



# Pulse Oximetry Screening of Newborn for Critical Congenital Heart Disease in Developing Countries

Lakra MS<sup>1\*</sup>, Taksande A<sup>2</sup>, Lakra A<sup>3</sup> and Ahlawat KS<sup>4</sup>

<sup>1</sup>Department of Neonatology, Jawaharlal Nehru Medical College, Datta Meghe Institute of Medical Sciences, India

<sup>2</sup>Department of Pediatrics, Jawaharlal Nehru Medical College, Datta Meghe Institute of Medical Sciences, India

<sup>3</sup>Datta Meghe Medical College and SHMRC, India

<sup>4</sup>World college of Medical Sciences, Research and Hospital, India

## Mini Review

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**\*Corresponding author:** Mahaveer Singh Lakra, Department of Neonatology, Jawaharlal Nehru Medical College, Datta Meghe Institute of Medical Sciences, Sawangi Meghe, Wardha, Maharashtra State, India 442004, Tel: 9992693363; Email: lakra.mahaveer@gmail.com

## Abstract

Congenital heart disease is the most commonly diagnosed congenital anomaly in the neonatal period. It has been proved by studies that neonatal examination and murmur are not reliable signs in newborns and we may miss underlying heart problems. If routine neonatal screening is not undertaken, there is a 25% possibility of missing congenital heart disease and 40% of these cases may present with shock and circulatory collapse in the hospital in the subsequent days. As the delay in diagnosis may increase the neonatal mortality so all newborn babies must be screened before discharge. All babies who failed pulse oximetry threshold of less than 95% must be screened by preductal and post ductal pulse oximetry as underlying hypoxaemia may be missed clinically. Many studies have proven that if a newborn is screened within the first week, the chances of missing cardiac problems drop dramatically, to less than 30%. Seeing the burden and severity of this illness, it is recommended by the American Academy of Pediatrics and the American Heart Association that neonatal screening should be done in all developed, affordable countries. This article aimed at making physicians and policymakers in developing countries aware of the need to detect critical heart disease at the right time and addresses to implement policies so that intervention can be done timely to prevent neonatal mortality.

**Keywords:** Critical Congenital Heart Disease; Pulse Oximetry; Newborn Screening; Developing Countries; Neonatal Mortality

## Introduction

The major chunk of birth defect in neonatal period is constituted by congenital heart disease with the incidence of around 9 per 1000 live birth. It is defined as any structural abnormality of heart and major vessels in neonatal period,

resulting into poor perfusion of tissue. It mostly manifest in first week of life. Critical congenital heart disease is defined as the disease where urgent catheter mediated intervention or surgery is required with in the first week or in first month of life to avoid death or circulatory collapse [1]. There are no universal screening guidelines, it varies from country

to country and depends upon the disease prevalence, affordability, feasibility and standard guidelines.

### The Burden of Disease

Seeing the burden of morbidity and mortality among the newborn period, it is important to identify, screen all the newborns and intervene timely before the disease manifests. The study database collected globally in 2017 showed that the incidence and prevalence of congenital heart disease varies globally and have heterogeneity in etiology and prevalence. Congenital heart disease is more prevalent in African, Asian, in developing and low-income countries as compared to developed countries. The overall incidence varies from 0.8 % to 1.2 % of total live birth [2]. According to data the neonatal mortality is more in sub Saharan, Asia and African countries and it varies from 41.9 to 56.9% per 1000 live birth. One baby in every 10 baby is born with some or other type of congenital heart disease and out of then 25% babies have severe or critical heart disease. Although incidence of congenital heart disease has not increased but almost remains static in last three decade [1,3].

### Pulse Oximetry Screening

The aim is to pick up the disease earlier so that precautionary measures can be taken care of and can be intervened early to increase survival rate of newborn. Screening is not a diagnostic test and the pulse oximetry screening helps us to detect the disease earlier when baby is asymptomatic and disease have not manifested. By adopting this method universally, the sick babies having underlying severe congenital heart disease can be identified earlier and intervention can be done at right time even at first day of life [4]. If this routine screening is not done in neonates, then there is always a chance of 25% of missing congenital heart disease and out of these missed cases, 40% present with shock and circulatory collapse in hospital in next few days. Many studies in US and Europe have shown that if newborn is screened after birth or in first week, the chances of missing the heart disease decreases substantial to even less than 30% [1].

The saturation of newborns is determined by using a pulse oximetry probe at two locations: one on the right index finger and the other on the left hand or lower leg referred to as pre ductal and post ductal screening, respectively. Screening at the right time is necessary. Because there is a danger of false negative rates if it is done before 24 hours, the best screening time is between 24 and 48 hours or before discharge from the healthcare setting [1,4,5]. The dictum is that, if the neonate failed the pulse oximetry test, then he should be treated and managed like a congenital heart disease unless proved otherwise.

### Effectiveness of Pulse Oximetry Screening

A systemic review done by Thangaratinam S, et al. [6] have shown that the sensitivity for pulse oximetry screening for heart disease varies from 25 percent to 98.5 percent and specificity from 99 % to 100 %. The false positive rate from various study varies from 0-2 %. The sensitivity increases when the pulse oximetry was taken from two different sites and when cut of threshold is 95% [5,6].

A multicentric study done by Riede FT, et al. [7] over 42240 newborn over a duration of 2 years proved that it is a very good effective method of diagnosis of critical heart disease in newborn and the false positive rates are minimal. The sensitivity and specificity was found to be 77.78 % and 99.90% respectively. The negative predictive value was almost nearly 100 % (99.99%) reducing the percentage of late diagnosis of heart disease in newborn to a minimum of 4.4%.

The majority of developed nations have included pulse oximetry newborn screening in their normal neonatal screening programmes. Although the United States, as a developed country, has issued a newborn screening advisory since 2011, it was universally accepted and implemented in 2016 after analyzing the benefits and risks of this screening programmes, and it is now used in almost all of the individual hospitals in the United States [8]. In contrast to the United States, the United Kingdom has not made it mandatory in hospitals and has not adopted it in its universal newborn screening programmes fully [9].

### Timings and Threshold

All new born are screened at 24-48 hours of the birth with pulse oximetry which detects the hypoxaemia in body tissue. The threshold used for pulse oximetry is less than 90 and 95 percent. If the pulse oximetry is less than 90 percent, it indicates high possibility of underlying severe critical heart disease and baby should be immediately screened for echocardiography. If the pulse oximetry reading is 95 percent, then second reading should be taken after a gap of 24 hours and if baby fails again, then he or she should undergo echocardiography. The pulse oximetry is said to be positive and the screen test is labeled as failed, if the pulse oximetry reading is less than 90% in any of the limb or less than 95% in both limb or the difference between pre ductal and post ductal is less than 3% on three occasions measured after a gap of 1 hour [4]. The heart disease which can be identified by pulse oximetry include Truncus arteriosus, Tetralogy of Fallot, critical pulmonary stenosis, pulmonary atresia, transposition of great arteries, coarctation of aorta and total anomalous pulmonary return [1,10]. In neonatal period the clinical examination, cyanosis and presence of

murmur is not reliable so if relied on only examination, then many of the heart disease are missed [11].

If antenatal screening is clubbed with fetal screening by echocardiography and pulse oximetry in newborn, then the chances of missing of any critical heart disease is very low and the specificity and sensitivity increase drastically. As most of the babies are asymptomatic at birth, so if they are intervened earlier, then we can prevent the end organ damage, cardiovascular collapse and promote good neurodevelopment outcome. The clinical examination, pulse oximetry and echocardiography all in a combined fashion increase the sensitivity and specificity of early diagnosis of heart disease [12].

Antenatal echocardiography should also be performed in mothers to screen for any structural or congenital cardiac defects. It can be done in the first trimester, but the accuracy is not as good, thus the best time to undertake fetal echocardiography is usually between the ages of 18 and 22 weeks. It detects structural and chromosomal abnormalities and assists us in arranging medical or interventional surgical therapy for a better outcome shortly after birth [12,13]. This will contribute in the early detection and treatment of significant cardiac illness. By implementing this screening method internationally, we will be able to significantly improve infant survival rates and outcomes [4,14].

### Implication of Pulse Oximetry Screening in Developing Countries

The pulse oximetry screening is a very reliable, non-invasive, cost-effective methods of screening of babies with underlying critical heart disease [1,4,11]. The sensitivity and specificity of this method is high [6,7]. If the baby fails in oximetry test, then he or she should be immediately undertaken for echocardiography by an expert. In a study conducted by Trujillo LD, et al. [15] it has been shown that when physical examination was included along with pulse oximetry screening it doesn't lead to any rise in cost to patient. The cost effectiveness of physical examination and pulse oximetry was 0.93 and it is 0.07 more than physical examination only, so there was hardly any significant difference in cost between 2 methods. The screening within time period of one week is cost effective and a good strategy for diagnosis of critical heart disease in newborn.

The majority of developed nations' regular neonatal screening programmes now incorporate pulse oximetry newborn screening. After a thorough examination of the benefits and risks of this screening programme, it was unanimously approved and implemented in 2016, and it is now used in practically every hospital in the United States [8]. In contrast to the United States, the United Kingdom has

neither made it mandatory in hospitals or fully integrated it into its universal newborn screening programmes [9]. A conference and workshop was held regarding the need of starting pulse oximetry screening in neonate by pan African countries in Rabat 2019 to address the issue and urgent need of start of pulse oximetry in neonates in their countries. Various cardiac hospitals, newborn foundations, newborn screening centers and expert committee presented their data's on the screening of babies in developing countries. It was decided that there is an urgent need of start of various pilot projects, research studies and any supported programme by various agencies and national universal programme which will help the policy makers to build necessary infrastructure and to allocate resources to strengthen this special new born programme at national and regional level [16].

Though it is a cost-effective, affordable, feasible and non-invasive method of screening babies for heart disease, it has not been included in the newborn universal screening programme in developing countries. Many studies have recommended that it should be routinely included in newborn screening programme in developing countries also [17]. Pulse oximetry is a very useful modality and a good reliable screening test to detect critical cyanotic heart disease in a newborn.

### Conclusion

Pulse oximetry screening aimed at earliest picking up of babies having underlying congenital heart disease immediately after birth. All babies should be routinely screened by pulse oximetry for critical cyanotic heart disease before discharge from hospitals. All the strategies should be directed to improve neonatal survival rate and to decrease neonatal mortality and morbidity. It should be included in universal screening neonatal program in developing countries also.

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