

New 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 International Journal of Neonatal Screening in which researchers in Marrakesh, Morocco, conducted the first Moroccan study on critical congenital heart disease (CCHD) screening for newborns using Masimo SET® pulse oximetry.1 The authors concluded that "Our results encourage us to strengthen screening for CCHD by adding pulse oximetry to the routine newborn screening panel."

This press release features multimedia. View the full release here

Dr. Slitine and colleagues sought to improve early detection of CCHD in Morocco by studying the feasibility of implementing CCHD screening using pulse oximetry. From March 2019 to January 2020, 8,013 asymptomatic newborns at Mother and Child Hospital (part of the Mohammed VI University Hospital of Marrakesh), who were "normal" according to neonatal examination using the current standard, were screened for CCHD in accordance with American Academy of Pediatrics (AAP) guidelines, including pre- and post-ductal oxygen saturation measurement, using Masimo Rad-97® and Radical-7® Pulse CO-Oximeters® with Masimo SET® pulse oximetry sensors.

The researchers found that, of the 8,013 infants screened, 7,998 newborns had a negative screen (99.82%) and 15 newborns were screen positive (0.18%). Of those 15, five were later diagnosed with CCHD and five with non-critical CHD; five were false positives (three of which had other underlying conditions). Of the 7,998 infants who passed, there was one false negative, an infant who was later diagnosed, at 2 months of age, with coarctation of the aorta.

The researchers noted that the screening test was "easy, simple, reliable, reproducible, acceptable, discriminating, well-accepted by parents and caregivers, and did not involve parental anxiety." They also noted that "Pulse oximetry has a good specificity and sensitivity and thereby fulfills the criteria for screening. Additionally, most of the data in the literature suggest a favorable cost-effectiveness of this technique."

The authors concluded, "Screening for CCHD is a reliable method for the early detection of critical congenital heart disease and even non-cardiac conditions. We think that it will have positive repercussions on infant mortality and morbidity in Morocco. It is an optimal test and it adapts perfectly to our context. We hope to implement it locally and nationally, as consistent with international best practice for newborn screening, to allow for timely detection of the infants born with CCHD in Morocco."

Although the researchers at times use the term pulse oximetry generally, the specific pulse oximetry technology used in this study, as noted, was Masimo SET®. To date, six other large published CCHD screening studies,2-7 as well as additional, smaller studies,8-9 have used Masimo SET®. Cumulatively, the large studies represent 284,800 infants, which includes the largest CCHD study to date, of 122,738 newborns.2 All of these CCHD studies with Masimo SET® pulse oximetry showed improved screening sensitivity with the use of Masimo SET® alongside clinical assessment when compared to routine physical exam alone. With its ability to accurately measure through motion and low perfusion, alongside its performance in outcome studies, Masimo SET® stands out as the established choice of pulse oximetry technology for clinicians and policy makers hoping to implement CCHD screening processes.10

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