

Sri Lankan Study Expands Evidence of the Benefits of CCHD Screening Using Masimo SET® Pulse Oximetry



Masimo today announced the results of a prospective study published in the Sri Lanka Journal of Child Health in which researchers in Colombo, Sri Lanka evaluated the efficacy of a pulse oximetry-based critical congenital heart disease (CCHD) newborn screening strategy using Masimo SET® pulse oximetry.¹ The authors concluded that pulse oximetry is a “simple, noninvasive, cost-effective, feasible, and reliable test,” and found that it had higher CCHD screening sensitivity than physical exam. Combining the two methods led to detection of all cases of CCHD in the study cohort, and they recommended that, “Pulse oximetry screening as a combined strategy with newborn physical exam should be implemented as a basic routine at discharge for every newborn in maternity units island-wide.” As they note, their work is the first published CCHD study of this nature in Sri Lanka.

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Noting that while “developed countries have abundant research on pulse oximetry screening” for CCHD, “there are few studies in developing countries,” Dr. CR Gunaratne and colleagues sought to study the utility of such a screening strategy in their local setting. From November 2018 to April 2019, researchers assessed the rate of detection of CCHD using Masimo SET® pulse oximetry compared to routine physical exam alone in 5,435 asymptomatic newborns admitted to the post-natal wards at Castle Street Hospital, Colombo. Physical exam was performed at ≥ 24 hours of age “to identify any visible central cyanosis, weak/absent femoral pulses or cardiac murmur” by an experienced medical officer, blinded to pulse oximetry results. Radical-7® Pulse CO-Oximeters® with Masimo SET® pulse oximetry were used to measure pre-ductal and post-ductal oxygen saturation (SpO₂) on the right hand and right foot, respectively, as part of a standardized screening algorithm. For newborns with positive results, an echocardiogram was performed within 48 hours to diagnose CCHD.

The researchers found that Masimo SET® pulse oximetry had a CCHD detection rate of 91%, compared to 82% for physical exam. The addition of Masimo SET® pulse oximetry to physical exam screening led to the detection of 2 cases missed by physical exam alone, with a combined detection rate of 100%. The positive predictive value and positive likelihood ratio were both higher for SET® pulse oximetry compared to physical exam (71.4% vs. 8.6% and 1232.7 vs. 46.2, $p = 0.0001$). The researchers also found that the false positive rate was “substantially” lower for SET® pulse oximetry compared to physical exam (0.07% vs. 1.76%, $p = 0.0001$).

The researchers concluded, “Prevalence of CCHD in our study was 2.02 per 1000 live births. Using a pulse oximetry strategy as an adjunct to routine physical exam can substantially reduce the diagnostic gap in CCHD as [a] combined approach has an additive effect resulting in more efficient screening.”

Since its introduction in 1995, Masimo Measure-through Motion and Low Perfusion™ Signal Extraction Technology® (SET®) has been shown in more than 100 independent and objective studies to outperform other pulse oximetry technologies, providing clinicians with increased sensitivity and specificity to help them make critical patient care decisions.² To date, nine other published CCHD screening studies, all with positive conclusions and representing over 300,000 infants, have used Masimo SET®,³⁻¹¹ which includes the largest CCHD study to date, of 122,738 newborns.⁵ All of the CCHD studies with Masimo SET® pulse oximetry have shown improved screening sensitivity with the use of Masimo SET® alongside clinical assessment when compared to routine physical exam alone. Results from CCHD studies using other pulse oximetry technologies have shown that other technologies do not offer the same performance as Masimo SET® during CCHD screening.¹²⁻¹⁴

With its ability to accurately measure through motion and low perfusion, alongside its performance in outcome studies, SET® stands out as the choice of pulse oximetry technology for clinicians and policy makers hoping to implement newborn-related screening processes—and has indeed been used in the establishment of screening guidelines used around the world.¹⁵

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