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Surgical Mortality in Pediatric Congenital Heart Surgery: 10-Year Experience in a Chilean Cardiac Surgery Center

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Abstract

Background: Cardiac surgery is one fundamental pillars in the treatment of patients with Congenital Heart Disease (CHD). Various scales have stratified the risk of Surgical Mortality (SM). Risk Adjustment for Congenital Heart Surgery-1 (RACHS-1) scale classifies the different procedures according to their complexity and associated mortality risk, comparing SM of the same center or with peers according to the complexity of the surgery performed.

Objectives: To determine the current overall SM for general cardiac surgery in pediatric patients with CHD, according to the RACHS-1 stratification and to compare it with the results published at

Methods: Descriptive study. Patients under 18 years of age who underwent surgery for CHD at the Hospital Clínico de la Pontificia Universidad Católica de Chile between August 2010 to July 2020 were analyzed. Risk stratification was performed by RACHS-1. Ductus ligation in premature babies, surgery for acquired heart diseases and heart transplants were excluded. Results were compared with previously published results of the same institution for the period 2000-2010.

Results: 2,039 surgeries were performed in 1,589 patients. 56.7% of the patients were men with a median age of 6 months (range 0 days - 17 years). The main diagnoses were: ventricular septal defect 17.8% and tetralogy of Fallot 14.3%. 19.2% were syndromatic, of which 13.9% had Down syndrome. 89.6% of the surgeries were with Cardiopulmonary bypass with a mean duration of 121.8 min. Overall SM was 3.3%. Stratified by RACHS-1 score surgical mortality was: Category 1: 1.6%, Category 2: 1.3%, Category 3: 3.5%, Category 4: 4.0%, Category 5: 33.3%, Category 6: 15.5%.

For overall surgical procedures: 69.7% were operated on during the first year of life and 90% before the age of 6 years, 75% went to the biventricular pathway. Compared to our previous 10-year study, the SM decreased significantly from 5.9% to 3.3% (p<0.01), despite an increase in the number and complexity of surgeries, especially in RACHS 3 and 4 groups.

Conclusion: At our Institution, overall surgical mortality of congenital heart surgery decreased in the last 10 years from 5.9% to 3.3%, despite an increase in the number of procedures and their complexity compared to a similar period published at the same center previously.

Keywords: Mortality; Congenital heart disease; Congenital heart surgery

Introduction

Congenital Heart Defects (CHD) are the most frequent malformations in the pediatric population [1,2]. They occur during the first eight weeks of fetal embryological development of the cardiovascular system [3]. Worldwide prevalence is estimated at approximately 8 cases per 1,000 live births [4,5]. Chilean studies have reached figures of up to 10 per 1,000 live births, being similar to the incidence reported worldwide regardless of factors such as race, socioeconomic status or geographical location [6]. There are different factors associated with an increased risk for

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presenting heart disease, which are classified as maternal, fetal and environmental, which are present in 10% to 15% of children carrying some CHD [7]. Cardiac surgery is one of the fundamental pillars in the treatment of patients with CHD, improving the short- or long-term survival of these patients.

The survival of these patients has improved in recent years as a result of advances in early diagnostic techniques, therapeutics, surgical approaches, extracorporeal circulation and improvements in preoperative and postoperative intensive care [8-10]. The aforementioned advances have led to an increase in survival rates and a decrease in Surgical Mortality (SM). The latter is defined as death occurring within 30 days after the surgical date and independent of the cause [11].

In order to stratify the risk of SM associated with different surgical procedures, several scales have been created. The Risk Adjustment for Congenital Heart Surgery-1 (RACHS-1) scale published in 2002, which groups the different CHD into 6 groups according to their technical complexity and risk of SM associated with the procedure [12]. Thus, category 1 corresponds to the group of CHD associated with a lower risk of SM, while category 6 is the highest risk [13,14]. The RACHS-1 scale It is characterized by ease of implementation and usefulness, is also frequently used to evaluate the performance of an institution and compare it with respect to the same center over time [15,16] and with other national and international centers, in terms of the level of complexity of the cardiac surgeries performed and the associated SM rates, especially if other scales have not been used in the past [17].

For the last several years, mortality reporting in The Society of Thoracic Surgeons Congenital Heart Surgery Database (STS-CHSD) has adjusted for a relatively small number of case-mix factors, namely age, weight, and categories of procedural risk, as defined by STS—European Association for Cardiothoracic Surgery (EACTS) Congenital Heart Surgery (STAT) Mortality Categories. Because of the increased availability of robust clinical data, it is now possible to develop a more detailed risk model, with adjustment for individual procedure types and for a variety of specific patient characteristics. The STAT system assigns operations to 1 of 5 categories on the basis of a similar risk of in-hospital mortality, where category 1 has the lowest risk of death and category 5 has the highest [18].

The STS CHSD mortality risk model is used to calculate risk-adjusted operative mortality and adjusts for the following variables: Age, primary procedure, weight (neonates and infants), prior cardiothoracic operations, non-cardiac congenital anatomic abnormalities, chromosomal abnormalities or syndromes, prematurity (neonates and infants), and preoperative factors [19].

Mortality due to congenital heart disease in children under 1 year of age in Chile has been reported in about 1/3 of deaths due to congenital anomalies and in about 1/10 of all deaths in that period of life [6]. The average infant mortality in Chile for the years 2000 to 2010 was 8.2 per 1000 live births, in the last 10 years (2010-2020) mortality decreased to 6.9 per 1000 live births [20].

In Chile, at the Hospital Clínico de la Pontificia Universidad Católica de Chile (one of the four cardiac surgery centers in the country) over a period of 10 years (2000-2010), the SM due to CHD in the pediatric population was reported as 5.9% [21].

The main objective of this study is to determine the current

overall SM for general cardiac surgery in pediatric patients with CHD, according to RACHS-1 stratification and compare it with results previously published by our cardiac surgery center.

Patients and Methods

Descriptive study

All patients under 18 years of age with CHD who underwent cardiac surgery at the Hospital Clínico de la Pontificia Universidad Católica de Chile from August 2010 to July 2020 were analyzed. The following patients were excluded: Ligation of patent ductus arteriosus in premature patients younger than 30 days, valve replacements due to acquired heart disease such as infective endocarditis, Kawasaki disease, dilated cardiomyopathies and cardiac transplant patients. In summary, all patients who did not have a congenital heart disease were excluded, such as patients who, secondary to an infection or some other cause, have developed a heart condition that required surgical resolution.

Demographic and clinical data were collected for each patient (sex, age, weight, presence of genopathies or any malformation syndrome), echocardiograms were analyzed to determine the main anatomical diagnosis and the type of circulation (univentricular/biventricular). Palliative or staged procedures are primarily designed to improve systemic blood flow, modify pulmonary blood flow, enhance intracardiac mixing, or rehabilitate a ventricle prior to definitive surgery. For example, aortopulmonary shunts, Norwood procedure, pulmonary artery band, Glenn or Fontan procedure, etc.

Surgical risk was stratified according to RACHS-1 and the need for connection to Cardiopulmonary Bypass (CPB) and quantification of the duration time in minutes according to the operative procedure. Patients who underwent more than one surgical procedure during the same intervention were categorized according to the highest risk RACHS-1 score. If more interventions were performed during the 10 years of the study, they were considered as independent episodes. The mortality registry was obtained from the cardiac surgery follow-up database of patients operated at the Hospital Clínico de la Pontificia Universidad Católica de Chile and from the web page of the Civil Registration and Identification Office of Chile. The results obtained were compared with the study performed at the same center 10 years earlier

Surgical mortality was defined as death occurring within 30 days after the surgical date and independent of the cause.

Statistical analysis

Categorical variables were described in terms of number and percentage, while continuous variables were described in terms of average and range.

Mortality rates were calculated according to the following formula: (Number of deaths/Number of surgical procedures) \times 100, and were subsequently compared by calculating Poisson Rate Ratios (RT). P-value <0.05 was considered statistically significant in the study. Calculations were performed using SSPS version 22 software.

Results

During the studied period, 2016 cardiac surgeries and 1,589 patients under 18 years old carrying CHD were considered (Table 1). Most of the patients underwent surgery only once (1289 patients). Palliative surgical procedures were 502 (24.2%), while 75% of the procedures were towards the biventricular pathway (Table 2).

Table 1: Number of cardiac surgery in pediatric patients with CHD.

Number of surgeries*	Number of patients	%	
1 st	1289	81.12	
2 nd	184	11.58	
3 rd	106	6.67	
4 th	9	0.57	
5 th	1	0.06	

^{*}Overall 1,589 patients that represent 100%

Table 2: Demographic and clinical characteristics of overall surgical procedures for CHD operated at the Hospital Clínico de la Pontificia Universidad Católica de Chile during the period 2010-2020.

	Mean	Range	
Age (months)	6	0 - 204	
Weight (kg)	6.2	1.57 - 108	
	Number	Percentage (%)	
Age distribution:			
≤ 30 days	448	22.2	
>1 month - 1 year	958	47.5	
>1 years - 6 years	409	20.3	
>6 years - 15 years	169	8.4	
>15 years	32	1.6	
Sex:			
Male	1143	56.7	
Female	873	43.3	
Physiology:			
Univentricular circulation	502	24.9	
Biventricular circulation	1512	75	
Malformative Syndrome and/or	Genopathy:		
Yes:	387	19.2	
Down syndrome	281	13.9	
Other genopathy	106	5.3	
No:	1629	80.8	
Cardio-Pulmonary Bypass (CPE	3)		
Without CPB	209	10.4	
With CPB	1807	89.6	
	Mean	Range	
CPB time (minutes)	121.8	0-900	

For overall surgical procedures: 56.7% were male, the median age was 6 months (range 0 days - 17 years) 69.7% were operated on during the first year of life and 90% before the age of 6 years. The mean weight was 6.2 kg (range: 1.57 kg to 108 kg).

The main diagnoses of the surgeries were ventricular septal defect 17.8%, tetralogy of Fallot 14.3% and single ventricle right morphology with hypoplastic left heart syndrome with 10.4%. Pathologies such as Ebstein's anomaly, anomalous partial pulmonary venous drainage, aorto-pulmonary window, subaortic membrane, L-transposition of the great arteries and other diagnoses non mentioned on the table were grouped as others with 14.9% (Table 3). 19.2% had a malformation syndrome or genopathy, of which 13.9% was Down syndrome (n=281) being the most frequent genopathy. 89.6% of the surgeries were performed with CPB (n=1807) with a mean duration

Table 3: The main diagnoses of surgical procedures during the period 2010-2020 at the Hospital Clínico de la Pontifica Universidad Católica de Chile.

Diagnosis	Frequency	Percentage	
Ventricular septal defect	358	17.8	
Tetralogy of Fallot	289	14.3	
Single ventricle. Right Morphology. Hypoplastic left heart syndrome	210	10.4	
Aortic coarctation	169	8.4	
Complete Atrioventricular canal defect	154	7.6	
Atrial septal defect	118	5.9	
D-Transposition of the great arteries	97	4.8	
Single Ventricle. Left Morphology. Tricuspid atresia	82	4.1	
Total anomalous pulmonary return	51	2.5	
Single Ventricle. Left Morphology. Pulmonary atresia with intact septum	48	2.4	
Single Ventricle. Left Morphology. Others	34	1.7	
Interrupted aortic arch	29	1.4	
Single Ventricle. Right Morphology. Non hypoplastic left heart syndrome	29	1.4	
Truncus arteriosus	27	1.3	
Coronary artery anomalies	8	0.4	
Patent ductus arteriosus	7	0.3	
Single ventricle to Biventricular physiology	6	0.3	
Others**	300	14.9	
Overall	2016	100	

Others**: Ebstein's anomaly, Anomalous partial pulmonary venous drainage, Aorto-pulmonary window, L-Transposition of the great arteries, Subaortic membrane and other diagnosis non mention on the table

of 121.8 min (range 0-900 min).

Surgical mortality and risk stratification according to RACHS-1 score

The SM in the period 2010-2020 was 3.3% corresponding to 67 deceased patients in a total of 2016 procedures performed (Table 4). Twenty-three cardiac transplants were excluded because they were not classifiable by RACHS-1, of which there was no associated SM. According to the RACHS-1 score, 47.5% corresponded to low-risk categories (categories 1 and 2), 46.7% to intermediate-risk categories (categories 3 and 4) and 5.2% corresponded to higher-risk categories (categories 5 and 6).

The SM according to RACHS-1 was lowest in Category 2 with 1.3% followed by Category 1 with 1.6% (Table 4). During the period under evaluation, we also considered an extra category called Non-Classifiable (NC) in the case of procedures made in patients who, due to their clinical condition and severity, underwent hybrid procedures (cardiac surgery associated with hemodynamic procedures). Of these 11 procedures, 2 patients died during the period under evaluation, so they were considered within the total SM result of the study in order to have a more representative value of reality.

Comparing both periods' results, a significant decrease in SM by 43% (Rate Ratio =0.57 (p-value <0.001)) considered as a statistically significant decrease associated with an increase in the number of total procedures performed in the last decade (1658 ν s. 2016) can be evidence. Throughout the RACHS-1 categories, an increase in the number of moderate-high complexity procedures (RACHS-1 categories 3 and 4) of 39.4% to 46.7% of overall procedures with a decrease in overall SM can be evidenced, mainly in categories 3 with

Table 4: Comparison of surgical mortality in procedures for CHD at the Hospital Clínico de la Pontificia Universidad Católica de Chile between 2010-2020 and the results previously published in the same institution for the period 2000-2010 [21].

DACUE 4		Period of 2000-2010 [21]		Period of 2010-2020			
RACHS-1	Deaths	Surgeries	Surgical mortality (%)	Deaths	Surgeries	Surgical mortality (%)	p-value
1	5	242	2.1	3	190	1.6	1
2	14	675	2.1	10	768	1.3	0.35
3	34	546	6.2	27	764	3.5	0.04
4	26	107	24.3	7	177	4	<0.01
5	0	1	0	3	9	33.3	1
6	18	87	20.7	15	97	15.5	0.51
NC	-	-	-	2	11	18.2	-
Overall	97	1.658	5.9	67	2.016	3.3	<0.01

Abbreviations: NC: Not Classifiable (hybrid procedures)

decrease of 6.2% to 3.5% (p-value 0.04) and category 4 with decrease of overall SM of 24.3% to 4.0% (p-value <0.01). It should be noted that these categories mainly include a group of complex patients with severe and often decompensated CHD, often being palliative surgeries [9].

Discussion

The study considered surgical procedures performed on patients under 18 years of age carrying CHD during the period 2010-2020 with an overall SM rate of 3.3% (67 patient deaths in 2016 surgeries). Compared to a previous study, performed in the same center with the same risk stratification tool (RACHS-1) during the year 2000-2010, this was a significant reduction in SM (from 5.9% to 3.3%) and was more evident in RACHS-1 3 and 4 categories [21].

A decrease in the number of low complexity procedures (RACHS-1 categories 1-2) can be seen, also reducing the SM in these categories. The decrease in the number of procedures of low complexity could be explained by the increase in procedures performed by cardiac catheterization or referral to centers of lower complexity [22]. In the results it is worth mentioning that in RACHS-1 category 5 there was an increase in the number of procedures, from 1 surgery to 9 associated with high SM in this category. It is important to consider that they continue to be low frequency procedures of very high complexity.

As for the interventions by age group, 69.7% of the procedures were in patients younger than 1 year, with 22.2% of the procedures performed in patients younger than 30 days of life, a period of greater hemodynamic and clinical lability.

When comparing our results with international series such as the reported by Berger et al., at The Journal of Thoracic and Cardiovascular Surgery in 2017 with an overall SM of 3.2% with a total of 1,550 patients (newborn to age 18 years), an overall SM similar to our series is evidenced. The distribution of the RACHS-1 in their series were concentrated in categories 2 and 3 with 71% of the total [23].

In the latest published studies reported by Bateson et al., at World Journal for Pediatric and Congenital Heart Surgery in 2023 the overall surgical mortality across the cohort was 2.27% consisted of 16,040 individual procedures submitted over a two-year period (2017-2019). The entire cohort was categorized by STAT Mortality risk category and RACHS Mortality risk group [24].

In South America, the results reported for surgical mortality due

to congenital heart disease are scarce, one of the most recent was an observational and interventional study conducted at a tertiary children's hospital in Cordoba, Argentina. Patients undergoing surgery for congenital heart defects between 2012-2015 were included. A total of 373 surgical procedures for congenital heart defects were performed on 203 male patients and 170 female patients. In-hospital mortality not adjusted to RACHS-1 it was 5.6% and, at 30 days, 5.9%; and adjusted to RACHS-1 categories 1: 0%, 2: 3.7%, 3: 11.2%, 4: 27.3% [25].

In relation to this decrease in overall SM associated with cardiac surgeries in this last decade in our Institution, this could be explained due to various factors such as the increase in the learning curve over a decade by the cardiac surgery team, myocardial protection, pre- or post-surgical care in intensive care and the entire multidisciplinary team. In addition, since 2013 the inauguration of the new pediatric ICU was carried out with an increase in the number of slots in the intensive care unit and the acquisition of new supplies and more staff, at this point it's important the permanent presence of a cardiologist in addition to the pediatric intensivist. Besides, from the same date, daily visits by pediatric infectologists were incorporated in order to reduce intrahospital infections.

Limitations of the Study

Retrospective review of a single center. The use only of the RACHS-1 scale to compare the results of surgical mortality. However, in new studies the most up-to-date scales will be used.

Conclusion

There is a statistically significant decrease in the overall SM of pediatric cardiac procedures at our Institution in these last 10 years when compared to a similar period published previously, despite an increase in the number of procedures and their complexity.

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