Rev Bras Cir Cardiovasc 2013;28(2):263-9

Heart surgery programs innovation using surgical risk stratification at the São Paulo State Public Healthcare System: SP-SCORE-SUS STUDY

Estratificação de risco cirúrgico como instrumento de inovação em programas de cirurgia cardíaca no Sistema Único de Saúde do Estado de São Paulo: ESTUDO SP-SCORE-SUS

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DOI: 10.5935/1678-9741.20130037

RBCCV 44205-1466

Abstract

Cardiovascular diseases represent the greatest burden of morbidity and mortality for the health system and cardiac surgery has an important impact on their resolutivity. The association and correlation of patients' demographic and clinical relevant information with the resources required for each stratum represent the possibility to adapt, improve and innovate into the healthcare programs. This project aims to remodel the "InsCor" risk score for the formulation of the SP-SCORE (Sao Paulo System for Cardiac Operative Risk Evaluation) in order to better reflects the complexity of cardiac surgical care. The participating hospitals include the Health Technology Assessment Centers in of the Health Secretariat' HTA Network of São Paulo State (HTA-NATSs / SES-SP). The SP-SCORE will use 10 variables of the InsCor model and others 8 variables with presumed influence in Brazil. The primary endpoints are morbidity and mortality. Bootstrap technique besides automated selection of variables (stepwise) will be used to develop a parsimonious model by multiple logistic regression. This project will contribute for the SUS-SP regionalized health-care (RRAS) sustainability and financing of the CABG and/or heart valve surgery programs promoting equitable allocation, increasing access and effectiveness, as well as characterizing the magnitude of available resources and its impact.

Descriptors: **Risk factors. Cardiovascular surgical procedures. Hospital mortality. Morbidity. Database.**

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Support: FAPESP, CNPq and DCIT/MS.

Article received on February 1st, 2013
Article approved on May 17th, 2013

Abbreviations, acronyms & symbols	
ADGs	Aggregated Diagnosis Groups
CAPPesq	Ethics Committee for Research Projects Analysis
	Extended Diagnosis Clusters
EDCs	Health Care Financing Administration
HCFA	Health Technology Assessment Centers of the Health
NATSs/SES-SP	Secretariat of the state of São Paulo
NYHA	New York Heart Association
RRAS	Regionalized Healthcare Network
SP-SCORE	São Paulo System for Cardiac Operative Risk Evaluation

Resumo

Doenças cardiovasculares representam a maior carga de morbimortalidade para o sistema de saúde e a cirurgia cardíaca desempenha importante impacto na sua resolutividade. O agrupamento das informações demográficas e clínicas relevantes dos pacientes acometidos, no nível de estratos específicos e em correlação com os conjuntos de recursos requeridos, representa a possibilidade de adaptar, aprimorar e inovar nos programas assistenciais. Este projeto tem por objetivo remodelar o escore de risco "InsCor" para formulação do SP-SCORE (São Paulo System for Cardiac Operative Risk Evaluation), visando refletir melhor a complexidade da assistência cirúrgica cardíaca. Os hospitais participantes integram os Núcleos de Avaliação de Tecnologias da Secretaria de Estado da Saúde de São Paulo (NATSs/SES-SP). Para a elaboração do SP-SCORE, serão utilizadas as 10 variáveis do modelo InsCor e 8 outras com suposta influência no Brasil. Os desfechos primários consistem na morbidade e na mortalidade hospitalar. A técnica de bootstrap junto a procedimentos de seleção automatizada de variáveis "stepwise" será utilizada para desenvolver um modelo parcimonioso por meio da regressão logística múltipla. Este projeto visa subsidiar a sustentabilidade e o financiamento do SUS-SP para as Redes Regionalizadas de Atenção à Saúde (RRAS) de cirurgias de coronária e/ou valva, promovendo alocação equitativa, incremento do acesso e efetividade, bem como caracterizar a magnitude dos recursos disponíveis e seu impacto.

Descritores: **Fatores de risco. Procedimentos cirúrgicos cardiovasculares. Mortalidade hospitalar. Morbidade. Base de dados.**

INTRODUCTION

Cardiovascular diseases represent the greatest burden of morbidity and mortality for the health system and cardiac surgery has had major impact on their resolution [1]. However, Brazilian programs lack many subsidies. The grouping of relevant demographic and clinical data of affected patients, in specific strata and correlated with a set of required resources, can help in adapting, improving and innovating assistance programs.

The biggest example is in the state of New York, where a public mandatory registry of every cardiac surgery performed in the state allows for gradual improvement of results [2]. Great Britain was the first to learn from this process [3] followed by other American states [4-7]. The same happens in Brazil, with better systematization and technology in one of the countries with the largest volume of cardiac surgery in the world [8].

Currently, the use of risk scores for decision making (indication level) in cardiac surgery is based on good levels of scientific evidence [9]. That is why the use of EuroScore [10], the most popular model, in main European services has led to the Hawthorne effect, showing that nothing has improved cardiac surgery results in the beginning of the century as much as integration and monitoring through EuroScore [11].

However, caution should be exercised when using models derived from different realities as they must first be validated and ideally remodeled [12]. As an example, rheumatic disease is highly prevalent in Brazil, where the application of known models derived from populations with diseases of predominantly degenerative etiology is questionable.

In our midst, formulation of InsCor [13], a product of the remodeling of two of the most popular models [10,14] that had been validated [15] and adapted to our reality, has become an important instrument for patients being treated at InCor-HCFMUSP. Therefore, in order to better reflect the complexities of cardiac surgical assistance in the state of São Paulo, this study sets out to remodel InsCor to create the SP-SCORE (São Paulo System for Cardiac Operative Risk Evaluation).

METHODS

Design

Prospective cohort, blind, and multicenter study; based at state level and on consecutive case reports.

Sample

Patients who underwent coronary and/or heart valve surgery, within established inclusion period, will be consecutively included in the study.

Initially, data will be collected from eight centers belonging to the Health Technology Assessment Centers of the Health Secretariat of the state of São Paulo (NATSs-SES-SP).

Blinding will take place in terms of data origin. Stratified analysis of diagnostic subgroups will be performed so that no hospital data will be assessed in isolation.

Outcomes

A. Structure and resources installed (defined as a set of departments, processes, approaches, and personnel available for diagnosis, therapy, and rehabilitation used in these cases);

B. Morbidity (stroke; postoperative myocardial infarction; acute renal failure) or;

C. Surgical mortality (defined as death from any cause occurred within 30 days after the surgical procedure).

Participating centers

- Clínicas Hospital of State University of Campinas;
- Irmandade Santa Casa of Marília;
- Clínicas Hospital of Ribeirão Preto;
- Base Hospital of State Medical School of São José do Rio Preto;
- Heart Institute – HCFMUSP;
- Irmandade Santa Casa de Misericórdia of São Paulo;
- Clínicas Hospital of Botucatu Medical School.

Duration of study

24 months.

Inclusion criteria

- Patients aged 18 or older;
- Indications for coronary and/or heart valve surgery;
- Agreement to participate in the study and signing of a written informed consent form.

Exclusion criteria

- Indications for associated surgery, except coronary + valve;
- Inability to access variables relevant to the study.

Variables

Variables chosen were the ones derived from the InsCor model [13]: age ≥ 70 years old; female; associated surgery (myocardial revascularization + valve); recent myocardial infarction < 90 days; reoperation; surgical treatment of aortic valve; surgical treatment of tricuspid valve; creatinine > 2 mg/dl; ejection fraction < 30%; and events (including at least one of the following situations prior to surgery: intra-aortic balloon, cardiogenic shock, tachycardia or ventricular fibrillation, orotracheal intubation, acute renal failure, use of inotropic drugs, and cardiac massage).

Other variables with alleged influence in Brazil, according to their prevalence are [15]: differences in clinical presentation due to socioeconomic, cultural, and geographical factors; uneven distribution of medical facilities; and high endemicity of subclinical inflammation, infection and rheumatic disease. Thus, the other variables collected would be: heart rheumatic disease, defined by Jones criteria adapted for heart rheumatic disease [16]; functional class, established by New York Heart Association (NYHA) [17] to assess the progression of the disease in its presentation [18]; educational level, defined as none, primary, secondary, and university, based on available evidence [19] correlated with differences found in Brazil; previous coronary stent, as evidenced in the national context [20]; systolic pulmonary pressure, determined through echocardiographic methods and directly related to severity and progression of cardiac disease [21]; emergency, defined as high risk of death unless surgery is performed within 24 hours of hospitalization, and urgency, defined as high risk of death with surgery being performed after the first 24 hours of hospitalization (these variables, though not very objective, have proven to be predictors of death in major risk models) [10,14]; atrial fibrillation, diagnosed through electrocardiogram or heart monitor before the beginning of surgery, considered as an independent variable in mortality of patients who underwent cardiac surgery [22]; and insulin-dependent diabetes, defined by continuous use of any type of insulin [23], where category would be chosen in accordance with the new EuroScore II [24].

Statistical analysis

The acquired database will be randomly divided into two groups: a development group (2/3 of the sample), which will be used to build the risk model, and a validation group (1/3 of the sample), which will be used to test and validate the model.

Model development group: SP-SCORE-SUS

Bootstrapping as well as automated selection of variables (stepwise) will be used to develop a parsimonious model by multiple logistic regression [25]. This technique attempts to do what would be desirable in real life: "replicate the experiment". Observations are randomly selected and estimates are recalculated. The technique assumes that the observed sample is representative of the population, and then same-size samples are repetitively selected, generating a large number of samples. The statistic solution in applied to each individual sample in order to extract desired estimates. It is expected that these separate estimates will converge into a single one.

The variables used in the present study had a $P<0.10$ in the initial univariate analysis. Continuous variables will be analyzed according to the partition previously chosen during the analysis. Next, bootstrapping will be used in 2/3 of the population by selecting 1000 repeated samples (every one of them containing the same number of cases of death and non-death as the original sample). Later, stepwise multiple logistic regression models will be carried out for every sample and the variables that are selected for every one of the 1000 models generated will be recorded. Ranking of variables will consist of the number of times a variable is selected. Hence, chosen variables will be not be adjusted in the final model, keeping their odds ratio from the initial univariate analysis.

Model validation group

Assessment of model performance of data not derived from the development group (1/3 of the population) is known as internal validity. In this regard, model accuracy will be assessed through computation of sensibility, specificity, and positive and negative predictive values in addition to sequential tests for calibration (Hosmer Lemeshow goodness-of-fit test) and discrimination (ROC curve) [26].

Ethics

This study was approved by the Ethics Committee for Research Projects Analysis (CAPPesq), Clínicas Hospital, University of São Paulo Medical School, under number 9696, in accordance with the Declaration of Helsinki.

DISCUSSION

In the history of cardiovascular surgery, the event that led to the advent of risk scores for patient stratification was the publication of gross results, without risk adjustment, of mortality in American hospitals by the Health Care Financing Administration (HCFA) in March 1986 [27]. Twenty years later, a similar event took place in Brazil [28] when it was published that there was 8% mortality (without risk adjustment) in patients who undergo cardiac surgery in Brazil's Unified Public Health System (SUS). Results that are stratified according to complexity groups help health system managers to predict how many and which resources are needed for diagnosis, therapy, and rehabilitation so that excellence programs can be established. Furthermore, they allow for estimation of specific probabilities of transitions among several stages of morbidity which are present or prevalent in our midst [29]. In Canada, a description of the 5% top users of the health system enabled the identification of the combination of factors and chronic and acute diagnoses of these patients in addition to the most efficient and integrated strategies to assist them [30]. Different but complementary perspectives on the prevalent morbidity in these cases can be verified through the Aggregated Diagnosis Groups (ADGs) and Extended Diagnosis Clusters (EDCs) [31]. Other studies have shown that recognizing the complexity of cases, in terms of both outpatient [32-35] and hospital care [36-38], can lead to optimized and patient-oriented management strategies and solutions. In the state of São Paulo, stratification adjusted for risk factors together with underlying morbidity can help to identify improvement opportunities, policy strategies for allocation of differentiated resources, or cases where there is a need to structure more complex services so that procedures in cardiac surgeries can be done.

Jones et al. [39], regarding myocardial revascularization specifically, suggest that most of the information related to prognoses is in relatively few clinical variables. At the time, Tu et al. [40], and, currently, Ranucci et al. [41] tested this proposition (PANEL Group) and concluded that simpler models containing only essential variables not only would reduce the risk of juxtaposition, multicollinearity, and human error, but would also be cheaper than complex models. That is the explanation for dropping the number of variables collected per patient for EuroScore and EuroScore II, from 97 to 29, respectively. Thus, the current trend when choosing an instrument for risk assessment in cardiac surgery is based on the comeback of the remodeling concept described by the groups, who besides applying a model, reshape it, by adding or simplifying variables according to their reality. New unique models, which have been validated and compared to international ones, have been created out of these applications [42-45].

In our midst, it has been proven that InsCor and EuroScore performed better than the 2000Bernstein Parsonnet in every step of the validation process. However, InsCor, besides identifying with local risk factors, was simpler and more objective when predicting mortality in patients who had undergone coronary and/or heart valve surgery at InCor-HCFMUSP [13]. Therefore, taking InsCor statewide (remodeling it) is a key strategy to disclose the appropriate model for evaluating results of coronary and/or heart valve surgeries in the state of São Paulo.

Consequently, this project sets out to build arguments to subsidize SUS-SP regionalized health-care (RRAS) sustainability and financing of coronary and/or heart valve surgeries (conventional and new technologies), promoting equitable allocation, increasing access and effectiveness, as well as characterizing the magnitude of available resources and their impact.

Throughout the study, every center will be able to better observe the complexity of patients who underwent surgery, the resources they require, their own performance as surgeons in addition to differences and changes in the risk profile of these patients. During the preliminary and the final analysis, every center will be assigned a state average compiled from data provided by every participating center to parametrize their own observed average in terms of complex-

ity strata of their cases. At the same time, with the support of Health Secretariat of the state of São Paulo, the present study will start the "Registro Estadual Paulista de Cirurgia Cardiovascular" (Paulista State Registry of Cardiovascular Surgery), in order to improve the quality of the results as well as the safety of patients who underwent cardiac surgery in the state of São Paulo.

ACKNOWLEDGEMENTS

Besides the authors of this study, the SP-Score-SUS study group consists of the following professors: Dr. Nelson Yatsuda, Dr. Fátima Bombarda, Dr. Paula Tanaka, Dr. Daniele Marie Guerra, Dr. Orlando Petrucci Junior, Dr. Joaquim Murray Bustorff Silva, Dr. Rubens Tofano de Barros, Dr. Lucieni Oliveira Conterno, Dr. Marcos Gradim Tiveron, Dr. Walter Villela de A. Vicente, Dr. Paulo Roberto Barbosa Évora, Dr. Domingo Marcolino Braile, Dr. Carlos Alberto dos Santos, Dr. Marcelo Nakazone, Dr. Maurício de Nassau Machado, Dr. Luiz A. Rivetti, Dr. Eduardo Gregório Chamlian, Dr. Antônio Sérgio Martins, and Dr. Silvana Andrea Molina Lima.

This study is supported by the Foundation for Research Support of the State of São Paulo (FAPESP), in partnership with the Health Secretary of São Paulo (SES-SP), the Ministry of Health (MOH) and National Council for Scientific and Technological Development (CNPq).

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