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A noninvasive hemoglobin monitor in the pediatric intensive care unit

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ABSTRACT

Background: Critically ill pediatric patients frequently require hemoglobin monitoring. Accurate noninvasive Hb (SpHb) would allow practitioners to decrease anemia from repeated blood draws, traumatic blood draws, and a decreased number of laboratory Hb (LabHb) medical tests. The Food and Drug Administration has approved the Masimo Pronto SpHb and associated Rainbow probes; however, its use in the pediatric intensive care unit (PICU) is controversial. In this study, we define the degree of agreement between LabHb and SpHb using the Masimo Pronto SpHb Monitor and identify clinical and demographic conditions associated with decreased accuracy.

Materials and methods: We performed a prospective, observational study in a large PICU at an academic medical center. Fifty-three pediatric patients (30-d and 18-y-old), weighing >3 kg, admitted to the PICU from January–April 2013 were examined. SpHb levels measured at the time of LabHb blood draw were compared and analyzed.

Results: Only 83 SpHb readings were obtained in 118 attempts (70.3%) and 35 readings provided a result of "unable to obtain." The mean LabHb and SpHb were 11.1 g/dL and 11.2 g/dL, respectively. Bland–Altman analysis showed a mean difference of 0.07 g/dL with a standard deviation of ±2.59 g/dL. Pearson correlation is 0.55, with a 95% confidence interval between 0.38 and 0.68. Logistic regression showed that extreme LabHb values, increasing skin pigmentation, and increasing body mass index were predictors of poor agreement between SpHb and LabHb ($P < 0.05$). Separately, increasing body mass index, hypoxia, and hypothermia were predictors for undetectable readings ($P < 0.05$).

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Conclusions: The Masimo Pronto SpHb Monitor provides adequate agreement for the trending of hemoglobin levels in critically ill pediatric patients. However, the degree of agreement is insufficient to be used as the sole indicator for transfusion decisions and should be used in context of other clinical parameters to determine the need for LabHb in critically ill pediatric patients.

1. Introduction

Critically ill pediatric patients frequently require hemoglobin (Hb) monitoring. When compared to adults, serial Hb monitoring presents unique challenges specific to the pediatric population, including: anemia from repeated blood draws [1], difficulties with venous access, and decreased patient cooperation with blood draws [2,3]. These challenges, and the traumatizing nature of venipuncture laboratory draws in children, are balanced with a clinician's desire to avoid unnecessary laboratory blood draws and medical tests. In an effort to provide rapid and cost-effective Hb analysis, noninvasive hemoglobin (SpHb) devices have been developed and approved by the FDA. One of these monitors is the Masimo Pronto SpHb Monitor (Masimo Corporation, Irvine, CA).

Before and since the time of Food and Drug Administration approval, several studies have examined the use of SpHb in neonates, children, and adults. The focus of these studies has been the degree of agreement between the SpHb and laboratory Hb (LabHb). Previous studies done in pediatric patients have found "acceptable" agreement between SpHb and LabHb in the outpatient [4], preoperative [5], and operating room settings [6–8]. However, the data regarding its use and implementation in critically ill children are sparse as there is only a single study examining the use of Masimo technology in a Pediatric Intensive Care Unit (PICU) [9]. However, if the accuracy of the device could be demonstrated in critically ill children, the PICU would provide an ideal setting for the use of SpHb given the need for serial monitoring in a large number of patients to address the challenges specific to pediatric patients. The present study examines the use of the Masimo Pronto SpHb Monitor, the agreement with LabHb levels in critically ill children in a busy tertiary care setting, as a first step in ultimately determining the clinical utility of the monitor in this patient population.

2. Methods

We conducted a prospective, observational study to determine the accuracy of the Masimo Pronto SpHb Monitor and associated Rainbow probes for the detection of Hb concentration in a cohort of critically ill pediatric patients admitted to the University of North Carolina PICU between January and April 2013. The study protocol was reviewed and approved by the University of North Carolina Internal Review Board (IRB #12-2019) in compliance with the guidelines on the treatment of human subjects; this study was registered at clinicaltrials.gov (NCT01750463).

2.1. Eligibility criteria and recruitment

Pediatric patients (aged 30 d–18 y), who required hospitalization in the PICU with Hb monitoring during the 3 month enrollment period, were eligible for the study. Patients were excluded if they did not have exposed fingers or toes because of congenital anomalies, wound dressings, or another injury. Also patients weighing less than 3 kg were excluded.

At the time of admission to the PICU, attending physicians, nurses, or advanced care providers determined whether patients met inclusion criteria. Parents or legal guardians of eligible patients were provided with an information sheet regarding the study. Consent forms and Health Insurance Portability and Accountability Act research authorization forms were obtained by a member of the research team. Demographic data were extracted from patient charts after discharge, including date of admission, date of discharge, body mass index (BMI), admission diagnosis, race, ethnicity, date and time of LabHb and SpHb, device number, perfusion index (PI—which is the "ratio of pulsatile blood flow to nonpulsatile or static blood flow" [10]) measured by the device, oxygen saturation (SpO_2), mode of ventilation or oxygen support, body temperature, heart rate, mean arterial pressure, Richmond Agitation and Sedation Score, the use of vasopressors, and the LabHb result.

The extent of each subject's participation was dependent on the frequency of Hb monitoring required for medical management, which was determined by the pediatric intensivist on-call. Patients requiring a Hb assessment on admission were enrolled in the study and continued through four blood draws or discharge from unit.

2.2. Protocol

Nurses or phlebotomy personnel drew specimens for laboratory processing as per provider orders and standard hospital protocol. Pediatric Respiratory Therapists (RTs), received training before initiation of the study, on the use and application of the Masimo probes. Each RT demonstrated competence in the use of the device, and a designated RT manager was on-call to answer questions regarding the function and application of the device. The RT in the PICU was called to the bedside before the blood draw (venous or arterial samples were accepted). The RT obtained noninvasive measurement of Hb using the Masimo Pronto device to correlate SpHb values with LabHb results at the time of venipuncture. The specimens were sent to the hospital's central laboratory for processing (Adviat 120/2120 hematology system CBC/Diff) per standard operating procedures. Hb, oxygen saturation, pulse rate, and PI values measured with the Masimo Pronto device were recorded at each time point for each subject. RTs conducted measurements per manufacturer protocol and received training and practice before initiation of the study.

2.3. Sensor site

For consistency, toes or fingers were used as sensor sites, usually the nondominant ring or index finger; avoiding limbs