

Effectiveness of the critical congenital heart disease screening program for early diagnosis of cardiac abnormalities in newborn infants

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ABSTRACT

الأهداف: تم حديثاً تطبيق برنامج استقصاء حديثي الولادة عن طريق قياس نسبة أوكسجين الدم في الطرف العلوي الأيمن واحد الطرفين السفليين باستعمال جهاز قياس الأكسجة في العديد من المراكز الطبية في المملكة العربية السعودية للتشخيص الباكر لعيوب القلب الخلقية.

الطريقة: تم إجراء هذا البحث في قسم الأطفال وحديثي الولادة في مستشفى الملك فهد بالباحة، المملكة العربية السعودية بين الشهر الثاني 2016م وحتى الشهر الثاني 2017م حيث تم فحص كل المواليد بالمشفى لمعرفة فعالية ودقة هذا البرنامج في التشخيص الباكر لعيوب القلب.

النتائج: تم فحص 2961 (95.4%) من بين 3103 حديث الولادة ولم يفحص 142 (4.6%) طفل، حيث كان الفحص إيجابياً في 114 (3.9%) حالة وسلبياً في 2847 (96.1%) حالة. كان الفحص موجباً حقيقياً عند 20 (0.7%) تم عندهم تشخيص مرض خلقي بالقلب كان منها 7 (0.2%) حالات حرجة و 13 (0.4%) حالة تم تشخيص ارتفاع شديد بالضغط الرئوي في حين كان الفحص موجباً 94 (3.2%) دون وجود عيب خلقي شديد والمرضى كانوا بحالة مستقره. كان الفحص سلبياً حقيقياً دون وجود مرض قلبي خلقي عند 2841 (96%) حالة في حين كان سلبياً رغم وجود عيب خلقي بالقلب عند 6 (0.2%) فقط. تم مقارنة نتائج هذا البحث مع بعض البحوث العالمية التي أجريت حول هذا البرنامج. لوحظ أن نتيجة الفحص السلبية تنفي بشكل كبير وجود عيوب خلقية بالقلب حيث وجدنا أن حساسية الفحص 77% والنوعية عالية جداً وصلت 99.8%. وكانت قيمة التكهن الإيجابية 18% والسلبية 99.8% كما كانت دقة التحليل حوالي (95% فترة الثقة 13.78-19.18 والقيمة الإحصائية $p=0.0001$).

الخاتمة: أن هذا الإستقصاء مهم ومفيد في التشخيص الباكر لأمراض القلب الخلقية الحرجة ويعتبر فحصاً آمناً وسهلاً وفعالاً وغير مؤذي.

Objectives: To evaluate the effectiveness of critical congenital heart disease (CCHD) screening program

for early diagnosis of cardiac anomalies in newborn infants.

Methods: This is a hospital-based prospective cross-sectional study conducted in the Pediatric and Neonatology Department, King Fahad Hospital at Albaha, Saudi Arabia, between February 2016 and February 2017.

Results: We screened 2961 (95.4%) of 3103 patients in a nursery unit; 142 (4.6%) patients were not screened. The test was positive in 114 (3.9%) patients and negative in 2847 (96.1%). There were 94 (3.2%) false positives and 20 (0.7%) true positives. Critical cardiac defects were diagnosed in 7 (0.2%) patients of all screened infants, and severe pulmonary hypertension was diagnosed in 13 (0.4%) patients. True negative results were found in 2841 (96%) patients, and no cardiac defect was diagnosed, whereas false negative results were seen in 6 (0.2%) patients diagnosed with ventricular septal defect. The sensitivity was 77%, and the specificity was very high at 97%, with a positive predictive value of 18%, and a negative predictive value of 99.8% (95% confidence interval 13.78-19.18, $p=0.0001$).

Conclusion: Pulse oximetry was found to be easy, safe, sensitive, and highly specific for diagnosis of CCHD.

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Newborn physical examinations sometimes do not detect critical congenital heart disease (CCHD), particularly in infants with subtle clinical signs.¹ In many cases, symptoms of CCHD do not present until after hospital discharge.² Heart murmurs, one of the hallmarks of critical and non-critical heart disease typically diagnosed later in life, may be absent or misleading even with ductal-dependent defects,³ which may be because of the underlying anatomy, prolonged decline of pulmonary vascular resistance, or reduced ventricular function.^{2,4} Still there was significant high number of affected newborns not diagnosed despite the prenatal and postnatal evaluation. Because the diagnosis of CCHD is important in early infancy for early intervention or management, adding a CCHD screening program to newborn screening is an important strategy to assure that screening of all newborns specifically includes CCHD. Studies from UK,⁵ the American Academy of Pediatrics,⁶ Sweden,⁷ Germany,⁸ several international studies,⁹ Poland,¹⁰ Taipei,¹¹ and Norway,¹² have recommended a pulse-oximetry screening program for early detection of CCHD. Presently in the United States of America (USA), several states started the CCHD program. These organizations have found that CCHD screening can be an effective way to detect serious health problems in newborn infants. In addition to detecting CCHD, screening using pulse oximetry can detect other serious medical problems, including sepsis or pneumonia.¹²⁻¹⁴ It is important to recognize that a baby with a failed screening result (does not meet the criteria of a disease) can appear to be completely well on examination, but have a significant underlying medical problem.^{13,15} The Saudi Ministry of Health (MOH) recommended and added CCHD screening to the country's newborn screening programs. Screening at age 24 hours is now performed in many centers in Saudi Arabia, with clear guidance that is compatible with the guidance of AAPs⁶ and AH to facilitates successful screening. And recently has been implemented in many centers in Saudi Arabia, and all newborns are screened by pulse oximetry as part of newborn screening to develop strategies for implementation of easy, safe, and effective, screening for diagnosis of CCHD as early as possible. The implementation of this screening program was started in King Fahad Hospital, Albaha, Saudi Arabia in February 2016.

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The aim of this study was to evaluate the effectiveness of the CCHD screening program in Saudi Arabia for early diagnosis of CCHD in newborn infants.

Methods. The study was conducted in the Pediatric and Neonatology Department, King Fahad Hospital, Albaha, Saudi Arabia from February 2016 to February 2017. The study was approved by the Scientific Research and Ethical Committee of the hospital. This was a prospective cross-sectional study that included all live-birth newborns delivered in King Fahad Hospital at Albaha and screened in this program before discharge from the Nursery Department. According to Helsinki Declaration, parents were informed and consents for all patients were taken despite it was not invasive procedure and applied as screening for all live birth neonates in the hospital. The data was collected prospectively from February 2016 to February 2017 for all live-birth infants delivered in King Fahad Hospital Albaha. The screening was performed using the CCHD policy and guidelines of the Saudi MOH at 24 hours of age for all newborn infants, or between 12 and 24 hours of age if the baby was to be discharged early from the hospital. Screening was performed by using a pulse oximeter with an adhesive sensor placed on the baby's skin (Masimo Corporation, 40 Parker Irvine, CA, USA). Echocardiography was performed by a pediatric cardiologist to all patients with positive test results for any cardiac abnormalities confirmation. The echocardiograph used was a Philips IE33 Ultrasound (Philips, Bothel, WA, USA). The screening was performed in a quiet nursery environment with no active crying. Bright or bilirubin lights were turned off prior to screening. The screening is painless and takes only a few minutes. Waiting until 24 hours of age may decrease false-positive results. The screening was performed first in the right hand, then in either foot by using one pulse oximeter. The baby passed the screening if the oxygen saturation was $\geq 95\%$ in the right hand and either foot and the difference in values was $\leq 3\%$. A failed screening result was defined as an oxygen saturation of $< 90\%$ in the right hand and either foot in the initial or repeated screens. If the oxygen saturation was $> 90\%$ and $< 95\%$ in the right hand and either foot or there was a $> 3\%$ difference between the right hand and either foot, then the screening was repeated after one hour, and the same process as described above was followed. Some babies required 3 screenings. Patients with a positive CCHD result were referred to a pediatric cardiologist, and all referred infants were evaluated by clinical cardiovascular examination and screened by echocardiography (Table 1). Gestational hypertension,

gestational diabetes, consanguineous parents, and family history of heart disease or hearing problem were registered and evaluated as risk factors. Hearing assessment screening was performed for the majority of newborns included in this study. The patients were divided into 2 groups: Group 1, preterm 34-36 weeks and Group 2, term ≥ 37 weeks. The presence of CHD and associated risk factors were evaluated in each group. To avoid missing screening opportunities. All live-birth newborn infants delivered in King Fahad Hospital at Albaha, and admitted to nursery unit for observation without any associated medical problem were included and screened in the study. Preterm newborns < 34 weeks gestational age, newborns diagnosed as having CHD by fetal echocardiography, syndromic newborns, newborns with signs of sepsis or who were admitted to the neonates intensive care unit (NICU) after delivery because of other medical problems, and patients referred from other hospitals were excluded. Newborns with positive screening test results were diagnosed as having a normal heart, or acyanotic congenital heart diseases: patent foramen ovale, patent ductus arteriosus (PDA), atrial septal defect (ASD), ventricular septal defect (VSD), valvular diseases, were classified as a false-positive case. While the test was considered true positive if the diagnosis was CCHD: critical tetralogy of fallot, interrupted aortic arch, hypoplastic left heart syndrome (HLHS), transposition of great arteries (TGA), pulmonary atresia (PA), and total anomalous pulmonary venous return needing urgent intervention.⁵

The main outcome measures were the sensitivity, specificity, positive and negative predictive values, false positives, false negatives, odds ratio (OR), *p*-value, and 95% confidence intervals (CI). The significant statistical values was calculated by using the users' guides to the medical literature third edition.¹⁶

Results. A total of 3300 live-birth newborn infants were delivered during the study period, 197 patients were admitted to the NICU, and 3103 patients were admitted to the observational nursery. Critical congenital heart disease screening was performed for 2961 (95.4%) patients, and 142 (4.6%) patients were not screened. All patients with positive test results were referred to and evaluated by pediatric cardiologists, and echocardiography was performed for all. Failed test results (positive) were observed in 114 (3.9%) patients, and passed test results (negative) were observed in 2847 (96.2%). In the positive test group, true positive test was seen in 20 (0.7%), critical cardiac defects were diagnosed in 7 (0.2%) distributed as 2 male cases (0.1%) with HLHS, 1 (0.03%) male with TGA, 1 (0.03%) male with PA, 1 (0.03%) male with PS, 1 (0.03%) male with AVC, and 1(0.03%) male with truncus arteriosus, and severe pulmonary hypertension was diagnosed in 13 (0.44%), (95% CI: 13.78-19.18; *p*=0.0001). False positive test was considered in 94 (3.2%) patients and no critical cardiac anomalies were diagnosed. Patent foramen ovale without pulmonary hypertension was diagnosed in 45 (1.5%), and echocardiography results considered as normal for age, and stable acyanotic CHD were diagnosed in 49 (1.7%) distributed as 5 (0.2%) patients with VSD, and 44 (1.5%) patients with large symptomatic PDA. Regarding the gender of the patients with CCHD, there were 6 (86%) male and 1 (14%) female patients. In patients who passed the test, true negative test results were seen in 2841 (96%), and no cardiac defect was diagnosed, whereas false negative were seen in 6 (0.2%) diagnosed with VSD. Hearing assessment was performed for 2642 (89%) patients. Ten patients was referred to the Ear, Nose and Throat Department for evaluation. Analysis of our result showed that the accuracy of the test was 97%,

Table 1 - Saudi Ministry of Health protocol criteria for critical congenital heart disease (CCHD) screening program, SaO₂%.

| CCHD screening | Pass (negative test) | Failed (positive test) |
|---|--|--|
| First screening result | If criteria met (pass): Saturation $\geq 95\%$ and difference $\leq 3\%$ between right hand or a foot. No further action required. | If criteria are not met (failed): Saturation $< 90\%$ in right hand or a foot, or between 90% and 95% or difference $> 3\%$. Go to second screening after one hour. |
| Second screening result (after one hour) | If criteria met (pass): Saturation $\geq 95\%$ and difference $\leq 3\%$ between right hand or a foot. No further action required. | If criteria are not met (failed): Saturation $< 90\%$ in right hand or a foot, or between 90% and 95%, or difference $> 3\%$. Go to third screening after one hour. |
| Third screening result (after one hour) | If criteria met (pass): Saturation $\geq 95\%$ and difference $\leq 3\%$ between right hand or a foot. No further action required | If criteria are not met (failed): Saturation $< 90\%$ in right hand or a foot, or between 90% and 95 %, or difference $> 3\%$. Refer patient to a cardiologist. |
| SaO ₂ - percentage of arterial oxygen saturation | | |

the sensitivity was 77%, and the specificity was very high 98%. The positive predictive value was 18% and the negative predictive value is 99.8%. There were no significant differences in the positive test results between the male and female ($p=0.45$), but it was significantly high in male patients with CCHD, ($p=0.04$) (Table 2). No significant difference regarding gestational age was found in the test results.

Discussion. We found that pulse oximetry screening for CCHD was simple, safe, easy, and non invasive and was useful for early diagnosis of CHD, a finding that supports those of previous international studies in other countries are shown in Table 3. A total of 2961 newborns underwent CCHD screening in our study. We compared our results with those of previously published studies from Europe,^{5,7,8,17} with large samples of data. Prostaglandin infusion was started for ductus-

dependent patients diagnosed by this screening, and patients were urgently transferred to a higher cardiac center for proper intervention. True-negative tests were confirmed in 2841 (95.9%) patients, whereas false negatives were found in 6 (0.2%) who were diagnosed in follow up clinic with stable CHD as a form of VSD. Statistically, the negative predictive value was 99.8%, with a very high specificity of 98%, and the true-negative value was very high at 95.9%, with a very low false-negative value of 0.2%, both of which were similar to the values reported in other international studies.^{5,7,8,17} We found that our false-positive result of 3.2% was higher than the values reported in the international studies in various countries, including 0.8% in the UK,⁵ 0.17% in Sweden,⁷ 0.1% in a large study conducted in Germany,⁸ very low 0.026% in Poland,¹⁰ and 0.14% in Norway.¹⁷ The high percentage of false positive in our study may be because of the early screening time 12-24 hours of age and in some cases before 12 hours of age if the patient was planned for early discharge, or it may be because of some other illness, such as neonatal sepsis or pneumonia for which earlier diagnosis was important. Therefore, most publications have recommended that pulse oximetry screening be performed at ≥ 24 hours of age.^{9,13,15} The positive predictive value (18%) was similar with other studies (UK [13.3%], Sweden [30.7%], Germany [25.9%], Poland [51.7%], and Norway [8.3%]).^{5,7,8,10,13,17} The sensitivity 77% and specificity 98% in our study were similar among the international studies, 75% and 99.3% in a UK;⁵ 79%

Table 2 - Distribution of patients with positive CCHD test in our study in Albaha, Saudi Arabia.

| Screening | Dx | n | (%) | Male | Female | P-value |
|----------------|------------|-----|-------|------|--------|---------|
| All positive | All | 114 | (3.9) | 59 | 55 | 0.45 |
| False positive | PFO | 45 | (1.5) | 23 | 22 | 0.63 |
| | PDA stable | 44 | (1.5) | 21 | 23 | 0.66 |
| | VSD stable | 5 | (0.2) | 3 | 2 | 0.44 |
| True positive | PHN | 13 | (0.4) | 7 | 6 | 0.71 |
| | CCHD | 7 | (0.2) | 6 | 1 | 0.04 |

Dx - diagnosis, PDA - patent ductus arteriosus, PHN - pulmonary hypertension, VSD - ventricular septal defect, PFO - patent foramen ovale, CCHD - critical congenital heart disease

Table 3 - Effectiveness of critical congenital heart disease (CCHD) screening program, comparison of our study outcomes with those of some international studies.

| Main outcome | Present study | United Kingdom ⁵ | Sweden ⁷ | Germany ⁸ | Norway ¹⁷ |
|-----------------------------|-----------------------------|-----------------------------|-----------------------|-------------------------------|-----------------------|
| Type of study | Prospective cross-sectional | Systematic review | Systematic review | Prospective multicenter study | Systematic review |
| Total screened babies | 3103 | 20055 | 38429 | 41445 | 50008 |
| Sensitivity | 77 | 75 | 79 | 77.78 | 77.1 |
| Specificity | 98 | 99.3 | 99.8 | 99.9 | 99.4 |
| Positive predictive value | 18 | 13.3 | 30.7 | 25.9 | 8.3 |
| Negative predictive value | 99.8 | 99.98 | 99.9 | 99.9 | 99.9 |
| Accuracy | 98.3 | | | | |
| False positive | 90 (3.2) | 169 (0.8) | 69 (0.2) | 40 (0.1) | 0.14 |
| False negative | 6 (0.2) | 27 (0.1) | 0.03 | 4 (0.01) | 0.6 |
| SaO ₂ cutoff (%) | ≥ 95 | ≥ 95 | ≥ 95 | ≥ 96 | ≥ 95 |
| 95% CI from OR, RR | 13.78-19.18 | 53.29-90.23 | 350.3-1479 | | |
| P Value | 0.0001 | | 0.0001 | | |
| Protocol | Difference $\geq 3\%$ | Difference $>2\%$ | Difference $\geq 3\%$ | Difference $\geq 3\%$ | Difference $\geq 3\%$ |

Values expressed as number and percentage (%), CI - confidence interval, OR - odds ratio, RR - relative risk

and 99.8% in Swedish study,⁷ 77.78% and 99.9% in a German study,⁸ 78.9% and 99.9% in Poland,¹⁰ and 77.1% and 99.4% in Norway.¹⁷ Also negative predictive values were similar among the international studies and the present study. Some newborns with failed test results may appear to be completely well on clinical examination, but actually have significant cardiac problems. On the other hand, some newborns passed the test but were diagnosed later as having congenital heart disease.^{1,15} We applied the Saudi MOH protocol in our study (Table 1), which included screening between 12 and 24 hours of age and repeating the test after one hour if the initial saturation was between 90% and 95% or $\geq 95\%$ with a difference $>3\%$. This protocol could have increased the number of positive results relative to those of other international studies (Table 3). We found that pulse oximetry was sensitive and highly specific, as in the international studies.^{5,7,8,17} Additionally, a meta-analysis by Thangaratinam et al,¹³ showed that the mean sensitivity was 76.5% (67.7% - 83.5%), specificity was 99.8% (99.7% - 99.9%), and false positive rate was 0.14% (0.06% - 0.33%). Although the goal of screening was to detect CCHD, pulse oximetry also identified other life-threatening disorders of non-cardiac origin, including sepsis, pneumonia, and PHN. Acyanotic forms of congenital heart disease are not expected to be detected by pulse oximetry, but that occasionally they may result in false positive results which was high in our study. In the study from Sweden, they found that pulse oximetry screening had more than 7 times the positive predictive value of physical examination in detection of CHD.

Study limitations. This study was conducted at a single center. Although our data sample was large, it was smaller compared with the international studies described in a systematic review. We think that the patients should have been followed up for a longer period also. The high false-positive rate in our study needs to be confirmed or refuted in a future study with a larger study subject sample. In false negative results, we can not exclude some missed cases with CHD may have been followed and admitted in other hospitals after discharged from our neonatology unit.

In conclusions, CCHD screening was found to be safe, simple, noninvasive, reasonably accurate, effective and has high specificity for early diagnosis of CCHD in newborns in our hospital. The results of this study provided evidence from Saudi Arabia further supporting the advantages of CCHD screening using pulse oximetry as routine screening for all newborn infants. A

multi-center study is needed to evaluate the benefits of this program. Successful implementation of the CCHD screening program depends on the collaboration of all centers and between neonatologists and pediatric cardiologists in all participating hospitals in which the program has been initiated.

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 - **The following are the typical headings:**
 - Objectives (background, why the study was done, specific aims)
 - Methods (setting, date of study, design, subjects, intervention and analysis)
 - Results (findings, data and statistical tests) and
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