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Design and validation of the Cuban prognostic scale PREDICMED to stratify the risk of postoperative mediastinitis

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ABSTRACT

Introduction: Phenomena prediction through prognostic scales is a valuable tool in medical sciences nowadays and it should be included in the decision-making process. Predicting postoperative mediastinitis allows to count on resources for its prevention.

Objective: To build a prognostic scale to stratify the risk of suffering from postoperative mediastinitis.

Methods: A case-control study for the risk factors of postoperative mediastinitis was carried out at the Cardiocentro Ernesto Guevara from Santa Clara, Cuba. After the logistic regression, the model was obtained and from it, the predictors to obtain the Cuban prognostic scale of postoperative mediastinitis PREDICMED were included and weighted, which was validated through several methods.

Results: This scale was obtained, counting on six predictors and two risk strata. Its performance was analyzed through adjustment, calibration and determination of its discriminating capacity, showing good results. Internal validation was carried out through the data splitting method and its capacity was compared in both subsets (development and validation) showing no differences. Its good construct validity was demonstrated, since there were no differences between the predicted and the observed probabilities. Its contents validity was also analyzed by experts. Finally, its criteria validity was determined when compared with another similar scale (Medscore). PREDICMED showed a very good discriminatory capacity (area under the curve 0.962) as well as high values of sensitivity (84.62%) and specificity (92.31%).

Conclusions: The Cuban prognostic scale PREDICMED, to stratify the risk of postoperative mediastinitis showed good validation parameters and it was able to stratify the risk in not high and high.

Keywords: Prognostic scores, Prognostic model, Validation study, Postoperative mediastinitis, Risk prediction models, Cardiac surgery

Diseño y validación de la escala pronóstica cubana PREDICMED para estratificar el riesgo de mediastinitis postoperatoria

Authors' contribution
GJBY: Idea and design of the research, raw data collection and analysis as well as final report confection.
EEBF: Raw data analysis, statistical processing as well as helping in the final report confection.
ECB, YLC, AMNU y MARLC: Idea and design of the research as well as helping in the final report confection.
ALLH, RMR y RGLC: Raw data collection and analysis.
AVIE, AAG y YFQF: Information search and contrasting as well as raw data collection.
All authors critically reviewed the manuscript and approved the final report.

RESUMEN

Introducción: La predicción de fenómenos en las ciencias médicas mediante escalas pronósticas constituye una herramienta valiosa en la actualidad y deben incluirse en el proceso de toma de decisiones. Pronosticar la mediastinitis postoperatoria permite disponer de recursos para su prevención.

Objetivo: Construir una escala pronóstica para estratificar el riesgo de padecer mediastinitis postoperatoria.

Método: Se realizó un estudio de casos y controles para los factores de riesgo de mediastinitis postoperatoria en el Cardiocentro Ernesto Guevara de Santa Clara, Cuba. Luego de la regresión logística se obtuvo el modelo y, a partir de este, se incluyeron y ponderaron los predictores para obtener la escala cubana pronóstica de mediastinitis postoperatoria: PREDICMED, que se validó por diversos métodos.

Resultados: Esta escala se obtuvo con seis predictores y dos estratos de riesgo. Se analizó su rendimiento mediante ajuste, calibración y determinación de su poder discriminante, con buenos resultados. Se realizó validación interna por el método de división de datos y se comparó su capacidad en ambos subconjuntos (desarrollo y validación) sin diferencias. Se probó su buena validez de constructo, al no existir diferencias entre las probabilidades predichas y las observadas. También se analizó su validez de contenido mediante expertos. Por último, se determinó su validez de criterio al comparar con otra escala similar (MEDSCORE). PREDICMED presentó muy buena capacidad discriminatoria (área bajo la curva 0,962) y elevados valores de sensibilidad (84,62%) y especificidad (92,31%).

Conclusiones: La escala pronóstica cubana PREDICMED, para estratificar el riesgo de mediastinitis postoperatoria, mostró buenos parámetros de validación y logró estratificar el riesgo en no alto y alto.

Palabras clave: Escalas pronósticas, Modelos pronósticos, Estudio de validación, Mediastinitis postoperatoria, Modelos de predicción de riesgo, Cirugía cardíaca

INTRODUCTION

Cardiovascular surgery involves a certain surgical risk and the longitudinal median sternotomy is universally used as the incision of choice, since it offers an excellent exposure of the heart and the great vessels[1,2]. According to González *et al.*[2] it was proposed by Milton since 1897 and its usage became widespread from the 1950s on[2].

Surgical wound infection is still a serious problem to be solved nowadays. In addition to being one of the most important quality indicators in any surgical department, when they are clean wounds, such as this one. Postoperative mediastinitis is the deep infection of this incision, with an incidence between 1-2%[3] and a lethality between 8.6 and 40%, which is why it is considered a feared major adverse event of cardiovascular surgery[3,4].

If postoperative mediastinitis is suspected, prompt reintervention is necessary for the debridement and surgical cleaning of the cavity. A rapid and effective medical-surgical treatment is essential to avoid serious major adverse events that can lead to the patient's death[1].

The prediction of a phenomenon is nothing more than establishing its occurrence prediction (according to the Dictionary of the Royal Spanish Academy), so the construction of mathematical scales to predict and classify risk should be included in current work protocols for any condition or major adverse event. Prediction contributes to the decision-making process regarding prevention and optimal use of resources according to risk.

Like other diseases, mediastinitis can be predicted by its risk factors. For this purpose, mathematical models are designed which lead to prognostic scales. Frequently, a bivariate analysis of the risk factors is used as a starting point, then, step by step, those with the strongest association are introduced through a logistic regression in the multivariate analysis, which generates a prognostic model from which the scale is constructed, subsequently requiring validation methods. Some researchers have used modern methods for constructing risk scales, such as artificial intelligence and neural networks[5].

The objectives of this research were to construct and validate a prognostic scale for stratifying the risk of postoperative mediastinitis in the *Hospital Universitario Cardiocentro Ernesto Guevara* of Santa

Clara, Cuba.

METHOD

An analytical, retrospective and case-control study was carried out at the aforementioned hospital, which included 20 years (2000-2019). The sample consisted of the 45 patients (total of cases) who presented the diagnosis of postoperative mediastinitis and they were compared to four controls per case, selected according to type of intervention, proximity in terms of date with the onset of infection, close age (up to five years) and same gender.

The bivariate analysis of the risk factors was carried out and those with the greater relationship with the dependent variable were obtained, according to the odds ratio (OR) and the significance of the Wald statistics.

Model

To develop the model, a multivariate binary logistic regression analysis adjusted to the actual incidence was performed, where the presence of mediastinitis was considered as a dependent variable (1-present, 0-absent). As possible predictive factors, variables with coefficients significantly different from zero were included in the study, in which the confidence interval corresponding to the OR was not excessively wide.

The selection of variables to construct the model was carried out step-by-step through the "introduce" method, which allowed mitigation of the undesired effect of collinearity of the independent variables and considerations based on the researcher's medical practice and expert criteria were taken into account. The bivariate analysis and the logistic regression model obtained, in addition to its performance and validation tests, were already published in the journal of the Spanish Society of Cardiovascular and Endovascular Surgery, in 2019[6].

Scale

The selection of the scale variables was made from the predictors of the model obtained from the adjusted multivariate binary logistic regression[6], and all were included. To assign weights or scores to these variables, the variant of rounding the corresponding β coefficients obtained in the previously constructed model to the upper integer was used.

From the scores, the scale is defined as a linear combination as follows:

Scale value = $p_1X_1 + p_2X_2 + p_3X_3 + ... + p_sX_s$, where s represents the number of variables included in the scale, and p_i is interpreted as the score or weight for the i^{th} variable.

In order to facilitate the calculation of the scale value corresponding to the risk in each patient, to dichotomize its variables was decided. The value 1 represents the presence of the characteristic or attribute associated to the variable, and 0, its absence.

Risk levels were classified in two strata: high and not high. The value of the 90^{th} percentile was taken as cut-off point. If the scale value is higher than or equal to the cut-off point, it was considered as high risk.

In order to confirm the scale performance on the prediction of mediastinitis a binary logistic regression was carried out. The dependent variable was again defined as the presence of postoperative mediastinitis (yes or no), and the value of the scale as a possible factor. The analysis focused on the significance of the Hosmer-Lemeshow test statistic for its calibration, and on the area under the ROC (receptor operative characteristic) curve for its discriminating capacity. Both values were compared with those of the prognostic model. The result of the Omnibus test and the value of the Nagelkerke R^2 statistic were also analyzed.

The coefficient of the term corresponding to the independent variable (scale) and its exponential were shown, which corresponds to the odds ratio value accompanied by its confidence interval.

The same internal validation method was used as for the prognostic model[6] (data splitting). It was chosen as well the 70% as development sample and the 30% for the validation.

Based on the groups predicted through the binary logistic regressions applied to the development and validation samples, two contingency tables were constructed in which the risk strata were associated with the prediction of groups membership (with or without mediastinitis). In both samples (development and validation), the predictive probabilities of mediastinitis according to strata were also calculated and compared.

Finally, the significance values of the Hosmer-Lemeshow test (calibration) and those of the area under the ROC curve (discrimination) were com-

pared in both samples (development and validation). In addition, the efficacy indicators were contrasted for a prognostic model in the two groups of patients.

For the analysis of the experts criteria, the pairwise comparison method was used in the same way as described above[6]: each aspect of the scale was evaluated independently by each expert and categories and scores were equated. The category VA (very adequate) with five points, FA (fairly adequate) with four points, A (adequate) with three points, PA (poorly adequate) with two points and I (inadequate) with one point. Content validity was considered good if the variables obtained the first two categories (VA or FA), after determining Kendall's coefficient of concordance (W) and the lowest variability for each variable (**Appendix**).

In order to evaluate a scale criterion it is convenient to compare it with another existing and previously endorsed tool. In this study, the Medscore scale was chosen because it is the most complete according to the reviewed literature, since it includes all types of cardiovascular surgery interventions, unlike others whose purpose was only the prediction in coronary surgery. The discriminatory capacity of both scales was studied through the area under the ROC curve and its association was determined through the Pearson's correlation coefficient.

RESULTS

As previously expressed, the bivariate analysis and the prognostic model obtained, as well as their tests, have already been published[6]. The results of the current article only establish the construction and validation of the Cuban prognostic scale PREDICMED to stratify the risk of postoperative mediastinitis, which included six variables (**Table 1**), in correspondence with the original model. Chronic obstructive pulmonary disease and transfusion of more than two units of blood products were weighted with three points, postoperative hyperglycemia, postoperative pneumothorax and endovascular sepsis with two points, and mechanical artificial ventilation time of longer than 24 hours with one point; therefore, the possible range ranged from 0 to 13 points.

Based on the genesis of the scale and its score, the patients were stratified into two risk levels: not high for patients with a score between zero and six points, and high between seven and 13. The cut-off point was drawn at the 90th percentile, which coincided with the value seven; therefore, scores equal to or higher were considered high risk. As a result of the scale application 201 patients (89.3%) were classified as not high risk and 24 (10.7%) as high risk (**Table 2**). In the case of the first ones, only 10.9% presented mediastinitis, while 95.8% of those identified as high risk had it.

Calibration

Table 3 shows the result of the simple binary logistic regression, in which the dependent variable is the presence or absence of mediastinitis; the value of the scale was included as explanatory variable.

Table 1. Variables included in the Cuban prognostic scale PREDICMED.

Predictor	Score
Chronic obstructive pulmonary disease	3
Postoperative hyperglycemia	2
Time on mechanical ventilation longer than 24 hours	1
Transfusion of more than two units of blood products	3
Postoperative pneumothorax	2
Endovascular sepsis	2

Table 2. Estimación del riesgo de mediastinitis mediante la aplicación de la escala PREDICMED.

B risk	Mediastinitis				Total	
	Yes		No			
	Nº	%	Nº	%	Nº	%
Not high	22	10,9	179	89,1	201	89,3
High	23	95,8	1	4,2	24	10,7
Total	45	20,0	180	80,0	225	100

Table 3. Statistical test applied to assess PREDICMED performance, calibration and discriminating capacity.

Variables in the equation Step 1[a]		B	TE	Wald	FD	Sig.	Exp(B)	CI 95% for Exp(B)	
								Lower	Upper
Omnobus test	B Scale	0,788	0,115	47,329	1	0,000	2,200	1,757	2,754
	Constant	-4,679	0,598	61,218	1	0,000	0,009		
Chi square		105,843			1	0,000			
Nagelkerke R^2		-2 log of the verisimilitude				Cox and Snell R2		Nagelkerke R2	
		119,339[a]				0,375		0,593	
Hosmer-Lemeshow		Chi square			FD	Sig.			
		6,141			5	0,293			

[a] Variable(s) introduced in step 1: B Scale.
FD, freedom degree; Sig, signification; TE, typical error.

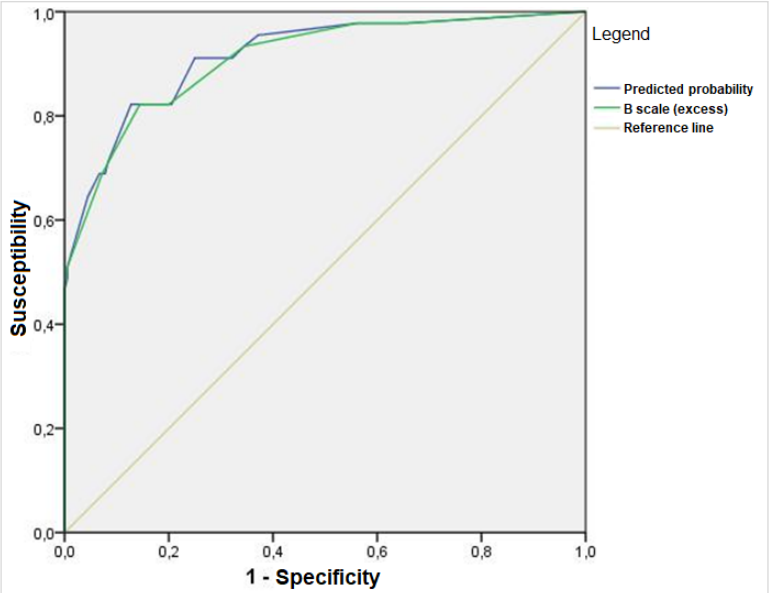
All this to assess the PREDICMED performance, with calibration and discriminatory capacity. The coefficient corresponding to the independent variable was considered significantly different from zero, with OR = 2.2, that is, for each point increased on the scale, the possibility of postoperative mediastinitis was twice as high.

Among the criteria determined to evaluate the adjustment of the scale are: the Omnibus test with a significant result; the Nagelkerke R^2, whose value of 0.593 explains that approximately 60% of the data variability is contemplated by the scale; and the corresponding Hosmer-Lemeshow test statistic, with a value of 0.293, which when exceeding 0.05 denotes a good calibration.

Discriminating capacity

The scale discriminating capacity was compared to that one of the logistic regression which gave origin to it[6] and it was observed that there are no significant differences between them with 0.916 of area under the ROC curve for the prognostic model and 0.910 for PREDICMED (**Figure 1**).

The validation of PREDICMED was performed through the data division method, which is an internal validation method. **Table 4** shows the contingency in which the risk strata are associated with mediastinitis prediction. Of the 160 patients composing the development sample, it was predicted that 100% of those classified as high risk would have mediastinitis and that of those classified as not high risk, only 9.7% would have it. Of the 65 composing the validation



Area under the curve

Variables resultado de contraste	Área	Error típ.[a]	Sig. asintótica[b]	Intervalo de confianza asintótico al 95%	
				Límite inferior	Límite superior
Probabilidad pronosticada	,916	,025	,000	,867	,965
Escala B por exceso	,910	,026	,000	,859	,961

La variable (o variables) de resultado de contraste: Probabilidad pronosticada, Escala B por exceso tiene al menos un empate entre el grupo de estado real positivo y el grupo de estado real negativo. Los estadísticos pueden estar sesgados.

a. Bajo el supuesto no paramétrico
b. Hipótesis nula: área verdadera = 0,5

Figure 1. ROC curves to compare the discriminatory capacity of the scale.

Table 4. Association between risk strata and prediction of postoperative mediastinitis.

Risk strata	Prediction of mediastinitis					
	Development sample			Validation sample		
	No	Yes	Total	No	Yes	Total
Not high	131 (90,3)	14 (9,7)	145 (100)	50 (89,3)	6 (10,7)	56 (100)
High	0 (0,0)	15 (100)	15 (100)	0 (0,0)	9 (100)	9 (100)
Total	131 (81,9)	29 (18,1)	160 (100)	50 (76,9)	15 (23,1)	65 (100)

Data express n (%)

Table 5. Correlation between the predicted and the observed probabilities for the occurrence of postoperative mediastinitis.

Risk strata	Predicted mediastinitis			Observed mediastinitis		
	Yes	No	Total	Yes	No	Total
Not high	20 (10,0)	181 (90,0)	201 (100)	22 (10,9)	179 (89,1)	201 (100)
High	24 (100,0)	0 (0,0)	24 (100)	23 (95,8)	1 (4,2)	24 (100)
Total	44 (19,6)	181 (80,4)	225 (100)	45 (20,0)	180 (80,0)	225 (100)

Data express n (%)

sample, it was predicted that, likewise, all those classified as high risk would suffer the major adverse event and that in those classified as not high risk, it would only appear in 10.7% (**Figure 2**). This shows similar behavior in both prognostic groups 9,7%.

The analysis of the correlation between the predicted probabilities and the observed ones −that is, the occurrence of postoperative mediastinitis− express the construct validity of PREDICMED (**Table 5** and **Figure 3**). Out of the 201 patients with not high risk that PREDICMED predicted that only 10.0% would present postoperative mediastinitis, a 10.9% actually had it; so there was no significant difference, neather there was in the high risk group of patients (100% predicted vs. 95.8% of diseased cases, p> 0.05).

The results of the comparisons of PREDICMED performance and efficacy in the development and validation samples are presented in **table 6**. In both groups of patients the performance indicators are favorable and in the validation sample the best dis-

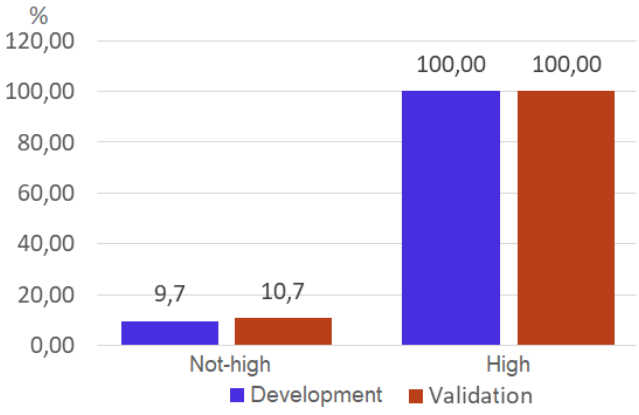


Figure 2. Prediction probabilities percentage, according to strata and type of sample.

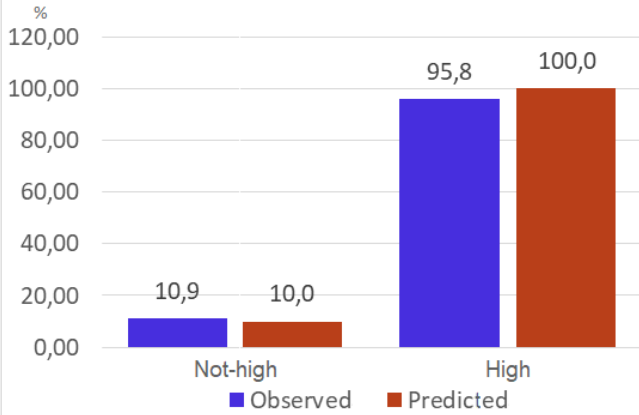


Figure 3. Predicted and diseased cases ratio, according to risk classification.

Table 6. Eficacy and performance of PREDICMED.

Indicators	Development sample	Validation sample
Performance indicators		
Calibration (Hosmer-Lemeshow)	0,524	0,106
Discrimination (ROC area)	0,910	0,962
CI (ROC area)	0,816 – 0,957	0,914 – 1,000
Efficacy indicators		
Sensitivity	62,5	84,62
Specificity	92,97	92,31
Positive predictive values	8,09	9,82
Negative predictive values	99,6	99,84

CI, confidence interval; ROC, receptor operative characteristic.

Table 7. Experts qualitative evaluation of each variable.

Predictor	Calificación
Chronic obstructive pulmonary disease	VA
Postoperative hyperglycemia	VA
Mechanical ventilation time longer than 24 hours.	VA
Transfusion of more than two units of blood products	VA
Postoperative pneumothorax	FA
Endovascular sepsis	VA

Kendall W = 0.409; p<0.0001
FA, fairly appropriate; VA, very appropriate

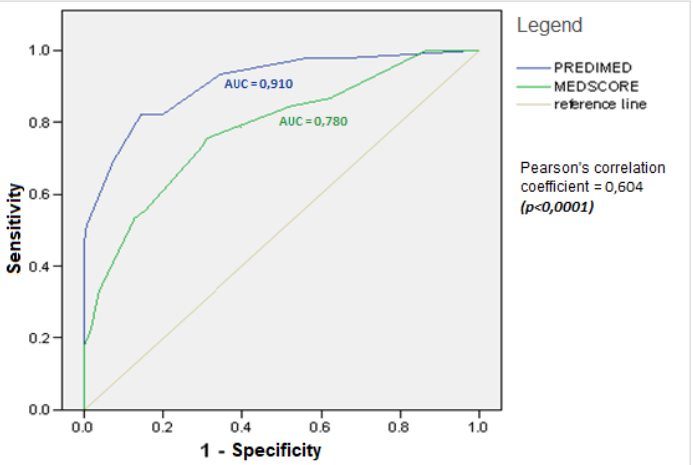


Figure 4. Comparison of discriminatory capacity of PREDICMED and MEDSCORE through ROC curves.

criminatory capacity (0.962) stands out. It was notable that the performance indicators referring to prediction favored the validation group, especially in the values corresponding to sensitivity (84.62%) and to positive predictive value (9.82%), which, although low, for the reason already explained, is slightly higher than in the development sample. Validation was favorable in general according to what the results from the comparative analysis show.

The content assessment of PREDICMED was carried out by experts and it was performed through the pairwise comparison method (**Table 7**). Each one of the predictor variables of the scale could be evaluated qualitatively with the categories very adequate (VA), fairly adequate (FA), adequate (A), poorly adequate (PA) or inadequate (I). Chronic obstructive pulmonary disease, postoperative hyperglycemia, mechanical ventilation time longer than 24 hours, transfusions of more than two units of blood products and endovascular sepsis were classified as VA, and postoperative pneumothorax as FA. In addition, a Kendall's W coefficient of 0.409 (p<0.0001) was obtained, which showed a relatively high consensus among experts, with high statistical significance and low variability in each predictor. Due to these reasons, PREDICMED was considered to have a good content validation.

The criterion of PREDICMED as a prognostic scale was assessed by comparing its discriminatory capacity with that of Medscore, which is an already validated tool for the prediction of postoperative mediastinitis. This was performed through comparison of the area under the curve of both scales (**Figure 4**). Note that both have a good discriminatory capacity, but PREDICMED is superior with an area under the ROC curve of 0.910, which indicates a very accurate value. In addition, the association between both scales was evaluated through Pearson's coefficient, which showed a good correlation of 0.604 between both prognostic tools, with a highly significant statistical difference (p<0.0001).

DISCUSSION

From the statistical point of view, in the prognostic scale and its weighting, the value of the "beta" of the logistic regression model was preferred, which was rounded up to the upper integer. Many authors choose the value of the beta exponential because it coincides with that of the odds ratio´s[7-10], others choose the same method of this study, with other rounding variants[7]; but from the mathematical point of view, and in accordance with the sample and type of study, this is the most accurate method.

Almost all risk scales have three or more strata[10,11]. In PREDICMED only two were preferred due to the use they would have and the available risk predictors. The aim is to stratify the risk of postoperative mediastinitis as an infectious major adverse event of longitudinal median sternotomy. Due to its high lethality, it is necessary to establish effective prevention measures and if a medium level of risk is defined, there would be no clarity in the measures that this group would require; that is to say, it would be complex to adopt a precise behavior in this stratum. For this reason, based on the 90th percentile, the appropriate cut-off point for dividing the strata coincided with the value seven; which is why two groups were defined: not high risk (< 7 points) and high risk (≥ 7 points). In this sense, as shown in **table 2**, PREDICMED correctly classified the total of the analyzed patients.

It is necessary to demonstrate the efficacy of any prognostic scale, for which validation tests are carried out to guarantee its relevance in the prediction of the event under study[1212]:

a) Performance is evaluated through its calibration and discriminatory capacity.
b) Internal or external validation is performed through different methods.
c) Construct validity.
d) Content assessment.
e) Criteria assessment.

To evaluate the performance of PREDICMED, adjustment and calibration techniques were applied, this last one through the Hosmer-Lemeshow test, which is the most widely used for this purpose[13,14]; as it can be seen in the research of Nogues[7], Nieto[8], Oliveira Sá[10] and Machín[15]. Other methods such as logistic regression with the scale and the dependent variable, as well as the Omnibus test and Nagelkerke's R^2 have not been found in the reviewed literature.

The discriminatory capacity of PREDICMED, expressed in **figure 1** is good; with an area under the ROC curve of 0.910. Most of the reviewed scales use this test and its optimal cut-off points to assess their discriminating capacity[5,7-11,13,16,17].

PREDICMED underwent internal validation through the data division method. The 70% of the sample was used for the development of the scale and the remaining 30% for its validation, and its capacities were compared in both samples. The internal validation of a prognostic scale can be performed through methods such as the one applied in this study[18], as well as others such as cross-validation and bootstrapping. The internal one is certainly the most frequently used, especially in small sample size series[13]. It is stated that an external validation would be ideal[13,18], but it is less possible because the preparation of prognostic scales presupposes that they cannot be extrapolated due to the differences in the populations under study in terms of race, economic or social reasons, comorbidities and survival.

The construct validity of PREDICMED was explored according to the correlation between the predicted postoperative mediastinitis and those observed in the sample, information that is provided in **table 5** and **figure 3**. This type of validity has been widely recommended and used in social and psychological sciences[12]. On the other hand, the content of this scale was assessed through the opinion of experts, who were selected for all stages of this research using the recognized method of competences[19], which evaluated the concordance of their opinion through Kendall's coefficient, widely used for these purposes[19].

Finally, the PREDICMED criterion assessment was established by comparing it with other tools already validated for predicting the same type of event[12]. There are several scales, but most of them have been created only for coronary surgery. Recently, based on the Argentine multicenter registry of cardiac surgery statistics, a prognostic scale was developed which predictors are: severe left ventricular dysfunction, reoperation, postoperative renal dysfunction and smoking habit. It has a good calibration and discriminatory capacity, but it has been being used during few time in clinical practice[7]. The research team considered that the most complete scale endorsed for the prediction of postoperative mediastinitis is Medscore[8,20]; therefore, it was selected to compare the discriminatory capacity of PREDICMED.

CONCLUSIONS

The Cuban prognosis scale PREDICMED to predict the risk of postoperative mediastinitis as a major adverse event of the longitudinal median sternotomy was built. Chronic obstructive pulmonary disease, postoperative hyperglycemia, mechanical ventilation time longer than 24 hours, transfusions of more than two units of blood products, postoperative pneumothorax and endovascular sepsis were its six predictors. With this tool to stratify the risk in high and not high is achieved. PREDICMED showed good performance and its internal construct, content and criteria validation was performed.

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Appendix. Criteria of every expert regarding the analyzed variables.

Predictor	E_1	E_2	E_3	E_4	E_5	E_6	E_7	E_8	E_9	E_{10}	E_{11}	E_{12}	E_{13}	E_{14}	E_{15}	RA
COPD	5	5	5	5	5	5	5	5	5	4	5	5	4	5	5	5
Postoperative hyperglycemia	5	5	5	5	5	5	5	5	5	5	5	5	4	5	5	5
Time of MV > 24 hours	5	5	4	5	5	5	5	5	5	4	5	4	4	5	5	5
Transfusion of more than two units of blood products	5	5	5	5	5	5	5	5	5	4	5	5	5	5	5	5
Postoperative pneumothorax	4	4	4	5	5	5	5	5	4	4	4	4	4	4	4	4
Endovascular sepsis	5	5	5	5	5	5	5	5	5	4	5	4	4	5	5	5

Kendall W = 0.409; p <0.0001; Variance < 0.50.
COPD, chronic obstructive pulmonary disease; E, experts; MV, mechanical ventilation; RA, rounded average.