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Pulse Oximetry Screening for Congenital Heart Disease in Newborns: Performance in Brazzaville Hospitals

Aymar Pierre Gildas Oko[1,2*], Neli Yvette Ngakengni[1,2], Judicaël Kambourou[1,2], Lorna Frangella Kanga[1], Flora Nombo Mavoungou[2], Leticia Lombet[2], Georges Marius Moyen[1]

[1]Faculty of Health Sciences, Marien Ngouabi University of Brazzaville, Brazzaville, Republic of the Congo
[2]Department of Pediatrics, Teaching Hospital Center of Brazzaville, Brazzaville, Republic of the Congo
Email: *aymaroko@yahoo.fr

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Abstract

Background: While pulse oximetry is a well-established screening tool for the early detection of congenital heart disease (CHD) in newborns, its diagnostic performance and feasibility have not been evaluated in the Republic of the Congo. **Objective:** The aim is to analyse the performance of pulse oximetry in screening for congenital heart disease in newborns in hospitals in Brazzaville, comparing its accuracy in detecting all congenital heart diseases versus cyanotic congenital heart diseases. **Methods:** We conducted a two-stage, multicenter, cross-sectional study from March 1 to August 31, 2022. Mother-newborn dyads were enrolled post-delivery. All included newborns underwent pulse oximetry screening, followed by confirmatory Doppler echocardiography as the diagnostic gold standard. Sociodemographic, reproductive, and clinical data were collected. The sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of pulse oximetry screening were calculated. **Results:** We included 300 mother-newborn dyads. Mothers were predominantly aged 20 - 34 years (73%). Newborns were mostly male (54.3%) and term (75%). Screening was performed at 12 - 24 hours of life in 55.3% of cases and at 24 - 72 hours in 44.7%. Twelve cases of CHD were diagnosed: atrial septal defect (n = 4), ventricular septal defect (n = 2), complete atrioventricular canal (n = 2), tetralogy of Fallot (n = 2), truncus arteriosus (n = 1), and double outlet right ventricle (n = 1). For detecting all CHD, pulse oximetry showed a sensitivity of 41.7%, specificity of 86.8%, PPV of 11.6%, and NPV of 97.2%. For cyanotic CHD specifically, its performance was superior, with 100% sensitivity, 86.7% specificity, 9.3% PPV, and 100% NPV. **Conclusion:** In our setting, pulse oximetry proved to be a highly sensitive and reliable screening tool for cyanotic forms of congenital heart disease. These find-

ings support its potential utility in routine neonatal care. Further large-scale studies are warranted to inform policies for its systematic implementation across Congolese maternity units.

Keywords

Performance, Pulse Oximetry, Neonatal Screening, Congenital Heart Disease, Brazzaville Maternity Wards

1. Introduction

Congenital heart disease (CHD) encompasses a heterogeneous group of cardiac malformations. Its clinical spectrum ranges from simple lesions with minimal or no impact on the newborn's health to complex defects that may be life-threatening if not treated promptly and, in some cases, incompatible with life [1] [2]. With an estimated global incidence of 7 to 8 per 1000 live births, CHD represents the most common group of congenital malformations worldwide [3] [4]. It is the leading cause of mortality among all congenital malformations, responsible for approximately 10% of deaths in affected live births. CHD also ranks as the second leading cause of death during the first year of life, after infectious diseases. In 2017, CHD was responsible for an estimated 261,247 deaths, 69% of which occurred in children under one year of age. This substantial burden highlights CHD as a major public health concern. [3] [5]-[9]. This burden falls disproportionately on sub-Saharan Africa, where reported prevalence of CHD ranges from 2.2 to 14.4 per 1000 live births. Concurrently, over the course of a decade, mortality increased in the central, eastern and western sub-Saharan regions by 38.1%, 4.6% and 40.3%, respectively [3] [10] [11].

Prognosis is closely linked to early diagnosis and, consequently, to timely therapeutic intervention [12]. In high-income countries, systematic prenatal screening using fetal echocardiography has significantly improved early detection. However, this strategy is difficult to implement in sub-Saharan Africa due to limited access to this technology. Consequently, diagnosis often relies on neonatal clinical examination, which has low sensitivity and leads to a substantial proportion of affected newborns being missed [13]-[15]. This diagnostic gap underscores the urgent need for simple, accessible, and effective complementary screening tools in these regions.

Pulse oximetry, a non-invasive, inexpensive, and widely accessible method for measuring oxygen saturation, has emerged as a promising screening tool. Indeed, its effectiveness in detecting critical congenital heart disease has led to its endorsement by several international neonatology and paediatric cardiology societies [16] [17]. Several learned societies now recommend its systematic use for all newborns prior to discharge from maternity ward [18] [19].

Despite these strong recommendations and favourable cost-effectiveness, this

tool has not yet been integrated into neonatal care in Republic of the Congo, where a hospital-based study reported a CHD prevalence of 10.7% [20]. In this context, evaluating the relevance and diagnostic performance of pulse oximetry in a Congolese setting is warranted.

This study aims to analyse the performance of pulse oximetry in screening for congenital heart disease in newborns in hospitals in Brazzaville, comparing its accuracy in detecting all congenital heart diseases versus cyanotic congenital heart diseases.

2. Patients and Method

2.1. Study Design, Setting and Duration

This was a cross-sectional analytical study with prospective data collection. The study was conducted over a six-month period, from 1 March to 31 August 2022, in the maternity wards of two facilities in Brazzaville: the Brazzaville University Hospital Centre (CHU-B) and the Talangaï Reference Hospital (HRT).

2.2. Study Populations

The target population was newborns of at least 34 weeks' gestational age born in Brazzaville.

The source population included mother-newborn pairs in the immediate postpartum period within the delivery and obstetrics units of the CHU-B and the HRT.

2.3. Eligibility Criteria

2.3.1. Inclusion Criteria

We included in the study newborns with a gestational age of at least 34 weeks of amenorrhea and a birth weight of at least 2000 grams.

2.3.2. Exclusion Criteria

We excluded newborns with poor adaptation to extrauterine life (requiring immediate advanced resuscitation or transfer to neonatal intensive care), those born to mothers with known neuropsychiatric disorders, and those born to mothers who did not provide consent for participation.

2.4. Sampling

2.4.1. Type of Sampling

A two-stage sampling procedure was used. In the first stage, a simple random sample was drawn from the eight hospitals in Brazzaville, resulting in the selection of two hospitals: Brazzaville University Hospital and Talangaï Referral Hospital. These hospitals constituted the primary sampling units. In the second stage, for each selected hospital, the days of visit were randomly chosen. Finally, all mother-newborn pairs present on the days of visit were consecutively included in the study, constituting the secondary sampling units.

2.4.2. Sample Size

The minimum sample size was calculated using the SCHWARTS formula:

$$N = P(1 - P)(Z\alpha)^2/(m)^2$$

N: minimum sample size.

P: Estimated proportion of the population with the characteristic under study, which is 7.4% based on data from Philippe Mahouna ADJAGBA's Beninese study on the contribution of pulse oximetry in the screening for cyanogenic congenital heart disease in newborns at CNHU-HKM Cotonou [21].

$Z\alpha = 1.96$ (corresponding to a 95% confidence level).

$m = 5\%$ (tolerated margin of error).

Thus, the minimum sample size should be 105. After accounting for an anticipated non-response rate of 15%, the final minimum required sample size was increased to 121 newborns.

2.5. Data Collection

2.5.1. Collection Tools and Sources

Data were collected using a standardized, anonymous survey form. Information was obtained through individual interviews with mothers, antenatal care records, medical records, hospitalization and delivery registers, surgical reports, clinical examinations, pulse oximetry measurements, and cardiac Doppler ultrasound examinations of newborns

2.5.2. Collection Procedure

Face-to-face interviews with mothers were conducted by the same interviewer in a private setting, after obtaining parental consent. The interview was followed by a physical examination of the newborn, during which the interviewer also took pulse oximetry readings.

2.6. Pulse Oximetry

Pulse oximetry was performed using a PC60E pulse oximeter equipped with a neonatal sensor. Measurements were taken while the newborn was calm and at rest. Two measurements were obtained: one from the right upper limb (finger or wrist) and one from a lower limb. The difference between the two saturation values was then calculated.

2.6.1. Interpretation of Pulse Oximetry Results

Pulse oximetry screening was considered positive if oxygen saturation was ≤90% in either the upper or lower limb, or if the difference in saturation between the upper and lower limbs exceeded 3%.

Screening was considered negative if oxygen saturation was ≥95% in both the upper and lower limbs and the difference between the two measurements was less than 3%.

Screening was considered inconclusive if both saturation values were between 90% and 95% and the difference was ≤3%. In such cases, a second measurement

was performed. If the results remained unchanged, the screening was ultimately classified as positive.

2.6.2. Doppler Echocardiography Procedure

Cardiac Doppler ultrasound was performed in all newborns using a multi-frequency pediatric probe connected to a tablet running the Philips Lumify application (version 1950105.428118487). All examinations were carried out by the same pediatric cardiologist, who was blinded to the pulse oximetry results.

2.6.3. Cardiac Doppler Ultrasound Results

Findings were categorized as follows:

No congenital heart disease: absence of structural cardiac abnormalities.

Transitional congenital heart disease: this referred to congenital heart conditions observed during the transition period between foetal circulation and mature circulation, namely patent foramen ovale and restrictive ductus arteriosus. These heart conditions were considered non-pathological and as absence of congenital heart disease in the data analysis.

Congenital heart disease: all other structural congenital cardiac anomalies.

2.6.4. Interpretation of Combined Oximetry and Ultrasound Results

True positive: positive pulse oximetry screening and presence of congenital heart disease on ultrasound.

False positive: positive pulse oximetry screening with no congenital heart disease on ultrasound.

True negative: negative pulse oximetry screening and no congenital heart disease on ultrasound.

False negative: negative pulse oximetry screening with congenital heart disease confirmed on ultrasound.

2.7. Study Variables

The dependent variable or variable of interest was pulse oximetry.

The independent (explanatory) variables included maternal, neonatal, clinical, and ultrasound-related factors:

Maternal variables: maternal age, household socioeconomic status, history of chronic maternal disease, family history of congenital heart disease or other congenital malformations, medication use during pregnancy, and type of pregnancy (singleton or twin).

Pregnancy and delivery variables: number and quality of antenatal care visits, gestational age at delivery, and mode of delivery.

Neonatal variables: Apgar score, birth weight, postnatal age at screening, sex, skin colour, respiratory rate (RR), heart rate (HR), pulse symmetry, heart rhythm, presence of a cardiac murmur, and characteristics of the first and second heart sounds (S1 and S2).

Ultrasound variables: number of echocardiographic examinations and results,

including the presence or absence of congenital heart disease (CHD), type of CHD, and CHD classification (cyanotic or non-cyanotic).

2.8. Definitions of Concepts

Non-cyanotic congenital heart disease: congenital heart disease in which haemodynamic occur without mixing of arterial and venous blood in the systemic circulation (e.g. VSD, ASD, PCA, atrioventricular canal, coarctation of the aorta).

Cyanotic congenital heart disease: congenital heart disease with mixing of arterial and venous blood in the systemic circulation. (e.g., Tetralogy of Fallot, Transposition of the Great Arteries).

2.9. Statistical Analysis

Microsoft Excel (version 10) and SPSS Statistics (version 17.0, 2010) were used for data entry, database management, and the production of tables and graphs. Results for categorical variables are presented as frequencies (n) and percentages (%). For quantitative variables, data are expressed as medians with interquartile ranges (Q1 - Q3) for non-normal distributions, and as means ± standard deviations for normally distributed variables

We used the student's t-test to compare means and the Mann-Whitney U test to compare medians. the variable of interest (pulse oximetry) was correlated with each explanatory variable. Odds ratios (OR) with their 95% confidence intervals (CI) were calculated, with statistical significance set at $p < 0.05$.

The diagnostic performance of pulse oximetry was assessed by calculating sensitivity, specificity, and positive and negative predictive values.

2.10. Ethical Considerations

The study was conducted in compliance with patient anonymity and privacy. All participants provided informed consent prior to data collection. Ethical clearance was obtained from the Health Sciences Research Ethics Committee (N° 0036-28/MESRSIT/DGRST/CERSSA/-22).

3. Results

3.1. Prevalence of Congenital Heart Disease

During the study period, congenital heart disease (CHD) was identified in 12 out of 300 newborns screened at CHU-B and HRT, yielding a prevalence of 4%.

3.2. Sociodemographic Characteristics

The sociodemographic characteristics of the mothers and newborns are reported in Table 1.

Gestational characteristics, parity, and quality of prenatal care: Fifty-six percent (56%) of the mothers were primigravida. All mothers who underwent obstetric ultrasound had normal findings.

Gestational characteristics, parity, and the quality of prenatal care are summa-

rized in Table 2.

Table 1. Sociodemographic characteristics of mothers and newborns.

Variables	N = 300	%
Mother		
Age (year)		
≤19	31	10.3
[20 - 34]	219	73.0
≥35	50	16.7
Level of education		
Not in school	14	4.7
Primary	3	1.0
Secondary	193	64.3
Tertiary	90	30.0
Newborn		
Age (hour)		
[12 - 23]	166	55.3
[24 - 47]	128	42.7
[48 - 72]	6	2.0
Gender		
Male	163	54.3
Female	137	45.7

Table 2. Pregnancy, parity and quality of mothers' prenatal contacts.

Variables	N = 300	%
Gravidity		
Primigravida	168	56.0
Paucigravida	83	27.7
Multigravida	49	16.3
Morphological ultrasound		
Normal	207	69.0
Not performed	93	31.0
Type of pregnancy		
Singleton	284	94.7
Multiple	16	5.3
Quality of antenatal care		
Optimal	49	16.4
Suboptimal	241	80.3
Unmonitored pregnancy	10	3.3
Mode of delivery		

Continued

vaginal	254	84.7
Caesarean	46	15.3
Chronological term (week of amenorrhea)		
[34 - 36]	26	8.7
[37 - 41]	274	91.3
Birth weight		
Macrosomic	16	5.3
Appropriate for gestationnel age	283	94.4
Small for gestationnel age	1	0.3

3.3. Pulse Oximetry Screening Results

Pulse oximetry screening was negative ($SpO_2 \geq 95\%$) in 85.7% of newborns. An inconclusive result (SpO_2 between 91% and 94%) was observed in 8% of cases, while 6.3% of newborns had a positive screening result ($SpO_2 \leq 90\%$).

All newborns (8%) with an initial inconclusive pulse oximetry reading (SpO_2 91% - 94%) had a positive result upon repeat measurement.

3.4. Cardiac Doppler Ultrasound Findings

Regarding cardiac Doppler ultrasound, 72% of newborns had normal results, 24% had transitional abnormalities, and 4% of newborns had congenital heart disease.

The congenital heart defects identified included atrial septal defect (ASD) in 33.3% of cases, followed by ventricular septal defect (VSD), complete atrioventricular canal defect (CAVD), and tetralogy of Fallot, each accounting for 16.7%. Truncus arteriosus and double-outlet right ventricle each represented 8.3% of cases.

3.5. Performance of Pulse Oximetry for Screening Congenital Heart Disease

3.5.1. Performance of Pulse Oximetry for Screening All Congenital Heart Diseases

The performance of pulse oximetry for detecting all CHD are summarized in Table 3.

Table 3. Performance of pulse oximetry for the screening of all congenital heart diseases.

Variable	Congenital heart disease		Total
	Present n = 12(%)	Absent n = 288(%)	
Pulse oximetry			
Positive	5(41.7)	38 (13.2)	43
Negative	7(58.3)	250(86.8)	257

1) Sensitivity: 41.7%; 2) Specificity: 86.8%; 3) Positive predictive value: 11.6%; 4) Negative predictive value: 97.2%; 5) Positive likelihood ratio: 4; 6) Negative likelihood ratio: 0.5.

3.5.2. Performance of Pulse Oximetry According to Congenital Heart Disease Group

Of the 12 congenital heart diseases diagnosed, 8 (66.7%) were non-cyanotic and 4 (33.3%) were cyanotic.

Performance of pulse oximetry for screening for non-cyanotic congenital heart disease

The performance of pulse oximetry in screening for non-cyanotic CHD is detailed in Table 4.

Table 4. Performance of pulse oximetry for non-cyanogenic congenital heart disease.

Variable	Non-cyanogenic congenital heart disease		Total
	Present n = 8(%)	Absent n = 288(%)	
Pulse oximetry			
Positive	1 (12.5)	42 (14.5)	43
Negative	7 (87.5)	246 (85.4)	253

1) Sensitivity: 12.5%; 2) Specificity: 85.4%; 3) Positive predictive value: 2.3%; 4) Negative predictive value: 97.2%.

Performance of pulse oximetry for screening cyanotic congenital heart disease

The performance of pulse oximetry in screening for cyanotic CHD is detailed in Table 5.

Table 5. Performance of pulse oximetry for cyanogenic congenital heart disease.

Variable	Cyanogenic congenital heart disease		Total
	Present n = 4 (%)	Absent n = 294 (%)	
Pulse oximetry			
Positive	4 (100)	39 (13.3)	43
Negative	0	255 (86.7)	255

1) Sensitivity: 100%; 2) Specificity: 86.7%; 3) Positive predictive value: 9.3%; 4) Negative predictive value: 100%.

4. Discussion

The prevalence of congenital heart disease (CHD) observed in our study (4%) is comparable to the rates of 3.3% and 7% reported by Taksande *et al.* in India and Adjagba *et al.* in Benin, respectively [21] [22]. However, this prevalence appears to be higher than that reported by most other authors [15] [22]-[24]. This discrepancy may be explained by several factors. Most previous studies focused exclusively on screening for critical or severe CHD and excluded cases diagnosed antenatally. In contrast, such exclusion was not feasible in our study due to the unavailability of routine antenatal CHD diagnosis in Brazzaville.

Moreover, CHD has a multifactorial etiology, and variations in prevalence have

been documented across regions and ethnic groups. The Global Burden of Disease Study 2017 corroborates this observation [2] [11]. Similarly, Kucik *et al.*'s work in the United States has highlighted variations between different ethnic groups [25].

4.1. Characteristics of Newborns

Sex and age at screening for congenital heart disease using pulse oximetry: In our series, a slight male predominance was observed, with 54.3% of cases (sex ratio 1.2). This finding is consistent with the results of Majani in Tanzania and Janjua Zakarimanana, who documented male proportions of 52.4% and 52.6%, respectively [24] [26].

No scientific explanation has been put forward to account for this slight overrepresentation of males.

The timing of pulse oximetry screening is flexible after birth. However, the optimal timing depends mainly on each country's health and socio-cultural context, particularly the usual length of stay in maternity wards, the availability of healthcare staff, and parental acceptance of the test. In settings where early discharge from maternity wards is common, screening within the first 24 hours of life is recommended to maximise coverage.

This approach also facilitates earlier detection of serious congenital heart disease (CHD), nearly half of which becomes symptomatic within the first 24 hours of life. Among these cases, 9% present with cardiogenic shock, as reported by de-Wahl Granelli *et al.* and Riede *et al.* [27] [28]. However, early screening is associated with a higher rate of false-positive results [29] [30].

Despite this limitation, the American Academy of Pediatrics (AAP) recognised in 2020 the clinical value of pulse oximetry screening within 24 hours of birth in contexts of early postnatal discharge [31]. This recommendation is also endorsed by the European Pulse Oximetry Screening Workgroup [17]. However, in China, the screening window is broader wider, ranging from six to 72 hours after birth [32].

In line with this strategy, and to account for local organizational constraints and a high rate of early maternity discharges, over half of the newborns in our study (55.3%) were screened between 12 and 24 hours after birth. This timing aimed to optimize coverage.

4.2. Performance of Pulse Oximetry in Screening for Congenital Heart Disease

Sensitivity and specificity of pulse oximetry in screening for congenital heart disease: Although pulse oximetry is a valuable screening tool for CHD, it cannot detect all forms of the disease [15]. Pulse oximetry's principle of detecting hypoxemia means it is most effective in identifying cyanotic congenital heart diseases. In our study, the overall sensitivity and specificity of pulse oximetry for detecting all CHD were 41.7% and 86.8%, respectively. These figures are lower than the ranges reported by most authors (sensitivity: 67% - 72%; specificity: 90% - 100%)

[30] [33]. This discrepancy may be partly attributed to our smaller sample size. Furthermore, reference studies often focus specifically on critical CHD, which is predominantly hypoxemic. When our analysis was restricted to cyanotic heart disease, our results improved markedly (sensitivity: 100%; specificity: 86.7%), aligning with or surpassing published data [29] [32]. Conversely, the diagnostic performance for non-cyanotic CHDs was significantly lower (sensitivity of 12.5%, specificity of 85.4%). Similarly, the positive predictive value in our cohort was 11.6%, which is lower than values reported elsewhere [30] [33].

4.3. False Negatives and False Positives

In our study, screening for all congenital heart diseases yielded 38 false positive cases (12.8%). This rate increased slightly to 13.1% (39 cases) for cyanotic heart disease screening specifically, and to 14.2% (42 cases) for non-cyanotic heart disease screening. These rates are significantly higher than those reported in the literature. For instance, Adjagba in Benin and Plana and al. reported rates of 0.04% (one case) and 0.14%, respectively [16] [21].

Several factors may explain this discrepancy. In our cohort, more than half of the newborns were screened between 12 and 24 hours of life. This period is characterized by persistent transitional circulation and physiological pulmonary arterial hypertension, which can temporarily lower oxygen saturation. Other studies support this hypothesis, showing an association between early screening (conducted within the first 24 hours) and a higher false-positive rate. For instance, a systematic review by Thangaratinam *et al.* found that screening performed before 24 hours of live was associated with a 10% increase in the false-positive rate [30] [34] [35]. However, the timing of screening alone is unlikely to fully explain the markedly elevated false-positive rate observed in our study. Additional contributing factors may include technical conditions during measurement, such as neonatal movement, inadequate peripheral perfusion, low skin temperature, and the type or placement of the sensor.

Regarding false negatives, our study identified six cases. In contrast, the studies by Arlettaz *et al.* and Adjagba *et al.* reported none [21] [23]. This discrepancy is likely attributable to our study's inclusion of non-cyanotic congenital heart disease. These conditions often evade detection by pulse oximetry, as they typically do not cause hypoxemia.

4.4. Types of Congenital Heart Disease Detected

A total of 12 cases of congenital heart disease were diagnosed in our study. Atrial septal defect (ASD) was the most frequent lesion, accounting for 33.3% of cases, followed by ventricular septal defect (VSD) (16.7%), complete atrioventricular septal defect (16.7%), tetralogy of Fallot (16.7%), truncus arteriosus (8.3%), and double outlet right ventricle (8.3%).The spectrum of congenital heart disease observed in this study is comparable to that reported by Bakr *et al.* [36]. However, comparisons with other studies are limited, as most investigations focus exclu-

sively on screening for critical congenital heart disease, which restricts the diversity of lesions identified.

Six of the congenital heart defects diagnosed in our study were associated with a risk of haemodynamic decompensation within the first month of life. Pulse oximetry successfully detected five of these cases. Overall, pulse oximetry identified all cases of cyanotic congenital heart disease but detected only one of the eight cases of non-cyanotic congenital heart disease.

5. Conclusion

This study confirms the clinical utility of pulse oximetry as a screening tool for congenital heart disease in the Congolese context, particularly for hypoxaemic forms. However, its large-scale implementation may be limited by a high false-positive rate. Identifying the causes is essential to optimise screening and ensure efficient integration into the national health system.

6. Limitations of This Study

The study was conducted in two maternity wards in Brazzaville. A study involving a larger number of facilities would have enabled a more robust assessment of the performance of pulse oximetry for neonatal screening of congenital heart disease.

Conflicts of Interest

We declare no conflicts of interest related to this study.

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