

Published Study Demonstrates Patients with Low Hemoglobin Levels Can be Managed Without Blood Transfusions

Findings Suggest the Current Practice of Single Hemoglobin Transfusion Triggers Leads to Unnecessary Transfusions and a Better Physiological Basis for Transfusion Decisions is Warranted

Irvine, California – A comparison study of nearly 1,900 patients published in *Perfusion*, a peer-reviewed academic journal, questions the long-standing practice of basing blood transfusion decisions on a single low hematocrit measurement result. In the study, titled *Is it the Patient or the Physician who Cannot Tolerate Anemia?*, researchers showed that a single measure of hematocrit is not a reliable indicator of transfusion need and that lower-than-normal hemoglobin levels have no adverse impact on patients. The study showed that a blood transfusion is largely administered because the physician deems it necessary, not because of quantified changes in the patient's physiology.

The study prospectively analyzed the outcomes of 1,854 patients with high (>21%) and low (≤21%) hematocrit levels who underwent coronary artery bypass graft surgery without receiving red blood cells at any time during their hospital stay. In comparing outcomes between the two groups, researchers found that the rates were similar in both groups regarding time on ventilator, duration of intensive care unit stay, intensive care unit re-admission, hospital re-admission, reoperation for bleeding or tamponade, low cardiac output, postoperative atrial fibrillation, stroke, creatinine level at hospital discharge, new onset renal failure, mediastinitis, pulmonary complication, and mortality rates. The study results showed that hematocrit levels that are considered "low" (between 17-21%) "are well tolerated and have no adverse impact on outcome," leading researchers to conclude "it is the physician, not the patient, who cannot tolerate low hematocrit levels."¹

Despite mounting clinical evidence linking adverse patient outcomes to blood transfusions during cardiac surgery, including increased operative mortality and decreased long-term survival,^{3,4} almost half of patients undergoing coronary artery bypass in the U.S. still receive at least one unit of packed red blood cells.^{5,6} In the *Perfusion* study researchers contend that the decision to unnecessarily transfuse blood in cardiac surgery patients is often based solely on a single low hematocrit level of below 20-22%—a clinical practice more than a half century old.

According to the American Society of Anesthesiologists (ASA) practice guidelines: "red blood cell transfusions should not be dictated by a single hemoglobin 'transfusion trigger' but instead should be based on the patient's risk of developing complications of inadequate oxygenation."²

In fact, Dr. Aryeh Shander, President-Elect of the Society for the Advancement of Blood Management (SABM) and the Executive Medical Director for The Institute for Patient Blood Management & Bloodless Medicine and Surgery at Englewood Hospital and Medical Center in Englewood, New Jersey, says that "transfusion guidelines such as the ASA's are becoming increasingly important for the clinician. The transfusion decision is quite complex because of mounting data surrounding risks and negative outcomes coupled with the unproven benefit of red cell transfusions. Deciding to transfuse based on a single static measurement more often results in patients receiving unnecessary transfusions with increased risks, costs and the depletion of an already scarce blood supply. New medical technologies and devices that continuously monitor hemoglobin, oxygen, and perfusion will become essential for transfusions."

One of the early pioneers of blood conservation and bloodless surgery techniques, Dr. Thomas Crimi, a founding member of SABM, Director of the Blood Conservation Program at Brookdale University Medical Center, and long-time proponent of single transfusion avoidance believes that "the lack of enabling medical technology to accurately and continuously measure key physiological parameters such as hemoglobin, fluid responsiveness, tissue oxygenation, and perfusion simultaneously has historically led physicians to make transfusion decisions based on single hemoglobin value reflecting measures obtained at a single point in time. However, today with Masimo Pulse CO-Oximetry, I get the real-time hemoglobin, oxygenation, tissue perfusion, and fluid responsiveness measurements and trending data that I need," he confirmed.

Masimo Rainbow SET Pulse CO-Oximetry—a breakthrough noninvasive blood constituent monitoring platform capable of measuring multiple blood constituents that previously required invasive procedures, including: total hemoglobin (SpHb™), oxygen content (SpOC™), carboxyhemoglobin (SpCO®), methemoglobin (SpMet®), and PVI®, in addition to oxyhemoglobin (SpO2), pulse rate (PR), and perfusion

index (PI). Masimo SpHb, PVI, and SpO₂ have been shown in multiple clinical studies to provide accurate, reliable, real-time measurements that help clinicians to proactively monitor and manage hemoglobin, fluid, and oxygen saturation levels more appropriately and conservatively.

¹ Senay S, Toraman F, Karabulut H, Alhan C. "Is it the Patient or the Physician who Cannot Tolerate Anemia? A Prospective Analysis in 1854 Non-transfused Coronary Artery Surgery Patients." *Perfusion*, November 2009; Vol. 24(6):373-80. Available online: <http://prf.sagepub.com/cgi/content/abstract/24/6/373>

² American Society of Anesthesiologists. "Practice guidelines for blood component therapy: a report by the American Society of Anesthesiologists Task Force on Blood Component Therapy." *Anesthesiology* 1996; 84: 732-747.

³ Surgenor SD, DeFoe GR, Fillinger MP, et al. "Intraoperative Red Blood Cell Transfusion During Coronary Artery Bypass Graft Surgery Increases the Risk of Postoperative Low-output Heart Failure." *Circulation* 2006; 114: 143-148.

⁴ Murphy GJ, Reeves BC, Rogers CA, Sizvi SIA, Culliford L, Angelini GD. "Increased Mortality, Postoperative Morbidity, and Cost after Red Blood Cell Transfusion in Patients Having Cardiac Surgery." *Circulation* 2007; 116: 2544-2552.

⁵ Rawn JD. "Blood Transfusion in Cardiac Surgery: A Silent Epidemic Revisited." *Circulation* 2007; 116: 2523-2524.

⁶ Koch CG, Li L, Duncan AI, et al. "Morbidity and Mortality Risk Associated with Red Blood Cell and Blood-Component Transfusion in Isolated Coronary Artery Bypass Grafting." *Crit Care Med* 2006; 34: 1608-1616.