

Early screening for critical congenital heart defects in asymptomatic newborns in Mazovia province: experience of the POLKARD pulse oximetry programme 2006–2008 in Poland

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Abstract

Background: Early diagnosis of critical congenital heart defects (CCHD) may be missed both during prenatal echocardiography and the short stay in the neonatal nursery, leading to circulatory collapse or death of the newborn before readmission to hospital.

Aim: To assess the usefulness of pulse oximetry as a screening test in early diagnosis of CCHD in newborns.

Methods: A prospective screening pulse oximetry test was conducted in 51 neonatal units in the Mazovia province of Poland as part of the POLKARD 2006–2008 programme between 16 January, 2007 and 31 January, 2008. Newborns with no circulatory symptoms or coexisting diseases, and no prenatal diagnosis, were enrolled. The test was performed between the 2nd and 24th hours of life in stable newborns. A double arterial oxygen saturation (SpO₂) reading < 95% on a lower extremity led to cardiovascular evaluation and echocardiography.

Results: From a population of 52,993 newborns (14.2% of births in Poland), a group of 51,698 asymptomatic infants was isolated. CCHD was diagnosed solely by pulse oximetry in 15 newborns, which constituted 18.3% of all CCHD; 14 (0.026%) false positives were obtained and there were four false negative results. The sensitivity of the test was 78.9% and specificity 99.9%. The positive predictive value was 51.7% and negative 99.9%.

Conclusions: Pulse oximetry fulfilling the screening test criteria, performed on a large population of newborns in Poland, proved useful in supporting prenatal diagnostics and postnatal physical examination in the early detection of initially asymptomatic CCHD. Good sensitivity and specificity results of the pulse oximetry test have allowed it to be recommended for use in neonatal units nationwide.

Key words: congenital heart defect, pulse oximetry, newborn, screening

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INTRODUCTION

Congenital heart defects (CHD) form the largest group of congenital malformations, affecting 8–12/1,000 newborns [1]. They are responsible for approximately 20% of deaths in the neonatal period, 3% of deaths in the infant group, and 46% of deaths of infants with congenital diseases in the first year of life [2]. The survival rate among infants with CHD has incre-

ased significantly in the last few years, as a result of significant progress in early detection and treatment, both interventional and cardiosurgical, in this group of patients.

The prevalence of critical defects i.e. requiring an interventional procedure or cardiac surgery in the first month of life, has not changed, averaging 1.5–3 cases/1,000 live births. Detecting life-threatening ductus dependent heart defects in

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the first days of life using clinical, ECG and CXR information may prove difficult. The current worldwide policy of earlier discharge from neonatal units limits the number of neonatal physical examinations. Dramatic symptoms associated with physiological closing of ductus arteriosus may occur after discharge from the neonatal unit, which, by delaying the moment of appropriate intervention, may diminish the child's chances of recovery, and in some cases lead to death [3].

Although the percentage of critical CHD (CCHD) diagnosed by ECHO in the foetus has recently increased, some critical defects i.e. coarctation of the aorta (CoA) or total anomalous pulmonary venous drainage (TAPVD), remain difficult to detect prenatally [4]. Therefore new diagnostic modalities, fulfilling the criteria of a screening test, have been sought to enrich the current techniques for detecting CHD in newborns.

The aims of this study were to increase the detection rate of CCHD in newborns by introducing a screening pulse oximetry programme, to assess the usefulness of the pulse oximetry test in early detection of CCHD in newborns, and to implement a pulse oximetry programme in the whole population of Polish newborns.

METHODS

Population

The test was performed in all newborns born in 51 neonatal units in the province of Mazovia. They included five 3rd reference level, nine 2nd reference level, and 37 1st reference level hospitals. In total, 52,993 newborns out of 55,944 born between 1 February, 2007 and 31 January, 2008 in the study area were included in the programme. Between 16 January, 2007 and 31 January, 2007, a pilot study was conducted in the Department of Neonatology and Neonatal Intensive Care at Warsaw Medical University.

The study was approved by the Bioethical Committee of the Children's Memorial Health Institute in Warsaw.

Staff preparation

The programme was co-ordinated by the Department of Neonatology and Neonatal Intensive Care at Warsaw Medical University and supervised by the Department of Cardiology at the Children's Memorial Health Institute. During the preparatory period, training for neonatologists, paediatric cardiologists and nurses in the study area was conducted in order to familiarise staff with the methodology and protocol of the study.

Pulse oximetry equipment

The measurement was performed using Novamatrix, Nellcor and Masimo pulse oximeters. After each measurement, multiple-use sensors were disinfected.

Study protocol

A pulse oximetry test was performed in all newborns with parental consent. In all cases, the test was performed when the newborn was calm, fed, and with normal temperature.

The measurement was carried out by specially trained nurses for 2–3 min on the infant's lower extremity between the 2nd and 24th h of life after normalisation of the plethysmographic curve of the pulse oximeter. The SpO₂ cut-off value was 95%. Newborns in the study were divided into two protocol groups:

- Protocol A (symptomatic/prenatal): newborns < 34 weeks of gestation (who are postnatally routinely monitored by pulse oximetry and have prolonged hospital stay under careful observation which lowers the risk of discharge with undetected CCHD); with circulatory symptoms (murmur, cyanosis, tachypnoea, weak peripheral pulses); with co-existing large congenital malformations or CHD diagnosed prenatally. In newborns with SpO₂ on lower extremity < 95%, further evaluation of the aetiology of desaturation was conducted based on general assessment of the newborn's clinical status. In cases with suspected CHD, a hyperoxia test was performed (saturation measurement after 10 min. of breathing with 80–100% oxygen).
- Protocol B (asymptomatic): newborns ≥ 34 weeks of gestation, with no pathological symptoms. If the SpO₂ value was ≥ 95%, the study protocol was ended. If the SpO₂ was < 95%, a measurement on a lower extremity was repeated after 60 min. In the period between measurements, test objectivity was verified (assessment of the newborn's well-being, neutrality of external factors). In newborns with SpO₂ < 95% on a lower extremity, further assessment of the aetiology of abnormal saturation was carried out according to standard protocol for suspected congenital heart disease (saturation measurement on upper extremity, hyperoxia test).

Study documentation

Results of the pulse oximetry test, together with the date and the hospital code, were recorded on the programme stamp put on the inside cover of the Child's Health Booklet. Moreover, data about the patients, their symptoms, diagnostic and therapeutic process and follow-up were recorded in a computer database: www.kardiologiadzieci.pl.

Results verification

Verification of positive results was conducted by paediatric cardiologists in the study area. Negative results were verified by the analysis of follow-up of infants re-admitted to hospitals due to late diagnosis of congenital heart disease, or based on data from the Mazovian Centre of Public Health.

Psychological questionnaire

A psychological questionnaire, presented to mothers together with the informed consent form, included two questions: "Was it easy for you to decide for your child to have the saturation measurement?" and "Do you think such a test should be performed in all newborns in Poland?".

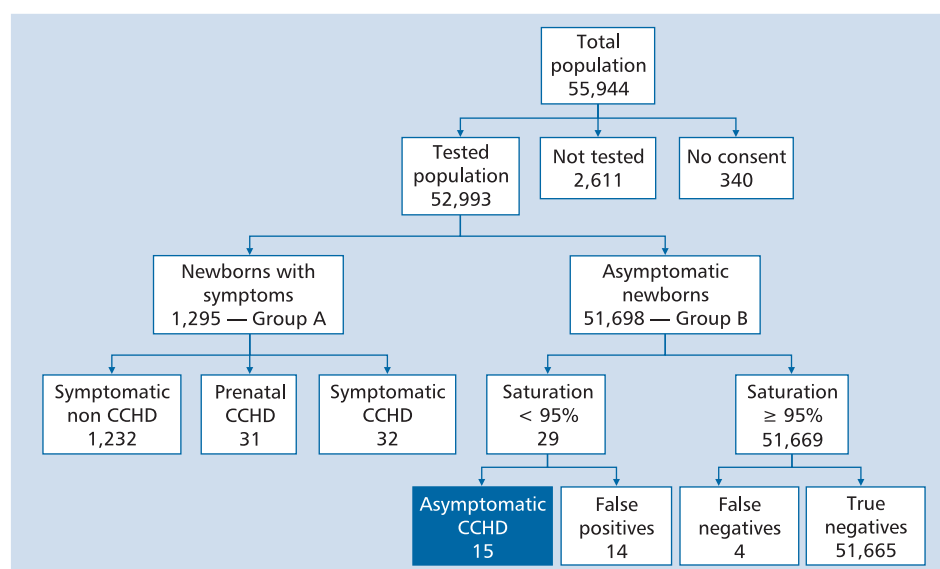


Figure 1. Diagnostic diagram of pulse oximetry program in Mazovia; CCHD — critical congenital heart defects

Statistical analysis

Statistical analysis assessed the sensitivity, specificity, positive and negative predictive value of the pulse oximetry test.

RESULTS

Characteristics of study population

The study included 52,933 newborns, i.e. 94.5% of 55,944 born between 1 February, 2007 and 31 January, 2008 in the study area (Fig. 1). Due to lack of consent, 340 newborns were excluded. In 2,611 newborns, the test could not be performed due to technical problems (equipment failure, absence of trained staff due to holiday). In the studied population, 49% of newborns were female and 51% were male. The group comprised approximately 14.2% of the total population of infants born in Poland during that time. CCHD were diagnosed in 82 newborns, which constitutes 1.55/1,000 births.

Results of pulse oximetry test — diagnosis of CCHD (Table 1)

Protocol A. Symptomatic/prenatal group. Among 1,295 symptomatic newborns, 63 patients with CCHD were selected based either on circulatory abnormalities such as cyanosis, murmur, tachypnoea, or weak peripheral pulses, (this totalled 32 newborns), or where there was a prenatal detection of CCHD (a total of 31 newborns).

Prenatal diagnosis. The group comprised 31 (37.8% of all 82 CCHD) newborns with CCHD diagnosed prenatally and confirmed after birth. All newborns postnatally presented desaturation < 95%.

Postnatal diagnosis — symptomatic patients. The group comprised 32 newborns, which constituted 39% of all the CCHD population.

Protocol B. Asymptomatic group. The test was performed between the 2nd and 24th h of life, on average 7.29 (median 5th) h of life. Mean SpO₂ was 97.4% (median 98%). Among 51,698 asymptomatic newborns, CCHD was suspected in 29 cases.

Asymptomatic patients — positive results (SpO₂ < 95%); diagnosis of critical CHD solely on the basis of screening pulse oximetry test — 15 newborns, 18.3% of total CCHD.

Asymptomatic patients — false positive results (SpO₂ < 95%); no critical CHD — 14 newborns (0.026% of the total population): transitional circulation — eight newborns; atrial septal defect ostium secundum — one newborn; intrauterine infection — two newborns; pneumonia — three newborns.

Asymptomatic patients at the moment of pulse oximetric screening — false negative results (SpO₂ ≥ 95%); late diagnosis of congenital heart disease in an initially asymptomatic newborn — four patients (4.9% of total CCHD). It should be noted that in this group, only one newborn (with CoA) had been discharged without a prior hospital diagnosis.

Results of psychological questionnaire

Both questions: “Was it easy for you to decide for your child to have the saturation measurement?” and “Do you think such a test should be performed on all newborns in Poland?” received affirmative answers from 91% of those surveyed.

Statistical analysis

According to the aims of the programme, only newborns with CCHD from group B, i.e. with no coexisting clinical symptoms, were subjected to statistical analysis verifying the usefulness of the pulse oximetry test. The estimated sensitivity for detecting CCHD was 78.9%, specificity 99.9%, positive predictive value 51.7%, and negative predictive value 99.9%.

Table 1. Critical congenital heart defects diagnosed in 82 newborns in the study population

Protocol A. Symptomatic newborns				Protocol B. Asymptomatic newborns			
Pulse oximetry test				Pulse oximetry test			
Positive test				Positive test (true positive result)		Negative test (false negative result)	
Prenatal CHD diagnosis		Postnatal CHD diagnosis		Postnatal CHD diagnosis		CHD non diagnosed at the moment of test	
31 (37.8%) newborns		32 (39%) newborns		15 (18.3%) newborns		4 (4.9%) newborns	
CHD	No.	CHD	No.	CHD	No.	CHD	No.
TGA/DORV	5	TGA	6	TGA	3	CoA	2
TA	4	SV	5	TAPVD	3	SV	1
Heterotaxy	4	TOF	4	PA	2	TGA/VSD	1
CoA	3	AVS	3	IAA	1		
PA/IVS	3	CoA	3	HLHS	1		
SV	3	PA/IVS	2	CoA	1		
TGA	2	TAPVD	2	TA	1		
TOF	2	TGA/DORV	1	cTGA	1		
TAC	2	TA	1	TOF	1		
HLHS	2	HRHS	1	RPA fistula	1		
Ebstein	1	PVS	1				
		Heterotaxy	1				
		HAoA	1				
		IAA	1				

CHD — congenital heart defect; TGA — transposition of the great arteries; DORV — double outlet right ventricle; TA — tricuspid atresia; CoA — coarctation of the aorta; PA/IVS — pulmonary atresia/intact ventricular septum; SV — single ventricle; TOF — tetralogy of Fallot; TAC — truncus arteriosus communis; HLHS — hypoplastic left heart syndrome; AVS — aortic valve stenosis; TAPVD — total anomalous pulmonary venous drainage; HRHS — hypoplastic right heart syndrome; PVS — pulmonary valve stenosis; IAA — interrupted aortic arch; HAoA — hypoplastic aortic arch; cTGA — corrected TGA; RPA — right pulmonary artery; VSD — ventricular septum defect

DISCUSSION

In the presented multicentre pulse oximetry screening programme conducted on a large population of newborns in Mazovia, we evaluated the usefulness of the screening pulse oximetry test in the early diagnosis of congenital heart disease.

Significant progress in the care of CHD patients has been observed in recent years, mostly due to improvements in prenatal ECHO, and interventional and cardiosurgical treatment in newborns. However, no spectacular change in the detection of CHD in newborn nurseries in the first days of life has been noted. Among these, initially asymptomatic defects with ductus dependent systemic circulation, as well as anomalies with pulmonary venous drainage, are of particular interest. Missed early detection of these anomalies, together with the current tendency towards earlier postpartum discharge, carry the risk of serious circulatory complications or death before readmission to hospital [5].

Foetal detection of CHD has increased in many countries from 10 to 50–60% over the last decade. Due to the introduction of the Health Ministry Programme — ‘Polkard Prenatal 2003–2005’, and its continuation ‘Kardio-Prenatal 2006–2008’, Poland has gained a network of centres specialising in prenatal ECHO, and a unique database of prenatally

diagnosed heart defects (National Registry of Foetal Heart Defects — www.orpkp.pl) has been created [6]. There are two perinatal cardiology centres in the study area, with the leading one at Warsaw Medical University. The high percentage of prenatal detection of CCHD, amounting to 37% in our material, proves the good co-operation of these centres with obstetricians performing screening ultrasounds during pregnancy. In our study, the main CCHD amenable to diagnosis were lesions detected via four-chamber imaging of the foetal heart, but there were also cases of prenatal diagnosis of isolated transposition of the great arteries (TGA) and CoA.

Physical examination is still the gold standard in the detection of CHD in neonatal units [7]. However, characteristic symptoms of CCHD are not always present in the first postnatal days. In this review, the percentage of post-natal diagnosis was 39%, although, as mentioned above, all newborns with CCHD detected prenatally presented symptoms suggestive of a heart defect. In total, symptomatic diagnosis of CCHD was 76.8%, which is in accordance with the literature. Apart from difficulties in diagnosing initially clinically asymptomatic CCHD, the reviews mention the problem of

a high percentage of false positive results based on a non-characteristic heart murmur in the postnatal period.

It is also worth mentioning that the results of a common diagnostic test when CCHD is suspected, namely the hypoxia test, in particular lesions i.e. hypoplastic left heart syndrome and with common mixing (single ventricle) circulation, might be confusing. Saturation might exceed 95% due to a decrease of pulmonary resistance while oxygen breathing, with a subsequent increase in pulmonary blood flow at the expense of systemic flow. In order to increase the effectiveness of CHD detection in neonatal units, the pulse oximetry measurement was proposed as a non-invasive, inexpensive, repeatable and easily performed test supporting postnatal physical examination.

Since the publication of Hoke et al. in 2002 [8], a number of studies on this diagnostic method from different parts of the world have been presented [9–13]. In the scientific statement by the American Academy of Pediatrics and American Heart Association, Mahle et al. [14] summarised ten studies comprising 123,846 newborns, including a cohort from our former pulse oximetry programme, a part of POLKARD 2003–2005. The mean sensitivity of the pulse oximetry test in presented studies was 69.6% and the positive predictive value 47%. The percentage of false positive results in the first 24 h after birth was 0.87%, but in newborns examined after 24 h post partum it was only 0.035%. In the pulse oximetry programme in Mazovia, the test sensitivity was 78.9% and the positive predictive value 51.7%. De Wahl-Granelli et al. [13] in their very comprehensive study, commented on several important issues regarding pulse oximetry screening. Particular defects, i.e. CoA and TAPVD, are difficult to diagnose both prenatally and in postnatal physical examination. Also, in our study, two out of four false negative results were newborns with coarctation both of the juxtaductal type. However, our study proved highly useful in the detection of TAPVD in the presymptomatic phase. Three out of five cases of this anomaly were diagnosed with pulse oximetry.

Another issue refers to pulse oximetry examination time. Early measurement may lead to improved detection of CCHD in asymptomatic newborns, but also to a higher percentage of false positive readings resulting from the adaptive period of the newborn [13]. However, we had a much lower percentage of false positive results (0.026%) than in the meta-analysis by Mahle et al. [14]. De-Wahl Granelli et al. [13] also proved the usefulness of the additional saturation measurement on an upper right extremity, and showed that a difference of saturation of more than 3% between right hand and lower extremities might be a useful marker, either in cases of defects with ductus dependent systemic circulation, or in subjects with reversed differential cyanosis i.e. in TGA with coexisting CoA or TGA with features of persistent pulmonary hypertension. In our study, the measurement on the upper extremity was carried out only in cases with repeated $SpO_2 < 95\%$ on a lo-

wer extremity. Koppel et al. [9], in assessing the cost of the examination, attributed it to the time of the measurement, consumption of sensors etc. In our previous review [11], we calculated the cost of one pulse oximetry measurement at 0.5 euros. Considering the diagnosis in this programme of CCHD in 15 asymptomatic newborns in a population of 51,698 newborns, the cost of diagnosing one asymptomatic newborn with CCHD in a pulse oximetry screening test amounted to 1,723 euros, which was significantly lower than the cost of diagnosing other metabolic disorders or diseases which are screened for. There are additional benefits of a pulse oximetry measurement. Despite a lack of CCHD diagnosis, the detection of false positive cases allowed us to reveal other transient circulatory problems not requiring early intervention in eight newborns, one non critical CHD, and also the early detection of respiratory problems or infection before the appearance of symptoms — these observations are in accordance with the literature [12, 13]. The results of the psychological questionnaire, not previously carried out in pulse oximetry studies, showed almost unanimous approval for conducting the screening test in the whole population of newborns.

To summarise, in our study, the addition of pulse oximetry to the routine diagnostic screening module increased perinatal detection of CCHD from 76.8% to 95%. The most recent summary of pulse oximetry studies by Hoffman [15] concludes that: “it is time for routine neonatal screening by pulse oximetry”.

Limitations of pulse oximetry

Particular attention has been drawn to two aspects leading to possible mistakes: the human factor and equipment. In the study by Reich et al. [16], there was a significant difference in measurements performed by trained and experienced staff compared to those performed by less experienced medical personnel. The time of performing the measurement (i.e. day/night) may be another source of erroneous results. In our study, training concerning the study protocol was organised before the programme started, but performing the test in 51 study teams obviously carries the possibility of human error. Another important factor is the diversity of pulse oximetry diagnostic equipment in the study area. The use of new generation pulse oximeters with signal extraction technology has been recommended, particularly in recent publications. It should also be remembered that saturation differences might result from the shift in haemoglobin dissociation curve influenced by many factors. For example, in alkalosis, lower values of arterial partial pressure of oxygen (PaO_2) correspond to relatively higher SpO_2 as compared to acidosis. Therefore, in certain cases, PaO_2 should be evaluated.

CONCLUSIONS

Pulse oximetry measurement performed on a large population of newborns in Poland, fulfilling the criteria for a scre-

ening test, proved to be a useful tool supporting prenatal detection and postnatal physical examination in early diagnosis of initially asymptomatic CCHD. Due to the good sensitivity and specificity of pulse oximetry measurement, according to the Ministry of Health order in 2010, the pulse oximetry test was recommended for use in neonatal units nationwide [17].

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Conflict of interest: none declared

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Wczesne przesiewowe wykrywanie krytycznych wad wrodzonych serca u bezobjawowych noworodków w województwie mazowieckim: doświadczenia Programu Pulsoksymetrii w ramach POLKARD 2006–2008

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Streszczenie

Wstęp: Brak wczesnego rozpoznania krytycznej wady wrodzonej serca zarówno w diagnostyce prenatalnej, jak i w czasie krótkiego pobytu na oddziale noworodkowym może prowadzić do zapaści krążeniowej lub zgonu noworodka przed ponownym przyjęciem do szpitala.

Cel: Celem pracy była ocena przydatności i wiarygodności testu pulsoksymetrycznego we wczesnym wykrywaniu krytycznych wad wrodzonych serca u noworodków.

Metody: W 51 oddziałach noworodkowych województwa mazowieckiego w ramach programu POLKARD 2006–2008 w okresie 15.01.2007–31.01.2008 przeprowadzono prospektywne przesiewowe badanie pulsoksymetryczne. Wyodrębniono grupę noworodków bez objawów krążeniowych, wad towarzyszących, bez diagnostyki prenatalnej. Pomiar wykonywano w > 2–24 godz. życia u noworodka w stanie stabilnym. Dwukrotna wartość saturacji < 95% na stopie powodowała przeprowadzenie diagnostyki kardiologicznej.

Wyniki: Z populacji 52 993 noworodków (14,2% urodzeń w Polsce) wyodrębniono grupę 51 698 bez objawów, wśród których wyłącznie za pomocą pulsoksymetrii rozpoznano krytyczne wady wrodzone serca u 15 noworodków, co stanowiło 18,3% wszystkich tych wad. Uzyskano 14 (0,026%) wyników fałszywie dodatnich. U 4 noworodków nie rozpoznano wady serca w okresie przed wystąpieniem objawów. Czułość badania wynosiła 78,9%, swoistość 99,9%, wartość predykcyjna wyniku dodatniego 51,7%, a ujemnego 99,9%.

Wnioski: Przeprowadzony w dużej populacji noworodków w Polsce test pulsoksymetryczny spełniający kryteria testu przesiewowego okazał się przydatny jako wspomagający diagnostykę prenatalną i badanie lekarskie moduł diagnostyczny we wczesnym wykrywaniu początkowo bezobjawowych krytycznych wad wrodzonych serca w populacji polskich noworodków. Uzyskane dobre wyniki czułości i swoistości badania pulsoksymetrycznego pozwoliły na rekomendowanie go do zastosowania na oddziałach noworodkowych w całym kraju.

Słowa kluczowe: wady wrodzone serca, pulsoksymetria, noworodek, badania przesiewowe

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