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Stratification of complexity in congenital heart surgery: comparative study of the Risk Adjustment for Congenital Heart Surgery (RACHS-1) method, Aristotle basic score and Society of Thoracic Surgeons-European Association for Cardio-Thoracic Surgery (STS-EACTS) mortality score

Estratificação da complexidade em cirurgias de cardiopatias congênitas: comparação dos modelos Risk Adjustment for Congenital Heart Surgery (RACHS-1), escore básico de Aristóteles e escore de mortalidade da Society of Thoracic Surgeons-European Association for Cardio-Thoracic Surgery (STS-EACTS)

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Abstract

Objective: **To determine whether stratification of complexity models in congenital heart surgery (RACHS-1, Aristotle basic score and STS-EACTS mortality score) fit to our center and determine the best method of discriminating hospital mortality.**

Methods: **Surgical procedures in congenital heart diseases in patients under 18 years of age were allocated to the categories proposed by the stratification of complexity methods currently available. The outcome hospital mortality was calculated for each category from the three models. Statistical analysis was performed to verify whether the categories presented different mortalities. The discriminatory ability of the models was determined by calculating the area under the ROC curve and a comparison between the curves of the three models was performed.**

Results: **360 patients were allocated according to the three methods. There was a statistically significant difference between the mortality categories: RACHS-1 (1) - 1.3%, (2) - 11.4%, (3)- 27.3%, (4) - 50 %, (*P*<0.001); Aristotle basic score (1) - 1.1%, (2) - 12.2%, (3) - 34%, (4) - 64.7%, (*P*<0.001); and STS-EACTS mortality score (1) - 5.5 %, (2) - 13.6%, (3) - 18.7%, (4) - 35.8%,**

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Abbreviations, acronyms & symbols	
CI	Confidence Interval
EACTS	European Association for Cardio-Thoracic Surgery
RACHS-1	Risk Adjustment for Congenital Heart Surgery-1
STAT	Society of Thoracic Surgeons-European Association for Cardio-Thoracic Surgery
STS	Society of Thoracic Surgeons

(*P*<0.001). The three models had similar accuracy by calculating the area under the ROC curve: RACHS-1- 0.738; STS-EACTS- 0.739; Aristotle- 0.766.

***Conclusion:* The three models of stratification of complexity currently available in the literature are useful with different mortalities between the proposed categories with similar discriminatory capacity for hospital mortality.**

***Descriptors:* Hospital Mortality. Heart Defects, Congenital. ROC Curve. Cardiac Surgical Procedures.**

Resumo

***Objetivo:* Verificar se os modelos de estratificação da complexidade em cirurgias de cardiopatias congênitas atualmente disponíveis (RACHS-1, escore básico de Aristóteles e escore de mortalidade do STS-EACTS) se adequam ao nosso serviço, determinando o de melhor acurácia em discriminar a mortalidade hospitalar.**

***Métodos:* Procedimentos em pacientes menores de 18 anos foram alocados nas categorias propostas pelos modelos de estratificação da complexidade. O desfecho de mortalidade hospitalar foi calculado para cada categoria dos três modelos. Análise estatística foi realizada para verificar se as categorias apresentavam distintas mortalidades dentro de cada modelo. A capacidade discriminatória dos modelos foi determinada pelo cálculo de área sob a curva ROC e uma comparação entre as curvas dos três modelos foi realizada.**

***Resultados:* 360 pacientes foram alocados pelos três modelos. Houve diferença estatisticamente significante entre as mortalidades das categorias propostas pelos modelos de RACHS-1 (1) - 1,3%, (2) - 11,4%, (3) - 27,3%, (4) - 50%, (*P*<0,001); escore básico de Aristóteles (1) - 1,1%, (2) - 12,2%, (3) - 34%, (4) - 64,7%, (*P*<0,001); e escore de mortalidade do STS-EACTS (1) - 5,5%, (2) - 13,6%, (3) - 18,7%, (4) - 35,8%, (*P*<0,001). Os três modelos tiveram semelhante capacidade discriminatória para o desfecho de mortalidade hospitalar pelo cálculo da área sob a curva ROC: RACHS-1- 0,738; STS-EACTS- 0,739; Aristóteles- 0,766.**

***Conclusão:* Os três modelos de estratificação da complexidade atualmente disponíveis na literatura tiveram utilidade com distintas mortalidades entre as categorias propostas, com semelhante capacidade discriminatória para o desfecho de mortalidade hospitalar.**

***Descritores:* Mortalidade Hospitalar. Cardiopatias Congênitas. Curva ROC. Procedimentos Cirúrgicos Operatórios.**

INTRODUCTION

After half a century of developments in the diagnosis and surgical treatment of congenital heart disease, significant progress has been made and, nowadays, we may state that the natural history of these patients has been modified[1].

In parallel evolution, we had the development of universally accepted tools that allowed the establishment of benchmark outcomes, crucial for comparisons between different periods and institutions. In this scenario, aiming to improve the quality of patient care for surgical congenital heart diseases, scientific societies joined forces (STS- Society of Thoracic Surgeons, EACTS- European Association for Cardio-Thoracic Surgery and the Association for European Paediatric Cardiology) seeking a common classification for use in a multicenter database[2,3].

Among the essential elements for the establishment of a database universally accepted, stands out beyond the need for a standard nomenclature of congenital defects and surgical procedures, the creation of stratification of complexity methods[4-6].

Given the large number of different surgical procedures (more than 150) in congenital heart disease, it became necessary the grouping into categories or relatively homogeneous strata, so that the comparisons between the outcomes were performed within each category. In pediatric cardiac surgery, mortality analysis without stratification of complexity is considered failure[7] and this risk stratification has been identified as essential in the organization of multicenter database STS-EACTS and appears as one of the key points in a recent article that aimed at assessing and improving the quality[8,9].

The stratification of complexity methods

RACHS-1 method

The RACHS-1 method was developed by the Children's Hospital Boston team through a panel of 11 nationally representative members of pediatric cardiologists and cardiac surgeons. Initially using clinical judgment, with further refinement based on 2 national databases data, it allocated 207 surgical procedures in 6 different categories with similar risk for hospital mortality. Three additional clinical factors (age, prematurity and noncardiac congenital structural abnormalities) complement the model and, when used, increase the discriminatory power of the model.

Aristotle score

In 1999, Lacour Gayet and a committee of experts created a tool for stratification of complexity and called it a score of Aristotle, in reference to the philosophy of Aristotle (Rhetoric, Book I, 350 BC): "Where there is no available scientific answer, the opinion perceived and accepted by the majority has the truth value".

A group of 50 surgeons from 23 countries, representatives of the four largest international societies of pediatric cardiac surgery (STS, EACTS, Congenital Heart Surgeons Society - CHSS and ECHSA), postulated that the complexity of a procedure would be the sum of 3 factors: 1- Potential for operative mortality; 2- Potential for operative morbidity and 3- Technical difficulty of the surgery.

Each surgical procedure received a score for each of the three factors ranging from 0.5 to 5, forming a score which ranged from 1.5 (0.5 + 0.5 + 0.5) to 15 (5 + 5 + 5). The procedures were divided into categories (similar to RACHS-1) according to the score: Level 1 (1.5 to 5.9); Level 2 (6.0 to 7.9); Level 3 (8.0 to 9.9) and Level 4 (10.0 to 15.0). According to the required analysis, both score and level (categories) may be used.

In a second step, the Aristotle score received some refinements according to the patient characteristics, until then, stratified only taking into account the type of procedure performed. The so-called "Comprehensive Aristotle Score" adds some patient factors dependent or not of the procedure. Because it is not part of the aim of our study, we will not go into details of this method.

STS-EACTS mortality score

The newest of the three tools for stratification of complexity is the STS-EACTS mortality score, published in 2008. It was developed primarily using objective data, with minimal use of subjective probability. The mortality risk was estimated for 148 procedure types, using real data from 77,294 patients (33,360 patients from the EACTS and 43,934 patients from the STS) between 2002 and 2007. Using Bayesian statistics that fits the data for small denominators, mortality rates were calculated for each procedure.

Each procedure received a score which ranged from 0.1 to 5.0, based on the estimated mortality. The procedures were then distributed by the growing risk and grouped into 5 categories. This model had its performance subsequently evaluated in an independent sample of 27,700 patients and compared with previous methods (RACHS-1 and Aristotle).

The STS-EACTS mortality score represents an evolution of the previous stratification models which were highly subjective.

The new score stratifies the mortality according to real data for each surgical procedure from the STS-EACTS multicenter database.

The main objective of this study is to verify whether the stratification of the complexity methods for congenital heart surgery currently available (RACHS-1, Aristotle basic score and STS-EACTS mortality score) is useful, showing different mortality rates between the proposed categories, and to determine which method is best suited to our institution.

METHODS

Patients

We retrospectively reviewed 360 consecutive patients who underwent surgical treatment for congenital heart disease from June 2007 to December 2012, at the Pronto Socorro Cardiológico de Pernambuco (PROCAPE), University of Pernambuco. The Research Ethics Committee has been approved the study (CAAE 06036313.5.0000.5192 number).

Patients aged under 18 years, who underwent palliative surgery or definitive correction were eligible, including those who presented with any dysfunction or organ failure at the time of correction (hemodynamic, respiratory, renal, hepatic, neurological and hematological). The patients who underwent surgery had their outcomes established (hospital mortality or discharge).

Data collection was performed through multiple sources of information available, and at each step the data consistency was verified. Surgical reports, extracorporeal perfusion report, administrative data from the hospital system and patient files were checked in search for the information. Data were collected and stored in the Excel software, with double data entry.

The variables used to characterize the patients were: gender, age, weight and height.

The exclusion criteria were: reoperation for hemostasis, permanent pacemaker implantation and those cases in which the proposed surgery could not be performed after the surgical access. When a patient had undergone more than one surgical procedure in the same hospital admission, the most complex procedure was computed.

Pictures of the surgical reports were taken and the image files were assessed by two surgeons independently. Then, each surgical procedure was allocated in a category using the three methods of stratification. In case of disagreement between the two surgeons, the case was discussed and direct consultation with the surgeon who performed the surgical procedure was made when necessary. We consider this method the most appropriate for allocation of each surgical procedure in a certain category, given the complexity of the subject.

Independent variables: the categories from the stratification of complexity methods

The independent variables of interest for our study were the categories proposed by the stratification of complexity methods currently available and briefly explained below (Chart 1).

Chart 1. The risk categories from the stratification of complexity methods with some procedures.

RACHS-1	STS-EACTS (STAT) mortality score	Aristotle basic score
Category 1 PDA>30d, OS ASD, sinus venosus septal defect, aortic coarctation>30d, PAPVC	Category 1 ASD, VSD, Fontan (lateral tunnel, fenestrated), aortic coarctation repair (end to end), TOF repair (no TAP)	Category 1 ASD repair, AVSD repair (intermediate and partial), PDA, PAPVC repair
Category 2 VSD, TOF, Glenn, OP ASD, aortic coarctation at age≤30d, ASD and VSD, repair of total anomalous pulmonary veins at age >30d	Category 2 PDA, mitral plasty, Glenn, TOF (TAP), Fontan (external conduit, fenestrated)	Category2 VSD, Glenn, Systemic to pulmonary shunt (MTBS and central), TOF (ventriculotomy, non-TAP)
Category 3 Fontan procedure, Systemic to pulmonary artery shunt, mitral valvotomy or valvuloplasty, MVR, PA banding	Category 3 Arterial switch operation, coarctation repair (patch aortoplasty), AVSD repair (complete), coarctation repair + VSD repair, Rastelli.	Category 3 TOF (TAP), Fontan, TAPVC repair, mitral valvuloplasty, MVR
Category 4 Arterial switch operation with VSD closure, atrial septectomy, repair of total anomalous pulmonary veins at age ≤30d	Category 4 Arterial switch operation and VSD repair, Arterial switch procedure + aortic arch repair, PA banding, systemic-pulmonary shunt (MBTS or central), MVR, TOF-AVSD repair	Category 4 Senning, ASO, ASO and VSD, DORV (intraventricular tunnel repair), Rastelli, Norwood
Category 5 Repair of truncus arteriosus and interrupted arch, tricuspid valve repositioning for neonatal Ebstein anomaly at age ≤30d	Category 5 Norwood procedure, Damus-Kaye-Stansel procedure	
Category 6 Norwood operation, Damus-Kaye-Stansel procedure		

PDA=patent ductus arteriosus; OS ASD=ostium secundum atrial septal defect; PAPVC=partial anomalous pulmonary venous connection; VSD=ventricular septal defect, TOF=tetralogy of Fallot; OP ASD=ostium primum atrial septal defect; MVR=mitral valve replacement, PA=pulmonary artery; TAP=transannular patch; AVSD=atrioventricular septal defect; MBTS=modified Blalock-Taussig shunt; TAPVC=total anomalous pulmonary venous connection; ASO=arterial switch operation; DORV=double-outlet right ventricle

Dependent variable: hospital mortality (in-hospital mortality)

Concepts in relation to diagnostic and surgical procedures employed, as well as precise definitions of outcomes to be measured are of paramount importance in order to seek a standardization of what is being studied and analyzed.

The definition of operative mortality reported traditionally refers to any mortality after surgery, regardless of cause, in the first 30 days of surgery (whether the inpatient or home), or even after the 30 days during the same hospitalization[10].

In face the of data unavailability to check whether patients who were discharged alive are in good cindition or not on the thirtieth day of surgery, our reported outcome was hospital or in-hospital mortality (i.e. any mortality after the procedure performed, regardless of length of hospital stay). It is important to underline that there is no hospital for referral of chronic patients.

Statistical analysis

Statistical analysis was performed using the SPSS (Statistical Package for Social Sciences) for Windows, version 17 and Medcalc for Windows, version 12.5 (MedCalc Software, Ostend, Belgium). Categorical variables were represented as frequencies; the numeric variables as mean or median with the respective measures of dispersion.

Comparisons between groups were performed using Pearson's chi-square test. Analysis of the discriminatory ability of the surgical risk stratification methods were performed using the C statistic comparison with ROC curves of the three methods according to DeLong et al.[11].

RESULTS

Profile of operated patients and hospital mortality

The data in Table 1 and 2 below summarizes the used variables to characterize the study sample. One hundred and ninety-eight patients were male (55%) with a median age of 2.1 years (0.1 to 17.9 years). The median weight was 10.2 Kg (1.5-61 Kg) and 122 patients (34.1%) had less than 8 Kg.

The distribution of patients according to the categories proposed by 3 different risk stratification methods are described in Figure 1.

To demonstrate the variability of surgical cases, we used the nomenclature of the Aristotle score (Figure 2).

Given the large number of performed procedures and in order to facilitate the description of the center profile and the operated cases, we allocated the cases in diagnostic groups and then divided the total sample into two large groups, as follows (Table 3): GROUP 1 - Procedures that had more than 10 cases during the study period (5.5 years) - 280 patients or 77.7% of the sample: TOF, VSD, VSD and ASD, systemic-pulmonary shunt, ASD (including OP ASD), PDA (> 30 days), complete or transitional AVSD and aortic coarctation; and GROUP 2 - Procedures that had fewer than 10 cases during the study period - 80 patients or 22.3% of the sample. Hospital mortality of the total sample was 14.7%.

Hospital mortality stratified by categories

When we look at the mortality rates according to the proposed categories by the three risk stratification methods, we found distinct rates in each of their categories with statistically significant differences, as shown in Table 4.

To determine the stratification method with the best discriminatory ability for the hospital mortality outcome, i.e. with the best accuracy, we performed the analysis of the area under the ROC curve or statistical C. In other words, this method represents the probability that a randomly selected patient, who has an outcome of interest (such as mortality), has a higher predicted risk for the outcome when compared with a randomly selected patient who does not have this outcome. An unable method to discriminate between patients evolving to death or discharge has an area under the ROC curve of 0.5. A method that can perfectly discriminate between death or discharge has an area of 1.0.

The results of the areas under the ROC curve of our study are shown in Figure 3. The RACHS-1 categories, Aristotle and STAT (STS-EACTS) had a satisfactory performance (above 0.7). There was no statistical difference between the three forms of categorization and the areas under the ROC curve of the 3 methods for the discriminatory capacity for hospital mortality outcome were similar (Table 5).

Table 1. Characteristics of patients.

Variables	N	%
Gender		
Male	198	55.0
Female	162	45.0
Age		
< 3 months	27	7.5
3-6 months	36	10.0
6-12 months	52	14.4
1-12 years	208	57.8
12-18 years	37	10.3
Weight(1)		
<8 Kg	122	34.1
8-16 Kg	129	36.0
>16 Kg	107	29.9
Cardiopulmonary bypass		
Yes	268	74.4
No	92	25.6
Total	**360**	**100.0**

(1)=information unavailable for two patients

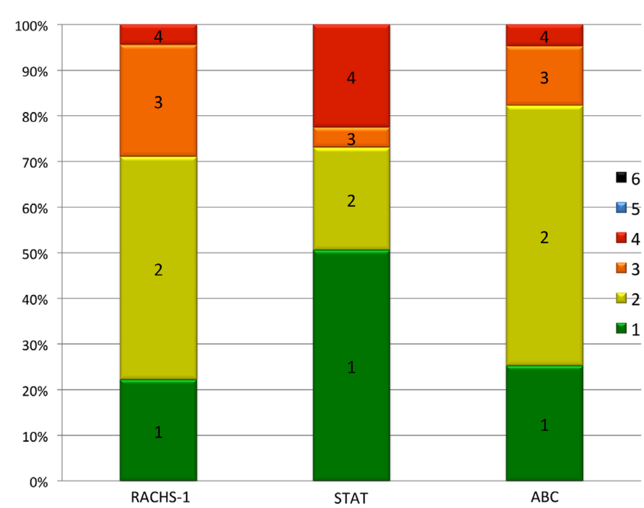

Fig. 1 - Distribution of procedures in the categories of the three methods of stratification of complexity: RACHS-1, STS-EACTS (STAT) and Aristotle Basic (ABC). RACHS-1 (Categories 1,2,3,4,5 and 6); STS-EACTS (STAT) (1,2,3,4 and 5 categories); Aristotle basic (ABC) (categories 1,2,3 and 4). We did not have procedures in categories 5 and 6 according to RACHS-1, as well as the category 5 STAT.

Table 2. Characteristics of patients.

Variables	Mean±SD	Min	Q1	Median	Q3	Max
Age (Years)	4.1±4.4	0.05	0.8	2.1	5.9	17.9
Weight (Kg)	14.3±11.8	1.5	6.3	10.2	18.0	61.0
Height (Cm)	91.7±31.8	30.0	68.0	84.0	112.0	172.0

SD=standard deviation; Q1=first quartile; Q3=third quartile

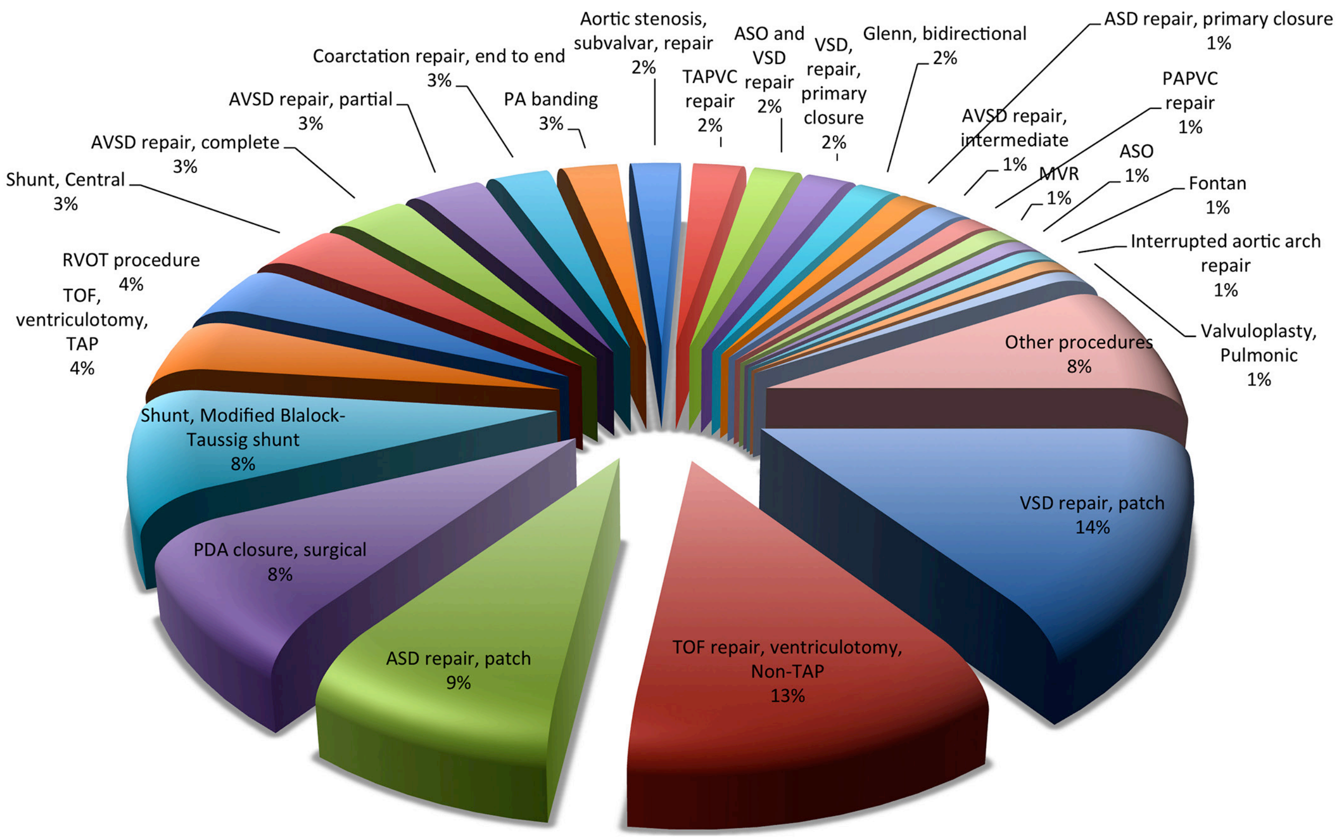

Fig. 2 - Distribution according to the nomenclature of the procedures proposed by Aristotle score. Graph showing the variability of the treated patients between surgical cases. To facilitate the graphical representation of the total sample, 15 different procedures grouped under 2 cases in the entire period under "Other procedures" (<2 cases).

Table 3. In-hospital mortality according to the 2 groups.

Group	Percentage of the total sample	Description of the Group	In-hospital mortality
Group 1	77.7%	Procedures that had 10 or more cases in the studied period	6.69%*
Group 2	22.3%	Procedures that had fewer than 10 cases in the studied period	32.5%

**Except the systemic to pulmonary shunts whose mortality was 26.82%.*

Table 4. In-hospital mortality according to the categories of the three models of risk stratification.

Categories	Outcome				Case		*P*-value
	Death		Discharge				
	N	%	N	%	N	%	
RACHS-1							
1	1	1.3	79	98.8	80	100.0	$P^{(1)}$ <0.001*
2	20	11.4	156	88.6	176	100.0	
3	24	27.3	64	72.7	88	100.0	
4	8	50.0	8	50.0	16	100.0	
STS-EACTS (STAT)							
1	10	5.5	172	94.5	182	100.0	$P^{(1)}$ <0.001*
2	11	13.6	70	86.4	81	100.0	
3	3	18.7	13	81.3	16	100.0	
4	29	35.8	52	64.2	81	100.0	
Aristotle							
1	1	1.1	90	98.9	91	100.0	$P^{(1)}$ <0.001*
2	25	12.2	180	87.8	205	100.0	
3	16	34.0	31	66.0	47	100.0	
4	11	64.7	6	35.3	17	100.0	

(1)Chi² test

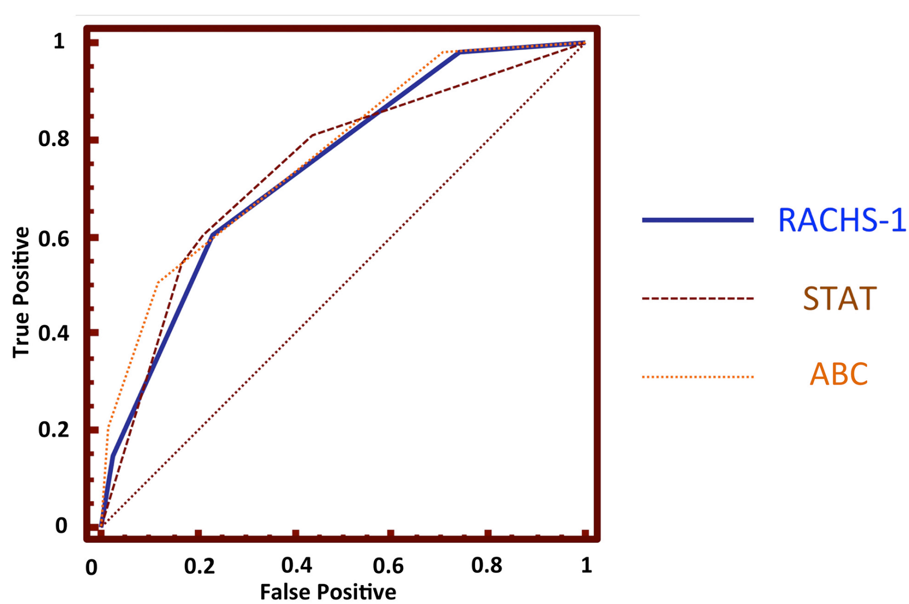

Fig. 3 - Area under the ROC curve of the categories proposed by laminating three models hospital mortality as the endpoint. Graph of the ROC curves (Receiver Operating Characteristic) for the three models plotted with different colors. Observe the superposition of three curves.

Table 5. Results regarding area under the ROC curve and comparative results between the methods concerning the mortality outcome.

Model/Method	Area uinder ROC curve	CI 95%	*P*-value
RACHS-1	0.738	0.690-0.783	P^1=0.9651
STS-EACTS (STAT)	0.739	0.691-0.784	P^2=0.9651
Aristotle (ABC)	0.766	0.718-0.808	P^3=0.5054

P^1=DeLong at al.[11] test - RACHS-1 x STAT; P^2=DeLong at al.[11] test - RACHS-1 x ABC; P^3=DeLong at al.[11] test - STAT x ABC; CI=confidence interval

DISCUSSION

What is the best method for stratification of complexity?

There are several published studies that compared different methods of stratification of complexity, using both the score from the models (Aristotle and STS-EACTS) as well as the predictive capacity of the proposed categories[8,12-17]. In our country, we did not find published studies that made comparisons between the methods of stratification of complexity. Al-Radi et al.[14], in order to compare the predictive value of the RACHS-1 and Aristotle basic score for the hospital mortality outcome, allocated 11,438 patients in the mortality categories. With a higher area under the ROC curve in both the unadjusted and adjusted models to the year of surgery, the RACHS-1 method was the best one (0.733 x 0.698, *P*=0.018 and 0.763 x 0.737, *P*=0.03, respectively).

In a study performed by Bojan et al.[13] that enrolled 1384 patients, the RACHS-1 method was compared to the comprehensive Aristotle score (not used in our study) regarding the discriminatory capacity for operative mortality outcome. There were statistical differences in favor of the Aristotle comprehensive model showing higher area under the ROC curve (difference of 0.044 to 0.196; *P*=0.003). However, after use of the full model proposed by RACHS-1, i.e., the model adjusted for age, prematurity and extra-cardiac abnormalities, the difference between the two methods (RACHS-1 and comprehensive Aristotle) became statistically non-significant (0.05 [-0.023-0.131]; *P*=0.19).

In the study that resulted in the STS-EACTS model, O'Brien et al.[6] made comparisons of the new model with its predecessors. In a subgroup of patients whose procedures could also be grouped into RACHS-1 categories and received the Basic Aristotle score, the discriminatory capacity of STS-EACTS categories by area under the ROC curve (0.778) was higher than the RACHS-1 (0.745) and Aristotle basic score (0.687).

Following an evolutionary process starting from highly subjective methods (RACHS-1 and Aristotle), the method proposed by the STS-EACTS was superior in discriminatory capacity and has been recommended to the data gathering in the STS-EACTS multicenter database[18].

Notwithstanding its advantage over other methods due to the differences in the design methodology, the STS-EACTS (STAT) was not better than other methods when used in our study. Probably owing to the size of our sample, we did not find any statistical differences between the areas under the curves of the three models.

Stratified hospital mortality in Brazil

In a literature review, we identified a lack of studies reporting data related to hospital or operative mortality in congenital heart disease in our country over the last 10 years[19-21].

The latest publication includes results of patients operated over 4 years ago and reports 10 years of surgical treatment of congenital heart disease (including adults) in the state of Sergipe, examining differences in outcomes after the surgery centralization from three hospitals[21].

Having operated an average of 93 patients/year, the overall hospital mortality (including congenital adult patients) was 8.3%, whereas in the group under 12 years was 10.32% (77 deaths in 746 patients). There was statistical difference between the mortality of the two analyzed periods with a drop in the overall mortality from 9.8% (58/586) to 5.4% (19/346) (*P*=0.02). When assessing the predictive ability of RACHS-1 categories for the hospital mortality outcome, the result was an area under the ROC curve of 0.860 (95% CI, 0.818-0.902).

In relation to the stratified mortality by RACHS-1, the group found the following mortality rates at the total period: Category 1=0.26% (1/386); Category 2=6.60% (27/409); Category 3=11.11% (7/63); Category 4=62.07% (36/58) and Category 6=100% (3/3). Considering that the mortality in children was grouped with the adults for statistical reasons, as mentioned in the study, we did not carry out comparative analysis between our results and those found by the authors, because our study did not involve adult population.

In our state (Pernambuco), Mattos et al.[20] studied 818 patients who had undergone surgery between 2000 and 2004 by 4 different surgical teams. Analyzing five main variables (age, nutritional status, presence of clinical risk factors, surgical complexity stratified by RACHS-1 and Aristotle and time of cardiopulmonary bypass), a risk score was developed and showed to be useful in predicting the mortality outcome when performed at the bedside during ICU admission.

With the overall mortality similar to ours, 14.7% (120/818), this study stands out for its excellent methodology and details of the information reported. Using the RACHS-1 categories to stratify the complexity of the cases, the authors reported mortality of 8.76% (48/548) for categories 1 and 2 pooled and 26.12% (70/268) to the categories 3 and 4. In the presence of clinical factors associated (Chart 2), the mortality reported in the study was 23.04% (OR, 4.73 [95% CI, 2.84-7.90]; *P*<0.0001) when only one factor was present, and 53.95% when 2 or more factors were present (OR, 18.52 [95% CI, 10.03-34.36]; *P*<0.0001).

Considerations about our hospital mortality

Before designed studies with the appropriate methodology for the study of risk factors (before, during and after surgery) associated with mortality are performed in our service, we highlight four important points whose influence on our hospital mortality is not negligible.

Chart 2. Clinical risk factors and definitions considerated in Mattos' study.

Risk factor	Definition
Pulmonary hypertension	Pulmonary arterial systolic pressure over two-thirds of the systemic pressure (Doppler echo)
Refractary cardiac failure	When it was not well controlled despite adequate doses of diuretics and vasodilators
Severe cyanosis	Peripheral arterial saturation <75% at rest
Acidosis	pH <7.25
Presence of infection	clinical + radiological or laboratorial documentation
Genetic syndrome	clinical grounds
Mechanical ventilation	When it was commenced because of a deterioration in the clinical condition
Prolonged hospital stay	Preoperative period of hospitalization of over one week

First point - Center in establishment phase: Considering the initial establishment of a center (first five years), even with experience in the surgical treatment of congenital heart disease (team with more than 30 years working together), the patient outcomes are extremely dependent of the infrastructure at pre-, trans- and postoperative times, with special emphasis on the many difficulties faced in the establishment process of a surgical center of high complexity in our country.

In a study published by Nina et al.[19] reflecting the first two years of establishment of a universitary center of cardiac surgery in the Northeast, we found that mortality rates also reflect the many difficulties encountered, even in cases of low complexity (3.8% for category 1 and 26% for category 2, using the RACHS-1 method).

Second point - low total volume: Despite having a cardiovascular surgery center and a medical residency program with an annual volume of cardiac surgeries in 2011 and 2012 exceeding 600 surgeries/year, the annual average of surgery in congenital heart disease in patients under 18 years is fewer than 80 surgeries/year.

The surgical volume is a factor whose association with hospital mortality is well established in the literature[22-24]. We bring to attention the recent retrospective study of Vinocur et al.[25] enrolling 49 American centers, which was included in the Pediatric Cardiac Care Consortium database. After analysis of 85,023 surgeries (45.5% of which were Category 1 and 2 by RACHS-1 method), the mortality rate was 6.2%. Multivariate analysis including the volume of the centers as a continuous variable showed a significant inverse correlation between the surgical volume and the mortality (OR 0.84 per additional 100 operations/year; 95% CI, 0.78–0.90; P<0.0001).

It is important to underline the findings of the study of Welke et al.[24] and the fact that the inverse correlation between volume and mortality has been demonstrated for the group with more complex procedures (Aristotle score> 3). Centers with a volume <150 surgeries / year had higher mortality rates in comparison with centers with volume ≥350 surgeries (OR, 2.41 [95% CI, 1.89-3.06]; P<0.0001).

Our view agrees with what was described in the study by Welke et al.[24], in which there might be intrinsic factors associated with the centers, other than surgical volume itself, influencing the outcomes. It is necessary to identify these factors with appropriate studies in parallel to the employment of measures aiming to augment the surgical volume. It is precisely this increase of the volume that theoretically reduces the influence of these factors, promoting the interaction of staff and the establishment of a necessary routine in all steps involved (pre-, trans- and postoperative).

Third point - Impaired "analysis per procedure": The PROCAPE presents a clinical profile of heterogeneous congenital patients regarding the procedures performed, obviously decreasing the N of each specific procedure, which impairs the analysis of individual mortality. To analyze the specific mortality for some procedures as total anomalous pulmonary venous correction, Glenn or Fontan or arterial switch operation lacks scientific value, in that our volume for such procedures is not significant (less than 10 cases in a 5.5-year period). Alternatively, we gathered a group of such diseases based on surgical volume: GROUP 1 (> 10 cases/ total period) and GROUP 2 (≤ 10 cases / total period) above mentioned, leaving aside the systemic-pulmonary shunts for further analysis (although it belongs in the GROUP 1).

This group, created by convenience, achieved a mortality for the GROUP 1 of 6.69% (except for the shunts), GROUP 2 of 32.5% and systemic-pulmonary shunts of 26.82%. We observe that even without proper statistical analysis correlating the volume with mortality, in spite of the different sample sizes between groups, we obtained very different mortality rates for heart diseases in which fewer than 10 cases in the total period were operated. In addition, we underline the higher mortality of systemic-pulmonary shunts in the procedures of GROUP 1. When the analysis of cases through the STS-EACTS stratification method was performed, the hospital mortality was 33% for more complex procedures (STS-EACTS categories 3 and 4) against 7.98% for the less complex (STS-EACTS categories 1 and 2).

Fourth point - urgent/emergency surgery - Given our wide area coverage, taking patients from outpatient clinics and referrals of 3 large hospitals in the region, as well as coverage of patients regulated by CNRAC (National Center of High Complexity Setup) coming from the North and the Northeast, our institution becomes a reference for the more complex cases and emergencies. Such critical situations are characterized by a need of surgical approach normally without time to appropriate preoperative imaging diagnosis and exams. In the presence of clinical dysfunctions already installed, patients undergo the surgical procedure with increased risk of mortality, as previously mentioned in the study by Mattos et al.[20]. This study demonstrated that the presence of 2 or more clinical factors associated (commonly found in patients with indication for emergency surgery) resulted in a mortality rate of approximately 55%.

This is demonstrated by our prevalence of systemic-pulmonary shunts surgeries, corresponding to 11.38% of all surgeries performed. Taking into consideration that the STS-EACTS mortality score[6] groups both the central shunt as the Blalock-Taussig shunt in risk category 4 (range up to 5), whose mortality rates were respectively 12.3% (95% CI, 9.9%-15%) and 8.9% (95% CI, 7.9%-10.1%), we have a scenario formed by a high prevalence of surgical procedures associated with high mortality. Although a study of the profile of patients undergoing systemic-pulmonary shunts in our service is needed to better characterize the sample, we state that the vast majority of this patients were not eligible for a biventricular repair or staging Fontan.

Given the nature of the current study, retrospective and without the purpose of measuring the risk of preoperative clinical disorders (or only clinical factors associated) for mortality outcome, we have no objective data to discussion of our series. We infer only that the presence of such clinical factors and even organ dysfunction in our sample is not negligible, imposing a negative influence on our results.

Limitations of the stratification of complexity and hospital mortality as a quality indicator

Unlike the adult population in that the regression analysis is often used in the analysis of outcomes in cardiac surgery in the postoperative period, in children involving congenital heart disease we used the statistical tool called stratification of complexity. Whereas the regression analysis is a mathematical equation developed to predict an individual's risk of a patient developing a specific outcome, based on predetermined relevant clinical variables, the stratification of complexity controls only the variables used to create the strata and other variables may influence the outcomes.

Recent studies have questioned the use of hospital mortality as an indicator of quality of a center[26,27]. In an article published by Pasquali et al. whose title refers to a new indicator called "failure to rescue", 40,930 patients (STS bank between 2006 and 2009) of 72 different centers had their results analyzed taking into consideration the prevalence of postoperative complications and hospital mortality. With an overall complication rate of 39.3%, the hospitals with lower mortality rate had significantly lower rates of "failure to rescue" (6.6% vs. 12.4%; $P<0.0001$). In other words, this study suggests that hospitals with low mortality rates don't have fewer complications but a lower mortality on those that face complications [27].

CONCLUSION

In order to improve the quality of our care for congenital heart disease, knowing that we still face high hospital mortality rates especially for more complex groups (categories 3 and 4), the stratification methods appear as useful tools, so that we could direct the necessary attention towards the high-risk groups.

The three models of stratification of complexity currently available in the literature are useful even with different mortality rates between the categories proposed. With similar discriminatory capacity for hospital mortality outcome, it was not possible to determine the superiority of one method over another in the sample.

Authors' roles & responsibilities	
PEFC	Analysis and/or interpretation of data; statistical analysis; final approval of the manuscript; study design; operations and/or experiments conduct; writing of the manuscript or critical review of its content
MPBOS	Analysis and/or interpretation of data; statistical analysis; final approval of the manuscript; writing of the manuscript or critical review of its content
CAS	Conception and design; operations and/or experiments conduct; writing of the manuscript or critical review of its content
IME	Conception and design; operations and/or experiments conduct; writing of the manuscript or critical review of its content
MLC	Conception and design; operations and/or experiments conduct; writing of the manuscript or critical review of its content
RFAL	Analysis and/or interpretation of data; final approval of the manuscript; study design; writing of the manuscript or critical review of its content
RCL	Analysis and/or interpretation of data; statistical analysis; final approval of the manuscript; study design; writing of the manuscript or critical review of its content

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