

OFFICIAL TITLE:

"Intraoperative Continuous Noninvasive Hemoglobin Monitoring in Patients Undergoing Thoracic Surgery"

NCT NUMBER: still not available

DOCUMENT DATE:

July 13, 2024

Intraoperative continuous noninvasive hemoglobin monitoring in patients undergoing thoracic surgery.

Background: hemoglobin levels similar to how a pulse oximeter provides continuous oxygen saturation. The spot check hemoglobin monitor works by the same principle as the continuous monitor but is a point-of-care device that calculates the serum hemoglobin level within 1 min of placement of the probe. The accuracy and reliability of both these monitors vary and the clinical applicability in trauma remains to be defined. Accuracy of continuous non-invasive hemoglobin monitoring.

Methods: This observational study evaluated the correlation between noninvasive hemoglobin monitoring (SpHb) and invasive hemoglobin measurements (InvHb) in guiding blood transfusions during thoracic surgery. A total of 80 patients aged 18 years or older, all scheduled for thoracic procedures between July 2024 and July 2025, were enrolled. Continuous SpHb monitoring was performed throughout the surgeries, with simultaneous InvHb samples collected to validate the readings. The primary outcome will be the degree of correlation between SpHb and InvHb values.

Introduction:

Technology has always been an essential component of patient care. As technology has advanced over the years, the way we have practiced medicine has evolved as well. Perhaps no field in medicine has been affected by technology as much as surgery. From operations being performed without any pain control to robotic surgery, technology has completely revamped our practice of surgical care and the field of trauma surgery and critical care remains no exception. One of the major influences of technology on patient care has been the shift in paradigm away from highly invasive diagnostic and therapeutic procedures to non-invasive procedures. This has resulted in reduced time for diagnosis, critical decisions making, and treatment as well as improved patient satisfaction. Hemoglobin measurement is one of the most frequently performed laboratory tests after injury [1]. Non-invasive hemoglobin monitoring is a more recent introduction to the growing list of point-of-care testing capabilities that allows for the ability to monitor hemoglobin concentration in a continuous, accurate, and non-invasive fashion [2]. It is still growing in popularity and it is our impression that many trauma and critical care providers do not know about its utility nor the basic principles behind the mechanism of function. In this review, we will briefly discuss the basic principles of how non-invasive hemoglobin monitoring technology works, the different factors that affect its accuracy, and demonstrate how this technology may translate into added benefits to patient care.

Invasive measurement, although accurate is time-consuming, costly, painful for the patient, and may have potential risk for exposure to biohazards. It can significantly delay patient care because of the time required for the phlebotomy, transport of the sample to the laboratory, time required for analysis and validation, and the reporting of results back to physician. Hemoglobin (Hgb) measurement is one of the most frequently ordered laboratory tests in the trauma settings; it can help guide therapeutic plan of management [1]. In trauma patients, these decisions range from blood transfusions to operative intervention. There has been a significant paradigm shift towards non-operative management in trauma patients and the rate of operative intervention in blunt abdominal and pelvic trauma has significantly declined. The majority of these patients are managed non-operatively and undergo surgical intervention only for ongoing bleeding or hemodynamic instability [3,4]. This approach however requires close monitoring in the Intensive Care Unit (ICU) and repeated phlebotomy for hemoglobin measurement to assess for ongoing hemorrhage [5]. The use of continuous or spot-check non-invasive hemoglobin monitoring provides the ability to monitor these patients in real time and react to changes in hemoglobin levels. A Cochrane review from ten trials reported outcomes on 1780 patients and found that a restrictive transfusion strategy is associated with 20% lower mortality, reduced hospital and ICU length of stay [6]. On the other hand, post operative anemia is also associated with increased post operative morbidity and mortality [7]. Accurate continuous measures of hemoglobin can help avoid the extremes of over or under transfusion. This is another avenue where a quick non-invasive measurement of hemoglobin can help in the implementation of restrictive transfusion strategy.

3. Basics of function

There is some variation in the basic principles that govern the functioning of most commercially available non-invasive devices. Most non-invasive hemoglobin measurement devices rely on spectrophotometry. Light is transmitted through or reflected from tissues and blood differentially depending on their biochemical variables. This difference in the degree of reflection allows for calculation of the hemoglobin and hematocrit using a mathematical model [8]. Other devices rely on photoplethysmography, which is the study of volume changes in the body. They detect the relative magnitude of the photoplethysmographic signal at different times of the cardiac cycle using different wavelengths of light. Separate photodetectors detect this signal and utilize it to determine the hemoglobin content and hematocrit of blood [9,10].

4. Non-invasive hemoglobin monitors

Masimo Corporation (Irvine Ca.) has developed a Pulse COoximeter capable of measuring hemoglobin concentration using a noninvasive, multi-wavelength sensor for spot check and continuous measurement: the Radical 7 (Rad7) [11]. The technology emits multiple wavelengths of light and then calculates the hemoglobin concentration based on the adsorption of light in the blood [12]. The device uses a finger tip probe similar to a standard pulse oximeter sensor and determines the hemoglobin noninvasively. There are two types of hemoglobin measuring devices; continuous hemoglobin monitor and spot check hemoglobin monitor. The continuous non-invasive hemoglobin monitor, as the name suggests, monitors serum hemoglobin continuously and provides real time

References

[1] B. Joseph, V. Pandit, H. Aziz, et al., Transforming hemoglobin measurement in trauma patients: noninvasive spot check hemoglobin, *J. Am. Coll. Surg.* 220 (1) (2015) 93e98.

[2] B. Joseph, P. Hadjizacharia, H. Aziz, et al., Continuous noninvasive hemoglobin monitor from pulse ox: ready for prime time? *World J. Surg.* 37 (3) (2013) 525e529.

[3] K.J. Brasel, C.M. DeLisle, C.J. Olson, D.C. Borgstrom, Splenic injury: trends in evaluation and management, *J. Trauma Acute Care Surg.* 44 (2) (1998) 283e286.

[4] H.L. Pachter, A.A. Guth, S.R. Hofstetter, F.C. Spencer, Changing patterns in the management of splenic trauma: the impact of nonoperative management, *Ann. Surg.* 227 (5) (1998) 708e719.

[5] N.A. Stassen, I. Bhullar, J.D. Cheng, et al., Selective nonoperative management of blunt splenic injury: an Eastern association for the surgery of Trauma practice management guideline, *J. Trauma Acute Care Surg.* 73 (5) (2012) S294eS300.

[6] A. Shander, K. Knight, R. Thurer, J. Adamson, R. Spence, Prevalence and outcomes of anemia in surgery: a systematic review of the literature, *Am. J. Med.* 116 (Suppl. 7A) (2004) 58se69s.

[7] A.H. Nelson, L.A. Fleisher, S.H. Rosenbaum, Relationship between postoperative anemia and cardiac morbidity in high-risk vascular patients in the intensive care unit, *Crit. care Med.* 21 (6) (1993) 860e866.

[8] Y. Mendelson, Blood constituent determination based on differential spectral analysis, Google Patents, (1993) [cited 2015 July 15]. Available from: <http://www.google.com/patents/WO1993012712A1?cl=en>.

[9] Y. Mendelson, Y. Wang, B.D. Gross, Noninvasive measurement of hematocrit and hemoglobin content by differential optical analysis, Google Patents, (1994) [cited 2015 July 15]. Available from: <http://www.google.com/patents/US5277181>.

[10] B.R. Soller, R.H. Micheels, Non-invasive optical measurement of blood hematocrit, Google Patents, (1999) [cited 2015 July 15]. Available from: <http://www.google.com/patents/US6006119>.

[11] Masimo Corporation. 2015; <http://www.masimo.com/>. Accessed August 1, 2015.

[12] Masimo Corporation. 2015; <http://www.masimo.com/>. Accessed July 15, 2015.