Letters to the Editor

December 18, 2020

Letter to the Editor:

Khoury et al. published an online article in the Journal of Perinatology in November 2020, comparing the times taken to achieve stable readings for Masimo and Nellcor pulse oximeters in neonates immediately after delivery (1). The study described in the article did not use Masimo's current technology developed in response to the 2015 update of the American Academy of Pediatrics Newborn Resuscitation Protocol (NRP) to address the measurement conditions during the first few minutes after birth (2). Based on the revised NRP, Masimo optimized a new solution in 2016, using its newborn specialty sensor to provide stable pulse rate readings earlier. This solution was not included in the Khoury study.

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In the case plot of pulse rate versus time in a neonate shown below (unpublished), the blue trace is from the Nellcor pulse oximeter, the red trace is from the Masimo pulse oximeter used by Khoury et al., and the green trace is from the 2016 Masimo pulse oximeter with newborn specialty sensor solution. This comparison of the pulse rates is limited to the first 3 minutes from the start of monitoring. The actual heart rate during this time period was in the 170-180 range.

As shown in this case example, Masimo's 2016 newborn specialty sensor solution provided stable pulse rate readings earlier than either the standard Masimo pulse oximeter or the Nellcor pulse oximeter.

An additional concern with the Khoury study is the use of 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. The ECG can display heart rates far greater than the actual pulse rate in this situation. There are several studies affirming this fact

(2,3). This is a possible explanation of some of the “low pulse rate” data points shown in Khoury's Figure 2: the actual peripheral pulse rate can be significantly lower than the ECG rate.

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Masimo welcomes clinical studies of the ability of pulse oximetry to display data rapidly and reliably in the period immediately following birth. We appreciate this effort by Khoury et al. and recommend that this study be repeated with the current Masimo technology. Masimo would be happy to support such a study.

References:

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Sincerely,

Steven J Barker, PhD, MD

Chief Science Officer

Masimo Corporation

Dear Dr. Barker:

Comparison trials of relevant devices define usage parameters. These studies are essential not only for understanding boundaries where these devices are useful but also to identify instances when a device may function less well or provide erroneous results. (1) That said, these comparison trials only produce useful clinical information when the most current technology from one manufacturer is compared to another manufacturer's most current technology. To demonstrate superiority over a technology that is no longer current does not provide useful clinical information and may unduly prejudice clinical decision-making against a more competent and current device. The absence of head-to-head controlled studies does not mean that an effect is absent. When making use decisions, unless the revisions are those that have been studied, the comparison is irrelevant. (2, 3)

Pulseless Electrical Activity in the delivery room is not without consequence. The decision to intervene and provide resuscitation must not be delayed in the absence of perfusion. While an ECG may be the gold standard for heart rate, there is not absolute concordance of heart rate and pulse rate even in well individuals. Ultimately, what is associated with distal perfusion is most important. While an ECG may identify rhythms that can produce alterations in perfusion, it is a poor surrogate for perfusion. If there is no HR identified on the ECG, there is no distal perfusion; but the reverse is not always true even if there is a strong steady ECG rhythm. (4-6)

Indeed, this study should have incorporated the most current device from both manufacturers. Should Khoury et al. have doubts as to whether the improvements were significant, incorporating another sensor and comparing the three may be a worthwhile endeavor.

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Sincerely,

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