



Outcomes of neonatal critical congenital heart disease: results of a prospective registry-based study from South India

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ABSTRACT

Objectives Congenital heart disease (CHD) is now a leading contributor of infant and neonatal mortality in many low/middle-income countries including India. We established a prospective neonatal heart disease registry in Kerala to understand presentation of CHD, proportion of newborns with critical defects who receive timely intervention, outcomes at 1 month, predictors of mortality and barriers to timely management.

Methods The congenital heart disease registry for newborns (≤ 28 days) in Kerala (CHRONIK) was a prospective hospital-based registry involving 47 hospitals from 1 June 2018 to 31 May 2019. All CHDs, except small shunts with a high likelihood of spontaneous closure, were included. Data on demographics, complete diagnosis, details of antenatal and postnatal screening, mode of transport and distance travelled and need for surgical or percutaneous interventions and survival were collected.

Results Of the 1474 neonates with CHD identified, 418 (27%) had critical CHD, 22% of whom died at 1 month. Median age at diagnosis of critical CHD was 1 (0–22) day. Pulse oximeter screening identified 72% of critical CHD and 14% were diagnosed prenatally. Only 8% of neonates with duct-dependent lesions were transported on prostaglandin. Preoperative mortality accounted for 86% all deaths. On multivariable analysis, only birth weight (OR 2.7; 95% CI 2.1 to 6.5; $p < 0.0005$) and duct-dependent systemic circulation (OR 6.43; 95% CI 5 to 21.8, $p < 0.0005$) were predictive of mortality.

Conclusions While systematic screening, especially pulse oximetry screening, enabled early identification and prompt management of a significant proportion of neonates with critical CHD, important health system challenges like low use of prostaglandin need to be overcome to minimise preoperative mortality.

INTRODUCTION

Congenital heart disease (CHD) has emerged as a leading contributor to infant mortality in many low/middle-income countries (LMICs). This is especially true in regions that have demonstrated a significant reduction in infant mortality rate from readily preventable causes.¹ The state of Kerala in India is one such example with a notably low infant mortality rate of 8/1000 live births.² Efforts

WHAT IS ALREADY KNOWN ON THIS TOPIC

- ⇒ Congenital heart disease is a leading cause of infant mortality in low/middle-income countries.
- ⇒ Antenatal and postnatal screening has resulted in improved survival in this subset in developed countries.

WHAT THIS STUDY ADDS

- ⇒ With early diagnosis, prompt referral and timely intervention, a significant majority of newborns with critical congenital heart disease can be expected to survive.
- ⇒ Survival is significantly less for babies with low birth weight and those with duct-dependent systemic circulation.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

- ⇒ This study underscores the need for health systems to integrate systematic neonatal and prenatal screening for congenital heart disease at the primary care level in low/middle-income regions.
- ⇒ It is necessary to develop robust transport systems for neonates with congenital heart disease with standardised protocols that include the liberal use of prostaglandin.

to reduce infant mortality due to CHD have focused on antenatal diagnosis and pulse oximeter screening in newborns prior to discharge. The recent introduction of a population-based and real-time approach to reduce CHD mortality through a systematic program since 2017 in the state of Kerala involves systematic triaging of critical CHD and early referral to dedicated paediatric cardiac centres.³ This web-based initiative enabled the creation of a system that allowed identification and referral of all newborns with CHD in the state. We established a CHD registry for newborns in Kerala as a prospective hospital-based registry (June 2018–May 2019) aimed at studying the prevalence of critical CHD and outcome of these babies. Additionally, we sought to understand the current practice pattern of management, the proportion of newborns with critical defects who receive timely

surgery or intervention and to identify the barriers that come in the way of timely care.

METHODS

Study design and setting

The information was collected prospectively from 47 tertiary referral centres catering to newborn care across the state. The demographic data and complete diagnosis were entered in a Google data form by medical staff in the participating centres after written informed consent. These data were verified by the project nurse and social worker of the principal investigating centre by telephone contact with the patient's parents/guardian. Follow-ups at 1 month, 6 months and at 1 year were also done by the project staff nurse at the time of visit to parent referral hospital or through telephonic follow-up. The registry was funded by Cardiological Society of India (Kerala Chapter). All newborns (≤ 28 days of age) with CHD other than physiological branch pulmonary artery stenosis, small atrial septal defects (< 4 mm), small muscular ventricular septal defects (< 3 mm) and arterial ducts (< 1.5 mm) were included. These babies were followed longitudinally for a month and outcome was noted by trained nurses. The CHDs were classified as mild, moderate, severe and critical disease. Critical heart disease was defined as those in whom intervention was recommended within 1 month of life and included duct-dependent systemic and pulmonary circulation, transposition of great arteries (TGA), total anomalous pulmonary venous drainage, common arterial trunk, severe aortic or pulmonary stenosis, coarctation and critical Ebstein's anomaly. Conditions for which intervention was advised within 1 year of life were classified as severe and these included large post-tricuspid left-to-right shunts, cyanotic heart disease with reduced and increased pulmonary blood flow, and severe valvar stenoses. Mild and moderate diseases were arbitrarily classified as those in whom the need for intervention was not anticipated in the first year of life. Kerala has an almost universal practice of pulse oximetry screening in health centres conducting deliveries including primary health centres (the pulse oximetry screening was done in 96% of all cases in our registry). The screening is done after 24 hours and within 48 hours of delivery. Two positive tests are needed to consider pulse oximetry screening as 'failed' ($SpO_2 < 95\%$). The newborn is immediately transferred to a centre with paediatric cardiac services for further evaluation and management. We have recently introduced a web-based

program for triaging and effective referral of these newborns, with stabilisation and transport embedded on the existing health infrastructure of the state as part of the web-based Hridayam Project. All referrals are tracked and followed in the website.

Data collection

Demographic data of the parents and the baby, complete diagnosis, details of antenatal and postnatal screening, mode of transport to the tertiary referral centre and distance travelled were collected for the babies with critical CHD. Recommendations on the need for interventions were made by a panel of paediatric cardiologists and they were recorded. One-month follow-up data were also collected.

Statistical analysis

Categorical data were described as proportions and comparative analysis done using the Fisher's test or X^2 test as appropriate. Quantitative data are expressed in mean and SDs and analysed using the independent Student's t-test or Mann-Whitney test as appropriate. Multivariable analysis for the predictors of outcome was done using binary logistic regression including the variable that was statistically significant in the univariate analysis. Survival analysis was done both with the Cox regression to derive the HR, and also using the Kaplan-Meier curves with the log-rank test.

RESULTS

A total of 1474 newborns who fulfilled the inclusion criteria of significant CHD were recruited in the registry and were categorised according to severity of disease. Babies with critical ($n=418$, 27%) and severe (32%) heart disease constituted more than half of the cohort (figure 1). Baseline characteristics of the babies with critical heart disease are mentioned in table 1.

Gender distribution was nearly equal for most of the critical heart diseases (table 1), but showed a surprising male preponderance for persistent arterial trunk. Pulse oximeter screening was done in almost all the newborns (96%) and the diagnosis was made within first 48 hours of life in the majority (89%). The decision on the mode of delivery was not affected by the availability of antenatal diagnosis (39% of caesarean section (C-section) among those with antenatal diagnosis vs 40% with no antenatal diagnosis). The decision of C-section was never made based on

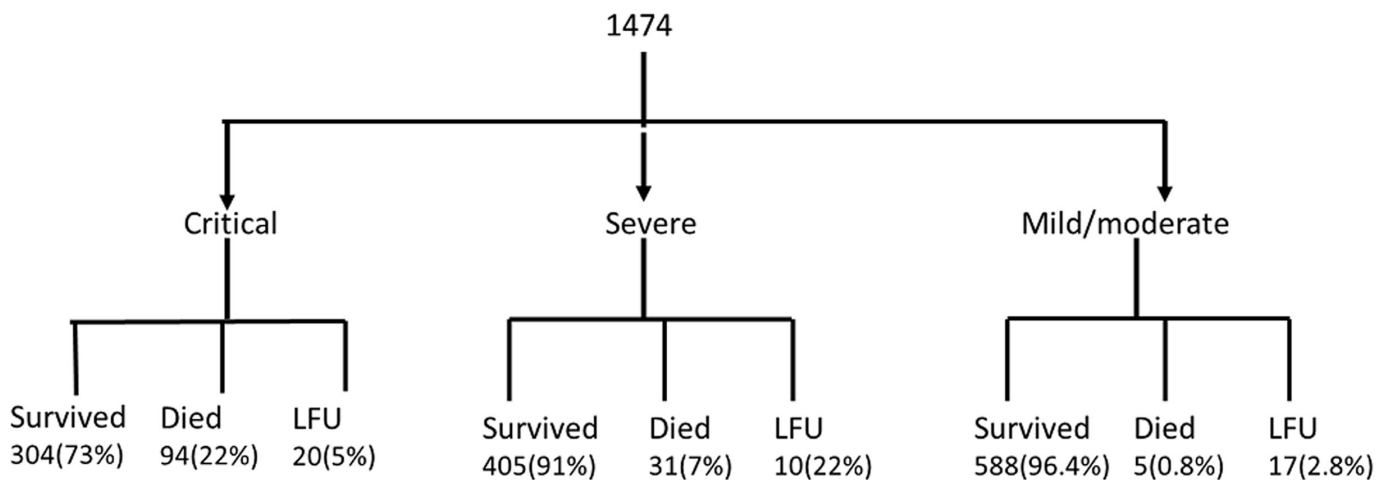


Figure 1 Flow chart depicting the classification of newborns with congenital heart disease based on severity and the outcome at 1 month. LFU, lost to follow-up.

Table 1 Baseline characteristics of newborns with critical congenital heart disease

	DDSC (50)	DDPC (139)	TGA IVS (69)	TGA VSD (25)	Obstructed TAPVC (42)	Unobstructed TAPVC (26)	Truncus arteriosus (12)	Others (55)	Total (418)
Males	26 (52%)	70 (50%)	43 (61%)	12 (48%)	24 (57%)	16 (62%)	11 (92%)	36 (65%)	238 (57%)
Age at diagnosis, days (median/range)	1 (0–16)	0 (0–21)	1 (0–10)	0 (0–11)	1 (0–10)	1 (0–22)	0.5 (0–19)	1 (0–17)	1 (0–19)
Birth weight, kg (mean/SD)	2.6 (0.6)	2.7 (0.48)	2.9 (0.5)	2.85 (0.6)	2.7 (0.5)	2.7 (0.5)	2.5 (0.4)	2.8 (0.7)	2.7 (0.5)
Gestational age <30 weeks	0	0	0	0	0	0	0	1 (1.8%)	1 (0.2%)
30–34 weeks	3 (6%)	5 (4%)	2 (3%)	0	0	0	0	2 (3.6%)	12 (2.9%)
35–37 weeks	8 (16%)	20 (14%)	9 (13%)	4 (16%)	3 (7%)	3 (12%)	2 (17%)	9 (16%)	58 (13.9%)
>37 weeks	39 (78%)	114 (82%)	59 (84%)	21 (84%)	39 (93%)	23 (88%)	10 (83%)	43 (78%)	348 (83.3%)
Mode of delivery (vaginal)	33 (66%)	86 (62%)	38 (55%)	18 (72%)	23 (55%)	18 (69%)	9 (75%)	30 (55%)	255 (61%)
Type of centre (tertiary)	26 (52%)	69 (50%)	23 (33%)	11 (44%)	10 (24%)	13 (50%)	4 (33%)	21 (38%)	158 (37.8%)
Antenatal diagnosis	5 (10%)	26 (19%)	12 (17%)	6 (24%)	0	0	0	8 (15%)	57 (13.6%)
Pulse oximeter screening	50 (100%)	137 (99%)	64 (93%)	23 (92%)	42 (100%)	24 (92%)	12 (100%)	51 (93%)	403 (96.4%)
Extracardiac anomalies	1 (2%)	4 (3%)	1 (1%)	2 (8%)	2 (5%)	0	1 (8%)	2 (3.6%)	13 (3.1%)
Genetic anomalies	0	8 (6%)	1 (1%)	0	2 (5%)	0	0	2 (3.6%)	13 (3.1%)

DDPC, duct-dependent pulmonary circulation; DDSC, duct-dependent systemic circulation; TAPVC, total anomalous pulmonary venous connection; TGA IVS, transposition of great arteries with intact ventricular septum; TGA VSD, transposition of great arteries with ventricular septal defect.

Table 2 Details of transport of the critically ill newborns

	DDSC (50)	DDPC (139)	TGA IVS (69)	TGA VSD (25)	Obstructed TAPVC (42)	Unobstructed TAPVC (26)	Truncus arteriosus (12)	Others (55)	Total (418)
Medic/paramedic transport	40 (80%)	102 (74%)	38 (56%)	10 (40%)	29 (71%)	9 (35%)	4 (33%)	27 (49%)	259 (62%)
Distance travelled, km (median, range)	1.5 (0–207)	29.9 (0–750)	55.5 (0–451)	56 (0–350)	78 (0–480)	9.3 (0–133)	61.5 (0–364)	32 (0–401)	43 (0–750)
Ventilated transport	12 (24%)	34 (25%)	15 (23%)	10 (38%)	15 (38%)	1 (3.8%)	2 (16%)	18 (32%)	107 (25.6%)
PGE1	3 (5%)	11 (8%)	1 (1.4%)	0	0	0	0	0	15 (3.59%)
SpO ₂ at arrival, % (mean/SD)	88.9 (7.5)	83.2 (12.5)	81 (13.3)	86.7 (8.1)	81.2 (10.7)	88.7 (6.8)	92(8)	89.2 (10.4)	84.1 (8.3)

DDPC, duct-dependent pulmonary circulation; DDSC, duct-dependent systemic circulation; PGE1, prostaglandin E1; TAPVC, total anomalous pulmonary venous connection; TGA IVS, transposition of great arteries with intact ventricular septum; TGA VSD, transposition of great arteries with ventricular septal defect.

the cardiac condition as all those diagnosed antenatally were counselled regarding the safety of normal vaginal delivery and informed that C-section was indicated only for obstetric or other fetal reasons like fetal distress. However, there does seem to be a trend favouring C-section in the population studied. Fourteen per cent of babies had prenatal diagnosis. Mean birth weight and presence of prematurity were similar among all groups. The 22q11 deletion was the most common genetic anomaly noted (54% of all genetic anomalies) followed by trisomy 21 (38%).

Duct-dependent systemic circulation (DDSC) comprised of hypoplastic left heart syndrome (52%), other univentricular hearts (12%) and biventricular heart with interrupted aortic

arch/critical coarctation/critical aortic stenosis (36%). Of the patients with duct-dependent pulmonary circulation, 67% were biventricular candidates, 25% had univentricular hearts and 12% had associated heterotaxy.

Majority of the babies with duct-dependent systemic and pulmonary circulation and those with obstructed total anomalous pulmonary venous connection (TAPVC) (70%–80%) were transported accompanied by doctors/nurses/paramedics (table 2). Approximately one-third were transported on mechanical ventilation. However, the use of prostaglandin E1 (PGE1) was quite low in all groups (0%–8%). The median distance transported was shortest for the babies with DDSC.

Table 3 Thirty-day outcome of the newborns with critical heart disease

	Survived		Died		
	Surgery/intervention done	Not done	Surgery/intervention done	Not done	Lost to follow-up
DDSC (50)	8 (16%)	0	2 (4%)	35 (70%)	5 (10%)
DDPC (139)	60 (43%)	48 (34.5%)	5 (3.5%)	19 (14%)	7 (5%)
TGA IVS (69)	53 (76.8%)	1 (1.4%)	5 (7.2%)	6 (8.7%)	4 (5.9%)
TGA VSD (25)	8 (32%)	17 (68%)	0	0	
Obstructed TAPVC (42)	34 (81%)	1 (2.3%)	2 (4.8%)	4 (9.6%)	1 (2.3%)
Unobstructed TAPVC (26)	4 (15%)	21 (81%)	0	0	1 (4%)
Common arterial trunk (12)	2 (17%)	7 (58%)	1 (8%)	2 (17%)	0
Other critical (55)	36 (65%)	4 (7%)	3 (5.5%)	10 (18%)	2 (3.6%)
Total (418)	205 (49%)	99 (23.7%)	18 (4.3%)	76 (18.2%)	20 (4.8%)

DDPC, duct-dependent pulmonary circulation; DDSC, duct-dependent systemic circulation; TAPVC, total anomalous pulmonary venous connection; TGA IVS, transposition of great arteries with intact ventricular septum; TGA VSD, transposition of great arteries with ventricular septal defect.

At 30 days, majority (74%) of the babies with DDSC had succumbed. Survival was substantially better for other critical heart diseases, with majority undergoing surgery/intervention within the first month of life (table 3).

Predictors of adverse outcome

On univariable analysis, diagnosis of DDSC, lower birth weight and lesser distance travelled to the tertiary referral centre were significant predictors of mortality (table 4). However, on multivariable analysis, only birth weight and DDSC were predictive of mortality with ORs of 2.7 for lesser birth weight and 6.4 for DDSC, respectively (table 5). The Kaplan-Meier survival curve (figure 2) further indicates the dismal survival of DDSC.

DISCUSSION

The Kerala model of healthcare delivery is based on a multi-layered health system for first-contact access at community level and integrated primary healthcare coverage for a range of preventive and curative services.² This has resulted in achievement of healthcare indices comparable with the Western world.³ The low neonatal and infant mortality rates can only be further improved by targeted approach to specific illnesses like critical

CHD.⁴ The addition of pulse oximetry screening for all newborns and triaging using a state-wide web-based program have led to tremendous improvement in the care of these babies.⁵ Further reduction in infant mortality can be achieved only by identification of loopholes in the system to ensure timely care. In Kerala, 99.8% of deliveries take place in hospitals³ and interventions can be easily made to improve outcome. We studied the outcome of critical CHD in various groups such as TGA, DDSC, duct-dependent pulmonary circulation, total anomalous pulmonary venous drainage, common arterial trunk and other critical diseases like right and left ventricular outflow obstruction.

Table 5 Multivariate analysis for mortality and survival

Variable	Multivariate predictors of mortality		
	OR	95% CI	P value
Birth weight	2.7	2.07 to 6.53	<0.0005
Distance travelled	1.0	0.99 to 1.0	0.296
DDSC	6.4	4.96 to 21.8	<0.0005

DDSC, duct-dependent systemic circulation.

Table 4 Univariate analysis

Variable	Survived	Died	P value
Gender: Males	182 (79%)	48 (21%)	0.3
Females	127 (75%)	42 (25%)	
Centre of delivery: tertiary	127 (74%)	45 (26%)	0.19
Others	182 (80%)	45 (20%)	
Gestational age: preterm	50 (77%)	15 (23%)	0.90
Term	259 (78%)	73 (22%)	
Mode of delivery: vaginal	184 (76%)	58 (24%)	0.50
C-section	125 (79%)	33 (21%)	
Antenatal diagnosis: yes	46 (81%)	11 (19%)	0.5
No	263 (77%)	79 (23%)	
Transport: doctor/nurse/paramedics	199 (79%)	53 (21%)	0.45
Family	110 (75%)	37 (25%)	
DDSC	7 (14%)	43 (86%)	<0.0005
Birth weight, kg	2.8 (0.5)	2.5 (0.5)	<0.0005
Oxygen saturation at arrival (%)	85 (11)	83 (13)	0.16
Distance travelled to referral centre, km	85 (110)	56 (87)	0.02
Delay to diagnosis, days	2.2 (3.7)	1.7 (3.1)	0.26

C-section, caesarean section; DDSC, duct-dependent systemic circulation.

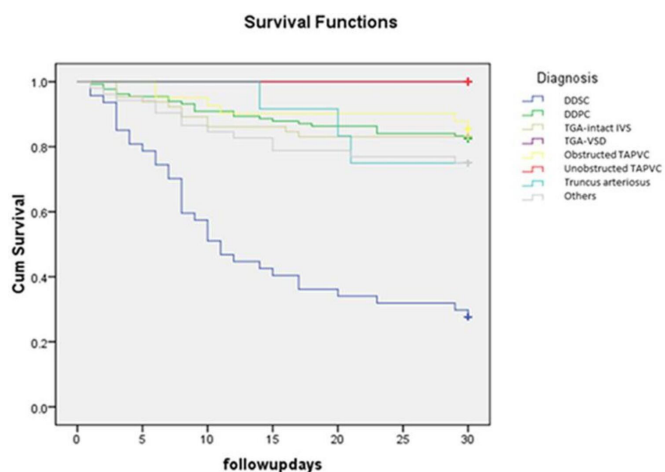


Figure 2 Kaplan-Meier survival curve showing the survival of different subsets of congenital heart disease at 1 month. DDPC, duct-dependent pulmonary circulation; DDSC, duct-dependent systemic circulation; TAPVC, total anomalous pulmonary venous connection; TGA IVS, transposition of great arteries with intact ventricular septum; TGA VSD, transposition of great arteries with ventricular septal defect.

The total number of live births in Kerala during the study period was 488 000.⁶ Therefore, the approximate prevalence of CHD based on our registry was 0.3%. We believe the reasons for the apparently low prevalence of CHD in the newborn in our registry are: (1) all the CHDs are not picked up in the newborn period, for example, small or moderate-shunt lesions, subaortic membrane, mitral valve prolapse (MVP), etc; and (2) some tertiary hospitals did not participate in the registry. We included tertiary referral centres with obstetric and newborn care in our registry. The few hospitals that did not participate were also tertiary referral centres, but none of them were paediatric cardiac centres. While some mild or moderate CHD may have been missed, it is unlikely that severe or critical CHD would have been missed. The prevalence of critical CHD in our study (0.08%) is likely to represent the true numbers as all these patients were transferred to tertiary referral centres and thus were noted in the registry. In our study, 79.3% of all newborns with critical heart disease were diagnosed within 3 days of birth as against 70% of that reported by Peterson *et al.*⁷ The diagnosis was made at a median age of 1 day which was likely facilitated by the widespread use of pulse oximeter screening before discharge (96%); 72% of all critical CHDs were detected by 'failed' pulse oximeter screening test in our registry. This matches the test accuracy in previously reported large studies on pulse oximetry screening.^{8–10} Inclusion of this screening modality in all primary health centres has improved the diagnosis of almost all critical CHDs except DDSC. Age at diagnosis was not a predictor of mortality in our study (1.7 days among those who died vs 2.2 days in those who survived; $p=0.26$) in contrast to other studies which found younger^{11 12} or older¹³ age at diagnosis to be a predictor of mortality.

Antenatal diagnosis was made in 14% of all critical CHDs. The relatively low antenatal diagnosis of babies with DDSC in our series may be misleading as there may be high termination rates of fetuses with antenatally detected hypoplastic left heart syndrome which are not identified in our registry. The registry data in Malaysia¹⁴ showed antenatal detection rate of 9%, while that from the USA¹⁵ showed rates ranging from 9% for TAPVC to 60%–70% for duct-dependent pulmonary and systemic circulation. Training of obstetricians and radiologists on the three cardinal fetal echo views can enable bridging the gap in antenatal diagnosis.

One-month survival for babies with TGA and intact ventricular septum was 78%. The postoperative survival in our study was 91%, which is comparable with early outcome (92% survival) after arterial switch operation noted in a systematic review of ~30 000 participants.¹⁶ Of concern was the finding that 9% died before surgery and 6% were lost to follow-up, which are relatively high figures because all patients were detected early and promptly referred. The preoperative mortality is likely related to the distance travelled to the nearest tertiary referral centre and may be improved by antenatal detection and in utero transfer.^{17 18} All the antenatally diagnosed babies with TGA-intact ventricular septum in our registry (13%) were delivered in a tertiary referral centre or had to travel very short distance (0.5–2 km) after delivery and all were operated early with 100% survival. There was no mortality in the group with TGA and ventricular septal defect though surgical repair was done for only one-third of these patients at 1-month follow-up. Close follow-up protocols are needed to ensure the surgical correction of this subset by 4–6 weeks of life as attrition may happen rapidly after this period.

Mortality was high (93%) for patients with hypoplastic left heart syndrome, as surgery was either not offered or was declined by the parents in these cases. However, 38% of the

patients with DDSC (with critical coarctation or arch interruption) who were biventricular candidates also succumbed. They were diagnosed relatively late at median age of 2.4 days (IQR 5) and they presented with intractable heart failure, shock or sepsis. Wren *et al.*¹⁹ found that 40%–50% of newborns with left ventricular outflow tract obstruction and DDSC were diagnosed after discharge from hospital. The perioperative mortality was also high in this group in our study (20%). Poor preoperative clinical status with end-organ dysfunction is well-known to have negative impact on survival^{20 21} and efforts have to be directed for early diagnosis and stabilisation in this subgroup. The incorporation of peripheral pulse examination²² (either the femoral or dorsalis pedis), together with the analysis of peripheral perfusion index during routine pulse oximetry, will aid in detecting critical coarctation and interrupted aortic arch.

The outcome of patients with duct-dependent pulmonary circulation was vastly better than DDSC with 83% survival at 1 month. Nearly 80% of the mortality was preoperative; 95% of the preoperative deaths were at home and 63% were univentricular hearts. The caregivers of 13% of patients with duct-dependent pulmonary circulation with univentricular hearts or heterotaxy opted for comfort care. Procedural mortality was 7.5% which is comparable with the 30-day mortality after intervention in other studies.

All the patients with obstructed TAPVC were operated early with good survival. However, only 15% of patients with unobstructed TAPVC underwent surgery within 1 month. Overall preoperative state and survival were better for this subset.

Survival at 1 month

Among newborns with critical CHD, 72% survived at 1 month. Most of the mortality (86%) occurred preoperatively. Of the 222 patients who underwent surgery, 92% were alive at 1 month demonstrating good procedural survival. The highest procedural mortality was observed in common arterial trunk (8%) followed by TGA-intact ventricular septum (7.2%). The procedural survival is comparable with the UK database study by Gibbs *et al.*,²³ which showed 9.1% mortality in newborns undergoing surgical or catheterisation interventions. The mortality was predominantly preoperative (68%) in our study which points significantly towards correctable factors that may improve outcomes in this fragile subset.

A total of 22.5% of the babies with critical heart disease travelled more than 100 miles to reach a tertiary paediatric care centre as compared with 25% in a study by Welke *et al.*²⁴ in the USA. Further improvement in these figures will be possible with better antenatal diagnosis and in utero transfer to a tertiary referral centre.²⁵ Use of PGE1 during transport was low, though one-fourth of transport was by trained medical personnel, indicating the need for more medical education programmes to educate neonatologists on safe use of PGE1. Easy availability of PGE1 in all tertiary newborn facilities should also be ensured to encourage more widespread use of PGE1. Quality of transport has been shown to correlate with good outcome²⁶ and methods to ensure safe transport are mandatory for newborns travelling long distances.

Low birth weight is a known contributor to increased mortality in LMICs^{27 28} and higher birth weight predicted a better outcome in our study as well. Despite the relatively good overall healthcare indices, 27% of our study population had birth weight less than 2.5 kg, and 90% of these were term small-for-gestational-age newborns. Though three mandatory health visits are prescribed for all antenatal women in Kerala, more

emphasis needs to be laid on ensuring adequate nutrition and weight gain by follow-up home visits.

Study limitations

The data of the total number of newborns with CHD were incomplete as some hospitals did not consent to participate in the registry. However, the number of critically ill newborns is accurate as all were referred to tertiary referral centres which participated in the registry. A significant proportion of newborns with critical heart disease were lost to follow-up at 1 month. Mortality data may be inaccurate as most of these patients may have succumbed. Cause of mortality of some of the newborns who succumbed at home was unclear as the parents refused autopsy.

CONCLUSION

Setting up and maintaining a CHD registry is important in LMICs as it provides a yardstick to measure prevalence, referral system efficacy and outcomes. Systematic screening with pulse oximetry has enabled early identification and prompt management of a considerable proportion of neonates with critical CHD though antenatal detection rates are suboptimal. However, important health system challenges like low use of prostaglandin, low antenatal detection rate and prevalence of low birth weight need to be overcome to minimise preoperative mortality. A more effective surveillance and follow-up are needed to prevent attrition of newborns who were diagnosed early.

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Competing interests None declared.

Patient consent for publication Not required.

Ethics approval This study involves human participants and was approved by the Institutional Ethical Committee (IEC) of Sree Chitra Tirunal Institute for Medical Sciences and Technology (Trivandrum number: IEC/SCT/696; IEC approval of CSI (Kerala): IEC/CSI/2018/02). Participants gave informed consent to participate in the study before taking part.

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