

Comparison Of Two Newer-Generation Pulse Oximeters In The Neonatal Intensive Care Unit (NICU).

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Background

Pulse oximeters used in the NICU setting must provide reliable data during various conditions of signal interference, including light, motion, and reduced perfusion. Improved system designs in newer generation pulse oximeters are intended to allow proper operation under the conditions commonly encountered in the NICU environment. This study aims to assess differences in device posting in newer oximeter systems.

Methods

Following informed consent, 10 infants between 27-40 weeks gestational age and < 1 month old in chronological age were recruited from the NICU. A Nellcor® OxiMax® N-600 T Pulse Oximeter, version 1.1.2.0 (Nell) and Masimo® SET® Radical® pulse oximeter, v4 (Mas) using MAX-N and LNOP® Neo sensors, respectively. Sensors were placed on either foot and optically shielded to prevent cross-talk. Each subject study was targeted for 4 hrs with 2 hr sensor rotation. Pulse oximeter data was captured via serial interface connection to a lap-top computer and sampling of 1Hz. McNemar's test analysis used to compare ability of oximetry systems to record saturation (SpO₂) and pulse rate (PR). Dropout rate was defined as the percentage of total monitoring time where data is not detected the pulse oximeter.

Results

GA (wks) 36.5 ± 2.5 Study Age (d) 11.7 ± 5.19 Resting ECG HR (bpm) 140 ± 10.6 Birth/Study wt (kg) $3 \pm .616 / 3.11 \pm 0.549$. Recording time available for analysis was 39.2 hours. SpO₂ mean difference $\pm$ SE (Mas - Nell) was 1.46 ± 0.36 , which was statistically significant ($p < 0.0032$). PR mean difference (Mas - Nell) was -1.21 ± 0.74 , which was not statistically significant, $p = 0.137$. Both PR and SpO₂ differences were adjusted for repeated observations on the same patient using a mixed model.

Overall Mas drop-out rate was statistically higher than Nell $p < 0.0001$ (McNemar's Test). Adjusting for correlations between observations on same patient using generalized linear modeling, $p < 0.0001$. While SpO₂ and PR dropouts with both monitors was less than 1% of the recorded time, Mas SpO₂ was 1.94 times more likely to drop out than Nell (95% CI = 1.74 - 2.17), and Mas PR was 1.55 times more likely to dropout than Nell (95% CI = 1.40 - 1.72).

Conclusions

Although the OxiMax N-600 had fewer dropouts compared to the Radical, both oximeters posted values >99% of the total monitoring time. Both the Nellcor OxiMax N-600 and Masimo SET Radical, as new generation oximeters, performed similarly with regard to overall drop-out rate and both are judged to be clinically equivalent in providing reliable pulse rate and saturation monitoring of babies in the NICU.