

Evaluation of Pulse Oximetry in the Early Diagnosis of Cardiac and NonCardiac Diseases in Healthy Newborns

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ABSTRACT

Background: Critical congenital heart diseases (CCHDs) are among the most common birth malformations. This study aimed to determine the cardiac and noncardiac diseases in the Iranian healthy newborns using pulse oximetry (POX) as a suggested screening method.

Methods: In this cross-sectional study, healthy term and near term neonates who were born from October 2017 to March 2018 were evaluated. Preductal and postductal POX was performed in all asymptomatic healthy newborns after 24 hours of life or at any time before discharge from the nursery. Oxygen saturation (SPO₂) was considered normal if SPO₂ was $\geq 95\%$, and the difference between preductal O₂ saturation and postductal POX was obtained at $\leq 3\%$. The POX was repeated after 2 hours for abnormal patients. In the case of the same results in both repeated measures, echocardiography, chest X-ray, sepsis screening, and blood glucose were conducted.

Results: A total of 413 asymptomatic healthy term and near term neonates underwent the pulse oximetry screening (POX). The mean birth weight and gestational age of the neonates were 3256.31 ± 509.62 gr and 38.2 weeks, respectively. The POX was performed averagely 19.5 hours after birth. Finally, a total of 10 cases were detected with abnormal POX. Among these 10 patients, three cases had cardiac diseases (i.e., transposition of the great arteries, ventricular septal defect/pulmonary atresia, and ventricular septal defect/pulmonary hypertension), three cases had noncardiac diseases (i.e., esophageal stenosis, hypoglycemia, and persistent pulmonary hypertension/sepsis), and four subjects were healthy.

Conclusion: The obtained findings showed that routine pox, along with clinical examinations could be applied, especially in developing countries for the early detection of cardiac and noncardiac diseases in asymptomatic newborns.

Keywords: Cardiac and noncardiac diseases, Critical congenital heart disease, Newborns, Pulse oximetry, Pre and postductal saturation

Introduction

Cardiovascular disorders as congenital malformations account for the majority of neonatal mortalities (1). Critical congenital heart diseases (CCHDs) are among the most common congenital malformations and leading cause of infant death with a worldwide incidence rate of 4 to 10 per 1000 live births (2). The CCHDs are responsible for more than 40% of all congenital deaths and 3-7.5% of infant deaths (3).

Discovering screening strategies for the early detection of CCHDs is considered one of the main healthcare system concerns. Missed or late detection of such defects leads to circulatory collapse resulting in shock and acidosis with a substantial adverse effect on disease prognosis (2). Therefore, timely diagnosis of CCHDs plays a crucial role in achieving the best outcomes regarding neonates (2). It has been reported that

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more than 50% of newborn infants may easily miss and frequently die or endure major morbidities using conventional methods (2).

Low blood oxygen levels as the most common problems that can be appeared in babies with CCHDs and other severe noncardiac disorders can be detected quickly using pulse oximetry screening (POS) (4, 5, 6). Pulse oximetry (POX) is an accurate, noninvasive and cost-effective screening technique for the detection of CCHDs in healthcare settings before hospital discharge (6). The POX has been found acceptable and successful in decreasing the rate of missed CCHD cases to 4% (2, 6). It is also applicable in the detection of other significant noncardiac neonatal disorders, including respiratory illnesses and other causes of neonatal hypoxemia (2). It has been reported that performing POX after 24 h of birth reduces false-positive results of CCHDs, compared to that before the first 24 h of birth (0.05% vs. 0.5%) (3).

Unique neonatal screening methods for CCHDs, including POX, have not yet been widely adopted in most Iranian healthcare systems. On the other hand, studies were very limited in this regard, and no comprehensive study was conducted on the screening of noncardiac diseases by POX. In the current single-center study, we aimed to evaluate cardiac and noncardiac diseases before the onset of major symptoms and before entering the incurable phase of the disease.

Methods

Study population

This cross-sectional study was conducted on 427 asymptomatic term and near term healthy newborns who were born at Vali-Asr Maternity Hospital in Imam Khomeini Hospital Complex in Tehran, Iran, from October 2017 to March 2018 (a 6-month period). The POX was performed on all newborns before discharge from the hospital after obtaining permission from the institutional review board. Written informed consent was obtained from the parents or guardians.

Inclusion and exclusion criteria

All asymptomatic and healthy term and near term neonates born during the 6 months of study were included in the study. The newborn infants with any symptoms immediately after birth leading to admission in the neonatal unit, congenital abnormalities, positive prenatal screening, and gestational age less than 34 weeks, as well as those whose parents refused consent and early discharge (less than 2 h) from the

nursery were excluded from the study.

Screening and data collection

The POX was performed by a trained clinician based on the measurement criteria proposed by ABADIS 907 portable pulse oximeter (Persian Medical, IRAN). The functional saturations were measured in the right hand (i.e., preductal) and either of feet (i.e., postductal) in all asymptomatic healthy newborns after 24 h of life or at any time before discharge from the nursery. The POX was read after the observation of pulsatile waves according to cardiac monitoring.

Oxygen saturation (SPO₂) was considered normal if SPO₂ was $\geq 95\%$ in both limbs, and a $\leq 3\%$ difference was observed between the right hand and foot. If SPO₂ was less than 90% in either of limbs, it was considered an abnormal test, and the infant was referred for a cardiac consult and echocardiography detection. When an SPO₂ of 90-95% or a difference of more than 3% was detected in either of limbs, the test was repeated after 2 h. If similar results were obtained, the test was considered positive, and the following diagnostic tests, including echocardiography, chest X-ray, sepsis screening tests (e.g., complete blood count, C-reactive protein [CRP], and blood culture), and blood glucose were conducted.

Hypoglycemia was defined as a plasma glucose level of less than 45 mg/dL in the first 24 h of life. The PPHN was diagnosed as an increased pulmonary arterial pressure using echocardiography. Sepsis was defined as clinical with positive screening, CRP more than 6 ng/ml and leukocytosis or leukopenia or proven by positive blood culture.that was one part of our data collection.

Ethical considerations

This study was approved by the Research and Medical Ethics Committee of Tehran University of Medical Sciences in accordance with the Helsinki declaration (IR.TUMS.CHMC.REC.1396.4384).

Statistical analysis

The obtained data were analyzed using SPSS software (version 21). Qualitative variables, such as age and weight, were presented as mean and standard deviation. The Chi-square test was used to compare variables. The paired t-test was used for the analysis of the right hand and foot POX results due to the equal distribution of data between the groups of study (i.e., normal and abnormal). P-value less than 0.05 was considered

statistically significant.

Results

Pulse oximetry screening

During the study period, a total of 427 asymptomatic healthy term and near term infants born at Vali-Asr maternity Hospital in Imam Khomeini Hospital Complex, underwent POS. In this study, 49% and 51% of the subjects were male and female, respectively. The mean birth weight was 3256.31 ± 509.62 gm, and the mean gestational age was 38.2 weeks. The mean age of the mothers was 29.78 ± 5.829 years (age range: 15-45 years). Most (53.3%) of the infants were the

first child. The mean age of neonates when the POX was performed, was 19.5 h. The general scheme of dividing of the study subjects according to POX results is shown in Figure 1.

The demographic characteristics of newborns based on normal or abnormal results of POX are summarized in tables 1 to 4. One newborn had > 3% difference between right-hand POX and foot POX. Demographic and pregnancy historical characteristics of this neonate are shown in tables 5 and 6. The correlation between demographic characteristics of newborns and normal and abnormal POX of the right hand and left foot are listed in Table 7.

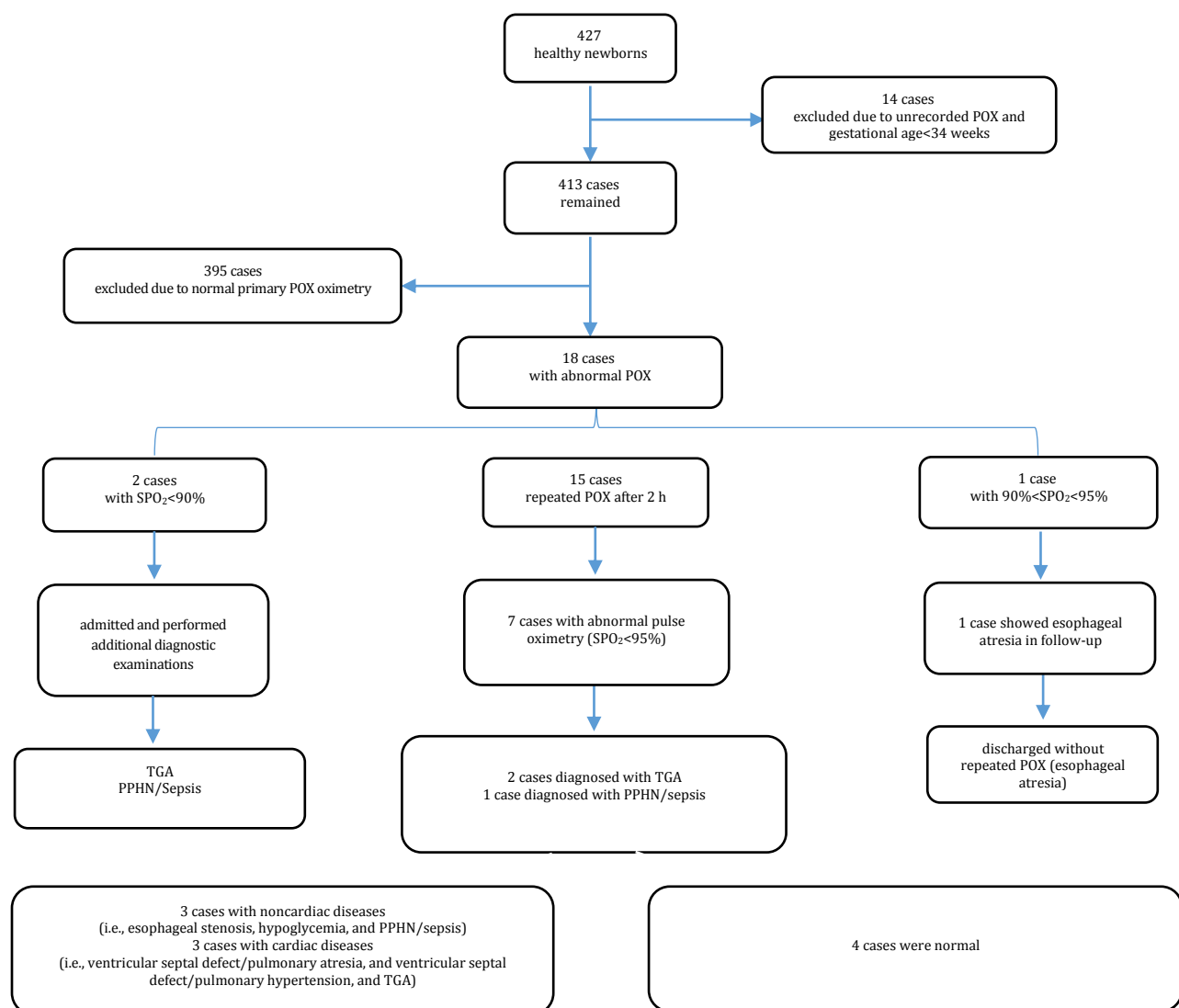


Figure 1. Flowchart of congenital heart disease detection and oxygen saturation

SPO₂: Oxygen saturation

POX: Pulse oximetry

TGA: Transposition of the great arteries

PPHN: Persistent pulmonary hypertension

Table 1. Demographic characteristics of newborns with impaired pulse oximetry

Repeated SPO ₂ Right hand	n=10	Birth weight (gm)	Age at pulse oximetry evaluation	Gestational age (week)	Apgar score	Gender	SPO ₂ Right hand	SPO ₂ Foot	Detected disorders
55	1	.	30	39	8	Male	55	.	PPHN
81	1	3000	12	37	9	Male	81	79	TGA/VSD
90	1	2600	19	38	9	Male	90	89	Esophagus disorder
91	3	3450	13	38	9	Female	90	88	Normal
		2850	17	38	9	Female	92	93	Normal
		3000	15	37	9	Female	94	92	VSD/PA
92	1	3700	21	38	9	Male	90	97	Normal
93	1	4350	20	38	9	Female	91	89	VSD/PH
94	2	2750	24	42	9	Female	95	91	Hypoglycemia
		3100	24	38	9	Female	95	93	Normal

SPO₂: Oxygen saturation

PPHN: Persistent pulmonary hypertension

TGA: Transposition of the great arteries

VSD/PA: Ventricular septal defect/pulmonary atresia

VSD/PH: Ventricular septal defect/pulmonary hypertension

Table 2. Pregnancy historical characteristics of newborns with impaired right-hand pulse oximetry

Repeat SPO ₂ Right hand	n=10	Mother's age (year)	History of cardiac diseases	History of diseases in previous child	Type of delivery	History of common diseases in mother	Screening result	Sonographic result	History of familial marriage	Detected disorders
55	1	35	No	No	C/S	Yes	Normal	Normal	No	PPHN
81	1	22	No	No	C/S	No	Normal	Normal	Yes	TGV/VSD
90	1	43	No	No	C/S	Yes	Normal	Normal	Yes	Esophagus disorder
91	3	21	No	No	NVD	No	Normal	Normal	No	Normal
		20	No	No	NVD	No	Normal	Normal	Yes	Normal
		27	No	No	C/S	No	-	-	No	VSD/PA
92	1	37	No	No	C/S	No	Normal	Normal	No	Normal
93	1	32	No	No	C/S	Yes	-	-	No	VSD/PH
94	2	35	No	No	NVD	No	Normal	Normal	No	Hypoglycemia
		32	No	No	C/S	No	Normal	Normal	Yes	Normal

SPO₂: Oxygen saturation

C/S: Cesarean section

NVD: Normal vaginal delivery

PPHN: Persistent pulmonary hypertension

TGA: Transposition of the great arteries

VSD/PA: Ventricular septal defect/pulmonary atresia

VSD/PH: Ventricular septal defect/pulmonary hypertension

Normal primary pulse oximetry was observed in 95.7% of the newborns, and 4.3% of them had abnormal primary POX of hand and feet or both. Two cases were hospitalized and had additional diagnostic evaluations due to primary POX less than 90%. One of the cases had the transposition of the great arteries (TGA), and the other case had persistent pulmonary hypertension (PPHN) due to sepsis. One of the infants with a 90-95% pulse rate was discharged before doing the repeated POX. The subsequent follow-ups showed the presence of esophageal atresia.

The POX was repeated 2 h later for 15 cases. In total, 10 cases were admitted among whom four infants had a normal examination, and six

newborns showed cardiovascular problems (i.e., TGA, ventricular septal defect/pulmonary hypertension [VSD/PH], and ventricular septal defect/pulmonary atresia [VSD/PA] in three cases) and noncardiac disease (i.e., esophageal atresia, hypoglycemia, and PPHN due to sepsis in three cases) requiring treatment.

In the case with TGA, SPO₂ in the right hand was 81%, and SPO₂ in the foot was 79%. Echocardiography was conducted on this case without repeated POX due to SPO₂ < 90%. In the cases with VSD/PH, SPO₂ in the right hand was 91%, and SPO₂ in the right foot was 89%. Repeated SPO₂ in the right hand was 93%, and SPO₂ in the right foot was 94%. In the cases with

Table 3. Demographic characteristics of newborns with impaired foot pulse oximetry

Repeat SPO ₂ Foot	n=8	Birth weight (gm)	Age at pulse oximetry evaluation	Gestational age (week)	Apgar score	Gender	SPO ₂ Right hand	SPO ₂ Foot	Detected disorders
79	1	3000	12	37	9	Male	81	79	TGV/VSD
87	1	3450	13	38	9	Female	90	88	Normal
89	2	2600	19	38	9	Male	90	89	Esophagus disorder
		3000	15	37	9	Female	94	92	VSD/PA
93	1	2750	24	42	9	Female	95	91	Hypoglycemia
94	3	4350	20	38	9	Female	91	89	VSD/PH
		2850	17	38	9	Female	92	93	Normal
		3100	24	38	9	Female	95	93	Normal

SPO₂: Oxygen saturation

TGA: Transposition of the great arteries

VSD/PA: Ventricular septal defect/pulmonary atresia

VSD/PH: Ventricular septal defect/pulmonary hypertension

Table 4. Pregnancy historical characteristics of newborns with impaired foot pulse oximetry

Repeat SPO ₂ Foot	n=8	Mother's age (year)	History of cardiac diseases	History of diseases in previous child	Type of delivery	History of common diseases in mother	Screening result	Sonographic result	History of familial marriage	Detected disorders
79	1	22	No	No	C/S	No	Normal	Normal	Yes	TGV/VSD
87	1	21	No	No	NVD	No	Normal	Normal	No	Normal
89	2	43	No	No	C/S	Yes	Normal	Normal	Yes	Esophagus disorder
		27	No	No	C/S	No	-	-	No	VSD/PA
93	1	35	No	No	NVD	No	Normal	Normal	No	Hypoglycemia
94	3	32	No	No	C/S	Yes	-	-	No	VSD/PH
		20	No	No	NVD	No	Normal	Normal	Yes	Normal
		32	No	No	C/S	No	Normal	Normal	Yes	Normal

SPO₂: Oxygen saturation

C/S: Cesarean section

NVD: Normal vaginal delivery

TGA: Transposition of the great arteries

VSD/PA: Ventricular septal defect/pulmonary atresia

VSD/PH: Ventricular septal defect/pulmonary hypertension

Table 5. Demographic characteristics of newborns with right-hand pulse oximetry-foot pulse oximetry >3

SPO ₂ Right hand-SPO ₂ Foot>3	Birth weight (gm)	Hour	Week	Apgar	Gender	SPO ₂ Right hand	SPO ₂ Foot	Detected disorders
1	3700	21	38	9	male	90	97	Normal

SPO₂: Oxygen saturation**Table 6.** Pregnancy historical characteristics of newborns with right-hand pulse oximetry-foot pulse oximetry >3

SPO ₂ Right hand- SPO ₂ Foot>3	Mother's age (year)	History of cardiac diseases	History of diseases in previous child	Type of delivery	History of common diseases in mother	Screening result	Sonographic result	History of familial marriage	Detected disorders
1	37	No	No	Cesarean section	No	Normal	Normal	No	Normal

VSD/PA, SPO₂ in the right hand was 94%, and SPO₂ in the right foot was 92%. Repeated SPO₂ in the right hand was 91%, and SPO₂ in the right foot was 89%.

In cases with PPHN and sepsis, SPO₂ in the right hand was 55%. Echocardiography was conducted on this case without repeated POX due to SPO₂ < 90%. In the case with esophageal

atresia, SPO₂ in the right hand and right foot were 90% and 89%, respectively. In cases with hypoglycemia, SPO₂ in the right hand was 95%, and SPO₂ in the right foot was 91%. Repeated SPO₂ in the right hand was 94%, and SPO₂ in the right foot was 93%.

In the evaluation of newborns with abnormal POX (SPO₂<95%) in the right hand (i.e.,

Table 7. Correlation between demographic characteristics of newborns with normal and abnormal pulse oximetry

Variable		<95	≥95	P-value
Gender	Male	4	199	1
	Female	6	200	
Gestational age	<37 weeks	0	46	1 (FET) ^a
	≥37 weeks	10	353	
Mean of birth weight		3200	3243	0.301
History of maternal diseases	Yes	3	218	0.761
	No	7	185	
Sampling time after birth	<24 h	7	301	0.738
	≥24 h	3	97	
Delivery type	Normal vaginal delivery	3	131	1
	Cesarean section	7	270	
Familial history of heart diseases	Yes	0	384	1
	No	10	19	
History of consanguineous marriage	No	6	344	0.066
	Yes	4	59	

a: Fisher's exact test

Table 8. Detected disorders

Detected disorders	SPO2 (RH)	Repeat SPO2 RH	SPO2 (Foot)	Repeat SPO2 (Foot)	Birth weight	Hour	Week	Gender	Mother age	History of Cardiac disease	History of diseases in previous child	History of common disease in mother
TGV/VSD	81	No repeat	79	No repeat	3000	12	37	male	22	no	No	No
VSD/PH	91	93	89	94	4350	20	38	female	32	no	No	Yes
VSD/PA	94	91	92	89	3000	15	37	female	27	no	No	No
Hypoglycemia	95	94	91	93	2750	24	42	female	35	no	No	No
PPHN	55	No repeat	No repeat	No repeat	-	30	39	male	35	no	No	Yes
Esophagus disorder	90	90	89	89	2600	19	38	male	43	no	No	Yes

preductal), 10 cases had different problems. Out of 10 neonates, 8 newborns showed abnormal POX in the left foot (i.e., postductal) too. The average time of performing POX was 18 h after birth. There was no history of familial cardiac diseases in all cases. All of these cases had Apgar score 9 and were monotonous. In this regard, only one case had Apgar score 8 (Table 8).

Discussion

Timely diagnosis and therapy of CCHDs in asymptomatic newborns before the onset of signs and symptoms, especially as a main clinical concern, have been more frequently focused in many studies over the last decades (2, 7). Other screening methods, including prenatal ultrasound, physical examination after birth, and echocardiography, can detect CCHDs (8, 9). However, the application of methods, such as echocardiography, is not cost-effective despite its highest detection rate (1).

Hypoxemia is the most important criterion in

newborns with CCHDs. It is essential to use accurate, noninvasive, and inexpensive screening methods, such as POX, for the early detection of CCHDs (1, 9). In the present study, a total of 413 healthy term and near term newborns underwent preductal and postductal POX at a delivery center. However, adding preductal screening may cause more false-positive findings, but the sensitivity of the tests increases, which have been reported by some other studies (1, 10). The rate of false-positive results of POX for cardiac and noncardiac diseases was 40% in our study.

Other studies reported that the results of POX tests were more false-positive in noncardiac diseases. In our study, 30% of all cases with abnormal POX had a noncardiac disease. We found that 10 neonates had abnormal POX, and out of 10 cases, 6 neonates had cardiac and noncardiac problems. In addition, four newborns had no problems. Indeed, 40% of false-positive cases in our study could be due to testing during first 24 h of life. The mean age of neonates with abnormal

POX in this study was 19.5 h, and 75.4% of neonates were tested before 24 h of life. However, other studies suggested that testing before the first 24 h of life could increase false-positive cases (2, 3, 7, 11). In our study, there was no significant relationship between the first 24 h of testing and abnormal POX results.

We tested all healthy term and near term infants in the present study. Although the false positives of POX test increased in premature neonates, none of our abnormal POXs were below 37 weeks (i.e., preterm). In this study, 51% of the neonates were female, and 49% of them were male. These percentages in infants with abnormal POX were 60% and 40% for females and males, respectively, but there was no significant relationship between gender and abnormal POX. In line with the results of our study, no significant relationship was observed between gender and abnormal POX by other studies (12). Among 10 infants who had abnormal right-hand POX, the left-foot POX was impaired in 8 cases. It has been reported that the false-positive results could increase by performing preductal pulses (12).

Among the newborns evaluated in our study, 45.5% of mothers had gestational hypertension, diabetes or hypothyroidism, with the highest percentage (18%) of hypothyroidism. Out of 10 cases with abnormal POX, 2 mothers had diabetes and high blood pressure, but there was no significant relationship between diseases in mothers and abnormal POX. In other studies, there was no significant relationship between diseases in mothers and abnormal POX results (13, 14). It should be noted that this relationship was measured in newborns who were healthy and had normal screenings that could not be generalized to the relationship between the mother's diseases and neonate's abnormal POX.

Although 67.4% of the infants were born via cesarean section, there was no significant relationship between the type of delivery and abnormal POX results that is consistent with the results of previous studies. No significant correlation was observed between variables, including consanguineous marriage and mean birth weight of neonates, with abnormal POX results. However, out of three neonates with noncardiac diseases, two cases weighed less than 3 kg (2600 and 2700 gm) that could emphasize the need for IUCR neonatal screening, compared with a normal neonate.

Considering that screening was carried out only in 26% of pregnant women, the results of

prenatal screening and ultrasound were normal in 99.5% of the newborns and 8 abnormal POX cases. Moreover, two abnormal POX cases did not have prenatal screening and ultrasound. This finding is suggestive of inadequate prenatal care in Iran and emphasizes the need for POS. None of the six sick infants had abnormal ultrasound or screening results. In a study conducted by Johnson et al., out of 6838 neonates, only 1 newborn showed abnormal POX concluding the high quality of prenatal screening (13).

Our findings showed that although POX is ongoing in developed countries, there is insufficient data on the feasibility and utility of this method for the detection of cardiovascular and noncardiovascular diseases in low-income and middle-income countries (8, 5). In Iran, as a developing country, there are limited studies in this regard. Considering the socioeconomic status in Iran and inadequate efforts of families to carry out prenatal screenings, it is required to perform POX before discharge regarding life-threatening diseases (i.e., both cardiac and noncardiac).

In the present study, there were some limitations, including the discharge of neonates before 24 h of life, and we had to conduct POX in these cases before 24 h of life that may lead to some false-positive results in our evaluations. It is required to carry out further studies with longer periods and larger sample sizes in this regard. In conclusion, POX could be proposed as an effective, noninvasive, economical, and less time-consuming screening tool not only for the early detection of several types of CCHDs in newborns but also for the early detection of noncardiac diseases that could be life-threatening. However, repeating the test for abnormal results and using complementary diagnostic tools to reduce false-positive results are necessary.

Conclusion

In conclusion, this study tried to identify the efficacy of POX screening in healthy newborns, in addition to its role in the early detection of congenital cardiac and non-cardiac diseases during a specific time period. Based on the results, POX could be proposed as an effective, non-invasive, economical, and less time-consuming screening tool for early detection of several types of CCHDs in newborns with improved outcome, as well as early detection of non-cardiac diseases which could be life-threatening.

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Conflicts of interests

The authors declare no conflict of interest.

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