ACTAS MÉDICAS (ECUADOR) ORIGINAL ARTICLE
actasmedicas.ec

Internal Medicine

Analysis of the evolution of surgical treatment versus transcatheter aortic valve implantation in patients with severe aortic valve stenosis. A single-center observational study.

Eliezer Arellano Rojas [1] ID *, Eduardo Barrio Nuñez [2] ID, Armando Bucheli [2] ID, Jaqueline Quisanga [1] ID

1. Cardiology Service, Hospital Alcívar, Guayaquil, Ecuador.
2. Hemodynamics Service, Hospital Alcívar, Guayaquil, Ecuador.

Abstract

Introduction: Aortic valve replacement surgery (AVRS) has significantly reduced mortality in patients with severe aortic valve stenosis (SAVS). Transcatheter aortic valve implantation (TAVI) is a new alternative. The study hypothesis is that patients undergoing TAVI have fewer complications and shorter hospital stays than those undergoing AVRS.

Methods: The present observational study was conducted at the Alcívar Hospital in Guayaquil, Ecuador, retrospectively reviewing the period 2017 to 2020 of patients with SAVS. Variables were sex, age, NYHA functional class, comorbidities, complications, mortality, and days of hospitalization. The sample was nonprobabilistic. Inferential statistics were used.

Results: Twelve cases with TAVI and 30 with CRV were analyzed. There were no demographic or clinical differences before treatment. Complications were higher in AVRS group 3 (25%) versus 21 (70%) in TAVI (P<0.001). Mortality was the same between both groups. The hospital stay was longer in the AVRS group (10.7 days) than in the TAVI group (6.33 days) (*P*<0.01).

Conclusions: The patients who underwent TAVI had a shorter hospital stay, fewer nonfatal complications, and the same mortality as those who underwent AVRS.

Keywords:

MeSH: Transcatheter Aortic Valve Replacement, Aortic Valve Stenosis, Heart Disease

Abbreviations

AVRS: aortic valve replacement surgery
SAVS: severe aortic valve stenosis.
TAVI: Transcatheter aortic valve implantation.

Supplementary information

No supplementary materials are declared.

Acknowledgments

Not declared.

Author contributions

Eliezer Arellano Rojas: Conceptualization, data curation, formal analysis, fundraising, research, writing - original draft.
Eduardo Barrio Nuñez: Conceptualization, data curation, formal analysis. Armando Bucheli: Acquisition of funds, research, methodology, resources, supervision.
Jaqueline Quisanga: Validation, Visualization, Writing – original draft, Writing – review and editing.

All the authors have read and approved the final version of the manuscript.

Financing

The authors of this article financed the costs of this research. The procedures and surgeries performed are part of the regular activity of the hemodynamics and surgery services, so they did not constitute an additional cost to the patients.

Availability of data and materials

Not declared.

Introduction

Aortic stenosis causes a progressive decrease in the area of the aortic valve, which causes a restriction in the outflow of left ventricular blood flow into the aorta [1-3]. The most common causes are degenerative, rheumatic, and congenital valve disease. 5% of adults older than 65 have degenerative aortic stenosis, and 11% have severe aortic valve stenosis (SAVS) [4]. SAVS is established when the aortic valve orifice is less than one cm^2, and the mean transvalvular aortic gradient is more significant than 40 mm Hg.

Patients with SAVS are initially asymptomatic; however, in the evolution, they present dyspnea, angina, and syncope, which produces a deterioration in the quality of life and an increase in mortality. The risk of sudden death in asymptomatic patients is 1% per year, while in symptomatic patients, this risk increases to 3% at six months [5, 6].

Aortic valve replacement surgery has significantly reduced mortality in these patients. In patients with a contraindication or high risk for aortic valve replacement surgery, transcatheter aortic valve implantation is a safe and effective alternative [2].

Transcatheter aortic valve implantation (TAVI) has played an increasingly relevant role in the care of patients with aortic stenosis who, due to their age or the difficulties they present, have an unacceptably high anesthetic risk for undergoing sternotomy and extracorporeal circulation therapy [5].

The objective of the present study was to describe the clinical characteristics of a group of patients with SAVS treated surgically and with TAVI in a local reference center in Guayaquil-Ecuador, establishing the hypothesis that patients undergoing TAVI have fewer complications and less hospitalization time.

Materials and methods

Study design

The present study is cross-sectional. The source is retrospective.

Scenery

The study was carried out in the cardiothoracic surgery and hemodynamics department of the Alcívar Hospital in Guayaquil, Ecuador. The study period was from January 1, 2017, to December 31, 2021.

Participants

Patients of legal age diagnosed with SAVS and who required valve replacement were included. Cases with incomplete data were removed for analysis.

Variables

The variables were sex, age, mortality, assessment of the NYHA functional scale, presence of type 2 diabetes mellitus, arterial hypertension, cerebrovascular event, renal failure, smoking, alcohol consumption, presence of atrial fibrillation, presence of atrioventricular block, presence of hypovolemic shock, pneumothorax, hemothorax, delirium, sepsis, pleural effusion, and length of hospital stay.

Data sources/measurements

The source was indirect; An electronic form was filled out from the data of the institutional clinical history of the patients who entered the hospitalization period. A review of the registry of the hemodynamics and cardiothoracic surgery unit was performed to recruit cases. The information was treated confidentially; Personal data that would allow the identification of the study subjects was not included.

Biases

To avoid possible interviewer, information, and memory biases, the principal investigator always kept the data with a guide and records approved in the research protocol. Observation and selection bias was avoided by applying the participant selection criteria. Two researchers independently analyzed each record in duplicate, and the variables were recorded in the database once their concordance was verified.

Study size

The sample was nonprobabilistic, of the census type, where all possible cases of the study period were included.

Quantitative variables

Descriptive and inferential statistics were used. The results are expressed on a scale of means and standard deviation. Categorical data are presented in proportions.

Statistic analysis

Inferential statistics compare the groups of open surgery versus percutaneous intervention. Among the scaled variables, the averages are reached through the student's t-statistical test. Among the categorical variables, the proportions are compared with Chi-Square. The P value taken as statistically significant was less than 0.05. The statistical package used was SPSS 26.0 (IBM Corp. Released

2019. IBM SPSS Statistics for Windows, Version 26.0. Armonk, NY: IBM Corp).

Results

Participants

The study included 42 patients with SAVS. 12 cases were treated with TAVI, and 30 were treated with conventional surgery.

Group characteristics

There was no sex difference between both groups (Table 1). There was no difference in age classification between the groups. The largest group that intervened in both types of treatment was the group older than 60 years to 70 years of age. In both groups, heart failure, according to the NYHA classification, was functional class III.

Table 1. Descriptive variables of the groups.

		TAVI n=12	Conventional surgery n=30	*P*
Sex	Women	6 (50%)	10 (33.3%)	0.314
Age (years)	>60-70	7 (58.3%)	18 (60%)	0.345
	>71-80	1 (8.3%)	7 (23.3%)	
	>80	1 (33.3%	5 (16.7%)	
NYHA	Class III	7 (58.3%)	22 (73.3%)	0.342
	Class IV	5 (41.7%)	8 (26.7%)	
Comorbidities	Diabetes	4 (33.3%)	8 (26.7%)	0.665
	AHT	11 (91.7%)	24 (80.0%)	0.359
	CVD	1 (8.3%)	1 (3.3%)	0.491
	CKD	0 (0%)	7 (23.3%)	0.066
	Smoking	1 (8.3%)	5 (16.7%)	0.485
	Alcohol	1 (8.3%)	1 (3.3%)	0.491
	AF	2 (16.7%)	6 (20.0%)	0.803
	AVB	1 (8.3%)	0 (0%)	0.109

NYHA: New York Heart Association clinical classification of heart failure. HTA: arterial hypertension. CVD: cerebrovascular event. CKD: Chronic kidney disease. AF: atrial fibrillation. AVB: complete atrioventricular block.

Within the comorbidities before treatment, there was no difference in distribution between the groups concerning arterial hypertension, diabetes, and cerebrovascular events. Although there were seven more cases of patients with chronic kidney disease in the conventional surgery group, there was no significant difference (Table 1).

Therapeutic results

There was no significant difference between the complications presented individually between each group; however, the total sum of nonfatal complications was higher in the conventional surgery group compared with TAVI 3 (25%) versus 21 (70%) ($P < 0.001$) (Table 2). Mortality was the same between both groups. There was a longer hospitalization time in the conventional surgery group; 43% of the patients remained hospitalized for more than 13 days in the traditional group of surgery ($P < 0.01$) (Table 2). Hospital stay was longer in the conventional surgery group, with a mean of 10.7 days compared to 6.33 in the TAVI group.

Table 2. Therapeutic results between the groups.

		TAVI n=12	Conventional surgery n=30	*P*
complications	Hypovolemic shock	0 (0%)	1 (3.3%)	0.522
	Pneumothorax	0 (0%)	3 (9.9%)	0.255
	Hemothorax	0 (0%)	1 (3.3%)	0.522
	Delirium	3 (25%)	7 (23.3%)	0.908
	Sepsis	0 (0%)	3 (9.9%)	0.255
	Pleural effusion	0 (0%)	6 (20.0%)	0.094
	Total complications	3 (25%)	21 (70.0%)	<0.001
	Mortality	2 (16.7%)	4 (13.3%)	0.78
HS	1 – 12 days	12 (100%)	17 (56.7%)	<0.01
	13 – 30 days	0 (0%)	13 (43.3%)	

HE: hospital stay .

Discussion

The study's results accept the hypothesis that patients undergoing TAVI have fewer complications and shorter hospital stays.

The essential results of the present study, which included 42 patients with SAVS, are defined in that there were no differences between the populations in demographic or clinical data before undergoing TAVI versus conventional surgery for aortic valve replacement. In the therapeutic results, the group that underwent TAVI in no case was hospitalized longer than 12 days, while in 43.3% of patients who underwent conventional surgery, it was ($P<0.01$). There was no difference in mortality between the two groups; however, there were more nonfatal complications in the conventional surgery group (70%) than in the TAVI group (25%) ($P<001$). In several

aspects, the results were similar to those reported in the literature; the average age in our study was 76 years. Worldwide, the presentation of this pathology is more frequent in men, and likewise, it was found in this study in 61.9% of the cases [6].

The main symptom in the study was precordial pain, manifested by 63% of patients and associated with congestive heart failure, which in the literature is reported in up to 50% of patients, followed by syncope and collapse in 37% [6].

The survival rate in multiple studies is 50% at five years in symptomatic patients with angina, which decreases to 20% in 2 years if heart failure develops [4]. This suggests that most patients are diagnosed in very advanced stages of the disease, considering the higher prevalence of congestive symptoms at diagnosis.

Among the comorbidities, arterial hypertension was the most frequent (85.7%) found in 36 patients, followed by type 2 diabetes mellitus at 30.9% and less frequently: smoking at 14.2%, and chronic kidney disease at 19%.

The general mortality in this study was 14.2%, the same for both groups. Cardiac arrhythmia occurred 30% more frequently in patients undergoing conventional surgery. The most frequent arrhythmias were atrial fibrillation and AV block. According to the literature, the rates of vascular complications, pacemaker implantation, and paravalvular regurgitation are significantly higher with TAVI. At the same time, the incidence of major bleeding, acute renal failure, and de novo atrial fibrillation were more frequent with the conventional surgical approach [7-10].

This is a nonprobabilistic sample and, therefore, not comparable with results from other groups. Its purpose is to publicize the experience and profile of patients undergoing TAVI at Hospital Alcívar. However, it seems to be a group of patients, similar to other series. The complications presented are what is described in the literature. TAVI is an increasingly used technique in our environment, with specific considerations in the immediate postoperative period. New data will be presented as the number of cases increases.

The limitations of the study were the origin of the data, which are ICD10 diagnostic records of clinical histories, which have a greater risk of memory and information biases and the probability of missing data increases, as well as the noninclusion of relevant clinical information regarding the condition of the individual beyond the data recorded in the source of information.

The design allows the identification of the clinical and demographic characteristics of the patients with aortic valve replacement; it is a starting point for other studies for identifying risk associations with clinical and survival outcomes, including the variables described here in the patients.

The study's results allow knowledge of the demographic and clinical context of the patient treated at the Alcívar Hospital in Guayaquil. This makes it possible to establish the clinical context of the patient and determine risk associations for clinical or survival outcomes in subsequent studies.

Conclusions

In the present observational study of patients with SAVS, the patients who underwent TAVI had shorter hospital stays and fewer nonfatal complications but the same mortality as those who underwent conventional valve replacement surgery.

References

1. Ribera A, Slof J, Ferreira-González I, Serra V, García-Del Blanco B, Cascant P, et al. The impact of waiting for intervention on costs and effectiveness: the case of transcatheter aortic valve replacement. Eur J Health Econ. 2018 Sep;19(7):945-956. doi: 10.1007/s10198-017-0941-3. Epub 2017 Nov 23. PMID: 29170843.

2. Bernal E, Ariza-Solé A, Bayés-Genís A, Formiga F, Díez-Villanueva P, Romaguera R, et al. Management of Nonagenarian Patients With Severe Aortic Stenosis: The Role of Comorbidity. Heart Lung Circ. 2018 Feb;27(2):219-226. doi: 10.1016/j.hlc.2017.02.033. Epub 2017 Apr 12. PMID: 28473215.

3. Baumgartner H, Falk V, Bax JJ, De Bonis M, Hamm C, Holm PJ, et al; ESC Scientific Document Group. 2017 ESC/EACTS Guidelines for the management of valvular heart disease. Eur Heart J. 2017 Sep 21;38(36):2739-2791. doi: 10.1093/ eurheartj /ehx391 . PMID: 28886619.

4. Wang TKM, Wang MTM, Gamble GD, Webster M, Ruygrok PN. Performance of contemporary surgical risk scores for transcatheter aortic valve implantation: A meta-analysis. Int J Cardiol. 2017 Jun 1;236:350-355. doi: 10.1016/j.ijcard.2016.12.188. Epub 2017 Jan 16. PMID: 28111053.

5. Singh K, Carson K, Rashid MK, Jayasinghe R, AlQahtani A, Dick A, Glover C, Labinaz M. Transcatheter Aortic Valve Implantation in Intermediate Surgical Risk Patients With Severe Aortic Stenosis: A Systematic Review and Meta-Analysis. Heart Lung Circ.

2018 Feb;27(2):227-234. doi: 10.1016/j.hlc.2017.02.032. Epub 2017 Apr 12. PMID: 28473216.

6. Cayla G, Schmutz L, Soullier C, Ricci JE, Robert C, Cambon-Viala M, Goger AL, Lattuca B. Which patient will propose a TAVI in 2019? [Which patient for TAVI in 2019?]. Ann Cardiol Angeliol (Paris). 2019 Dec;68(6):405-409. French. doi: 10.1016/j.ancard.2019.10.002. Epub 2019 Oct 25. PMID: 31668846.

7. Möllmann H, Husser O, Blumenstein J, Liebetrau C, Dörr O, Kim WK, Nef H, Tesche C, Hamm CW, Elsässer A, Achenbach S, Gaede L. Lower mortality in an all-comers aortic stenosis population treated with TAVI in comparison to SAVR. Clin Res Cardiol. 2020 May;109(5):611-615. doi: 10.1007/s00392-019-01548-1. Epub 2019 Oct 1. PMID: 31573055.

8. Cepas-Guillén PL, Regueiro A, Sanmiguel Cervera D, Blanco Mata R, Francisco Oteo J, Amat-Santos I, et al. Prognosis of Nonagenarian Patients After Transcatheter Aortic Valve Implantation. REC Interv Cardiol.2021;66-22.

9. Azraai M, Gao L, Ajani AE. Cost-Effectiveness of Transcatheter Aortic Valve Intervention (TAVI) Compared to Surgical Aortic Valve Replacement (SAVR) in Low-to Intermediate-Surgical-Risk Patients. Cardiovasc Revasc Med. 2020 Sep;21(9):1164-1168. doi: 10.1016/j.carrev.2020.01.009. Epub 2020 Jan 15. PMID: 31980399.

10. Zhou J, Liew D, Duffy SJ, Walton A, Htun N, Stub D. Cost-effectiveness of transcatheter aortic valve implantation compared to surgical aortic valve replacement in the intermediate surgical risk population. Int J Cardiol. 2019 Nov 1;294:17-22. doi: 10.1016/j.ijcard.2019.06.057. Epub 2019 Jun 21. PMID: 31255453.

Statements

Ethics committee approval and consent to participate

The ethics committee of the Alcívar Hospital approved the study.

Publication Consent

Not required when patient-specific images, radiographs, and studies are not published.

Conflicts of interest

The authors declare they have no conflicts of interest.

Author Information

Eliezer Arellano Rojas, Physician - University of Los Andes (Mérida-Venezuela, 2002). PostGraduate: Specialist in Cardiology- Institute of Cardiovascular Research Hospital Universitario de Los Andes (Mérida-Venezuela, 2007)
Sub–Specialty: Master in Interventional Cardiology and Hemodynamics- Universidad Complutense de Madrid (Madrid-Spain, 2011).
Training in Hemodynamics and Interventional Cardiology at the Hospital Clínica San Carlos (Madrid-Spain, 2009-2011). Email: eliezerarellano24@hotmail.com
ORCID https://orcid.org/0009-0001-5490-7375

Eduardo Barrio Nuñez, Physician from the University of Guayaquil (Guayaquil, 2005). Medical specialist in hemodynamics, angiography, and interventional cardiology from the University of Buenos Aires (Buenos Aires, 2022).
Email: ebarriomd@gmail.com
ORCID https://orcid.org/0009-0003-6337-8641

Armando Bucheli, Coordinator of Hemodynamics at Hospital Alcívar.
ORCID https://orcid.org/0009-0009-4457-4632

Jaqueline Quinsaga, Level I postgraduate doctor in cardiology at Hospital Alcívar and the Universidad De Especialidades Espíritu Santo. Alcívar Hospital Cardiology Department.
ORCID https://orcid.org/0000-0002-1493-5291

Editor's Note

The Journal Actas Médicas (Ecuador) remains neutral regarding jurisdictional claims on published maps and institutional affiliations.

Received: February 12, 2023.
Accepted: March 29, 203.
Published: June 12, 2023.
Editor: Dra. Mayra Ordonez Martinez.

Cite:
Arellano E, Barrio E, Bucheli, Quinsaga J. Analysis of the evolution of surgical treatment versus transcatheter aortic valve implantation in patients with severe aortic valve stenosis. A single-center observational study. Actas Médicas (Ecuador) 2023;33(1):11-16.

Correspondence: Eliezer Arellano Rojas, Mail: eliezerarellano24@hotmail.com
Address: Colonel 2301 and Azuay. Department of Cardiology, Hospital Alcívar, Guayaquil, Ecuador. Telephone: (5934) 3720100