

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

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## Research Article

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## *Research Article*

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

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## **Abstract**

**Background:** Screening of all congenital heart malformations (CHD & CCHD) , as early as possible, is essential to save children's lives and, vanishing undetected CHD before becoming adult congenital

heart disease (ACHD). As it is known, over 50% of neonates with heart malformations are not recognized at birth. Accurate screening of congenital heart malformations can be accomplished by a certified and patented passive intelligent machine known as Pouya Heart. The objective of this study is 2-fold: to evaluate true prevalence of neonates heart malformations and to evaluate screening of critical congenital heart diseases (CCHD) by the intelligent machine.

**Methods:** 840 neonates with a median age of 31.16 hours and a median weight of 3.11 Kg from the well-baby nursery have been screened by the passive intelligent machine. 20 seconds of heart sounds are recorded into the intelligent machine from two thoracic sites. Each neonate is then classified as normal or abnormal. Echocardiography diagnosis is carried out for verification of each abnormal case.

**Results:** The prevalence of heart malformations (CHD & CCHD), in our well-baby nursery, is 5%. Where, 44% of the heart malformations have not been recognized at birth through the standard medical examination routine.

**Conclusions:** Screening of congenital heart malformations, in all neonates, can be accomplished accurately and cost-effectively by using the Pouya Heart. It detects even CCHD in which it has not been detected through standard medical routine. The innocent murmurs are interpreted as healthy heart sounds.

**Keywords:** Congenital heart malformations; Congenital heart diseases; Critical congenital heart diseases; Pouya Heart; Innocent murmurs.

## **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 social and economic status of different societies. According to different studies, CHD and CCHD, account for 10% of all congenital anomalies, but the cause of around 30% of mortalities caused by congenital malformations can be traced back to CCHD and CHD [2,3]. Several studies also show that the number

of adult patients living with CHD is remarkably high. High pulmonary pressure, high heart rate, innocent murmurs, among other factors, make screening of congenital heart malformations through the Neonates' standard medical routine inaccurate, while rendering high positive errors. Due to various factors, innocent murmurs are often diagnosed as pathological murmurs through the standard medical routine examinations. More than 70% of neonates' heart sounds contain additional sounds, which are not sign of any diseases; they are merely sounds rooted in the physiology of a newborn's heart, called innocent murmurs. Many children who have a normal heart with innocent murmurs are referred to the subspecialist medical department just to be on the safe side. Referring children to subspecialist children cardiovascular centers is a major concern for families, causes anxiety for the parents as well as unnecessary echocardiography expenses [3,4]. However, it is widely accepted that prevalence of congenital heart defects is 1%, which is obviously questionable and well underestimated.

Accurate screening of heart malformations (CHD & CCHD), in newborns saves lives and substantially reduces the costs of medical care; practically, unrecognized adults' CHD will disappear. Doppler echocardiography is the gold standard for accurate detection of heart malformations in newborns. But echocardiography requires intervention of a pediatric cardiologist and the diagnostic timing is relatively long. Therefore, the use of Doppler ultrasound for screening all newborns is not practical [4, 5]. Based on artificial intelligence and mathematical modeling, there is a new and passive technology for accurate screening CHD and CCHD, in neonates. This is done using an intelligent phonocardiography machine called Pouya Heart [6].

#### **Pouya Heart:**

Pouya Heart is a passive intelligent machine, and it is operated by a qualified technician. The intelligent machine consists of an electronic stethoscope, a medical computer cart and a medical monitor. Screening of the heart defects is carried out by recording 10 seconds of heart sounds from two different thoracic sites of a newborn into the intelligent machine. The machine classifies each neonate

as either normal or abnormal and the result is shown on the monitor and there is also the printout. The diagnostic result is shown in real-time, and a printout of the heart sounds status is provided for both normal and abnormal cases. A newborn is considered healthy only if the diagnostic results from both thoracic sites are normal. Innocent murmurs are automatically and precisely classified as healthy sounds by the intelligent machine [6].

The main technology of the intelligent machine is based on an internationally patented mathematical modeling of a child heart sound production. The mathematical model is integrated into the intelligent machine and it groups the heart sounds into two classes, normal or abnormal, in real-time. The models are designed by introducing and using advanced artificial intelligence algorithms [7, 8]. Considering the specificities of a neonate's heart and cardiac changes during the first 28 days, a maternity version of Pouya Heart is designed and after a long period of clinical verifications, it has been validated and certified for screening congenital heart malformations in newborns.

prevalence of relatively small PFO and closing PDA is high in newborns [9, 10]. there is an option of choosing screening all relatively small PFO and closing PDA or not choosing detection of such non-significant CHD by the intelligent machine. The latter case has been chosen in the present research work study.

Pouya Heart has been clinically validated and approved by several pediatrics and maternity university hospitals as well as pediatrics medical centers including private sectors for screening congenital heart malformations (CHD & CCHD), in neonates as well as in children. Moreover, the intelligent machine has obtained approval of the Iranian Society of Neonatology. Pouya Heart is certified by the Ministry of Health and Medical Education.

## **Methods**

There are on average, around 15 newborns per day at Shahid Akbarabadi University Hospital. Each of whom, is subjected to the standard clinical routine examination. All the 840 examined neonates also

have undergone the standard medical routine. This procedure is performed by experienced neonatologists who are the university scientific members. The cardiac examination includes the rate and strength of the pulse, auscultation, pulse oximetry of four limbs, family records, etc. Echocardiography is requested if there is any sign of the heart malformations; 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 her child.

In this study, 840 neonates from our well-baby nursery have been examined by means of the maternity version of the passive intelligent machine. However, all neonates of our well-baby nursery undergo standard clinical routine examination. Each newborn with an abnormal diagnosis, either through standard clinical routine examination or by the passive intelligent machine, undergoes echocardiographic diagnosis, performed by pediatric cardiologist. Pouya Heart screening has been done from 2 hours to 216 hours after the birth. The Doppler echocardiography diagnosis has taken place from 2 hours up to 72 hours after Pouya Heart screening. Table 1 shows details of the 42 abnormal cases.

As it is shown in table 1, there is not any timing restriction for performing the examination by the intelligent machine, it can be done right after the birth.

Table 1. Screening results of the 840 neonate for congenital heart malformations

| <b>Heart malformations</b> | <b>Neonate</b> | <b>Follow up</b>   | <b>Heart malformations</b> | <b>Neonate</b> | <b>Follow up</b> |
|----------------------------|----------------|--------------------|----------------------------|----------------|------------------|
| small ASD                  | 5              | Three months later | PFO                        | 2              | One week later   |
| small ASD, mild TR         | 1              | Three months later | PFO/small PDA/mild IHSS    | 2              | One week later   |
| small VSD                  | 1              | Two months later   | PDA/PFO                    | 2              | One week later   |

|                                   |   |                |                                |   |                |
|-----------------------------------|---|----------------|--------------------------------|---|----------------|
| PDA (with significant shunt) + MA | 1 | 5 days later   | large PFO/mid mmc VSD/LR shunt | 1 | NICU           |
| PDA with continues shunt          | 1 | One week later | PFO/small PDA/mild IHSS        | 2 | One week later |
| PFO/mild IHSS                     | 2 | One week later | PFO/LVH                        | 1 | One week later |
| small PDA                         | 5 | One week later | mild TR                        | 1 | One week later |
| PFO/mild TR                       | 2 | One week later | LVH                            | 2 | One week later |
| PFO/small PDA                     | 5 | One week later | mild LVH/mild IHSS             | 2 | One week later |
| PFO                               | 2 | One week later | mild LPA stenosis              | 2 | One week later |
| PDA/PFO                           | 2 | One week later | IHSS/IVS                       | 1 | One week later |
| PDA/LVH/IHSS                      | 1 | One week later | COA(CCHD)                      | 1 | NICU           |

Result of medical routine examination of 840 neonates plus Pouya Heart printouts are available in CAPIS repository, the links are given in section of availability of data and materials section.

## Results

Screening the 840 neonates for congenital heart malformations (CHD & CCHD), by the Pouya Heart, has resulted in 43 abnormal heart sounds. The echo diagnosis of the abnormal cases has shown that 42 cases had severe, moderate, and mild heart defects. One case has been verified by echo diagnosis as normal, in other words, the positive error occurrence rate is 0.1%. However, echocardiography diagnosing of this case has been performed by the pediatric cardiologist, 48 hours after the intelligent machine auscultation. There is a possibility that a mild heart disease has been detected by the intelligent machine and it has been self-recovered after 48 hours. Self-recovery of a mild CHD after 48 hours is highly probable. 44% of the 42 abnormal cases were not recognized through the standard

medical routine. For 56% of the 42 cases, echocardiography examination has been also requested by the standard clinical routine examination. The prevalence of the congenital heart malformation in our well-baby nursery is 5%.

## **Discussion**

44% of the 42 neonates with congenital heart malformations, including one CCHD case, have not been recognized at birth through the standard medical routine. Consequently, without the Pouya Heart examination, the unrecognized neonates (44% Of 42 cases) with heart malformations would have been considered as healthy. Therefore, if the standard medical routine were not performed by the subspecialists or if the hospital was not well-equipped, the rate of the unrecognized newborns with heart malformations at birth, would have risen considerably. As it is shown by some studies, over 50% of neonates with congenital heart malformations, are not recognized at birth in a standardized maternity hospital [1]. Consequently, adding Pouya Heart to the neonates' standard medical routine examination, will increase recognition of newborns with congenital heart malformations (CHD & CCHD) by around 50% in standardized maternity university hospitals consequently, the number of adult patients living with congenital heart defects (ACHD) decreases considerably. The whole process of screening congenital heart malformation by the passive intelligent machine takes a few minutes, operated by a trained technician. Consequently, with the rise of this new patented technology, there is a practical and cost-effective solution for overcoming the past obstacles. Screening all neonates for heart malformations at birth, can be accomplished by Pouya Heart auscultation. The screening is performed through a mathematical model of the newborns' heart sounds generation. As our experiments show, screening CHD and CCHD are performed with high accuracy by the Pouya Heart even just after birth.

## **Conclusions**

Screening of the heart malformations of all neonates at birth, can be accomplished accurately and cost-effectively by using the passive intelligent machine, Pouya Heart. The machine precisely detects CCHD. The intelligent machine interprets innocent murmurs as healthy heart sounds. The prevalence of the heart malformations in our well-baby nursery is around 5%. 44% of the neonates with heart malformation have not been recognized at birth through standard medical routine in the well-baby nursery. The widely accepted prevalence of 1% for the congenital heart defects is obviously not correct and it is largely underestimated. Screening all newborns' heart malformation by Pouya Heart not only will save children's lives, but also the number of adults living with CHD will drop considerably. We have not practically observed any negative error during the trial of the passive intelligent machine by random verification in our well-baby nursery as well as in our NICU. The passive intelligent machine interprets the innocent murmurs as healthy heart sounds. Considering the high number of the screening positive errors which cause anxiety for the parents as well as unnecessary echocardiography expenses, the clear distinction between innocent murmurs and pathological murmurs is a great scientific and medical achievement.

Screening heart malformations of all neonates can be accomplished accurately and cost-effectively by using Pouya Heart, in other words, there is a practical and cost-effective solution for accurately screening CHD and CCHD in all neonates.

## **Abbreviations**

CHD: Congenital Heart Diseases; CCHD: Critical Congenital Heart Diseases; ACHD: Adult Congenital Heart Disease; NICU: Newborn Intensive Care Unit.

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## **Authors' Contributions**

Dr. Bordbar, is the head of medical team, Dr. Kashaki is the collaborator supervisor in the medical team. Dr. Vafapour is resident under supervision of Dr. Bordbar and working as researcher in this study. Dr. Sepehri is the technical supervisor and the principal inventor of Pouya Heart. Mrs. Partovi has managed the neonate's examinations by Pouya Heart and has performed the data analysis.

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## **Availability of data and materials**

The datasets generated and analyzed during the current study are available in CAPIS repository:

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

<https://capis.be/media/sl2lttcB/printout.rar>

## **Declarations**

### **Ethics approval and consent to participate**

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