






Postoperative Noninvasive Hemoglobin Monitoring Is Useful to Prevent Unnoticed Postoperative Anemia and Inappropriate Blood Transfusion in Patients Undergoing Total Hip or Knee Arthroplasty: A Randomized Controlled Trial

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Abstract

Introduction: Postoperative nadir hemoglobin (Hb) is related to a longer length of stay for geriatric patients undergoing orthopedic surgery. We investigated whether postoperative pulse Hb (SpHb) measurement is useful for avoiding anemia and inappropriate blood transfusion after total hip arthroplasty and total knee arthroplasty. **Material and Methods:** This prospective randomized controlled study included 150 patients randomly assigned to receive blood transfusion, either guided by SpHb monitoring (SpHb group) or based on the surgeons' experience (control group). The target laboratory Hb value was set to >8 g/dL at postoperative day 1 (POD1). The primary endpoints were the product of total time and degree of SpHb <8 g/dL (area under SpHb 8 g/dL) during the period up to POD1 and the incidence of laboratory Hb <8 g/dL at POD1. The secondary endpoints were the amount of blood transfusion and inappropriate blood transfusion, which was defined as allogeneic blood transfusion unnecessary in a case of SpHb >12 g/dL or delayed transfusion in a case of SpHb <8 g/dL. **Results:** The area under SpHb 8 g/dL was 37.6 ± 44.1 g/dL-min (5 patients) in the control group and none in the SpHb group ($P = .0281$). There was 1 patient with Hb <8 g/dL at POD1 in the control group. There was no difference in laboratory Hb levels and the amount of blood transfusion. Forty-one patients (19 in the control group and 22 in the SpHb group) received an allogeneic blood transfusion. Among these patients, 7 in the control group and none in the SpHb group received inappropriate blood transfusion ($P = .0022$). **Discussion:** The SpHb monitoring could reduce unnoticed anemia, which may prevent complications and be useful in avoiding unnecessary and excessive blood transfusion. **Conclusion:** Postoperative SpHb monitoring decreased the incidence of transient, unnoticed anemia during the period up to POD1 and inappropriate blood transfusion.

Keywords

elderly, anemia, blood transfusion, hemoglobin, pulse hemoglobin, total hip arthroplasty, total knee arthroplasty

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Introduction

Total joint arthroplasty is often associated with significant postoperative blood loss.¹ Preoperative anemia is related to prolonged length of hospital stay and increased perioperative blood transfusion rates.^{2,3} A recent report showed that postoperative nadir hemoglobin (Hb), but not preoperative anemia, is related to a longer length of stay for geriatric patients undergoing orthopedic surgery.⁴ Patients undergoing total hip arthroplasty (THA) and total knee arthroplasty (TKA) are generally older adults with coexisting diseases such as cardiovascular disease. Therefore, anemia management is of utmost importance; periodic observation and monitoring of blood loss are essential, and the Hb level should be evaluated as necessary. However, frequent blood sampling should also be avoided because of the increased amount of blood loss; it is also against the concept of patient blood management, as it increases the patients' burden.⁵

In addition to anemia, blood transfusion is also related to infection, adverse cardiac events, mortality, and morbidity in surgical patients.⁶⁻⁹ Blood transfusion in patients who underwent TKA and THA is controversial because it has been found to be both a risk factor¹⁰ and protective factor¹¹ for joint infection. Currently, adequate minimal transfusion to avoid excessive anemia is considered necessary.⁵ The management of anemia with antifibrinolytic therapy and timely blood transfusion, including adopting more conservative transfusion, is important in these patients.¹² Therefore, a perioperative blood management program is important to reduce and minimize the use of allogeneic blood transfusion in patients undergoing TKA and THA.

Pulse hemoglobin (SpHb) measurement using a pulse CO-Oximeter (Radical-7[®] Pulse CO-Oximeter, Masimo Corporation, Irvine, CA, USA) was introduced as a noninvasive method for Hb monitoring. It was found to concur with laboratory Hb measurements in healthy volunteers undergoing hemodilution¹³ and in several clinical conditions.¹⁴ It was also determined to be useful in reducing red blood cell transfusion rates or predicting blood transfusion.^{15,16} However, its clinical usefulness is still controversial.¹⁷ In particular, the usefulness of postoperative SpHb monitoring is not well known. To reduce the rate of allogeneic blood transfusion, it is important to prevent inappropriate, excessive blood transfusion by monitoring the Hb level.

To the best of our knowledge, only a few studies have investigated the usefulness of SpHb monitoring in the postoperative period.^{18,19} Therefore, we hypothesized that SpHb monitoring would reduce the incidence of postoperative anemia and inappropriate blood transfusion in the postoperative period of patients undergoing THA and TKA.

Materials and Methods

Study Design and Patients

This randomized parallel-group study included patients aged >20 years undergoing THA or TKA for osteoarthritis in Fukuoka University Hospital, Fukuoka, Japan, between December 20, 2015 and January 31, 2017. The exclusion criteria were patients aged <20 years, patients with preoperative Hb level >13 g/dL, patients who received blood transfusion before surgery, or patients on dialysis. This study was approved by the Institutional Review Board (IRB No. 15-8-05) of Fukuoka University Hospital, Fukuoka, Japan. Written informed consent was obtained from all patients.

Surgery was performed under peripheral nerve block and general anesthesia for TKA and under epidural and general anesthesia for THA. SpHb monitoring was performed in all patients, including the control group. In the control group, the display area of the SpHb monitor was covered with paper and was made invisible to the attending physician. SpHb was measured with the Radical-7 Pulse CO-Oximeter (Masimo Corporation, Irvine, CA, USA) using the R1-25 Rev L sensor (Masimo Corporation, Irvine, CA, USA). The SpHb sensor was applied on the second or third finger of the contralateral side of the blood pressure cuff before leaving the operating room until the morning of postoperative day 1 (POD1). It was covered with an optical shield and connected to a Radical 7 Pulse CO-Oximeter. Laboratory venous Hb was measured with the hematology analyzer XN-1000 (Sysmex Corporation, Kobe, Japan). The SpHb value was calibrated using the *in vivo* adjustment feature at the start of the monitoring with laboratory venous Hb value. This study was discontinued if the SpHb sensor was disconnected or when the patient's anemia (Hb <7 g/dL) or hypotension continued even after the blood transfusion or the vasopressor was administered. Patients with perfusion index <1 were excluded from the final analysis because low peripheral perfusion can affect the accuracy of SpHb.

Interventions

The patients in the SpHb group received blood transfusion to maintain SpHb >8 g/dL because the threshold for perioperative blood transfusion for patients undergoing orthopedic surgery is a Hb level of 8 g/dL.²⁰

In the control group, the SpHb values of these patients were not revealed to the attending physician. The patients in the control group received blood transfusion according to standard care and assessment of clinical signs, blood loss, laboratory Hb, and hemodynamic parameters during the postoperative period. The laboratory Hb level was measured as needed at the attending physician's discretion. The attending physician was informed that the target laboratory Hb level on POD1 was set to >8 g/dL.

Laboratory Hb measurement was performed on POD1 and up to POD7 as needed.

Primary and Secondary Outcomes

The primary endpoints were the product of total time and degree when the postoperative SpHb value fell below the target SpHb value (8 g/dL) (area-under SpHb 8 g/dL [g/dL-min]) during the period up to POD1 and the incidence of laboratory Hb <8 g/dL at POD1. The secondary endpoints were the amount of autologous and allogeneic blood transfusion, inappropriate allogeneic blood transfusion,

defined as an unnecessary allogeneic blood transfusion in case of SpHb >12 g/dL or delayed allogeneic transfusion in case of SpHb <8 g/dL, and cardiovascular event.

Sample Size Calculation

Based on the preliminary study results, patients with a preoperative Hb level of ≥ 13 g/dL were excluded, and the incidence of anemia and inappropriate blood transfusion after surgery was approximately 10%. We hypothesized that blood transfusion management with SpHb monitoring could reduce the incidence of inappropriate allogeneic blood transfusion by

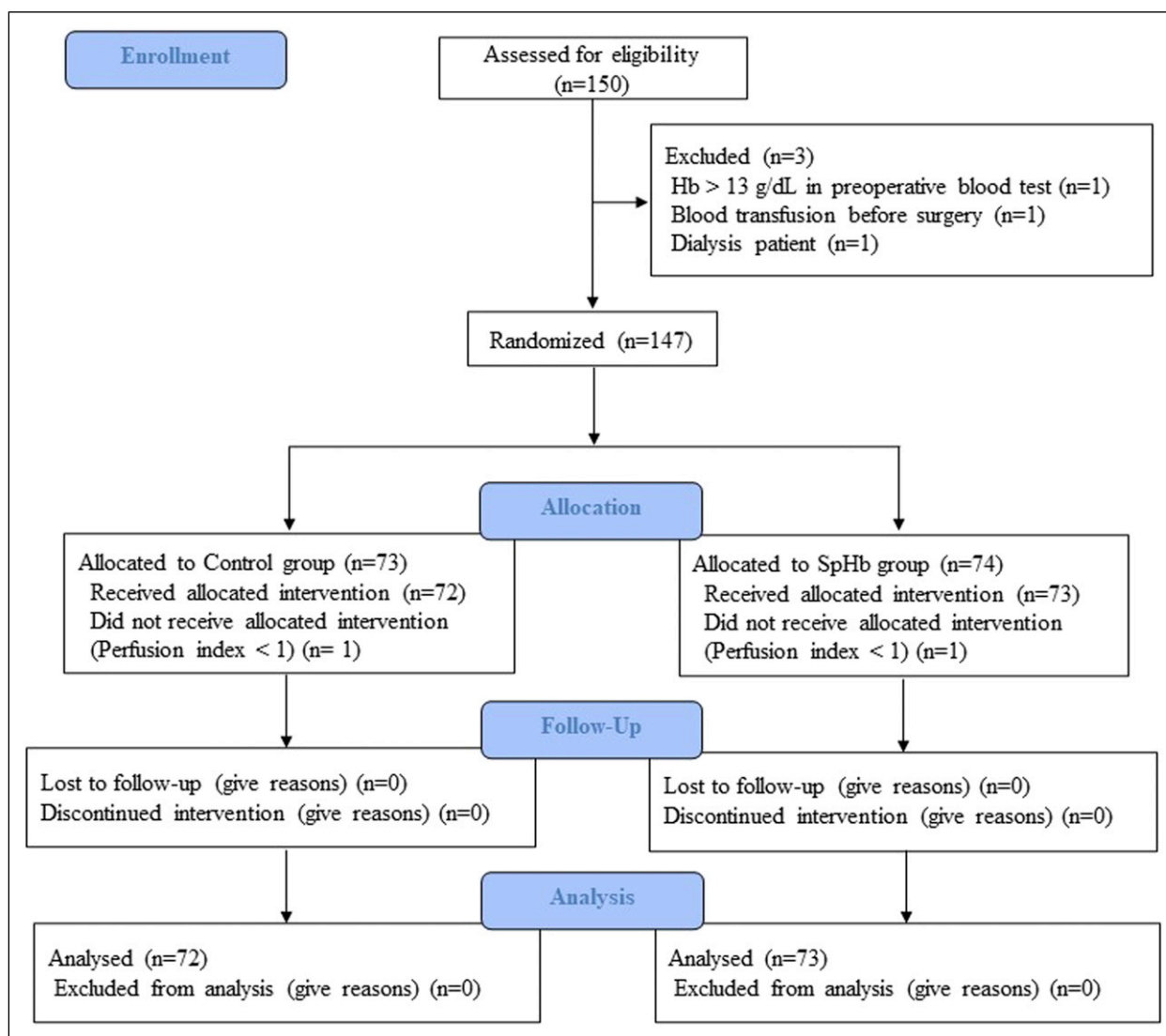


Figure 1. Flowchart of the patient recruitment process. A total of 150 patients underwent total hip arthroplasty (THA, n = 75) or total knee arthroplasty (TKA, n = 75). After excluding patients who had a hemoglobin (Hb) level of >13 g/dL (n = 1), received blood transfusion before surgery (n = 1), were on hemodialysis (n = 1), and had a perfusion index (PI) of <1 (n = 2), a total of 145 patients were included in the final analysis. They were divided into either the SpHb group (n = 73; THA: n = 36, TKA: n = 37) or control group (n = 72; THA: n = 36, TKA: n = 36). THA, total hip arthroplasty; TKA, total knee arthroplasty; Hb, Hemoglobin, PI, perfusion index, SpHbTM, continuous noninvasive total hemoglobin.

a factor of 10 in the study and configured α at 0.05 and β at 0.2. The required number of participants was estimated as 65 for each group. We recruited 150 patients in this study, considering that approximately 20% would be excluded.

Randomization

The patients were randomly assigned to receive blood transfusion, either guided by SpHb monitoring (SpHb group) or based on surgeons' experience (control group), through computer-generated randomization using Excel 2013 (Microsoft Inc., Redmond, WA, USA).

Statistical Analyses

Continuous variables are expressed as means \pm SD. Differences between groups were examined for statistical significance using Student's t-test or the chi-square test with Fisher's exact test depending on the data distribution. A P -value $< .05$ was considered statistically significant. Statistical analyses were performed using GraphPad Prism (version 6; GraphPad Software Inc., San Diego, CA, USA). Sample size calculation was performed using Stata 14.2 (Stata Corp, College Station, TX, USA).

Results

A total of 150 adult patients were enrolled: 75 patients underwent THA, and 75 patients underwent TKA. Patients with Hb >13 g/dL ($n = 1$), those who received blood transfusion before surgery ($n = 1$), those who were on hemodialysis ($n = 1$), and patients with perfusion index <1 ($n = 2$) were excluded from the final analysis. A total of 145 patients were included in the final analysis (Figure 1). There were 72 in the control group (THA: $n = 36$, TKA: $n = 36$) and 73 patients in the SpHb group (THA: $n = 36$, TKA: $n = 37$) (Figure 1).

The patients' characteristics are listed in Table 1. There were no significant differences in the baseline characteristics between the 2 groups.

The area under SpHb 8 g/dL was 37.6 ± 44.1 g/dL-min (5 patients) in the control group and none in the SpHb group ($P = .0281$).

The mean Hb and minimum Hb level up to POD7 are shown in Table 2. The mean Hb level at POD1 was 10.7 ± 1.3 g/dL in the control group and 10.8 ± 1.2 g/dL in the SpHb group, and there was 1 patient with Hb <8 g/dL in the control group and none in the SpHb group. The minimum Hb level was 6.2 g/dL in the control group and 7.4 g/dL in the SpHb group. One patient and 3 patients in the control and the SpHb groups, respectively, had Hb <8 g/dL on POD2.

41 patients received allogeneic blood transfusion up to the morning of POD1. There was no significant difference between the control and the SpHb groups in the proportion of patients who received allogeneic transfusion after surgery ($n = 19$ [26%], vs $n = 22$ [30%], $P = .71$) or amount of blood transfusion (354 ± 127 mL vs 382 ± 138 mL of allogeneic blood transfusion, $P = .50$). Among patients transfused with allogeneic blood, 7 in the control group received an inappropriate allogeneic blood transfusion, 5 received an unnecessary blood transfusion (SpHb >12 g/dL), and 2 received a delayed blood transfusion (SpHb <8 g/dL). However, none of the patients in the SpHb group received inappropriate allogeneic blood transfusion ($P = .0022$). The typical examples of the trend of SpHb and the timing of blood transfusion in the control group and in the SpHb group are shown in Figure 2: a case of unnecessary blood transfusion in the control group (Figure 2(A)), a case of delayed blood transfusion in the control group (Figure 2(B)), and a case in the SpHb group (Figure 2(C)).

After SpHb monitoring (study protocol), the amount of allogeneic transfusion was not significantly different between the control and the SpHb groups: 392 ± 154 mL ($n = 5$, from POD1 to POD2) vs 400 ± 150 mL ($n = 7$, from POD1 to POD4), $P = .93$.

There were no patients to stop the study due to anemia or hypotension in each group.

Table 1. Patients' Characteristics and Perioperative Data.

	Control group (n = 72)	SpHb group (n = 73)	P value ^a
Age, years	71 \pm 11	72 \pm 10	.84
Female, no (%)	68 (94)	62 (85)	.099
Height (m)	1.52 \pm 0.07	1.52 \pm 0.08	.81
Body weight (kg)	58 \pm 10	55 \pm 10	.10
BMI (kg/m ²) ^b	25 \pm 4	24 \pm 4	.090
Operation time (min)	88 \pm 32	85 \pm 25	.66
Anesthesia time (min)	158 \pm 36	160 \pm 30	.84
Preoperative Hb (g/dL)	11.9 \pm 0.76	11.8 \pm 0.85	.46

Data are presented as mean \pm SD or number (percentage).

^aDerived using Student's t-test and/or chi-square test, $P < .05$ was considered to indicate statistical significance.

^bBMI, body mass index; Hb, hemoglobin.

Table 2. POD Mean Hb and Minimum Hb Level up to POD7.

		Control group (n = 72)	SpHb group (n = 73)	P value ^a
POD1	Mean Hb (g/dL)	10.7 ± 1.3 (n = 72)	10.8 ± 1.2 (n = 73)	0.60
	Minimum Hb (g/dL)	7.7	8.5	
POD2	Mean Hb (g/dL)	9.1 ± 1.3 (n = 10)	9.0 ± 1.8 (n = 9)	0.95
	Minimum Hb (g/dL)	6.2	7.4	
POD3	Mean Hb (g/dL)	10.3 ± 1.3 (n = 31)	10.0 ± 1.1 (n = 26)	0.81
	Minimum Hb (g/dL)	7.7	8.1	
POD4	Mean Hb (g/dL)	9.8 ± 1.3 (n = 36)	10.3 ± 1.8 (n = 29)	0.24
	Minimum Hb (g/dL)	6.3	8.6	
POD5	Mean Hb (g/dL)	9.3 ± 1.8 (n = 6)	9.5 ± 1.5 (n = 5)	0.84
	Minimum Hb (g/dL)	7.1	8	
POD6	Mean Hb (g/dL)	9.9 ± 1.3 (n = 12)	9.8 ± 1.0 (n = 11)	0.71
	Minimum Hb (g/dL)	7.6	8.2	
POD7	Mean Hb (g/dL)	10.1 ± 1.1 (n = 44)	10.1 ± 1.1 (n = 46)	0.78
	Minimum Hb (g/dL)	7.9	8.1	

Data are presented as mean ± standard deviation or number (n). POD, postoperative day; Hb, hemoglobin.

^aDerived using Student's *t*-test and/or chi-square test, *P* < .05 was considered to indicate statistical significance.

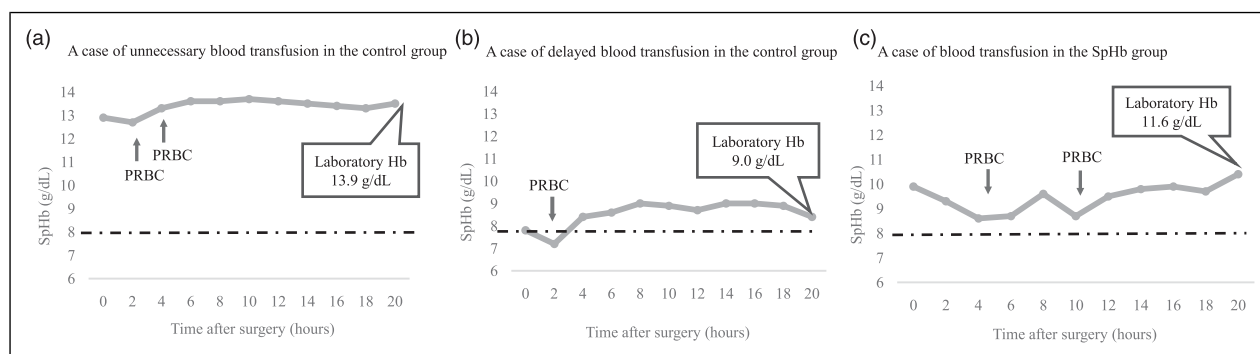


Figure 2. The typical examples of the trend of SpHb and timing of blood transfusion. (A) A case of unnecessary transfusion in the control group: 560 mL of allogeneic PRBC transfusion was performed based on the surgeons' experience, even though SpHb (blinded to attending physician) was maintained over 12 g/dL. (B) A case of delayed transfusion in the control group: 280 mL of allogeneic PRBC transfusion was performed based on the surgeons' experience, but it was under 8 g/dL with SpHb monitoring (blinded to attending physician). (C) A case of blood transfusion in the SpHb group: 560 mL of allogeneic PRBC transfusion was adequately administered before SpHb decreased under 8 g/dL. PRBC, packed red blood cell transfusion; Hb, Hemoglobin.

Discussion

The main finding of this study was that postoperative SpHb-guided blood transfusion management decreased the incidence of transient and unnoticed anemia but did not decrease anemia at POD1 and decreased the rate of inappropriate (unnecessary or delayed) allogeneic blood transfusion.

In this study, SpHb monitoring could prevent the anemia unnoticed by medical staff in postoperative rooms. This SpHb monitoring is useful in preventing postoperative nadir Hb, which is related to a longer length of stay for geriatric patients undergoing orthopedic surgery.⁴ The blood transfusion decisions to avoid anemia depend on

clinical signs and the Hb value. Therefore, the accuracy and trend of the Hb values are important. The accuracy of SpHb had a relatively wide range of agreement (−1.3 to 1.3 g/dL).²¹ However, a recent multicenter study showed that the Hb accuracy mean bias for SpHb was 0.24 g/dL.²² In vivo SpHb adjustment, which was used in this study, improved the accuracy of SpHb.^{23,24} For a timely blood transfusion, the trending capability of SpHb is important, and it more accurately estimates the appropriate timing for invasive Hb measurements than do clinicians.^{22,25-27} However, SpHb monitoring is still controversial for postoperative management. It was reported to be unsuitable to maintain the Hb level >8 g/dL, particularly in those with lower Hb levels in the intensive care unit.²⁵ A recent study

also showed that the use of the transfusion threshold determined using SpHb monitoring than using laboratory Hb had changed the clinical decision in only 1.9% of patients undergoing THA.²⁸ However, our results that SpHb can detect the anemia unnoticed by medical staff and reduce the total time and severity of accidental anemia at the postoperative rooms suggest that SpHb monitoring can reduce postoperative nadir Hb and prevent complications from unnoticed anemia after orthopedic surgery, which is an advantage, especially for elderly orthopedic patients. In another study, SpHb monitoring was useful in detecting delay in the detection of lower Hb levels, which is related to postoperative delirium in elderly patients with hip fractures.¹⁹ At this time, SpHb might be used as a good indicator to determine when laboratory measurement of Hb is essential to make the final decision on blood transfusion.²⁶ Further studies are needed in various postoperative situations in the future.

We defined inappropriate allogeneic blood transfusion as unnecessary allogeneic blood transfusion for laboratory Hb >12 g/dL. This threshold has not been clarified in previous reports but is supported by a recent study showing postoperative nadir Hb >12 g/dL with the shortest and Hb <10 g/dL with the longest mean length of stay.⁴ In this study, there were significantly more patients who received inappropriate allogeneic blood transfusion when the Hb level did not require blood transfusion (SpHb >12 g/dL) among those with surgeon's experience-guided blood management (control group) than among those with SpHb monitoring (SpHb group), and the final power of the analysis was 0.951. Therefore, SpHb-guided postoperative blood transfusion management could be useful to avoid unnecessary and excessive blood transfusion.

In this study, there was no statistical difference in patients with Hb <8 g/dL at POD1 and the amount of blood transfusion between SpHb-guided and surgeon-guided management. In the first place, this study design had fewer patients with anemia in the control group than expected, and there was only 1 patient in the control group with Hb <8 g/dL. This was affected by bias in the control group during Hb level evaluation due to the research intervention. Second, the fact that 62 of the 145 patients (42.8%) had autologous blood might have affected blood transfusion behavior. Therefore, our study protocol could not evaluate whether SpHb monitoring-guided blood transfusion can prevent anemia and reduce blood transfusion.

Study Limitations

There were some limitations in this study. First, we used the earlier version of the SpHb sensor (Rev L). Both the sensor and assessment algorithm for SpHb have been further developed (the recent version is Rev O), and the results might have been different if a newer version of the device had been used. Second, in our study protocol, the

SpHb was monitored up to POD1, but the study period may have been inadequate and insufficient as the minimum hemoglobin levels were observed on POD2.

Conclusion

Postoperative SpHb monitoring can prevent transient, unnoticed anemia, and inappropriate allogeneic blood transfusion in the recovery rooms. However, it could not ultimately evaluate whether it prevents anemia at POD1 in this study protocol.

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Author's Note

The datasets generated and/or analyzed during the current study will be available from the corresponding author on reasonable request. This study was approved by the Institutional Review Board (IRB No. 15-8-05) of Fukuoka University Hospital, Fukuoka, Japan. Written informed consent was obtained from all patients. This randomized prospective study was registered in the clinical trials database UMIN (ID 000019341, <https://upload.umin.ac.jp/cgi-open-bin/ctr/ctr.cgi?function=brows&action=brows&receptno=R000022230&type=summary&language=E>) on October 14, 2015.

Author Contributions

Erisa Nakamori: investigation, resources, visualization, writing—review and editing.

Midoriko Higashi: data curation, writing—review and editing.

Kenji Shigematsu: formal analysis.

Ken Yamaura: conceptualization, methodology, writing—original draft, supervision.

All authors read and approved the manuscript.

Declaration of Conflicting Interests

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: Ken Yamaura has been a consultant for Masimo Japan since January 2021. Erisa Nakamori, Midoriko Higashi, and Kenji Shigematsu declare that they have no competing interests.

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Ethical Approval and Consent

This study was approved by the Institutional Review Board (IRB No. 15-8-05) of Fukuoka University Hospital, Fukuoka, Japan. Written informed consent was obtained from all patients.

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