentages. For group comparisons, and frequency comparisons in categorical variables the chi-square test were used. The independent sampling test was used for comparing the mean values of the continuous variables. The nonparametric Mann-Whitney test was used for comparison of the median values. A p-value of <0.05 was accepted for statistical significance.

Results

The data of a total of 115 TAVI patients were analyzed. Two patients who had cardiac arrest, 2 patients who underwent cardiac surgery during the procedure, and 11 patients with incomplete mortality data were excluded from the study. S-LA (n=80) ve GA (n=20) patients who underwent the TAVI procedure were evaluated for the anesthesia methods. The clinical and demographic data of the patients before and during the procedure are presented in Table 1.

Table 1 Patients' demographic features.

Variable	Group 1 (n=80)	Group 2 (n=20)	P
Age, years	76,5(71-82)	75(73-82)	0,841
Gender, n (%)			
Female	39(48,8)	9(45,0)	0,764
ASA, n (%)			
III	60(75,0)	12(60,0)	0,181
IV	20(25,0)	8(40,0)	0,181
Smoking, n (%)	25(31,3)	8(40,0)	0,457
EF,(mean \pm SD)	47,16 \pm 11,95	41,25 \pm 16,61	0,072
Disease diagnosis, n (%)			
Aortic stenosis	53(66,3)	27(33,8)	0,916
Aortic stenosis-CAD	13(65,0)	7(35,0)	0,916
Logistic EuroSCORE,(mean \pm SD)	23,21 \pm 11,04	30,00 \pm 19,93	0,043
STS risk score,(mean \pm SD)	6,71 \pm 6,18	5,21 \pm 3,79	0,303
Operation duration, min	95,68 \pm 22,17	116,26 \pm 24,48	<0,001
Total anesthesia time, min	107,12 \pm 22,95	134,75 \pm 33,96	<0,001
Valve type, n (%)			
Edwards-Sapien valve	22(27,5)	7(35,0)	0,509
Medtronic-core valve	37(46,3)	8(40,0)	0,615
Portico St. Jude valve	21(26,3)	5(25,0)	0,909
TAVI route, n(%)			
Right transfemoral	63(78,8)	19(95,0)	0,091
Left transfemoral	15(18,8)	1(5,0)	0,134
Right subclavian	1(1,3)	0(0,0)	0,615
Left Subclavian	1(1,3)	0(0,0)	0,615
Length of stay in the ICU (days)	1(1-2)	4(3-5)	0,092
Length of stay in hospital (days)	2(1-3)	4(2-9)	0,854
30-day mortality	4(5,0)	5(25,0)	0,005
3-month mortality	8(10,0)	6(30,0)	0,021
6-month mortality	16(20,0)	7(35,0)	0,154

The results are expressed as: median (25-75), mean and standard deviation (SD), number (n) and percent (%). Chi-square Test, Mann-Whitney U Test,

The median age of the patients was 76 (48-94) years. The patients did not differ significantly with respect to age, gender, ASA, EF, and the STS score. In the GA group, the mean Logistic EuroSCORE (30.00 \pm 19.93), duration of the operation (116.26 \pm 24.48 min.) and duration of anesthesia (134.75 \pm 33.96 min.) were significantly higher (p=0.043, p<0.001 and p<0.001,

Table 2

Distribution of comorbidities and laboratory by groups

Variable	Group 1 n=80	Group 2 n=20	P
Comorbidity n (%)			
HT	61(76,3)	11(55,0)	0,058
DM	30(37,5)	9(45,0)	0,539
COPD	8(10,0)	5(25,0)	0,074
CVD	5(6,3)	0(0,0)	0,251
Kidney diseases	5(6,3)	1(5,0)	0,833
Coronary artery disease	33(41,3)	8(40,0)	0,919
Heart failure	7(8,8)	3(15,0)	0,405
Hemogram			
Preoperative	11,12±2,13	11,92±2,49	0,154
Postoperative	10,26±2,67	10,02±4,08	0,747
Hematocrit			
Preoperative	33,18±5,53	34,43±6,44	0,384
Postoperative	31,04±7,45	29,97±11,22	0,607
BUN			
Preoperative	28,01±13,53	21,40±10,92	0,046
Postoperative	28,08±14,87	21,15±13,01	0,060
Creatine			
Preoperative	1,18±0,43	1,12±0,48	0,570
Postoperative	1,12±0,44	0,92±0,51	0,098

The results are expressed as: mean and standard deviation (SD), number (n) and percent (%).

HT:Hypertantion, DM:Diabetes Mellitus, COPD:Chronic Obstructive Pulmoner Disease, CVD:Cerebrovascular disease, BUN: Blood Urea Nitrogen

Table 3

Comparison of intra and postoperative complications of the groups

	Group 1	Group 2	P
Intraoperative, n (%)			
Hemodynamic instability	7(8,8)	10(50,0)	<0,001
Ephedrine use	6(7,5)	9(45,0)	<0,001
Use of inotropic drugs	4(5,0)	9(45,0)	<0,001
NTG use	1(1,3)	0(0,0)	0,615
Temporary pacemaker application	79(98,8)	19(95,0)	0,284
Permanent pacemaker application	10(12,5)	4(20,0)	0,387
IABP insertion	0(0,0)	2(10,0)	0,004
Postoperative, n (%)			
Bleeding	1(1,3)	1(1,3)	0,284
Paravalvular leak	1(1,3)	0(0,0)	0,615
Neurological dysfunction	2(2,5)	1(5,0)	0,558
Infection	0(0,0)	1(5,0)	0,044
Process site infection	3(3,8)	1(5,0)	0,799
Process site hematoma	7(8,8)	2(10,0)	0,861
Procedure site pseudoaneurysm	3(3,8)	1(5,0)	0,799
Renal dysfunction	1(1,3)	0(0,0)	0,615
Myocardial infarction	3(3,8)	2(10,0)	0,251
Cardiac tamponade	0(0,0)	2(10,0)	0,004

The results are expressed as: number (n) and percent (%).

NTG: Nitroglycerin, IABP: İntraaortic Balloon Pump

respectively). In both the GA and the S-LA groups the right femoral approach and the Medtronic valve were used most frequently. The groups did not differ significantly in terms of ICU and hospital stay but the 30-day and 3-month mortality rates were significantly higher in the GA group of patients ($p=0.005$ and $p=0.021$, respectively). The preoperative and postoperative laboratory investigation results and comorbidities of the two groups are shown in Table 2. The preoperative blood urea nitrogen (BUN) was significantly higher ($p=0.046$) in the SA group. The most frequently found comorbidity was hypertension in both groups. The intraoperative and postoperative recorded complications of the S-LA and GA groups of patients are compared in Table 3. The results on intraoperative hemodynamic

instability, ephedrine use, inotropic medication use and intra aortic balloon pump (IABP) fitting, postoperative infection, and cardiac tamponade were significantly higher in the GA group of patients ($p<0.001$, $p<0.001$, $p<0.001$, $p=0.004$, $p=0.044$ ve $p=0.004$, respectively).

Discussion

In our study, in which we retrospectively analyzed the data of patients who underwent TAVI with the diagnosis of severe AS, according to the anesthesia method; in the GA group, the mean logistic EuroSCORE was significantly higher, and the operation and anesthesia times were significantly longer. There was no difference between the groups in intensive care and hospital stay, but the 30-day and 3-month mortality rates were found to be significantly higher in the GA group than in the S-LA group.

Severe AS is a common degenerative valve disease in the elderly patient group with a high incidence of mortality. TAVI, which has been applied as a noninvasive method in patients with high surgical risk in recent years, has become an alternative to surgical aortic valve replacement [10]. In the PARTNER study (Placement of aortic transcatheter valves, multi-center study) [11], it was stated that the procedure is an effective and safe treatment. In TAVI procedures, anesthesia applications vary depending on the experience of the team, the patient's systemic comorbidities, and the approach techniques are chosen for valve implantation [11,12]. Various anesthesia methods such as GA, S-LA, or regional anesthesia have been defined for TAVI applications [13]. In our study, S-LA was preferred in 80 (80.00%) of 100 patients and GA was preferred in 20 (20.00%) patients (Table 1).

Büyükoçban et al. [14] and Çakier et al. [15] reported the mean age of patients who underwent TAVI as 78.25 ± 8.24 and 78.19 ± 6.90 , respectively. In our study, the mean age was 75.99 ± 7.83 years and was consistent with the literature. Comorbidities such as advanced age are also important in increasing the surgical risk score and determining the type of anesthesia to be administered to patients. Although there was no difference between the groups in our study, hypertension was the most common comorbidity. This result was similar to many studies [14,15].

Preoperative surgical risk assessment in patients with severe AS is made according to Logistic EuroSCORE and STS risk scoring. While there was no difference between STS scores in our patients, the logistic EuroSCORE value was significantly higher in GA patients than in S-LA patients (30.00 ± 19.9 , 23.21 ± 11.04 , $p=0.04$, respectively). In many studies, it has been stated that GA with a high EuroSCORE value increases the risk of mortality and therefore S-LA should be preferred [16]. In our study, 30-day and 3-month mortality rates were found to be high in GA patients and this result was consistent with the literature. However, there are studies indicating that GA facilitates the management of hemodynamic instability in patients with a high EuroSCORE value and is an appropriate anesthesia method to enable the surgical team to work more comfortably [17]. On the other hand, technological developments and the increasing experience and experience of the team have brought S-LA applications to the fore in TAVI patients. In the literature, it has been stated that the transfemoral approach is a factor in the choice of anesthesia [17]. In our study, the transfemoral approach was used in 97.6 % of S-LA patients. While the TAVI procedure is preferred over surgery in high-risk patients because of its less invasiveness, it is stated that performing anesthesia with S-LA instead of GA may be beneficial for the patient [18]. Many

studies have reported that patients who underwent GA showed longer processing times compared to the LA group [11,12]. In this study, the duration of the procedure and the anesthesia of the patients in the GA group were significantly longer than in the S-LA group.

In general, patients before TAVI may be hypovolemic due to diuretic and vasodilator treatments that can be applied, and the cardiac depressant effects of anesthetic drugs used in GA may cause hemodynamic instability [19]. For these reasons, some publications have noted that the use of vasopressors and inotropic agents is more common during GA [19,20]. According to the results of our study, intraoperative hemodynamic instability, ephedrine use, and inotropic drug use were highest in the GA group.

Some complications that may occur during and after the TAVI procedure have been reported in the literature [15,21]. Villablanca et al. [21] stated that there was no difference in complications such as cardiovascular mortality, stroke, permanent pacemaker requirement, vascular complications, and annular rupture in GA and S-LA applications in TAVI procedure. Cakier et al. [15] compared anesthesia methods in TAVI procedure and found no difference in terms of complications such as minor vascular complications, sepsis, pneumonia, acute renal failure, infection, and cerebrovascular disease. However, they reported that it was higher in the group that underwent GA due to complications such as sudden rupture of the procedure and cardiac tamponade. In our patients, postoperative cardiac tamponade and infection were found to be significantly higher in the GA group with IABP insertion during the TAVI procedure.

There are many studies in the literature that have evaluated ICU and hospital lengths of stay and 30-day mortality after anesthesia management for TAVI procedures [21-23]. In these studies, it was stated that S-LA significantly shortened the length of stay in the ICU and hospital, and the 30-day mortality rate was lower than GA. In a few studies, no difference was found

in the 30-day mortality rate in the comparison of GA and S-LA in the TAVI procedure [24,25]. In our study, in contrast to the literature, no difference was found between the groups in terms of ICU and hospital length of stay and 6-month mortality, while 30-day and 3-month mortality rates were significantly lower in the S-LA group. The low number of patients undergoing GA may be the reason why we could not find a difference in ICU and hospital stays.

Our study had several limitations. This study was single-center, retrospective, and had a relatively small sample size. The other limitation is that the group of patients in S-LA is much larger than the group in GA. In terms of the effect of the anesthesia method on mortality and complications, there is a need for further studies with an equal or higher number of patients. Another limitation is that cost-effectiveness was not included in the study. However, we think sharing experiences with 100 patients is also important to contribute to the literature.

Conclusion

We compared the effects of two different anesthesia techniques in 100 patients who underwent transcatheter valve implantation. We found more stable hemodynamics, shorter operative and anesthetic times a reduced number of intraoperative and postoperative complications with reduced mortality in patients that underwent S-LA. S-LA application during the TAVI procedure is a more reliable alternative to GA.

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