

Impact of different anesthetic managements in outcomes of transcatheter aortic valve implantation: the first Turkish experience

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Received: 13.03.2015 • Accepted/Published Online: 29.07.2015 • Final Version: 19.04.2016

Background/aim: Transcatheter aortic valve implantation (TAVI) has emerged as a new therapy in aortic stenosis patients with high operative risk. Advances in experiences have shifted the choice of anesthesia from general to local anesthesia and sedation for these patients. We compared our anesthetic experiences in our institute in a period of 2.5 years.

Materials and methods: A total of 151 (86 females, 65 males, mean age 76 years) symptomatic aortic stenosis patients undergoing transfemoral TAVI under general anesthesia (GA) (n = 79) and local anesthesia and sedation (LAS) (n = 72) were evaluated retrospectively in regards to anesthetic issues.

Results: The mean European System for Cardiac Operative Risk Evaluation (EuroSCORE) values of patients in the GA and LAS groups were 17 and 12, respectively. The anesthesia duration was significantly shorter in the LAS group ($P < 0.001$) and 16.7% of the patients in the LAS group were switched to general anesthesia. Length of stay in the intensive care unit was similar in the two groups.

Conclusion: TAVI, applied in high-risk populations, has many challenges for anesthesiologists. With technological advances, it is possible to perform these procedures under sedation with variable advantages. Thus, future studies in regard to anesthesia are required for the success of the procedure and patient safety.

Key words: Transcatheter aortic valve implantation, aortic stenosis, general anesthesia, local anesthesia, sedation

1. Introduction

Transcatheter aortic valve implantation (TAVI) is an alternative technique to surgical aortic valve replacement in inoperable/high-risk patients with aortic stenosis (1). Anesthetic techniques in these interventions are quite important due to significant challenges about their management in a population of old and high-risk patients (2). However, there is still a lack of consensus with respect to the best anesthesiological approach for these patients. Taking into account that these patients will have more advantages from a noninvasive surgical approach, it is also suggested that they will benefit from less invasive anesthesia techniques (3–5). However, general anesthesia (GA) provides multiple advantages by maintaining patient immobility, use of transesophageal echocardiography (TEE), and facilitating the management of procedural complications (6). Local anesthesia and sedation (LAS) has recently been described as an alternative valid technique that probably brings the necessity of increased experience of the team (7).

We herein investigate the anesthesia-linked outcomes of patients undergoing TAVI at our institution over a period of 2.5 years.

2. Materials and methods

We investigated the data of patients retrospectively in regards to anesthetic issues. Between July 2011 and January 2014, 151 TAVI procedures were performed via a transaxillary (n = 3) or transfemoral (n = 148) approach at our institution.

Routinely, following the evaluation of the individual patient on the basis of international recommendations by the cardiologist, cardiac surgeon, and anesthesiologist, a decision for not only high risk of conventional surgery but also the suitability of TAVI is made in our clinics (8–12). Preoperatively, in addition to clinical evaluation, all patients are screened by transthoracic echocardiography (TTE), coronary angiography, iliofemoral contrast angiography, and computed tomography. Thus, the anesthesiologist determines the anesthetic management to be offered.

For this report, the patients were followed up in the aspect of clinical data, transthoracic echocardiographic results, parameters related to the procedure, and intensive care unit and hospital stay lengths until hospital discharge. Afterwards, information on survival in the following 30 days was obtained by telephoning the patient. We

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performed the procedure in the cardiac catheterization laboratory (CCL), which has sterility precautions similar to those the operating room, with mobile C-arm fluoroscopy. A retrograde transfemoral arterial valve implantation was initially planned for the patients. For those patients who were not suited for a transfemoral approach, subclavian access was performed. The CoreValve (Medtronic CV, Luxembourg) or the Edwards Sapien (Edwards Lifesciences, USA) bioprostheses were implanted. Standard technical applications of the TAVI procedure were applied as have been previously described (13). Routine anesthetic preprocedural evaluation focused on cardiovascular parameters, airway control, and other systemic dysfunctions. Before the procedure, oral acetylsalicylic acid (100 mg), clopidogrel (300 mg), and IV antibiotic were administered to all patients. No premedication was given.

In the operating room, a heating blanket was placed beneath the patient to prevent hypothermia and nasopharyngeal temperature was measured during the procedure. After inserting an IV catheter into a large arm vein, we applied a 5-lead electrocardiogram, invasive arterial blood pressure measurement, pulse oximetry, and central venous pressure monitorization. Pulmonary artery catheterization was not performed in any of the patients. At the beginning of the procedure, we administered heparin (5000 IU, IV) to achieve an activated clotting time (ACT) of more than 250 s. Local anesthetic infiltration consisting of 10–20 mL of 1% lidocaine was performed in each groin. The anesthesiologist decided to perform either GA or LAS, according to the patient's health status. For those undergoing GA, either sodium thiopental (3–5 mg kg⁻¹), etomidate (3 mg kg⁻¹), or propofol (1–2 mg kg⁻¹) was used for anesthesia induction. Rocuronium (0.6 mg kg⁻¹) was used for muscular relaxation. All patients were orally intubated and mechanically ventilated with a tidal volume of 4–6 mL kg⁻¹ and a respiratory rate of 12–16 breaths min⁻¹. End-tidal CO₂ concentrations of 30–35 mmHg were considered as adequate. Then the TEE probe was inserted. For maintenance of anesthesia, the anesthesiologists used either sevoflurane (0.8%–1.1% minimum alveolar concentration) in an oxygen/air mixture at FiO₂ of 50% combined with a remifentanyl infusion (0.02–2 µg kg⁻¹ min⁻¹) or a propofol/remifentanyl infusion (3–5 mg kg⁻¹ h⁻¹ / 0.02–2 µg kg⁻¹ min⁻¹) (total intravenous anesthesia technique, TIVA). Due to the difficulty in keeping the hemodynamic stability in elderly patients with reduced cardiac output by TIVA, only 5 suitable patients had been reported to be applied TIVA (6.3%). In the rest of the patients, inhalational anesthesia with sevoflurane in combination with remifentanyl infusion was chosen. Remifentanyl infusion provided earlier recovery with a short-lasting muscle relaxant (rocuronium) in these

patients. At the end of the procedure, the patients' extubation was decided by the anesthesiologist following the procedure.

Those patients undergoing LAS first had IV midazolam at 0.05 mg kg⁻¹ and fentanyl at 1 µg kg⁻¹. Supplemental oxygen by face mask (FiO₂ 0.5) was provided during the procedure. The aim was to evaluate the patient's neurological status; thus, we paid attention to the patient being consciously or deeply sedated, according to the guidelines established by the American Society of Anesthesiologists (ASA) (14). The patients were sedated such that they responded purposefully to verbal commands. They were asked to respond after repeated verbal or painful stimulation if the sedation level was deepened. If the sedation level was observed to be insufficient, additional midazolam (1–3 mg IV bolus) or remifentanyl infusion (0.025–0.2 µg kg⁻¹ min⁻¹) or propofol infusion (2–5 mg kg⁻¹ h⁻¹) was applied.

The patients had their ACT controls and arterial blood gas controls routinely during the procedure (for ACT once at the beginning and once at the end of the procedure, as well as one control after heparin application). Arterial blood gas analysis was also performed once at the beginning and at the end of the procedure. During the follow-up, the end-tidal CO₂ concentrations and respiratory rates were checked every 5 min. For those under LAS proper breathing was monitored by observing the rate and depth of chest and abdominal movements and pattern of respiration. Oxygen saturation levels under 90%, respiratory rate <6/min, and apnea >20 s or airway obstruction were treated by the stopping of all sedative drugs and assisted ventilation by facial mask until an adequate respiratory drive was reached. Conversion to GA was performed if the patient tolerated the procedure poorly or in case of complications.

All through these periods, the mean arterial pressure was aimed to be kept above 65 mmHg during the procedure. To achieve this goal, hypovolemia (initial transthoracic echocardiography findings and central venous pressure <8 mmHg) was corrected by volume expansion initially (500 mL colloid infusion). When preload and contractility were evaluated as optimal (by TEE or hemodynamic parameters), bolus ephedrine (5 mg) or epinephrine (5 µg) and/or norepinephrine (0.03–0.06 µg kg⁻¹ min⁻¹) infusions were used to correct arterial hypotension (systolic arterial pressure <80 mmHg). Nevertheless, the mean arterial pressure was increased above 75 mmHg to prevent deterioration in hemodynamic parameters. Two external defibrillator pads were attached. Under fluoroscopic guidance, ventricular pacing was performed at a rate of 180 beats min⁻¹ with a decrease in systolic arterial pressure to <50 mmHg. The ventricular outflow was minimized and balloon dilatation of the stenotic valve was performed. TEE (in intubated patients) was used to confirm proper

positioning of the prosthesis and to assess perivalvular or transvalvular aortic regurgitation at the end of the procedure. However, TEE was not used in patients under LAS. This decision was made by the team according to the cardiologist's experiences and the patient's aortic valve. In patients under LAS, fluoroscopic imaging and aortograms were reported to be as safe as TEE in providing anatomical details (15).

The femoral artery was closed percutaneously, except in cases of difficulties, for which the closure was performed surgically. Extubation immediately after the procedure in the CCL has been routinely done in our clinic. However, the long distance between the intensive care unit (ICU) and the CCL made some of the anesthesiologists prefer extubation in the ICU. Patients with hemodynamic instability, acute complications related to femoral/subclavian vessel manipulations, or rhythm disturbances at the end of the procedure were not extubated and were transferred directly to the ICU. Postoperative analgesia was provided by 1.0 mg kg⁻¹ IV tramadol every 6 h.

Data analysis was performed by using SPSS 11.5 for Windows (SPSS Inc., Chicago, IL, USA). Whether the distributions of metric discrete and continuous variables

were normal or not was determined by Shapiro–Wilk test. Data are shown as mean ± SD or median (min–max) as applicable. While the mean differences between groups were compared by Student's t-test, the Mann–Whitney U test was applied for comparisons of the median values. Nominal data were analyzed by Pearson's chi-square or Fisher's exact test as appropriate. Whether the differences between pre- and posttreatment measurements regarding LEVF, peak AV, and peak MV were statistically significant or not was analyzed by the Wilcoxon signed rank test. $P < 0.05$ was considered as statistically significant.

3. Results

A total of 151 TAVI patients were evaluated in this study (86 females, 65 males). While 52% of the patients in this report received GA, as the early phase of the physician learning curve progressed, we preferred LAS. The mean age of the patients was 76 years. Baseline characteristics and comorbidities of the TAVI population are listed in Table 1. There were significant differences in comorbidities of the two anesthesia groups since the patients were not randomly assigned to any group before the procedure and the data were studied retrospectively.

Table 1. Demographic data and comorbidities of the TAVI patients.

Parameters	Group GA (n = 79)	Group LAS (n = 72)	P-value
Age	76.3 ± 8.6	77.4 ± 8.7	0.458
Sex			0.003
Male	25 (31.6%)	40 (55.6%)	
Female	54 (68.4%)	32 (44.4%)	
Height (cm)	157.7 ± 11.1	161.8 ± 8.1	0.029
Weight (kg)	69.3 ± 14.4	71.2 ± 14.4	0.514
BMI	27.2 ± 5.1	27.2 ± 5.4	0.955
AF	21 (26.6%)	16 (22.2%)	0.534
RF	4 (5.1%)	6 (8.3%)	0.520
DM	22 (27.8%)	6 (8.3%)	0.002
PVD	8 (10.1%)	10 (13.9%)	0.476
CAD	46 (58.2%)	45 (62.5%)	0.592
MI	5 (6.3%)	32 (44.4%)	<0.001
PCI	42 (53.2%)	20 (27.8%)	0.002
CABG	8 (10.1%)	20 (27.8%)	0.005
COLD	15 (19.0%)	23 (31.9%)	0.067
CVE	3 (3.8%)	10 (13.9%)	0.027
CVS	4 (5.1%)	4 (5.6%)	1.000

AF: Atrial fibrillation, RF: renal failure, PVD: peripheral vascular disease, CAD: coronary artery disease, MI: myocardial infarction, PCI: percutaneous coronary intervention, CABG: coronary artery bypass grafting, COLD: chronic obstructive lung disease, CVE: cerebrovascular event, CVS: coronary valve surgery.

All the patients presented a high surgical risk (logistic EuroSCORE: 17.3 in GA group versus 12 in LAS group). However, the Society of Thoracic Surgeons (STS) score between the groups was significantly different (STS score: 17 in GA group and 6.7 in LAS group) ($P < 0.001$).

A retrograde transfemoral approach was suitable in 148 cases in the series, but in three cases, TAVI was performed by subclavian artery approach. In 6 of the patients with the transfemoral approach, the procedure required an open cut down to the vessels. The Edwards Sapien valve was implanted in the majority of patients ($n = 97$), while the Medtronic CoreValve Revalving System was chosen in only 54 patients. Procedural and anesthesia-related outcomes are reported in Table 2. No complications, such as device migration, prosthesis malpositioning, obstruction of coronary ostia, or myocardial infarction, occurred in the patients. The persistent atrioventricular block resulting after the procedure in 3 patients in GA group and 5 patients in LAS group was treated with permanent pacemaker implantation.

In the GA group, 62% of the patients were extubated in the ICU. Those were the patients with hemodynamic instability, vascular complications, and rhythm disturbances at the end of the procedure. Only 6% had mechanical ventilation periods longer than 48 h. In the LAS group, 16.7% of the patients failed to go on with this technique as a consequence of restlessness and a case of refractory ventricular fibrillation, and thus they had general anesthesia. The mean length of stay in the ICU in both of the groups was 3 days. However, mean length of stay in the hospital was significantly different between the groups (13 days vs. 6 days, $P < 0.001$). Fifteen patients in the GA and

six patients in the LAS group had vascular complications. The percentage of survival in the GA and LAS groups was 91% and 86% respectively after 30 days ($P > 0.05$). Both groups had significantly better echocardiographic results after the procedure (Table 3). Although neither the patients nor the cardiologist described any complaints, we did not document their satisfaction states.

4. Discussion

The results of this comparative study show that both GA and LAS are safe and feasible techniques for noninvasive transcatheter procedures.

At our institution, we preferred general anesthesia with tracheal intubation and continuous TEE monitorization in our first experiences. A balanced anesthesia technique (sevoflurane combined with remifentanyl infusion) allowed rapid recovery in the elderly patients. Another protocol with propofol/remifentanyl infusion (TIVA) was also used for maintenance of anesthesia. However, the hemodynamic stabilization was not easy in these elderly patients with reduced cardiac output by TIVA technique. That is why we applied this technique only in 5 suitable patients (6.3%). All of our patients were transferred to the ICU at the end of the procedure. The number of patients extubated in the ICU was more than the ones extubated in CCL. Nevertheless, like Covello et al. we switched to the use of local anesthesia and sedation following an assumed learning curve (16). Interestingly, the STS scores of the GA group were significantly higher than those of the LAS group. There are other studies comparing experiences with anesthesia techniques in patients undergoing TAVI (13,17–21). Goren et al, reported a rate of 4.6% conversion

Table 2. Procedural and anesthesia-related outcomes.

Parameters	Group GA (n = 79)	Group LAS (n = 72)	P-value
EuroSCORE (logistic)	17.3 (1.0–69.5)	12.0 (1.4–41.1)	0.027
STS score	17.0 (2.4–73.0)	6.7 (1.7–31.0)	<0.001
Anesthesia duration (min)	149.0 ± 48.7	124.7 ± 34.3	<0.001
Procedure duration (min)	109.3 ± 46.6	91.6 ± 34.7	0.010
Permanent pacemaker requirement	3 (3.8%)	5 (6.9%)	0.479
Length of stay in ICU (days)	3 (1–29)	3 (1–13)	0.225
Length of stay in hospital (days)	13 (3–33)	6 (1–25)	<0.001
Postop inotropic agent requirement	8 (10.1%)	7 (9.7%)	0.934
Vascular complication	15 (19%)	6 (8.3%)	0.059
Emergent vascular surgery	8 (10.1%)	5 (8.3%)	0.486
Mortality in first 30 days	7 (8.9%)	10 (13.9%)	0.329

Table 3. Comparison of echocardiographic parameters between the groups.

Parameters	Before TAVI	After TAVI	P-value	Change (Δ)
LEVF				
Group GA	60 (15–70)	65 (20–65)	<0.001	0 (-15 to 30)
Group LAS	60 (10–69)	65 (12–65)	<0.001	0 (-14 to 29)
P-value	0.835	0.693		0.269
Peak AV				
Group GA	74.5 (37.0–125.0)	19.5 (8.0–34.0)	<0.001	-56.5 (-108 to -28)
Group LAS	83 (54–136)	20 (7–40)	<0.001	-61.5 (-118 to -33)
P-value	0.107	0.676		0.138
Mean AV				
Group GA	49.5 (24.0–101.0)	9.0 (3.0–17.0)	<0.001	-41 (-90 to -20)
Group LAS	48.5 (29–83)	9 (3–23)	<0.001	-38 (-73 to -20)
P-value	0.497	0.114		0.601

from sedation to GA recently (18). The difference between that and our findings might be attributable to the experiences of anesthesiologists in TAVI procedures. We also collected the data retrospectively. Although the limits of dosages of sedative agents were exact and known, every anesthesiologist had his own applications. These data could have been interpreted more precisely if the total consumptions of agents had been documented.

In early studies, it was reported that GA with a fast-track protocol is the most appropriate and safest anesthesia technique for this approach (5,15,16). Billings et al. described 29 cases of TAVI, suggesting GA as a mandatory technique, because of the consequence of the procedure itself and the necessity of TEE (4). However, TEE could sometimes be misleading in distinguishing the prosthesis while crimped on the delivery system and it may interfere with fluoroscopic imaging, necessitating probe withdrawal at the time of implantation (22–24). Angiography could thus be associated with the same clinical and hemodynamic results (22).

Some authors prefer GA even after an initial experience with sedation. Gümüş et al. and Yamamoto et al. preferred local anesthesia and sedation in their practice after a period of experience with GA (17,25). Yamamoto et al. failed to show any difference in procedure success; 30-day mortality and the difference in length of stay in the ICU and hospital was significant in the sedation group in comparison to the GA group. However, they suggested the importance of experience for this switch, since they evaluated the conversion of 6 patients from local anesthesia and sedation to GA as an early and urgent

attempt for a change in anesthesia technique (17). In their experience, Petronia et al. described that patients in the GA group had higher EuroSCOREs and longer procedural times. Conversely, length of stay in the hospital was significantly shorter in their local anesthesia group (19). The EuroSCOREs of our patients in the GA group were also higher in our study. Interestingly, STS scores of the LAS group were found to be significantly higher in our study. One explanation for this could be more parameters taking place in the STS scoring system. More detailed information about these elderly patients could have included increased disabilities and morbidities, thus increasing the score. Nevertheless, patients with increased frailty could have led the anesthesiologists to avoid GA for this procedure, in our experience. Similarly to Petronia et al., our patients in the LAS group stayed in the hospital for shorter times.

In another study, there was a trend toward more postprocedural pulmonary complications in the GA group (18).

Dall'Ara et al. could not show any difference in complication rates such as myocardial infarction, major stroke, and hospital deaths between the GA and LAS groups (20). However, we had no such complications during the procedure. We investigated 30-day mortality in our patients, which gave similar results. In-hospital mortality was comparable between the two groups in another study also (18).

We performed GA for the first 79 patients in our practice. Following this period, we had the LAS group. There was a significant difference in anesthesia durations

between GA and LAS groups (149 ± 48.7 min vs. 124.7 ± 34.3 min, $P < 0.001$), although the procedure times were comparable to each other (109.3 ± 46.6 min vs. 91.6 ± 34.7 min). This could be the result of longer anesthetic preparation time for GA than for LAS. The procedure time in the GA group was also significantly longer than that of the LAS group. This might be due to TEE usage, and also more comfortable working conditions of the cardiologists.

Occasionally it has been reported that the anesthetic drugs used in GA contribute to the depression of cardiovascular function, leading to hemodynamic instability requiring inotropic support (16). Additionally, aortic stenosis patients cannot easily compensate for hypotension and bradycardia. Guinot et al. had serious hemodynamic instability required to be treated with two concomitant vasoactive drugs in their patients undergoing GA (9). However, this was just the opposite in the study of Balanika et al., who reported a stable hemodynamic profile in the patients undergoing GA (26). Thus, some authors argue that more hemodynamic stability requiring less inotropic support may be provided by sedation in awake patients safely undergoing TAVI (24). This was confirmed by another study as well (18). On the other hand, Dehedin et al. found not only significantly less hemodynamic instability and a shorter length of hospital stay in the monitored anesthesia care (MAC) group compared to the GA group, but also a significantly lower requirement for vasoactive or inotropic drug use. The complication incidence was higher in GA patients (27). These data were comparable with Behan et al. and Motloch et al.'s findings, but contrasted with a previous work by Bergmann et al. that did not show any superiority of MAC over GA

management (28–30). Although length of stay in the ICU and 30-day and 1-year mortality were comparable between the groups, a high conversion rate (17%) from GA to MAC was evaluated as a disadvantage of MAC (20). Only two patients in this observation needed GA as a result of lack of coordination with the anesthesiologist and the procedure. It has been reported that almost 7%–20% of patients under sedation required GA, with the urgent management of intraoperative complications (27,29,30). Unfortunately these were complications related to the procedure; thus, it can be concluded that the procedure itself, not the anesthesia technique chosen, determined the prognosis (7). Although the patients were sedated to be easily arousable, some patients had restlessness and decreased oxygen saturations, although face mask ventilation was applied. Thus, the anesthesia method was changed to general anesthesia. These patients were elderly and had compromised respiratory and cardiovascular functions, such that drug eliminations and responses were not always as we had imagined. As a result of this, keeping airway safety was necessary in these patients.

We also had a high conversion rate from LAS to GA of 16.7%, especially in those heavily sedated patients experiencing hypercapnia, hypoxia, and hypotension.

In conclusion, we think that TAVI is emerging as a safe and successful therapy in high-risk patients with severe aortic stenosis in the case of no surgical options. The anesthesiologist plays an essential role in the TAVI team. For successful anesthetic management in these patients, it is important to select the best approach with the understanding of the patient's health status and the cardiac team and their choices.

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