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by Fatchul Wahab

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Research Article

Oxygen saturation among newborns in the first 10 hours of life to detect Critical Congenital Heart Disease - Ductus Dependent

Fatchul Wahab[1]*, Mahrus A Rahman[2], Teddy Ontoseno[3], Risa Etika[4], Alit Utamayasa[5], Taufiq Hidayat[6], Sarmanu[7]

1*, 2, 3, 4, 5, 6) Department of Child Health, Dr. Soetomo Hospital, Faculty of Medicine, Universitas Airlangga, Surabaya, Indonesia
7) Departement of Public Health, Faculty of Medicine, Universitas Airlangga, Surabaya, Indonesia

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Correspondence:
wfatchul045@gmail.com

Abstract

Delay diagnosis of Critical Congenital Heart Disease (CHD) can be associated with sudden clinical deterioration and dangerous cardiovascular conditions. The oxygen saturation screening among newborns in the first 10 hours of life is essential for early detection of critical CHD. This study aims to prove that measuring oxygen saturation among newborns in the first 10 hours of life can detect critical CHD. This study is a diagnostic experimental with consecutive sampling subjects in the infant care unit of Dr. Soetomo Hospital, including all newborns with birth weight ≥ 1500 grams and oxygen saturation at ≥ 1 hour of age below 90%. The measurement of oxygen saturation uses fingertip pulse oximetry in the right hand and foot at the age of 10 hours. A "positive oxygen saturation" is defined as oxygen saturation ≤ 85% or different oxygen saturation ≥ 3%, while a "negative oxygen saturation" is when the oxygen saturation is 85% to 90% or different oxygen saturation is 3%. Echocardiography is performed for the gold standard. From November 2019 to January 2020, 11 newborns underwent an oxygen saturation examination. Five subjects (45.46%) in the category of positive oxygen saturation, echocardiographic showed all Critical CHD (100%). Six subjects (54.54%) with negative oxygen saturation category, echocardiographic results showed two critical CHD (33.34%) and four non-critical CHD (66.66%). Fisher's exact test $p < 0.005$ (α). The diagnostic oxygen saturation test among newborns at 10 hours of life shows ≤85%, all subject's echocardiography (100%) shows detection of critical CHD, while saturation 85% to 90% has of 33.3% for detection of critical CHD. The sensitivity and specificity of oxygen saturation for early diagnosis of critical CHD are 100% and 67%, respectively.

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INTRODUCTION

Routine neonatal inspection fails to detect more than 50% of infants with congenital heart disease (CHD). More than 55% of neonates with CHD do not show symptoms of murmurs in the nursery, and about 82% are discharged before diagnosis results are obtained, so this will increase mortality and morbidity (Du et al., 2017). More than 50% of infants with Critical CHD die at home or emergency room before the diagnosis is established, and every year 100-200 infants die in America due to the unknown critical CHD (Goetz, Elizabethm; Hokanson, 2012). Based on Riskesdas 2007 data, the most common cause of infant death in neonates 0 - 6 days is due to cardiovascular disorders (35, 9%) (Chalid, 2014).

Pulse oximetry screening in newborns has been shown to increase the detection of Critical CHD (Narvey et al., 2017). However, the official pulse oximetry screening protocols for CHD by the SACHDNC (Secretary's Advisory Committee on Heritable Disorders in Newborns and Children), AAP (American Academy of Pediatrics), AHA (American Heart Association), and the CDC (Centers for Disease Control and Prevention) recommend pulse oximetry measurements before discharge from the hospital limited to ages 24 to 48 hours (Goetz, Elizabethm; Hokanson, 2012; Engel & Kochilas, 2016). While other screening has inconsistent variations in pulse oximetry testing time, giving rise to variations in the diagnostic accuracy of pulse oximetry screening (Du et al., 2017). On the other hand, critical CHD requires early detection and surgical or non-surgical intervention in the first year of life to sustain life (Du et al., 2017), because its systemic or pulmonary circulation which cannot tolerate the transition from fetal circulation to serial circulation after birth and will depend on central shunts, especially patent ductus arteriosus (PDA) (Lee, 2010).

Delay in the diagnosis of critical CHD can be associated with sudden clinical deterioration, dangerous cardiovascular conditions, collapse, heart failure, end-organ damage, and even death (Movahedian et al., 2016; Du et al., 2017). Infants with duct-dependent lesions will experience severe desaturation, shock, or collapse when the PDA closes within hours or days after birth due to systemic hypoperfusion. These lesions include ductal pulmonary and systemic circulation (Lee, 2010; Tomar, 2016).

Congenital heart disease is reported to occur around 6 to 8 per 1000 live births. Critical CHD occurs in 2.5 to 3 per 1,000 live births (Du et al., 2017). About 15% of all CHDs are cyanotic, and about 30% of these cyanotic lesions are critical and potentially fatal lesions without treatment (Tsuda, 2016). However, until no,w there has never been a study of a critical CHD screening program with pulse oximetry in the first 10 hours of life. It is necessary to measure oxygen saturation with pulse oximetry based on the initial time of functional closure of the ductus arteriosus lumen (the first 10 hours of life) to get an accurate, early, and effective screening program; and assess its sensitivity and specificity to the gold standard of critical CHD by echocardiography. This study aims to prove that measuring oxygen saturation among newborns in the first 10 hours of life can detect critical CHD. The benefit is to reduce mortality and morbidity of critical CHD in neonates. Our research is in line with the 2016-2030 SDGs target: reduce infant and toddler mortality, by reducing neonatal mortality by 12 per 1,000 live births; reduce 1/3 of premature deaths due to non-communicable diseases (Ermelana, 2017).

METHODS

This study is a diagnostic test – experimental for newborns treated by selecting consecutive sampling subjects in the Neonatal Care Unit of Dr. Soetomo Hospital; which included, oxygen saturation of infants aged over 1 hour < 90%, birth weight ≥1500 grams, and parents of

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infants agreed to join the study. Infants who did not qualify the study criteria were excluded in the study.

Researchers made informed consent, observed, and recorded oxygen saturation with fingertip pulse oximetry Onyx II® (Medical USA) attached to the right palm or foot. The recording of maximal oxygen saturation values includes pre-ductal and post-ductal with stable pulse frequencies when subjects are calm, and monitoring lasts for about 1 to 2 minutes.

A positive result is defined as the oxygen saturation in the first 10 hours of life in the hands or feet is ≤ 85% or the difference in oxygen saturation between the right hand and foot ≥ 3%. Whereas, the negative result is when the oxygen saturation in the right hand or foot is > 85 - < 90%, or the difference in oxygen saturation between the right hand and the foot < 3%. Echocardiography as the gold standard is performed after the results of oxygen saturation with fingertip pulse oximetry is obtained.

Approval of research ethics was obtained from the Health Research Ethics Commission Dr. Soetomo Surabaya. Certificate of Passing Ethics Review Number 1621/KEPK/XI/2019, dated 1 November 2019.

Data processing was performed with the SPSS computer program version 17.0. Assessment of diagnostic tests by tabulating negative and positive detection results in the 2x2 table was used for the Fisher extract test. The determined sample size (n), p values, α, and critical values are presented in tables. The results are the sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), positive likelihood ratio (PLR), and negative likelihood ratio (NLR). A value of $p < 0.05$ was considered statistically significant. The data is then presented descriptively in tabular and narrative form. The sample size in this study uses the formula n = factor level 1 x factor level 2 x constants; n ≥ 10 (Sarmanu, 2017).

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RESULTS

Table 1. Subject Characteristics

Characteristics	Amount (n=11)	Presentation
Sex		
Boys	7	64%
Girls	4	36%
Gestational Age		
< 37 weeks	3	27%
37-42 weeks	8	73%
>42 weeks	0	0%
Delivery		
Spontaneous	6	55%
Caesarian	5	45%
Forceps or Vacuum	0	0%
Weight born (gram)		
< 2500	5	45%
2500-4000	6	55%
> 4000	0	0%
Apgar score first 1 minutes		
< 6	2	29%
≥ 7	9	71%
Family history in CHD		
Yes	0	0%
No	11	100%
Diagnosis of antenatal CHD		
Yes	0	0%
No	11	100%
Other congenital abnormality		
Yes	1	10%
No	10	90%
Murmur		
Yes	4	36%
No	7	64%

Table 2. Oxygen saturation of pulse oximetry and echocardiography result

No	S	Sex	Cyanosis	Murmur	Sat pre	Sat post	Δ Sat	SpO2	Echo
1	SI	L	-	+	87	85	2	-	-
2	LAF	L	-	+	71	72	1	+	+
3	FJP	P	-	+	86	84	2	-	+
4	EN	L	+	-	73	73	0	+	+
5	FA	L	-	+	73	74	1	+	+
6	SS	L	-	-	89	89	0	-	+
7	EPW	P	-	-	89	89	0	-	-
8	NO	L	+	-	79	78	1	+	+
9	DR	L	+	-	76	75	1	+	+
10	DN	P	-	-	88	88	0	-	-
11	NWM	P	-	-	88	88	0	-	-

S: Subject, Sat pre: pre-ductal saturation, Sat post: post-ductal saturation, Δ Sat: difference between pre-ductal and post-ductal saturation, SpO2: oxygen saturation, Echo: echocardiography, +: CCHD, -: not CCHD

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Table 3. Compatibility of Echocardiography with Oxygen Saturation

Result of Echocardiography	Oxygen Saturation 5 infants (+)	6 infants (−)	Total
+	5 (a)	2 (b)	7 (a + b)
-	0 (c)	4 (d)	4 (c + d)
Total	5 (a + c)	6 (b + d)	11 (n)

The type of CHD that can be indicated by oxygen saturation

In this study, there were 11 newborns examined using fingertip pulse oximetry. The positive detection results obtained in five subjects (46%), and the echocardiographic confirmed all (100%) have critical CHD. While the negative detection results were obtained in 6 subjects (54%), and the echocardiography showed 33.33% confirmed critical CHD and 66.67% non-critical CHD. The data are shown in Table 2.

Diagnostic Value of Oxygen Saturation - Fingertip Pulse Oximeter

The results of detecting oxygen saturation from fingertip pulse oximetry on echocardiography in diagnosing congenital heart disease depend on the duct by using the Fisher test and the 2x2 table are shown in Table 3.

From Table 3, can be calculated:

- Sensitivity : a/(a+c) = 1
- Specificity : d/(b+d) = 0.67
- Positive predictive value (PPV) : a/(a+b) = 0.71
- Negative predictive value (NPV) : d/(c+d) = 1
- Positive likelihood ratio (PLR) : a/(a+c) : b/(b+d) = 3.33
- Negative likelihood ratio (NLR) : c/(a+c) : d/(b+d) = 0

Limitations of Oxygen Saturation-Fingertip Pulse Oximetry Test in Infants

Examination of oxygen saturation with a fingertip pulse oximeter (Onyx II ®) takes longer to achieve maximum results, and the baby must be in a calm condition.

DISCUSSION

Advantages and Limitations of this study

This research is the first attempt to apply oxygen saturation screening with pulse oximetry for the early detection of critical CHD among newborns at the first 10 hours of life at a hospital in Indonesia. Many hospitals in developed countries have routinely implemented oximetry screening to prevent neonatal morbidity and mortality due to late critical CHD diagnosis. In Indonesia, this has not yet become an official policy of hospitals and related government institutions. Critical CHD screening using pulse oximetry according to AAP recommendations requires expensive equipment (Miller et al., 2016); therefore the use of fingertip pulse oximeter (which is more affordable) is expected to be a breakthrough effort so that screening can be widely applied in limited facilities both hospitals and other health care centers in Indonesia.

In addition to the above advantages, the oxygen saturation with fingertip pulse oximeter has limitations in terms of tool specifications. This type of oximeter can work well on fingers with a thickness of 8-26 mm, so it is more appropriate for use in pediatric-adults. However, a research shows that the use of fingertip pulse oximeter in newborns has good results (Phattraprayoon et al., 2012).

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Characteristics of Subjects

The age of the subjects in this study was 10 hours. The age limit was chosen because it is related to the time of constriction and closure of the ductus arteriosus in term infants. It is well known that the initial 'functional' closure of the ductus arteriosus lumen is in the first 10-18 hours of life, so that perhaps at that time, there has been a hemodynamic change that causes desaturase. Functional closure of the ductus arteriosus is up to 72 hours after birth, followed by the anatomical closure process at the age of 3-4 weeks after birth. In premature neonates, the mechanism of the closure of the ductus arteriosus occurs more slowly, within two days in most premature infants even up to the age of 4-12 months (Clyman, 2006; Gournay, 2011; Ontoseno, 2014; and Chacko et al., 2016). In addition, a premature examination can increase false-positive results due to the circulation of the fetal to neonatal transition and stabilization of systemic oxygen saturation levels. If the examination is carried out later, then the opportunity for CHD intervention before the duct closes can be missed (Mahle et al., 2009; Kemper et al., 2011). A systematic review showed that examinations at the age of >24 hours decreased the false positive rate from 0,87% to 0.035% (Mahle et al., 2009). Another study found lower false positives at> 24 hours of age than <24 hours of age (0.05% [95% CI 0.02-0.12%] compared to 0.5% [95% CI 0.29- 0,86%]; p = 0,0017) (Thangaratinam et al., 2012).

The median gestational age in this study was 38 weeks (37 weeks minimum and 41 weeks maximum. Another study involved infants with gestational age ≥37 weeks (Riede et al., 2010), and ages >34 weeks and ≥35 weeks (Ewer et al., 2011; Bradshaw et al., 2012). Gestational age is related to the time of constriction and closure of the ductus arteriosus. In full-term infants, functional ductal closure occurs within 24 hours, whereas in preterm infants, the duct is more likely to remain open because the ductal smooth muscle has no constrictor response to fully developing oxygen (Park, 2008).

In this study, prior to pulse oximetry examination, no subjects diagnosed with CHD during antenatal examination with ultrasound and murmurs were shown in 4 subjects out of 11 subjects who showed CHD. The study of de-Wall Granelli et al. by including a much greater number of subjects received a low incidence of hearing cardiac noise that was 9/38374 subjects (Granelli et al., 2009). Riede et al. also got a low incidence of subjects who showed symptoms of cardiovascular abnormalities before the pulse oximetry examination that was 18/48384, while subjects who received a diagnosis of antenatal CHD were 54/48384 (Riede et al., 2010).

Incidence Rate and Type of Critical CHD.

Pulse oximetry screening in newborns aims to detect critical CHD before the onset of clinical manifestations before the baby is discharged from the hospital, thereby reducing neonatal morbidity and mortality. Various ductal-dependent abnormalities are expected to be detected, such as left heart hypoplasia syndrome, pulmonary atresia (with intact septum) total anomalous pulmonary venous drainage, transposition of large arteries, tricuspid atresia, or truncus arteriosus (Madjus & Abou Al-Seoud, 2014).

In this study, oxygen saturation screening with pulse oximetry can find subjects with critical CHD, which is likely influenced by the lowering of the oxygen saturation target. In the Sendelbach et al. study, there were no subjects diagnosed with critical CHD through pulse oximetry screening (Sendelbach et al., 2008). The study of Koppel et al. showed a prevalence of critical CHD 1 per 564 births, and in an asymptomatic population undergoing screening

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1 per 2256, while the number of critical CHD that was successfully detected with oximetry was 3/11,281 or 1 per 3760. The study found 2 cases of total anomalous venous drainage pulmonary and 1 case of truncus arteriosus (Koppel et al., 2003). Ewer et al. obtained a prevalence of 2.6 per 1000 life disorders (53/20,055) cases of major heart abnormalities (Ewer, Andrew K; Middleton, Lee J; Furmston, Alexander T; Byohar, Abhay; Daniels, Jane P; Thangaratinam, 2011).

Oxygen Saturations Pulse Oximetry Diagnostic Value

In this study, the median pre-ductal oxygen saturation in the right hand was 86% and post-ductal in the leg 84% in 10-hour-old infants, with an average oxygen saturation of 85.4%. The Poets et al. study found results with a median oxygen saturation of 97.6% in infants aged 2-7 days (Poets CF, Stebbens VA, Lang JA, O'Brien LM, Boon AW, 1996). Lavesque et al. received a median oxygen saturation of 97% with a mean of 97.2% in all newborns in rooming-in/bedding-in (Levesque et al., 2000).

In this study, none of the subjects differed between pre- and post-ductal > 3%. Ewer et al. obtained 195/20,055 (0.97%) of newborns with abnormal oxygen saturation for CHD by pulse oximetry examination (Ewer et al., 2011). Sendelbach et al. received results of 15,233 subjects who underwent an oximetry examination; only one subject showed positive detection results and normal echocardiographic examination results. No subject with critical CHD was detected through oximetry screening. The study included a large number of subjects, sensors attached to the feet, screening time when the subject was 4 hours old, abnormal oxygen saturation limits <96%, screening was repeated when the subject was about to leave the hospital (Sendelbach et al., 2008).

In this study, the results of the oximetry test with fingertip pulse oximetry (Onyx II ®) at the age of 10 hours of life were compared with the gold standard that is echocardiography to detect critical CHD. In this study, at 10 hours of age, oxygen saturated subjects at extremities < 85% echocardiographic results 100% showed Critical CHD, while subjects with oxygen saturation ≥85% to <90%, echocardiographic results 33.33% showed Critical CHD and 66.67% showed CHD that did not critical. The sensitivity of oxygen saturation in diagnosing critical CHD in newborns at 10 hours is 1. The specificity of oxygen saturation in diagnosing Critical CHD in newborns at ten hours of life is 0.67. The positive predictive value of oxygen saturation in diagnosing Critical CHD in newborns at 10 hours of age is 0.71. The negative predictive value of oxygen saturation in diagnosing Critical CHD in newborns at 10 hours of age is 1. The ratio of the positive likelihood of oxygen saturation in diagnosing Critical CHD in newborns born at the age of 10 hours is worth 3.33. The negative likelihood ratio of oxygen saturation in diagnosing Critical CHD in newborns at 10 hours is 0. Sensitivity results that vary, which cannot be assessed up to 100%, are shown by a systematic review of Mahle et al. The difference in methodology seems to affect these results. In addition, the review also received a high specificity of 95.5% to 100% (Mahle et al., 2009). Another systematic review by Thangaratinam et al. in 13 studies found moderate sensitivity (76.5% (95% CI 67.7-83.5%)) with high specificity (99.9% (95% IK 99, 7 -99.9%)) (Thangaratinam et al., 2012).

Limitations of Oxygen Saturation Fingertip Pulse Examination in Newborns

Oxygen saturation with pulse oximetry is performed when the baby is calm; there is no excessive movement, fighting, or crying. This study found that fingertip pulse oximetry

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examination was needed to achieve maximum results. Reading the results of oxygen saturation measurements on the monitor screen can reach a constant value ,usually takes 10-30 seconds (Pullen, 2010). A research `using Masimo SET® in newborns shows the average total time needed to achieve accurate data is 25 (± 7) seconds (O'Donnell et al., 2005). Some factors that can affect the length of time the results are achieved are the tool, baby, and examiner (Bradshaw et al., 2012). Researchers encountered obstacles when carrying out oxygen saturation, which resulted in repeated oxygen saturation in order to achieve maximum results. These obstacles are related to the tool and baby factors. Fingertip pulse oximeter is a type of conventional oximeter with technology that is not designed to be resistant to movement.

CONCLUSION

In this study, oxygen saturation screening with fingertip pulse oximetry in newborns at 10 hours of age shows that oxygen saturation ≤ 85% all showed critical CHD and on oxygen saturation >85% to <90% showed 33.33% critical CHD, and 66.67% are not critical CHD. The sensitivity, specificity, positive predictive value, negative predictive value, positive likelihood ratio, negative likelihood ratio, pretest probability, and post-test probability of pulse oximetry fingertip (Onyx II ®) compared to echocardiography for early detection of critical CHD in infants newborn has significant value. The measurement of oxygen saturation with fingertip pulse oximetry in newborns at 10 hours of age with the oxygen saturation ≤ 85% reflects the presence of critical CHD in newborns. Fingertip pulse oximetry examination in newborns has limitations mainly related to the influence of the baby's movements and tool factors.

Fingertip pulse oximeter can be an alternative of oximetry device for critical CHD-duct dependent screening in the newborns; however, it is worth noting the limitations of the tool above. Research with a greater number of subjects by screening pulse oximetry in all newborns at the age of 10 hours in a hospital in a rooming-in/bedding-in.

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PAGE 1

PAGE 2

PAGE 3

PAGE 4

PAGE 5

PAGE 6

PAGE 7

PAGE 8

PAGE 9