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Research Article

Primary Report of Anesthesia Methods and Comorbidities in Patients Undergoing Transcatheter Aortic Valve Implementation (TAVI): An Observational Study

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ABSTRACT

Background: Transcatheter aortic valve implantation (TAVI) stands for a significant advancement in the treatment of patients suffering from aortic valve stenosis (AS). TAVI offers a significantly less invasive approach for aortic valve replacement compared to traditional thoracic surgery. Nonetheless, the anesthesiology component of TAVI remains underexplored. Consequently, our objective in this paper has been to explore this matter.

Methods: This trial is a unicenter observational study involving 32 patients undergoing TAVI with two methods of anesthesia, including general anesthesia and sedation. The study was conducted at Imam Hossein Hospital. The primary goal was to compare anesthesia methods regarding cardiac arrest and mortality, stroke, and thromboembolic events.

Results: This study included a total of 32 patients. 84.4% of the patients were male, while 15.6% were female. The average age of the patients participating in this study was 80.06±6.0 years. The most common comorbidities included hypertension, ischemic heart disease, diabetes, and hyperlipidemia, with prevalence rates of 62.5%, 56.3%, 46.9%, and 46.9%, respectively. 78.1% of patients underwent TAVI solely due to AS, whereas 21.9% underwent TAVI for AS together with other cardiovascular diseases. Nearly half of the patients, 46.9%, underwent general anesthesia, and 53.1% received sedation. 12.5% of patients experienced side effects following the procedure, which included atrial fibrillation rhythm, left bundle branch block, atheroembolism, and cardiac arrest. The occurrence of cardiac arrest was recorded at 3.1%.

Conclusion: This key report illustrates the safety of TAVI along with various anesthesia techniques, such as general anesthesia and sedation. General anesthesia was associated with more side effects than sedation. Nonetheless, further research is essential to establish the causal relationships between variables, side effects, and mortality.

Introduction

Aortic valve stenosis (AS) is a progressive condition impacting over 3% of the elderly population aged 65 and older [1]. The definitive approach for this AS continues to be aortic valve replacement [2]. Given that individuals with AS are predominantly elderly, particularly those over 65, thoracic surgery entails significant complexities and unavoidable complications. Furthermore, the presence of conditions like diabetes mellitus (DM) complicates the management of AS significantly [3]. For many years, the surgical approach to aortic valve replacement has been recognized as the leading method for effectively treating AS. However, certain patients are not presented with this

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invasive option because of the significant risk of complications that may arise during or following the procedure [4]. Furthermore, there is currently no medical intervention available to stop or reduce the progression of AS. Conversely, neglecting treatment for cardiovascular diseases can worsen cardiovascular health and also affect other organs, including the brain, kidneys, and eyes [5]. Consequently, thoracic surgery for AS, despite its inherent risks, might become an essential plan of action. In light of these limitations and challenges, transcatheter aortic valve implantation (TAVI) emerged as a minimally invasive approach, representing a significant advancement in the treatment of AS.

However, TAVI remains a procedure that requires anesthesia and is considered invasive. Given that TAVI is a relatively new approach, there is limited evidence regarding the safety and challenges associated with anesthesia for TAVI. General anesthesia and sedation are the main methods used for TAVI. However, there is still controversy over which one is safer. Although at first look, it may seem sedation should be safer, however, current evidence has not been able to finalize this discussion [6-7]. This study seeks to enhance the understanding of TAVI and its associated anesthesia practices.

Methods

This study was a prospective, observational, and unicenter cohort study conducted at Imam Hossein Hospital, affiliated with Shahid Beheshti University of Medical Sciences. This research focused on exploring different anesthesia techniques, including general anesthesia and sedation, for patients undergoing TAVI procedures. Patients underwent standard treatment in accordance with the most recent protocols. The research was entirely observational, with no additional interventions implemented in the management of the patients, encompassing both surgical and anesthetic approaches. All patients eligible for TAVI who provided informed consent were included in the study. The sole criterion for exclusion was the patient's refusal to participate in the study. The research received approval from the ethics committees at Shahid Beheshti University of Medical Science (ethical code: IR.SBMU.RETECH.REC.1402.496). Our research aligns with the foundational principles outlined in the Helsinki Declaration. Consent was obtained from the patients involved in the study. Throughout this investigation, the approach to patient management remained consistent, and there was no alteration in the cost associated with their health care.

Variables

The anesthesiologist in charge of the patient carried out the data recording. Consequently, the patient was observed closely from the onset of anesthesia. The research was conducted without any financial support. The preoperative data were gathered using a standardized questionnaire that was meticulously designed. The variables in this study encompass age, gender, past medical history, past surgical history, habits, indication for TAVI, method of anesthesia, routes of access in TAVI, the necessity for blood products, duration of anesthesia, and complications related to anesthesia until the patient is discharged from the hospital. The period of anesthesia was characterized as the interval from the initiation of patient monitoring to the moment of extubation.

Statistical analysis

Statistical analysis was conducted using IBM SPSS Statistics version 27. The data were evaluated in terms of frequency, percentages, mean, and standard deviation.

Results

Patients and comorbidities

The study included a total of 32 patients. The average age of patients was 80.6 ± 6.0 years. The oldest participant in the study was 91 years of age, while the youngest was 65 years old. 84.4% of patients were male, while 15.6% were female. 18.8% of patients were either addicted or smokers. The most common disorders in patients' medical histories were hypertension (HTN), ischemic heart disease (IHD), DM, and hyperlipidemia (HLP), with prevalences of 62.5%, 56.3%, 46.9%, and 46.9%, respectively (Figure 1). Other comorbidities were chronic kidney disease (CKD) or end-stage renal disease (ESRD), stroke, cancer, and pulmonary diseases with prevalences of 18.8%, 12.5%, 12.5%, and 9.4%, respectively.

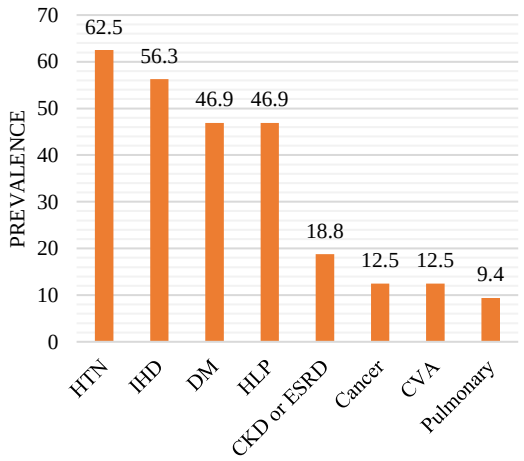

Figure 1- This chart summarizes the prevalence of various diseases in the past medical history of patients.

96.9% of patients had a history of prior surgery or invasive procedures. 9.4% of the included patients had previously had coronary artery bypass grafting (CABG). 9.4% of patients had a permanent pacemaker, whereas 3.1% had a temporary pacemaker.

Procedure of TAVI

This study includes right-sided transfemoral and left-sided transfemoral access methods. In 84.1% of patients, the right femoral artery was used. In 12.5% of patients, the left femoral artery was used. Severe AS alone was the predominant factor, with a prevalence of 78.1%, which rendered patients eligible for TAVI. In the other patients, additional cardiovascular conditions such as mitral valve stenosis, decompensated heart failure, and the presence of a pacemaker were included alongside AS as criteria for TAVI. 46.9% of patients received general anesthesia, while the remaining 53.1% underwent sedation. The length of anesthesia for the general anesthetic group was 156 minutes, while for the sedation group, it was 122.65 minutes. The average duration of anesthesia in this study was 138.28±54.91 minutes. The duration of hospitalization following anesthesia was 5.06±2.57 days.

Short-term outcomes and side effects

A total of 18.7% of patients required transfusion during TAVI. The remaining 81.3% of patients did not receive transfusions or any other blood-derived products during the procedure. Among 18.7% of patients who needed blood transfusions, 12.5% was attributed to the sedation group, and 6.2% was attributed to general anesthesia (Figure 2). 12.5% of patients experienced complications such as AF rhythm, atheroembolism, and left bundle branch block (LBBB), with each occurring at an incidence of 3.1%. A cardiac arrest event occurred in an 85-year-old man undergoing general anesthesia, with an incidence rate of 3.1%. Three-quarters of the side effects were linked to patients who underwent general anesthesia, while one-quarter were associated with those who received sedation.

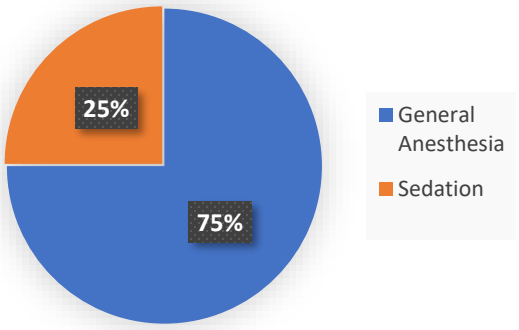

Figure 2- Percentage of cardiac arrest based on anesthesia method.

Discussion

In conclusion, our findings indicate that TAVI and the necessary anesthesia methodologies are both safe and effective, with minimal side effects (summarized in Table 1). The average age of participants was 80.06 years, with a predominant male representation at 84.4%. The incidence of cardiac arrest was recorded at a low rate of 3.1%. 9.4% of other complications included atrial fibrillation, LBBB, and atheroembolism, which were managed successfully without permanent sequelae. Nearly half of the patients, 46.9%, underwent general anesthesia, while the remaining 53.1% received sedation. In the group receiving general anesthesia, 75% of side effects, including cardiac arrest, were reported (Figure 3).

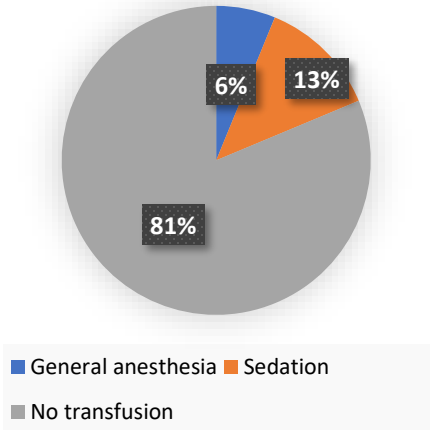

Figure 3- Blood transfusion based on anesthesia method.

The achievement of this low incidence of side effects coincided with a mean patient age of approximately 80 years. This finding could advance research on older patients who cannot undergo thoracic surgery. In the past medical history of patients, we also identified a high prevalence of hypertension (HTN), ischemic heart disease, DM, hyperlipidemia (HLP), cancer, pulmonary diseases, and stroke.

TAVI is primarily indicated for patients with AS [3]. In our investigation, severe AS was the primary criterion for the selection of all patients involved in our research. Approximately 78% of patients presented with only severe AS, while the remaining individuals exhibited additional indications concurrently. Some of these indications include mitral valve stenosis, decompensated heart failure, and the presence of a pacemaker that was added to AS concurrently. According to earlier research, the femoral artery serves as the primary access pathway for initiating TAVI [8]. The access route for the initiation of the procedure in this study was primarily through the femoral artery. In the context of femoral arteries, the left femoral artery was selected in 84.1% of cases.

Table 1- The summary of the study

Variable		Frequency	Percent
Gender	Man	27	84.4
	Woman	5	15.6
Smoker or addict	No	26	81.3
	Yes	6	18.8
Previous surgery or intervention	no	1	3.1
	yes	31	96.9
History of CABG	no	29	90.6
	yes	3	9.4
History of PCI	no	21	65.6
	yes	11	34.4
Access site for TAVI	left femoral	4	12.5
	right femoral	27	84.4
	Others	1	3.1
Type of anesthesia	General	15	46.9
	Sedation	16	50.0
Side effects	AF rhythm	1	3.1
	Atheroambolism	1	3.1
	CPR	1	3.1
	LBBB	1	3.1

A study conducted by Thiele et al. demonstrated that there is no significant difference between general anesthesia and sedation in terms of the success rate and safety of TAVI [6]. In a different investigation carried out by Butala et al., sedation was favored over general anesthesia in terms of mortality rate [7]. A further investigation by Human et al. demonstrated the advantages of sedation, which correlated with reduced hospital stay duration and a decreased mortality rate [9]. As previously noted, patients in our study undergoing general anesthesia experienced a greater occurrence of side effects alongside an extended duration of anesthesia. Moreover, the sedation group had more need for blood transfusion compared to the other group, who went under general anesthesia. The likelihood of increased side effects may be attributed to the extended duration of anesthesia during general procedures. Future research on this topic may be beneficial. In theory, general anesthesia is associated with more adverse effects, and local anesthesia is considered a better replacement for it [10-11]. However, such a claim needs more studies to provide strong evidence.

This study revealed a significant prevalence of comorbidities, with HTN, ischemic heart disease, DM, hyperlipidemia, chronic kidney disease or end-stage renal disease, cancer, and pulmonary diseases being the most common. This raises a concern for two reasons. Initially, the presence of comorbidities influences the choice between TAVI and thoracic surgery [12]. A study conducted by Gard et al. demonstrated that comorbidities influence the functional improvement of patients following the TAVI procedure. Notably, their research indicated that chronic kidney disease and pulmonary disorders are linked with lesser improvement following TAVI [13]. An investigation by Feldman et al. demonstrated that the presence of comorbidities can elevate the likelihood of rehospitalization and mortality within 30 days following TAVI. Consequently, upcoming research regarding the impact of comorbidities on TAVI results and their relationship with anesthesia techniques will yield valuable insights for future clinical applications [14].

Secondly, the significant prevalence of comorbidities highlights the necessity for preventive measures before the onset of AS and for preventing the advancement of comorbidities in individuals with AS. It is widely recognized that DM heightens the risk of AS and also speeds up the advancement of AS [15]. HTN plays a significant role and is identified as a comorbidity in over half of the patients in our study. HTN is an established risk factor for AS. Consequently, implementing preventive strategies to alleviate the impact of HTN could assist in diminishing the burden of AS. Furthermore, high blood pressure can worsen heart remodeling and increase mortality rates in individuals with AS [16]. Chronic kidney disease was another prevalent disease identified in our research. Chronic kidney disease is a recognized risk factor for AS and its advancement. Chronic kidney disease worsens the outlook for AS and heightens the risk of death in these individuals [17]. A significant portion of the burden of chronic kidney disease in patients with AS may be attributed to DM and HTN. DM presents various complications, including nephropathy and cardiovascular diseases. Thus, an integrated approach to managing these complications via common signaling pathways could enhance our ability to regulate the onset and advancement of comorbidities more effectively than previously possible [5, 17]. This approach should not be delayed until the beginning of diabetes. Recent progress has shown that higher levels of glucose within the normal range and prediabetes are associated with increased risk of cardiovascular and neurovascular diseases [18-20]. When diabetes begins, more diseases such as valvular diseases, atherosclerotic diseases, and cardiomyopathy increase [21-22]. After that, the psychological burden of diabetes begins to rise [23]. Therefore, it is very important to start early prevention to reduce the future burden of DM complications.

Our study had some limitations. The research was conducted at a single center and featured a brief follow-up period that concluded at the time of hospital discharge. Furthermore, this was an observational study that restricts our capacity to establish causations in the data gathered throughout the study. A further constraint of our study was the limited patient population, which could influence the reported adverse events. Consequently, we avoided trying to establish a direct causality between the side effects and other variables. Since this was a purely observational study, we did not do randomization. This study will facilitate the recognition of side effects and

challenges associated with TAVI and the anesthesia tailored for this procedure.

Conclusion

This investigation revealed a minimal incidence of mortality and adverse effects among patients undergoing TAVI. These outcomes were obtained with a mean patient age of approximately 80 years, and the majority of patients presented with comorbidities that could influence the prognosis of both AS and TAVI. Furthermore, it was discovered that sedation correlates with a lower occurrence of side effects in patients undergoing TAVI. Consequently, it is recommended that future studies involving a larger population be conducted to explore the relationship between anesthesia techniques and their associated side effects.

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