Ascertaining the Prevalence of Heart Malformations in Neonates: A Novel Clinically Approved Solution

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Research Article

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Abstract

Background: It is vital to screen all critical congenital heart defects as early as possible. Screening for congenital heart diseases in neonates is essential for saving children's lives and reducing undetected adult congenital heart diseases. Unfortunately, over 50% of neonates with heart malformations are unrecognized at birth. Accurate screening for congenital heart malformations can be accomplished using the certified and internationally patented digital intelligent phonocardiography machine. The objective of this study is 2-fold: assess the actual prevalence of newborn heart defects in our well-baby nursery and evaluate the digital intelligent phonocardiogram screening for critical congenital heart diseases.

Methods: In this study, we have accomplished "The Neonates Cardiac Monitoring Research Project" (ethics approval IR-IUMS-FMD. REC.1398.098) at Shahid Akbarabadi Maternity Hospital. Eight hundred forty neonates from our well-baby nursery have undergone both the standard clinical examinations at birth and the digital intelligent phonocardiogram examination in a double-blinded format. The median age of the neonates was 30,85 hours, and the median weight was 3.12 Kg. In addition, the pediatric cardiologist has performed echocardiography diagnosis for each neonate classified as abnormal either by the intelligent machine or by the standard medical examinations of a neonate. Detailed dataset of the eight hundred neonates' examinations and printouts of the intelligent machine are available online.

Results: We have found that the prevalence of heart malformations in our well-baby nursery is 5%. 44% of the heart malformations are unrecognized at birth through the standard medical examination of the hospital, including neonates with CCHD, Whereas the intelligent phonocardiogram has recognized 100% of neonates with heart malformations.

Conclusions: We have accomplished screening for congenital heart malformations in all neonates accurately and cost-effectively in our hospital using the digital intelligent phonocardiogram. The intelligent machine has detected CCHD, where we have not detected it through the hospital's standard medical examinations, including pulse oximetry and the heart sound auscultation. In addition, the intelligent machine interprets innocent murmurs as healthy heart sounds.

Background

Various studies show that more than 50% of neonates with congenital heart malformations are unrecognized at birth [1, 2]. The actual prevalence of heart malformations is subject to the social and economic status of different societies. According to different studies, CHD and CCHD account for 10% of all congenital anomalies but cause of around 30% of mortalities caused by congenital malformations traces back to CCHD and CHD [2, 3]. Several studies show that the number of adult patients living with CHD is remarkably high [4]. High pulmonary pressure, high heart bit rate, innocent murmurs, among other factors, make screening for congenital heart malformations of neonates through the standard medical examinations inaccurate while rendering high positive errors. Most neonates heart sound inherent additional sounds, which are not indications of any diseases; they are merely sounds rooted in the

physiology of the newborn heart, called innocent murmurs. Due to various factors, physicians who auscultate neonates' heart sounds often diagnose innocent murmurs as pathological murmurs. Many babies with healthy heart are referred to the subspecialist medical department to be on the safe side. Referring children to subspecialist children cardiovascular centers is a significant concern for families, causes anxiety for parents, and unnecessary echocardiography expenses [3, 4].

Accurate screening of heart malformations in newborns saves lives and substantially reduces the costs of medical care; practically, if all neonates go through screening for heart defects, unrecognized adult CHD will disappear. Doppler echocardiography is the gold standard for accurate detection of heart malformations in newborns. However, echocardiography requires the intervention of a pediatric cardiologist, and the diagnostic timing is relatively long. Therefore, Doppler ultrasound for screening all newborns is not practical [4, 5]. Fortunately, there is a new and passive technology for accurate CHD and CCHD screening in neonates based on artificial intelligence and spectral mathematical modeling.

Intelligent Phonocardiography Machine

The intelligent phonocardiogram comprises an electronic stethoscope, a medical computer cart, and a medical monitor. The technician records 10 seconds of heart sound from two different sites of either one of four thoracic sites of a newborn into the intelligent machine. The diagnosis result appears on the screen, either normal or abnormal in real-time, along with a printout. There are printouts samples in the data repository, and the links are in the availability of data and materials section. The machine considers a neonate's heart sound a healthy sound if the diagnostic results from both thoracic sites are healthy. Innocent murmurs are automatically and precisely classified as healthy sounds by the intelligent machine [6]. The spectral mathematical modeling of a child's heart sound generation in conjunction with advanced artificial intelligence is the theoretical scientific tool of the intelligent machine. The technology of the digital intelligent phonocardiogram that accurately screens CHD and CCHD in children is internationally patented. The intelligent machine groups the heart sounds into two classes, normal or abnormal in real-time [7, 8]. Proportionate to the physiological characteristics of neonate's heart and the cardiac changes during the first 28 days, a maternity version of the digital intelligent phonocardiogram is now available.

The prevalence of small PFO and closing PDA is relatively high in newborns [9, 10]. The intelligent machine has the option of choosing whether to screen all heart defects, including small PFO and closing PDA or not. We have selected the latter option in the present research work-study.

The digital intelligent phonocardiography machine has obtained approval and certifications from the Iranian Society of Neonatology and the Ministry of Health and Medical Education.

Methods

Around 15 babies are born every day in our hospital. Each neonate undergoes the standard medical examinations. In this study, eight hundred forty neonates from our well-baby nursery have undergone both the standard medical examinations at birth and the intelligent machine examination in a double-

blinded format. The median age of the neonates was 30,85 hours, and the median weight was 3.12 Kg. In addition, the pediatric cardiologist has performed echocardiography diagnosis for each neonate classified as abnormal either by the intelligent machine or by the standard medical examinations. The echocardiography is also performed for neonates under 34 weeks of gestational age, weighing less than 1,500 grams, and those whose mothers have gestational diabetes or any other sickness with a risk of causing heart malformations for their children. The dataset includes detailed results of all the examinations, including rate and strength of the pulse, neonatologist auscultation, pulse oximetry testing of four limbs, family records, echocardiography diagnosis results, echocardiography follow-up, comments on the family records. The dataset of the eight hundred forty neonates and the printouts of the intelligent machine are available in the CAPIS repository, in which the links come in the availability of data and materials section.

There is no timing restriction for performing the intelligent machine examination. The dataset shows that the intelligent machine examination has taken place from 1 hour to 192 hours after birth. The Doppler echocardiography diagnosis has been performed from 2 hours up to 72 hours after the intelligent machine screening. Tables 1 and 2 show detailed data of the 42 abnormal cases.

Table 1. Echo diagnoses of the 42 neonatesrecognized of having heart defects by the intelligent machine

5 small ASD; 1 small ASD/mild TR; 1 small VSD; 1 PDA with significant shunt; 1 large PFO/mid mmc VSD/LR shunt; 1 PDA with continuous shunt; 1 PDA with the mild left to right shunt; 5 small PDA; 5 PFO/small PDA; 2 PFO; 2 PDA/PFO; 2 PDA/mil TR; 2 PFO/small PDA/mild IHSS; 2 PFO/mil IHSS, 1 PDA/LVH/IHSS; 1 PFO/LVH; 1 mild TR; 2 LVH; 2 mild LVH/mild IHSS; 2 mild LPA stenosis; 1 IHSS/IVC; 1 COA (CCHD)

Results

Screening 840 neonates for congenital heart malformations by the intelligent machine has resulted in detecting 42 neonates with heart defects. The echocardiography diagnoses of the 42 cases have shown that all the cases have had at least one critical, severe, moderate, or mild congenital heart disease. Types of the 42 congenital heart malformations that the echocardiography diagnosis has found are in table 1. Table 2 shows that forty-four percent of the 42 abnormal cases were unrecognized at birth through the standard medical examinations. Table 2 also shows that the prevalence of congenital heart malformation in our well-baby nursery is 5%.

Table 2
Data extracted from the 840 neonates dataset

1	Neonates examined	840	9	Standard medical examination including auscultation, CHD & CCHD detection negative error	44%
2	Median age	30,85 hours	10	Intelligent machine, CHD & CCHD detection negative error	0%
3	Limit of age	1 hour to 192	11	Number of CCHD & severe CHD detected in the well-baby nursery	2
4	Median weight	3,12 Kg	12	Negative error rate of CCHD detection through the standard medical examinations of the hospital in this study	100%
5	Female neonates	414	13	Intelligent machine, CCHD detection negative error	0%
6	Male neonates	426	14	Auscultation (human ear), precise CHD & CCHD detection	21%
7	Heart malformations Detected	42 (13 f & 29 m)	15	Standard medical examination including auscultation, precise CHD & CCHD detection	56 %
8	Auscultation (human ear) negative error	79%	16	Intelligent machine, CHD & CCHD precise correct detection	100%

Tables 2 also demonstrates that through the standard medical examination, the neonate with CCHD was unrecognized at birth. Detail of the examinations for the CCHD case is in row 70 of the dataset. The standard medical examinations results of the neonate with CCHD includes pulse oximetry of 96, the neonatologist auscultation as healthy, no family records (under comment section). The link to the dataset is in the availability of data and materials section. Table 2 shows that the standard medical examinations have recognized only 56% of the neonates with heart malformations at birth. At the same time, the digital intelligent phonocardiogram examination has recognized 100% of the 42 abnormal cases, including one neonate with CCHD and one with severe CHD (row 585 of the dataset).

Discussion

The dataset shows that the intelligent machine has detected 43 neonates as having heart malformations. The echocardiography diagnoses have confirmed that 42 cases of the 43 neonates have heart defects; table 1 presents the echocardiography results of the 42 confirmed cases. The echo diagnosis shows the one in row 747 of the dataset as healthy, whereas the intelligent machine examination has shown it as having a heart defect; in other words, the positive error rate of the intelligent machine is 0.1%. However,

the pediatric cardiologist has performed echocardiography diagnosing 48 hours after the intelligent machine auscultation. Therefore, there is a possibility that the intelligent machine has detected mild heart defects but, it has been self-recovered after 48 hours. Nevertheless, Self-recovery of a mild CHD after 48 hours is highly probable.

44% of the 42 neonates with congenital heart malformations, including one CCHD case, have not been recognized at birth through the standard medical examinations, (Table 2). We have encountered one CCHD during this study among neonates of our well-baby nursery, referring to Tables 1 and 2. As indicated in row 70 of the dataset, the CCHD was detected only by the intelligent machine examination and not detected through the standard medical examinations at birth, which includes Pulse oximetry testing (pulse oximetry has indicated 96, which is in the accepted range, no murmur heard by the auscultation examination and no family records indication). Also, one severe CHD existed in our well-baby nursery during the study, Tables 2 (row 585 of the dataset). Consequently, without the intelligent machine examination, unrecognized neonates with heart malformations at birth would have been considered healthy and would have left the hospital with unrecognized heart malformations. Therefore, if the subspecialists did not perform the standard medical examinations of the hospital or if the hospital were not well-equipped, the rate of unrecognized newborns with heart malformations at birth would have risen considerably. Some studies show that over 50% of neonates with congenital heart defects leave the hospitals with unknown heart malformations [1]. Therefore, adding the intelligent machine into neonates' standard medical examinations at birth will increase the recognition of newborns with congenital heart malformations by around 50%. Other studies show that adult congenital heart defects are increasing by 5% annually [4]. Adding the intelligent machine examination to the standard medical examination of the hospital not only detects all neonate congenital heart malformations on time, but it will considerably reduce adult patients living with congenital heart defects (ACHD). The whole process of screening congenital heart malformation by the passive intelligent machine takes a few minutes. A trained technician does the operation of the intelligent machine. Screening all neonates for heart malformations at birth can be accomplished by the intelligent phonocardiography machine auscultation. Screening CHD and CCHD are performed with high accuracies by the digital intelligent phonocardiogram, even just after birth, as shown in the dataset and Tables 1 and 2.

Conclusions

Screening for heart malformations of all neonates at birth can be accomplished accurately and cost-effectively by using the intelligent phonocardiography machine. The intelligent machine precisely detects unrecognized CCHD left through the standard medical examinations. The intelligent machine interprets innocent murmurs as healthy heart sounds. Unnecessary echocardiography diagnosis is no longer needed but, echo diagnosis demand will rise by 50% in maternity hospitals and later, for known children with heart malformations. Choosing small PFO and closing PDA detection mode of the intelligent phonocardiography machine, increases echocardiography diagnosis demand considerably. The prevalence of heart malformations in our well-baby nursery is 5%; Table 2 shows the 840 neonates' examinations data statistics. Forty-four percent of neonates with heart malformations would have left the

hospital through the standard medical examinations of our well-baby nursery. Therefore, the Widely accepted prevalence of 1% for congenital heart defects is not correct. Screening all newborns for heart malformations by the intelligent phonocardiography machine causes a drop in the number of adults living with CHD considerably. We have not observed any negative error during the trial of the passive intelligent machine by random verification neither in our well-baby nursery nor in our NICU. As shown in the dataset, the intelligent phonocardiography machine interprets the innocent murmurs as healthy heart sounds.

Now, there is a practical and cost-effective solution for accurately screening CHD and CCHD in all neonates; having the exact prevalence of congenital heart malformations of neonates will significantly impact pediatrics healthcare and vanishing unrecognized ACHD.

Abbreviations

CHD: Congenital Heart Diseases; CCHD: Critical Congenital Heart Diseases; ACHD: Adult Congenital Heart Disease; NICU: Neonatal Intensive Care Unit; VSD: Ventricular Septal Defect; ASD: Atrial Septal Defect; COA: Coarctation of the Aorta; TR: Triscupid Valve Regurgitation; PDA: Patent Ductus Arteriosus; PFO: Patent Foramen Ovale; IVC: Inferior Vena Cava; LPA: Left Pulmonary Artery; LVH: Left Ventricular Hypertrophy; IHSS: Idiopathic Hypertrophic Subaortic Stenosis.

Declarations

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Authors' Contributions

‘AB’ is head of the medical team, ‘MK’ is collaborator supervisor in the medical team. ‘MV’ is the resident under ‘AB’ and has worked as the researcher in this study. ‘AS’ is the technical supervisor and the principal inventor of the digital intelligent phonocardiogram. EP has operated the intelligent machine examination and has performed some data analysis.

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Availability of data and materials

The dataset includes detailed results of all the 840 neonates examinations, echocardiography diagnosis results, echocardiography follow-up, and comments on the family records. The dataset and the printouts of the intelligent machine are available in the CAPIS repository, in which the links come hereunder. The forty-three printouts carry the same numbers that correspond to the dataset. There are 42 printouts of neonates with heart malformations and one printout of a healthy neonate sample.

The dataset

https://capis.be/media/hstlreco/840-neonates-examination-result.pdf

The Printouts

https://capis.be/media/gznagtbc/pouya-heart-printouts.rar

Ethics approval and consent to participate

In this study, each neonate has undergone the examination after obtaining informed consent from the legal guardians, according to the study protocol. The local ethic committee of Shahid Akbarabadi Clinical Research & Development Unit (ShACRDU) has approved the study concerning IR.IUMS.FMD.REC.1398.098, conducted according to the codes of the World Medical Association and Declaration of Helsinki.

Consent for publication

Not applicable

Competing interests

The authors declare that they have no competing interests.

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