

## **Impact of pulse oximetry screening on the detection of duct dependent congenital heart disease: a Swedish prospective screening study in 39,821 newborns.**

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### **Introduction**

Newborns discharged from the hospital with undiagnosed congenital heart disease are at much greater risk for morbidity and mortality compared to those who receive a diagnosis. Pulse oximetry has been proposed as an easy and inexpensive method for the universal screening of newborns for life-threatening congenital heart disease prior to hospital discharge. To evaluate the accuracy of pulse oximetry to detect congenital heart disease in newborns, Granelli and colleagues screened all newborns from five maternity units in West Götaland, Sweden and determined the detection rate of congenital heart disease by pulse oximetry compared to neonatal physical exam alone.

### **Methods**

Babies born between July 1, 2004 and March 31, 2007 from five maternity units in West Götaland, Sweden were included in the study (n = 39,821). Infants admitted to neonatal specialty care units or with prior admissions to the NICU were excluded. Pre and post ductal oxygen saturation measurements were obtained by placing multisite LNOP Y1 sensors connected to Radical-7 Pulse CO-Oximeters on the palm of the right hand and either foot of each baby. The screening procedure was incorporated into the daily nursing routine, usually before the daily weighing prior to the discharge examination. Pre and post ductal oxygen saturation readings less than 95% or a difference between the two measurements of greater than 3% was considered to be a positive result. Babies with two or three repeated positive measurements were referred for echocardiography. Detection rate of duct dependent circulation from the five maternity units in the study was compared to that in other regions that did not use pulse oximetry screening but did refer children to the same supra-regional center for congenital cardiac surgery. Sensitivity, specificity, positive and negative predictive values, and likelihood ratio for pulse oximetry screening and for neonatal physical examination alone were calculated.

### **Results**

Twenty nine of the 39,821 babies screened had duct dependent circulation undetected before neonatal discharge examination. In 13 cases, pulse oximetry showed oxygen saturations  $\leq 90\%$ . In the remaining 16 cases, physical examination alone detected 10 (63%). Combining physical examination with pulse oximetry screening detected 24/29 (82.8%) and 100% of the babies with duct dependent lung circulation. Five cases, all with aortic arch obstruction were not detected. The false positive rate with pulse oximetry was substantially lower than that with physical examination alone (0.17% vs. 1.90%),  $P < 0.0001$ . Forty five percent of the "false positive" cases with pulse oximetry had other pathology. In the cohort study, the risk of leaving the hospital with undiagnosed duct dependent circulation was 8 % in West Götaland and 28% in other referring regions. No baby died from undiagnosed duct dependent circulation in West Götaland versus five babies from the other referring regions.

### **Conclusion**

Pre and postductal screening of oxygen saturation with Masimo SET Pulse Oximetry before discharge improved the total detection rate of duct dependent circulation to 92% compared to 72% found in other regions that did not use pulse oximetry screening. The high rate of detection

along with the low false positive rate found in the study, suggests that pulse oximetry screening can provide an easy and effective means of identifying infants with congenital heart disease which is superior to physical exam alone.