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Continuous Non-invasive Hemoglobin Monitoring during Orthopedic Surgery: A Randomized Trial

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Abstract

Blood transfusions during orthopedic surgery increase the risk of adverse outcomes and are costly. In current practice, laboratory hemoglobin values are used to determine the need for blood transfusion, but testing is intermittent. We hypothesized that continuous non-invasive hemoglobin monitoring (SpHb) could reduce intraoperative blood transfusions. Patients undergoing elective orthopedic surgery were randomized to receive standard care alone or standard care with SpHb monitoring. Of the 327 patients enrolled (170 intervention, 157 control), 0.6% received intraoperative transfusions in the intervention group compared to 4.5% in the control group, for an absolute risk reduction of 4% (95% CI: -7% to -0.4%). The amount of red blood cell units transfused did not differ between the groups, nor did the rate of laboratory hemoglobin testing. The use of continuous non-invasive hemoglobin monitoring may reduce the rate of transfusions when compared to standard care using intermittent laboratory hemoglobin testing.

Keywords: Intraoperative monitoring; Blood transfusions; Orthopedic surgery

Introduction

When available, Hemoglobin concentration (Hb) values are used as a primary indicator of need for red blood cell transfusion [1]. Laboratory Hb determination requires provider directed blood sample collection and significant time to process - delaying the receipt of the laboratory result from when the clinical need for Hb measurement is established [2,3]. This means that during surgery, initial and subsequent transfusion decisions may be made without recent Hb results. Not surprisingly, inadequate information about a patient's circulating hemoglobin is strongly associated with inappropriate transfusions [4]. Since blood transfusions are associated with postoperative infection, cancer recurrence, length of stay, and mortality, in addition to being costly, continued efforts to reduce unnecessary transfusions are warranted [5-10].

Recent advancements have made continuous and non-invasive hemoglobin monitoring (SpHb) possible through multiwavelength Pulse CO-Oximetry [11]. Several studies have indicated that SpHb provides values comparable to laboratory Hb for both absolute and changes in hemoglobin values, while others have suggested SpHb is unreliable and correlates poorly with laboratory Hb [12-21]. In spite of its limitations, continuous SpHb monitoring may provide useful real-time information to the anesthesiologist during the transfusion decision making process, perhaps by making Hb trend data visible. We hypothesized that SpHb monitoring could reduce both the rate of intraoperative blood transfusions and the amount of red blood cell units transfused.

Materials and Methods

The study setting was a large tertiary care center (Massachusetts General Hospital, Boston, MA). The study (#2009P002600) was approved by the Partners Healthcare Human Research Committee (IRB). Designed to be a 6-month pilot study, subjects were screened for eligibility and enrolled between February and July of 2010. An a priori power analysis was not performed, as we did not have a reasonable estimate of the effect size prior to launching the pilot study. Adult patients (age ≥ 18 years) were eligible if they were undergoing elective orthopedic surgery under general anesthesia. There were no exclusion criteria.

After study enrolment, randomization to receive either standard care alone (Standard Care Group) or standard care with SpHb monitoring (SpHb Group) was conducted for this parallel-group study using block randomization with a block size of 4. All orthopedic cases were randomized without regard for procedure type. Case demographics and clinical data were obtained from the electronic intraoperative record. Demographic data included American Society of Anesthesiologists (ASA) physical status classification, age, and gender. Clinical data included procedure, surgical duration, estimated blood loss, Hb values, and intraoperative transfusions. We also collected information (date, time, number of units transfused) about transfusion, for both the initial postoperative period (defined as twenty-four hours post-surgical end time) and the entire hospitalization. Intraoperative and postoperative blood transfusions were considered to be transfusions of packed red blood cells or whole blood, but not other blood products such as fresh frozen plasma or platelets.

Laboratory Hb was obtained by venous or arterial blood samples taken at the discretion and direction of the patient's anesthesiologist. Because the focus of our study was on understanding if continuous monitoring of hemoglobin during surgery could reduce the rate of red blood cell transfusions, rather than the accuracy of the SpHb device, we did not dictate as a part of the study protocol intraoperative hemoglobin values. When available however, samples were analyzed in the hospital's central laboratory with a Siemens Rapidlab 1265 calibrated

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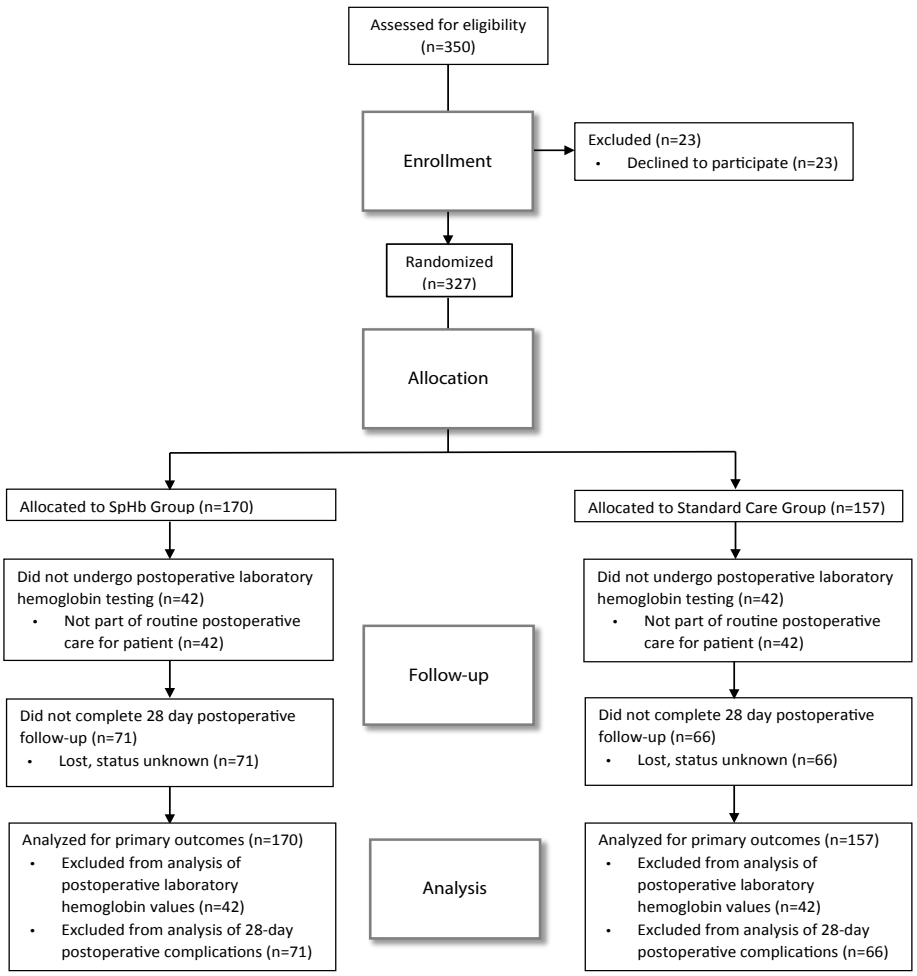

Figure 1: Flow diagram of pilot randomized controlled trial comparing standard care with continuous hemoglobin monitoring during surgery.

to manufacturer's specifications. Records were obtained through an electronic database query of the hospital clinical data repository to obtain preoperative, intraoperative, and postoperative hemoglobin values. Preoperative Hb values were defined as the most recently available laboratory Hb results prior to entering the operating room; postoperative Hb values were defined as the first available laboratory Hb result after the patient left the operating room.

SpHb values were obtained with a multiwavelength Pulse CO-Oximeter and adhesive sensor (Radical-7 Monitor and Rainbow Resposable Adhesive Sensor, Rev E, Masimo, Irvine, CA). Pulse CO-Oximetry technology utilizes multiple wavelengths of light with advanced signal processing and adaptive filters to identify, isolate, and quantify blood constituents including total hemoglobin, methemoglobin, and carboxyhemobin, along with oxygen saturation (SpO_2), pulse rate, and perfusion index. The SpHb monitor was mounted in the operating room on the anesthesia machine in a readily accessible and visible position for the anesthesia care team to view. The anesthesia care provider was informed of the device and its proper use. The SpHb monitors displayed and recorded SpHb and other measurements continuously.

At Massachusetts General Hospital during the study period, there were no formally agreed upon hospital or departmental transfusion guidelines. Decisions about transfusions were made by the anesthesia care team although most practitioners favored a restrictive transfusion approach during the conduct of the study. 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 in the use of SpHb values to help guide need for laboratory Hb tests and blood transfusions. Notably, there was no attempt to standardize transfusion practices or initiate a specific transfusion protocol during the study period, as we were primarily interested in understanding the impact of adding the SpHb technology to existing practice.

The primary outcome variables were the frequency of intraoperative red blood cell transfusions and the number of red blood cell units transfused per patient. Secondary outcome variables included the frequency of laboratory Hb testing and the frequency of postoperative blood transfusions. To monitor safety, each patient also received a follow-up phone call by a trained research assistant 28 days after their surgery to identify the presence of postoperative complications. Patients were asked if they had been to an emergency room or urgent care clinic since their original surgery, and if they had been readmitted to a hospital after their original surgery. Additionally, we screened each patient's medical record to determine if patients had been readmitted

to the study hospital, had a second surgery, or visited the emergency department at the study hospital.

Concerned that clinicians might alter their transfusion practices solely on the basis of their patient being enrolled in our study, we identified a retrospective cohort (from before the time of the study) to check this possibility. For each patient enrolled in the standard care group (N=157), we obtained a matched patient from a retrospective cohort taken from the six-month period prior to this study at the same study site. Electronic records were used to identify patients who were matched on three criteria: age, ASA physical status classification, and procedure. We compared the Standard Care Group to the matched retrospective cohort on primary outcomes only, in a set of comparisons planned in advance and separate from the main outcome comparisons between the SpHb and standard care groups in the active study.

Continuous variables were assessed for normality using histograms. When normally distributed, continuous variables are expressed as mean (SD). Skewed continuous variables are expressed as median (range). Categorical variables are presented as N (%). We calculated differences between the groups as the difference between means, medians, or proportions depending on the variable type. These were considered statistically significant when the confidence interval for the difference (95% CI) did not contain zero.

Results

We recruited patients from February 2010 through July 2010. A total of 350 patients were screened, and 327 patients were enrolled with 157 patients in the Standard Care Group and 170 patients in the SpHb Group (Figure 1). For all patients, procedures included primarily hip replacement (33%), knee replacement (30%), and spinal surgery (13%). The retrospective cohort, who received no intervention and was matched to the Standard Care Group, consisted of 157 subjects. As shown in Table 1, baseline characteristics between the Standard Care Group, the SpHb Group, and the matched retrospective cohort were similar. The standard care group was 53.5% male and had an average age of 61.0 ±15.8 years. The majority (73.9%) of the standard care group had an ASA class of 2. The SpHb group was 48.2% male and had an average age of 61.9 ± 15.9 years. Of the 170 patients in this group, 107 (62.9%) had an ASA class of 2. The mean preoperative laboratory hemoglobin value was 13.5 ± 1.6 g/dL in the SpHb Group and 13.6 ± 1.5 g/dL in the Standard Care Group.

Table 2 provides information on the primary and secondary outcomes for the Standard Care Group and SpHb Group. The risk difference for intraoperative RBC transfusion between the SpHb Group and the Standard Care Group was -0.04 (95% CI: -0.07, -0.004). Among the SpHb Group, only one patient received an intraoperative RBC transfusion. This patient underwent a spine procedure. The median number of RBC units transfused among both the SpHb Group and the Standard Care Group was 0. We observed no difference between the groups in the amount of estimated blood loss (median difference between groups: 0). The likelihood of patients receiving intraoperative Hb testing was similar in the SpHb and Standard Care Groups (risk difference: -0.03, 95% CI: -0.11 to 0.04).

No patient from either group received any additional transfusion during the immediate twenty four-hour postoperative period, and only one patient (in the control group) received a transfusion during their entire postoperative hospital course. Of the 327 patients recruited, 190 patients responded to a follow up call (58%). There were no observed differences at 28 days in the rate of postoperative complications (defined as death, readmission to a hospital, a second surgery, or a visit to the emergency room or an urgent care clinic in the 28 days after surgery) between the SpHb and Standard Care Groups (risk difference: -0.09, 95% CI: -0.20 to 0.02). As shown in Table 3, the Standard Care Group had a similar RBC transfusion rate compared to the matched retrospective cohort (risk difference: 0.01, 95% CI: -0.04 to 0.06). Median RBC units transfused per case in the Standard Care and the retrospective cohort groups were both 0.

Discussion

Our results demonstrate that SpHb-guided blood management in a diverse group of orthopedic surgical is associated with a 4% (95% CI: -7% to -0.4%) absolute reduction in the risk of having a blood transfusion during surgery compared to standard care. However,

	Retrospective Cohort (N=157)		SpHb Group N=170)		Standard Care Group (N=157)	
		Total*		Total*		Total*
Age (years), Mean (SD)	61.0 (15.4)	157	61.9 (15.9)	170	61.0 (15.8)	157
ASA Status, N (%)						
1	10 (6.4)	157	19 (11.1)	170	8 (5.1)	157
2	111 (70.7)	157	107 (62.9)	170	116 (73.9)	157
3	35 (22.3)	157	43 (25.2)	170	30 (19.1)	157
4	1 (0.6)	157	1 (0.6)	170	3 (1.9)	157
Male, N (%)	84 (53.5)	157	82 (48.2)	170	84 (53.5)	157
Laboratory Hb value (g/dL), Mean (SD)[a]	-	-	13.5 (1.6)	155	13.6 (1.5)	147
Surgical Procedure, N (%)[b]						
Hip Replacement	-	-	55 (32.4)	170	52 (33.1)	157
Knee Replacement	-	-	56 (32.9)	170	42 (26.8)	157
Spine Surgery	-	-	21 (12.4)	170	22 (14.0)	157
Incision and Drainage	-	-	4 (2.4)	170	9 (5.7)	157
Shoulder Surgery	-	-	6 (3.5)	170	8 (5.1)	157
Other	-	-	28 (16.5)	170	46 (29.3)	157

*Total refers to the number of patients for whom relevant data was available (e.g. responded to follow up).
[a]Preoperative laboratory Hb values unavailable for the Retrospective Cohort
[b]Surgical procedure data unavailable for the Retrospective Cohort. Other includes ankle, femur, tibia, Achilles tendon, humerous, elbow, hallux valgus, calcaneous, tibial, and wrist repairs; tumor and hardware removal, and leg tendon transplants.

Table 1: Characteristics of patients in the Retrospective Cohort, Standard Care Group, and SpHb Group.

	SpHb Group (N=170)		Standard Care Group (N=157)		Difference[a]	95% CI
Intraoperative		**Total***		**Total***		
Received RBC transfusions, N (%)	1 (0.6)	170	7 (4.5)	157	-0.04	(-0.07, -0.004)
By procedure type, N	Spine Surgery,1		Spine Surgery, 3 Hip Surgery, 3 Knee Surgery, 1			
RBC units transfused, Median (Range)	0 (0-2)	170	0 (0-5)	157	0.00	(0.00, 0.00)
Estimated blood loss (mL), Median (Range)	100 (0-2,000)	170	100 (0-1,500)	157	0.00	(0.00, 50.00)
Received laboratory Hb test, N (%)	18 (10.6)	170	22 (14.0)	157	-0.03	(-0.11, 0.04)
Postoperative						
Received RBC transfusions, N (%)	0 (0.0)	170	1 (0.6)	157	-0.01	(-0.02, 0.01)
Laboratory Hb value (g/dL), Mean (SD)	11.8 (1.5)	128	11.7 (1.5)	115	-0.02	(-0.40, 0.36)
Suffered complications within 28 days, N (%)	15 (15.2)	99	22 (24.2)	91	-0.09	(-0.20, 0.02)

*Total refers to the number of patients for whom relevant data was available (e.g. responded to follow up).
[a]For categorical variables, difference refers to the risk difference. For normally distributed continuous variables, difference refers to the difference in means. For skewed continuous variables, difference refers to the difference in medians.

Table 2: Intraoperative and postoperative outcomes among the Standard Care Group (control) and SpHb Group (intervention).

	Retrospective Cohort (N=157)		Standard Care Group (N=157)		Difference[a]	95% CI
Intraoperative		**Total***		**Total***		
Received RBC transfusions, N (%)	9 (5.7)	157	7 (4.5)	157	0.01	(-0.04, 0.06)
RBC units transfused, Median (Range)	0 (0-3)	157	0 (0-5)	157	0.00	(0.00, 0.00)

*Total refers to the number of patients for whom relevant data was available (e.g. responded to follow up).
[a]For categorical variables, difference refers to the risk difference. For normally distributed continuous variables, difference refers to the difference in means. For skewed continuous variables, difference refers to the difference in medians.

Table 3: Intraoperative outcomes among the Standard Care Group (control) and the matched retrospective cohort.

we observed no statistically significant difference in the amount of RBC units transfused between the two groups. Since patients were randomized to the SpHb and Standard Care Groups, we conclude the difference in the rate of intraoperative transfusions was due to the presence of continuous and non-invasive Hb values in the SpHb Group. The reduction in intraoperative transfusion rate was not temporary, as evidenced by the absence of postoperative transfusion rates in the SpHb Group. We believe that the availability of SpHb decreases inappropriate transfusion (either by preventing an initial transfusion, or the transfusion of additional blood products after a single unit has been delivered). To our knowledge, this is the first study to assess the impact of continuous non-invasive hemoglobin monitoring during surgery on the frequency of red blood cell transfusions.

We chose to study orthopedic surgical patients because of their high procedural volume and our desire to assess benefit in patients with a moderate overall risk for transfusion. Thus, if SpHb monitoring provides clinical and financial benefit in this population, then this result could be robust in patients at higher risk for transfusion. We chose not to create a specific transfusion protocol in either group because we wanted the Standard Care Group to represent real-world behavior at our hospital and also because we wanted to observe the naturally occurring impact of SpHb monitoring (as distinct from protocol adherence) on clinician behavior.

A small sample size and limited statistical power are obvious limitations of this pilot randomized trial. Another major limitation of our study was the relatively rare event occurrence of a transfusion in the population studied. While a higher risk group (e.g. trauma, cardiac, vascular) may have provided more events for comparison, their case volume would be both dramatically lower, and already heavily biased towards a more apparent clinical indication for transfusion. We sought to capture the population of patients for whom transfusions were a fair possibility, yet where the decision to transfuse was less clear and could be influenced by Hb monitoring. Although the absolute risk reduction was statistically significant, the low percentage of patients receiving RBC transfusions may mean that the actual reduction experienced by hospitals could be higher or lower.

A further limitation is that clinicians may have altered their transfusion practices solely on the basis of their patient being enrolled in our study (i.e. Hawthorne effect). We created a retrospective cohort to investigate this possibility, to see if transfusion practices matched historical controls. The transfusion rate and mean RBC units transfused per case in our retrospective cohort group were consistent with the rate of transfusion in our prospective control, the Standard Care Group. This validates that the results achieved in the Standard Care Group did in fact represent standard care for our hospital, and did not represent lower or higher transfusion activity than is typical at our institution for this population. Furthermore, Hb values were not universally measured in patients, nor were pre and post transfusion Hb values universally available. Because our institution did not possess transfusion guidelines, it was difficult to assess rationale for transfusion. However, a strong reason for performing the study was the idea that perhaps there are, in fact, robust clinical markers that can help guide our decision-making. Only a small subset, little more than half, of our patients responded to follow-up calls, making postoperative evaluation difficult to generalize.

In the absence of objective information to guide intraoperative transfusion decisions, clinicians can react to readily available indicators that are secondary indicators of circulating red cell mass, such as visual estimation of blood loss or changes in vital signs. While visual estimation of blood loss is commonly performed, its accuracy is limited and should not be used to solely determine need for RBC transfusion [22]. Point of care hemoglobin measurement is also an option, but it is invasive as it requires a blood sample and likely similar in accuracy to SpHb [23]. The lack of continuous Hb values during surgery may lead to inaccurate assumptions about anemic status, as incomplete knowledge

of Hb values is a major factor in inappropriate RBC transfusions [24,25]. In theory, continuous anemia assessment with SpHb could guide both the decision to transfuse when hemoglobin values are low or unstable, and the decision to withhold transfusion when Hb values are not low or unstable. Continuous SpHb monitoring may allow clinicians to more confidently manage patients at lower Hb levels with the knowledge that further drops into a critical anemic range will become readily apparent. Assuming that cardiac output remains roughly constant, continuous SpHb and SpO_2 monitoring gives a rough approximation of oxygen delivery, enabling clinicians to focus more holistically on the patient physiology than on a static Hb trigger for transfusion.

Given the results of our pilot study, we believe that SpHb shows promise as an adjunct to current perioperative monitoring practice. However, care should be given to ensure that new technologies are appropriately evaluated in the context of patient care to confirm that the benefits provided outweigh the associated risks and costs.

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