Letters to the Editor

February 22, 2021

Dr. Mitchell Goldstein, Editor, Neonatology Today

To the Editor

I write in reference to the recently published study by Khoury R et al., which I have reviewed in detail, in which the authors compared the times taken to achieve stable heart rate readings for Masimo and Nellcor pulse oximeters in neonates immediately after delivery (1). Pulse rate stability was compared using a qualitative measure (looking at it and writing the number down).

The 60 babies studied were all healthy, and they cannot be compared to a manuscript I authored (2) and this is the basis for this letter, where I will summarize the major limitations and differences between previous publications and the current findings in Khoury's paper.

" Furthermore, I believe that the findings are of no clinical significance and could not support any changes in the current clinical guidelines of neonatal resuscitation."

The manuscript used interchangeably several aspects - "during delivery room transition," "neonatal transition," and "an uncomplicated resuscitation setting," and this has led to confusion. Furthermore, I believe that the findings are of no clinical significance and could not support any changes in the current clinical guidelines of neonatal resuscitation.

In many places of the world, there remains a significant need for education in order to improve the skill and training so that care of sick newborns after birth is improved. Adequate auscultation of the heart and palpation of the base of the umbilical cord have a more significant clinical impact than spending precious time and resources trying to apply ECG electrodes that have been shown to have reduced function in ill babies before 60 seconds of life. The scant resources in many areas should be diverted to neonates at risk due to gestational age or clinical condition to ensure the required clinical interventions are instituted in a timely manner.

This study was conducted in healthy babies born by cesarean section who did not require resuscitation with Apgar scores of 8-9 at 1 minute; 91.7% of them were born by elective Cesarean-section. None of the infants required resuscitation, and comparisons were made after the healthy babies were placed on a warmer. Pulse rate stability was compared using a qualitative measure (looking at it and writing the number down).

As mentioned by Khoury, the findings of his study cannot (and should not) be extrapolated to other groups of newborns, like those who are ill, premature, or have potentially serious conditions.

I would also like to share a concept in relation to the Masimo sensor that was used. In response to the 2015 American Academy of Pediatrics Newborn Resuscitation Protocol (NRP) to address the measurement conditions during the first few minutes after birth (3), Masimo optimized the sensor in 2016 to provide stable pulse rate readings earlier. This sensor, which upon application automatically set the Masimo oximeter settings to 2-4 second (fast) averaging time and maximal sensitivity, was not utilized in the study cohort. Matching technology is essential for performance as approved by the FDA. Additionally, many published clinical studies in preterm and term infants in the delivery room report SpO_2 nomograms in thousands of babies using Masimo SET technology (4-6). What is reported in Khoury's study cannot be extrapolated to what happens in the NICU in critically ill babies. SET technology use in thousands of babies (including many studies and all recent publications with ventilators with closed-loop technology) (7-10) led to a significant reduction in severe ROP and the need for laser therapy. Pulse oximetry selection is important in managing critically ill infants.

"What is reported in Khoury's study cannot be extrapolated to what happens in the NICU in critically ill babies. SET technology use in thousands of babies (including many studies and all recent publications with ventilators with closed-loop technology) (7-10) led to a significant reduction in severe ROP and the need for laser therapy. Pulse oximetry selection is important in managing critically ill infants."

Lastly, Khoury's study mentions using the electrocardiogram (ECG) heart rate as a "gold standard" for pulse rate from pulse oximetry. Pulseless Electrical Activity (PEA, also known as Electro-Mechanical Dissociation or EMD) is not rare during the first minutes after birth, especially during asphyxia, as is clearly mentioned in NRP documents of AAP. The ECG can display heart rates far greater than the actual pulse rate in this situation. Several studies affirm this fact (11, 12). This is a possible explanation of some of the "low pulse rate" data points shown in Khoury's Figure 2 when the actual peripheral pulse rate can be significantly lower than the ECG rate.

In summary, I consider the statistically significant difference reported in this study to be clinically insignificant and do not provide any basis for the improvement of clinical care and outcomes of sick babies in the delivery room and in the NICU, and could actually distract clinicians from the first important steps that are essential during neonatal resuscitation.

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Dear Dr. Latorre:

As noted in my previous response to Dr. Barker, "comparison trials of relevant devices define usage parameters." Further, as you have noted, the populations studied must be complementary to justify conclusions. Health newborns in the delivery room are different from those who are sick in the NICU. Speed of response, notwithstanding, the technology is not just about speed alone. Accuracy, precision, and reproducibility are a *sine qua non*. Early pulse oximetry was neither designed to work on NICU patients nor any sick patients for that matter. The pulse oximeter was referred to as a "fair-weather friend." (1) We were taught that reliance on a pulse oximeter was problematic when a patient was moving or had low perfusion. Signal Extraction technology (SET) is an entirely different technology. Comparing SET to other technologies is like comparing a late model semiautonomous electric vehicle to a 1950s gas guzzler. However, shut down the electric grid, take away the software innovation, and provide only fossil fuel, and the 1950s gas guzzler will win every race. The innovative modes, software, sensors, and usage should have been included in the study. The fact remains that although the authors of the study have reached statistical significance, there is no clinical relevance because the Masimo devices were not used in their most optimized settings and did not have the latest software revision. (2, 3)

Pulseless Electrical Activity (PEA) is definitively an issue. Earlier AAP resuscitation guidance questioned whether pulse oximetry might "falsely" indicate that there was no pulse when there was sufficient EKG activity resulting in unnecessary resuscitation. Although there is no substitute for a full exam, the reverse is undoubtedly true and much more dangerous should a "reassuring" EKG lead to a resuscitation delay. (4-6) Arguably, the EKG is analogous to "fool's gold." It seems like the real thing (i.e., pulse), but it's not.

Your concerns are well stated and essential. Khoury et al. should have incorporated these considerations into the initial study design.

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Sincerely,

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Erratum (Neonatology Today February, 2021)

Neonatology Today acknowledges that the Erratum box in the January 2021 edition referred to "2020" instead of "2021." Dr. Paula Whiteman's name was mispelled in the Table of Contents in December, January and February editions.

Corrections can be sent directly to LomaLindaPublishingCompany@gmail.com. The most recent edition of Neonatology Today including any previously identified erratum may be downloaded from www.neonatologytoday.net.

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