Local Against General Anesthesia For Transcatheter Aortic Valve Replacement

Transkateter Aort Kapak Replasmanı İçin Genel Anesteziye Karşı Lokal Anestezi

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Abstract

Background/Aims Transcatheter aortic valve replacement (TAVR) poses significant challenges concerning anesthesia management. There is no consensus on the type of safer anesthesia for TAVR procedures. We aimed to evaluate the effectiveness and safety of TAVR performed with a trans-femoral approach under local anesthesia with sedation (LAS) versus general anesthesia (GA).

Materials and Methods This observational and retrospective analysis included individuals who were admitted on a planned basis from 2016 to 2022 and underwent transfemoral TAVR. Effectiveness and safety outcomes were evaluated at 30 days. Individuals were separated into two groups: GA and LAS. Demographic characteristics and procedural data were recorded during the hospitalization.

Results 115 patients were included, of whom 62 (53.9%) received LAS and 53 received GA (46.1%). 59 female (48.8%) patients with a mean age of 83.2±5.7 participated in the study. A successful TAVR procedure was performed in 100 (86.9%) of 115 patients with the transfemoral approach. The mean procedure time was 136.7±46.7 minutes, and the procedure time was shorter in patients who underwent LAS compared to GA (p=0.001). There were no differences among the groups in fluoroscopy time, contrast, or radiation dose (p>0.05). Anesthesia technique was changed in 2 patients (3.2%) because aortic dissection required emergency surgery. Overall 30-day mortality was 5.2%, with no significant differences among the groups (GA 7.5% vs. LAS 3.2%, p =0.28). GA had substantially longer ICU and total hospitalization stays than LAS (p=0.009 and p =0.004, respectively).

Conclusion In our study, TAVR via the transfemoral route using LAS was an alternative for GA.

Keywords Local anesthesia, aortic stenosis, trans-femoral, TAVR.

Özet

Arkapaln/ Amaçlar Transkateter aort kapak replasmanı (TAVR), anestezi yönetimi açısından önemli zorluklar doğurur. TAVR prosedürleri için daha güvenli anestezi türü konusunda fikir birliği yoktur. Sedasyonlu lokal anestezi (LAS) altında transfemoral yaklaşımla yapılan TAVR'nin genel anesteziye (GA) karşı etkinlik ve güvenilirliğini değerlendirmeyi amaçladık.

Gereç ve Yöntemler Bu gözlemsel ve retrospektif analiz, 2016'dan 2022'ye planlı olarak başvuran ve Transfemoral TAVR uygulanan bireyleri içermektedir. Etkinlik ve güvenlik sonuçları 30 günde değerlendirildi. Bireyler GA ve LAS olmak üzere iki gruba ayrıldı. Hastanede yatışları sırasında demografik özellikler ve prosedürel veriler kaydedildi.

Bulgular 62'sine (%53.9) LAS, 53'üne GA (%46.1) olmak üzere 115 hasta dahil edildi. Çalışmaya yaş ortalaması 83,2±5,7 olan 59 kadın (%48.8) hasta katıldı. Transfemoral yaklaşımla 115 hastanın 100'üne (%86.9) başarılı TAVR işlemi uygulandı. Ortalama işlem süresi 136.7±46.7 dakika olup GA'ya karşı LAS yapılan hastalarda işlem süresi daha kısaydı (p=0.001). Gruplar arasında floroskopi süresi, kontrast ve radyasyon dozu açısından fark yoktu (p>0.05). 2 hastada (%3.2) aort diseksiyonu acil cerrahi girişim gerektirdiğinden anestezi tekniğinde değişiklik yapıldı. Genel 30 günlük mortalite %5.2 idi ve gruplar arasında önemli bir fark yoktu (GA %7.5'e karşılık LAS %3.2, p =0.28). GA, LAS'tan önemli ölçüde daha uzun YBÜ ve toplam hastanede kalış süresine sahipti (sırasıyla p=0.009 ve p =0.004).

Sonuç Çalışmamızda LAS kullanılarak transfemoral yoldan TAVR, GA'ya bir alternatifti.

Anahtar Kelimeler Lokal anestezi, aort stenozu, transfemoral, TAVR.

INTRODUCTION

Transcatheter aortic valve replacement (TAVR) has undergone numerous modifications since its inception, becoming an efficient, successful therapy with established results for individuals with severe symptomatic aortic stenosis and high surgical risk (1). Currently, it has indications that are universally acknowledged and is a novel therapeutic instrument in cardiology practice (2). Transfemoral TAVR is preferred over other access routes owing to its increased technical simplicity and documented superior outcomes (3).

Despite this, there are disagreements regarding the optimal method of procedure implementation. TAVR was initially performed under general anesthesia (GA), surgical access and controlled transesophageal echocardiography (TEE) (4). With the evolution of devices and the increased experience of operators, many are moving towards a minimalist strategy that includes the administration of local anesthesia with sedation (LAS), percutaneous access, and without the use of intraprocedural TEE (5,6).

Recent reports from large centers have demonstrated the practicability of performing transfemoral TAVR with LAS, based on their own experience (7,8). Although this is an appealing option for the management of patients with high risks, the published clinical outcomes are debatable (9).

We aimed to evaluate the effectiveness and safety of TAVR performed with a trans-femoral approach under LAS against GA.

MATERIAL and METHODS

Study design

This observational and retrospective analysis included patients who were admitted on a planned basis from 2016 to 2022 and underwent TAVR with the transfemoral approach. A multidisciplinary group (Heart Team) assessed and chose the patients according to surgical risk, comorbidities, lifespan, and the viability of the transfemoral approach. This research eliminated participants for whom data were unavailable. The Dicle University Ethics Committee granted ethical approval (Date: 17/03/2022; Number: 2022-71). It complied with the Helsinki Declaration's ethical criteria for human testing (2013).

Study protocol

Demographic, clinical, CT images, and follow-up information were gathered from the cardiac intervention department's registry. Before the procedure, valve anatomy was evaluated. Current routines include TEE and multislice CT angiography for evaluation of the femoral entrance, measurement of the aortic ring (ring diameter, calcification pattern, distance to coronaries), and assessment of coronaries. Selective coronary or iliofemoral angiography and aortograms were carried out if necessary. In the catheterization chamber, interventional cardiologists and an anesthesiologist performed procedures. Prosthetic valves were implanted with rapid pacing. Process success was defined as the absence of embolization and mortality during the procedure, and moderate-severe paravalvular aortic regurgitation (AR) after valve implantation. The duration of an intensive care unit (ICU) stay was defined as the time between admission to the ICU and the discharge. Clinical follow-up was performed for 30 days.

Anesthetic management

Endotracheal intubation was used for GA, with the most dominant regimen being a titrated continuous infusion of remifentanil and propofol. The anesthetic protocol was altered to allow for rapid extubation after the procedure's completion. This was carried out on the operating table. There was no protocol-defined instruction for employing TEE in either group. The results of periprocedural TAVR were evaluated using angiographic, hemodynamic, and, in certain cases, echocardiographic assessments of valves.

The interventionist used local anesthesia. Anesthesiologists used a continuous infusion of dexmedetomidine, propofol, or other nonbenzodiazepine drugs to cause light to moderate sedation and keep the patient breathing on their own without using an airway device. All patients were given supplemental oxygen via a face mask to maintain arterial oxygen saturation at 90% (10). To assess spontaneous ventilation, capnography was utilized. The continual administration of remifentanil was avoided.

Statistics

IBM SPSS software (version 24.0, IBM, Armonk, New York) was used for the analysis (version 24.0). The mean standard deviation or median is utilized to represent initial continuous variables (interquartile range). The Kolmogorov-Smirnov and Shapiro-Wilk tests were utilized to determine the normality of the variable distribution. Frequencies and percentages were utilized to represent categorical variables. The chi-squared or Fisher's exact test was employed for categorical variables. The Student's t-test, or Mann-Whitney U-test was used to evaluate continuous variables. Statistical significance was stated at 0.05 for all tests.

RESULTS

115 patients were included, of whom 53 received GA (46.1%) and 62 (53.9%) LAS. 59 female (51.3%) and 62 male (48.7%) patients with a mean age of 83.2±5.7 participated in the study (Table 1). Although no significant differences were observed in the risk measured by STS, the GA group presented greater symptom severity based on the New York Heart Association Classification (p>0.05). There were no statistically substantial differences among the groups, including atrial AF, CAD, hypertension, PVD, diabetes, COPD, and CRF (p>0.05). Ventricular function was comparable in all groups; however, there was a larger mean gradient detected by TEE in the GA group (p=0.03). TEE usage was high overall (92.8%), without substantial variations across groups (LAS 88.7% vs. GA 96.2%, p =0.38).

Table 1: Clinical characteristics of the patients

PARAMETERS	Total (*n*=115)	General anesthesia (*n*=53)	Local anesthesia (*n*=62)	P-value
Age, years	83.2±5.7	82.9±5.2	83.5±6.1	0.54
Sex, female, n (%)	59 (51.3)	26 (49.1)	33 (53.2)	0.73
STS	7±4.1	6.44±3.8	7.5±4.3	0.13
NYHA 3-4, n (%)	70 (60.9)	37 (69.8)	32 (51.6)	0.68
AF, n (%)	30 (26.1)	13 (24.5)	17 (27.4)	0.84
CAD, n (%)	15 (13.1)	5 (9.4)	10 (16.1)	0.34
Hypertension, n (%)	32 (27.8)	12 (22.6)	20 (32.3)	0.14
PVD, n (%)	23 (20)	10 (18.9)	13 (20.9)	0.87
Diabetes, n (%)	20 (17.4)	6 (11.3)	14 (22.6)	0.11
COPD, n (%)	28 (24.3)	9 (16.9)	19 (30.6)	0.09
CRF, n (%)	20 (17.4)	8 (15.1)	12 (19.4)	0.72
TEE, n (%)	106 (92.8)	51 (96.2)	53 (88.7)	0.38
LVEF, %	55.9±12	56.4±12.1	55.8±12.1	0.64
Valvular area, cm^2	0.62±0.16	0.59±0.13	0.63±0.18	0.14
Mean gradient, mmHg	46.5±13.5	49.2±12.8	44.2±13.8	0.03
Peak systolic velocity, m/s	4.2±0.61	4.3±0.63	4.1±0.57	0.13

STS: Society of thoracic surgeons, NYHA: NewYork Heart Association, AF: Atrial fibrillation, CAD: Coronary artery disease, PVD: Peripheral vascular disease, COPD: Chronic obstructive pulmonary disease, CRF: Chronic renal failure, TEE: Transesophageal echocardiography, LVEF: left ventricular ejection fraction.

A successful TAVR procedure was performed in 100 (86.9%) of 115 patients with the transfemoral approach (Table 2). The success rate of the device was comparable in both groups (GA 84.9% vs. LAS 88.7%, p =0.83). In 15 patients, mortality (5), valve embolization (2), and post-implantation moderate-to-severe paravalvular AR (8) were evaluated as unsuccessful implantation (11). The rates of moderate-to-severe paravalvular aortic regurgitation (AR) quantified by TEE (performed post-implantation) were comparable in both groups (GA 11.3% vs. LAS 13.3%, p =0.73). Post-dilatation was performed in 10 (8.7%) patients. The mean procedure time was 136.7±46.7 minutes, and the procedure time was shorter in patients who underwent LA compared to GA (p=0.001). There were no differences among the groups in fluoroscopy time, contrast, or radiation dose (p>0.05). Two patients (3.2%) converted to GA because of an aortic dissection that required prompt surgical treatment. There was no substantial variance across the groups in hospital readmission (including sepsis, acute renal failure, and pulmonary edema), ischemic stroke/TIA, or pacemaker implantation that developed within 30 days (p>0.05). Overall 30-day mortality was 5.2%, with no significant differences among the groups (GA 7.5% vs. LAS 3.2%, p =0.28). GA had substantially longer ICU and total hospitalization stays than LAS (p=0.009 and p =0.004, respectively).

Table-2 Procedural results and safety and efficacy outcomes according to the VARC-2 classification at 30 days

	Total (*n*=115)	**General anesthesia** (*n*=53)	**Local anesthesia** (*n*=62)	**P-value**
Procedural results				
Devices success, n (%)	100 (86.9)	45 (84.9)	55 (88.7)	0.83
Fluoroscopy time, min	32 (24.6-40)	30.7 (22.1-43.7)	32 (25.2-38.1)	0.61
Contrast, (ml)	100 (52.5-192.5)	125 (60-200)	100 (50-150)	0.88
Radiation dose, Gy	1092 (658-2336)	1291 (715-1738)	1058 (6128.5-1357)	0.24
Rotation to GA, n (%)	2 (1.7)	—	2 (3.2)	NS
Device embolization, n (%)	2 (1.7)	2 (3.7)	—	NS
Moderate-severe paravalvular AR, n (%)	8 (7)	5 (9.4)	3 (4.8)	0.36
Post dilatation, n (%)	10 (8.7)	4 (7.5)	6 (9.7)	0.71
Aortic dissection, n (%)	7 (6.1)	5 (9.4)	2 (3.2)	0.12
Clinical results at 30 days				
In-hospital mortality, n (%)	5 (4.3)	3 (5.6)	2 (3.2)	0.41
All-cause mortality, n (%)	6 (5.2)	4 (7.5)	2 (3.2)	0.28
AMI, n (%)	1 (0.8)	1 (1.8)	—	0.27
Ischemic stroke/TIA, n (%)	7 (6.1)	3 (5.6)	4 (6.5)	0.71
Complete A-V block, n (%)	15 (13)	5 (9.4)	10 (16.1)	0.54
Pacemaker implantation, n (%)	10 (8.7)	7 (13.2)	3 (4.8)	0.32
Readmission, n (%)	19 (16.5)	8 (15.1)	12 (17.7)	0.78
Key times during the hospital stay				
Procedure time, min	136.7±46.7	155.6±56.6	123.9±32.8	0.001
Length of stay in the ICU, days	3 (1-3)	3 (2-4)	2 (1-3)	0.009
Total hospitalization time, days	5 (3-8)	6 (4-8)	4 (3-6.5)	0.004

GA: General anesthesia, AMI: Acute myocardial infarcts, ICU: Intensive care unit.

DISCUSSION

In TF-TAVR, the administration of LAS by a versed anesthesiologist appears to be safer and more effective than GA. We've noticed that LAS necessitates less overall procedure time, as well as lesser ICU days and complete hospital days. Additionally, safety and efficacy outcomes at 30 days showed no statistically significant differences.

The TAVR protocol was initiated via GA with orotracheal intubation, surgical access was conducted, and TEE was performed in every patient to control the intervention. This methodology lasted until 2019, when we had completed 28.1% of all interventions. Since then, the institution's increased experience, the development of valve devices, and the adoption of percutaneous closure devices have all gradually changed our work system in favor of a minimalist one.

In our sample, we did not notice any statistically substantial variations in 30-day death rates, and articles with extended follow-up intervals revealed comparable results (12,13). Nonetheless, a few authors discovered an increased short-term death rate in the GA group (14,15). Due to the design of these investigations, the baseline disparities among the two groups, and the frequent application of GA in nations like the United States, it is possible that these disparities are the result of biased selection (16). In our study, the severity of symptoms was higher in the GA group. Despite the fact that the surgical risk measured by STS has remained consistent, we decided to employ GA for individuals with breathing problems who cannot tolerate decubitus throughout the process. For these explanations, we deem it inappropriate to assert that GA alone causes a rise in TAVR mortality until we have access to higher-quality data. Even a recently published study did not find any variations over 30 days for this result (17).

The application of TEE for guiding the procedure is one of the benefits of GA in TAVR (18). It is reasonable to assume that this improves implant accuracy and prevents valve malfunction.

In this regard, it has been stated that LAS is related to a greater likelihood of AR that is moderate or severe. Some authors have linked this to the decreased application of TEE, but the causes are not entirely clear (19). In our sample, individuals with GA had a higher TEE utilization rate. We did not, however, detect any statistically substantial variations in the incidence of more severe AR. Considering our method, 87.6% of the procedures were directed by TEE, and utilization of this technique was prevalent in the LAS group (80.3%), as was the case in other studies with comparable findings (20). Conversely, in the FRANCE-2 registry, the LAS group had a greater incidence of AR, and this group utilized TEE at a rate of just 16 percent (21). It is essential to note that, even though the application of TEE has been a protective factor against the development of AR, other variables may influence the findings (22). In a similar vein, some researchers discovered substantial variations in the requirement for permanent pacemaker implantation in favor of individuals receiving GA, whereas we did not observe any such differences in our experience (23).

A fundamentally important piece of information is the reduction in procedure duration in the LAS group, coinciding with other reports (24,25). This has a substantial impact on the operational planning of the catheterization room, which makes it possible to optimize human, material, and time resources.

On the other hand, we observed a significant reduction in the length of stay in the ICU and total hospitalization in individuals in the LAS group. It is common knowledge that long-term hospitalization is associated with many complications, the majority of which are unrelated to the admission issue (26). In elderly patients, bed rest accelerates the loss of muscle mass, decreases plasma volume and ventilation, and favors a rise in the incidence of complications such as falls from one's own height, delirium, and hospital-acquired infections (27,28,29). In TAVR, the rate of delirium is estimated to be between 21% and 56%, and those who develop it have more days of hospitalization, a higher death rate, and an elevated referral incidence to rehabilitation facilities (61%) (30). We consider early mobilization of patients, if feasible within the initial twelve hours, and early discharge with attentive aftercare to be of the utmost importance for these reasons.

In the end, the rate of conversion to general anesthesia was

3.1% in every instance, owing to significant vascular complications throughout the procedure. The real rate ranges from 2.2% to 16.7%, with cardiac arrhythmias, hypotension, and cardiac arrest (37.5%), vascular complications (16.1%), individual anxiety (7.1%), respiratory complications (16.1%), conversion of the procedure to a surgical route (16.1%), and laryngeal trauma due to TEE (7.1%) being the most common causes (31). In our cases, vascular complications such as pseudoaneurysms, ileo-femoral rupture or dissection, arterial stenosis, and thrombosis were not observed since the femoral access was performed under ultrasound guidance.

In accordance with these findings, we believe that the appropriate planning of the procedure, the selection of a work system that is tailored to each patient, and the experience of every center are of the utmost importance. As a component of the minimalist strategy, some researchers argue that the procedure should be performed without an anesthesiologist in the chamber (32). Even though TAVR complications are becoming less frequent, they have the potential to be catastrophic, in our opinion (33). From the perspective of the safety of patients, we believe collaboration is indispensable in order to be able to respond swiftly and effectively to problems.

Our study has significant limitations that merit mention. Due to their observational character, findings may be susceptible to biases and confounders regarding variables that weren't tracked in our database. Another factor of crucial significance is that there is a chronological separation across the two approaches, and we cannot exclude the possibility that some of the observed differences, especially regarding the times assessed may be, attributable to our institution's greater operational development. Lastly, it should be pointed out that in our work system, GA remains the method of choice for individuals who cannot tolerate decubitus properly throughout the procedure, which unavoidably produces a bias in the selection that could explain the tendency toward the application of LAS stated in the combined result.

CONCLUSİON

In our study, TAVR via the transfemoral route using LAS was an alternative to GA. The total procedure time and recovery time were shorter in the LAS group. LAS could be safely applied and should be considered the recommended approach.

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Ethıcal Declerations

The Dicle University Ethics Committee granted ethical approval (Date: 17/03/2022; Number: 2022-71). It complied with the Helsinki Declaration's ethical criteria for human testing (2013).

Conflict of Interest Statement:

The authors have no conflicts of interest to declare.

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Author Contributions:

Conceptualization; Serhat GÜNLÜ (SG), Tuncay GÜZEL (TG), Adem AKTAN (AA), Fethullah KAYAN (FK), Muhammed Raşit TANIRCAN (MRT), Mehmet Zülkif KARAHAN (MZK); Data curation; SG, AA, MZK, MRT; Formal analysis; SG, FK, AA; Funding acquisition; SG, AA, TG, MZK; Investigation; SG, FK, TG; Methodology; SG, FK, AA; Project administration; SG, AA, FK; Resources; SG, MZK; Software; SG, MZK; Supervision; SG, MZK; Validation; SG, AA; Visualization; SG, FK; Roles/Writing - original draft; SG, FK, AA, MZK; Writing - review & editing; SG, MZK, TG, MRT.

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