Neonatal screening with pulse oximetry

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CHAPTER 3

Adapted protocol for pulse oximetry screening for congenital heart defects in a country with home births

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Eur J Pediatr. 2015 Jan;174(1):129-32.

ABSTRACT

Pulse oximetry has been recommended for neonatal screening for critical congenital heart defects (CCHD) and is now performed in several countries where most births take place in hospital. However, there is a wide variation in perinatal care in European countries and studies are now recommended to determine the cost-effectiveness CCHD screening in individual countries. In the Netherlands, a large part of births is supervised by a community based midwife, at home or policlinical. A screening protocol has been developed to fit into the Dutch perinatal setting, and also has the potential to increase safety in home birth deliveries.

Conclusion*:* the provided protocol might be useful for other countries that are planning to implement CCHD screening after home births or early discharge from hospital.

What is known: pulse oximetry screening is a recommended tool to screen newborns for critical congenital heart defect and is implemented increasingly. So far, the screening only takes place in hospital.

What is new: The presented screening protocol is adapted to fit into a perinatal setting with home births and early discharge after delivery in hospital.

INTRODUCTION

Congenital heart defects (CHD) are the most common birth defects, occurring in 0.8% of live births and are a leading cause of infant death in the developed world. Approximately 20-30% of the CHD are critical (CCHD) and require surgical or catheter intervention in the first month of life.[1] Early detection of CCHD in both pre- and postnatal period is vital for the prognosis.[2] However, recent unpublished data from the Amsterdam-Leiden region, in the Netherlands, have shown that still around 50% of CCHD cases remain undetected in the prenatal stage. Also, after birth around 30% of CCHD are missed since physical examination alone is not sensitive enough for screening.[3] It is expected that early detection can decrease the incidence and severity of brain injury and increase chances of survival.[3]

Pulse oximetry (PO) is a simple and non-invasive method for screening for CCHD in low risk infants.[4] A systematic review of 13 studies has shown a sensitivity of 76.5%, a specificity of 99.9% and a false positive rate of 0.14%.[2] Moreover, studies imply that 27-70% of infants with false positive tests were diagnosed with other significant pathology, such as non-critical CHD, persistent pulmonary hypertension of the newborn (PPHN), infection and sepsis.[1, 4] In 2011 PO screening was recommended by The Health and Human services, and it is now introduced in the United States, Switzerland and regionally in Abu Dhabi, recommended in Poland, and piloted in several countries, including the United Kingdom, Nordic European countries and China.[1,5] In these countries the screening normally takes place in hospital, prior to discharge, at least two hours and mostly 24-48 hours after birth.[6] Thangaratinam *et al.* showed that the false positive rate is lower when the screening is obtained >24 hours after birth.[2] However, a recent study of Singh *et al.* with screening <12 hours after birth showed a false positive rate of 0.16% of which 79% suffered from other significant pathology and a Polish study with screening at median age of 7 hours showed a false positive rate of only 0.026% with other significant pathology found in 43% of these false positive screening tests.[4, 12] Early screening can have the potential of detecting CCHD and other significant pathology in an early stage leading to a lower morbidity and mortality. So far, CCHD screening has only been performed in countries where almost all mothers give birth in hospitals. Recently, experts on PO screening published their awareness of variable settings in international perinatal health care systems. For this reason, they recommend the performance of individual pilot studies.[6]

In the Netherlands, the perinatal health care of low-risk infants is unique compared to other countries. Community based midwives supervise 33% of all deliveries, either at home, at a birth clinic or in hospitals. In case of a home birth, the midwife stays for approximately three hours after birth, to return for follow-up on the second or third day. After an uncomplicated birth in hospital mother and child are discharged within a few hours. The baby will be checked

upon at home by the midwife one or two days later. Although studies have shown the benefits of implementing PO for CCHD screening, the question remains if it is possible to fit the PO screening in the Dutch setting of perinatal care and to reach the same benefits. To perform an adequate PO screening in the Netherlands would implicate that all 1854 midwives from home practices would need a pulse oximeter at their disposal. Although recent cost-effectiveness studies have shown that PO as an additional screening tool for CCHD is likely to be cost-effective[8], it remains to be determined whether the benefit of CCHD screening in the Netherlands weighs against the costs of providing all midwives with a pulse oximeter. In addition, infants with positive screenings at home should be transported to hospitals by ambulance, possibly causing more distress in parents and midwives supervising the births than previously described in mothers of infants with false positive screenings.[9] Also, logistics would be a challenge; in very few regional hospitals echocardiography is possible and all infants with persistent unexplained abnormal SpO_2 readings would need to be referred to the academic hospitals.

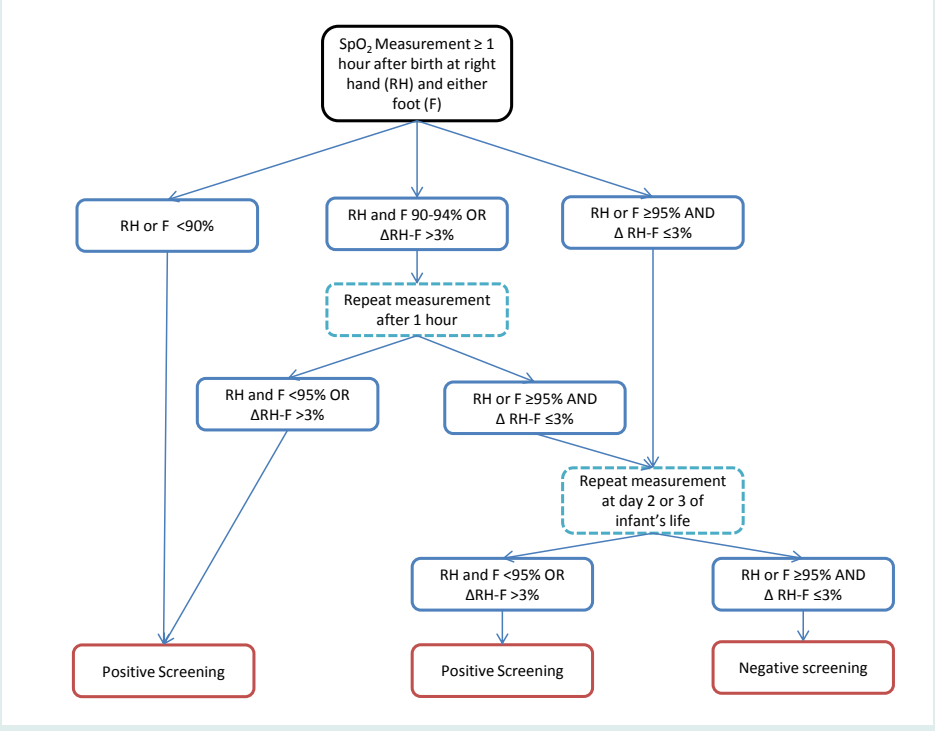
Next to early detection of CCHD, the use of PO at home could also play a role in detecting other potential life-threatening diseases. Indeed, in previous screening studies 27-70% of the false positive screenings were due to other pathology, such as early-onset sepsis or transitional problems.[1,4,12] It is vital that infants with those problems who were born at home are diagnosed and referred to hospital early in the course of the disease. Studies are required, but using pulse oximetry at home can have the potential to increase the safety of home births. A previous study with community based midwives has shown the feasibility of PO to assess infants born at home.[10]

A screening protocol that would take all the above-mentioned issues into account was needed and the current recommended protocol was adapted to the Dutch perinatal setting. The algorithm of the presented protocol (Figure 1) deviates in some aspects from the screening protocol proposed by an American work group of experts. The measurements will be performed at two time points, with a first measurement in the first hours (at least one hour) after birth and the second on day two or three. Another deviation is that the measurement is repeated only once instead of twice after being abnormal but above 90%.[11]. The oxygen saturation (SpO_2) is measured using a portable pulse oximeter (Nellcor™ N-65 portable pulse oximeter (Covidien, Dublin, Ireland)) with the probe placed at the right hand (pre-ductal) and consecutively at the right or left foot (post-ductal). The measurements are performed at least 1 hour after birth.

If the pre- or post-ductal SpO_2 at the measurement at least 1 hour after birth is <90%, the screening test is considered positive. If the pre- and post-ductal SpO_2 are 90-94% or if the difference between pre- and post-ductal SpO_2 is >3%, the test will be repeated after one hour. If the pre- or post-ductal SpO_2 is ≥5% and the difference between pre- and post-ductal

SpO_2 is ≤3%, the screening test will be repeated on day two or three. The screening test on day two or three of life is considered positive if the pre- and post-ductal SpO_2 are <95% or if the difference between pre- and post-ductal SpO_2 is >3%.

Figure 1. flowchart of pulse oximetry screening.



The decision tree of the protocol is shown. SpO_2: peripheral oxygen saturation; RH: right hand; F: either foot

There is no medical follow up for infants with a negative screening. In case of a positive screening, the infant will be referred to the paediatric department to rule out CCHD. Physical examination including pre- and post-ductal SpO_2 measurements will be performed. Echocardiography will be performed in the Leiden University Medical Center in case of persisting abnormal SpO_2 values.

This is the first screenings protocol adapted to a health care system with a high proportion of home births, with measurements taken in the first hours after birth and on day 2 or 3. Other early screening studies did not show a higher amount of false negatives or a lower sensitivity, but these studies were performed with a median screening time of at least 7 hours after birth.[1,4,12] As our first measurement is performed in the very first hours after birth, even 1

hour after birth, SpO_2 values of infants with CCHD may be just within the normal limits due to wide patency of the ductus arteriosus. The PO measurement at the second or third day of life allows for a second chance to detect CCHD with lower SpO_2 values during functional closure of the ductus. A possible advantage of early screening would be the early catch of cardiac and non-cardiac pathology, enabling early intervention and possible prevention of deterioration of the clinical state of the infant and shorter hospitalization.[1,4,12]

The protocol might be useful for other countries that are planning to perform CCHD screening after home birth or with early discharge from hospitals after a delivery.

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