

# In-hospital Outcomes of Surgical Aortic Valve Replacement: The Benchmark for Transcatheter Valve Implant

## *Resultados hospitalarios de la cirugía del reemplazo valvular aórtico: el punto de referencia para el implante valvular transcáteter*

RAÚL A. BORRACCI<sup>1</sup>, MIGUEL RUBIO<sup>1</sup>, JULIO BALDI (H)<sup>1</sup>, RODOLFO A. AHUAD GUERRERO<sup>2</sup>, VÍCTOR MAURO<sup>3</sup>, CARLOS A. INGINO<sup>4</sup>

### ABSTRACT

**Background:** The aim of this study was to analyze the current in-hospital outcomes of aortic valve replacement (AVR) surgery in order to serve as a benchmark for comparing the local results of transcatheter aortic valve implantation (TAVI).

**Methods:** We retrospectively analyzed the in-hospital outcomes of 422 patients undergoing isolated AVR between 2012 and 2017 in our institutions associated with the University of Buenos Aires.

**Results:** Overall in-hospital mortality was 3.6%, and 3.8% at 30 days, while the in-hospital and 30-day mortality rate of 71 patients older than 80 years was 4.2%. In the entire series, in-hospital mortality in the low-risk group (EuroSCORE II <4%) was 2.2%, and in the moderate risk group (EuroSCORE II between 4% and 7%) it was 5.0%.

**Conclusions:** This updated information on the local outcomes of AVR surgery stratified by risk could serve as a standard for comparing TAVI results.

**Key words:** Aortic Valve Replacement - Aortic Valve Stenosis - Surgery - Mortality

### RESUMEN

**Objetivo:** El objetivo de este estudio fue analizar los resultados hospitalarios actuales de la cirugía del reemplazo valvular aórtico (RVA) a fin de que sirvan como patrón estandarizado para comparar los resultados locales del implante valvular aórtico transcáteter (TAVI).

**Material y métodos:** Se analizaron en forma retrospectiva los resultados hospitalarios de 422 pacientes sometidos a RVA aislado entre 2012 y 2017 en las instituciones asociadas a la Universidad de Buenos Aires.

**Resultados:** La mortalidad hospitalaria global fue 3,6%, y 3,8% a los 30 días, mientras que la mortalidad hospitalaria y a 30 días de 71 pacientes mayores de 80 años, fue 4,2%. En toda la serie la mortalidad hospitalaria en el grupo de bajo riesgo (EuroSCORE II < 4%) fue 2,2%, y en el de riesgo moderado (EuroSCORE II entre 4% y 7%) fue 5,0%.

**Conclusiones:** Esta información actualizada sobre los resultados locales de la cirugía de RVA en todos los estratos de riesgo podría servir como punto de referencia para comparar el TAVI.

**Palabras clave:** Reemplazo valvular aórtico - Estenosis valvular aórtica - Cirugía - Mortalidad

### INTRODUCTION

The advent of transcatheter aortic valve implantation (TAVI) is a significant technological advance in the treatment of aortic valve stenosis, particularly for high surgical risk patients. (1, 2) While most patients who are currently recommended for surgery are at high risk, the use of TAVI could be extended to other groups at lower risk. (3) In the meantime, TAVI has to overcome a number of limitations to reach the usual traditional surgical standards, such as paraval-

vular residual aortic regurgitation, (4, 5) high rate of permanent pacemaker implantation, (6) impact of residual mismatch considering the traditional threshold of 0.75 cm<sup>2</sup>/m<sup>2</sup> effective orifice area (7) the inconvenience of implanting a less durable bioprosthetic valve in patients aged <70 years, (8) the risk of subclinical thrombosis, (9, 10) remote and immediate structural damage secondary to crimping, (11) acute renal dysfunction, (12) and cost-effectiveness ratio in our setting. (13)

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Address for reprints: R.A.B. Hospital de Clínicas, Facultad de Medicina, Universidad de Buenos Aires - Av. Córdoba 2351 - Buenos Aires, Argentina  
e-mail: raborracci@gmail.com

<sup>1</sup> Department of Cardiac Surgery, Hospital de Clínicas, Universidad de Buenos Aires, Argentina.

<sup>2</sup> Department of Cardiology and Cardiac Surgery, Corporación Médica, San Martín, Buenos Aires, Argentina.

<sup>3</sup> Department of Cardiology and Cardiac Surgery, Clínica Bazterrica, Buenos Aires, Argentina.

<sup>4</sup> Department of Cardiology and Cardiac Surgery, ENERI-Sagrada Familia, Buenos Aires, Argentina.

However, considering that TAVI has started to include moderate and low-risk patients in its protocols, (14) it is essential to have updated information on the local results of aortic valve replacement (AVR) surgery in all risk strata. The purpose of this study was to analyze current in-hospital AVR outcomes as reference to compare with local TAVI outcomes.

## METHODS

In-hospital outcomes of isolated AVR patients were retrospectively analyzed between 2012 and 2017 at the institutions associated with the University of Buenos Aires. Baseline population characteristics, postoperative complications, and observed in-hospital and 30-day mortality were assessed. For in-hospital data, patients were divided according to the expected risk arising from the classification used to indicate TAVI, namely: low risk (< 4%), intermediate risk (4% to 7%), and high risk (> 7%).

For statistical analysis, discrete variables were expressed as percentages or ratios. Normality of continuous variables was analyzed with the Kolmogorov-Smirnov (K-S) goodness-of-fit test. Normal data distributions were expressed as mean  $\pm$  standard deviation (SD), and non-normal distributions were expressed as median, quartiles, and interquartile range (IQR). The observed-to-expected mortality ratio was compared with the chi-square test, or Fisher's exact probability, as appropriate. EuroSCORE II discrimination for predicting in-hospital mortality was assessed with the area under the ROC curve (Receiver Operating Characteristics) and its standard error (SE). Statistical analysis was performed with the Statistical Package for the Social Sciences (SPSS) version 17.0 (SPSS Inc., Chicago, IL). The protocol was reviewed and approved by the review committees of each participating institution.

## RESULTS

A total of 422 consecutive patients who underwent isolated AVR in the study period were included. Table 1 shows baseline characteristics of the study population. In-hospital mortality for the entire series was 3.6% (n: 15) (O/E ratio 1.5,  $p = 0.310$ ), and 30-day mortality 3.8% (n: 16). In-hospital mortality divided by EuroSCORE-II risk quartiles shown in Figure 1a, indicates that 75% of the lowest risk sample presented 1.6% mortality rate for an expected risk between 0.50 and 2.44%. Figure 1b shows observed in-hospital mortality for isolated AVR, divided into low or moderate expected risk, according to the usual classification for TAVI indication. The observed mortality was not calculated above 7% (high risk) because only 17 patients remained in the residual sample.

Figure 2 shows the frequency distribution of EuroSCORE II values for the entire cohort, showing prominent positive bias (median: 1.3%, IQR: 1.68, K-S goodness-of-fit  $p < 0.001$ ). The area under the ROC curve for EuroSCORE II was 0.78 (SE: 0.07).

Postoperative complications of the entire series were stroke 1.2% (n: 5), pacemaker implantation 1.2% (n: 5), re-exploration for bleeding 0.9% (n: 4), mediastinitis 0.9% (n: 4), de novo dialysis 1.2% (n: 5), and no postoperative infarctions were registered.

In turn, 16.8% (n: 71) of the patients were  $\geq 80$

**Table 1.** Baseline and operative characteristics of the population (n 422)

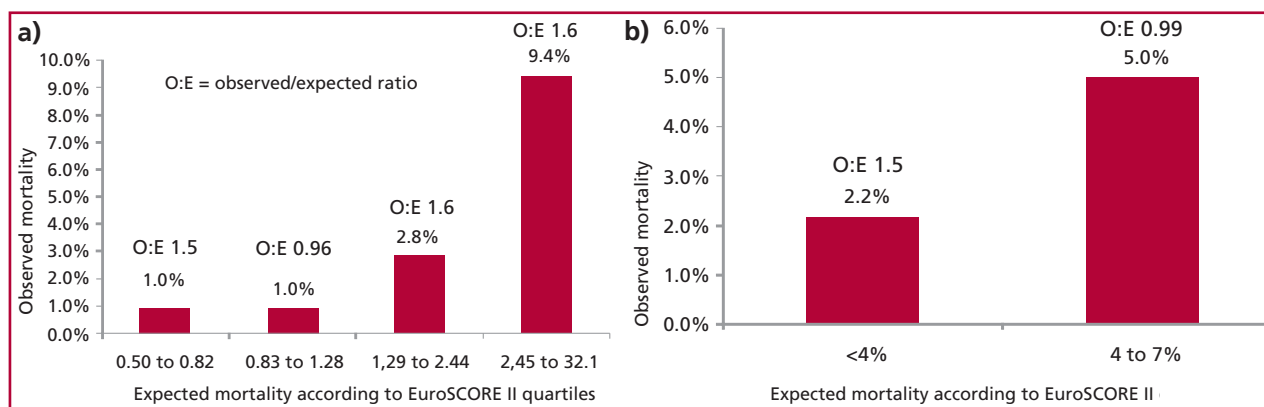
	n	%
Age in years	69.1 (11.0)	
Male sex	237	56.2
Body mass index	27.6 (4.3)	-
Body surface area in m <sup>2</sup>	1.86 (0.20)	-
Hypertension	203	48.1
Dyslipidemia	95	22.5
Diabetes	71	16.8
Current smoking	30	7.1
Previous stroke	12	2.8
Peripheral artery disease	7	1.7
Chronic obstructive pulmonary disease	25	5.9
Previous myocardial infarction	3	0.7
Heart failure	21	5.0
Chronic atrial fibrillation	24	5.7
Pulmonary systolic pressure (mmHg)	39 (11)	-
Previous cardiac surgery	14	3.3
Previous pacemaker implantation	15	3.6
Previous dialysis	2	0.5
Ejection fraction %	58 (10.2)	-
Baseline creatinine clearance in ml/min	72 (39) <sup>†</sup>	-
Type of implanted valve:		
Mechanical	172	40.8
Biological	250	59.2
Implanted valve size:		
N° 19	18	4.3
N° 21	201	47.6
N° 23	163	38.6
N° 25-27	40	9.5
Aortic annulus enlargement	14	3.3
Perfusion time (min)	62 (11.3)	-
Cross-clamping time (min)	42 (6.6)	-

<sup>†</sup> Median and interquartile range; the rest of the continuous variables in the table are expressed as mean and standard deviation.

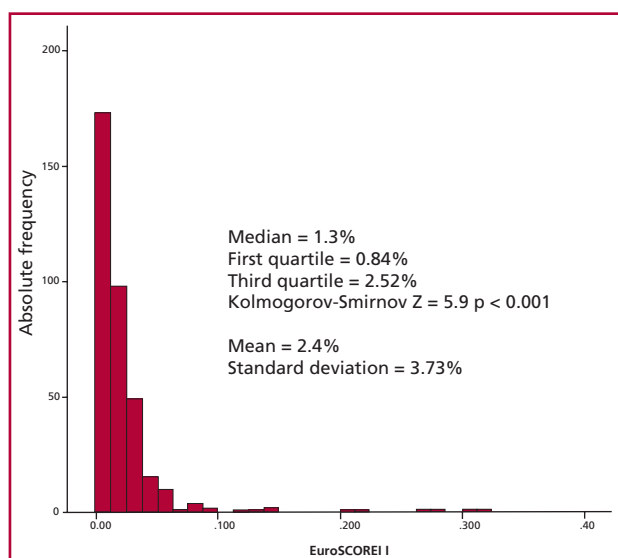
years (mean age  $83 \pm 2.2$  years, range 80-90). In this group, in-hospital and 30-day mortality was 4.2% (n: 3), while expected mortality with EuroSCORE II had a median of 3.0% (IQR: 2.25, K-S goodness-of-fit  $p < 0.001$ ).

## DISCUSSION

Seventy-five percent of the AVR patients in this series had an expected mortality risk <2.5% according to EuroSCORE II, and an observed in-hospital mortality of only 1.6% in this subgroup. This information is a benchmark that should be taken into account at the local level when trying to expand the indication of TAVI in the future. At present, TAVI might only be proposed for the remaining 25% at higher risk. However, if we extended the definition of low risk to an expected mortality of 4%, it would include almost 90% of our series; in that case, the new mortality standard



**Fig. 1.** Observed in-hospital mortality rate of isolated aortic valve replacement, divided by quartiles (a), and by low and moderate risk (b) according to EuroSCORE II



**Fig. 2.** Frequency distribution of EuroSCORE II values for the entire cohort.

for TAVI should not exceed 2.2% of deaths at 30 days. (Figure 1B)

In the case of moderate risk, between 4% and 7%, TAVI mortality rate should not exceed 5%. It is important to point out that, comparatively, immediate TAVI mortality should be measured at least at 30 days. Thus, observed mortality in the Partner 2 trial increased from 0.9% on the third day to 3.9% at 30 days, (3) while in our entire series, in-hospital mortality was almost the same than at 30 days.

From a TAVI perspective, it should be noted that half of the patients in the current series were <70 years old, many of them had a bicuspid valve, and 40% of the total series received a long-term durability mechanical valve instead of a biological implant.

Unfortunately, there are no reports of large TAVI series in Argentina. Boissonnet et al. (15) carried out a systematic review of 1,156 patients with an average age of 81 years, who underwent TAVI in 27 South

American studies between 2008 and 2015. In-hospital and 30-day mortality was 8.1% and 12.5% respectively, and complications during hospitalization included 2% rate of moderate or severe residual aortic failure, 3.5% stroke, and 23% permanent pacemaker implantation. In our series of patients >80 years, 30-day mortality was only 4.2%; however, the expected EuroSCORE II risk was also low.

The Society of Thoracic Surgeons (STS) score is commonly used to classify the risk of TAVI as low (<4%), moderate, and high (>7%). In turn, EuroSCORE II has a poor correlation with STS, and 7% EuroSCORE II risk is considered to be equivalent to 10% STS risk. (16) This observation implies that patients in this series with EuroSCORE II expected moderate risk would actually have a higher risk if assessed with STS.

In conclusion, this updated information on the local results of AVR surgery in all risk strata could serve as a benchmark for comparing TAVI performance in our setting.

#### Conflicts of interest

None declared. (See authors' conflicts of interest forms on the website/Supplementary material).

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