Clinical Study Summary

Impact of Continuous and Noninvasive Hemoglobin Monitoring on Intraoperative Blood Transfusions

Ehrenfeld JM, Henneman JP, Sandberg WS. *American Society of Anesthesiologists.* 2010;LB05.

Introduction

Blood transfusions continue to pose real patient risk in the form of adverse outcomes such as postoperative infection, cancer recurrence, impaired pulmonary function, as well as increased length of stay and mortality.[1-10] Additionally, transfusion is a costly and a significant contributor to the expense of surgical care, with total costs per unit transfused between $522 to $1,183,[11] without modeling in short- or long-term costs associated with transfusion-related events. Laboratory hemoglobin (Hb) values are a primary indicator of the need for blood transfusion, but testing is intermittent and results are often delayed. This means that during surgery, initial and subsequent transfusion decisions can be made without recent Hb results. Continuous, noninvasive hemoglobin (SpHb®) monitoring is now possible with a Pulse CO-Oximeter™ and multiwavelength adhesive sensor. We hypothesized that SpHb monitoring could reduce intraoperative blood transfusions.

Methods

We undertook a prospective, randomized, controlled trial at an academic medical center (Massachusetts General Hospital, Boston, MA) to assess the impact of SpHb monitoring upon transfusions in adult patients undergoing elective orthopedic surgery during a six month period. The study (#2009P002600) was approved by an institutional review board. Patients were randomized to receive either standard care alone or standard care plus SpHb monitoring (Radical-7™ Pulse CO-Oximeter and Rainbow ReSposable™ Adhesive Sensor, Revision E, Masimo, Irvine, CA). Laboratory Hb was obtained by venous or arterial blood samples taken at anesthesiologist direction. Anesthesiologists were instructed to care for patients in the Standard Care Group as they normally would. For patients in the SpHb Group, anesthesiologists were instructed to care for patients as they normally would but to use their own discretion on the use of SpHb values to help guide need for laboratory Hb tests and blood transfusions. For each patient enrolled in the study, we obtained a matched patient from a retrospective cohort taken from the six-month period prior to this study.

Primary outcome variables were the frequency of intraoperative transfusions and mean number of red blood cell (RBC) units transfused. Secondary outcome variables were the frequency of laboratory Hb testing and agreement between SpHb and laboratory Hb values. Post-operative transfusion rates and complication rates for each group were assessed at 30 days post-surgery as a safety endpoint. Statistical analysis was performed with commercially-available software (JMP, SAS, Cary, NC). Differences in baseline variables were determined by the Student's t-test. Differences in outcome variables were determined by the Fisher exact test.

Results

A total of 350 patients were screened and 327 patients were enrolled (170 SpHb, 157 Standard Care). Procedures included hip replacement (31%), knee replacement (29%), and spinal surgery (14%). The matched retrospective cohort mirrored both Groups and consisted of 327 subjects. There were no differences between the SpHb and Standard Care Groups in baseline characteristics (Table 1), pre-operative lab hemoglobin (13.5 vs. 13.6 g/dL), intraoperative estimated blood loss (157 vs. 210 mL), surgical duration (114 vs. 127 minutes), or surgical type (Table 2).

Table 1: Demographics of Study Population

	Standard Care Group (N=157)	SpHb Group (N=170)	Retrospective Cohort (Matched to Standard Care Group) (N=157)	Retrospective Cohort (Matched to SpHb Group) (N=170)
ASA Status 4	3 (2%)	1 (1%)	3 (2%)	2 (1%)
3	30 (19%)	43 (25%)	29 (19%)	41 (24%)
2	117 (75%)	107 (63%)	117 (75%)	107 (63%)
1	7 (4%)	19 (11%)	8 (5%)	20 (12%)
Male gender, %	54%	48%	54%	48%
Age (years)	61	62	61	62

Table 2: Procedures Performed

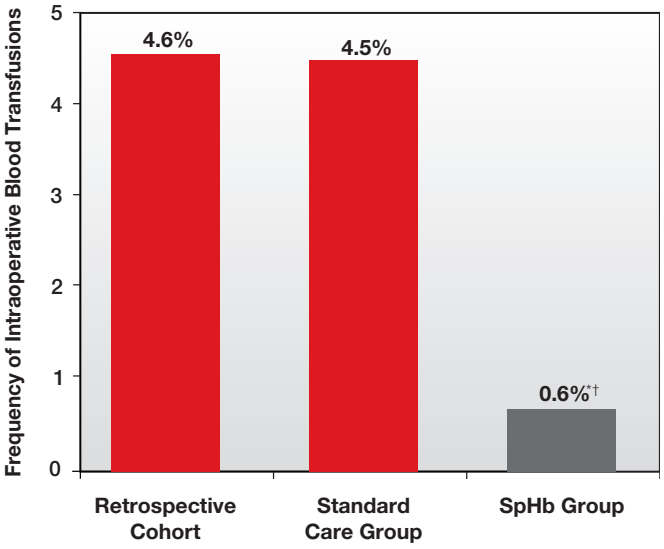
Standard Care Group N	Standard Care Group Procedure	SpHb Group N	SpHb Group Procedure
49	Hip Replacement	52	Hip Replacement
44	Knee Replacement	52	Knee Replacement
24	Spine	21	Spine
9	Leg Injury	8	Leg Injury
6	Shoulder Replacement	4	Hip Injury
5	Knee Injury	4	Knee Injury
4	Ankle Injury	4	Shoulder Injury
3	Shoulder Injury	4	Ankle Injury
2	Ankle Replacement	3	Shoulder Replacement
2	Arm Injury	3	Ankle Hardware
2	Leg Hardware Removal	2	Wrist Injury
1	Elbow Injury	1	Achilles Repair
1	Finger Injury	1	Ankle Tumor
1	Foot Injury	1	Back Injury
1	Hip Injury	1	Elbow Hardware
1	Leg Tumor	1	Elbow Injury
1	Irrigation and Debridement	1	Foot Replace
1	Total Elbow	1	Hip Tumor
		1	Knee Tumor
		1	Leg Hardware Removal
		1	Leg Tumor
		1	Neck Injury
		1	Shoulder Tumor
		1	Skin Graft

The matched retrospective cohort had a similar RBC transfusion frequency and mean number of RBC units transfused compared to the Standard Care Group that served as the active control in the study (4.6 vs. 4.5%, p=ns; and 0.08 vs. 0.10, p=ns, respectively). Intraoperative RBC transfusion frequency was lower in the SpHb Group compared to the Standard Care Group (0.6% vs. 4.5%, p=0.03). The mean number of RBC units transfused was also lower in the SpHb Group compared to the Standard Care Group (0.01 vs. 0.10, p<0.0001) (Table 3 and Figure 1). Intraoperative RBC transfusion frequency and the mean RBC units transfused were also lower in the SpHb Group compared to the retrospective cohort (0.6% vs. 4.6%, p=0.02; and 0.01 vs. 0.08, p<0.0001, respectively).

Table 3: Study Results

	Retrospective Cohort (N=327)	Standard Care Group (N=157)	SpHb Group (N=170)
Patients receiving a blood transfusion, N (%)	15 (4.6%)	7 (4.5%)	1 (0.6%)* †
Total units transfused, N (mean)	26 (0.08)	15 (0.10)	2 (0.01)** ††

**p=0.03 vs. Standard Care Group; †p=0.02 vs. Matched Retrospective Cohort; **p<0.0001 vs. Standard Care Group; ††p<0.0001 vs. Matched Retrospective Cohort*



**p=0.03 vs. Standard Care Group*
†p=0.02 vs. Matched Retrospective Cohort

Figure 1: Frequency of Patients Receiving RBC Transfusion (%)

No patient from either group received a transfusion during the immediate 12 hour post-operative period. The frequency of patients receiving intraoperative Hb testing and the mean number of Hb tests performed were similar in the SpHb and Standard Care Groups (11.8% vs. 16.3% and 0.21 vs. 0.24 tests per case). Intraoperative SpHb and laboratory Hb values showed good agreement (mean difference 1.1 + 0.68 g/dL). There was no difference between SpHb and Standard Care Groups in 30-day complication rates (1.9% vs. 3.0%, p=ns).

Discussion

Our results demonstrate that SpHb-guided blood management in orthopedic surgical patients resulted in a lower frequency of blood transfusion and a lower mean number of units transfused, compared to both the active control and retrospective cohort groups. Continuously monitoring anemic status with SpHb may prevent unnecessary intraoperative blood transfusions.

The transfusion frequency and mean units transfused in our retrospective cohort group were consistent with our prospective control. This validates that the results achieved in the Standard Care Group did not represent lower or higher transfusion activity than is typical at our institution.