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Ten-year experience in cardiac surgery for congenital heart disease at a high specialty hospital

Experiencia de 10 años en cirugía cardíaca para cardiopatías congénitas en un hospital de alta especialidad

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ABSTRACT

Objective: to describe the initial historical experience of a third-level hospital in surgery for congenital cardiovascular malformations performed by a single surgeon, to present the postoperative results based on their morbidity and mortality, and to compare the preoperative surgical risk with internationally accepted quality standards. **Material:** a retrospective, analytical, cross-sectional clinical study was carried out, which included pediatric patients diagnosed with congenital heart disease who underwent surgery over a 10-year period. Sociodemographic, diagnostic, therapeutic, morbidity and mortality variables were considered. **Results:** a total of 112 patients with congenital heart disease were studied. A predominance of females and schoolchildren was observed in this series. The main malformations operated on were patent ductus arteriosus and atrial septal defects. A morbidity of 22% and an overall mortality of 8% were observed. **Conclusions:** the creation of regional third-level hospitals has promoted the development of pioneering programs in cardiovascular surgery such as the one described in this article, obtaining favorable results comparable with international mortality standards. However, the care of increasingly complex heart diseases remains a challenge to face in the future.

Keywords: cardiac surgical procedures, congenital heart disease, health services.

RESUMEN

Objetivo: *describir la experiencia histórica inicial de un hospital de tercer nivel en cirugía de malformaciones congénitas cardiovasculares por un único cirujano, exponer los resultados postoperatorios en función de su morbimortalidad, y comparar el riesgo quirúrgico preoperatorio con los estándares internacionalmente aceptados de calidad.* ***Material:*** *se realizó un estudio clínico retrospectivo, analítico y de corte transversal donde se incluyeron pacientes pediátricos con diagnóstico de cardiopatía congénita operados en un periodo de 10 años. Se consideraron variables sociodemográficas, diagnósticas, terapéuticas, morbilidad y mortalidad.* ***Resultados:*** *se incluyeron 112 pacientes con cardiopatías congénitas. Se observó una predominancia del género femenino y los escolares en la serie. Las principales malformaciones operadas fueron la persistencia del conducto arterioso y la comunicación interauricular. Se observó una morbilidad del 22% y una mortalidad global del 8%.* ***Conclusiones:*** *la creación de hospitales regionales de tercer nivel ha impulsado el desarrollo de programas pioneros en cirugía cardiovascular como el expuesto en este artículo, obteniendo resultados favorablemente comparables con los estándares internacionales de mortalidad. Sin embargo, la atención de cardiopatías cada vez más complejas sigue siendo un reto a vencer en el futuro.*

Palabras clave: *procedimientos quirúrgicos cardíacos, cardiopatías congénitas, servicios de salud.*

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Abbreviations:
ASD = atrial septal defect
CPB = cardiopulmonary bypass
PDA = patent ductus arteriosus
RACHS-1 = Risk Adjustment in Congenital Heart Surgery -1 Scale
VSD = ventricular septal defect

Heart defects are the most frequent congenital malformations[1] and are the result of an alteration in the heart morphology during intrauterine development[2] that lead to a functional impact at birth. The worldwide incidence is 8 to 12 per 1,000 newborns, and they are associated with an increased perinatal and long-term morbidity and mortality.[3] Clinical presentation has a wide spectrum that ranges from the absence of symptoms to cyanosis, shock and heart failure. During the first month of life, at least one third of congenital heart defects will require some type of intervention with a high risk of death. They can also be detected in the pediatric stage due to a delay in timely diagnosis.[4]

Surgery is one of the therapeutic alternatives for congenital heart disease. Although there are several perioperative risk scales, the most widely used due to its practicality is the Risk Adjustment in Congenital Heart Surgery -1 Scale (RACHS-1) developed by Boston Children's Hospital, which classifies 207 surgical procedures into six groups with increasing mortality risk. The procedures with the lowest surgical risk are placed in the first group, while the sixth group contains those with the greatest surgical complexity and highest risk of perioperative mortality.[5]

Regionalization aims to rationalize medical care based on the population and existing resources, in order to increase the number of treated cases, improve the quality of care and reduce mortality. Based on international recommendations, Mexico requires 21 to 25 specialized medical-surgical centers, of which there are 10, eight of them located in Mexico City, one in Monterrey and one in Guadalajara. The high frequency of congenital heart disease implies the need for more prepared cardiovascular surgical centers.[1] Our Institution (Ixtapaluca Regional High Specialty Hospital) is one of the hospitals that was created in the country to meet these decentralization needs, formally beginning its healthcare activities in 2012.[6] The objective of this article is to describe the initial historical experience at our Institution in the surgical therapeutic approach to cardiac malformations in pediatric patients, to present the postoperative results based on their morbidity and mortality, and to compare the preoperative surgical risk with internationally accepted quality standards.

MATERIAL

A retrospective, analytical, cross-sectional clinical study was designed including all pediatric patients operated on for congenital heart disease at our Institution from the beginning of its cardiac surgical care activities (2013) until completing the first 10 years of institutional experience by a single surgeon. All pediatric patients with congenital heart disease were included, without distinction of gender or surgical opportunity (elective or emergency surgery). Those patients that were not operated on at our institution in the indicated period were excluded.

Table 1: Sociodemographic variables.

Variable	n (%)
Gender	
Male	43 (38)
Female	69 (62)
Age	
Neonates (< 1 month)	9 (8)
Young infants (1 month to one year)	12 (11)
Older infants (> 1 year to two years)	17 (15)
Preschoolers (Three to five years)	31 (28)
Schoolchildren (Six to 12 years)	35 (31)
Adolescents (13 to 17 years)	8 (7)
Diagnosis according to sequential classification	
Malformations of venous return	2 (2)
Atrial malformations	25 (22)
Malformations of the AV connection	0 (0)
Ventricular malformations	14 (12)
Malformations of the VA connection	0 (0)
Malformations of the great arteries	68 (61)
Other congenital and/or pediatric heart diseases	4 (3)
Operative risk (RACHS-1 scale)	
RACHS-1 of 1	83 (74)
RACHS-1 of 2	9 (8)
RACHS-1 of 3	4 (4)
RACHS-1 of 4	5 (4)
RACHS-1 of 5	2 (2)
RACHS-1 of 6	0 (0)
RACHS-1 Non-classifiable	10 (9)
Type of procedure	
Primary surgery	112 (99)
Re-operation	1 (1)
Opportunity of surgery	
Elective	89 (78)
Urgent	24 (22)
Need for CPB	
Without CPB	74 (65)
With CPB	39 (35)
Cardiothoracic surgical procedure performed	
Cardiovascular procedure	111 (98)
Thoraco-pulmonary procedure	2 (2)
Total number of surgical procedures performed	113 (100)
Total number of patients operated	112 (100)

AV = atrioventricular. CPB = cardiopulmonary bypass. RACHS-1 = Risk Adjustment in Congenital Heart Surgery -1. VA = ventriculoarterial.

Table 2: Diagnostic variables.

Sequential classification	n (%)
Level 1 - Venous return	2 (2)
Obstructive supracardiac TAPVC	1 (1)
Non-obstructive supracardiac TAPVC	1 (1)
Level 2 - Atrial	25 (22)
Ostium secundum type ASD	23 (20)
ASD + Amplatzer failure	1 (1)
Common atrium + left superior vena cava	1 (1)
Level 3 - AV connection	0 (0)
Level 4 - Ventricular	14 (12)
Perimembranous VSD	12 (10)
Infundibular VSD	2 (2)
Level 5 - VA Connection	0 (0)
Level 6 - Great arteries	68 (61)
Aortic coarctation	2 (2)
Aortic coarctation + aortic arch hypoplasia	3 (3)
Type A aortic arch interruption	3 (3)
PDA	58 (51)
PDA + major aortopulmonary collateral arteries	1 (1)
AoPu window + anomalous origin of PA from Ao + AoCo + aortic arch hypoplasia	1 (1)
Level *- Other congenital and/or pediatric heart diseases	4 (3)
Complete congenital AV block	2 (1)
Mediastinal hemorrhage + stroke post VSD closure	1 (1)
Bilateral hemopneumothorax	1 (1)

* Unclassifiable level. Ao = aorta. AoCo = aortic coarctation. ASD = atrial septal defect. AV = atrioventricular. PDA = patent ductus arteriosus. Pu = pulmonary. TAPVC = total anomalous pulmonary vein connection. VA = ventriculoarterial. VSD = ventricular septal defect.

Sociodemographic variables, weight, height, diagnosis, need for cardiopulmonary bypass (CPB), postoperative morbidity and mortality, and the preoperative RACHS-1 scale were taken into account. Data were obtained from the institutional electronic medical record and compiled in an Excel spreadsheet in order to subsequently be analyzed with SPSS v.21 statistical software. Numerical variables are presented as mean ± standard deviation, with minimum and maximum variability ranges. Categorical variables are presented as frequency (n) and percentage in relation to the population at risk. Institutional operative mortality was compared with that predicted by the RACHS-1 risk scale using the χ^2 test, calculating the Odds Ratio with a 95% confidence interval. A $p < 0.05$ was considered statistically significant. The study was registered and approved by the institutional research and research ethics committees. Confidential handling measures for the data obtained were followed.

RESULTS

This study presents 112 pediatric patients diagnosed with congenital heart disease operated on at a third-level hospital as an initial experience, exposing the results in the three stages of the surgical procedure: preoperative, intraoperative and postoperative.

Preoperative results

Table 1 shows the sociodemographic characteristics, diagnosis according to the type of malformation, preoperative history, and immediate postoperative results. Regarding gender, it can be observed that more than half of the patients were women (female:male ratio of 1.6:1). Almost a third of the patients were schoolchildren, followed by preschoolers and older infants. According to the sequential classification of congenital heart defects, more than half of the pediatric patients were operated on for level 6 malformations (of the large vessels), followed by atrial (level 2) and ventricular (level 4) malformations. All patients were given the RACHS-1 surgical risk scale, classifying them into 6 main risk categories and a complementary category of non-classifiable ones. It can be observed that more than half of the cases were classified in category 1 (73%), and almost a tenth of them were unclassifiable (9%). All patients underwent primary surgery, except for one case that needed re-operation (1%). According to the clinical condition of the heart disease at the time of hospitalization, most of the surgeries performed were scheduled, with less than a quarter of the surgical procedures being urgent. Almost two thirds of the surgeries were performed without CPB and the rest required CPB. It can also be observed that almost all of the surgeries performed were cardiovascular procedures, with those of a thoracopulmonary nature being practically negligible.

Intraoperative results

Table 2 shows the cardiovascular diagnoses of the patients on admission to the operating room. More than

Table 3: Postoperative morbidity variables.

Overall operative morbidity (23 of 112 patients)	n (%)
Right pneumothorax	2 (2)
Respiratory infection	5 (4)
Anaphylactic shock and surgical wound infection	3 (3)
Re-coarctation	1 (1)
Hemopneumothorax	3 (3)
Mediastinal hemorrhage and stroke	1 (1)
Intraoperative hemorrhagic shock	2 (2)
Post-surgical AV block	3 (3)
Residual VSD with hemodynamic repercussions	3 (3)
Total	23 (22)

AV = atrioventricular. VSD = ventricular septal defect.

Table 4: Postoperative mortality variables.

Diagnosis of the deceased patients	Overall operative mortality n (%)	Cause	Age
VSD	2 (1.79)	Septic shock Cardiogenic shock	Three months Four years
VSD + ASD + PDA	1 (0.89)	Severe PAH	Two years
PDA + endocarditis	1 (0.89)	Massive pulmonary hemorrhage	Eight years
Coarctation of aorta + hypoplasia of the aorta	1 (0.89)	Cardiogenic shock	One month
Supracardiac obstructive TAPVC	1 (0.89)	Biventricular failure	Two months
Mediastinal hemorrhage and stroke after VSD closure	1 (0.89)	Cerebral edema due to intraoperative hypoxia due to CPB	Nine years
AoPu window + AoCo + LSCV anomalous origin of RPA from Ao + PDA	1 (0.89)	Severe PAH	14 days

Ao = aorta. AoCo = aortic coarctation. ASD = atrial septal defect. CPB = cardiopulmonary bypass. LSCV = left superior vena cava. PAH = pulmonary arterial hypertension. PDA = patent ductus arteriosus. Pu = pulmonary. RPA = right pulmonary artery. TAPVC = total anomalous pulmonary vein connection. VSD = ventricular septal defect.

Table 5: Observed mortality compared with predicted values of the RACHS-1 scale.

Risk	Patients, n	Deaths, n	Expected mortality, %	Obtained mortality, %	p
1	83	1	0.4-2.5	1.2	NS
2	16	1	3.8-8.6	6.3	NS
3	6	0	18.4-22.4	0	NS
4	4	3	29.4-34.2	75	0.005
5	0	0	36.4-42.4	SD	–
6	0	0	48.2-54.0	SD	–
NC	5	4	?	80	?

108 classifiable and 5 not classifiable.
NC = not classifiable. NS = not significant. SD = standard deviation. RACHS-1 = Risk Adjustment in Congenital Heart Surgery -1.

half of the patients operated on in our center presented malformations at the level of the large vessels, with the most frequent diagnosis being a patent ductus arteriosus (PDA) in its different varieties, followed by aortic arch defects, among which the interruption of the aortic arch and aortic coarctation stand out. In this last pathology, it is important to mention the concomitant presence of aortic arch hypoplasia. Atrial malformations were the second cause of surgical intervention, with ostium secundum type atrial septal defect (ASD) being the most frequent. All of them corresponded to those without margins for intervention, except for one case of failure due to this therapeutic modality. It is worth mentioning that there was another case of common atrium ASD with concomitant persistent left superior vena cava. Ventricular defects occurred in less than a quarter of the patients, with a perimembranous ventricular septal defect (VSD) predominance, except for two infundibular VSD cases. Although RACHS-1 level 1 predominates in this series, it should be noted that a significant percentage of the operated patients had a greater complexity, such as an unclassifiable level.

Postoperative results

Table 3 shows the operative morbidity, which occurred in less than a quarter of the patients in our series. Complications include respiratory infections, cardiac arrhythmias, surgical wound dehiscence, and hemopneumothorax. *Table 4* details the cause of mortality according to age group, underlying cardiovascular diagnosis for each deceased patient. It can be observed that more than half of the patients who died were neonates and infants (56%), most of whom had critical congenital heart disease. The most frequent causes of death were cardiogenic shock, septic shock, and pulmonary arterial hypertension. *Table 5* shows the mortality rates of our study series compared to the RACHS-1 scale, where we can observe

a statistically significant difference in those patients with category 4 only, who had higher mortality than predicted.

DISCUSSION

Congenital heart defects are the most common malformations at birth and include a wide range of pathologies and surgical techniques that are applied to a no less wide spectrum of patients. Currently, mortality from these diseases are considered as an indicator of progress. This was established at a global level in the sustainable development as a goal in order to reduce deaths in children under five years of age with these malformations. In Mexico, the health system was traditionally centralized in large cities, which promoted that patients with congenital heart defects received late and fragmented care, leading mortality from these diseases to be 1.3 times higher compared to international statistics.[7] In the last two decades, the Ministry of Health implemented a regionalization care project for patients with congenital heart defects with the objective of diminishing mortality. The Cardiovascular Diseases Committee of the European Association of Cardiothoracic Surgery recommends that one hospital with cardiovascular surgery service must be established for every 4 million inhabitants.[8] Taking into account these recommendations, and knowing the population of our country in 2010, at least 25 hospitals with these characteristics were required. Despite this fact, in that year there were only 11 hospitals in the country, of which 8 of them were in Mexico City. In order to improve the coverage of specialized care at a national level, High Specialty Regional Hospitals were built, among which our hospital center was created. Our work team was a pioneer in the 10-year cardiac surgical experience that is presented in this study starting in 2013. Therefore, the initial percentage of pediatric patients operated on was low.

This study presents the results of our surgical procedures performed by a single surgeon on patients under 18 years of age with congenital heart disease at a third level regional hospital. This historical experience in cardiovascular surgery at our site began with a 12-year-old boy with patent ductus arteriosus, which was closed without complications and was chosen particularly for the high success rate of the surgical procedure.

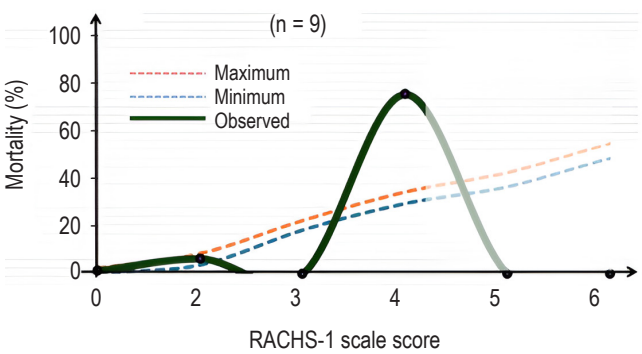

Figure 1: Observed mortality compared with predicted values of the RACHS-1 scale.
RACHS-1 = Risk Adjustment in Congenital Heart Surgery -1.

According to the literature, congenital heart defects mainly affect males. The data analysis of this study disagrees with this statement because a predominance of the female gender was observed in our series. However, it was also documented that atrial septal defect and patent ductus arteriosus were more frequent in women as observed in this study. In contrast, aortic stenosis, coarctation of the aorta and transposition of the great arteries were more frequent in males and were more serious heart diseases as well.[9] The procedures in these series were performed in schoolchildren and preschoolers. This is observed since, at the beginning of the congenital heart disease surgery program in our institution, we chose patients of these ages because they had lower surgical risk.

In the last 10 years of our experience, the most frequent heart disease was patent ductus arteriosus, probably due to hypobaric hypoxia associated with the altitude of the State of Mexico, where most of our patients came from.[10] The most frequently occurring heart diseases worldwide are ventricular septal defect, atrial septal defect, patent ductus arteriosus, pulmonary stenosis, tetralogy of Fallot, aortic stenosis, aortic coarctation, and transposition of the great arteries.[11,12] The initial experience that we present in this article included a minority of complex heart diseases, due to the rigorous selection that we made in our patients. This strategy allowed us to obtain a favorable historical experience in a newly created hospital, with recent personnel, processes, and machinery. Additionally, the beginning of a surgical program with this type of cases also offered the advantages of a low failure rate, low probability of needing postoperative therapy, and decreased costs and complications.

When analyzing our results applying the mortality predicted by the RACHS-1 scale, we observed that in categories 1, 2 and 3 we had a mortality rate that was favorably compared with internationally accepted standards, despite being a newly created center *(Fig. 1)*. For this reason, we also observed a statistically significant increase in operative mortality with increasing complexity of the cardiovascular surgery performed. Although 90% of the surgical procedures presented were concentrated in the lowest risk groups (categories 1, 2 and 3), our surgical series was not exempt from higher risk procedures, as corroborated by the 9% of patients operated on with unclassifiable risk. It is important to highlight that this scoring system does not allow determining the operative mortality of individual patients since it does not incorporate other variables recognized as determinants of mortality, such as pathological background and the opportunity of surgery,

among others.[13,14] Although there is a direct correlation between surgical risk and RACHS-1 category, in our experience, patients with higher complexity were mainly associated with an incomplete or nonspecific diagnosis. It is also important to mention that the historical experience created was not only based on elective patients, because there were 22% of patients who required urgent intervention, which increased the complexity.

CONCLUSIONS

Developing a surgical program for congenital heart disease represents a great challenge for the health personnel involved, since a series of administrative, technical, economic and, mainly, human resources problems must be considered. Many of the patients who underwent surgery were candidates for therapeutic intervention. However, the appropriate specialists in this area were not available at the beginning of our center experience. Although this is a clear example that shows the need for strengthening of the cardiovascular team, it must also be recognized that its absence allowed the consolidation of our surgical service, since this therapeutic alternative is useful in these circumstances. Finally, this set the precedent for continuing to progress in the future for establishing our center as a regional reference in increasingly complex pathology in the area of congenital heart disease.

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