Study Compares Performance of Masimo Next Generation SedLine® PSi to Original PSi During Anesthesia

Masimo has announced the findings of an abstract presented at Euroanaesthesia 2017 in Geneva, Switzerland. In the study, researchers at University Medical Center Groningen, Netherlands, compared original and Next Generation versions of Masimo Patient State Index (PSi, a processed EEG parameter related to the effect of anesthetic agents) during Masimo SedLine® brain function monitoring of patients under propofol and sevoflurane anesthesia.

SedLine brain function monitoring features four simultaneous EEG leads to enable continuous assessment of both sides of the brain, four EEG waveforms, a Density Spectral Array (DSA, an easy-to-interpret, high-resolution display of bi-hemispheric activity and EEG power), and PSi. Next Generation SedLine enhances PSi to make it less susceptible to electromyographic (EMG) interference and to improve its performance in low-power EEG cases.

In the study, Dr. Kuizenga and colleagues sought to compare the original and Next Generation PSi algorithms, referred to as PSi-1 and PSi-2, respectively, as they correlated with propofol and sevoflurane drug concentrations and with the Modified Observers Assessment of Alertness and Sedation (MOAAS) scale. They also sought to assess the influence of 2 and 4 ng/mL effect-site concentrations of remifentanil on the performance of the two algorithms.

The researchers enrolled 36 healthy volunteers, stratified by age, and assigned them randomly to a sequence of four sessions of anesthesia. In one session, propofol was administered in a series of graded steps; in the second, sevoflurane was similarly administered; in the third and fourth, the two concentrations of remifentanil were also administered. During each step of each session, after a twelve-minute delay for equilibration, MOAAS was tested and a blood sample was taken to measure drug concentrations. EEG was collected using Masimo Root® with SedLine®, from which time-synchronized PSi-1 and PSi-2 values were later extracted. The researchers then plotted MOAAS, drug concentration, PSi-1, and PSi-2 values over time.

The researchers found that when charted against drug concentrations, PSi-2 showed “reduced population variability and improved baseline stability” compared to PSi-1. When charted against MOAAS, PSi-2 had “lower interindividual variability” than PSi-1. They also noted that “Both PSis distinguish MOAAS 5, 4, and 3 better during propofol anesthesia compared to sevoflurane. This difference disappears when adding remifentanil.”
The investigators concluded that “PSi-2 [Next Generation SedLine PSi] has enhanced signal stability and a better description of the dose-response relationship. PSi-2 has therefore improved capacity as a pharmacodynamic monitor of anesthesia compared to PSi-1.”

Next Generation SedLine has not received FDA 510(k) clearance and is not available for sale in the United States.

Reference


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