

**Pulse oximetry: evaluation of a potential
tool for early detection of critical congenital heart disease**

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av
Anne de-Wahl Granelli

Fakultetsopponent:
Docent Anders Jonzon
Akademiska barnsjukhuset
Uppsala

The thesis is based on the following papers:

- I. de-Wahl Granelli A, Mellander M, Sandberg K, Sunnegårdh J, Östman-Smith I. **Screening for duct-dependent congenital heart disease with pulse oximetry: A critical evaluation of strategies to maximise sensitivity.** Acta Paediatrica 2005; 94:1590-1596.
- II. de-Wahl Granelli A, Östman-Smith I. **Noninvasive peripheral perfusion index as a possible tool for screening for critical left heart obstruction.** Acta Paediatrica 2007; 96:1455-9.
- III. de-Wahl Granelli A, Wennergren M, Sandberg K, Mellander M, Bejlum C, Inganäs L, Eriksson M, Segerdahl N, Ågren A, Ekman-Joelsson B-M, Sunnegårdh J, Verdicchio M, Östman-Smith I. **Impact of pulse-oximetry screening on the detection of duct-dependent congenital heart disease: a Swedish prospective screening study in 39 821 newborns.** BMJ 2009;338:a3037.
- IV. de-Wahl Granelli A*, Bratt E-L*, Östman-Smith I. **Important inaccuracies in pulse-oximetry readings in cyanosed children.** (*Equal contributors)
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Anne de-Wahl Granelli

Department of Paediatrics, Institute of Clinical Science at Sahlgrenska Academy, University of Gothenburg, Sweden

Abstract

Background: About one third of newborns with life-threatening congenital heart disease leave newborn nurseries without the problem being recognized, and risk death or serious damage from circulatory collapse. The main aim of this thesis has been to evaluate if routine newborn screening with pulse oximetry could improve early in-hospital detection of newborns with duct-dependent circulation (DDC). Papers I, II and IV are methodological studies describing optimal screening cut-offs for pulse oximetry (*Paper I*), normal range for perfusion index; PPI (*Paper II*), and deviation of pulse oximetry values from true arterial saturation in cyanosed children (*Paper III*). *Paper III* includes a multicentre screening-study that tests the method prospectively in all newborn nurseries in West Götaland Region (WGR) on 39821 newborns, with blind comparison with neonatal physical examination (NPE), as well as a complete cohort comparison of all newborns with DDC in WGR with all other referring regions (ORR) not screening newborns, and a cost-benefit analysis of screening.

Results: Best sensitivity for DDC was achieved with both pre- and postductal saturation cut-off $<95\%$ or a hand/foot difference of $>\pm 3\%$ with a New-generation oximeter(NGoxi) on 3 repeated measurements. 29 babies with DDC remained undetected until the discharge examination. NGoxi-screening detected 18/29 (62%) but combining with NPE increased sensitivity to 24/29 (83%). A positive pulse oximetry screening gives a relative risk of 719.8 (95% confidence interval 350.3 to 1479; $p < 0.0001$) of having duct-dependent heart disease. False-positive rate for NGoxi-screening was 0.17% (compared with 1.90% for NPE), and yielded other significant pathology in 45%. Total cohort-size of DDC in WGR was 60/46963 total live births, and in ORR 100/108604 live births. The risk of leaving hospital with undetected DDC was 5/60 (8%) in WGR compared with 28/100 (28%) in ORR; $p=0.0025$. In ORR an alarming 11/25 (44%) babies with transposition of the great arteries left hospital undiagnosed, versus 0/18 in WGR ($p=0.0010$). No baby died undiagnosed in WGR during the screening-study but 5 babies (5%) died undiagnosed in ORR, including two with duct-dependent cyanotic lesions. A PPI-value <0.7 gives an odds ratio for systemic duct-dependent circulation of 23.8 (95%CI 6.4 to 88.7), but its use in screening needs to be prospectively evaluated. *Paper IV* Both NGoxi and Conventional-technology oximeters(CToxi) show an increasing positive bias with falling arterial saturations, leading to significant overestimation of true arterial blood gas particularly in the below 80% saturation range. Overestimates by $>7\%$ of the arterial blood gas saturation occurred in 66.7% (10/15) of CToxi-readings and in 40.0% (6/16) of NGoxi-readings in the below 80% saturation range.

Conclusion: Adding NGoxi-screening to neonatal physical examination significantly improved detection of DDC, detected 100% of duct-dependent pulmonary circulation (present in 2 of 5 undiagnosed deaths in ORR), yielded only 0.17% false-positives, and came out cost-neutral.

Key words: pulse oximetry, duct-dependent, newborn screening, congenital heart disease, perfusion index