External and Temporal Validation 10 Years after the Development of the First Latin- American Risk Stratification Score for Cardiac Surgery (ArgenSCORE)

VICTORIO C. CAROSELLA[†, 1, 2], HUGO GRANCELLI[MTSAC, 1], WALTER RODRÍGUEZ[1, 2, 3, 4], MIGUEL SELLANES[1, 2, 3, 4], MIGUEL CÁCERES[1, 2, 3, 4], HERNÁN COHEN ARAZI[MTSAC, 1], CÉSAR CÁRDENAS[1], CARLOS NOJEK[MTSAC, 1, 2, 3, 4]

Received: 12/09/2010
Accepted: 03/28/2011

Address for reprints:
Dr. Victorio C. Carosella
Servicio de Cirugía Cardiovascular
Instituto FLENI
Montañeses 2325 - (1428) CABA
Argentina
Phone number:+54 (011) 5777-3200
Fax number:+54 (011) 5777-3209
e-mail: drcarosella@hotmail.com

SUMMARY

Background
During the last decades, several risk assessment models have been applied to predict the risk of mortality after cardiac surgery; however, none of them have been developed in Latin American populations. These models have inferior performance when applied to patient groups other than the ones on whom they were developed.

Objective
To perform external and temporal validation of a local risk score for cardiac surgery [Argentinean System for Cardiac Operative Risk Evaluation (ArgenSCORE)] and compare it to the EuroSCORE.

Material and Methods
A total of 5268 consecutive adult patients undergoing cardiac surgery were included from June 1994 to December 2009. The risk model was developed through logistic regression on the data of 2903 patients who underwent cardiac surgery between June 1994 and December 1999 at a center. Prospective internal validation was performed on 708 patients between January 2000 and June 2001. External and temporal validation of the recalibrated model were performed between February 2000 and December 2009, evaluating model discrimination and calibration in patients operated on at four centers different from the one where the score had been originally developed. The method was also compared to the EuroSCORE.

Results
The external validation was performed on 1657 patients, mean age was 62.8±13.3 years and global mortality was 4.58%. The ArgenSCORE showed both good discriminatory power with an area under the ROC curve of 0.80 and predictive capacity for risk assessment in all patients (observed mortality 4.58% vs. expected mortality 4.54%; p=0.842). The EuroSCORE showed good discriminatory power (area under the ROC curve of 0.79) but overestimated the risk (observed mortality 4.58% vs. expected mortality 5.23%; p <0.0001).

Conclusions
The ArgenSCORE showed an adequate capacity to predict in-hospital mortality in cardiac surgery 10 years after being developed. The score can be applied to populations with similar geographic characteristics, showing a better performance compared to an established international risk stratification model.

Rev Argent Cardiol 2011;79:500-507.

Key words > Myocardial Infarction - Vagal Stimulation - Atropine - Esmolol - Atenolol

Abbreviations >

ArgenSCORE	Argentinean System for Cardiac Operative Risk Evaluation	**ROC**	Receiver operating characteristic
EuroSCORE	European System for Cardiac Operative Risk Evaluation	**STS**	Society of Thoracic Surgeons
		CABG	Coronary artery bypass graft
		CI	Confidence interval

[MTSAC] Full Member of the Argentine Society of Cardiology
[†] To apply as full member of the Argentine Society of Cardiology
[1] Instituto FLENI, Buenos Aires, Argentina
[2] Clínica Suizo-Argentina, Buenos Aires, Argentina
[3] Sanatorio de la Trinidad, Buenos Aires, Argentina
[4] Sanatorio de Los Arcos, Buenos Aires, Argentina

BACKGROUND

The indication of cardiac surgery must be made on the basis of careful and exhaustive evaluation of the risks and benefits associated with the procedure. Therefore, risk stratification of operative risk is of great importance not only for physicians but also for patients and their families in the process of decision making.

During the last decades, several risk assessment models have been applied to predict the risk of mortality after cardiac surgery; however, none of them have been developed in Latin American populations. (1-6)

These models have inferior performance when applied to patient groups other than the ones on whom they were developed. (7-9) This limitation may be related to regional differences in the characteristics of the populations, in decision making and in the outcomes of the surgical procedures. (8-12) Particularly, these differences might have clinical relevance when Latin American populations are compared with those of North America or Europe where the risk scores commonly used were developed over the past decades.

Any statistical risk model must be scrutinized to determine whether it functions reliably for its intended purpose on other and more contemporary populations than those from which it was developed (temporal external validity). (13-16)

In 1999 we developed a local risk score of in-hospital mortality in cardiac surgery, the Argentinean System for Cardiac Operative Risk Evaluation (ArgenSCORE), that was recalibrated in 2007. The development and recalibration of this model has been previously published. (17)

The goal of the present study was to perform the temporal external validity of the recalibrated ArgenSCORE ten years after being developed, and to compare its predictive capacity with that of the logistic European System for Cardiac Operative Risk Evaluation (EuroSCORE). (5, 6) We hypothesized that our local model would show a better performance.

MATERIAL AND METHODS

Data on 5268 consecutive adult patients who underwent cardiac surgical procedures and were prospectively registered into an audited and monitored database between June 1994 and December 2009 were included in the study. Our database was established in line and based on the Society of Thoracic Surgeons (STS) database (4); thus, risk variables and outcomes were defined according to the STS (http://www.sts.org).

Model development and recalibration

The ArgenSCORE is a simple, additive and graphic risk model developed after analyzing 2903 consecutive patients undergoing cardiac surgery at the Instituto de Cardiología del Hospital Español in Buenos Aires from June 1994 to December 1999.

The development and recalibration of this model has been published previously. (17) Forty-nine preoperative variables were analyzed. Univariate analysis was performed with Pearson's chi-square test or Fisher's exact test. Continuous variables were transformed into categorical variables using appropriate cutpoints as previously published. (3) Categorical variables were expressed as percentages and continuous variables as mean ± standard deviation.

Preoperative variables were included in a multivariate logistic regression model. Factors included were those significant by univariate analysis or by following clinical importance criteria. The introduction of the variables was subsequently modified until finding the best adjusted model. Using the variable coefficients and constants for each multiple logistic regression model, patient-specific predicted probability of operative mortality was calculated by adding the positive coefficients to the regression constant. The logit of this value was calculated to estimate the predicted mortality rate. We identified 18 independent predictors of in-hospital mortality. (17)

We also developed a simplified graphic score to calculate the risk using a convenient printed grid. Each coefficient was multiplied by 10 to obtain a score for each variable, following empiric criteria for clinical significance. The total risk score is the sum of point values assigned to each risk factor detected at the time of patient evaluation. Finally, a distribution curve was put into a graph in order to correlate the absolute values of the score with the risk predicted by multiple logistic regression.

The performance of the model was initially evaluated by an internal prospective validation dataset performed on 708 patients operated between January 2000 and June 2001 at the same institution. The area under the ROC (receiver operating characteristic) curve (18) was 0.77 (95% CI: 0.74-0.80). The first temporal and external prospective validation of the model was performed on 1087 patients operated on at three other centers in Buenos Aires between February 2000 and January 2007. Although the model demonstrated a good discriminatory power with an area under the ROC curve of 0.81 (95% CI: 0.75-0.87), the calibration was imperfect due to significantly lower observed mortality rates compared to predicted mortality (3.96% vs. 8.20%; $p < 0.0001$). (17)

Recalibration was performed to improve the performance of the 1999-original model. (7, 15, 16, 19) A logistic regression equation for in-hospital mortality was derived with the 1999-original model as the independent variable and in-hospital mortality as the dependent variable. (19, 20) The 2007-recalibrated ArgenSCORE showed an area under the ROC curve of 0.81 (95% CI: 0.75-0.87); the Hosmer-Lemeshow test (21) was non-significant (chi-square =1.51; $p = 0.68$) and an adequate level of agreement between the observed and predicted rates of mortality on all patients ($p = 0.92$) was observed. Figure 1 shows the 2007-recalibrated model with the estimated mortality and the corresponding CI. (16)

EXTERNAL AND TEMPORAL VALIDATION OF THE MODEL

Data collection

Data were prospectively collected and incorporated into an Access database and supervised by the surgeons after and before the surgical procedure to ensure the quality of the information and of the different variables and outcomes. The quality of the information incorporated into the database was audited once a week by a coordinator. Inconsistent and/or incorrect data were subsequently controlled and corrected using hospital records from each center after the patient was discharged. Complete data of the variables analyzed was available in all the cases included.

Risk factor	Score
60-69 years	7,0
70-79 years	11,0
≥ 80 years	21,5
Female gender	5,0
Diabetes on insulin	11,0
Renal failure	6,0
Peripheral vascular disease	6,5
Reoperation	7,5
Urgent surgery	8,5
Emergent surgery	14,5
Salvage surgery	32,5
Preoperative IABP	6,0
Aortic valve replacement	2,5
Mitral valve replacement	15,5
Aortic valve repair	5,5
Mitral valve repair	5,5
Thoracic aorta replacement	13,0
Acute aortic dissection	5,5
Heart transplant	15,0
Combined surgery	5,0
One-vessel disease	4,0
Two-vessel disease	7,5
Three-vessel disease	14,0
Moderate LV dysfunction	2,5
Severe LV dysfunction	9,0
Total score	

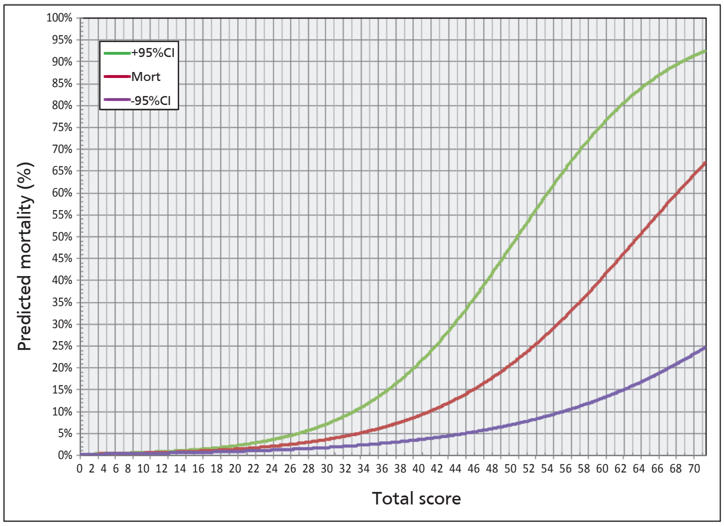

Fig. 1. Recalibrated 2007-ArgenSCORE. A simple graphic pocket-card score easy to use an apply. IABP: Intraaortic balloon pump LV: Left ventricular. PM: Predicted mortality. CI: confidence interval.

Study design

The external validation dataset consisted of 1657 patients included between February 2000 and December 2009.

These patients were operated on at four medical centers other than the one where the original score was developed: Instituto FLENI, Sanatorio Los Arcos, Sanatorio de la Trinidad and Clínica Suizo-Argentina. Cardiac surgical procedures included isolated coronary artery bypass graft surgery (CABG), isolated valve repair or replacement, valve surgery with CABG, thoracic aorta surgery, cardiac surgery with carotid endarterectomy, adult congenital cardiac surgery and heart transplantation. Patients who underwent implantation or explantation of ventricular assist devices as their primary surgery were excluded from the study. Clinical outcome was based on in-hospital mortality, defined as death until patient discharge.

In this external validation dataset, the discrimination of the model of local risk was assessed by the area under the ROC curve. (18) The reliability of the recalibrated model was evaluated by comparing the observed mortality rates with those predicted by the risk score in all patients and across the five quintiles of risk. (3, 10, 15, 22) The difference between the mean observed mortality and the mean predicted mortality was evaluated by the ttest . (23) A p value $p < 0.05$ was considered statistically significant.

The differences between the epidemiological data, risk variables and surgical outcomes of our -external validation dataset with those of the EuroSCORE (5, 8, 24, 25) were analyzed using Pearson's chi-square test. The performance of the additive ArgenSCORE was compared with the logistic EuroSCORE by calculating the area under the ROC curve and the calibration of both models in our validation dataset. (5, 6) Data analyses were performed using SPSS 17.0 statistical software package, version (SPSS Inc., Chicago, Ill).

RESULTS

The development dataset consisted of 2903 patients with in-hospital mortality of 8.2%. The external validation dataset consisted of 1657 patients with mortality of 4.58% ($p < 0.0001$). There were no differences in mean age (62.8 ± 11.6 vs. 62.8 ± 13.3 years) and in the prevalence of women (26.5% vs. 23.7%) between both populations. However, the validation dataset had a greater prevalence or preoperative risk variables compared to the development dataset: subpopulation ≥ 80 years (6.28% vs. 2.69%; $p < 0.0001$), urgent status (10.2% vs. 6.6%; $p < 0.0001$), combined surgery (24.02% vs. 14.8%; $p < 0.0001$), thoracic aorta replacement (9.47% vs. 4.5%; $p = 0.0046$) and lower prevalence of isolated CABG (53.05% vs. 64.0%; $p < 0.0001$). Patient characteristics and the respective mortality rates of the development and external validation datasets are summarized in Table 1.

The external and temporal validation confirmed the reasonable performance of the recalibrated ArgenSCORE to discriminate in-hospital mortality in this new population undergoing cardiac surgery. The area under the ROC curve was 0.80 (95% CI: 0.75-0.85) (Figure 2).

The performance of the model was also good to predict operative risk in the general population, with an excellent correlation between the observed mortality vs. predicted mortality (4.58% vs.4.54%, $p = 0.842$) (Table 2). This predictive power was irregular across the five quintiles of risk in the calibration model.

We found significant differences in the epidemiological data, operative risk and the complexity of the procedure between our local validation dataset and that of the EuroSCORE (Table 3). The local population had a greater incidence of patients ≥ 75 years (18.59% vs. 9.6%; $p < 0.0001$), with higher body mass index > 30 (18.17% vs. 5.0%; $p < 0.0001$), isolated valve surgery (39.65% vs. 29.4%; $p < 0.0001$) and thoracic aorta replacement (9.47% vs. 2.4%; $p < 0.0001$). In turn, The EuroSCORE dataset had greater incidence of kidney failure (3.5% vs. 2.17%; $p = 0.005$), chronic heart failure (13.7% vs. 5.13%; $p < 0.0001$), urgent surgery (21,0% vs. 10.2%; $p < 0.0001$) and isolated CABG (65.0% vs. 53.05%; $p < 0.0001$). Yet, observed in-hospital mortality was similar in both populations: 4.58 in our local dataset versus 4.80% in the EuroSCORE (p

= 0.69).

The performance of the EuroSCORE in our external validation dataset was appropriate to discriminate the risk of operative mortality, with an area under the ROC curve of 0.79 (95% CI: 0.74-0.84) (Figure 2). On the other hand, the performance to predict mortality in the global population was inadequate as it overestimated the risk: the correlation between the observed mortality vs. predicted mortality was 4.58% and 5.23%, respectively ($p < 0.0001$) (Table 2).

DISCUSSION

Risk stratification scores are commonly used to assess morbidity and mortality risk before cardiac surgery. The reliability of these systems should be based on their capacity to identify properly the operative risk; however, several limitations exist to apply them in different scenarios and subpopulations. Recent evidence has shown that risk scoring systems suffer inferior performance when used in patient populations with clinical characteristics and risk profiles or in procedures different from the ones on which they were developed. (7-10, 24)

The ArgenSCORE is a model of risk assessment in cardiac surgery developed in our country in 1999 and recalibrated in 2007. (17, 26) The results of the present study show the external and temporal validation of this model applied to a local population ten years after it was developed. The model has shown strong discriminatory power to predict mortality and for risk assessment in all the dataset, evidenced by an excellent relation between observed mortality (4.58%) and predicted mortality (4.54%).

The model uses different objective definitions

Table 1. Patient characteristics in development and external and temporal validation datasets

Variable	Development dataset 1994-1999 (%) n = 2903	External validation dataset 2000-2009 (%) n = 1657	p value
< 60 years	32,44	33.61	0.425
60-69 years	37,07	31.62	0.0002
70-79 years	27,8	28.49	0.644
≥ 80 years	2.69	6.28	< 0.0001
Female gender	25.0	23.72	0.361
BMI > 30	18.4	18.17	0.878
Diabetes	17.9	13.82	0.0004
Diabetes on insulin	1.6	1.99	0.371
CPD	5.9	4.89	0.174
Renal failure	2.5	2.17	0.578
Peripheral vascular disease	6.6	7.12	0.523
Active endocarditis	1.8	1.45	0.453
Reoperation	7.2	6.28	0.261
Elective status	90.4	86.6	0.0001
Urgent status	6.6	10.2	< 0.0001
Emergent status	2.3	2.66	0.479
Salvage status	0.8	0.54	0.432
Preoperative IABP	2.8	3.56	0.173
Isolated CABG	64.0	53.05	< 0.0001
Aortic valve replacement	20.9	25.53	0.0003
Mitral valve replacement	6.1	6.28	0.0015
Aortic valve repair	1.5	2.53	0.0156
Mitral valve repair	3.4	7.12	< 0.0001
Thoracic aorta replacement	4.5	9.47	0.0046
Acute aortic dissection	1.2	2.11	0.0174
Heart transplant	1.5	0.36	0.0007
Combined surgery	14.8	24.02	< 0.0001
Off-pump cardiac surgery	2.60	7.97	< 0.0001
One-vessel disease	9.2	6.4	0.003
Two-vessel disease	24.3	17.08	< 0.0001
Three-vessel disease	66.5	41.64	< 0.0001
Moderate LV dysfunction	17.6	17.8	0.864
Severe LV dysfunction	7.9	8.0	0.925
Overall mortality	8.20	4.58	< 0.0001

BMI: Body mass index CPD: Chronic pulmonary disease. IABP: Intraaortic balloon pump CABG: Coronary artery bypass graft. LV: Left ventricular.

(4, 10, 22); a simple graphic score with adequate performance can be easily applied to better comprehend the potential mortality risk of surgery based on the patient's preoperative parameters.

All risk assessment models should be prospectively evaluated and undergo external and temporal validation after being developed. (9, 13, 15) The clinical characteristics and risk profiles of the patients operated on, the criteria used to indicate surgery and certain special features related to surgical techniques may have geographic-related differences even in the centers of the same city. (8-12, 27) Wynne-Jones et al. evaluated populations at four centers in the north west of England with similar socioeconomic characteristics and close geographical proximity, finding important differences in patients' risk profile. (12)

The epidemiological characteristics of the population, comorbidities, indications for surgery, procedure-related techniques and operative outcomes change over the time, even in the same center. (7, 28) Despite an increase of the average preoperative mortality risk of patients referred to heart surgery during the last years, a decrease of hospital mortality has been observed in many surgical institutions. This phenomenon has been described as the "risk paradox" by Pinna-Pintor et al. (29) In this sense, our validation dataset showed a greater preoperative risk and lower postoperative mortality compared to the original population. These changes in the population profile and outcomes motivated us to recalibrate (15, 16, 19) our model in 2007. (17)

The international models for risk stratification used in our environment have been developed on populations and surgical centers that are different from our reality. For this reason, the predictive capacity of these systems might be limited. (1-6) As opposed to the ArgenSCORE, the EuroSCORE showed good discriminatory power in all patients but overestimated mortality (observed mortality/expected mortality: 4.58% vs. 5.23%), probably due to differences between the population of the EuroSCORE and our validation dataset in the clinical risk profiles and in the procedures performed. These findings support the advantages of developing and applying local models for preoperative risk assessment. (8-10, 30)

Our study has some limitations. The external validation was performed only at four centers in the city of Buenos Aires, without including centers from other geographical regions in our country. Preoperative evaluation should not only consider in-hospital mortality but also other complications as the different morbidities which are important for the outcomes and quality of life. (16, 22) Finally, these results cannot be extrapolated to off-pump cardiac surgery due to the low percentage of procedures performed on the populations analyzed.

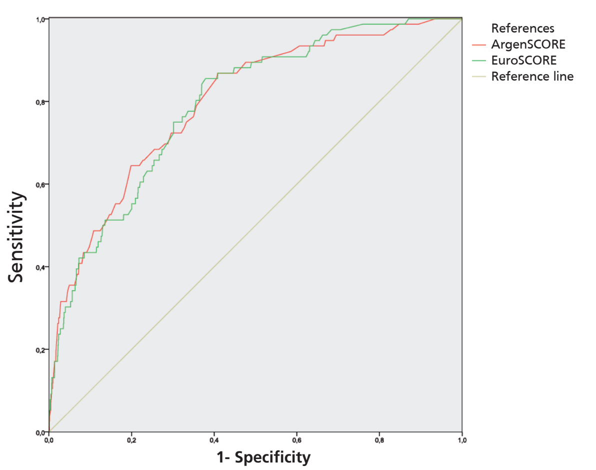

Fig. 2. Receiver operative characteristic (ROC) curves of the external validation dataset (n = 1657). The area under the ROC curve of the recalibrated 2007-ArgenSCORE was 0.80 (95% CI: 0.75-0.85) and the logistic EuroSCORE showed an area under the ROC curve of 0.79 (95% CI: 0.74-0.84).

CONCLUSION

The ArgenSCORE represents the first risk model for cardiac surgery developed and validated for risk stratification of in-hospital mortality in our country and Latin America. This simple graphic score can easily be applied to estimate risk in cardiac surgery. The external and temporal validation after 10 years of being developed demonstrated adequate discrimination and estimation of operative mortality. The score can be applied to populations with similar geographic and demographic characteristics, showing a better performance compared to an established international risk stratification model.

Quintile of risk	Number of of patients	Observed mortality (%)	Predicted mortality (%) p value	
			2007-recalibrated ArgenSCORE	Logistic EuroSCORE
First	416	(0,72)	(0,74) 0,116	(1,83) < 0,0001
Second	392	(1,27)	(1,61) < 0,0001	(2,78) < 0,0001
Third	225	(3,55)	(2,48) < 0,0001	(3,38) 0,37
Fourth	296	(5,74)	(4,07) < 0,0001	(6,10) 0,217
Fifth	328	(13,11)	(14,73) 0,025	(12,98) 0,859
Total	1.657	(4,58)	(4,55) 0,842	(5,24) < 0,0001

Table 2. Comparison of observed mortality versus predicted mortality in the 2007-recalibrated ArgenSCORE and logistic EuroSCORE across the five quintiles of risk in the external validation dataset (n = 1657)

Table 3. Prevalence of risk factors in our external validation dataset and EuroSCORE population

Variable	External validation dataset Prevalence (%) (n = 1657)	EuroSCORE population Prevalence (%) (n = 19030)	p
65-70 years	15,63	20,7	< 0,0001
≥ 75 years	18,59	9,6	< 0,0001
Female gender	23,72	27,8	0,0003
BMI > 30	18,17	5,0	< 0,0001
Hypertension	57,17	44,0	< 0,0001
Diabetes	13,82	17,0	0,001
Diabetes on insulin	1,99	4,0	< 0,0001
CPD	4,89	3,9	0,0481
Renal failure	2,17	3,5	0,0052
Extracardiac arteriopathy	7,12	11,3	< 0,0001
Intermittent claudication	1,09	5,8	< 0,0001
Neurological dysfunction	2,47	1,4	0,0007
Active endocarditis	1,45	3,6	< 0,0001
Chronic heart failure	5,13	13,7	< 0,0001
Atrial fibrillation	4,53	9,0	< 0,0001
Class 4 angina	8,63	21,0	< 0,0001
Unstable angina in CABG	20,04	12,0	< 0,0001
Unstable angina (all types)	22,27	8,0	< 0,0001
Elective surgery	86,60	74,0	< 0,0001
Urgent surgery	10,20	21,0	< 0,0001
Emergent surgery	2,66	4,9	< 0,0001
Preoperative IABP	3,56	1,0	< 0,0001
Isolated CABG	53,05	65,0	< 0,0001
Non CABG	46,95	36,4	< 0,0001
Heart valve surgery	39,65	29,4	< 0,0001
Single aortic valve surgery	61,95	57,0	0,0168
Single mitral valve surgery	24,81	29,0	0,0277
Double heart valve surgery	6,39	14,0	< 0,0001
Thoracic aorta replacement	9,47	2,4	< 0,0001
One-vessel disease	6,64	8,0	0,048
Two-vessel disease	17,08	25,0	< 0,0001
Three-vessel disease	41,64	66,7	< 0,0001
Left main coronary artery	18,11	22,0	0,0002
Moderate LV dysfunction	17,8	25,6	< 0,0001
Severe LVdysfunction	8,0	5,8	0,0002
Overall mortality	4,58	4,80	0,6993

BMI: Body mass index CPD: Chronic pulmonary disease. CABG: Coronary artery bypass graft. IABP: Intraaortic balloon pump LV: Left ventricular.

RESUMEN

Primer puntaje de riesgo latinoamericano en cirugía cardíaca (ArgenSCORE): validación externa y temporal a 10 años de su desarrollo

Introducción
En las últimas décadas se han aplicado diversos modelos de riesgo para predecir mortalidad en cirugía cardíaca, pero ninguno de estos sistemas de evaluación fue desarrollado en poblaciones de América Latina. Estos modelos presentan un rendimiento menor cuando son aplicados en poblaciones diferentes de aquellas en las que fueron desarrollados.

Objetivos
Validar un modelo de riesgo local de mortalidad intrahospitalaria en cirugía cardíaca [Argentinean System for Cardiac Operative Risk Evaluation (ArgenSCORE)] en forma externa y temporal y compararlo con el EuroSCORE.

Material y métodos
Se incluyeron 5.268 pacientes adultos, consecutivos, intervenidos quirúrgicamente desde junio de 1994 hasta diciembre de 2009. El modelo fue desarrollado mediante regresión logística en 2.903 pacientes intervenidos en un centro desde junio de 1994 hasta diciembre de 1999. Se realizó validación interna prospectiva desde enero de 2000 hasta junio de 2001 en 708 pacientes. Desde febrero de 2000 hasta diciembre de 2009 se validó en forma externa y temporal el modelo recalibrado evaluando su discriminación y calibración en pacientes operados en cuatro centros diferentes del de su desarrollo y se comparó su rendimiento con el EuroSCORE.

Resultados

La población de validación externa incluyó 1.657 pacientes, con una edad media de 62,8 ± 13,3 años y una mortalidad global del 4,58%. El ArgenSCORE mostró un buen poder de discriminación (curva ROC: 0,80) y buena capacidad para asignar riesgo en todos los pacientes (relación mortalidad observada: 4,58% vs. mortalidad predicha: 4,54%; p = 0,842). El EuroSCORE mostró un buen poder discriminativo (curva ROC: 0,79), pero sobrevaloró el riesgo estimado (relación mortalidad observada: 4,58% vs. mortalidad predicha: 5,23%; p < 0,0001).

Conclusión

El ArgenSCORE mostró una capacidad adecuada para predecir mortalidad intrahospitalaria en cirugía cardíaca a 10 años de su desarrollo. Su aplicación en poblaciones con características geográficas similares a las de aquellas donde fue desarrollado muestra un rendimiento mejor en comparación con un puntaje internacional ya consolidado y de uso global.

Palabras clave > Cirugía cardiovascular - Mortalidad - Evaluación de riesgo - Factores de riesgo

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