Original Article

InsCor: A Simple and Accurate Method for Risk Assessment in Heart Surgery

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Abstract

Background: Risk scores show difficulties to attain the same performance in different populations.

Objective: To create a simple and accurate risk assessment model for patients submitted to surgery due to coronary and/or valvular disease at Instituto do Coração da Universidade de São Paulo (InCor-HCFMUSP).

Methods: Between 2007 and 2009, 3,000 patients were submitted to surgical procedure due to coronary artery and/or valvular disease at InCor-HCFMUSP. From this record, data of 2/3 of the patients were used for model development (bootstrap technique), and 1/3 for internal validation of the model. The performance of the model (InsCor) was compared to the 2000 Bernstein-Parsonnet (2000BP) and EuroSCORE (ES) complexes.

Results: Only 10 variables were selected: age > 70 years, female sex; coronary revascularization + valve, myocardial infarction < 90 days; reoperation; surgical treatment of aortic valve; surgical treatment of tricuspid valve; creatinine < 2mg/dL; ejection fraction < 30%, and events. The Hosmer Lemeshow test for the InsCor was 0.184, indicating excellent calibration. The area under the ROC curve was 0.79 for the InsCor, 0.81 for the ES and 0.82 for 2000BP, confirming that the models are good and have similar discrimination.

Conclusions: The InsCor and ES performed better than 2000BP at all stages of validation, but the new model, in addition to showing identification with the local risk factors, is simpler and more objective for mortality prediction in patients undergoing surgery due to coronary and/or valvular disease at InCor-HCFMUSP (Arq Bras Cardiol. 2013;100(3):246-254).

Keywords: Cardiac Surgical Procedures, Mortality, Risk Factors, Statistical Models, Risk Assessment.

Introduction

Risk scores can help achieve better results by providing relevant information about patients. Current evidence for evaluating the results in cardiac surgery requires the use of these scores[1,2].

There are, however, different realities between the populations where the models originated and the places where they are applied[3]. In Brazil, the demand for a local model is justified by a more delayed disease presentation, the unequal distribution of hospital facilities, high prevalence of rheumatic disease, and mainly, one of the largest surgical volumes in the world.

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Therefore, as a precautionary measure, remodeling of risk scores (adapting the model to our reality) is always suggested to ensure that local or emerging risk factors do not go unnoticed[4]. For this purpose, each center must maintain its own database[5], and even if a simpler scoring system must sacrifice accuracy in favor of practicality, a new trend toward the creation of local models becomes stronger[6-10].

Nevertheless, it is essential that the study variables be derived from appropriately developed and validated models[11]. Of these, in Brazil, the best results were obtained with the EuroSCORE[12-14] and the 2000 Bernstein-Parsonnet[14]. Thus, remodeling and simplification (as few variables as possible), would result in accurate models with better applicability, as they are cheaper and easier to be added to care practice[15].

Therefore, the aim of this study was to develop a local model (InsCor), validate it and compare it with the 2000BP and EuroSCORE in predicting mortality in patients undergoing surgery for coronary and/or valvular disease at Instituto do Coração of Hospital das Clínicas da Faculdade de Medicina of Universidade de São Paulo (InCor-HCFMUSP).

Methods

Sample

This prospective and observational single center study was carried out at the Division of Cardiovascular Surgery of the Department of Cardiology of InCor-HCFMUSP.

As for the sample size, a rule of simulation studies is that it must have at least 10 events (successes or failures, the rarest) for each variable, regardless of the model[16]. It is also known that, to formulate a model, samples < 100 are risky, whereas the desirable number is > 500. One of the ways to reduce the model coefficient bias is to use the bootstrap techniques[17]. So our sample that included 3,000 patients with 268 deaths would be appropriate to develop a model and its respective validation.

Inclusion and exclusion criteria

Inclusion criteria: All patients (elective, urgency and emergency) submitted consecutively to:

• Valve surgery (valve replacement or repair);

• Coronary artery bypass grafting (on or off-pump);

• Associated surgery (coronary artery bypass surgery + valve surgery).

Exclusion criteria:

• Patients with loss of variables that are pertinent to the study.

• Coronary artery bypass grafting and/or valve surgery in patients < 18 years.

• Associated surgery that is not coronary artery bypass grafting + valve surgery.

Data collection, definition and organization

The data were collected preoperatively at clinical evaluation and from the electronic medical record system of InCor (SI3) and stored in a single spreadsheet. This spreadsheet was adapted in order to include all the variables described by the model of the 2000 Bernstein Parsonnet[18] and EuroSCORE[19]. We collected a total of 60 preoperative variables per patient. All definitions assigned to variables by both scores were observed with their respective values, according to its relevance to the death event.

Thus, after calculating the value of 2000BP and ES for each patient, they were ordered according to risk groups established by the scores. The data were placed in the database created on Excel for this purpose. All patients were followed until hospital discharge. No patient was excluded from analysis due to missing data. The outcome of interest was in-hospital mortality, defined as death occurring in the time interval between surgery and discharge.

Formulation of the local model (InsCor)

The bootstrap technique, together with the "stepwise" variable selection procedure, was used to develop a parsimonious model by multiple logistic regression[20]. This technique was introduced by Efron[21] and attempts to accomplish what would be desirable in practice, "to repeat the experience." The observations are chosen randomly and estimates are recalculated. It treats the observed sample as if it represented the entire population and thus, takes samples of the same size with repetition, therefore generating a large number of samples. The statistical analysis technique is applied in each sample and the desired estimates are obtained. It is expected that these estimates converge to a single estimate. There is strong evidence indicating that the predictive models produced with bootstrap techniques are more stable, have better accuracy and consist of variables that are actual reproducible and independent predictors[22]. For this study, the database that consisted of 3,000 patients, was divided into two groups: the model development group (2,000 patients) and model validation group (1,000 patients).

***Model development group (InsCor)* -** The variables used in the bootstrap samples were the ones that had $p < 0.10$ in the initial univariate analysis. Continuous variables were analyzed with the previously chosen partition during this analysis. Subsequently, the bootstrap technique was used in the first 2,000 patients, selecting 1,000 samples of repetition (each containing 2,000 patients and the same number of cases of death and non-death than that of the original sample). Thereafter, for each sample, the logistic regression model was used with the "stepwise" multivariate selection process and the variables that were selected in each of the 1,000 models obtained were recorded. By the number of times a variable was selected, a variable ranking was performed. Thus, the chosen variables entered the final model in a non-adjusted way, keeping the weight (odds ratio) resulting from the initial univariate analysis.

Model validation* group *(InsCor) - The evaluation of the model performance in data that do not belong to the development model group (next 1,000 patients) is known as internal validation. For that, the InsCor would have to undergo sequential calibration and discrimination tests. **Calibration** – The calibration evaluates the accuracy of the model to predict risk in a group of patients. In other words, the model proposes that mortality in 1,000 patients would be 5% and if the observed mortality is 5% or close to that, we say that the model is well calibrated. The strength of the calibration was assessed by testing the goodness of fit by using the Hosmer-Lemeshow test[23]. The p value > 0.05 indicates that the model fits the data and appropriately predicts mortality. **Discrimination** – The discrimination measures the capacity of the model to distinguish between patients at low and high risk. In other words, if most deaths occur in patients that the model identified as high risk, we say that the model has good discrimination. Conversely, if the majority of deaths occur in patients that the model identified as low risk, we say that the model has poor discrimination. The discrimination is measured by using the statistical technique called area under the ROC curve. Thus, excellent discrimination refers to values above 0.97; very good discrimination is in the range from 0.93 to 0.96, good discrimination between 0.75 and 0.92; and below 0.75 corresponds to models that are deficient in the capacity to discriminate[24].

For better understanding of the study, we also applied the 2000BP and ES in the same validation group.

Statistical Analysis **-** In the development model group, the bootstrap technique was used through the SAS System software version 9.2 for Microsoft Windows[25]. Variables with $p < 0.10$ were identified as plausible predictors of mortality after cardiac surgery. The additive risk was obtained from the estimated beta coefficients of the proposed risk prediction model. The risk categories are defined so that they were similar in size[19]. In the validation group (1,000 patients), the performance of InsCor was compared to that of 2000BP and ES by using the SPSS software, version 16.0 for Windows (IBM Corporation Armonk, New York). Calibration and discrimination were measured for each value of the score in this patient population. The value of $p < 0.05$ was considered significant.

Ethics and Informed Consent Form

This study was approved by the Ethics Committee for Analysis of Research Projects (CAPPesq), Hospital das Clinicas, Universidade de São Paulo under number 1575, being exempted from the need for informed consent explained by the type of the applied design.

Results

Cases

All patients undergoing coronary and/or valve replacement surgery between May 2008 and July 2010 at InCor-HCFMUSP were included in the study. Of the 3,000 patients who underwent surgery, 268 (8.9%) died. Of the total procedures, 57.7% (1,731) underwent coronary revascularization, 36.8% (1104), valve surgery, and 5.5% (165), coronary bypass + valve surgery. For descriptive purposes, Table 1 shows the prevalence of risk factors in the study population, ES and 2000BP.

The developed model: InsCor

After obtaining the models, the variables were ranked according to the number of times they were selected, and we choose the first 10, as we believe that with a reduced number of variables, we could obtain a good score. Thus, the selected model was the best among the three initial models (data not shown) regarding simplicity, objectivity and statistical power to predict mortality. The selected variables in the final model were those that appeared in more than 40% of the 1,000 bootstrap samples.

There was no evidence of first order interaction and multicollinearity between the variables of the final model (Table 2). The additive model was created from the "odds ratios" of selected variables:

InsCor:

(3*age ≥ 70) + (2*femalesex) + (2*CABG + valve) + (2*recentInfarction) + (3*Reoperation) + (2*STAoV) + (3*STTricV) + (5*Creatinine > 2) + (3*EF < 30) + (5*Events).

The additive model of the InsCor can range from 0 to 30. Figure 1 shows the curve of probability of death for all values of InsCor. The model was divided into three categories: low risk (0-3), medium risk (4-7), and high risk (≥ 8). For convenience and better adoption of the model, we created a mnemonic rule with the word FICARTE, in which the first three letters each contain two variables (F: female, ejection fraction, I: age, recent **I**nfarction, C: CABG + valve surgery, creatinine) and other letters one variable each (A: treatment of the **A**ortic valve, R: **R**eoperation, **T**: treatment of tricuspid valve; **E**: events). After the InsCor was developed, it went through the calibration and discrimination processes.

Validation of InsCor and comparison with EuroSCORE and 2000BP (1000 patients)- We performed the internal validation of InsCor in the validation group (1,000 patients). The EuroSCORE and the 2000BP validation was also performed in the same group, to compare them to the InsCor performance. The calibration of the

Table 1 – Prevalence of risk factors in the study group, compared with the risk factors of the population of EuroSCORE and 2000 Bernstein Parsonnet

Variables	Study (n = 3000)	EuroSCORE (n = 19030)	2000BP (n = 10703)	p
Age:				
70-74	12.20%	17.90%	18.50%	< 0.001
>75	11.50%	9.60%	13.70%	< 0.001
Female sex	35.90%	27.80%	31.30%	< 0.001
Chronic obstructive pulmonary disease	2.60%	3.90%	10.80%	< 0.001
Extracardiac arteriopathy	4.80%	11.30%	9.10%	< 0.001
Neurological dysfunction	6.90%	1.40%	8.40%	< 0.001
Previous cardiac surgery	17.80%	7.30%	7.60%	< 0.001
Creatinine > 2.3 mg/dL	4.40%	1.80%	4.50%	< 0.001
EF 30 – 50%	26.10%	25.60%	38.60%	< 0.001
EF < 30%	5.80%	5.80%	8.40%	< 0.001
Pulmonary hypertension > 60mmHg	8.10%	2.00%	10.70%	< 0.001

EF: ejection fraction.

Table 2 - InsCor

Variables		95% Confidence Interval	
	Odds ratio	Lower limit	Upper limit
Age ≥ 70 yrs.	3.14	2.26	4.37
Female sex	1.62	1.17	2.25
CABG + valve surgery	2.28	1.39	3.75
Recent infarction < 90 days	1.40	0.94	2.09
Reoperation	2.87	2.03	4.05
Surgical treatment of aortic valve	2.29	1.62	3.23
Surgical treatment of tricuspid valve	2.58	1.55	4.30
Creatinine > 2mg/dL	4.70	3.01	7.33
Ejection fraction < 30 %	3.24	2.02	5.20
Events (*)	5.48	3.84	7.82

(*) – Includes at least one of the following situations prior to surgery: intra-aortic balloon, cardiogenic shock, ventricular tachycardia or fibrillation, orotracheal intubation, acute renal failure, inotropic drugs and cardiac massage. CABG: coronary artery bypass grafting.

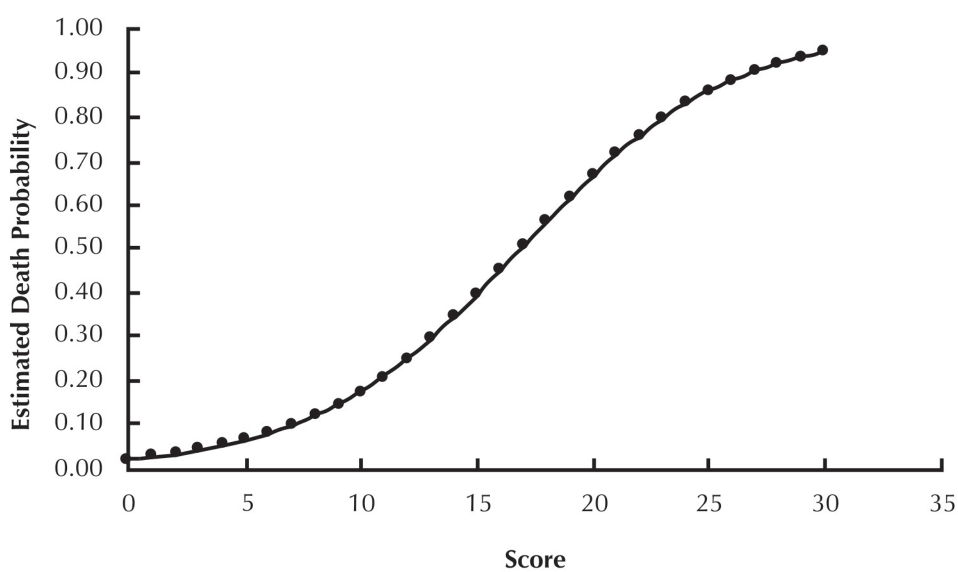

Figure 1 – *Estimated death probability curve according to InsCor.*

Table 3 – InsCor Calibration - Analysis per risk group

Risk	Number of cases	Mortality	
		% observed (95% Confidence Interval)	% predicted (95% Confidence Interval)
0 – 3	437	2.97	4.35
		(1.38; 4.57)	(2.44; 6.26)
4 – 7	317	10.09	8.83
		(6.78; 13.41)	(5.71; 11.96)
≥ 8	246	26.83	26.02
		(21.29; 32.37)	(20.53; 31.50)

Hosmer-Lemeshow Test (p = 0.184).

Table 4 – EuroSCORE Calibration - Analysis per risk group

Risk	Number of cases	Mortality	
		% observed (95% Confidence Interval)	% predicted (95% Confidence Interval)
0 – 2	333	2.10	2.40
		(0.56; 3.64)	(0.76; 4.05)
3 – 5	328	5.79	5.79
		(3.26; 8.32)	(3.26; 8.32)
≥ 6	339	25.07	24.79
		(20.45; 29.69)	(20.18; 29.37)

Hosmer-Lemeshow Test (p = 0.593).

Table 5 – 2000BP Calibration – Analysis per risk group

Risk	Number of cases	Mortality	
		% observed (95% Confidence Interval)	% predicted (95% Confidence Interval)
0 – 8.5	210	0.95	2.38
		(-0.36; 2.27)	(0.32; 4.44)
9 – 14	198	3.03	4.55
		(0.64; 5.42)	(1.64; 7.45)
14.5 – 20	217	5.53	6.45
		(2.49; 8.57)	(3.18; 9.72)
20.5 – 30.5	197	14.21	11.17
		(9.34; 19.09)	(6.77; 15.57)
≥ 31	178	35.39	33.71
		(28.37; 42.42)	(26.76; 40.65)

Hosmer-Lemeshow Test (p = 0.157).

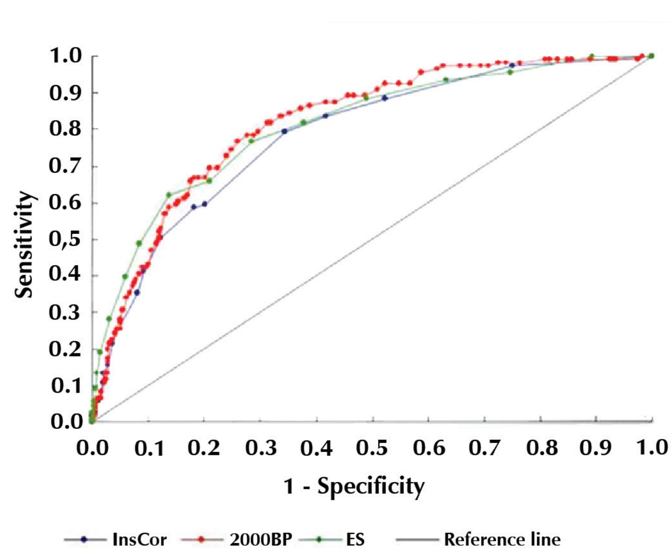

Figure 2 – *ROC curve for InsCor, 2000 Bernstein-Parsonnet (2000BP) and EuroSCORE (ES) to assess the power of discrimination performed in 1,000 patients.*

InsCor was adequate, with p = 0.184 in the Hosmer-Lemeshow test. Table 3 shows the calibration of the InsCor per risk groups. The calibration of EuroSCORE (p = 0.593) and 2000BP (p = 0.157) were also adequate in the Hosmer-Lemeshow test and grouped by risk groups in Tables 4 and 5, respectively. As for the discrimination, the area under the ROC curve was 0.79 for the InsCor, 0.81 for the ES and 0.82 for the 2000BP (Figure 2).

Table 6 shows an overlap of confidence intervals of the three models, showing no significant difference in the discrimination between the InsCor, ES and 2000BP.

Thus, each variable selected to create the InsCor e, its obtained value can be used to predict in-hospital mortality in patients undergoing surgery due to coronary artery and/or valvular disease at InCor-HCFMUSP.

Discussion

The great advantage of risk prediction models in cardiac surgery based on preoperative data is to allow the stratification of patients for the procedure, and being able to plan the intraoperative and postoperative period. We know that it is not possible to impartially compare institutions and professionals without considering the prevalence of risk factors, particularly when there is a significant difference as shown in this study (Table 1). However, we can see that models consisting of truly predictive variables (2000BP and EuroSCORE) managed to achieve good results in this first evaluation and for this outcome. The InsCor model, related to the prevalence of risk factors in the study population, did not show better discrimination power, when compared with the EuroSCORE and 2000BP.

Even though the aim of the study was to create a parsimonious model, and above all, a simple and objective one, it is important to report that local models include hidden variables that do not appear due to the multicollinearity of variables and sample size to be validated[11,15]. Jones et al[26], specifically analyzing myocardial bypass surgery (CABG), suggest that most of the information regarding prognosis is contained in relatively few clinical variables. Tu et al[27] at the time and Ranucci et al[15], currently, tested this proposal and concluded that simple models containing only the essential variables are as effective as complex models to evaluate results.

In 2007, Gomes et al[28] published in Brazil, the first Brazilian model for local use, but the internal validation of the model was not performed, which ended up as optimistic validation. Moreover, this model includes intraoperative variables and those from the first postoperative day, which hinders its applicability. In the same year, Antunes et al[7], analyzing 4567 patients undergoing isolated CABG, formulated a model with seven variables. The bootstrap technique was chosen, for the first time, for prediction models in cardiac surgery. The local model, called the Coimbra score, showed an area under the ROC curve of 0.752.

The InsCor created for patients undergoing CABG, valvular and associated surgeries, showed the following variables shared with the Coimbra score: age ≥ 70 years, reoperation and ejection fraction < 30%. The InsCor, even with three variables that are specific for valvular disease, can show an area under the ROC curve of 0.79. In 2008, D'Errigo et al[29] developed a model derived from the "Italian CABG Outcome Project". This model, which consists of 14 variables, has five variables that are shared with InsCor (age, female gender, creatinine > 2mg/dL, reoperation, and ejection fraction).

In this analysis, the additive EuroSCORE (p = 0.228) and the Italian model (p = 0.170) showed good calibration. In our analysis, it was also adequate with p = 0.595 for the EuroSCORE and p = 0.184 for InsCor. Regarding the discrimination, the area under the ROC curve was 0.796 for the Italian model, and 0.773 for the additive EuroSCORE, similar to that found in our study with an area under the ROC curve of 0.79 for the InsCor and 0.81 and for the additive EuroSCORE. In 2009, Ranucci et al[15] demonstrated, in Italy, that limiting the number of variables used by EuroSCORE would decrease the risk of overadjustment, multicollinearity and human error. Thus, the best model was obtained with five variables; of these, only emergency surgery is not shared with the InsCor. The area under the ROC curve for this model was 0.76 when compared to 0.75 in EuroSCORE, with no significant difference.

In 2010, Billah et al[10] published in Australia a twelve-variable model, also a product of the bootstrap technique. This model showed five variables related to InsCor (age, sex, reoperation, ejection fraction and type of procedure). In the Australian model calibration, the Hosmer-Lemeshow test showed a p = 0.81, compared to 0.18 of InsCor. The area under the ROC curve of the Australian model was 0.813 vs. 0.79 for the InsCor. The population size for the validation of the Australian model was ten times greater than the validation group of InsCor and this fact may have influenced the validation test results.

In the same year, Cadore et al[9] in Brazil, published the first preoperative risk score for patients undergoing CABG. This retrospective analysis of 1875 patients operated between 1996 and 2007 showed an area under the ROC

Table 6 – Area under the ROC curve for InsCor, the 2000 Bernstein-Parsonnet (2000BP) and EuroSCORE (ES) performed in 1,000 patients

	Area	95%CI	Standard Error	p
InsCor	0.79	0.74 – 0.83	0.02	< 0.001
2000BP	0.82	0.78 – 0.86	0.02	< 0.001
ES	0.81	0.77 – 0.86	0.02	< 0.001

95%CI: 95% confidence interval

curve of 0.86; however, the timing of surgery (> 5 years) and high mortality could overestimate results nowadays. Of the eleven variables in the model, four variables are shared with InsCor age, female sex, ejection fraction and creatinine. But the quantitative variables used show different cutoffs.

In March 2011, Shih et al[30] published in Taiwan, a multivariable analysis that showed seven risk factors; of these, four variables are shared with InsCor (age, critical preoperative condition, associated surgery, ejection fraction < 30). In March 2011, Berg et al[31] published in Norway, an analysis using the EuroSCORE (additive + logistic) in 5029 patients undergoing cardiac surgery. A preoperative model with eight variables shared three variables with InsCor: age, female gender and previous cardiac surgery.

In April 2011, a study published in Pakistan by Qadir et al[32] retrospectively analyzed 2004 patients submitted to isolated CABG. The multivariate analysis selected five variables; of these, three are related to InsCor (age, sex, and recent myocardial infarction).

The bootstrap technique with automated stepwise variable selection procedures is the newest innovation in prediction models for cardiac surgery. These models are convenient because they express the patient's overall risk represented by the sum of the values assigned to each variable. The disadvantage is the low-precision attributed to the scoring systems when compared to regression models, as rounding of numerical values and continuous variable grouping are performed[33]. However, the performance difference does not seem to be clinically important[34].

The InsCor considers the tricuspid valve surgery as a predictor of mortality, as well as the Pons[35] and 2000BP[18] models. However, in other models[36,37], it is pulmonary hypertension, instead. It could be the multicollinearity; however, the 2000BP considers the two variables in its model and at the bootstrap (ranking of variables) for the formulation of InsCor, pulmonary hypertension occupied the 13th position.

The only models that consider aortic valve surgery as a mortality predictor variable are the initial model of Parsonnet[36] and the InsCor. Except for InsCor, no current model considers aortic valve surgery as a predictor of mortality. Hidden variables, not clarified in the study and probably related to later disease manifestation, may have influenced the results.

The evidence confirms that the patient's preoperative clinical condition is the primary determinant of surgical outcomes. Isolated variables prior to surgery, such as intra-aortic balloon, cardiogenic shock, ventricular tachycardia or fibrillation, orotracheal intubation, acute renal failure, inotropic drugs and heart massage are important, but lose strength in the analysis because they are infrequent; thus, the combined variable critical preoperative status is necessary, being a predictor variable in InsCor and other risk models[19,36,37].

Study limitations

The limitations of this study were as follows: first, the InsCor was validated at a single center (internal validity), so the most important limitation is the generalization of the results (external validity). Second, although hospital mortality (up to 30 days after surgery) appears to be more complete than the in-hospital mortality (until discharge), current definitions suggest that both have equivalent accuracy, with in-hospital mortality being more practical and easy to use[38]. Third, advances in perioperative care in cardiac surgery could be better compared with the EuroSCORE II[39], especially where the EuroSCORE lost calibration, which was not demonstrated in our reality.

Thus, the InsCor allows monitoring of results over time and the control and follow-up of risk factors, both known and unknown, which may change their prevalence. It is comprehensive and can be used in 80%-90% of all adult cardiovascular surgeries at InCor-HCFMUSP. Therefore, it is the product of the synthesis of two of the most popular models (2000BP and ES) adapted to our reality.

Finally, we can say that the InsCor has similar performance to EuroSCORE and it is simpler than the latter and 2000BP to predict mortality in patients undergoing surgery in InCor-HCFMUSP. Thus, its external validation at level national is mandatory for its consolidation as the first preoperative risk score for coronary revascularization and/or valve surgery in Brazil.

Conclusions

InsCor was developed locally through the bootstrap technique. This model showed adequate validation and was comparable to the 2000 Bernstein Parsonnet and EuroSCORE in predicting mortality in patients undergoing coronary and/or valve surgery at Incor-HCFMUSP. This is our proposal for the future of risk assessment in coronary artery bypass and/or valve surgery in Brazil.

Author contributions

Conception and design of the research: Mejía OAV, Lisboa LAF, Puig LB, Moreira LFP, Pomerantzeff PMA, Jatene FB; Acquisition of data and Statistical analysis: Mejía OAV; Analysis and interpretation of the data: Mejía OAV, Lisboa LAF, Moreira LFP, Stolf NAG; Obtaining funding: Mejía OAV, Dallan LAO, Stolf NAG; Writing of the manuscript: Mejía OAV, Lisboa LAF, Stolf NAG; Critical revision of the manuscript for intellectual content: Mejía OAV, Lisboa LAF, Moreira LFP, Dallan LAO, Stolf NAG.

Potential Conflict of Interest

No potential conflict of interest relevant to this article was reported.

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Study Association

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