Screening Newborn babies for Congenital Heart Disease: Prospective Observational Study

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Abstract
Background: Screening for congenital heart disease is important as it accounts for 20% of the life threatening conditions resulting in Neonatal deaths. This screening programme is implemented in Government Vellore Medical College and Hospital aiming at reducing the morbidity and mortality of critical congenital heart disease.

Objective: Screening the asymptomatic newborns for congenital heart disease using saturation monitoring.

Design: Prospective observational study

Study period: Jan’2016-Dec’2016

Setting: Post Natal wards in a tertiary care Hospital, Government Vellore Medical College and Hospital, Vellore.

Study Subjects: Asymptomatic term newborn babies born in hospital after 48 hours of life.

Result: Of the 11268 babies delivered, 2450 babies were included in the study. Among these babies, 9 had low saturation with mean SpO2 of 78 and standard deviation of 12.7. Out of 9 neonates with low SpO2, 5 were confirmed to have CHD and other 4 found to have non CHD causes (3 PPHN and 1 sepsis). Among the 11268 deliveries, 43 babies had symptomatic CHD with incidence of 1 in 262 babies born.

Conclusion: Screening the New born with saturation Monitor detected 4 critical and 1 non-critical congenital heart diseases out of 2450 with SpO2 Monitor. These babies with critical congenital heart disease underwent corrective cardiac surgeries at tertiary care centre with help of CMCHIS and private partnership. Early Intervention prevented early death as well complications secondary to CHD. Screening for congenital heart disease should be included as a part of newborn assessment and early identification influences outcome.

Keywords: Saturation monitoring, critical congenital heart disease.

Introduction
Screening for congenital heart disease has been implemented in developed countries depending on the resource allocation, geography and availability of trained professional’s paediatric cardiology. In North America, the process for screening
Congenital heart disease was initiated in 2010 and now it is mandatory across all the states for screening of congenital heart disease. Cost of implementation and availability of adequate paediatric cardiologists was also one of the barriers for the implementation of universal screening programme.

**Patients and Methods**

Prospective observational study

**Inclusion criteria:** Asymptomatic term new born babies.

**Exclusion criteria:** Preterm, Cardiac failure, Cyanosis.

The incidence of congenital heart disease is 8-9 per 1000 worldwide. Critical congenital heart disease accounts 25% with an incidence of 1-2 per 1000. In our tertiary unit Government Vellore Medical College and Hospital with deliveries around 10,000 to 12,000 / year an incidence of 80 – 90 babies of congenital heart disease and 10 – 20 of critical congenital heart disease per year is anticipated.

Clinical presentation of the congenital heart disease depends on the anatomical defects, changes in Pulmonary, systemic vascular resistance and closure of the ductus arteriosus. Screening and recognition of these cohort of children with critical congenital heart disease is important as it can result in severe morbidity and mortality if untreated in the first few days or weeks of life.

Asymptomatic term newborn babies were screened by Medical Officers on call by using saturation monitors. SpO2 monitor were placed on the right hand and left foot of the newborn with warm extremities and appropriate calibration of the saturation monitor. If the SpO2 is more than 94% the babies were discharged and if SpO2 less than 92% or with a difference in saturation between the right arm and leg is more than 3% the saturation was repeated 3 times in one hour intervals. If it is less than 92%, on these 3 occasions neonates were transferred to Neonatal Intensive care unit for cardiac assessment with Echo cardiogram.

Screening Echo done by Paediatric Professor, trained in Echo cardiogram, were confirmed by Paediatric Cardiologist through telemobile. Only babies with low SpO2 were screened. Babies with Critical Congenital heart disease, after stabilization sent to cardiac critical centre for corrective cardiac surgeries. In our study only asymptomatic term newborn babies were included and symptomatic babies with cyanosis, CCF, Preterm were excluded.

**Data Analysis**

**Result**

Total no. of babies born 11268 out of which 5828 (51.72%) is normal deliveries, LSCS 4990 (44.28%) and Assist deliveries 450(3.99%).
Asymptomatic new born = 2450
Total no. of babies with low SpO$_2$ = 9
Mean SpO$_2$ = 78
Standard Deviation = 12.7
Normal Children are having more than 92%
SpO$_2$ Male and Female differentiation
1 out of 272 babies are having low SpO$_2$
Prevalence of CHD = 0.36% (0.18% - 0.67%)

Out of 9 neonates with low SpO$_2$, 5 were confirmed to have CHD (1. VSD with Overriding of Aorta, 2. VSD with TGA, 3. Intra cardiac TAPVC with ASD, 4. PDA, 5. Single Ventricle Large ASD Pulmonary Atresia) and other 4 found to have non CHD causes (3 PPHN and 1 sepsis).

**Prevalence of CHD**
Total no. of Deliveries = 11268
Total no. of CHD (Symptomatic) = 43
1 out of 262 babies in study had CHD
Prevalence of CHD in this study = 0.38% (0.28% - 0.51%)

**Discussion**
Currently, CCHD is not detected in some newborns until after their hospital discharge, which results in significant morbidity and occasional mortality. Furthermore, routine pulse oximetry performed on asymptomatic newborns after 24 hours of life, but before hospital discharge, may detect CCHD (1).
Robert Koppel et al screened 11281 and found 3 critical congenital heart diseases. False positive was only one case compared to our study. 2 cases with negative screens were re-admitted with critical congenital heart disease (2).
Andrew K Ewer et al screened more than 20,000 new born, and false positive was 169 or (0.8%). In our study there were only 4 cases of false positive screen (3).
Frank Thomas Riede et al screened more than 40,000 babies and had 40 false-positive screen of which 12 were healthy, 15 had pulmonary hypertension of newborn and 13 had sepsis (4).
Shakila Thagarathinam et al found that false-positive rate for pulse oximeter screen was low when SpO$_2$ monitoring was done after 24 hours for birth (5).
Granelli et al screened 39821 children using pulse oximetry and it improved total detection rate of duct dependent circulation to 92% (6).
Incidence of critical congenital heart disease is common 1-2/1000. Screening for newborn congenital heart disease should be incorporated in the newborn nursery. Challenges lie in performing Neonatal echocardiogram, training staff and assessment.

Physicians working especially in tertiary units should develop clinical skills in acquiring the basic echocardiographic views and clinical programmes are available for hands on training. There are unique challenges especially with the shortages of Paediatric cardiologists and challenges in not only doing functional echocardiography but also to recognise structural lesions which will need urgent intervention.

In developed countries there are programs and board certification available in Neonatal echocardiography, role of Neonatologists and Paediatric Cardiologists are well defined. However, from local perspectives training programmes and using telemedicine with obtaining the views and working in close collaboration with Paediatric cardiologists to tease out the cohort of patients who may need immediate intervention from babies who could be seen in a scheduled visit.

It is important that clinical skills are maintained in daily practice as repetition is the mother of all skills. Important to develop care coordination and collaboration with private and public sector and implement cost effective ways of using the Government Insurance to the children and families with critical congenital heart disease. Telemedicine units with modern technology, adaptation with mobile phones can be effectively used and effective communication with private health care sector with proper coding for reimbursement depending on the complexity of the surgery.

Further there should be a seamless smooth transition of care to the referring hospital with coordination of services for long term followup. Ideally this is should be done in a pooled manner with Paediatric cardiologists doing outreach outpatient clinics in the long term followup these important cohorts of children with critical congenital heart disease.

Further the comprehensive care package in the management of children with congenital heart disease should not only focus on the reimbursement of the surgical procedures and post cardiac intensive care but also for long term follow up. As there is emerging cohort of patients becoming adults having survived congenital heart disease in the developed countries Paediatric cardiologists are taking special interest in looking after these survivors of congenital heart disease even in late 30-40 years of age.

It is an emerging practice of adult cardiologists working in collaboration with paediatric cardiologist in long term care of these population with unique needs. With advancement of medical infrastructure and economic progress in India in the 21st century, there should be follow up programmes for this needy cohort of children and we should not short sighted in ignoring the importance of ongoing long-term follow up.

We have not only piloted the project in our hospital for screening for critical congenital disease in our Newborn nursery but also extended the screening programme to school going children as congenital heart disease undetected can present with complication due to non-intervention.

We have close links and collaboration with the private sector and ongoing discussion with administrator in devising a cost-effective model of delivering health service for these vulnerable population and roll out the model of care across the state of Tamil Nadu.

**Conclusion**

Screening the New born with saturation Monitor detected 5 critical congenital heart diseases out of 2450 with SpO2 Monitor. These children with critical congenital heart disease underwent corrective cardiac surgeries at tertiary care centre with help of CMCHIS and private partnership. Early Intervention prevented early death as well complications secondary to CHD.
Screening for congenital heart disease should be included as a part of newborn assessment as it is a common congenital problem. Early identification influences outcome. Barriers in implementation of the screening programmes in resource limited setting is a challenging feature.

However, with effective co-ordination of care, communication with the transport team and with collaborative working and support from Paediatric Cardiologists made this a reality. Further application of telemedicine, developing clinical skills in performing basic views in Cardiac Echocardiogram and effective use of comprehensive insurance scheme with private and public partnership can deliver care for these selective cohort of newborn babies with critical congenital heart disease.

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**Conflict of Interest:** None

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