Accuracy of Pulse Oximetry Screening for Critical Congenital Heart Defects after Home Birth and Early Postnatal Discharge

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Objective To assess the accuracy of pulse oximetry screening for critical congenital heart defects (CCHDs) in a setting with home births and early discharge after hospital deliveries, by using an adapted protocol fitting the work patterns of community midwives.

Study Design Pre- and postductal oxygen saturations (SpO_2) were measured ≥1 hour after birth and on day 2 or 3. Screenings were positive if the SpO_2 measurement was <90% or if 2 independent measures of pre- and postductal SpO_2 were <95% and/or the pre-/postductal difference was >3%. Positive screenings were referred for pediatric assessment. Primary outcomes were sensitivity, specificity, and false-positive rate of pulse oximetry screening for CCHD. Secondary outcome was detection of noncardiac illnesses.

Results The prenatal detection rate of CCHDs was 73%. After we excluded these cases and symptomatic CCHDs presenting immediately after birth, 23 959 newborns were screened. Pulse oximetry screening sensitivity in the remaining cohort was 50.0% (95% CI 23.7-76.3) and specificity was 99.1% (95% CI 99.0-99.2). Pulse oximetry screening was false positive for CCHDs in 221 infants, of whom 61% (134) had noncardiac illnesses, including infections (31) and respiratory pathology (88). Pulse oximetry screening did not detect left-heart obstructive CCHDs. Including cases with prenatally detected CCHDs increased the sensitivity to 70.2% (95% CI 56.0-81.4).

Conclusion Pulse oximetry screening adapted for perinatal care in home births and early postdelivery hospital discharge assisted the diagnosis of CCHDs before signs of cardiovascular collapse. High prenatal detection led to a moderate sensitivity of pulse oximetry screening. The screening also detected noncardiac illnesses in 0.6% of all infants, including infections and respiratory morbidity, which led to early recognition and referral for treatment. *(J Pediatr 2018;■■:■■-■■).*

Pulse oximetry is an accurate and cost-effective screening method for critical congenital heart defects (CCHDs) in healthcare settings with in-hospital deliveries and is acceptable to parents and caregivers.[1-5] Pulse oximetry also improves detection of other significant noncardiac illnesses in neonates, including respiratory illnesses and infections.[6,7] As a result, pulse oximetry screening increasingly is implemented as standard care throughout the world.[7-11] However, the accuracy of pulse oximetry screening in unique healthcare settings, for example, where home births predominate or where early postnatal discharge after a hospital delivery is encouraged, has not been studied in a large cohort.

The length of postdelivery hospital stay in many European countries is relatively short, with a trend toward discharge within 12 hours after an uncomplicated delivery.[8,12] In this situation, screening for CCHDs should be performed in the first hours after birth. Although most deliveries in developed countries occur

CCHD	Critical congenital heart defect
PPHN	Persistent pulmonary hypertension of the neonate
SpO_2	Oxygen saturation

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in the hospital, home births also occur. In Australia and New Zealand, the home birth rates are stable at 0.4% and 3.4%, respectively, and these rates have increased in England and Wales (2.4%) and the US (1.4%) in the last decade.[13-16] In The Netherlands, the perinatal care system has a high home birth rate (18%) and early postnatal discharge (within 5 hours) after an uncomplicated vaginal birth in hospital.[17] Community midwives supervise 29% of all deliveries in The Netherlands.[16-18] Furthermore, prenatal screening is well-structured, and only trained ultrasonographers perform the standard anomaly scans at 20 weeks of gestation. National implementation of pulse oximetry screening in the Dutch perinatal care setting would require community midwives to perform the measurements at home. Consequently, all 1850 community midwives would need to have a pulse oximeter as part of their standard equipment. The timing of screening also would need to consider the presence of a perinatal caregiver; community midwives stay for <3 hours after birth following an uncomplicated delivery and visit the mother and infant on day 2 or 3 of life for follow-up. Mothers and infants who are discharged home within 5 hours after an uncomplicated vaginal in-hospital delivery also are visited for follow-up by community midwives at day 2 or 3 of life.

We recently conducted a feasibility study of screening for CCHDs in this setting, in which we reported 99% screening rate of infants with parental consent.[19] We also observed that pulse oximetry screening detected other significant noncardiac illnesses in neonates at an early stage, such as perinatal infections and persistent pulmonary hypertension of the neonate (PPHN). Early detection of these morbidities might be of extra importance because these infants are born at home or discharged early from the hospital. However, this feasibility study with 3059 included infants was too small to analyze the accuracy of pulse oximetry screening for CCHDs.

The aim of the current study was to assess the accuracy of pulse oximetry screening for CCHDs in a larger study cohort in The Netherlands by using an adapted protocol fitting the work patterns of community midwives. We also assessed the detection of noncardiac illnesses.

Methods

Between July 2015 and December 2016, we performed a prospective trial in The Netherlands in the regions of Leiden, Haarlem, Hoofddorp, Amsterdam, Alkmaar, and Purmerend. The study was conducted in 75 regional community midwifery practices, 11 regional hospitals, and 3 academic hospitals. Approximately 30 000 infants are born annually in this region.

All infants with a gestational age ≥35 weeks who were not admitted to the pediatric department with a clinical indication for pulse oximetry monitoring were eligible for pulse oximetry screening. Parents were informed of the pulse oximetry screening by their caregiver before birth both verbally and by means of a flyer and website. An opt-out strategy was used. Infants with prenatally diagnosed CCHDs or symptoms directly after birth were not screened according to the protocol. The study was approved by the Leiden Medical Ethics Committee (institutional review board) in January 2015.

The primary outcome was the accuracy of pulse oximetry screening for CCHDs, determined by the sensitivity, specificity, false-positive rate, false-negative rate, and positive and negative predictive value. CCHDs were defined as all congenital heart defects that lead to death or require surgical or catheter intervention within the first 28 days of life, including hypoplastic left heart syndrome, pulmonary atresia with intact ventricular septum, simple transposition of the great arteries, interrupted aortic arch, critical coarctation of the aorta, critical aortic or pulmonary valve stenosis, critical tetralogy of Fallot, or total anomalous venous return. The secondary outcome was the detection of noncardiac illnesses with the screening.

We assessed the accuracy measures for all screened infants and separately for CCHDs with acyanotic left heart obstruction. Also, all infants with a prenatal diagnosis had pulse oximetry monitoring, and we obtained the oxygen saturation (SpO_2) values 1-2 hours after birth and on day 2 or 3 to assess whether pulse oximetry screening would have detected these defects as well in a secondary analysis.

The timing of pulse oximetry screening was adapted to coincide with the regular home visits of community midwives after birth, thereby avoiding the need for extra visits. The timing of the protocol provided by the American Association of Pediatrics and by de Wahl Granelli et al was changed from measuring between 24 and 48 hours after birth to screening on 2 separate moments: on day 1, at least 1 hour after birth, and on day 2 or 3 of life.[10,20] Also, the screening in our protocol was considered positive after 2 instead of 3 abnormal readings, because of limits in the visiting time of community midwives. Pulse oximetry measurements were performed by a nurse or midwife, with the sensor placed on the right hand/wrist and either foot of the infant in a nonspecified order. The screening performers were trained in a 1-day session to wait until a stable signal was obtained, based on the plethysmogram and messages on the pulse oximetry device. This was usually between 2 and 5 minutes. For this study, all caregivers used a Nellcor PM10N handheld pulse oximeter with reusable sensors and disposable adhesive sensor wraps (Medtronic, Dublin, Ireland). This device is suitable for screening for CCHDs as it cleared for use in newborns, is usable in low perfusion states, reports functional SpO_2, and is motion tolerant.

The first pulse oximetry screening after birth was considered positive if (1) the pre- or postductal SpO_2 reading was <90%; and (2) 2 independent measurements, with at least a 1-hour interval, revealed a SpO_2 <95% for both limbs or an absolute difference of >3% between the pre- and postductal readings. When the first SpO_2 screening was normal (SpO_2 ≥95% in either limb and <3% difference between both limbs), the pre- and postductal SpO_2 measurements were repeated on day 2 or 3 of life, either in the maternity ward or at home during the follow-up visit of the community midwife. This second SpO_2 screening was considered positive if SpO_2 <95% in both limbs or if a >3% difference between limbs was present (**Figure 1**).

Infants with positive pulse oximetry screening were referred to the pediatric department for physical examination

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