Absolute and Trend Accuracy of Continuous and Noninvasive Hemoglobin in Pediatric Surgery Patients.

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Introduction

Total hemoglobin concentration (tHb) is frequently ordered during surgery to detect blood loss and assess the effects of transfusion or fluid administration, but is only intermittent and requires invasive blood sampling and time-consuming lab analysis. A new device (Rainbow SET® Pulse CO-Oximeter Masimo Corporation, Irvine, CA, USA) provides continuous and noninvasive hemoglobin concentration (SpHb), which may provide earlier indication of bleeding and aid transfusion management decisions. The purpose of this study was to compare SpHb and a point-of-care (POC) tHb test device to standard laboratory measurements.

Methods

After IRB approval and patient consent, SpHb monitoring (software version 7.4.09 (first 5 cases) & 7.5.03 (next 10 cases) and sensor version C was applied to pediatric patients undergoing surgery. During the case, intermittent measurements of tHb were taken with both a POC device, i-STATTM (Abbott Laboratories, Abbott Park, IL) and a laboratory Cell-Dyn Sapphire Differential Cell Counter (Abbott Diagnostics, Santa Clara, CA), each maintained and calibrated according to the manufacturer's recommendations. At same time, data were collected from two SpHb sensors (Revision C: R1 20-L or R1 25-L) located on left & right ring finger, or on the toe if patient was too small. Absolute accuracy was determined by calculating bias, precision, and accuracy root mean square (A_{RMS}) of the difference between SpHb and point-of care tHb to Cell-Dyn Sapphire Differential Cell Counter tHb values. Trend accuracy was determined by retrospective panel review of each case for directional changes in tHb concentration and whether SpHb provided a similar directional indication.

Results

A total of 17 patients from a variety of surgery cases (craniotomy, cardiac surgery, spinal fusion, liver transplant) were enrolled. Two patients were removed from analysis, one because blood gas samples were not acquired and one because SpHb was not applied per protocol. Thus, 4 males and 11 females were analyzed, with a mean age of 9.3+/- 5.9 years (Range 0.1 to 17 years). An average of 2.7 +/- 0.9 arterial blood samples per patient were taken during the surgical procedure. 49 CO-Oximeter tHb measurements, 46 POC tHb, and 92 SpHb measurements were compared. Mean bias, standard deviation and A_{RMS} are shown in Table 1. Retrospective review indicated that all significant directional changes in tHb from the CO-Oximeter were indicated by changes in SpHb. In addition, SpHb provided earlier indications of directional changes than intermittent tHb values from the CO-Oximeter.

Discussion

SpHb offers clinically acceptable absolute accuracy and very good trend accuracy compared to a laboratory CO-Oximeter. The impact of continuous SpHb on clinical decision making should be further investigated.

Table 1. Pediatric Surgery Hemoglobin Comparisons

	SpHb - Lab Hb N=92	POC - Lab Hb N=45
Bias (g/dL)	0.18	-0.26
Standard Deviation (g/dL)	1.10	0.46
ARMS (g/dL)	1.12	0.53

Bias (g/dL)	0.18	-0.2