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PVI and SpHb Studies Presented at ESA 2014

Two Randomized Trials Presented at the Euroanaesthesia 2014 Congress Show Similar Fluid Administration and Risk Profile with PVI as with Invasive or Complicated Procedures

Two Additional Studies Presented on Noninvasive SpHb in Postpartum Hemorrhage Detection and Oral Surgery

Four new clinical studies evaluating Masimo noninvasive patient monitoring technologies were presented at the **European Society of Anaesthesiology's** (ESA) Euroanaesthesia 2014 Congress in Stockholm, Sweden.

PVI Studies

At University Hospital Linköping, in Linköping, Sweden, researchers evaluated whether fluid volume optimization using PVI would lead to similar fluid management and patient risk compared to Stroke Volume Optimization using Esophageal Doppler (ED) – an established method to optimize preload during abdominal surgery. Researchers noted the ED technique "is costly and sensitive to interference, requires training and is not possible in prone position or at limited access to the head." The investigators reported that there were no differences in colloid administration, total volume of fluids given during surgery, or lactate levels at the end of surgery. Higher lactate levels are strongly associated with greater patient risk. The investigators concluded: "Fluid optimization during open abdominal surgery guided by PVI seems to result in equal amounts of fluid administered compared to guidance using ED technique." 1

At CHU Brugmann (Brugmann University Hospital) in Bruxelles, Belgium, researchers compared conventional pulse pressure variation induced by mechanical ventilation (PPV) with noninvasive PVI to predict intraoperative fluid management in patients undergoing elective abdominal (laparoscopic) surgery. Seventy-two patients were randomized according to the monitoring used to guide intraoperative fluid therapy (PPV group: N=36, PVI group: N=36). Basal balanced crystalloid infusion rate was set at 2 ml/kg/h and boluses of 250 ml of 3% modified fluid gelatin were administered if the PPV was >13% or the PVI >15% in the respective groups for more than five minutes. Researchers concluded: "The type of monitoring does not influence significantly the volume of fluid administered in the intraoperative period."²

SpHb Studies

At Città di Roma Hospital in Rome, Italy, researchers compared noninvasive **SpHb** with values from an invasive central laboratory device (Horiba Pentra DX 120) in laboring mothers to evaluate whether SpHb (rainbow® ReSposable R2-25 Revision K sensor; **Radical-7** Pulse CO-Oximeter®) could detect changes in hemoglobin to enable earlier detection of postpartum hemorrhage. The investigators reported: "SpHb demonstrated bias and precision of 0.10 ± 0.71 g/dL compared to the central laboratory device with limits of agreement of 1.51 and -1.31 g/dL. More importantly, SpHb was able to trend changes detected by laboratory readings." They concluded that in this study: "SpHb was able to detect changes in hemoglobin concentration during and after delivery and therefore may provide a means for the early detection of bleeding and postpartum hemorrhage."

At Tokyo Dental College Ichikawa General Hospital in Chiba-ken, Japan, researchers evaluated the accuracy of SpHb compared with laboratory CO-Oximetry measurements of total hemoglobin (tHb) during prolonged oral surgery. The investigators reported that 73 tHb values were compared to SpHb. Bias and precision were 0.86 g/dL and 1.17 g/dL, respectively. Bland-Altman analysis showed limits of agreement of -1.43 to 3.15 g/dl. They concluded: "The accuracy of SpHb monitoring during prolonged surgery was clinically acceptable, as shown by the low bias, precision and moderate limits of agreement when compared to laboratory values, although percent error exceeded normal range slightly."⁴

The Masimo rainbow® SET platform enables the assessment of multiple blood constituents and physiologic parameters that previously could only be measured invasively or with complicated procedures, in addition to providing Masimo SET® Measure-through Motion and Low Perfusion [™] pulse oximetry including SpO₂, pulse rate, perfusion index, and PVI. Multiple noninvasive and continuous measurements – including SpHb, RRa®, SpCO® and SpMet® – offer an advancement in patient safety by helping clinicians better assess patients.

About Masimo

Masimo (NASDAQ: MASI) is the global leader in innovative noninvasive monitoring technologies that significantly improve patient care-helping solve "unsolvable" problems. In 1995, the company debuted Measure-Through Motion and Low Perfusion pulse oximetry, known as Masimo SET®, which virtually eliminated false alarms and increased pulse oximetry's ability to detect life-threatening events. More than 100 independent and objective studies have shown that Masimo SET® outperforms other pulse oximetry technologies, even under the most challenging clinical

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conditions, including patient motion and low peripheral perfusion. In 2005, Masimo introduced rainbow Pulse CO-Oximetry technology, allowing noninvasive and continuous monitoring of blood constituents that previously could only be measured invasively, including total hemoglobin (SpHb®), oxygen content (SpOCTM), carboxyhemoglobin (SpCO®), methemoglobin (SpMet®), and Pleth Variability Index (PVI®), in addition to SpO2, pulse rate, and perfusion index (PI). Additional information about Masimo and its products may be found at www.masimo.com.





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