Clinical Evaluation of the Effects of Signal Integrity and Saturation on Data Availability and Accuracy of Masimo SET and Nellcor N-395 Oximeters in Children.

Pulse oximetry manufacturers have introduced technologies that claim improved detection of hypoxemic events. Because improvements in signal processing and data rejection algorithms may differentially affect data reporting, we compared the data reporting and signal heuristic performance and agreement among the Nellcor N-395, Masimo SET, and GE Solar 8000 oximeters under a spectrum of conditions of signal integrity and arterial oxygen saturations.

A blinded side-by-side comparison of technologies was performed in 27 patients, and data were analyzed for time of data availability, measures of agreement and signal heuristics, and warnings stratified by signal integrity and SpO2.

The Solar 8000 had less total data dropout than either of the new technologies. Masimo's LoSIQ (signal quality) heuristic rejected less data than Nellcor's MOT/PS (motion/pulse search) flag. When no signal heuristic was displayed, there was little difference in precision and bias between the two newer technologies; however, agreement between devices deteriorated in the presence of SIQ, MOT, or hypoxemia. Both newer devices flagged questionable data, but their use of different rejection algorithms resulted in different probabilities of presenting data. Therefore, with poor SIQ or during hypoxemia, the Nellcor N-395 and Masimo oximeters are not clinically equivalent to each other or to the older Solar 8000 oximeter.

Implications: We compared new pulse oximeters from Nellcor and Masimo and found that, with good signal conditions, both new devices performed similarly to older technology. Overall, Masimo reported less data as questionable than Nellcor. With poor signal conditions or during hypoxemia, the new devices are not clinically equivalent to each other or to the older technology.