

Understanding the Challenge of Complex Congenital Heart Palliation Follow-Up in a Middle-Income Latin American Country

Comprendiendo el desafío del seguimiento de la paliación de cardiopatías congénitas complejas en un país latinoamericano de ingresos medios

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Abstract

Introduction. Congenital heart disease of great complexity like single ventricle are the most prevalent congenital defects, managing these requires multiple surgical procedures, usually three stages. Lethality during the interstage period has decreased due to practices as home monitoring. Given the significant resources invested in patient care, it is essential to improve long-term outcomes. There is limited research in cardiovascular disease within middle-income countries.

Objective. To identify factors associated with lack of medical follow-up and lethality in children during first interstage period.

Method. A retrospective cohort study was conducted including 173 children in their first interstage period after cardiovascular surgery for severe congenital heart disease. Reviewed clinical records and contacted caregivers through telephone/instant messaging software. Analysis included central tendency and dispersion measures. Associations between independent variables and the primary outcomes —loss to follow-up (LTF) and mortality during the interstage period— were evaluated using the Mann-Whitney, Chi-square or Fisher’s exact tests.

Results. Of 173 patients, 65 (37.6%) patients LTF. The risk factors for LTF: rural residence (OR=5.05, CI95%1.32-19.26), lower educational level of parents. Global lethality was 13.3% (CI95%7.9-20.4) and factors associated were: rural origin (OR=22.78, CI95%3.68-140.83), malnutrition (OR=25.47, CI95%2.96-218.73), necrotizing enterocolitis (OR=13.34, CI95%2.34-75.97) and heterotaxia or situs

Ethics statement

This study was approved by the Ethics Committee of the Fundación Cardiovascular de Colombia (Approval No. CEI-2017-424). All caregivers provided informed consent prior to the telephone interviews.

Data availability

All data supporting the findings of this study are available within the article. For additional details, please contact the corresponding author.

Author Contributions

Laura Mantilla: conceptualization, data curation, formal analysis, funding acquisition, investigation, methodology, project administration, resources, supervision, validation, visualization, writing – original draft, writing – review & editing.

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Generative AI declaration

The authors declare that no generative AI tools were used in the writing, editing, data analysis, or any other part of the preparation of this manuscript.

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inversus (OR=8.05, CI95%1.26-51.34). The number of visits were a protective factor for interstage lethality (OR=0.71, CI95%0.55-0.9).

Conclusion. The interstage period entails significant challenges for patients and their families, which are possibly exacerbated by the socio-economic context of a middle-income country. Improving follow-up and support for caregivers of patients under similar conditions could help mitigate identified factors related to lethality.

Keywords

Heart defects; interstage period; loss to follow-up, Latin America; lethality.

Resumen

Introducción. Las cardiopatías congénitas de gran complejidad, como el ventrículo único, se encuentran entre los defectos congénitos más prevalentes. Su manejo requiere múltiples procedimientos quirúrgicos, generalmente en tres etapas. La letalidad durante el período interestadio ha disminuido gracias a prácticas como el monitoreo domiciliario. Dado el importante volumen de recursos invertidos en el cuidado de estos pacientes, es esencial optimizar los desenlaces a largo plazo. Sin embargo, la investigación en enfermedades cardiovasculares en países de ingreso medio es limitada.

Objetivo. Identificar los factores asociados con la falta de seguimiento médico y la letalidad en niños durante el primer período interestadio tras cirugía paliativa inicial.

Método. Estudio de cohorte retrospectiva con 173 niños en el primer período interestadio luego de cirugía cardiovascular por cardiopatía congénita severa. Se revisaron historias clínicas y se contactó a los cuidadores por vía telefónica o mensajería instantánea. El análisis incluyó medidas de tendencia central y dispersión. Se evaluó la asociación de variables independientes con los desenlaces principales: pérdida del seguimiento (LTF, por sus siglas en inglés) y letalidad durante el período interestadio, utilizando pruebas de Mann-Whitney, Chi-cuadrado o exacta de Fisher según correspondiera.

Resultados. De los 173 pacientes, 65 (37.6%) se perdieron del seguimiento. Factores de riesgo para LTF: residencia rural (OR=5.05, IC95% 1.32–19.26), bajo nivel educativo de los padres. La letalidad global fue del 13.3% (IC95% 7.9–20.4), asociada con origen rural (OR=22.78, IC95% 3.68–140.83), desnutrición (OR=25.47, IC95% 2.96–218.73), enterocolitis necrosante (OR=13.34, IC95% 2.34–75.97) y heterotaxia o situs inversus (OR=8.05, IC95% 1.26–51.34). El número de visitas fue un factor protector frente a la letalidad en el período intermedio (OR=0.71, IC95% 0.55–0.90).

Conclusión. El período interestadio representa desafíos importantes para los pacientes y sus familias, posiblemente exacerbados por el contexto socioeconómico de un país de ingreso medio. Fortalecer el seguimiento médico y brindar apoyo sistemático a los cuidadores podría mitigar los factores relacionados con la letalidad identificada.

Palabras Clave

Defectos cardíacos; periodo interquirúrgico; pérdida de seguimiento; América Latina; letalidad.

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Introduction

By 2017, congenital cardiac malformations had a birth prevalence of 3 to 6 cases per 1,000 live births in the USA, making them one of the most prevalent congenital defects [1,2]. Congenital heart disease (CHD) of great complexity [2], such as a single ventricle or a systemic right ventricle, are characterized by multiple intra- or extra-cardiac abnormalities, often involving abnormal vascular structures and ventricular hypoplasia. These conditions result in univentricular physiology, which is associated with increased morbidity and mortality [3]. Typically, managing these malformations requires multiple surgical or interventional procedures, usually conducted in three stages: Stages I, II, and III, with the goal of achieving hemodynamic stability [4].

The term “interstage” was coined for infants with hypoplastic left heart syndrome (HLHS) and refers to the period from discharge after the initial palliative surgery to admission for the subsequent intervention. Risk factors for increased mortality during interstage includes, young gestational weight, low birth weight, race and longer in hospital time after stage 1 palliation [5]. Unfortunately, mortality during the interstage period had been substantial, reaching up to 25% for HLHS. Additionally, morbidity and mortality may be higher for patients with major genetic abnormalities such as Trisomy 21, Turner syndrome or heterotaxy syndrome, due to the involvement of other organs and systems that modify the hospital course and ultimately the outcomes [6]. However, these rates have declined in recent years due to practices such as the increased use of the right ventricle-to-pulmonary artery shunt, earlier superior cavopulmonary connection, and innovative strategies such as home monitoring [5,7,8].

Other neonatal palliative procedures have been reported with similar challenges and significant mortality after discharge (3.7-14% for Blalock Taussig shunt and 4.8% for pulmonary artery banding) [9,10].

Given the significant resources invested in patient care, it is essential to improve long-term outcomes following complex hospitalizations. However, even though middle-income countries (MICs) represent 75% of the global population (five billion vs. 1.1 billion in HICs) and contend with 62% of global poverty, available data primarily emanates from high-income countries (HICs) [11]. We acknowledge the limited research output in cardiovascular disease within MICs, which restricts our ability to effectively address the current burden of CHD in a region marked by significant socioeconomic disparities [12,13].

This study aims to identify determinants of morbidity, mortality, and factors associated with inadequate follow-up and adverse outcomes during the interstage period after initial palliative management in children with complex CHD, focusing on a middle-income Latin American country.

Method

Design and population

This retrospective cohort study was conducted at a tertiary pediatric cardiology center in Latin America. The center provides comprehensive care for children with complex congenital heart disease, including surgical, interventional, and outpatient services.

Sampling and sample

A convenience sampling strategy was selected. The study included children diagnosed with complex CHD who underwent their first cardiovascular surgery during the study period and entered the interstage period. Complex CHD was defined according to ICD-10 codes Q20–Q26 (congenital malformations of the circulatory system) and restricted to cases requiring initial palliative cardiovascular surgery. Patients with non-cardiac congenital malformations or syndromes, as well as those with multiple congenital anomalies extending beyond the cardiovascular system, were excluded from the study. The study spanned from January 2015 to December 2019.

Data collection and variables

We retrieved patient data from electronic medical records, surgical databases, and outpatient clinic records. The data collected included demographic information, medical history, surgical details, and postoperative courses. Additionally, we contacted caregivers using telephone calls and instant messaging software to gather additional information and inquire about the child's current status. The study team included cardiologists, cardiothoracic surgeons, and research assistants.

The primary outcome variables were loss to follow-up (LTF) [14] and lethality (case fatality rate) during the interstage period. In line with epidemiological definitions, the term “lethality” was used instead of “mortality,” since the denominator corresponds to affected patients undergoing initial palliative surgery rather than the general population of live births. Loss to follow-up was defined as the absence of contact or information about the patient's status for a specified period after discharge from the initial surgery until the scheduled admission for the next stage. Lethality was determined based on available medical records or caregiver reports.

We considered various independent variables, including demographic factors (age, sex, residence), parental characteristics (educational level, occupation), clinical factors (preoperative clinical status, surgical details, postoperative complications), and socioeconomic factors (household income, access to transportation). The association of these variables with the primary outcomes was assessed.

Statistical methods

Descriptive statistics were performed for all variables for all variables, including measures of central tendency and dispersion. Continuous variables were expressed as means with standard deviations or medians with interquartile ranges, depending on the distribution. Categorical variables were presented as frequencies and percentages. Bivariate analysis was conducted using Mann-Whitney U tests, Chi-square tests, or Fisher's exact tests, as appropriate. Variables showing significance in univariate analysis were included in multivariate logistic regression models to identify independent predictors of LTF and lethality. Odds ratios (OR) with 95% confidence intervals (CI) were calculated, and p-values less than 0.05 were considered statistically significant. Statistical analysis was done in Stata -15.

Institutional Review Board Statement

The study followed the principles of the Declaration of Helsinki and approved by the Ethics Committee of Fundación Cardiovascular de Colombia (protocol code CEI-2017- 424, May 30th, 2017) under the name of “Programa de Monitoreo y Educación para el Seguimiento en Casa de Niños con Cardiopatías Congénitas Complejas”, project from which articles such as

the one presented here have been derived. Informed consent was obtained from the caregivers before conducting telephone interviews.

Results

A total of 173 patients were included; of these, 108 (62%) had complete follow-up data. Loss to follow-up (LTF) was identified in 65 patients (37.6%; 95% CI: 30.3–45.2). Among those, only 30.7% (20/65) were successfully contacted, and 11 (55%) were confirmed deceased. The vital status of the remaining 45 patients (69.2%; 95% CI: 19.6–33.2) remained unknown at the time of the finalization of the study (Figure 1)

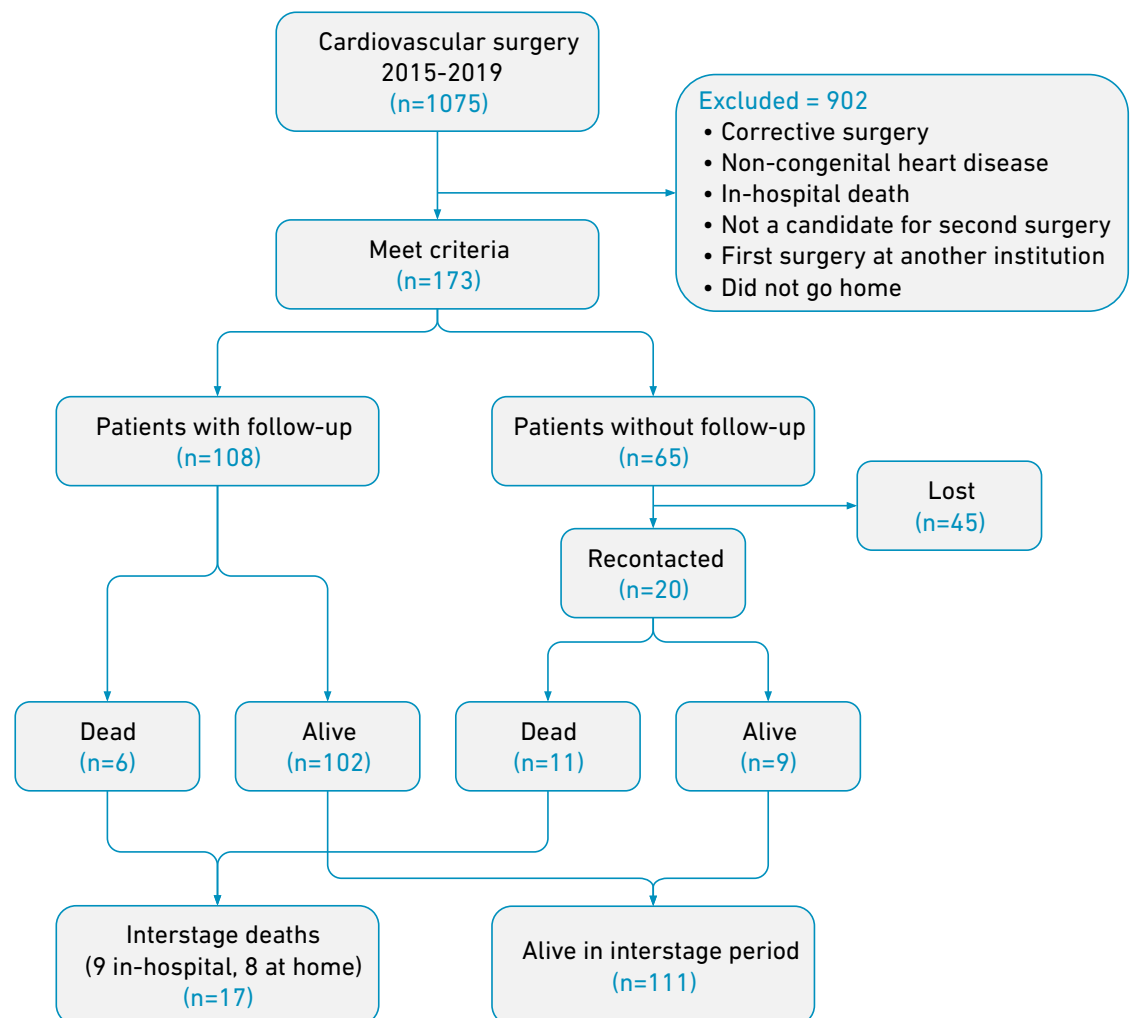


Figure 1. Flowchart Participants recruitment.

Socio-demographic and Clinical characteristics

Most patients were male (56.1%) with a median age of 45 days. Rural residence was reported to be 72%, and 38.1% came from municipalities with fewer than 10,000 inhabitants. Nearly half of the mothers had only primary education (36.9%) and 52.2% were housewives. Among fathers, only 33% had completed technical or professional education. These characteristics are summarized in Table 1.

Table 1. Socio-demographic characteristics.

Characteristic	n (%)	Without follow-up.		p-values	Lethality		p-values
	total=173	No n=108	Yes n =65		No (n=111)	Yes (n=17)	
Gender (Male)	97 (56.1)	67 (62.0)	30 (46.2)	0.05	64 (57.7)	11 (64.7)	0.79
Age (days) [†]	45 (21-123)	46 (21-117)	41 (21-138)	0.78	48 (22-120)	39 (16-92)	0.30
Gestational age at birth (Weeks) [§]	38 (37-39)	38 (37-39)	38 (36-39)	0.30	38 (37; 39)	38 (37; 38)	0.55
Low Birth Weight (<2500 Gr)	29 (21.8)	17 (20.5)	12 (24.0)	0.66	17 (20.7)	3 (20.0)	1.00
Cared by both parents	122 (84.7)	83 (86.5)	39 (81.3)	0.46	84 (86.6)	12 (85.7)	1.00
Cared by single mother	19 (13.2)	11(11.5)	8 (16.7)	0.43	11 (11.3)	1 (8.3)	1.00
Residence (Urban)	124 (71.7)	89 (82.4)	35 (53.9)	<0.001	91 (82.0)	7 (41.2)	0.00
Socioeconomic stratum 1 in the national census	24 (46.2)	18 (43.9)	6 (54.6)	0.73	15 (39.5)	4 (66.7)	0.37
Subsidized health insurance	106 (61.3)	56 (51.9)	50 (76.9)	0.001	56 (50.5)	15 (88.2)	0.00*
Municipality of residence (Santander)	52 (30.1)	44 (40.7)	8 (12.3)	<0.001	42 (37.8)	5 (29.4)	0.59
Lived in a metropolitan	30 (17.3)	28 (21.9)	2 (3.1)	<0.001	26 (23.4)	2 (11.8)	0.36
Categorized municipality of residence							
> 501.000	31 (19.4)	23 (23.0)	8 (13.3)	0.12	23 (22.8)	3 (17.6)	0.53
100.001 - 500.000	40 (25.0)	22 (22.0)	18 (30.0)		23 (22.8)	2 (11.7)	
10.001-100.000	28 (17.5)	21 (21.0)	7 (11.7)		21 (21.8)	3 (17.7)	
0 – 10.000	61 (38.1)	34 (34.0)	27 (45.0)		34 (33.7)	9 (52.9)	
Maternal age (N 160)							
≤20 Years	31 (19.4)	15 (15.2)	16 (26.2)	0.027	16 (15.7)	4 (23.5)	0.31
21 -30 Years	81 (50.6)	53 (53.5)	28 (45.9)		52 (51)	11 (64.7)	
31 - 35 Years	33 (20.6)	17 (17.2)	16 (26.2)		21 (20.6)	1 (5.9)	
36 - 40 Years	5 (3.1)	5 (5.1)	0 (0)		4 (3.9)	1 (5.9)	
> 40 Years	10 (6.3)	9 (9.1)	1 (1.6)		9 (8.8)	0	
Level of education mother (n=111)							
Primary	41 (36.9)	23 (30.7)	18 (50)	0.027	26 (34.7)	1 (8.3)	0.02
Secondary	26 (23.42)	15 (20)	11 (30.6)		13 (17.3)	7 (58.3)	
Technology	20 (18)	17 (22.7)	3 (8.3)		16 (21.3)	2 (16.7)	
Professional	24 (21.6)	20 (26.7)	4 (11.1)		20 (26.7)	2 (16.7)	

Parents age (115)							
≤20 Years	5 (4,4)	4 (5.13)	1 (2.7)	0.84	4 (5.1)	0	1.00
20 – 29 Years	71 (61,7)	47 (60.3)	24 (64.9)		49 (62.0)	9 (69.2)	
> 30 Years	39 (33,9)	27 (34.6)	12 (32.4)		26 (32.9)	4 (30.8)	
Level of education father (n=85)							
Primary school	35 (41.2)	16 (28.1)	19 (67.9)	0.007	17 (30.4)	5 (55.6)	0.38
Secondary school	22 (25.9)	18 (31.6)	4 (14.3)		16 (28.6)	3 (33.3)	
Technology	9 (10.6)	7 (12.3)	2 (7.1)		7 (12.5)	0 (0)	
Professional	19 (22.4)	16 (28.1)	3 (10.7)		16 (28.6)	1 (11.1)	
Mother is a housewife (n=138)	72 (52.2)	41 (43.6)	31 (70.5)	0.004	61 (50)	11 (68.8)	0.12

Notes. † Median (RIQ). Bold text indicates p-values that are statistically significant ($p < 0.05$).

Regarding cardiac physiology, 55.5% had univentricular physiology. Right-sided obstructive lesions (37.6%) and septal defects (21.4%) were the most common diagnoses. Malnutrition was observed in 44.5% at discharge, and 28.9% had a diagnosed genetic syndrome. The most frequent procedures were pulmonary artery banding (39.3%) and systemic-to-pulmonary shunt (34.7%). No significant differences were observed in hospital stay, pediatric intensive care unit (PICU) duration, or feeding route between follow-up groups. Clinical and surgical characteristics are presented in Table 2.

Table 2. Clinical characteristics.

Characteristic	n (%)	Without follow-up.		p-values	Mortality		p-values
	total=173	No n=108	Yes n =65		No (n=111)	Yes (n=17)	
Intraoperative							
Prenatal diagnosis	52 (30,1)	34 (31.5)	18 (27.7)	0.73	36 (32,4)	3 (17,7)	0.26
Physiological classification of congenital heart disease							
Univentricular	96 (55,5)	62 (57.4)	34 (52.3)	0.53	62 (55,9)	12 (70,6)	0.30
Biventricular	77 (44,5)	46 (42.6)	31 (47.7)		49 (44,1)	5 (29,4)	
Primary diagnosis							
Septal defect	37 (21.4)	20 (18.5)	17 (26.2)	0.31	22 (19.8)	4 (23.5)	0.15
Double outlet right ventricle	17 (9.8)	11 (10.2)	6 (9.2)		12 (10.8)	0	
Lesions of heart right	65 (37.6)	38 (35.2)	27 (41.5)		37 (33.3)	9 (52.9)	
Lesions of heart left	19 (11)	11 (10.2)	8 (12.3)		11 (9.9)	4 (23.5)	
Transposition of the great arteries	12 (6.9)	9 (8.3)	3 (4.6)		9 (8.1)	0	
Lesions of thoracic veins and arteries	12 (6.9)	9 (8.3)	3 (4.6)		10 (9.0)	0	
Single Ventricle	11 (6.4)	10 (9.3)	1 (1.5)		10 (9.0)	0	
Special anomalies (Heterotaxy and situs inversus)	13 (7.5)	9 (8.3)	4 (6.2)	0.76	7 (6.3)	4 (23.5)	0.04

Seizures during life	90 (52.0)	54 (50.0)	36 (55.4)	0.53	57 (51.4)	7 (41.2)	0.60
Malnutrition (W/A z-Scored <-2SD)	77 (44.5)	45 (41.7)	32 (49.2)	0.34	46 (41.4)	11 (64.7)	0.11
Genetic syndrome	50 (28.9)	31 (28.7)	19 (29.2)	1.00	34 (30.6)	6 (35.3)	0.78
Preoperative cardiopulmonary resuscitation	12 (6.9)	8 (7.41)	4 (6.2)	1.00	8 (7.2)	1 (5.9)	1.00
Intra-surgical							
Type of surgery							
Banding	68 (39.3)	40 (37.0)	28 (43.1)	0.50	46 (41.4)	4 (23.5)	0.20
Systemic pulmonary fistula	60 (34.7)	35 (32.4)	25 (38.5)		33 (29.7)	10 (58.8)	
Hybrid	15 (8.7)	10 (9.3)	5 (7.7)		10 (9)	1 (5.9)	
Norwood	18 (10.4)	14 (13.0)	4 (6.2)		13 (11.7)	2 (11.8)	
Others	12 (6.9)	9 (8.3)	3 (4.6)		9 (8.1)	0 (0)	
Bypass time (minutes)†	113 (75-208)	120 (80-217)	111 (72-150)	0.27	139 (86-217)	79 (64-247)	0.31
Arrest time (minutes)†	62 (40-71)	68.5 (46-72.5)	45 (29-68)	0.10	65 (40-72)	55.5 (40.5-69)	0.64
Clamping time (minutes)†	48 (27-84)	59.5 (24.5-86.5)	43 (30-77)	0.73	59.5 (26.5-85)	61.5 (40-83)	0.94
RCP intra-surgical	11 (6.4)	8 (7.4)	3 (4.6)	0.53	8 (7.1)	1 (5.9)	1.00
RACHS							
1	4 (2.3)	3 (2.8)	1 (1.5)	0.12	3 (2.7)	0 (0.0)	0.86
2	0	-	53 (81.5)		-	-	
3	131 (75.7)	78 (72.2)	-		82 (73.9)	14 (82.4)	
4	1 (0.6)	1 (0.9)	2 (3.1)		1 (0.9)	0 (0.0)	
5	2 (1.1)	-	-		-	-	
6	36 (20.7)	26 (24.1)	9 (13.9)		25 (22.5)	3 (17.7)	
Postoperative							
ECMO	11 (6.4)	10 (9.3)	1 (1.5)	0.05	10 (9.0)	1 (5.9)	1.00
RCP postoperative	20 (11.6)	96 (88.9)	57 (87.7)	0.81	11 (9.9)	3 (17.7)	0.39
Anticonvulsant medications	89 (51.5)	55 (50.9)	34 (52.3)	0.87	58 (52.3)	7 (41.2)	0.44
UCI (days)†	45 (27-70)	42 (22-67.5)	47 (34-82)	0.06	43 (23-69)	53 (34-99)	0.27
Hospital (days)†	59 (32-91)	55 (30-88)	68 (42-92)	0.09	58 (30-88)	63 (42-111)	0.24
Route of feeding							
Gastric tube	5 (2.9)	2 (1.9)	3 (4.6)	0.59	2 (1.8)	-	0.81
Yeyunal tube	5 (2.9)	4 (3.7)	1 (1.5)		4 (3.6)	-	
Gastrostomy	45 (26.0)	27 (25)	18 (27.7)		29 (25.1)	6 (35.3)	
Oral	118 (68.2)	75 (69.4)	43 (66.2)		76 (68.5)	11 (64.7)	

Notes. [†] Median (RIQ). Bold text indicates p-values that are statistically significant (p < 0.05).

Complications

Postoperative complications included sepsis (68.2%), dysphagia (69.9%), and severe atrioventricular valve regurgitation (53.8%). Necrotizing enterocolitis (28.9%) showed a significant association with lethality ($p=0.05$). Severe ventricular dysfunction occurred in 6.9%. All complication data are provided in Table 3.

Table 3. Complications.

Complications	n (%)	Without follow-up.		p-values	Lethality		p-values
	total=173	No n=108	Yes n =65		No (n=111)	Yes (n=17)	
Arrhythmia	35 (20.2)	18 (16.7)	17 (26.2)	0.17	22 (19,8)	3 (17,7)	1
Atrioventricular block with pacemaker permanent	4 (2.3)	2 (1.9)	2 (3.1)	0.63	2 (1,8)	0 (0,0)	1
Atrioventricular block with pacemaker temporary	11 (6.4)	102 (94.4)	60 (92.3)	0.74	7 (6,3)	2 (11,8)	0.34
Coarctation-residual	9 (5.2)	5 (4.5)	1 (5.9)	0.58	5 (4,5)	1 (5,9)	0.58
Pericardial effusion requiring drainage	17 (9.8)	100 (92.6)	56 (86.2)	0.13	8 (7,1)	2 (11,8)	0.62
Septicemia	118 (68.2)	73 (67.6)	45 (69.2)	0.86	75 (67,6)	14 (82,4)	0.26
Endocarditis	3 (1.7)	1 (0.9)	2 (3.1)	0.55	2 (1,8)	1 (5,9)	0.35
Necrotizing enterocolitis	50 (28.9)	34 (31.5)	16 (24.6)	0.38	32 (28,8)	9 (52,9)	0.05
Diaphragmatic paralysis	11 (6.4)	6 (5.6)	5 (7.7)	0.74	6 (5,4)	3 (17,7)	0.09
Abnormal swallowing	121 (69.9)	72 (66.7)	49 (75.4)	0.23	76 (68,5)	12 (70,6)	1
Vocal cord paralysis	26 (15)	13 (12)	13 (20)	0.18	15 (13,5)	4 (23,5)	0.28
Tracheostomy	1 (0.6)	1 (0.9)	0 (0)	1	1 (0,9)	0 (0,0)	1
Chylothorax	19 (11)	12 (11.1)	7 (10.8)	1	11 (9,9)	2 (11,8)	0.68
Mediastinitis	8 (4.6)	4 (3.7)	4 (6.2)	0.47	4 (3,6)	1 (5,9)	0.51
Regurgitation of atrioventricular valve							
Without	40 (23.1)	23 (21.3)	17 (26.2)	0.78	25 (22.5)	4 (23.5)	0.51
Mild	29 (16.8)	19 (17.6)	10 (15.4)		18 (16.2)	5 (29.4)	
Moderate	11 (6.4)	6 (5.6)	5 (7.7)		7 (6.3)	-	
Severe	93 (53.8)	60 (55.6)	33 (50.8)		61 (55)	8 (47.1)	
Ventricular Dysfunction							
Without Dysfunction	87 (50.3)	25 (23.2)	20 (30.8)		60 (54,1)	6 (35,3)	0.35
Mild	45 (26)	19 (17.6)	10 (15.4)		25 (22.5)	6 (35.3)	
Moderate	29 (16.8)	8 (7.4)	4 (6.2)		19 (17,1)	3 (17,7)	
Severe	12 (6.9)	56 (51.9)	31 (47.7)		7 (6,3)	2 (11,8)	
Renal replacement therapy	22 (12.7)	12 (11.1)	10 (15.4)	0.48	12 (10,8)	5 (29,4)	0.05
Stroke	20 (11.6)	13 (12)	7 (10.8)	1	13 (11,7)	2 (11,8)	1
Reintubation	53 (30.6)	76 (70.4)	44 (67.7)	0.73	32 (28,6)	8 (47,1)	0.16
Surgical re-intervention	34 (19.6)	()	()		23 (20,7)	6 (35,3)	0.21

Notes. † Median (RIQ). Bold text indicates p-values that are statistically significant ($p < 0.05$).

Loss to follow-up (LTF)

Multivariate analysis for LTF identified rural residence (OR=5.05; 95% CI: 1.32–19.26; $p=0.02$) and postoperative arrhythmia (OR=4.52; 95% CI: 1.03–19.84; $p=0.05$) as significant risk factors. Paternal education was protective, particularly for secondary (OR=0.11; 95% CI: 0.02–0.72; $p=0.02$) and professional-level education (OR=0.04; 95% CI: <0.01–0.74; $p=0.03$). See [Table 4](#).

Table 4. Multivariate analysis for patients with LTF.

	OR	p-values	IC 95%
Rural residence	5.05	0.02	1.32-19.26
Maternal occupation	0.15	0.12	0.01-1.62
Level of parental education			
Primary school	1.00		
Secondary school	0.11	0.02	0.02-0.72
Technology	0.49	0.48	0.07-3.54
Professional	0.04	0.03	0-0.74
Arrhythmia	4.52	0.05	1.03-19.84

Notes. Log Likelihood: -34.75; R²: 0.29; Akaike 83.50. Bold text indicates p-values that are statistically significant ($p < 0.05$). LTF Lost to Follow-up

Lethality

At study closure, the vital status of 74% (128/173) of patients was confirmed. Overall lethality was 13.3% (17/128; 95% CI: 7.9–20.4%). Among contacted LTF patients, lethality reached 55% (11/20), compared to 5.6% (6/108) in the follow-up group (OR=20.7; 95% CI: 6.22–69.4). Reported causes of death included underlying cardiac disease (55%), bronchoaspiration (27.3%), and unspecific symptoms such as respiratory or gastrointestinal distress (18.2%).

Multivariate analysis identified the following independent risk factors for interstage lethality: left heart lesions (OR=42.81; 95% CI: 2.78–659.7), malnutrition (OR=25.47; 95% CI: 2.96–218.73), rural residence (OR=22.78; 95% CI: 3.68–140.83), necrotizing enterocolitis (OR=13.34; 95% CI: 2.34–75.97), male sex (OR=8.45; 95% CI: 1.3–54.9), and heterotaxy or situs inversus (OR=8.05; 95% CI: 1.26–51.34). The number of follow-up visits was a protective factor, with a 29% risk reduction per visit (OR=0.71; 95% CI: 0.55–0.90; $p<0.01$). See [Table 5](#).

Table 5. Multivariate analysis for lethality.

	OR	p-values	IC 95%
<i>Lesions of Left Ventricle</i>	42.81	0.01	2.78-659.7
Malnutrition	25.47	<0.01	2.96-218.73
Residence rural	22.78	<0.01	3.68-140.83
Necrotizing enterocolitis	13.34	<0.01	2.34-75.97
<i>Gender (Male)</i>	8.45	0.03	1.3-54.9
Heterotaxy and situs inversus	8.05	0.03	1.26-51.34
Number of visits registered	0.71	<0.01	0.55-0.9

Notes. Log Likelihood: -25.17; R²: 0.50; Akaike 66.33. Bold text indicates p-values that are statistically significant (p < 0.05).

Discussion

This study aimed to assess factors associated with loss to follow-up (LTF) and lethality for Complex CHD after the first intervention. Approximately 4 out of 10 patients experienced LTF, with an overall lethality of 13.3%. Few data are available from the Latin American contexts, making this research valuable in understanding healthcare service challenges in a middle-income country (MIC). The study not only addresses traditional interstage periods for Hypoplastic Left Heart Syndrome (HLHS) but also included other conditions requiring initial palliation or surgery due to unstable hemodynamics.

In Colombia, the General Social Security Health System, regulated by Law 100 of 1993, has two types of affiliation: contributive regimen for employed, salaried, or pensioned individuals and independent workers, and subsidized regimen for those without payment capacity. Each child is assigned to specific healthcare centers according to contractual agreements between insurers and providers. Previous Colombian studies have linked low income to poorer health outcomes, suggesting that limited economic capacity impedes adequate care for medically complex children [15,16]. Our findings align with this, indicating higher rates of LTF and death in patients with subsidized insurance. With ongoing healthcare reforms in Colombia, the impact on LTF and lethality will need further studies.

Living outside the city where the health institution is located or residing in a rural area was associated with LTF in our study [17]. Geographical barriers—including reduced access to specialized health services, limited sanitation infrastructure, and scarce transportation options—restrict follow-up opportunities and are often perceived as insurmountable obstacles by caregivers [18,19]. In Colombia, mountainous topography, poor road conditions, limited public transport, and security concerns further exacerbate these difficulties, contributing to higher interstage mortality in children with CHD [18-20].

Parental education's impact on childcare was considered in our analysis. Although lower educational attainment was more frequent among families in rural settings and has been associated with greater caregiving burdens and lower quality of life [21,22], it did not remain significant in the final multivariate model, possibly due to narrowing educational gaps between rural and urban families. The strong association between the number of follow-up visits and survival underscores the crucial role of continuous access to specialized cardiac care [23,24].

Our study showed that each interstage period visit reduced the risk of death by 29%, even after adjusting for other variables.

Postoperative cardiac arrhythmias, previously associated with increased mortality in pediatric cardiac surgery [25], were also evaluated. While evidence for an association between arrhythmias and LTF was lacking, referrals to other healthcare institutions could be a contributing factor. Patients with heterotaxia had an eight times greater mortality risk, consistent with previous investigations [26]. Unexpectedly, the type of CHD physiology did not show a significant association with mortality, as informed by previous works [27], due possibly to sample size effect, suggesting the need for future studies.

Additionally, although our study population focused on patients who survived initial surgery and entered the interstage period, we observed that only 30% of cases had a prenatal diagnosis. This detection rate is considerably lower than that reported in high-income countries. Limited access to prenatal screening may therefore contribute to higher early mortality patterns observed in comparable cohorts from similar socioeconomic settings [28].

Limitations

This study, based on retrospective collection of data from medical records, introduces the possibility of missing values for certain variables in specific cases, potentially leading to information bias. The wide confidence intervals observed are likely due to the limited sample size, which reduces the reliability and generalizability of the outcomes. Nonetheless, it is noteworthy that the institution under study in Colombia hosts one of the country's most comprehensive programs for complex congenital heart disease, which supports the relevance of these findings despite sample constraints. Further research is needed to confirm and expand upon these observations. Another constraint pertains to the inability to explore all potential risk factors during the patients' home stays, such as conditions inherent to the family nucleus or unknown housing statuses. The study's retrospective and predominantly quantitative design did not allow for an in-depth exploration of the social determinants that may also act as mortality risk factors. Future qualitative studies are recommended to provide more nuanced insights into these sociocultural aspects.

Furthermore, the lack of information on the final condition of children categorized as Lost to Follow-up (LTF) presents an additional limitation. This data could have offered crucial insights that might influence the significance of other variables.

Finally, as this is a single-center study, caution should be exercised in extrapolating the findings to broader populations. However, the challenges identified are likely representative of those faced by other middle-income countries (MICs) with comparable health system structures.

Practice Implications

The insights gleaned from this research have direct implications for clinical practice. The identification of modifiable factors contributing to high mortality rates among neonates and infants with complex congenital heart diseases underscores the importance of early interventions and vigilant follow-up. Recognizing the protective role of a higher number of consultations empowers health care providers to play a pivotal role in ensuring comprehensive care during the interstage period, thereby mitigating mortality risks. Understanding the socioeconomic and geographic disparities that hinder adequate follow-up can help pediatric cardiology teams adapt their care strategies to the realities of each family. Moreover, it sheds light on risk factors specific to middle-income countries (MICs), which may differ from those

in high-income countries (HICs). These findings also have policy relevance, as they highlight the need for strategies that improve access to specialized care in rural settings, strengthen tele-medicine programs, and reduce inequities linked to socioeconomic and geographical barriers.

Conclusions

In conclusion, middle-income countries (MIC) face distinctive challenges in the follow-up of complex congenital heart disease patients, especially between the first and second interventions, become apparent. Identifying peri-operative risk factors like malnutrition, geographic residence, and postoperative morbidity in clinical practice highlights their potential role as risk factors for loss to follow-up (LTF) and lethality in these patients. Strengthening communication and coordination between cardiovascular centers and caregivers could reduce LTF and lethality, improving long-term outcomes, and optimizing the allocation of limited resources. Further research is essential to thoroughly investigate these identified risk factors.

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