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Validation of Risk Stratification Methods for Congenital Heart Disease Surgery in Mexico: RACHS-1 and Aristotle Scales

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Summary

Background: Currently, it has two methods of risk stratification in Congenital Heart surgery: Risk Adjustment in Congenital Heart Surgery (RACHS-1) and the complex integral Aristotelian (Aristotle). Although they have been tested in different countries, they have not been validated in hospitals of Mexico.

Objectives: Validating both methods at 3rd Level Hospital (Cardiology Hospital CMN-SXXI, IMSS, Mexico City) for patients submitted to cardiac surgery due to congenital heart defects, between January 2015 and December 2016.

Methods: A retrospective study of patients in the Hospital's cardiology of the National Medical Center C-XXI, IMSS-Mexico, of any age and gender undergoing surgery for congenital heart disease elective or emergency with clinical record is prepared full. For studying validity, internal consistency, calibration, capacity for discrimination and morbidity and mortality between the risk levels were analyzed.

Results: We included 201 patients with complete data. Both study scales in our study were statistically significant in the Logistic regression analysis ($p = 0.001$ and $p = 0.000$, respectively). Calibration test show to be non-significant for both scales (X2 of Hosmer-Lemeshow of 0.357 and 3.235 respectively). The areas under the ROC curve were 0.770 and 0.806, respectively, suggesting a good discrimination. The observed mortality was (6.46%). Nevertheless, each segment of the scales exceeded the expected in mortality according to the internationally accepted parameters for RACHS-1.

Conclusion: We conclude that it is valid to use RACHS-1 and basic Aristotle for surgery of congenital heart disease, with a Cronbach's alpha of 0.740. We suggested developing mechanisms to understand those variables that come out of the control of these instruments, such as the patient's low weight and a history of reoperation.

Key words: surgical risk; congenital heart disease; RACHS-1; Aristotle

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Introduction

Currently, the mortality of patients with congenital heart diseases has been significantly reduced. In little more than three decades, has gone from a mortality of around 25% to 5%. These advances drive the design of tools that allow to evaluate the quality of health care and inter-agency comparisons. Among these innovations, databases have characteristics such as uniformity in information, a complete and universal classification, verified information and quality, as well as mechanisms have been generated to evaluate the surgical complexity and structural congenital heart diseases [1, 2].

In terms of the nomenclature, the European Association of Cardiothoracic Surgery (EACTS) and the society of Thoracic Surgeons of the United States of America (STS) have created one of the most complete bases for various cardiovascular surgeries. It also has two methods for risk stratification: RACHS-1 and Aristotle [3-8].

The clinical practice guidelines of the American Heart Association and the American College of Cardiology is considered reasonable these models for the estimation of risk of hospital morbidity and mortality in surgery with two objectives: to control the quality surgical e institutional, and estimate the risk of death from specific causes for the particular patient. However, speaking of risk is not an easy task for the cardiothoracic surgeon. There are many and very varied factors involved to a fatal outcome, especially in patients with congenital heart disease, which are mostly very complex is given in the operating room.

Currently, physicians can support two models for stratifying risk in these patients; however, both have been created and used in populations other than the context in which is this research; Therefore, it is of great importance to assess the parameters of risk existing in the study population. For the proper implementation of these methods of risk stratification, required external validation, i.e., evaluation of the performance of the model proposed space-temporal delimitation. To achieve approval, will facilitate many aspects ranging from the creation of management guidelines in patients at risk, to provide to patients and families statistics real and consistent with its situation, in the case of some misfortune during the surgical management. In addition, it would provide an important legal support to possible legal demands.

Primary End Point

Validate methods of risk stratification: RACHS-1 and Aristotle, in surgery of congenital heart disease in the Cardiology Hospital of the National medical center SXXI, México City.

Secondary Points

1. To determine the predictive value in both methods in the mortality of patients undergoing surgery of any type of congenital heart disease.

2. To compare scores RACHS-1 and Aristotle with the technical difficulty and the times of hospital stay in the units and intensive care.

Methods

Patients admitted to the medical unit of high specialty of the Hospital's cardiology the Center doctor national - twenty-first century, of the Mexican Institute of Social Security (IMSS), in the city of Mexico. All of them have undergone heart surgery for a congenital heart disease, regardless of their age and gender, from the 01 of January 2015 to 31 December 2016. The methodology consisted of a retrospective cohort study. A data collection instrument was used for further analysis.

Statistics

To study the validity of methods, discussed their internal consistency, calibration and discrimination ability. The internal consistency was assessed using Cronbach's alpha coefficient, a value greater than or equal to 0.7 would indicate that the methods well predict the probability of postoperative morbidity and mortality of patients. Calibration was performed through the test of Hosmer-Lemeshow (comparison of observed probabilities with expected, given each method). The capacity of discrimination was analyzed by calculating the area under the ROC curve, a value less than or equal to 0.5, I would point out that the model does not discriminate better than random, and values close to 1 would indicate excellent discrimination.

Morbidity and mortality between the levels of risk of each method was performed using Chi square test. Finally, the correlation of variables was carried out with the Pearson correlation test. Continuous variables are expressed in mean ± standard deviation and categorical variables in percentage. The electronic analysis was performed with SPSS 22.0 IBM software.

Overview of the Study

We identified those patients who will undergo surgery for congenital heart disease to then evaluate methods of Aristotle and RACHS-1 risk stratification. Also, was the presence of co-morbidities, clinical parameters and cardiovascular risk factors before, during and after surgery. Later, at 30 days postoperative, we evaluated mortality and morbidity by reviewing the clinical record.

Results

They were 201 patients. Of these 134 (66.7%) were female, while that 67 (33.3%) were male. As for ages, 112 (56%) corresponded to minor patients, 89 (44%) were adults. Ages were grouped into six segments, as shown in the table 1.

The surgeries, were elective 194 (96.5%) and in seven (3.5%) corresponded to urgent surgeries. Surgery performed most frequently was the repair of ASD, in 119 (59%). Table 2 shows the breakdown of cases by type of surgery.

The mortality rate was calculated considering the deaths of patients during the first 30 days after the operation among the total number of procedures performed. Thus, for a total of 13 (6.5%) deaths, had a rate of 0.0646. Morbidity was calculated by dividing the total number of operations with more than seven days ICU stay (n = 46) among the total of valid procedures

Table 1: Distribution according to age groups		
Age (y.o.)	**N**	**%**
0-6	43	21.4
12-Jul	44	21.9
13-18	25	12.4
19-24	13	6.5
25-30	11	5.5
31-36	10	5
37-42	15	7.5
43-48	13	6.5
49-54	11	5.5
55-60	9	4.5
61-66	4	2
66-72	3	1.5
Total	201	100

Table 2: Distribution by type of surgery		
Type	**N**	**%**
ASD	119	59
VSD	15	7.5
Fallot	9	4.5
Ebstein	8	4
Rastelli	8	4
Pulmonar Valve plasty	7	3.5
AV chanel defect	6	3
Fontan	5	2.5
Blalock Taussing	4	2
Vein drain	4	2
Other	16	8

ASD: Atrial septal defect; **VSD**: Ventricle septal defect; **AV:** atrio-ventricular

(n = 197), obtaining a score of 0.233, amounting to a 23.3% of general morbidity. For the technical difficulty, was carried out the same operation with the total number of surgeries with cardiopulmonary bypass time > 120 minutes (n = 40) valid cases (n = 196), obtaining a score of 0.204, equivalent to a technical difficulty of the 2040 %. In this calculation values stay under a day - which correspond to patients who died in surgery, minutes after or before a day in ICU-as well as those who did not have the CPD were excluded.

Score Distribution

The distribution of the sample according to the RACHS-1 score was as follows: risk 1: 119 (59.2%) cases; Risk 2:34 (16.9%); Risk 3:42 (20.9 %); risk 4: 6 (3.0 %). Without finding in our series 5 and 6 risk. Meanwhile, the distribution according to the score was basic Aristotle: level 1: 120 (59.7 %) cases (1.5-5.9); Level 2:41 (20.4 %) (6.0 - 7.9 %); Level 3:29 (14.4%) (8.0-9.9); Level 4:11 (5.5 %) (10.0-15.0) demonstrating an overestimation of mortality with the RACHS-1 score.

In table 3, presents a breakdown of the mortality obtained by each category. As you can see, in each case shows a progressive in the mortality increase as it increases the category of each score, allowing you to determine at first and descriptive so that there is a correlation between the two variables.

Later, it was obtained the average days of stay in intensive and postoperative care for each category of RACHS-1 and basic Aristotle for valid cases. The results can be observed also grow the days of stay in both indicators as the category, rises which allows to establish which in most senior stay longer. This can be seen in table 3. In addition, these variables allowed to calculate the indices of morbidity and technical difficulty of the procedures carried out by each level of the score, in accordance with the mentioned calculation procedures. In table 4 the postoperative staying according with the score is shown.

Table 3: Mortality according to the categories of Aristotle and Rachs-1

Score	**Level**	**Population**	**%**	**Mortality**	**%**	**Expected**
RACHS-1	1	119	59.2	2	1.68	0.4
	2	34	16.9	3	8.82	3.8
	3	42	20.9	6	14.3	8.5
	4	6	3	2	33.3	19.4
Aristóteles .	1	120	60	2	1.67	ND
	2	41	20.4	3	7.32	ND
	3	29	14.4	4	13.8	ND
	4	11	5.5	4	36.4	ND

ND: no data

Mortality Related to other Indicators

In addition to those carried out with the proven scores, developed crosses bivariate between mortality and some packages and associated confounding variables modifier: modifier as the type of surgery performed and reoperation, as well as the times of DCP, Aortic cross-clamping, ICU stay and postoperative stay (Tables 4, 5). In this regard, it was found that in two (28.6%) cases of urgent surgery there was death, while in 11 (5.7 %) of elective surgery occurred the same. While in 10 (25 %) of the surgeries with a time of DCP exceeding 120 minutes there was death, what just happened with three (1.9 %) cases in which lasted less than

Table 4: Postoperative staying vs Score

Score	Postoperative staying			Postoperative staying	
	Population	Mean	SD	< 15 days	>15 days
RACH					
Risk 1	118	10.77	4.22	101	17
Risk 2	33	14.88	6.56	19	14
Risk 3	41	21.93	12.04	8	33
Risk 4	5	22.5	15.74	1	4
Aristóteles					
Risk 1	119	10.73	4.18	103	16
Risk 2	41	18.05	8.45	18	23
Risk 3	28	20.45	11.21	5	23
Risk 4	9	20.36	17.26	3	6

The valid population includes only those cases with postoperative stay

Table 5: ICU stay vs Score

Score	ICU stay			ICU stay		Mortality index
	Population	Media	DE	< 7 días	> 7 días	
RACH						
Risk 1	118	3.91	1.69	111	7	0.06
Risk 2	33	5.94	2.91	25	8	0.24
Risk 3	41	9.6	6.09	15	26	0.63
Risk 4	5	11	6.75	0	5	1
Aristóteles						
Risk 1	119	3.88	1.67	112	7	0.06
Risk 2	41	7.2	3.56	26	15	0.37
Risk 3	28	9.21	6.2	11	17	0.61
Risk 4	9	9.91	7.73	2	7	0.78

The valid population includes only those cases with intensive care unit (ICU) stay

Table 6: Cardiopulmonary bypass time vs Score

Score	CPD time			CPD time		Mortality Index
	Population	Mean	SD	< 120´	>120´	Technic
RACH						
Risk 1	118	54.31	37.04	109	9	0.08
Risk 2	33	97.76	50.95	26	7	0.24
Risk 3	41	142.4	92.92	20	21	0.44
Risk 4	5	174.8	63.45	4	1	1
Aristóteles						
Risk 1	119	53.24	36	111	8	0.07
Risk 2	41	108	80.82	26	15	0.27
Risk 3	28	135.8	72.85	18	10	0.39
Risk 4	9	187	54.32	1	8	1.11

The valid population includes only those cases with cardio-pulmonary derivation (CPD)

120 minutes. Similar figures were obtained in the case of aortic clamp time: 10 (25 %) and seven (4 %), respectively.

For this, it must have present that the simple averages of the times for the entire sample were: CPD: 83.66 minutes (of = 68.02); Clamping Ao: 46.84 minutes (of = 41.60); stay in the ICU: 5.65 (in = 4.21); stay in postoperative: 14.5 days (of = 8.67) (Tables 5, 6).

Consistency

To assess the internal consistency of the proposed score, applied Cronbach alpha test, obtaining a statistician from 0.740 to two methods, as well as one of 0.957 when the test is based on standardized elements, which is acceptable. The Chi square test of Friedman sheds a statistical significance with a value P = 0.000 [14]. This means that, together, RACHS-1 and basic ARISTOTELES present one adequate internal consistency to be able to be used together in our hospital unit.

Predictability

Later, the logistic regression model applied to each of the scores to evaluate its predictive capacity with mortality. As a result, RACHS-1 showed a significant association with mortality, making six iterations of the introduction of the variable (B = 10.59, et. = 0.310, Exp (B) = 2.884; - 2LL = 83.310, r = 0.063). Here, the change in - 2LL by introducing the variable with respect to having not entered is 15.686, which is significant (P = 0.001). Meanwhile, basic Aristotle was obtained also an association meaningful and slightly increased mortality, making seven iterations by introducing the variable (B = 0.450, et = 0.124, Exp (B) = 1.568; - 2LL = 80.076, r = 0.078). Here, the change in - 2LL produced by the introduction of the variable is 20.653, which is significant (P = 0.000). When performing regression by introducing both score manually, positive associations were obtained as a result (-2LL = 79.992, r = 0.078)); However, by requesting the software that incorporate the variables under the forward method, the program excluded the RACHS-1 risk score calculation, whereas Basic Aristotle explain better the dependent variable.

Calibration Test

Hosmer-Lemeshow test was then used to establish the proper calibration of both scores. This was not significant for both (P = 0.005), which indicates that the difference between the observed and expected is low. To the RACHS-1, was obtained a significance of 0.412 (Chi-square = 0.673), while for basic Aristotle was one of 0.333 (Chi-square = 4.584), and in the case of combining both score, one of 0.357 (Chi-square = 3.235). Thereby, it is accepted that the correlation between mortality observed and expected speaks of a correct calibration of the test.

Discrimination Test

When the curve of operational feature of the receiver (ROC, for its acronym in English, see Figure 1), was an area of 0.770 (P = 0.001;) 95% CI: 0.639-0.901) 0.806 to the RACHS-1 score (p = 0.000;) 95% CI: 0.674-0.938) for basic Aristotle. This means that both score have good discriminatory ability, however the basic ARISTOTELES is slightly higher. The comparison between the two can be seen in Figure 1.

Test outcome variables: RACHS-1, basic Aristotle has, at least, a draw between the Group of positive real state and negative real estate group. The statistics may be biased.

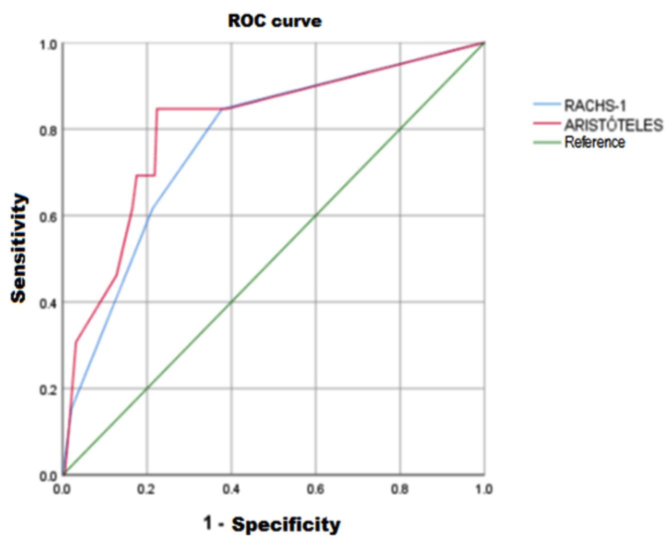

Figure 1: Roc Curve for Rachs-1 and Basic Aristotle

Relationship with Time in ICU and Postoperative

Regarding the relationship of scores RACHS-1 and basic Aristotle with the time of stay in the ICU and postoperative, as well as the DCP and aortic clamp times, conducted logistic regressions to determine the significance of each in the composition of each score. In the case of the RACHS-1, the only variable that was significant was how DCP (B = 0.332, P=. 000), while in the case of basic Aristotle, were significant DCP (B = 0.248, P = 0.005), aortic clamp (B = 0.210, P = 0.007) and stay in the ICU (B = 0.368), P = 0.037).

Other Indicators

Finally, we analyzed the relationship between mortality conditions of surgery - type of surgery and reoperation - and Comorbidities – arterial hypertension, diabetes mellitus, COPD, kidney disease and hypothyroidism - risk factors - smoking, Dyslipidemia, sedentariness and BMI - through the Pearson correlation coefficient. As a result, significant correlations were obtained at the 0.05 bilateral level with the variable type of surgery (- 0.171), and with reoperation (0.458) and underweight (0.254) bilateral 0.01 level.

Finally, there were some postoperative complications in patients in general and for each level of RACHS-1 and basic Aristotle. A total of 201 valid patients, complications arose in 73 (12.4%). Presented complications were: pneumonia at 52 (26%), bleeding in 21 (10.5%), urinary tract infection in 19 (9.5%), renal involvement in five (2.5%), in three cardiac rhythm disturbance (1.5%), and a case (0.5%) diarrhoea, wound infection, mediastinitis and tracheitis. To make the crossing bivariate against mortality, was found only in two (2.74%) cases that presented complications there was death, while 97% survived. Similarly, the Pearson correlation against variable mortality not showed significant results, so it can be said that there is a clear statistical relationship between both variables.

However, if shown a progressive increase in the complications in general as you scale the risk level on both scores, with significant and positive correlations of Pearson (RACHS-1: 0.511, P = 0.000;) Basic Aristotle: 0,461, P = 0.000), which suggests that postoperative complications are a transcendent variables for the formation of scores.

Discussion

RACHS-1 risk stratification method was published in 2002 and was developed based on a consensus of eleven medical authorities recognized, who included both clinical specialists and Surgeons of American nationality as they supported their work with information from multiple institutions [7]. This method includes 79 kinds of both open heart as closed heart surgery, divided into six levels or categories of risk, where the first is lower impact - involves closure of atrial septal defect or ligation of ductus ductus arteriosus-, and the sixth represents maximum level present in the surgeries of Norwood and the procedure of Damus - Kaye-stansel procedure.

According to the scale described, the average risk of mortality for the various levels of risk is as follows:

Given the small number of cases, it has not been possible to determine the percentage of risk within the level five (table 7). The surgeries included at this level are: repair of tricuspid valve in neonate with Ebstein's anomaly and repair of truncus arteriosus common with interruption of aortic arch [6].

Table 7: Scale That It Defines The Average Mortality Risk*

Level	Average risk of mortality (%)
One	0.4
Two	3.8
Three	8.5
Four	19.4
Five	No data
Six	47.7

*reference 6

Stratification by the system of Aristotle was published in 2004 [5]. In this consensus, involved 50 institutions from 23 countries and around cardiovascular surgeons. The objective was to evaluate in-hospital mortality, but also describe in more detail the complexity of the different procedures and the clinical status of patients. The system is based on the nomenclature of the EACTS and the STS. In addition, has established that it should remain unchanged for periods of four years. Updating should be based on its validation within the international database and the World Congress of Pediatric Cardiology and cardiac surgery. The independent factor for classification is shown in table 8.

Table 8: Classification Of Independent Factors*

Factors	Example
General	Weight ≤ 2.5 kg (2 points)
	Prematurity of 32-35 weeks of gestation (2 points)
	Extreme prematurity ≤ 32 weeks of gestation (4 points)
Clinics	Variables present in a maximum period of 48 hours before surgery
	Metabolic acidosis with pH ≤ 7.2 or ≥ 4 mmol/L lactate (3 points)
	Heart Failure EF ≤ 25% (2 points)
	Ventricular Tachycardia (0.5 puntos)
	Mechanical ventilation for management of heart failure (2 points)
	Pulmonary Hypertension ≥ 6 W U
Out Cardiac Surgical	Hydrocephaly (0.5 points)
	Down Syndrome (1 points)
	Re-surgery (2 points)
	Sternotomy for minimally invasive (0.5 points))

*reference 8

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A study conducted in England by Kang et al., looked for the validation of the RACHS-1 study through the analysis of 1,085 open-heart surgeries streak, with an overall mortality of 51 (4.7%) patients [10,11]. In their findings, found that preoperative mortality independent variables included age ($p \leq 0.002$) and RACHS-1 ($P \leq 0.001$) and those intraoperative, extracorporeal circulation ($P \leq 0.0001$) time [13].

At the Hospital for sick children in Toronto, Canada, Al - Radi et al., compared two methods of risk stratification (Aristotle and RACHS-1) through the analysis of 13,675 heart surgeries performed at that institution from 1982 to 2004, and compared with the mortality and hospital stay [1, 9]. The researchers concluded that the predictive value of the RACHS-1 is better compared with the Aristotle score 5. Lacour-Gayet F et al., evaluated the Aristotle score with a complexity-adjusted method to evaluate surgical result (Table 9).

Table 9: Results Of Study Carried Out In Denmark

Level	Average mortality risk (5)
One	18.4
Two	37.4
Three	34.6
Four	8.2
Five	0
Six	1.5

In Hanover, Germany, Boethig et al., also evaluated the RACHS-1 system within a period from 1996 to 2002 [15]. In the analysis, they included 4,370 patients and found that the predictive power was similar to referred to in American hospitals. As for the time of stay in the intensive care room, found that the RACHS-1 risk level rose exponentially, but allowed to predict the weather in 13.5% of the surviving group. Welke et al., conducted a study with the data base of eleven institutions where surgeons working members of the society of Surgeons of congenital heart disease (CHSS, for its acronym in English) [16]. Of the 16,800 surgical procedures performed, 12,672 (76%) could be placed at various levels of the RACHS-1 System.

Overall mortality was 2.9%, but there was a significant decline. Jenkins et al., report, there was a reduction of the percentage of the different levels of risk [7]. The figures were presented as follows: • level 1: 4vs 0.7%; • Level 2: 3.8vs 0.9%; • Level 3: 8.5 vs 2.7%; • Level 4: 19.4 vs. 7.7%; • Level 5: could not be applied; • Level 6: 47.7 vs. 17.2%. In the mentioned study, the largest volume of surgeries of some institutions was not correlated with operative mortality [16, 17].

In Argentina, Mariano Ithuralde et al., conducted a retrospective study between 2001 and 2006 to analyze mortality and distribution of surgical procedures for congenital heart disease using the RACHS-1 risk adjustment method [17]. 571 patients under 18 years of age undergoing cardiac surgery were included [12]. The results were as follows:

1. The distribution according to the RACHS: 1: 17.51%, 2: 38.00%, 3: 31.17%, 4: 8.23%, 5: 0.18%, 6: 4.90%.
2. Mortality score and validation of the score: 1: 0%, 2: 0.92%, 3: 3.37%, 4: 10.64%, 5: 0%, 6: 32.14%.
3. Hosmer-Lemeshow test: the result was $p = 0.50$; Therefore it arose as a non-significant and said a proper calibration, no differences in mortality observed versus expected. As for the ROC area, was equal to 0.84 and $p < 0.001$.
4. The observed mortality was 3.85%, while the set was 3.05% and (SMR, for its acronym in English) standardised mortality ratio was 0.47 (0.27-0.67).

Based on the resulting data, the authors concluded that the RACHS method included a tool valid stratification in their study population. The distribution according to the risk was similar to the original population. Adjusted mortality was lower than that observed, which indicates adequate results [17, 18].

Through the results obtained, it can be seen that both scores, both RACHS-1 and basic Aristotle, can predict mortality in the population studied. This, given the positive statistics obtained from tests with binary logistic regression, Hosmer-Lemeshow test and ROC curve. These data are similar to trends found in other studies during the review of the background. With this, we can say, from the outset, that the Association of both scores with mortality is high, with a value $P = 0.001$, Hosmer-Lemeshow non significant and area under curve ROC of 0.770 (moderate) to the RACHS-1; and P-value = 0.000, Hosmer-Lemeshow non significant and area under the ROC curve of 0.806 (high) for basic Aristotle.

To compare them, basic Aristotle shows better performance than RACHS-1, with greater associative capacity, greatest calibration and better discrimination. In fact, the attention the fact that, to combine them, RACHS-1 has been excluded of steps followed by binary logistic regression when applied to software application of the method forward, which is designed to make the system go incorporating the variables to the analysis, going from presents highest partnership until at least scores as the variance is fulfilled and until it has complied with a more or less extensive explanatory capacity.

This means that, by itself alone, Aristotle basic possesses sufficient associative capacity and provides results more or less equal to what would happen if he is to manage him in conjunction with RACHS-1. However, the application of both scores in dupla is feasible given the high affinity between the two with an alpha of Cronbach 0.740 and provides more tools to the doctor for the comparison and decision making.

Now, in contrast to other studies, there are values similar to those present in the package of articles that forms the literature review referred to in the first paragraph of this document, corroborating the results obtained found by other authors on the partnership between the score and the mortality. However, obtaining a better rate of significance as well as a higher discriminatory capacity with the score basic Aristotle makes a difference with respect to the rest of the articles in the literature, where generally to the RACHS-1 is you assigned a higher ability. In Table 10 some differences in this regard are shown.

Table 10: Comparison of the results of the study with literature

Study	Number	% Mortality	Significance	ROC Curve
RACH 1				
Kang et al.(10)	1,085	4.7	0.001	N/D
Al Radi et al.(1)	13,675	4.2	0.001	0.74
Macé et al.(12)	201	2.44	N/D	N/D
Vélez et al.(13)	3,161	7.7	N/D	N/D
Holm-Larsen et al.(14)	957	N/D	0.001	0.741
Boethig et al.(15)	4,370	6.8	0.001	0.784
Welke et al.(16)	12,672	2.9	0.05	0.77
Ithurralde et al.(17)	571	3.85	0.001	0.84
This Study	**201**	**6.46**	**0.001**	**0.77**
Aristóteles				
Kang et al.(11)	1,085	4.7	0.03	N/D
Al Radi et al.(1)	13,675	4.2	0.001	0.661
Macé et al.(12)	201	2.44	N/D	N/D
Heinrichs et al. (18)	787	3.05	0.002	N/D
This Study	**201**	**6.46**	**0**	**0.806**

However the results found, is clear that the predictive ability of both score exceeds the internationally standardized scores. This means that, although tests show an association between mortality variable and scores, this does not necessarily mean that the data obtained can adjust with the standards expected for RACHS-1. In fact, in any category was a value equal to or less than those provided by the Government. The solution to this situation may point to that, although both scores are properly designed and calibrated, and despite the fact that the variables exhibit Association positive and strong, the particular conditions of the hospital institution impossible prediction mortality based on the values accepted by the global consensus.

Thinking about the above, it was decided to merely tentative exercise to estimate what might be the percentages of mortality expected for each level of the RACHS-1 the institution addressed. This developed from the logistic regression using the segmented categorical variable. Here, the coefficient B and the Exp (B) was used to calculate what might be the new expected values of mortality for each of the four tested categories, obtaining the following results: RACHS-1=<3.4%, RACHS-2=3.4%, RACHS 3 = 19.4 %, RACHS-4 = 33.3 %. Moreover, the same coefficients associated with categorical basic Aristotle were: level 1 = < 3.0%, level 2 = 3.0 %, level 3 = 13.8 %, level 4 = 28.0 %.

Finally, it should be noted that the rest of the features related to surgical procedures, Comorbidities and risk factors show, in general, a low impact on mortality, except for the cases of type of surgery, reoperation, and BMI under. This means that, in surgery of congenital heart disease, mortality variance can be mostly explained by the elements considered in the assignment of scores and the score and less with other surrounding categories.

Conclusion

1. In accordance with the results obtained, the RACHS-1 and basic Aristotle risk stratification methods show a positive and close association with mortality in surgery of congenital heart disease in the analyzed hospital unit, which makes it valid use. In particular, basic Aristotle shows better performance. However, its predictive value was found below the values expected in accordance with international standards; but identified two factors that show high correlation with mortality in our series: history of reoperation and low weight prior to surgery, which none of the two values.
2. It accepts the hypothesis that the RACHS-1 and Aristotle methods allow an adequate stratification of risk in surgery of congenital heart disease, since we found a coefficient alpha of Cronbach > 0.7.
3. Scores of both methods are related to the technical difficulty and the time of stay in the ICU and postoperative.

Recommendations

1. Take into consideration factors that increase mortality: a history of reoperation and low weight prior to surgery, to Stratify patients with RACHS-1 and Aristotle basic.
2. Self-assessment of each surgeon to determine improvements in the surgical technique that impact in the reduction of the DCP and aortic clamping time that influence in a way positive in the evolution of the patients.
3. It is suggested further studies whose purpose is to properly adjust the levels of mortality expected for each category

of the scores, to respond in certain way to the behaviour of the population observed in the hospital unit. In them, taking one larger sample from the incorporation and contrast with populations of other hospital units in the country would be desirable.

4. A study with factor analysis to determine specifically the actual incidence of time of stay in the ICU and postoperative in the conformation of the analyzed scores.

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