

Statement from the Regional HTA Centre of the Western Region in Sweden

The Regional Health Technology Assessment Centre (HTA-centre) of the Western Region in Sweden (Region Västra Götaland, VGR) has the task to make statements on HTA reports carried out in VGR. The statement should summarise the question at issue, level of evidence, efficacy, risks, and economical and ethical aspects of the particular health technology that has been assessed in the report.

Pulse oximetry (POX) screening for congenital heart defects in newbornsQuestion at issue:

Does pulse oximetry (POX) screening alone, or in addition to physical examination, of asymptomatic newborns before discharge from the well baby nursery lead to increased detection of critical congenital heart disease (CCHD) and to reduced mortality and morbidity?

PICO: (Patient, Intervention, Comparison, Outcome)

P = Asymptomatic newborns

I₁ = POX, regardless of location of the pulse oximeter probe, combined with physical examination of the newborn at any age before discharge from the well baby nursery

I₂ = POX under the same conditions, but with no physical examination

C = Physical examination

O = Primary outcome: Sensitivity and specificity in detecting CCHD using echocardiography as reference standard

Secondary outcomes:

1. Undetected CCHD at discharge
2. Mortality in newborns with CCHD
3. Morbidity in newborns with CCHD

Summary of the health technology assessment:Method and patient category

Congenital heart defects account for about 6-10% of all infant deaths. The incidence is estimated to be 8-12 per 1000 live births. *Critical* congenital heart defects (CCHD), i.e. hearts with circulation that are dependent on an open ductus arteriosus, are potentially life threatening and pose a particular challenge for early diagnosis. Discharge of a newborn with undiagnosed CCHD with subsequent ductal closure at home may lead to severe consequences with hypoxia, acidosis, severe heart failure, and even circulatory collapse. Therefore a timely diagnosis of CCHD is of utmost importance. Presently, all newborns are screened for CHD by physical examination in the well baby nursery. Infants with positive findings undergo further diagnostic evaluation with echocardiography.

Pulse oximetry (POX) is a non-invasive method to measure oxygen saturation. Currently 28% of all newborns with CCHD and duct dependent circulation are discharged undiagnosed from well baby nurseries in Sweden, which do not use POX screening. The rationale for screening of newborns with POX is early identification of newborns with CCHD already in the hospital before severe circulatory complications occur.

Level of evidence

The systematic literature search identified eight studies (nine articles), which have evaluated the diagnostic accuracy of POX screening. The scientific quality ranged from low to high. Two studies also evaluated the clinical outcomes discharge with undetected CCHD (moderate quality), mortality (low quality) and morbidity (moderate quality). The level of evidence was evaluated according to the GRADE system for cohort studies with clinical outcomes, and according to SBU's previous system for diagnostic accuracy studies.

Diagnostic accuracy

The level of evidence in support of good diagnostic accuracy of POX screening combined with physical examination or POX screening alone to detect CCHD is moderate. Furthermore, the outcome in two studies (of high and moderate quality, respectively) indicates that the combined screening with POX and physical examination has better diagnostic accuracy (sensitivity 83-89%, specificity 98-99%) than POX screening alone (sensitivity 62-77%, specificity 99-100%) or merely screening with physical examination alone (sensitivity 62%, specificity 98%).

Discharge of newborns with undetected CCHD

POX screening combined with physical examination was associated with a reduced risk of undetected CCHD before discharge (RR 0.38; 95% CI 0.20-0.71) in comparison with physical examination alone. Low level of evidence (GRADE ⊕⊕).

Mortality in newborns with CCHD

There were too few events to evaluate mortality in newborns with CCHD. No deaths occurred in the POX-screened groups. Very low level of evidence (GRADE ⊕).

Morbidity (severe acidosis) in newborns with CCHD

POX screening combined with physical examination was associated with a reduced risk of severe acidosis in newborns with CCHD in comparison with physical examination alone (RR 0.40 (0.20-0.80)). Low level of evidence (GRADE ⊕⊕).

Ethical aspects

It is important that parents are well informed about the purpose of a screening test as well as its limitations. A false-negative test result may lead to a delayed diagnosis since the health care professionals may be incorrectly reassured by the negative result, and, therefore, may be less responsive to parental concerns. On the other hand, a false-positive test result may cause unnecessary parental concerns and unnecessary costly investigations.

Economical aspects

The cost per timely diagnosis is estimated to be 265.000 SEK (€ 29.400) during the first year and at 212.000 SEK (€ 23.600) annually thereafter. The calculation is based on the assumption that POX screening combined with physical examination will detect three infants with CCHD per year at Sahlgrenska University Hospital. In contrast to this estimation, previous publications have reported that the addition of POX screening to physical examination of asymptomatic newborns most likely will be cost-neutral. However, these studies have not considered any time for information to the parents or preparations for the test.

Concluding remarks

POX screening is a simple, non-invasive method with a good diagnostic accuracy to detect CCHD in the asymptomatic newborn before discharge from the well baby nursery. Studies indicate that the combination of POX and physical examination has better diagnostic accuracy than either of the examinations alone. There are still insufficient data to evaluate whether this also will affect mortality and morbidity. The costs associated with an introduction of the method at Sahlgrenska University Hospital are estimated to be around 800.000 SEK during the first year, and thereafter the annual cost will be somewhat lower.

On behalf of HTA-centre Göteborg, Sweden, 2011-04-06

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Head of HTA-centre

Ingemar Tessin, Director, Division of Neonatology, The Queen Silvia Children's Hospital, Sahlgrenska University Hospital, Göteborg, Sweden and Anneli Falk, Director, Division of Obstetrics, Sahlgrenska University Hospital, Göteborg, Sweden, requested the present HTA.

A working group under the chairmanship of Ulla-Britt Wennerholm, MD, PhD, Associate Professor, Division of Obstetrics, Sahlgrenska University Hospital, Göteborg, Sweden produced the HTA report. The other members of the working group were Anastasia Fassoulas, MD, Pediatrician, Division of Pediatric Cardiology, The Queen Silvia Children's Hospital, Sahlgrenska University Hospital, Göteborg, Sweden and Ola Hafström, MD, PhD, Division of Neonatology, The Queen Silvia Children's Hospital, Sahlgrenska University Hospital, Göteborg, Sweden. The participants from the HTA centre were Annika Strandell, MD, PhD, Associate Professor, Ola Samuelsson MD, PhD, Associate Professor, Eva-Lotte Daxberg, information specialist and Ann Liljegren information specialist.

Maria Browall, RN, PhD, School of Life Sciences, University of Skövde, Skövde Sweden and Maria Svensson, MD, PhD, Dept of Molecular and Clinical Medicine –Nephrology, Sahlgrenska University Hospital, Göteborg, Sweden have critically appraised the report.

The project lasted during the time period September 22, 2010 to April 6, 2011. The question was requested in April 2010. Last search updated in October 2010.