# Multicenter Experience of Transcatheter Aortic Valve Implantation Stratified by Risk in Latin American Centers

*Experiencia multicéntrica de implante valvular aórtico percutáneo discriminada por riesgo en centros de Latinoamérica*

GERARDO NAU[1], EZEQUIEL ZAIDEL[1], MARCELO ABUD[2], FERNANDO CURA[2], ENRIQUE RIVERO[3], EMER VITOR[4], DARÍO ECHEVERRI[5], CARLOS GIULIANI[1], MARCELO BETTINOTTI[1], MATÍAS SZTEJFMAN[1]; ON BEHALF OF THE TRYTOM RESEARCH TEAM

## ABSTRACT

**Background:** Transcatheter aortic valve implantation (TAVI) has been evaluated in different scenarios from the wide-spectrum of patients with severe symptomatic aortic stenosis. The choice of the type of treatment is based on risk assessment by a multidisciplinary heart team.

**Objective:** The aim of this study was to analyze the characteristics of patients undergoing TAVI in Latin America and to evaluate the outcomes of the intervention according to estimated risk.

**Methods:** Patients from the multicenter Latin American TAVI registry were consecutively included from March 2009 to December 2018. The indication of TAVI was made in each case by a local multidisciplinary team. The STS-PROM score was used to stratify risk in this population. Three groups were defined according to the established cutoff points of the STS-PROM: high risk (HR, > 8%), intermediate risk (IR, 4-8%) and low risk (LR, < 4%).

**Results:** A total of 770 patients were included in the analysis; mean age was 81 years (IQR 75.6-85.7) and 50.2% were women. Among these patients, 230 (29.8%) corresponded to the HR group (mean STS-PROM 11 [9.3-16.7]); 339 patients (44%) to the IR group (mean STS-PROM 6 [4.8-6.71]); and the remaining 201 (26.1%) were LR patients (mean STS-PROM 2.7 [2-3.24]). The proportion of low-risk patients considerably increased over the registry period (p trend 0.011). The femoral access was used in 95% of the cases and was percutaneous in 69%. Self-expanding valves were implanted in 80% of the patients. Twenty-three percent (n = 177) of the valves implanted corresponded to repositioning procedures without differences between groups. There were no differences in mortality at 30 days (HR 10.4%, IR 6.48%, LR 5.9%, p = 0.154). A reduction in mortality was observed in HR and LR patients (HR 13.7%-4.1%, p = 0.001; LR 11.7%-0%, p = 0.0023).

**Conclusions:** Risk stratification using surgical risk scores is still useful to guide therapeutic decisions; however, the indication of TAVI in the real world incorporates other factors not contemplated in the classical scoring system, which modify our decisions in daily practice.

**Keywords:** Aortic Valve Stenosis /Therapy - Heart Valve Prosthesis Implantation - Risk Assessment.

## RESUMEN

**Introducción:** El implante valvular aórtico percutáneo ha sido valorado en diferentes escenarios del amplio espectro de la población portadora de estenosis aórtica grave sintomática. La elección del tipo de tratamiento parte de una evaluación del riesgo de un equipo multidisciplinario.

**Objetivos:** El objetivo de este estudio fue analizar las características y conocer los resultados de los pacientes sometidos a IVAP en Latinoamérica según el riesgo.

**Material y métodos:** Se incluyeron a partir de marzo de 2009 a diciembre de 2018 pacientes en forma continua del registro multicéntrico latinoamericano de implante valvular aórtico percutáneo. La indicación de implante valvular aórtico percutáneo fue realizada en cada caso por un equipo multidisciplinario local. Se estratifica la población en función del riesgo quirúrgico evaluado por el puntaje STS-PROM. Se definieron tres grupos en función de los puntos de corte del STS-PROM establecidos: riesgo alto (RA, mayor del 8%), riesgo intermedio (RI, entre el 4% y el 8%) y riesgo bajo (RB, menor del 4%).

**Resultados:** Se incluyeron en el análisis 770 pacientes; la mitad era de sexo femenino (50,2%) con una mediana de edad de 81 años (RIC 75,6-85,7). Del total, 230 pacientes (29,8%) fueron incluidos en el grupo AR (STS-PROM medio 11 [9,3-16,7]); 339 pacientes (44%), al riesgo intermedio (STS-PROM medio 6 [4,8-6,71]); y los restantes 201 (26,1%), al bajo riesgo (STS-PROM medio 2,7 [2-3,24]). La proporción de pacientes de bajo riesgo se incrementó a lo largo del período del registro (ptrend 0,011). Se utilizó acceso

[1] Sanatorio Güemes, Finochietto
[2] Instituto Cardiovascular Buenos Aires
[3] Instituto do Coração do Hospital das Clínicas da FMUSP, Brasil
[4] Hospital Albert Einstein, Sao Paulo, Brasil
[5] Fundación Cardioinfantil Bogotá, Colombia

femoral (95%), y fue percutáneo en el 69% de los pacientes. Se implantaron en el 80% válvulas autoexpandibles. Del total de válvulas implantadas, el 23% (n = 177) resultaron ser reposicionables sin diferencias a través de los grupos. No se evidenciaron diferencias en mortalidad a los 30 días (RA 10,4%, RI 6,48%, RB 5,9%, p: 0,154) Tanto en el RA como en el de RB se observó una reducción de la mortalidad (RA 13,7%-4,1%, p: 0,001; RB 11,7%-0%; p: 0,0023).
**Conclusiones:** La estratificación de riesgo mediante puntajes quirúrgicos continúa representando una guía de gran utilidad, sin embargo, la indicación de implante valvular percutáneo en el mundo real incorpora otros factores no contemplados en la puntuación clásica, que modifica nuestras decisiones en la práctica diaria.

**Palabras clave:** Estenosis de la Válvula Aórtica/Tratamiento - Implantación de Prótesis de Válvulas Cardíacas - Medición de Riesgo

## Abbreviations

| | | | | |
|---|---|---|---|---|
| **AS** | Aortic stenosis | | **STS** | Society of Thoracic Surgeons |
| **TAVI** | Transcatheter aortic valve implantation | | | |

## INTRODUCTION

Over the past years, there has been increasing evidence on the indication of percutaneous aortic valve replacement. Initially, the procedure was indicated for inoperable high-risk patients [1, 2], but later it was extended to intermediate-risk groups [3-5] and, more recently, to low-risk populations. [6, 7]

Selecting the type of intervention [conventional aortic valve replacement or transcatheter aortic valve implantation (TAVI)] in subjects with symptoms attributed to aortic stenosis (AS) requires a thorough cardiovascular and systemic assessment, including concepts such as frailty, life expectancy and quality of life after the procedure. Therefore, it is essential to create multidisciplinary teams for the correct stratification of patients' risk and to choose the best type of approach in each case. [8, 9]

For many years, the Society of Thoracic Surgeons (STS) score has been used for risk stratification of candidates for aortic valve replacement. [10] This score was designed for cases of open-heart surgery and does not consider multiple variables present in patients with AS who are candidates for a therapeutic alternative as TAVI.

Based on the favorable outcomes reported by randomized trials, the European, American and Latin American guidelines recommend TAVI in high-risk patients and as an alternative to surgical aortic valve replacement in intermediate-risk patients, [8, 9, 11]. However, there is currently little information about the outcomes of TAVI in Latin America.

The aim of this study was to recognize the characteristics of patients undergoing TAVI in Latin America and to evaluate the outcomes of the intervention according to risk estimated by the STS score.

## METHODS

An analysis of the Latin American multicenter TAVI registry of patients with severe symptomatic AS undergoing consecutive TAVI in five centers was performed between March 2009 and December 2018.

Centers should have performed more than 100 procedures at the time of inclusion and meet the recommended requirements for a center specialized in valve diseases to be included in the registry. [9] The severity of AS was defined according to the recommendations of the European Society of Cardiology. [9]

The indication of TAVI was made in every case by a multidisciplinary team in each center which includes at least one clinical cardiologist, one interventional cardiologist, one cardiovascular surgeon and one specialist in cardiovascular imaging. This team evaluated preoperative risk using different risk scores and considering other variables that were not included in these scores. Patients with concomitant coronary artery disease were treated according to the preference of the multidisciplinary team. The registry included all the prosthetic valves implanted by center and period of implantation. Emergency procedures were defined as those performed on patients admitted with persistent heart failure and refractory to outpatient treatment that required immediate management during hospitalization.

The STS-PROM score was used to predict risk in this population. Three groups were defined according to the established cutoff points of the STS-PROM: high risk (HR, > 8%), intermediate risk (IR, 4-8%) and low risk (LR, < 4%).

Patients with bicuspid aortic valve and pure aortic regurgitation were excluded from the analysis.

All the patients received similar antithrombotic therapy (aspirin and clopidogrel before the procedure and for six months after the procedure, and unfractionated heparin during the procedure). The definition of events related to the procedure (bleeding, thrombosis, myocardial infarction, stroke and valve insufficiency) was based on the VARC-2 document. [12]

### Statistical analysis

Discrete variables were described as numbers and percentages and were compared using the chi-square test or Fisher's exact test, as applicable. Continuous variables were expressed as mean ± standard deviation (SD) or median and interquartile range (IQR) according to their distribution and were analyzed using Student's t test or the Mann–Whitney test, as applicable.

The chi-square test for trend was used to evaluate the correlation between the year of the procedure and the proportion of patients with low, intermediate or high risk. The analysis was performed using the Epi Info V7.2.0.1 software package. A p value < 0.05 was considered statistically significant.

### Ethical considerations

As it was a retrospective study, an informed consent was not required (Law 3301, CABA). In accordance with Argentine Law No. 25.326 on the protection of personal data, all information will remain confidential.

## RESULTS

A total of 770 patients were included in the analysis. Mean age was 81 years (IQR 75.6-85.7) and 50.2% were women. Two hundred and thirty patients (29.8%) corresponded to the HR group (mean STS-PROM 11 [9.3-16.7]); 339 patients (44%) to the IR group (mean STS-PROM 6 [4-8-6.71]); and the remaining 201 (26.1%) were LR patients (mean STS-PROM 2.7 [2-3.24]). Figure 1 shows that the proportion of low-risk patients significantly increased over the period of the registry (p trend 0.011).

Baseline patient characteristics are summarized in Table 1. High-risk patients had a higher proportion of comorbidities, more severe symptoms (NYHA functional class IV in HR: 33.9%; in IR: 15.9% and in LR: 5.4%, p = 0.001), and more commonly underwent emergency procedures. (HR: 26%; IR: 17.5%; and LR: 13%, p = 0.0004). Among echocardiographic characteristics, mean aortic gradient was lower in the HR group (HR: 43.08 mm Hg ± 14.4; IR 47.1 mm Hg ± 15.2; LR 47.8 mm Hg ± 16.4; p = 0.003) with similar aortic valve area (HR: 0.68 [0.57-0.80], IR: 0.70 [0.53-

**Fig. 1.** Proportion of patients undergoing TAVI by risk score and year



Year of procedure

Low STS (p trend = 0.011)

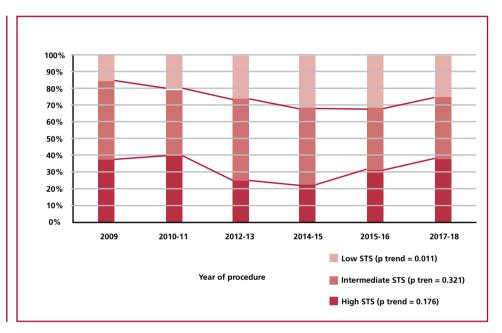Intermediate STS (p tren = 0.321)

High STS (p trend = 0.176)

**Table 1.** Baseline characteristics. HF: Heart failure. NYHA: New YorK Heart Association. LBBB: Left bundle branch block. AMI: Acute myocardial infarction. PCI: Percutaneous coronary intervention. COPD: Chronic obstructive pulmonary disease. LVEF: Left ventricular ejection fraction.

| | STS risk score | | | |
| | High | Intermediate | Low | p |
|---|---|---|---|---|
| Age (median (IQR) | 82 (79-86) | 82 (79-86) | 80 (75-83) | 0.03 |
| Hypertension (%) | 196 (85.2) | 290 (85.5) | 160 (79.6) | 0.12 |
| Current smoker (%) | 25 (11) | 78 (7) | 38 (19) | 0.001 |
| Dyslipidemia (%) | 147 (64) | 203 (60) | 112 (56) | 0.1 |
| Diabetes (%) | 75 (32.6) | 80 (23.5) | 46 (22.8) | 0.03 |
| History of cancer (%) | 35 (15.2) | 60 (17.6) | 21 (10.4) | 0.08 |
| Previous HF (%) | 156 (67.8) | 166 (48.9) | 84 (41.7) | 0.001 |
| NYHA class IV (%) | 78 (33.9) | 54 (15.9) | 11 (5.4) | 0.01 |
| Previous atrial fibrillation (%) | 49 (21.3) | 46 (13.8) | 31 (15.5) | 0.057 |
| Previous LBBB (%) | 27 (11.8) | 37 (11) | 23 (11.6) | 0.35 |
| Permanent pacemaker (%) | 32 (14) | 35 (10.3) | 12 (6) | 0.01 |
| Severe coronary artery disease (%) | 131 (56.9) | 166 (49) | 95 (47.2) | 0.09 |
| Previous AMI (%) | 50 (21.7) | 49 (14.5) | 22 (11) | 0.0072 |
| Previous PCI (%) | 77 (33.4) | 109 (32.1) | 51 (25.3) | 0.15 |
| Previous cardiac surgery (%) | 54 (23.4) | 37 (11) | 35 (17.4) | 0.006 |
| Stroke (%) | 7 (3) | 15 (4.4) | 7 (3.5) | 0.364 |
| COPD (%) | 69 (30) | 82 (24.1) | 32 (16) | 0.003 |
| Peripheral vascular disease (%) | 48 (20.8) | 76 (22.4) | 23 (11.4) | 0.005 |
| LVEF (%) | 50.5-14.4 | 56-12.1 | 58.5-11.1 | 0.001 |

0.80], LR: 0.70 [0.60-0.80], p = 0.08) and systolic pulmonary artery pressure (HR: 40 mm Hg [33-50], IR: 37 [30-49], LR: 43 [31-55], p = 0.42) to that of the other two groups.

The femoral access was used in most cases (95%). The procedure was performed under sedoanalgesia in 33.3% of the patients in the HR group, 40.6% in the IR group and 25.6% in the LR group; p = 0.03). The percutaneous access was used in 69% of the patients treated, with a trend toward greater use at lower risk (HR: 30.2%; IR: 34%; LR: 35.7%, p = 0.059). Echocardiography guidance was used in 60% of the procedures, particularly in the HR group (Table 2). The use of predilatation with valvuloplasty was significantly different between groups (HR: 47.3%; IR: 62.2%; LR; 63.6%, p = 0.0004). Self-expanding valves were implanted in 80% of the patients (n = 616) without significant differences between groups. Twenty-three percent (n = 177) of the valves implanted corresponded to repositioning procedures without differences between groups.

The rate of events at 30 days are described in Table 3. There was a trend toward lower in-hospital mortality across the risk groups (p = 0.053). A significant reduction in mortality was observed throughout the period of inclusion in the registry in the high-risk and low-risk groups (Figure 2).

## DISCUSSION

The analysis of a cohort of patients undergoing TAVI in Latin American centers revealed the following findings: a) there was a great diversity of risk since the beginning of the registry, based on the decision of a multidisciplinary team, with a trend toward a higher proportion of low risk patients and b) mortality decreased throughout the period of inclusion in the registry in high and low risk patients.

Over the past decade, the expansion of TAVI has changed patients' quality of life and outcome, as well as daily practice. Although surgical aortic valve replacement is still the treatment of choice in our region, (13) TAVI has found a fertile field of action in patients in whom standard treatment is limited due to advanced age, impaired functional capacity or presence of comorbidities.

The Euro Heart Survey and the experience of the University of Michigan corroborated a high percentage of patients with symptomatic AS who were not intervened mainly due to comorbidities (50%). However, half of these patients presented intermediate or low risk. (14, 15) This indicates that the heterogeneous selection of patients who are candidates for TAVI in the real world, as in our experience, considers multiple factors that exceed the calculated risk, and acknowledges that scores do not reflect the actual situation,

| | STS risk score | | | |
|---|---|---|---|---|
| | **High** | **Intermediate** | **Low** | **p** |
| Elective procedure (%) | 170 (74) | 280 (82.5) | 175 (87) | 0.0004 |
| TAVI with bioprosthesis (%) | 19 (8.26) | 9 (2.65) | 8 (3.98) | 0.006 |
| Transfemoral access (%) | 221 (96) | 315 (93) | 193 (96) | 0.166 |
| TEE guidance (%) | 144 (62.6) | 204 (60.1) | 116 (57.7) | 0.0027 |
| Predilatation with valvuloplasty (%) | 109 (47.3) | 211 (62.2) | 128 (63.6) | 0.0004 |
| Postimplantation valvuloplasty (%) | 72 (31.3) | 95 (28) | 53 (26.3) | 0.47 |
| Hemodynamic support (%) | 33 (14.3) | 52 (15.3) | 13 (6.46) | 0.0022 |

**Table 2.** Characteristics of the procedure



**Fig. 2.** 30-day mortality according to risk

**Table 3.** Outcomes at 30 days

| | STS risk score | | | |
| --- | --- | --- | --- | --- |
| | **High** | **Intermediate** | **Low** | **p** |
| Need for second valve (%) | 3 (1.3) | 12 (3.54) | 5 (2.49) | 0.256 |
| Cardiac tamponade (%) | 8 (3.48) | 18 (5.31) | 8 (3.98) | 0.54 |
| In-hospital coronary artery occlusion (%) | 1 (0.43) | 1 (0.29) | 1 (0.50) | 0.92 |
| Major vascular complications (%) | 17 (7.39) | 17 (5.01) | 6 (2.99) | 0.11 |
| Major bleeding (%) | 23 (10) | 41 (12.09) | 13 (6.47) | 0.108 |
| Disabling stroke (%) | 4 (1.74) | 4 (1.18) | 6 (2.99) | 0.314 |
| Need for new pacemaker (%) | 39 (17) | 62 (18.30) | 40 (20) | 0.749 |
| Moderate-severe aortic regurgitation | 13 (5.6) | 14 (4.1) | 10 (5) | 0.3 |
| postimplantation (%) | 2 (0.86) | 0 | 2 (1) | 0.053 |
| In-hospital mortality (%) | 22 (9.57) | 20 (5.92) | 8 (3.98) | 0.154 |
| 30-day mortality (%) | 24 (10.4) | 22 (6.48) | 12 (5.9) | |

and may lead to inaccurate therapeutic decisions for the patient. Nowadays, the therapeutic choice is based on multiple factors. Age, anatomy, risk for complications and durability, either individually or in combination, are key factors in the therapeutic decision and modify the parameters which guided surgical indication in previous decades.

The effectiveness of the endovascular technique has been evaluated and refined in recent years, with encouraging results across all risk categories. (1-7) Despite the different ways in which the population was included in randomized trials and in our registry, in which patients were not comparable in terms of surgical resolution, one of the main considerations in low-risk patients is life expectancy and valve durability. In our registry, minimum age was 75 years, which corresponds to a life expectancy of 7 years, with an incidence of reoperation of surgical biological valves of 3%-5%. (16, 17) This clinical endpoint underestimates the incidence of structural valve deterioration, a concept currently evaluated in the follow-up of TAVI patients to establish its durability. This index represents a small proportion (3.2%-7% at 7 years) in the endovascular group, and considers life expectancy of the treated patients and the higher risk of valve deterioration in this group. (18-20)

We should mention that our registry includes procedures since the TAVI program began in the region and encompasses a learning period of the technique both for the operators as for the postoperative care team. The STS/ACC TVT Registry, which included more than 40,000 patients, showed an inverse association between the number of cases and events. This association was most pronounced during the first 100 cases, indicating the effect of the learning curve. (21, 22) Similarly, Auffret et al. reported the experience in France with a reduction in mortality rate (10.1% vs. 5,4%; p = 0.001) throughout the national program. In addition to growing experience, technological changes and a minimalistic approach, one of the great changes was the type of population included in the program. (23) Our work reflects an increase in the inclusion of patients at lower risk, which contributes to a change

in outcomes and allows more patients to receive effective therapy resulting in better quality of life.

Among the limitations of the registry, we must mention the lack a unified classification of frailty, as well as non-conventional characteristics leading to therapeutic decisions. These shortcomings interfere with the full understanding of the individual patient. On the other hand, the centers included were arbitrarily chosen and their number was low, reflecting a partial reality of the region. However, we consider it a beginning in the understanding of regional data on such a prevalent disease and on a technique in continuous development worldwide.

## CONCLUSION

Risk stratification using preoperative scores is still useful to guide therapeutic decisions. However, the indication of TAVI in the real world incorporates other factors not contemplated in the classical scoring system, which modify our decisions in daily practice.

### Conflicts of interest
None declared.

(See authors' conflicts of interest forms on the website/Supplementary material)

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