

Pilot Observational Cohort study to assess the feasibility of initiating a paediatric cardiac registry

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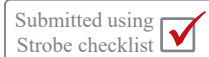
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Abstract

Background and Aims: Paediatric cardiac conditions are significant contributors to morbidity and mortality in childhood. Our main aim was systematic collection, storage, analysis, interpretation and reporting of data on paediatric cardiac patients to assess their burden classified by age, gender, residence, ethnicity, diagnosis and treatment and to assess the quality of hospital services.

Methods: A quantitative prospective cohort study was performed from January 2024 to June 2024. All children less than 16 years admitted to Shahid Gangalal National Heart Center were included in the study. Information collected in a structured proforma was carefully analysed.

Results: Of 656 patients, 374(52.4%) were admitted in medical and 282 (47.6%) in surgery wards. Nearly 19.0% of total admissions were for either consolidation of diagnosis or diagnostic catheterization prior to the subsequent stage of treatment, 403 (61.4%) patients benefited and overall mortality was 69 (10.6%). Acyanotic heart disease was the most common congenital while Rheumatic Heart Disease was the most frequent acquired heart diseases among admitted children. Children with median age 7 months and with Persistent Pulmonary Hypertension, Arterial switch operation and BTT or Central Shunt had higher mortality among others.

Conclusions: This study highlights the need for implementation of registry to identify measures to improve paediatric cardiac patients' care, like routine assessment for malnutrition, proper vaccination, regular audits, staff training, multidisciplinary meetings and recruiting specialists. This study could be a starting point for numerous follow-up studies that are essential for continuous progress.

Key Words: Registry, Hospital Based, Paediatric cardiology, Paediatric cardiac conditions

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INTRODUCTION

Congenital heart diseases (CHD) are described as the most common cardiac condition, followed by Rheumatic heart disease (RHD). Other conditions like Hypertension, Pericardial diseases and Cardiomyopathies are present in a smaller proportion of children^{1,2}. In the spectrum of congenital heart disease among paediatric population of Nepal, acyanotic heart diseases were more prevalent than cyanotic heart disease. Atrial Septal Defect (ASD) was the commonest acyanotic and Tetralogy of Fallot (TOF), the most occurring of the cyanotic heart disease^{3,4}. Rheumatic heart disease

was among one of the major reasons behind frequent hospital admissions and cardiac surgery^{5,6}.

Paucity of research in paediatric cardiac patients and lack of proper evidence-based protocols highlight the need of a registry. A registry is a collection of data for analysis and interpretation providing research base for appropriate strategy development in national level, ultimately improving quality and safety of patient care. This study measured the burden of paediatric cardiac patients stratified by age, gender, residence, ethnicity, diagnosis and treatment and to



evaluate the quality of hospital services. This collection of data will be valuable for future research.

Being one of the large volume referral centers with Paediatric Cardiology Department, the hospital-based registry of these patients at Shahid Gangalal National Heart Center (SGNHC) is reflective of the similar pattern nationwide. This type of study is the first to be done in the field of Paediatric Cardiology as well as in paediatric population of Nepal.

Objectives

Our objectives are

1. Systematic collection, storage, analysis, interpretation and reporting data of paediatric cardiac patients.
2. To assess the burden of paediatric cardiac population classified by age, gender, residence, ethnicity, diagnosis and treatment and to assess the quality of hospital services.

D. Methods

A quantitative Prospective Descriptive Cohort study was carried out at SGNHC for a duration of 6 months.

Inclusion criteria:

1. The age demarcation for paediatric population at Shahid Gangalal National Heart Center is 15 years. Hence, all patients aged less than 16 years old hospitalized with symptoms resulting from cardiac disease confirmed by routine tests like Electrocardiogram, Chest X-ray, Echocardiography and Laboratory parameters admitted at SGNHC were included.

Exclusion criteria:

- (i) Patients who are 16 years old and above.

Operational definitions

Improved: It was used for patients who were discharged from the hospital after successful treatment of the cardiac condition that led to their admission in the first place.

LAMA: Leave against medical advice was used when the patient party wanted to discontinue treatment or do not want to proceed with the surgical or catheter based procedure for their child.

Referred: It was used to define the population who required an expertise beyond cardiac care for treatment of the child.

No change: It was divided into two categories, Right Heart Catheterization (RHC) included patients only admitted for diagnostic catheterization prior to surgical procedure and Conservative management included a cohort of patients who were deemed inoperable or better left to its natural course upon admission to the hospital after thorough discussion with Congenital Heart Team.

Procedure Cancelled: It encompasses all the children who were admitted to the hospital for intervention either surgical or catheterization based, but postponed due to unavoidable circumstances like fever, deranged lab reports etc.

Mortality: Mortality in this study referred to an all-cause mortality following hospital admission, rather than specific to any procedure.

This study was approved by the ethical committee of SGNHC along with exemption from informed or written consent. Structured Proforma consisting of personal identification number,

socioeconomic-demographic characteristics, diagnosis, days of hospital stay, days of Intensive Care Unit (ICU) stay and outcome was used to collect the information. The collected data was entered into excel software meticulously excluding redundancies.

Data was then transferred to SPSS for statistical analysis. All continuous data were expressed as mean or median and categorical data were expressed in percentage (%).

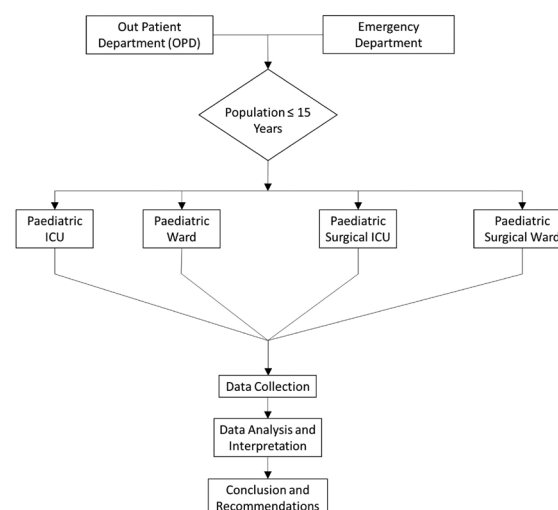


Figure 1. Methodology Flow chart

E. Results

All patients fulfilling inclusion criteria on admission to Shahid Gangalal National Heart Center from January to June 2024 were taken into consideration. 92.1% of patients had single admission, 7.3% of patients were admitted twice and 0.5% were admitted three times throughout the study. Notably there were no participants from Mugu, Mustang, Rukum (East and West) and Rasuwa districts (Figure 2) during the study period. Male and female were equally represented in the study as well as in gender wise distribution of overall cardiac condition (Table 1 and Figure 5). Maximum number of patients benefitted from the treatment received in the hospital. There were 69 (10.6%) fatalities during the study period. The mortality rate was 2.5% in Paediatric cardiology intervention and 21.6% in Paediatric surgery. Many patients had surgery postponed due to Upper respiratory infections, Otitis Media, deranged pre-operative investigation reports, lack of appropriately sized devices or conduits etc. (Table 1).

A variety of cases were admitted in both Paediatric medical and surgery wards of which acyanotic congenital heart disease was the commonest followed by cyanotic congenital heart disease. Unexpectedly, Cardiomyopathy (especially Dilated cardiomyopathy) also presented in significant number and many of them did not survive (Figure 3, Tables 2 and 3). As shown in Figure 3, Khas ariya ethnic group had highest representation in most categories of different heart conditions closely followed by Madhesi ethnic group. Figure 4 illustrated a similar trend in age wise distribution between cyanotic and acyanotic heart disease patients, with notable representation in the age group of >3months to 1 years.

The minimum wait for surgery was 1 day (for emergency procedures) with a maximum of 45 days (Table 1). Children undergoing VSD closure, Arterial Switch Operation and TAPVC repair had higher

mortality rates, approximately 6 (8.7%) in each category, during the course of study. Cath interventions accounted for 5 (7.2%) deaths. The median age of children who succumbed was 6 and 7.5 months and were intensively managed in ICU for a median of 2 and 3.5 days before passing away in Medical and Surgical ICUs respectively (Table 1).

Table 1. The table depicts the background profile of patients.

Total patients	N=656(100%)
Male	344 (52.4%)
Female	312 (47.6%)
Median age (in months)	36.0 (0.06-312.0)
Median age among mortality (in months)	7.0 (0.06-180.0)
Outcome LAMA (Leave Against Medical Advice)	13 (1.9%)
Improved	403 (61.4%)
Referred	9 (1.4%)
Mortality	69(10.6%)
Mortality in Medical ward	15(21.7%)
Median age (in months)	6 (0.63-168)
Median ICU stay (in days)	2 (0-28)
Median Hospital stay (in days)	5 (1-35)
Mortality in Surgical ward	54 (78.3%)
Median age (in months)	7.5 (0.06-180)
Median ICU stay (in days)	3.5 (0-60)
Median Hospital stay (in days)	14.5 (1-81)
Procedure cancelled	37 (5.6%)
No change	RHC/CT 121 (18.4%) Conservative Management 4 (0.6%)
Wait time (in weeks) ward before surgery	N (%)
<1 weeks	90 (40.3)
1-2 weeks	86(38.5)
2-3 weeks	32(14.3)
>3 weeks	15(6.7)
Median time (in days)	8 (1-45)

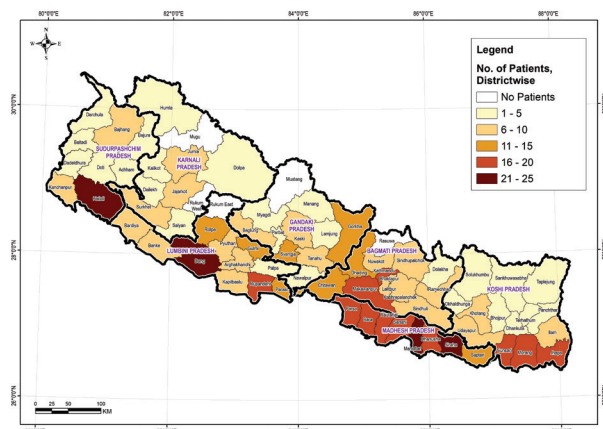


Figure 2: Nationwide distribution of cases by district

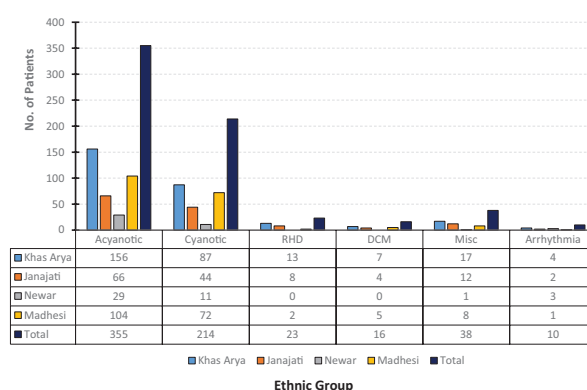


Figure 3: Distribution of overall cardiac condition by broad ethnic groups of Nepal⁷.

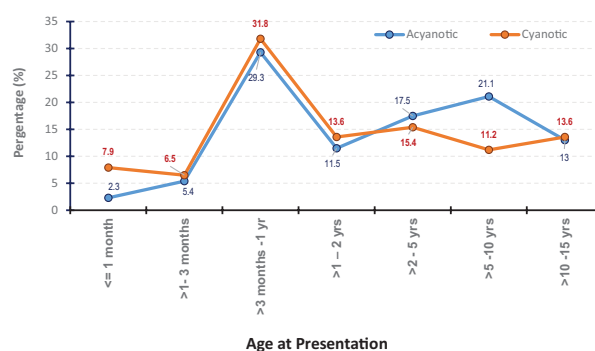


Figure 4: Distribution of congenital heart disease patients according to age group

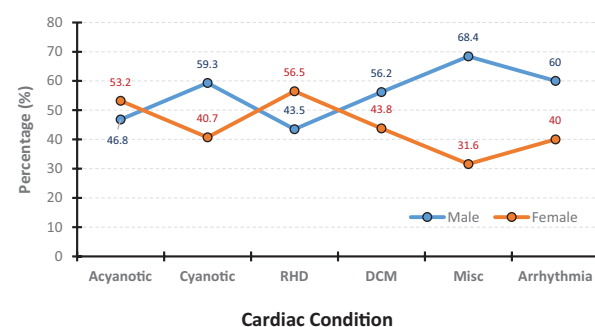


Figure 5: Gender wise distribution of overall disease condition

Table 2: Outline of patients admitted in Paediatric Medical and Surgery wards according to diagnosis and/or procedure carried out

Paediatric Medical ward (N=374)		Paediatric Surgery ward (N=282)	
Category	N (%)	Category	N(%)
Congenital Heart Disease	22 (5.8)	ICR for TOF and conditions with TOF physiology	47(16.6)
Rheumatic Heart Disease	11(2.9)	AVSD repair	12(3.2)
Cardiomyopathy	16(4.2)	VSD closure	55(19.5)

Pericardial effusion	5(1.3)	ASD closure	28(7.4)
Cath Intervention	199(53.2)	CoA/Arch repair	7(2.4)
CT diagnostic	82(21.9)	BDCPS	16(5.6)
Kawasaki disease	6(1.6)	Fontan	3(1.0)
Rhythm Abnormalities	3(0.8)	BTT/Central shunt	8(2.8)
Takayasu Arteritis	3(0.8)	ASO	8(2.8)
Myocarditis	3(0.8)	TAPVC repair	11(3.9)
Arrhythmogenic Right Ventricular Dysplasia	2(0.5)	Mitral Valve repair	6(2.1)
Persistent Pulmonary Hypertension	3(0.5)	Permanent Pacemaker Insertion	4(1.4)
Myxomatous Mitral Valve	3(0.8)	Discharged without intervention	33(11.7)
Miscellaneous	16(4.2)	Miscellaneous	44(15.6)

(VSD :Ventricular Septal Defect, ASD :Atrial Septal Defect, ICR: Intra Cardiac Repair, TOF: Tetralogy Of Fallot, AVSD: Atrioventricular Septal Defect, COA: Coarctation Of Aorta, BDCPS: BiDirectional CavoPulmonary Shunt, ASO: Arterial Switch Operation, BTT shunt: Blalock Thomas Tausig Shunt, TAPVC : Total Anomalous Pulmonary Venous Connection)

Table 3: Overall Mortality in Paediatric medical and Surgical ICUs

Medical ICU (N=15)		Surgical ICU (N=54)		
Category	N (%)	Category	N (%)	Procedural success (%)
S/P PDA device closure	1 (6.7)	ICR for TOF and conditions with TOF physiology	7 (12.9)	85.1
S/P PDA stenting	1 (6.7)	AVSD repair	4 (7.4)	66.6
S/P PV perforation and PDA stenting	1 (6.7)	VSD closure	6 (11.1)	89.0
S/P CoA ballooning	1 (6.7)	CoA/Arch repair	4 (7.4)	42.8
S/P BAV	1 (6.7)	BDCPS	5 (9.2)	68.7
RHD (ARF)	1 (6.7)	BT/Central shunt	5 (9.2)	37.5
VSD severe PAH	1 (6.7)	ASO	6 (11.1)	25.0
PPHN	3 (20.0)	TAPVC repair	6 (11.1)	45.4
Pericardial effusion	1 (6.7)	MV repair	2 (3.7)	66.6

Fulminant myocarditis	1 (6.7)	Miscellaneous	9 (16.6)	20.4
DCM	2 (13.3)			
AVSD with severe PAH	1 (6.7)			

(DCM: Dilated Cardiomyopathy, PPHN: Persistent Pulmonary Artery Hypertension, RHD: Rheumatic Heart Disease, ARF: Acute Rheumatic Fever, PDA: Patent Ductus Arteriosus, BAV: Balloon Aortic Valvuloplasty, VSD :Ventricular Septal Defect, ASD :Atrial Septal Defect, ICR: Intra Cardiac Repair, TOF: Tetralogy Of Fallot, AVSD: Atrioventricular Septal Defect, COA: Coarctation Of Aorta, BDCPS: BiDirectional CavoPulmonary Shunt, ASO: Arterial Switch Operation, BTT shunt: Blalock Thomas Tausig Shunt, TAPVC : Total Anomalous Pulmonary Venous Connection)

Discussion

This study has provided first-hand information on the demographic profile and outcome of patients with cardiac problem in one of the high-volume tertiary cardiac centers of Nepal. Patients from numerous districts and varied ethnic groups of Nepal have availed the facilities provided at this center. Significant progress in paediatric cardiac care has been achieved through the provision of timely and comprehensive interventional and surgical procedures, ensuring the best possible outcomes for patients.

The male and female ratio in our study was 1.1:1 which is similar to the studies done by Jain et al in Central India (2023) and Mohammad et al in Pakistan (2014) where it was 1.26:1 and 1.2:1 respectively^{8,9}. Admission of children with cyanotic congenital heart disease was 3-fold of that with acyanotic congenital heart disease in neonatal age (<1 month) as shown in figure 3 whereas at 5 to 10 years of age, twice as much children with acyanotic congenital heart disease than cyanotic congenital heart disease was admitted in our center. It is consistent with a retrospective cohort study of children born between 2009 and 2018 in a population of 175,153 live births done in Czech Republic, where cyanotic congenital heart diseases had higher chances of being detected in early neonatal age than acyanotic congenital heart defects¹⁰.

Many patients who opted for LAMA had complex congenital heart disease in our study. This emphasizes the role of Fetal echocardiography to detect and mitigate complex congenital heart disease in utero, to prepare parents to be, to improve preoperative clinical status and post-operative survival^{11,12}. Acute infection or deranged pre-operative investigations was the common cause for cancellation of procedures. Provision of immunization (like Influenza vaccine) and timely detection and management of malnutrition have known to reduce the infection susceptibility among children with cardiac disease¹³. Sincere efforts from the government for proper resource allocation to provide access to affordable and nutritious food, healthcare services, and educational programs for mothers on child nutrition are required to avert malnutrition and its untoward effects like repeated infections¹⁴.

Most children admitted to our center had congenital heart disease, followed by cardiomyopathies and Rheumatic heart disease. Few cases of pericardial effusion and Kawasaki disease with coronary involvement were also admitted during the study period. This is coherent with a study by Joshi et al done at Dhulikhel hospital (2016), where congenital heart disease was the leading cause for

admission. However, in their study Rheumatic heart disease was the second and pericardial effusion was the third common condition². More patients with cardiomyopathies getting admitted to our center than Rheumatic heart disease could be attributed to diverse etiology and types of cardiomyopathies and younger age as compared to children with Rheumatic heart disease for which they are directed to our center for detailed assessment, management and planning.

Persistent pulmonary artery hypertension which is not a cardiac condition per se rather an abnormal response of pulmonary vasculature, underdeveloped pulmonary vasculature or idiopathic etiology was the leading cause of mortality in paediatric medical ICU¹⁵. These children are referred to our center following Transthoracic Echocardiogram showing hugely dilated right side of the heart, otherwise the condition can be managed in most healthcare facilities throughout Nepal. Unless the national protocol for safe transport of critically ill children is strictly followed, there is immense risk during transport of these sick neonates¹⁶.

A study carried out in our center from 2015 to 2020 showed ASD and VSD being the most common conditions for admission for surgery followed by TOF (TOF like physiology), AVSD, TAPVC and so on¹⁷. In current study, VSD closure was the commonest surgical procedure done closely followed by Intracardiac repair (ICR) for TOF (TOF physiology). ASD closure and PDA closures were significantly less because of the provision of robust Paediatric Cardiology Interventional services at our center. More than half of the children (Table 2) admitted to paediatric medical ward benefitted from catheterization interventions, like device closure of defects and valvuloplasty procedures. As a result, more patients with complex cardiac conditions are getting operated at our center compared to previous years. And complex surgical interventions like Nikaidoh procedure have been successfully done in recent times.

The mortality rate presented in this study is a general figure, not providing details about the specific reasons for each death. Although the mortality rate seems higher as compared to studies from India or western data, the circumstances like provision of trained manpower, infrastructure and equipment setting, patient load, presentation time makes direct comparisons erroneous¹⁸.

Keeping abreast with latest guidelines for interventions is essential to provide optimal care to achieve best outcome¹⁹. Likewise, regular communication between multidisciplinary teams, strict professional guidelines and rigid teamwork routines, continuous recording and reporting of expected and observed outcomes, financial sustainability are crucial for improving outcome in paediatric cardiac procedures²⁰. A study by Windsor et al, 2016 suggested early resuscitation in Operating Room (OR) for the duration of 30-120 min depending on the clinical circumstances was an effective way to improve post cardiac surgery morbidity and mortality in Paediatric cardiac patients as the operating room setting offers the most capable environment to diagnose and treat life-threatening hemodynamic fluctuations²¹. Creating a thorough enhanced recovery after cardiac surgery (ERAS) program, akin to the one implemented at Boston Children's Hospital in the USA, which has demonstrated positive outcomes, could significantly improve survival rates at our center as well²².

Challenges to establishing a hospital based registry

This pilot study demonstrates the potential of a comprehensive paediatric registry for research, quality improvement, and disease surveillance. While hospital staff provided invaluable

assistance, data collection was initially hampered by the delayed implementation of electronic health records. Data confidentiality was maintained throughout the process, and a governance team (comprising paediatric surgeons, cardiologists, Institutional Review Committee members, and hospital administrators) is currently being established to oversee data access and ethical considerations. Currently, data management and privacy remain in limbo pending the team's formation. Securing funding from primary stakeholders (e.g., Nepal's Ministry of Health) and secondary stakeholders (treating clinicians) is crucial for long-term sustainability, especially in a developing country. While the registry's scope is broad, focusing initially on paediatric medical and surgical ICU patients appears prudent. Future expansion could include patient-based registries for conditions like Rheumatic Heart Disease and Grown-Up Congenital Heart Disease (GUCH). Despite challenges, establishing this registry at Shahid Gangalal National Heart Center has the potential to serve as a model for other institutions.

LIMITATIONS

Carried out at a center with the largest inpatient paediatric cardiac patients with optimum paediatric cardiology, catheterization as well as paediatric cardiology surgery services, this data is reflective of national data. However, the study duration is relatively short for the results to be extrapolated widely. And present study follows the patients up until their discharge from the hospital. Their post discharge complications, quality of life and life expectancy are largely unaccounted for. The outcome definitions are not standardized to WHO or STS database.

Conclusion

Paediatric cardiac care has made remarkable strides in the past two decades. Patients have access to all necessary emergency and elective procedures, including both interventional and surgical options, and cardiac intensive wards ensuring comprehensive care for young hearts. By leveraging the insights gathered from the paediatric registry, we can significantly enhance the quality of care provided to children with heart conditions, streamline policies and reallocate resources to maximize their effectiveness in addressing critical needs. Needless to mention, this dataset holds significant potential for future research.

Recommendations

Hospital should continue to maintain an electronic record system of every patient post procedure for better care and follow up. This small step can provide insight and experience for expansion into registry of individual cardiac disease. Experiences from this hospital can benefit other centers establish their own registry and conglomeration of all such data can then help formulate Nationwide registry. The Government of Nepal should play an important role by supporting any registry program, which will help to develop preventive and control strategies against the disease in the country.

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