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Value of Combination of ECG, Pulse oximetry & Blood Pressure in Screening of Congenital Heart Disease in Apparently Healthy Full Term Neonates

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Abstract

Background: Every year, roughly eight out of every one thousand newborns are born with congenital heart disease (CHD), which is the most frequent form of congenital disability reported.

Aim and objectives: To evaluate the validity of combining (Electrocardiogram (ECG), BL/P, and pulse oximetry), as a screening method for the primary identifying critical CHD (CCHD) in apparent healthy full-term neonates.

Patient and methods: This trial was a prospective observational study done on 100 full-term, apparent healthy neonates, and ages of gestation ranging from thirty-seven weeks to forty-two weeks from the beginning of the pregnancy were selected from deliveries at Alzahraa University Hospital Cairo, Egypt. Data were collected from May 2021 to March 2022.

Results: There was a statistically significant relation between echo-abnormality and the left axis of QRS. The difference between peripheral oxygen saturation (SPO2) pre- and post-ductal showed higher values in neonates with abnormal echo than those with normal echo. The total combination of clinical examination, ECG, and SPO2 increased the sensitivity by 83.3 0%, specificity of 96.6 %, area under the curve (AUC) of 0.950 than each one alone.

Conclusion: There was a high relationship between echo-abnormality and SPO2 post ductal, ECG, and clinical examination (murmur, respiratory rate, heart rate). This combination can improve the clinician's capacity to promptly recognize life-threatening congenital heart disease. Creating a national program that will prioritize screening for coronary heart disease is necessary to address this issue.

Keywords: CHD, Pulse Oximetry, ECG

1. Introduction

T Congenital heart disease is the prevailing congenital anomaly, with a prevalence of around 8 per 1000 live births annually. The incidence of Critical Congenital Heart Disease, which refers to the most severe types of heart defects, is estimated to be around 2.5 to 3 cases per 1000 live births. These more severe abnormalities result in substantial illnesses as well as death, contributing to about 40% of fatalities in infants with congenital malformations during their first year of life.^{1,2}

Pulse oximetry screening (POS) is a suggested method for early detection of critical congenital heart disease. It is a non-invasive and cost-effective tool that identifies lower-than-normal post-ductal oxygen saturation.

This abnormality indicates the potential presence of a right-to-left shunt across the ductus arteriosus (DA), alerting the clinician to the possibility of CHD.^{3,4}

Electrocardiography is a valuable tool for early detection of CHDs. ECG is a straightforward and non-invasive method that helps diagnose congenital cardiac disease. Electrocardiography changes frequently occur in individuals with congenital heart disease, typically associated with atrial or ventricular overload and enlargement. Examples of like conditions include ventricular septal defect, secundum atrial septal defect, patent ductus arteriosus, AV canal defect, aortic coarctation, pulmonary stenosis, congenitally corrected TGA, Ebstein's anomaly, dextrocardia, in addition to situs inversus.⁵

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More cases of incorrect screenings, repeated screenings, and screening failures occurred with neonatal blood pressure screening for congenital cardiac defects that identified aortic arch blockage compared to the pox component of the screening protocol.⁶

This research aimed to assess the accuracy of using a combination of electrocardiography, blood pressure (BL/P), and pulse oximetry as a screening tool to identify congenital heart disorders in apparently healthy full-term newborns.

2. Patients and methods

This prospective observational study contained 100 full-term, apparent healthy neonates, with gestational age from 37 weeks to 42 weeks, selected from deliveries at Alzahraa University Hospital Cairo, Egypt. Data were collected from May 2021 to March 2022.

Inclusion criteria: Full-term neonate with gestation age from 37 weeks to completed 42 weeks and all apparent healthy neonates.

Exclusion criteria: Premature neonate (not complete 37 weeks gestation), perinatal asphyxia, neonates with major congenital anomalies, meconium aspiration syndrome, NICU admission, cyanosis at birth, and respiratory distress.

Ethical consideration: All parents of the studied neonates gave informed oral consent. The steps of the study, the aims, the potential benefits, and the hazards were discussed with the parents of the studied neonates.

Methods:

All included neonates were subjected to history taking, clinical examinations, laboratory evaluation, and investigations.

Pulse oximetry test: A neonatologist used a specific blood oxygen saturation detector to perform a Pulse oximetry test (POX) on newborns. Positive results indicated a positive diagnosis and infants with negative results were sent for echocardiograms. Infants needing immediate intervention were moved to the NICU. In contrast, those diagnosed with CHD without immediate intervention were requested to come back for an evaluation of their echocardiography 90 days following delivery.

ECG testing was done using ten stickers on the neonate's chest, arms, and legs. The test took about 5 to 10 minutes to complete. First, we put the neonate in the supine position; then we placed ECG dots on the chest as follows, as measuring rib spaces was not usually possible in neonates: The first line, V1, is on the right side of the sternum, approximately half an inch from the midline. The second line, V2, is on the left side of the sternum, also about half an inch from the midline. The third line, V3, is midway among V2

and V4, below the nipple at the midclavicular line. The fifth line, V5, is on the same level as V4, about where the ribs curve back. The sixth line, V6, is on the same level as V4 and V5, below the armpit. Unlike torso leads, leg leads are applied to the limbs. A lead arm is positioned just above the elbows. Connecting the knee to the ankle is the leg lead.⁷ When the infant was lying quietly, and we had a clear tracing with minimal artifact, capture the ECG.

BP measurement: Pay close attention to the size, placement, and method of taking a baby's BP cuff. A cuff that is too small can overestimate the BP, and a larger cuff may give lower readings. If an artery's pulsations are large enough, oscillometric instruments can pick them up. After inflating the cuff to a level higher than the systolic pressure, the MAP was calculated by measuring the amplitude of the arterial pulsations as the cuff slowly deflated.⁸ Both systolic diastolic blood pressure are determined by using manufacturer-specific computational algorithms and estimating the patient's pulse pressure. **Noninvasive:** Measure the circumference of your arm (usually in cm) by wrapping a measuring tape around the middle of your upper arm. This will allow you to take blood pressure in your upper and lower limbs using an adequately sized cuff. Find the right size cuff by measuring your arm circumference.

Echocardiographic examinations: All neonates included in the study were examined with echocardiography by pediatric cardiologists thorough 2D assessment of the septa, chambers, and heart vessels, as well as the concordance of the atrium ventricle and the great vessels.

3. Results

There was male predominance in our study, with post-natal age ranged from 24 – 36 hours

Table 1. Demographic data of the examined neonates

| | | NO. = 100 |
|-------------------------|----------------|--------------|
| POSTNATAL AGE (HR) | Mean ± SD | 30.00 ± 6.03 |
| | Range | 24 – 36 |
| SEX | Female | 44 (44.0%) |
| | Male | 56 (56.0%) |
| BODY WEIGHT (KG) | Mean ± SD | 3.45 ± 0.61 |
| | Range | 2.7 – 4.5 |
| LENGTH (CM) | Mean ± SD | 48.87 ± 1.06 |
| | Range | 47 – 51 |
| HEAD CIRCUMFERENCE (CM) | Mean ± SD | 35.88 ± 1.83 |
| | Range | 33 – 38 |
| G.A (WEEKS) | Mean ± SD | 38.88 ± 0.82 |
| | Range | 38 – 40 |
| M. HISTORY | No infection - | 100 (100.0%) |
| | No disease | |

Both groups did not differ significantly from one another as regards SBP of UL and the SBP of LL in neonates & the variance amongst blood pressure of upper limb & lower limb

Table 2. Relation between echo abnormality and blood pressure measurement

| | | ECHO | | TEST VALUE | P-VALUE | SIG. |
|---|-----------|--------------------|----------------------|------------|---------|------|
| | | Normal No. = 88 | Abnormal No. = 12 | | | |
| SBP UL (MMHG) | Mean ± SD | 87.05 ± 8.01 | 87.42 ± 7.23 | -0.152 | 0.879 | NS |
| | Range | 65 – 105 | 79 – 105 | | | |
| DBP UL (MMHG) | Mean ± SD | 50.43 ± 9.83 | 52.00 ± 10.35 | -0.515 | 0.607 | NS |
| | Range | 34 – 75 | 40 – 70 | | | |
| SBP LL (MMHG) | Mean ± SD | 87.53 ± 7.92 | 82.00 ± 9.97 | 2.199 | 0.030 | S |
| | Range | 69 – 105 | 60 – 97 | | | |
| DBP LL (MMHG) | Mean ± SD | 49.40 ± 8.43 | 47.25 ± 9.30 | 0.818 | 0.415 | NS |
| | Range | 34 – 65 | 34 – 65 | | | |
| DIFFERENCE IN BLOOD PRESSURE (UPPER & LOWER LIMB) | Mean ± SD | 6.85 ± 5.70 | 10.42 ± 9.42 | -1.113 | 0.266 | NS |
| | Range | 0 – 21 | 1 – 29 | | | |

P-value >0.05: Non significant (NS); P-value <0.05: Significant (S); P-value < 0.01: highly significant (HS)

*: Chi-square test; •: Independent t-test

Statistical analysis revealed a notable decline in the SPO2 post ductal in neonate with abnormal echo than those with normal echo with p-value <0.001. The difference between SPO2 pre and post ductal showed higher value in neonates with abnormal echo than those with normal echo with p-value <0.001.

Table 3. Relation amongst echo abnormality & pulse oximetry oxygen saturation

| | | ECHO | | TEST VALUE | P-VALUE | SIG. |
|---|-----------|--------------------|----------------------|------------|---------|------|
| | | Normal No. = 88 | Abnormal No. = 12 | | | |
| SPO2 PREDUCTAL (%) | Mean ± SD | 99.18 ± 1.28 | 99.50 ± 0.90 | -0.830 | 0.409 | NS |
| | Range | 94 – 100 | 97 – 100 | | | |
| SPO2 POSTDUCTAL (%) | Mean ± SD | 97.91 ± 2.25 | 94.00 ± 1.95 | 5.720 | <0.001 | HS |
| | Range | 89 – 100 | 90 – 97 | | | |
| | >95 | 79 (89.8%) | 2 (16.7%) | | | |
| | <95 | 9 (10.2%) | 10 (83.3%) | | | |
| DIFF. BETWEEN SPO2 PRE AND POST DUCTAL (QUANTITATIVE) | Mean ± SD | 1.27 ± 1.53 | 5.50 ± 1.68 | -8.881 | <0.001 | HS |
| | Range | 0 – 6 | 2 – 8 | | | |
| SPO2 DIFFERENCE BETWEEN PRE DUCTAL .POST DUCTAL | ≤4 | 84 (95.5%) | 2 (16.7%) | 54.445 | <0.001 | HS |
| | >4 | 4 (4.5%) | 10 (83.3%) | | | |

There was statistically significant relation found between echo abnormality and left axis of QRS with p-value = 0.023 and also p-pulmonale showed higher percentage in neonates with abnormal echo (8.3%) than neonates with normal echo (0.0%) with p-value = 0.006.

Table 4. Relation among echo abnormality & ECG parameters of the studied neonates

| | | ECHO | | TEST VALUE | P-VALUE | SIG. |
|--------------|-------------|--------------------|----------------------|------------|---------|------|
| | | Normal No. = 88 | Abnormal No. = 12 | | | |
| RATE (MIN) | Mean ± SD | 153.60 ± 16.72 | 150.92 ± 17.67 | 0.518• | 0.605 | NS |
| | Range | 120 – 185 | 120 – 179 | | | |
| RHYTHM (MIN) | Regular | 88 (100.0%) | 12 (100.0%) | NA | NA | NA |
| QRS AXIS | Normal | 42 (47.7%) | 6 (50.0%) | 7.578* | 0.023 | S |
| | Right axis | 46 (52.3%) | 5 (41.7%) | | | |
| | Left axis | 0 (0.0%) | 1 (8.3%) | | | |
| QRS DURATION | Normal | 88 (100.0%) | 12 (100.0%) | NA | NA | NA |
| | P-wave | 88 (100.0%) | 11 (91.7%) | | | |
| | P-pulmonale | 0 (0.0%) | 1 (8.3%) | | | |
| T WAVE | Normal | 88 (100.0%) | 12 (100.0%) | NA | NA | NA |
| QTC | Normal | 88 (100.0%) | 12 (100.0%) | NA | NA | NA |
| V1 R | Mean ± SD | 13.94 ± 4.65 | 13.38 ± 2.86 | 0.408• | 0.684 | NS |
| | Range | 0 – 24 | 5 – 17 | | | |
| V1 S | Mean ± SD | 9.26 ± 1.39 | 8.63 ± 0.48 | 1.556• | 0.123 | NS |
| | Range | 8 – 17 | 7.5 – 9.5 | | | |
| V6 R | Mean ± SD | 5.61 ± 1.57 | 5.79 ± 2.08 | -0.351• | 0.726 | NS |
| | Range | 3 – 9.5 | 4 – 9.5 | | | |
| V6 S | Mean ± SD | 4.88 ± 1.67 | 5.63 ± 1.85 | -1.439• | 0.153 | NS |
| | Range | 0.3 – 7.5 | 3 – 7.5 | | | |
| ECG | Normal | 87 (98.9%) | 7 (58.3%) | 30.757* | <0.001 | HS |
| | Abnormal | 1 (1.1%) | 5 (41.7%) | | | |

The presence of murmur detected the abnormality of echo with sensitivity of 50.0%, specificity of 85.2% and AUC of 0.810.

Table 5. Relation between echo abnormality and clinical examination of studied neonates

| PARAMETERS | TP | TN | FP | FN | SENSITIVITY | SPECIFICITY | PPV | NPV | AUC |
|-------------------------------|----|----|----|----|-------------|-------------|------|-------|-------|
| HR > 160 (BEAT/MIN) | 8 | 75 | 13 | 4 | 66.7 | 85.2 | 38.1 | 94.9 | 0.830 |
| RR > 61 (CYCLE/MIN) | 8 | 79 | 9 | 4 | 66.7 | 89.8 | 47.1 | 95.2 | 0.870 |
| MURMUR | 6 | 75 | 13 | 6 | 50.0 | 85.2 | 31.6 | 92.6 | 0.810 |
| COMBINATION (HR, RR, MURMUR)* | 12 | 61 | 27 | 0 | 100.0% | 69.3% | 44.4 | 100.0 | 0.730 |

Combination of (Heart Rate > 160 or Respiratory Rate >61 or positive murmur) were done by considering the patient positive if any of the three methods of diagnosis were found positive

SPO2 postductal < 95 (%) can detect the abnormality of echo with sensitivity of 83.3%, Specificity of 89.8% and AUC of 0.890 while the difference between SPO2 pre and post ductal >4 had sensitivity of 83.3%, specificity of 95.5% and AUC of 0.940. The presence of abnormality in ECG had sensitivity of 41.7%, specificity of 98.9% and AUC of 0.920. Also the combination with SPO2 preductal, difference between pre and post ductal had a sensitivity of 83.3%, specificity of 97.7% and AUC of 0.968. The total combination between clinical examination, ECG and SPO2 increase the sensitivity of 83.3 0%, specificity of 96.6 % and AUC of 0.950 than each one alone.

Table 6. combination of SPO2, ECG

| PARAMETERS | TP | TN | FP | FN | SENSITIVITY | SPECIFICITY | PPV | NPV | AUC |
|---|----|----|----|----|-------------|-------------|-------|------|-------|
| SPO2 POSTDUCTAL < 95 (%) | 10 | 79 | 9 | 2 | 83.3 | 89.8 | 52.6 | 97.5 | 0.890 |
| DIFF. BETWEEN SPO2 PRE & POST DUCTAL > 4 | 10 | 84 | 4 | 2 | 83.3 | 95.5 | 71.4 | 97.7 | 0.940 |
| ECG | 5 | 87 | 1 | 7 | 41.7 | 98.9 | 83.3 | 92.5 | 0.920 |
| COMBINATION (SPO2 POSTDUCTAL, DIFF BETWEEN SPO2 PRE AND POST DUCTAL)* | 10 | 79 | 9 | 2 | 83.3 | 89.8 | 52.6 | 97.5 | 0.890 |
| TOTAL COMBINATION** | 10 | 85 | 3 | 2 | 83.3 | 96.6 | 76.92 | 97.7 | 0.950 |

4. Discussion

Our study revealed there were 44 females (44.0%) and 56 males (56.0%) with a mean post-natal age of (30.0±6.03) hours.

These results are in agreement with the study of Majani et al.⁹, which showed that 52% were males and 48% were females.

Our result also showed that the mean gestational age ± SD was 38.88 ± 0.82 weeks, and the average birth weight was 3.45 ± 0.61 kg.

The study of Chen et al.¹⁰ showed that the average gestational age at birth was 39:21 ± 1:23 weeks, and the average birth weight was 3236 ± 324 g.

Our trial results showed that no significant variance was detected amongst both groups regarding SBP and DBP of UL and LL in patients and also the change in blood pressure of the upper limb and lower limb.

The study of Crossland et al.¹¹ revealed that all forty newborns evaluated by echocardiography who were otherwise healthy had normal aortic arches. Normal newborns may exhibit a large difference in BP between limbs, as measured with a Dinamap Compact T 482210. It is more probable that a 20 mm Hg discrepancy in isolation is attributable to measurement variability than aortic coarctation. Echocardiography is the only test that can confirm or rule out aortic coarctation. The disparity among the sexes' blood pressure readings was twenty millimeters Hg for three.

This resulted in an eight percent false positive rate (3/39) or 92 cases of specific comparison of lower with upper limb blood pressures (36 out of 39).

Also, our results indicated a statistical reduction in the SPO2 post ductal in cases with abnormal echo than those with normal echo with p-value <0.001. At the same time, no statistically significant alteration originated among both groups regarding SPO2 pre-ductal with p-value = 0.409. The variance between SPO2 pre & post ductal showed higher value in patients with abnormal echo than those with normal echo with p-value <0.001. The post-ductal SPO2 at the level of <95 can detect abnormality of echo with sensitivity of 83.3% and specificity of 89.8%, and AUC of 0.890, while the difference between pre and post-ductal SPO2 >4 can detect the abnormality of echo with sensitivity of 83.3%, specificity of 95.5% and AUC of 0.940.

Chen et al.¹⁰ showed that Abnormal SpO2 Sensitivity was (%) 51.26, and Specificity was (%) 82.65.

In our trial, there was a statistical correlation between echo abnormality and the left axis of QRS as it showed a higher percentage in neonates with abnormal echo (8.3%) than neonates with normal echo (0.0%) with (p-value = 0.023). Also, p-pulmonale showed a higher percentage in neonates with abnormal echo (8.3%) than with normal echo (0.0%) with (p-value = 0.006). Finally, the presence of abnormality in ECG can detect abnormality of echo with a

sensitivity of 41.7%, specificity of 98.9%, and AUC of 0.920.

Our results agree with Mackie et al.¹², who discovered that electrocardiograms do not enhance the clinical evaluation's sensitivity for CHD identification. In a different study, the sensitivity and specificity of a superior QRS axis to diagnose a full atrioventricular septal defect were 100% and 96.8%, respectively. However, the majority of CHDs show normal ECG readings.

Our results showed that the combination with SPO2 pre-ductal the difference between pre and post ductal has a sensitivity of 83.3%, specificity of 97.7%, and AUC of 0.968; the total combination between clinical examination, ECG, and SPO2 increase the sensitivity of 83.3 0%, specificity of 96.6 % and AUC of 0.950 than each one alone. These results indicated that a combination of a heart murmur, ECG, po2 post-ductal, and the difference between po2 pre and post-ductal yield the best diagnostic performance for CHD.

Mohammad et al.¹³ confirmed that 25 newborns (about 3% of the total) showed positive screening results out of 830 babies who seemed to be in good health. Pulse oximetry screening failed to detect CCHD in 88.64% of cases. Preciseness was 91.67%. The positive predictive value (PPV) was 92 percent, the negative predictive value (NPV) was 88 percent, and the false-positive rate was 4 percent.

4. Conclusion

There was a strong relationship between echo-abnormality and SPO2 post ductal, ECG, and clinical examination (murmur, respiratory rate, heart rate). When used together, these tools can help doctors spot potentially fatal cases of congenital heart disease earlier. To address this issue, a national strategy to prioritize CCHD screening is necessary.

Disclosure

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