Implementation of pulse oximetry screening in a Danish maternity ward

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ABSTRACT

INTRODUCTION: Detecting critical congenital heart disease (CCHD) by prenatal ultrasound and routine examination of newborns is insufficient, and pulse oximetry screening (POS) has been recommended. POS has been implemented by some Danish maternity wards, but not by all. However no Danish studies of POS have been published. This study evaluates the first year with POS at Kolding Hospital, the Southern Region of Denmark.

METHODS: All apparently healthy newborns were offered POS few hours postpartum. Both pre-and post-ductal POS were carried out using a well-known protocol and registered as POS approved; POS repeated and approved; or POS not approved, paediatrician called. Paediatricians registered clinical data, and general experiences regarding POS were collected.

RESULTS: POS was performed in 2,855 newborns; 2,715 were approved immediately, 81 were repeated. Paediatric assistance was required for 59 newborns; 16 could stay in the maternity ward following assessment, while 18 were admitted for observation until their saturation normalised. One newborn had CCHD, while ten had other conditions needing treatment and 14 had more benign respiratory disorders. One sick newborn would not have been picked up by post-ductal screening only. No midwives performing the screening and no parents refrained from POS.

CONCLUSIONS: Early POS as part of the routine examination few hours postpartum seemed natural to midwives and parents but induced an increased false-positive rate. Early POS may discover other serious conditions in time for intervention.

FUNDING: none.

TRIAL REGISTRATION: none.

Until recently, maternity wards in Danish hospitals refrained from pulse oximetry screening (POS) of newborns as a method for detection of critical congenital heart disease (CCHD). One argument in support hereof was a high prenatal detection rate using ultrasound in the second trimester. However, the overall detection rate was reported to be only 71% in an evaluation of live-born major congenital heart disease in Denmark, with detection rates as low as 12%, depending on the specific anomaly [1].

Further reluctance has been based on the time spent on the procedure, distracting midwives from their core tasks. In addition, concerns about unnecessary parental worrying have been raised. In The United Kingdom, a large study concluded that POS was acceptable to mothers, and even false-positive results were not found to increase anxiety [2]. In Denmark, routine examination of newborns is performed primarily by midwives and does not include auscultation or palpation of femoral pulses. This may increase the risk of overlooking CCHD, especially taking the trend of early discharge after birth into account [3-5].

In 10,000 apparently healthy full-term newborn babies, six will have CCHD [6]. It may be vital to diagnose CCHD in near proximity to birth, as some undetected heart defects are fatal within the first few days of life, and surgery or catheter intervention may be required [7]. Newborns with CCHD do not always present clinical symptoms, and besides routine examination there is a need for an additional screening method to improve the detection rate [4]. In Sweden, a study including 39,821 screened newborns during a three-year period found a CCHD detection rate of 82.8% when POS and physical examination were combined, which was compared with an improvement of 72% in Swedish hospitals not using POS [8]. In the US, implementation of POS has been shown to decrease infant deaths due to CCHD by 33.4% [9]. Further support for POS comes from a large meta-analysis including data from 229,421 newborns, finding that the sensitivity of the method was 76.5% for detecting CCHD and the specificity 99.9% [10]. A recent Cochrane Review has shown consistent results with a sensitivity of 76.3% and a specificity of 99.9% [6]. Finally, an editorial from The Lancet concluded that: "Further trials are unnecessary. Now is the time for professional bodies to review the evidence and consider a pulse oximetry screening protocol that best suits their requirements" [11].

In theory, pre- and post-ductal POS might improve the CCHD detecting rate [8], but recently post-ductal screening has been considered acceptable [6, 12]. The timing of screening is another important discussion [5]. Some units choose to screen 24 hours after of birth at the earliest [4], hereby reducing false positives to approximately 0.05% [7, 9, 13]. Other maternity units screen within 24 hours of birth, accepting an increased

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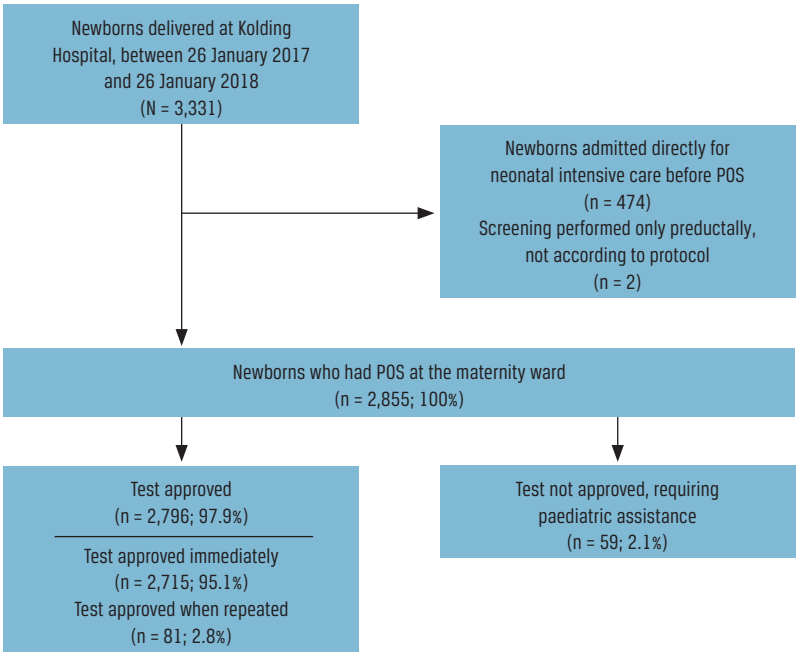
Dan Med J 2019;66(11):A5576

FIGURE 1 / Flow chart illustrating core data from the maternity ward of Kolding Hospital during the first year with pulse oximetry screening (POS) of all apparently healthy newborns.



false-positive rate, but taking into account that a non-approved POS often reveals other severe conditions requiring medical intervention [4, 14].

The Danish Health Authority has no official recommendation regarding POS, but screening has started at several Danish maternity wards. At the maternity ward in Kolding Hospital, a Danish hospital with approximately 3,400 annual births, POS was implemented in 2017 and the purpose of the present study was to evaluate the first year with screening.

METHODS

Screening procedure

Obviously, sick newborns were rapidly transferred to the neonatal intensive care unit (NICU), while all apparently healthy newborns were screened with POS before discharge from the maternity ward. Screening was implemented as part of the routine examination of the newborn performed by one of 75 midwives in the maternity ward. Both a pre-ductal (right hand) and post-ductal (either foot) measurement were performed, using handheld Nellcor pulse oximeters from Coviden (Nellcor portable SpO2 Patient Monitoring System, PM10N). Neonate wrap-sensors and paediatric clips gave reliable and stable measurements, and both were used for screening. Oximeters were set up for neonatal use, and settings were locked. Oximeters were checked regularly by the medicotechnical ward.

Screening was performed in accordance with a well-known protocol [4]. Results were coded electronically in the neonate's record as either POS approved (peripheral capillary oxygen saturation (SpO_2) ≥ 95%; ZZ4137B); POS repeated and approved (SpO_2 91-94%, followed by SpO_2 ≥ 95%; ZZ4137B + ZZ4137); or POS not approved, paediatrician called (SpO_2 < 90%, on either measurement site; ZZ4137A + ZNAA80). A difference between the hand and foot measurement of > 3% triggered re-screening.

Data collection and storage

The project was designed as a quality project and approved by the local hospital authority. Newborns involving paediatricians on the basis of a non-approved test were identified consecutively. Screening results as well as subsequent clinical outcomes were registered on a data sheet. Regularly, a search on the procedure codes ZZ4137A + ZNAA80 was carried out and the sheets were completed by adding anymising data. Data were fully anonymised and not patient identifiable. Other searches on approved tests (ZZ4137B) and repeated and approved tests (ZZ4137B + ZZ4137) established the number of newborns in these groups. The local data storage authority approved data storage.

Statistical analysis

Descriptive statistics are presented as means and standard deviations for variables showing normal distribution, and as medians and interquartile range (IQR) for non-normally distributed data.

All descriptive statistics were performed in Excel 2016, Microsoft Office.

Trial registration: none.

RESULTS

Figure 1 shows core data after the implementation of POS at Kolding Hospital, including 3,331 deliveries. **Table 1** presents more details regarding the 59 newborns requiring paediatric assessment.

Among the screening-positive newborns, 27% could stay with their mother in the maternity ward following paediatric assessment, whereas 31% were admitted for relatively short observation at the NICU while saturation normalised without treatment. One newborn diagnosed with polycythaemia, and treated with oxygen and intravenous glucose, only displayed a difference between pre- and post-ductal saturation and would not have been picked up by post-ductal screening only.

The median screening time after birth for the first POS was 2.5 (IQR ± 1) hours. The shortest screening time after birth was 0.5 hours; the longest 7.5 hours. If necessary, repeated screenings were conducted 0.5-1 hour later.

To midwives and parents alike, the routine examination of the newborn seemed to be a natural time to

carry out the POS. During the first year, no midwives refrained from screening and no parents refused attending the screening.

DISCUSSION

Screening of apparently healthy newborns by pulse oximetry was implemented at the regional hospital in Kolding and, during the first year, screenings were carried out of 2,855 newborns. Prior to implementation of POS, concerns were raised by midwives about the amount of time required for the procedure. Further concerns, shared by other professions, referred to unnecessary worries among newborns' parents. In Kolding, POS was initiated and fully implemented surprisingly fast and smoothly. One major explanation was the training given to the key midwives who hold the initial responsibility for POS in everyday practice, until all 75 midwives of the maternity ward were confident in performing the screening. Implementation of POS in the routine examination of the newborn minimised the time spent and seemed to make the extra assessment a natural part of every delivery. Previously, other studies have reported that parents seem to perceive POS as a natural procedure, ensuring the health of their baby [2, 14]. Our study endorses this conclusion.

One newborn (0.03%) presented with low saturation on the basis of pulmonary stenosis. The routine ultrasound performed at gestational age 20 weeks was reviewed, but the stenosis could not be recognised at this time. To our knowledge, no other newborns delivered at the maternity ward during the one-year period were diagnosed with CCHD after delivery. Previous studies have found that for every 10,000 apparently healthy newborns screened, six (0.06%) will have CCHD, and POS will detect five of these [6]. The false-positive rate was a problem associated with early screening. POS triggered paediatric assistance in 59 cases, and the false-positive rate for CCHD was 2.0%. This is substantially higher than the false-positive rate of 0.04-0.05% reported in a large American study and by the American Heart Association, respectively [7, 13], when screening was performed more than 24 hours after birth. Likewise, the rate was remarkably higher than reported in the Cochrane Review from 2018, when screening was performed within 24 hours (0.42%), probably because screening 2.5 hours postnatally is in the very low range of the 24 hour span.

A positive consequence of early screening is that it allows us to detect other important conditions in time for sufficient treatment [5]. In obvious cases, newborns were referred to the NICU immediately, while apparently healthy newborns often had another measurement of saturation carried out using paediatric equipment. This sensor is disposable, making each measurement much more expensive and unsuitable for screening procedures, but the saturation curve seemed more stable. Remarkably, thorough paediatric assessment could rule out the need for further treatment in 16 out of 59 cases, allowing these false positives to stay in the maternity ward by their mother.

TABLE 1 / Outcome of abnormal screening result, requiring paediatric assistance (N = 59).

	n (%)
Healthy newborns examined at the birth ward	16 (27.1)
Newborns admitted for observation	18 (30.5)
Newborns who required treatment	
Critical congenital heart disease (pulmonary stenosis)	1 (1.7)
Polycythaemia	1 (1.7)
Hypoglycaemia	1 (1.7)
Infection	8 (13.6)
Transitory tachypnoea	14 (23.7)
Subtotal	25 (42.4)

Fourteen newborns (23.7%) had low saturation caused by transitory tachypnoea, and ten newborns (16.9%) presented with other conditions, all requiring treatment at the NICU. This positive effect of screening is in line with results reported in previous studies [15] in which other severe illnesses were found among 37-70% of the newborns with false-positive results. All in all, 73% ended up being transferred to the NICU, 31% displaying no symptoms during observation while the remaining 42% did require treatment. The term false-positive rate therefore seems questionable, as about half the group requires treatment at the NICU.

To obtain an approved test, 2.8% (81 newborns) were exposed to more than one screening by the midwife. To our knowledge, this result has not been reported in other studies, but the rate of re-screening is an important observation as it extends the stay in the maternity ward for healthy newborns and may cause increased anxiety among parents of the newborns.

International and national recommendations

A European consensus report recommends that POS be implemented in all EU member countries, performing the screening after six hours of life, and preferably before 24 hours of life. The higher false-positive rate when screening < 24 hours of life is considered acceptable, recognizing the significant number with serious non-cardiac illness. In contrast to the recommendations of the Danish National Society of Paediatrics, the report concludes that screening should be performed in two extremities (right arm and one leg), although the level of evidence for this recommendation is low [15]. The Danish National Society of Paediatrics has made a com-

mon paediatric guideline recommending only post-ductal screening at 4-6 hours after birth [12]. This recommendation is mainly based on the recently published Cochrane review [6]. At present, The Danish Health Authority has no official recommendation in this respect.

After the screening period of this study, the maternity ward of Kolding Hospital decided to change the screening procedure to post-ductal screening following the Danish recommendation mentioned above. Post-ductal screening would minimize the problems of getting stable signals. However, this did not seem to be a major challenge during the one-year study period during which we performed both pre- and post-ductal screening. One sick newborn suffering from polycythaemia would not have been picked up by post-ductal screening. Currently, in the Southern Region of Denmark, two hospitals have decided to perform post-ductal screening while the other two hospitals, including the University Hospital of the region, adhere to pre- and post-ductal POS. Thus, within the region, there is a lack of consensus on the screening protocol.

Strengths and weaknesses of the study

The study was too small for calculation of an exact CCHD detection rate, and other rates should be considered with care. Still, experiences from the first year of screening at a typical Danish maternity ward may be of relevance and importance at a time when some Danish regions have chosen to follow Danish and international POS recommendation, and other regions than ours have, for different reasons, refrained from implementation of POS.

The formalised screening protocol made the screening procedure quite standardized even though it was carried out by a total of 75 midwives. The number of cases of POS approved; POS repeated and approved; and POS not approved, involving a paediatrician had to be stated through data extraction, and even though the quality manager has continuously monitored coding, some minor miscoding cannot be ruled out.

CONCLUSIONS

POS of all apparently healthy newborns was implemented at a Danish maternity ward without major practical problems. Performing POS while making the routine examination of the newborn 2.5 hours postnatally clearly resulted in more false-positive results. This disadvantage should be balanced against the advantage of POS as a natural step from the perspective of both the midwives and the parents and, importantly, the timely finding of newborns who required treatment. More than a quarter of the false positives could stay by their mother at the maternity ward following thorough paediatric assessment. We confirmed that severe CCHD may also in a Danish setting, be overlooked prenatally and picked up by POS.

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ACCEPTED: 26 September 2019
CONFLICTS OF INTEREST: none. Disclosure forms provided by the authors are available with the full text of this article at Ugeskriftet.dk/dmj

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