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Characterization of Transcatheter Aortic Valve Replacement (TAVR) in Adults Undergoing Intervention Over Eight Years

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Abstract

Introduction: *Aortic stenosis is the most common valve disease in the adult population. Many of the patients with this pathology are not candidates for surgical replacement of the aortic valve. Transcatheter aortic valve replacement (TAVR) is considered a less invasive treatment for patients with high surgical risk aortic stenosis.*

Method: *We carried out a retrospection based on the analysis of the clinical records of the CEDIMAT patients treated in the period from January 2015 to December 2022. To extract the information, we used a 14-itemquestionnaire including the EUROSCORE II; we evaluated echocardiographic and functional class changes before and after the procedure.*

Results: *With a sample of 11 patients, the study revealed echocardiographic changes in the valve area from0.7 ± 0.1 cm2 to 1.8 ± 0.4 cm2, mean gradient of 49.3 ± 9.3 mmHg at 6 .41 ± 2.19 mmHg, maximum velocity of4.1 ± 0.4 m/s to 1.7 ± 0.3 m/s, and ejection fraction of 59.6 ± 7.1% to 60.9 ± 5.1%. Pre-procedure, 54.5% of the patients studied were found to be in functional class II, 36.4% in functional class III, and 9.1% in functional class IV. After performing the procedure, the patients became asymptomatic or with mild symptoms, with90.9% in functional class I and 9.1% in functional class II.*

Discussion: *After the procedure, the patients significantly reduced their symptoms, with a great improvement in their echocardiographic findings and few post-procedure complications.*

Introduction

Aortic stenosis is a progressive disease that affects the aortic valve by narrowing its opening and causing obstruction of the left ventricular outflow. It is currently the most common valvular disease in elderly patients. This chronic condition has an insidious onset and is characterized by the presence of mild fibro calcifications in the valve, known as aortic sclerosis, which rapidly progresses to severe calcification, causing significant obstruction to the ejection of the left ventricle. Symptoms such as fatigue, exertional dyspnea, chest pain, syncope, and heart failure develop after decades of an asymptomatic period. The rapid progression following the onset of symptoms results in a disease with over 90% mortality in untreated patients [1].

Surgical aortic valve replacement (SAVR) reduces symptoms and significantly improves survival in patients with aortic stenosis, and in the absence of comorbidities, the procedure is associated with low operative mortality. However, at least 30% of patients with aortic stenosis cannot undergo surgical intervention due to advanced age, comorbidities, ventricular dysfunction, previous cardiac surgery, among others. For these high-risk surgical patients, a less invasive treatment is a valuable alternative [2].

Transcatheter Aortic Valve Replacement (TAVR or TAVI) has become the primary therapy for these patients. TAVR is an interventional cardiology procedure in which a bioprosthetic valve is inserted through a catheter via the femoral artery (transfemoral) or left ventricular apex (transapical) and implanted within the damaged valve [3]. The procedure was first performed in 2002 and has since experienced rapid growth in its use as a non-invasive treatment for severe aortic stenosis in high-risk surgical patients [2].

A prevalence and distribution study conducted in 2018 in the global population aged 60 years or older estimated that 3.2 million people suffer from severe aortic stenosis, with 1.9 million eligible for SAVR. Among patients eligible for TAVR, over 485,000 are high-risk or inoperable patients aged 75 years or older;152,000 are intermediate-risk surgical patients aged 75 years or older, and approximately 378,000 patients are low-risk surgical patients aged 65 years or older [4-7]. Due to the high prevalence of the disease and limitations of some patients for standard therapy or surgical aortic valve replacement (SAVR), TAVR is of great importance as a standard treatment in this condition. The purpose of this research is to characterize transcatheter aortic valve replacement in adults who underwent the procedure at the Center for Advanced Medicine and Telemedicine (CEDIMAT) in Santo Domingo, Dominican Republic, during the period of January 2015 to June 2022.

Materials and Methods

Context

Aortic stenosis is a valvulopathy characterized by significant obstruction to the ejection of the left ventricle of the heart caused by calcification of the aortic valve. The diagnosis and treatment of this condition are of utmost importance since, after the onset of symptoms, it results in a disease with a mortality rate of over90% in untreated patients. This research aims to determine the incidence of aortic stenosis, sociodemographic variables, and TAVR interventions performed on patients treated at the Center for Advanced Diagnosis and Telemedicine (CEDIMAT). This information was obtained from the medical records of patients in the database during the period January 2015 to June 2022.

Work Modalities

This research is of evaluative nature, as according to our objectives, it focuses on a detailed description of the procedure, considering risk factors and comorbidities in order to support why it is chosen over others.

Type of Study

This research project is an observational, descriptive, cross-sectional study with retrospective data collection. The characteristics observed are described without intervening or manipulating the variables.

Data Collection Instruments

The data collection for this research consisted of indirect observation through an analysis of records in the CEDIMAT database. The interpretation was conducted using the clinical records of patients who underwent Transcatheter Aortic Valve Replacement (TAVR). In order to extract relevant information from the records of patients who underwent the procedure at CEDIMAT, a questionnaire with 14 questions was administered. This questionnaire gathered the variables of interest for the study, including patient factors (age, comorbidities, life expectancy, etc.), procedural factors (anticipated perioperative risk, anatomy), and other relevant data.

Ethical Considerations

This research project required the approval of the ethics committee of the Universidad Iberoamericana (UNIBE) and the ethics committee of the Centro de DiagnósticoMedicinaAvanzada y Telemedicina(CEDIMAT). With the approval of both committees, the research proceeded. If the approvals were not obtained, the realization of this project would be immediately canceled. Protecting the integrity and privacy of patients is paramount. The approval of both committees ensures that the work were being carried out according to the necessary ethical criteria.

Population Selection and Sample

The population was composed of 13 patients attended and treated at the CEDIMAT center, who had been diagnosed with aortic stenosis and were candidates for Transcatheter Aortic Valve Replacement (TAVR) from January 2015 to December 2022. The sample used consisted of 11 patients (margin of error: 8%, CI: 90%) treated at CEDIMAT from January to June 2022. Non-probabilistic sampling was conducted. Inclusion criteria: Patients treated at the Center for Advanced Diagnosis and Telemedicine (CEDIMAT), patients over 18 years old, patients diagnosed with aortic stenosis, patients eligible for transcatheter aortic valve replacement (TAVR). Exclusion criteria: Patients with incomplete medical records (40) and patients who opted for a non-invasive procedure other than TAVR.

Procedures for Data Processing and Analysis

After collecting data through the medical records of patients undergoing TAVR at CEDIMAT center, a database was created. To gather and organize all the data obtained from the variables to be considered in the inclusion criteria, we used the Microsoft Excel Office 365 program. The next step was to code and analyze this information by performing statistical tests such as mean, median, mode, standard deviation, frequency, and percentages. Finally, this database was processed for analysis and description using the JASP and Excel programs. The purpose was to tabulate the results through graphs and tables in order to establish relationships between the variables and compare the obtained data, leading to the results and conclusions.

Results

The study population consisted of 11 elderly individuals with a mean age of 82.3 years (±2.8). The age distribution revealed that 9.10% (1) of the participants were between 69-74 years old, 27.30% (3) fell into the 75-80 age range, 45.50% (5) were aged 81-86, and 18.20% (2) were in the 87-92 age bracket. In terms of gender, 36.40% (4) of the participants were female, while 63.60% (7) were male. The primary etiology of the patients' conditions was degenerative by calcification, accounting for 81.80% (9) of the cases, whereas bicuspid aortic valve accounted for 18.20% (2) of the cases. The severity of aortic stenosis was classified as severe in all 11 participants. Among the comorbidities observed, hypertension was the most prevalent, affecting 90.90% (10) of the participants. Other comorbidities included diabetes mellitus II (36.40% - 4 individuals), coronary artery disease (36.30% - 4 individuals), dyslipidemia (27.30% - 3 individuals), asthma (18.20% - 2 individuals), heart failure (18.20% - 2 individuals), paroxysmal atrial fibrillation (9.10% - 1 individual), acute pulmonary edema (9.10% - 1 individual), and sudden cardiac death (9.10% - 1 individual). The participants' functional status, as assessed by NYHA classification, revealed a mean value of 2.5 (±0.3). Among the participants, 54.5% (6) were classified as NYHA class II, 36.4% (4) as NYHA class III, and 9.1% (1) as NYHA class IV (Table 1).

Description of sociodemographic factors, severity, and functional class of aortic stenosis in patients undergoing transcatheter aortic valve replacement (TAVR) at CEDIMAT during the period January 2015 - December 2022.

n=11	Frequency, mean ± SD or No. (%)
Clínic	
Age	82.3 ± 2.8
69-74 (1)	9.10%
75-80 (3)	27.30%
81-86 (5)	45.50%
87-92 (2)	18.20%
Sex (n=11)	
Feminine (4)	36.40%
Masculine (7)	63.60%
Etiology (n=11)	
Degenerative by calcification (9)	81.80%
Bicuspid aortic valve (2)	18.20%
Aortic Stenosis Severity (n=11)	
Mild (0)	
Moderate (0)	
Severe (11)	100%
Comorbidities	
Hypertension (10)	90.90%
Diabetes mellitus II (4)	36.40%
Coronary artery disease (4)	36.30%
Dyslipidemia (3)	27.30%
Asthma (2)	18.20%
Heart failure (2)	18.20%
Paroxistic atrial fibrillation (1)	9.10%
Acute pulmonary edema (1)	9.10%
Sudden cardiac death (1)	9.10%
NYHA classification (n=11)	2.5 ± 0.3
II (6)	54.5% (6)
III (4)	36.4% (4)
IV (1)	9.1% (1)

Among the 11 individuals included in the study, the Core Valve Evolut 26 was the most commonly used valve type, accounting for 63.60% of the cases. The Core Valve Evolut 29 and Core Valve Evolut 34 were used in 18.20% of the cases each. Regarding the access routes, femoral access was employed in all cases, representing 100% of the participants. These findings highlight the predominant usage of the Core Valve Evolut 26 and the exclusive use of the femoral access route in this cohort (Table 2).

Type of valve and access route used in patients undergoing transcatheter aortic valve replacement (TAVR) at CEDIMAT during the period January 2015 - December 2022.

	Frequency (n=11)	Percentage (%)
Valve Type		
Core Valve Evolut 26	7	63.60%
Core Valve Evolut 29	2	18.20%
Core Valve Evolut 34	2	18.20%
Access route		
Femoral	11	100%

The most frequent immediate complication was atrial fibrillation, which occurred in 3 individuals, representing 27.30% of the sample. Cardiac arrest and pleural effusion each occurred in 1 individual, accounting for 9.10% of the cases. Atrioventricular block was observed in 2 participants, constituting 18.20% of the sample. Persistent arterial hypertension and premature ven-

tricular contractions were each reported in 1 individual, representing 9.10% of the cases. Notably, 6 participants (54.50%) did not experience any immediate complications. These findings provide valuable insights into the distribution and prevalence of immediate complications within the studied population (Table 3).

Immediate post-procedure complications in patients undergoing transcatheter aortic valve replacement (TAVR) at CEDIMAT during the period January 2015 - December 2022.

Immediate Complications	Frequency (n=11)	Percentage (%)
Atrial Fibrillation	3	27.30%
Cardiac Arrest	1	9.10%
Pleural effusion	1	9.10%
Atrioventricular block	2	18.20%
Persistent arterial hypertension	1	9.10%
Premature ventricular contractions	1	9.10%
None	6	54.50%
Total	11	100

The data indicates a diverse range of complications within 1 year, with each complication accounting for 9.10% of the total frequency. These complications include vasovagal syncope, atrial flutter, mild exertional dyspnea, heart failure, and pericarditis, each presenting in a single participant. Notably, the majority of participants (72.70%) did not experience any complications within the specified timeframe. This data provides valuable insights into the prevalence and distribution of complications, highlighting the need for further investigation and potential interventions in the management of these conditions (Table 4).

Complications within one-year post-procedure in patients undergoing transcatheter aortic valve replacement (TAVR) at CEDIMAT during the period January 2015 - December 2022

Complications within 1 year	Frequency (n=11)	Percentage (%)
Vasovagal syncope	1	9.10%
Atrial flutter	1	9.10%
Mild exertional dyspnea	1	9.10%
Heart failure	1	9.10%
Pericarditis	1	9.10%
None	8	72.70%
Total	11	100

The mean Euro score II was found to be 2.79 ± 0.87, indicating an overall moderate risk profile for the cohort. When examining the distribution of Euro score II categories, 36.40% of participants fell into the low risk category (Euro score II 5). These findings provide insight into the risk stratification of the study population and serve as a foundation for further analysis and interpretation of outcomes (Table 5).

Euro SCORE II for surgical risk in patients undergoing transcatheter aortic valve replacement (TAVR) at CEDIMAT during the period January 2015 - December 2022.

Euro score II	Frequency (n=11)	Mean ± SD or percentage (%)
		2.79 ± 0.87
Low <2	4	36.40%
Moderate 2-5	5	45.40%
High >5	2	18.20%
Total	11	100%

The results of the study revealed significant improvements in echocardiographic findings following the procedure. Prior to the intervention, the mean aortic valve area was measured at 0.7 ± 0.1 cm2, accompanied by a mean gradient of 49.3 ± 9.3 mmHg, a maximal velocity of 4.3 ± 0.4 m/s, and an ejection fraction of 59.6 ± 7.1%. However, post-procedure assessments demonstrated substantial enhancement in cardiac function, as evidenced by an increase in the aortic valve area to 1.8 ± 0.4 cm2, a remarkable reduction in the mean gradient to 6.4 ± 2.2 mmHg, a significant decrease in maximal velocity to 1.7 ± 0.3 m/s, and a nearly unchanged ejection fraction of 60.9 ± 5.1%. These findings indicate a successful outcome of the procedure, highlighting its effectiveness in improving the measured parameters of aortic valve function (Table 6).

Pre-and post-procedure echocardiographic findings in patients undergoing transcatheter aortic valve replacement (TAVR) at CEDIMAT during the period January 2015 - December 2022

	Mean± SD
Pre-procedure echocardiographic findings	
Aortic Valve Area (cm2)	0.7 ± 0.1
Mean gradient (mmHg)	49.3 ± 9.3
Maximal velocity (m/s)	4.3 ± 0.4
Ejection fraction (%)	59.6 ± 7.1
Post-procedure echocardiographic findings	
Aortic Valve Area (cm2)	1.8 ± 0.4
Mean gradient (mmHg)	6.4 ± 2.2
Maximal velocity (m/s)	1.7 ± 0.3
Ejection fraction (%)	60.9 ± 5.1

Discussion

In the present research study, a population consisting of 13 patients was analyzed, from which a sample of 11 patients was obtained by applying our inclusion and exclusion criteria during the period from January 2015 to December 2022. The total sample was retrospectively obtained from the patients' medical records, with 2 patients excluded based on exclusion criteria due to incomplete data in the medical records.

In our research regarding sociodemographic factors (Table 1), the predominant sex in our study was male, accounting for 63.6% of the participants. These results are consistent with the TAVR report by STS-ACC TVT in 2020, where 55.8% of the patients were male [8]. The most represented age range in our study was between 81-86 years, accounting for 45.5% of the participants, with a mean age of 82.3 ± 2.8 years. This corroborates with the NOTION trial, where the mean age was 79.1 ± 4.8 years [9].

The etiology of valvular disease in the studied patients was degenerative due to calcification in 81.8% of cases and bicuspid aortic valve disease in 18.2% of cases, classified as severe stenosis in 100% of patients according to echocardiographic findings. This is consistent with an article in the RevistaMédica de Clínica las Condes in 2012, which states that degenerative aortic stenosis caused by calcification is "the most common valve pathology in the population over 65 years, with an incidence of 2-7%" [10].

The comorbidities presented in the studied sample are shown in Table 1 and include systemic arterial hypertension, which was the most common comorbidity at 90.9%, followed by type II diabetes mellitus at 36.4%, coronary artery disease at 36.3%, dyslipidemia at 27.3%, asthma and heart failure at 18.2%, and paroxysmal atrial fibrillation, acute pulmonary edema, and sudden death at 9.1%. In contrast to a study conducted at the University of Rosario in 2020, we agree that arterial hypertension is the most common comorbidity in these patients, while the other pathologies vary. It is important to note that the other listed comorbidities are dependent on the sociodemographic factors of the selected patient sample in each study and are not dependent on the underlying pathology, aortic stenosis [11].

The functional cardiac class according to NYHA classification was assessed based on the pre-procedural clinical presentation of each patient. In our study, 54.5% of the patients were in functional class II, followed by 36.4% in class III, and 9.1% in class IV. These results coincide with a publication in the Open-Heart journal in 2018, where a sample of 809 patients showed that NYHA functional class III pre-procedure represented 59.8%, followed by NYHA class II with 26.6% and NYHA class IV with 9.9%. Thus, NYHA class III is the most common in patients undergoing TAVR [12].

Among the 11 patients who underwent the replacement procedure in our research, the femoral access route was used in 100% of the patients, as shown in Table 2. This is consistent with a meta-analysis published in 2018 by Ho and Argáez, which reviewed 16 reports and showed that the health status significantly improved in high or intermediate surgical risk patients undergoing TAVR, but only through the transfemoral approach, which produced better immediate post-procedure results compared to transapical aortic valve replacement (TAVR) [4].

Similarly, we see how Table 2 indicates that in the entire population, the "Core Valve Evolut" model was used, differing only in size. The results show that the "Core Valve Evolut 26" prosthesis was used in 63.3% of patients, "Core Valve Evolut 29" in 18.2%, and "Core Valve Evolut 34" in 18.2%. It is important to note that the choice of valve size was based on the diameter of the aortic valve ring (mm) or its perimeter. These results align with international guidelines, as highlighted in an article from the journal "Cardiac Interventions Today" in 2019, which emphasizes that the best evidence and TAVR outcomes have been achieved using Medtronic's CoreValveEvolut valves and Edwards Lifesciences' Sapien valves [13].

Table 3 presents the immediate post-procedure complications experienced by patients, including atrial fibrillation in 27.3%, cardiac arrest in 9.1%, pleural effusion in 9.1%, atrioventricular block in 18.2%, persistent hypertension and ventricular extrasystoles each in 9.1%, and no complications in 54.5% of the cases. These findings are similar to those reported in a study published in the Colombian Journal of Cardiology in 2019, which states

that the new generation of bioprostheses (CoreValveEvolut PRO) is associated with very low mortality rates and a decreased incidence of paravalvular regurgitation and other complications when compared to surgical outcomes [14].

After reviewing the medical records of patients up to one-year post-procedure, we compiled the complications presented, as shown in Table 4. These included vasovagal syncope, atrial flutter, dyspnea on mild exertion, decompensated heart failure, and pericarditis, each representing 9.1% of the cases, while 72.7% of the patients did not experience any complications. These results are consistent with the Colombian Journal of Cardiology, which, in 2019, mentioned that multiple comparative evaluations have been conducted between valve types, showing positive results, including mortality rates. This confirms that no procedure-related deaths were reported among the patients operated on between January 2015 and December 2022. The article also notes a higher frequency of paravalvular leakage and advanced atrioventricular blocks in self-expanding valves, as well as a higher number of inserted pacemakers. These findings align with the immediate and one-year complications reported after the procedure [14].

The purpose of this project is to recognize and study the characteristics of transcatheter aortic valve replacement procedures in patients undergoing intervention at CEDIMAT between January 2015 and December 2022. One of the objectives is to analyze and calculate the surgical risk of these patients using the Euro Score II scale. Table 5 shows a mean Euro Score II of 2.79 ± 0.87%, where 36.4% of the sample had low surgical risk, 45.4% had moderate risk, and 18.2% had high surgical risk. This information is referenced from an article by the Spanish Society of Cardiology, which cites the Evolut Low Risk trial involving auto expandable valves from Medtronic (CoreValve, Evolut R, or Evolut PRO). The article states that these valves have demonstrated comparable results, indicating that TAVR is at least as effective and safe as surgical aortic valve replacement (SAVR) in patients with low surgical risk for severe aortic stenosis [14].

To assess the pre- and post-procedure valve changes shown in Table 6, we considered the aortic valve area, mean gradient, peak velocity, and ejection fraction. We compared these parameters with the severity of aortic stenosis and observed a decrease in valve area and an increase in mean gradient and peak velocity. The pre-procedure aortic valve area for the patients in our sample was 0.7 ± 0.1 cm2, with a post-procedure change to 1.8 ± 0.4 cm2, indicating a significant increase in valve area. The mean gradient pre-procedure was 49.3 ± 9.3 mmHg, which significantly decreased to 6.41 ± 2.19 mmHg post-procedure. The peak velocity also decreased from 4.1 ± 0.4 m/s pre-procedure to 1.7 ± 0.3 m/s post-procedure. Lastly, in terms of echocardiographic variables, the ejection fraction slightly increased from 59.6 ± 7.1% pre-procedure to 60.9 ± 5.1% post-procedure. It is worth noting that all values were measured up to one year after the procedure. These values closely align with the cardiac findings from the PARTNER trial, where the aortic valve area increased from 0.6 ± 0.2 cm2 to 1.5 ± 0.5 cm2, and the mean gradient decreased from 44.5 ± 15.7 mmHg to 11.1 ± 6.9 mmHg [2].

The NYHA functional class was evaluated post-procedure to assess patients' improvement and clinical relevance. We observed that 90.9% of the patients were asymptomatic in NYHA functional class I, and only 9.1% had mild symptoms in class II. This is a significant clinical improvement compared to the preprocedure functional classes, where 54.4% were in class II, 36.4% in class III, and 9.1% in class IV. This similarity to the study conducted by Leon et al. [2] in the PARTNER trial demonstrates that all patients were symptomatic in NYHA classes II, III, or IV pre-procedure, but after TAVR, they became asymptomatic or had mild symptoms (NYHA class I or II) ($p<0.001$).

Conclusions

In this research study, we analyzed a population of 13 patients, from which a sample of 11 patients was obtained, meeting our predefined inclusion and exclusion criteria. The retrospective data collection spanned from January 2015 to December 2022, with two patients excluded due to incomplete medical records. Our findings regarding sociodemographic factors revealed a predominance of males, consistent with previous studies on transcatheter aortic valve replacement (TAVR). The most represented age range was 81-86 years, aligning with similar studies that reported the mean age of TAVR patients. The etiology of valvular disease in our study predominantly consisted of degenerative calcification and bicuspid aortic valve disease, both classified as severe stenosis based on echocardiographic findings. Regarding comorbidities, systemic arterial hypertension was the most prevalent, followed by type II diabetes mellitus, coronary artery disease, dyslipidemia, asthma, heart failure, paroxysmal atrial fibrillation, acute pulmonary edema, and sudden death. Assessment of the functional cardiac class using the NYHA classification revealed that the majority of patients fell into class II, followed by class III and class IV.

The results indicate that the choice of valve size, primarily determined by the diameter of the aortic valve ring or its perimeter, aligns with international guidelines endorsing the use of Medtronic's CoreValveEvolut valves and Edwards Lifesciences' Sapien valves. Immediate post-procedure complications were consistent with previous studies, with atrial fibrillation, atrioventricular block, and pleural effusion among the observed complications. Complications observed up to one-year post-procedure included vasovagal syncope, atrial flutter, dyspnea on mild exertion, decompensated heart failure, and pericarditis. Assessing the surgical risk using the Euro Score II scale revealed that a significant portion of the patients had moderate surgical risk, while a smaller percentage had low or high surgical risk. Regarding pre- and post-procedure valve changes, a significant increase in valve area and improvement in echocardiographic parameters such as mean gradient, peak velocity, and ejection fraction were observed. Assessment of the NYHA functional class revealed a substantial clinical improvement post-procedure, with the majority of patients becoming asymptomatic or experiencing mild symptoms.

Disclosures

Human subjects: Consent was obtained or waived by all participants in this study. Universidad Iberoamericana (UNIBE) issued approval IRB00012142. Animal subjects: All authors have confirmed that this study did not involve animal subjects or tissue. Conflicts of interest: In compliance with the ICMJE uniform disclosure form, all authors declare the following: Payment/services info: All authors have declared that no financial support was received from any organization for the submitted work. Financial relationships: All authors have declared that they have no financial relationships at present or within the previous three years with any organizations that might have an interest in the submitted work. Other relationships: All authors have declared that there are no other relationships or activities that could appear to have influenced the submitted work.

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