Study Demonstrates Fluid Responsiveness Assessment In Cardiac Surgery

/PRNewswire/ -- Masimo has announced a new study in the Journal of Anesthesia demonstrates that for fluid responsiveness assessment, Masimo's noninvasive Pleth Variability Index (PVI®) is as accurate as invasive stroke volume variation (SVV) in patients undergoing cardiopulmonary bypass surgery. In the study conducted at the University Medical Center Hamburg-Eppendorf in Hamburg, Germany, researchers evaluated 18 patients who underwent elective cardiopulmonary bypass surgery. All patients had a central venous catheter as well as a femoral arterial catheter monitored with the PiCCO monitor (PiCCO2; Pulsion Medical Systems) for continuous measurement of SVV and intermittent assessment of cardiac index. PVI was measured using the Masimo Radical-7® monitor.

Fluid responsiveness was defined as a >10 percent increase in cardiac index after fluid administration and non-responsiveness was defined as <10 percent increase in cardiac index after fluid administration. Out of 22 fluid challenges, four resulted in a significant increase in cardiac index, while 18 did not. The optimal threshold value for fluid responsiveness was >11 percent for SVV and >16 percent for PVI. Both PVI and SVV correctly identified each of the four responders (100 percent sensitivity), while PVI identified 16 of 18 non-responders (89 percent sensitivity) and SVV identified 13 of 18 non-responders (72 percent sensitivity). Receiver operator characteristic curve analysis, which takes into account both sensitivity and specificity, showed a 0.95 area under the curve (AUC) for PVI and 0.87 AUC for SVV (p=0.31 for difference between PVI and SVV). Central venous pressure was a poor predictor of fluid responsiveness, with an AUC of 0.19.

The authors stated that both PVI and SVV are "much more valuable for prediction of volume responsiveness than CVP" and that PVI "is of high value, especially regarding sensitivity and negative predictive value. Thus, volume responsiveness is not to be expected when PVI is low."

Fluid administration is usually the first intervention in hemodynamically unstable patients to improve status and enable end organ preservation. Fluid is given to increase a patient's cardiac output, but only about half of critically ill patients actually increase cardiac output after fluid administration. Unnecessary fluid administration should be avoided because it's associated with increased morbidity and mortality. Clinical decision making is challenging using traditional invasive measurements such as central venous pressure, stroke volume/index, cardiac output/index, and pulmonary capillary wedge pressure, as they have not been shown to predict fluid responsiveness. Newer, dynamic indices such as SVV and pulse pressure variation can accurately predict fluid responsiveness and improve outcomes, but are invasive and/or complex and have a high procedural cost, estimated to be about $225 with an SVV monitoring system in one cost analysis. PVI

is also a dynamic measurement of changes over respiratory variations, but does so with the Masimo SET plethysmograph waveform instead of the arterial waveform. In contrast to other available methods, PVI is noninvasive, easy to use, and has no incremental procedural cost because pulse oximetry monitoring is already performed on all surgical and intensive care patients. No other pulse oximetry technology provides a parameter like PVI. Once Masimo SET® pulse oximetry or rainbow® Pulse CO-Oximetry™ with PVI is available in a hospital, it can be utilized in all patients.

Previously, PVI has been shown to help clinicians assess fluid responsiveness in adult surgical and intensive care patients under mechanical ventilation. In addition to the present study comparing PVI to SVV from the PiCCO invasive catheter from Pulsion, two previous studies have compared PVI to SVV from the FloTrac invasive catheter from Edwards Lifesciences and showed similar results. Masimo PVI has also been shown to help clinicians improve surgical fluid management to decrease patient risk in a randomized controlled trial.

The United Kingdom's National Health Service advises hospitals to use Intraoperative Fluid Management Technologies to improve patient outcomes and decrease costs. In June 2012, the NHS included PVI in its new Intra Operative Fluid Management pack, which serves as a guide for hospitals wishing to implement fluid responsiveness monitoring.

Michael O'Reilly, MD, Chief Medical Officer of Masimo, stated: "Masimo is indeed improving patient outcome and reducing cost of care with its breakthrough measurements, such as PVI. Masimo is the only pulse oximetry technology to offer automated assessment of fluid responsiveness with PVI, along with other breakthrough measurements available with rainbow® technology such as noninvasive and continuous hemoglobin (SpHb®) to help clinicians reduce unnecessary blood transfusions."

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