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Application of patient blood management protocol to reduce transfusion rates in limb salvage operations for osteosarcoma

A retrospective study

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Abstract

Oncologic orthopedic surgery stands as one of the primary causes necessitating blood transfusions. In an endeavor to mitigate transfusion requirements, the implementation of patient blood management (PBM) holds significant value. We undertook a retrospective study to juxtapose pre and post-PBM implementation scenarios in the context of treating osteosarcoma through limb salvage surgery in patients' extremities.

This study encompasses 25 patients who underwent surgery between 2008 and 2016 at our institution, with a comparison drawn between cases before and after PBM adoption. Parameters such as transfusion rate (TR), transfusion volume (TV), and complications were subjected to analysis for both strategies. The PBM group exhibited notably reduced TR and TV compared to the control group ($P < .01$). PBM-associated complications primarily included anemia, reduction in hematocrit levels, and limited declines in hemodynamic status, which were generally mild and well-tolerated.

In the control group, surgical site infections were observed in 13.3% of patients. When contrasted with the control group, the implementation of PBM in surgical interventions for osteosarcoma limb salvage procedures demonstrates its effectiveness in significantly reducing blood TRs.

Abbreviations: ABT = allogeneic blood transfusions, PBM = patient blood management, TR = transfusion rate, TV = transfusion volume.

Keywords: allogeneic blood transfusion, blood management, osteosarcoma, transfusion

1. Introduction

Osteosarcoma, characterized as a rare disease, represents a malignant spindle-cell sarcoma of the bone wherein malignant mesenchymal tumor cells possess the capability to generate osteoid and immature bone.[1] Osteosarcoma tends to affect relatively young individuals, with extremities being a commonly afflicted site. The current treatment strategy entails a sequence of actions, including preoperative (neoadjuvant) chemotherapy, followed by limb salvage surgery involving wide excision of the affected lesion and subsequent skeletal reconstruction, culminating in postoperative (adjuvant) chemotherapy.[2] Contemporary studies indicate that chemotherapy has emerged as the predominant therapeutic approach for osteosarcoma. The clinical survival rate of osteosarcoma patients has seen enhancement following successful neoadjuvant chemotherapy.[3] However, this neoadjuvant chemotherapy often precipitates an anemic state prior to surgery, necessitating the management of such issues prior to the surgical intervention. This is vital as anemic patients are at a heightened risk of postoperative complications.[4] Traditionally, the correction of anemia using allogeneic blood transfusions (ABTs) has been associated with potential complications. Hence, patient blood management (PBM) presents itself as a significant method to avert the necessity for transfusions[5]; yet there exists no study concerning PBM in orthopedic cancer surgery, especially within the context of extremities that are amenable to reconstruction with tumor prostheses. As a response to this gap, we embarked on a retrospective study conducted within a single center, with the comprehensive objective of assessing the viability of PBM and reconstructive surgery in young patients diagnosed with osteosarcoma in their extremities.

2. Patients and methods

2.1. Study population

We systematically recruited participants for our study from the electronic medical records of a single institution in South Korea. A total of 29 young patients, who sought medical care

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The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

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at our hospital for osteosarcoma in the extremities between January 2008 and September 2016, underwent surgical procedures. The inclusion criteria for participant selection were as follows: Patients aged between 18 and 35 years, who had received a diagnosis of osteosarcoma in the extremities, Patients with confirmed positive histopathology results from incisional biopsies, indicating the presence of osteosarcoma, and Patients who had undergone reconstructive surgery involving tumor prostheses. Conversely, the exclusion criteria encompassed: Patients who did not meet the aforementioned inclusion criteria, Patients with multiple lesions, Patients with concurrent systemic cardiopulmonary conditions that could potentially impact treatment or clinical outcomes, Patients who had undergone neoadjuvant chemotherapy outside the standard treatment regimen, and Patients with follow-up periods of <2 years. The study protocol was reviewed and approved by the institutional review board in alignment with the principles of the Declaration of Helsinki.

All patients underwent radiography, MRI, and histopathology assessments to establish a definitive diagnosis of osteosarcoma. The total number of patients enrolled aimed to identify statistically significant disparities between those treated prior to and subsequent to 2013, the year when PBM was implemented to mitigate the necessity for ABTs. Pertinent information, including age, gender, affected site, clinical manifestations, biopsy and histology outcomes, details of the PBM therapeutic approach, transfusion rate (TR), transfusion volume (TV), duration of hospital stay (HS), and any complications, were meticulously documented for each patient. Prior informed consent was procured from every patient. For a graphical representation of our study, refer to Figure 1, which serves as a flow chart elucidating the study's design and structure.

2.2. PBM protocol

The PBM protocol implemented in our study was as follows: Prior to surgery, we employed the following criteria. If the serum hemoglobin (Hb) level exceeded 13 g/dL, we deemed the patient to have a low risk of requiring blood transfusion. If the Hb level fell below 12 g/dL, we administered ferric carboxymaltose in accordance with the dosing matrix provided by the manufacturer. Alternatively, if the planned surgery was scheduled more than 4 weeks away, we initiated intravenous iron therapy. A day before the scheduled surgery, patients received anti-fibrinolytic drug treatment, involving the intravenous administration of 1 gram of tranexamic acid over a 15-minute period, in accordance with the FDA-approved dosage of 10 mg per kg body weight. In situations where intraoperative blood loss was anticipated to exceed 1 L or if unforeseen significant hemorrhage occurred during surgery, we conducted preoperative embolization and meticulously employed intraoperative hemostasis measures such as fibrin sealants. Furthermore, high-dose recombinant human erythropoietin, ranging from 300 to 600 units/kg, was administered through subcutaneous injection if the patient's ferritin level surpassed 100 ng/mL. During the perioperative period, if the Hb level fell below 7 g/dL, we administered 1000 mg of intravenous ferric carboxymaltose. Hb levels were also assessed in the week immediately preceding the surgery, as illustrated in Figure 1.

The surgical procedures employed in this study involved limb salvage operations centered around reconstructive surgery utilizing tumor prostheses. The implant was inserted into the bones, either with or without the addition of bone grafting. The surgical removal of the osteosarcoma encompassed en bloc resection of the biopsy track. A specimen was collected following wide excision, with surrounding muscle being excised as well. The reconstruction of the bone tumor was executed following the guidelines outlined by Enneking et al.[6]

2.3. Transfusion rate (TR), transfusion volume (TV)

Data was collected from each group and subjected to comparison with the aim of assessing the cumulative incidence of blood transfusion, estimating critical factors influenced transfusion necessity, and evaluating resulting outcomes. The quantification of intraoperative blood loss was jointly performed by the anesthetist and surgical scrub nurse. This involved combining the volume of blood collected within suction bottles with the weight of wound swabs. Clinical outcomes were evaluated concerning the viability and effectiveness of the PBM protocol, without recording any instances of mortality or morbidity.

2.4. Statistical analysis

Data analysis were performed using SPSS 10.0 statistical software (StataCorp, College Station). χ^2 test and *t*-tests were used to compare differences between groups and means. *P* values < .05 were considered significant.

3. Results

3.1. Demographic characteristics

Patients diagnosed with parosteal osteosarcoma (n = 2), metastasis occurring at other sites (n = 1), or those who did not undergo the complete protocol application (n = 1) were excluded from the initial number of 29 cases. Instances of follow-up loss or failure to complete a minimum of 2 years of follow-up were omitted from the analysis. Thus, our statistical examination encompassed 25 consecutive patients, with 15 individuals undergoing standardized reconstructive surgery without PBM, while 10 patients underwent the same surgical procedure with the PBM protocol. Among the patients, there were 14 males and 11 females, with a median age of 28.3 years (range, 18–35 years). The 2 groups exhibited comparable baseline characteristics, as showed in Table 1.

3.2. A shorter HS length were observed in PBM group

The PBM protocol was administered both in the outpatient clinic and the ward, attesting to the deemed safety of the procedure. Consequently, the average duration of HS for patients in the PBM group (12.8 ± 12.4 days) was notably shorter in comparison to the control group (*P* = .017), as depicted in Table 1.

3.3. Intra and postoperative blood management in the study

Patients undergoing limb salvage procedures with tumor prostheses often necessitate ABTs due to neoadjuvant chemotherapy. In the fortnight preceding the scheduled surgery, we implemented high-dose recombinant human erythropoietin administration and intravenous iron supplementation following the previously outlined protocol. Throughout the surgical intervention, if a patient exhibited low blood pressure, a continuous administration of 1 gram of tranexamic acid was administered. In the postoperative phase, we closely monitored the patient's Hb levels and their trend. By the third day following surgery, we meticulously observed laboratory results as well as signs of anemia such as dyspnea or tachycardia.

3.4. Transfusion, hemodynamic changes, and complications

Within the control group, intraoperative or postoperative blood transfusions were administered in 13 out of 15 surgeries

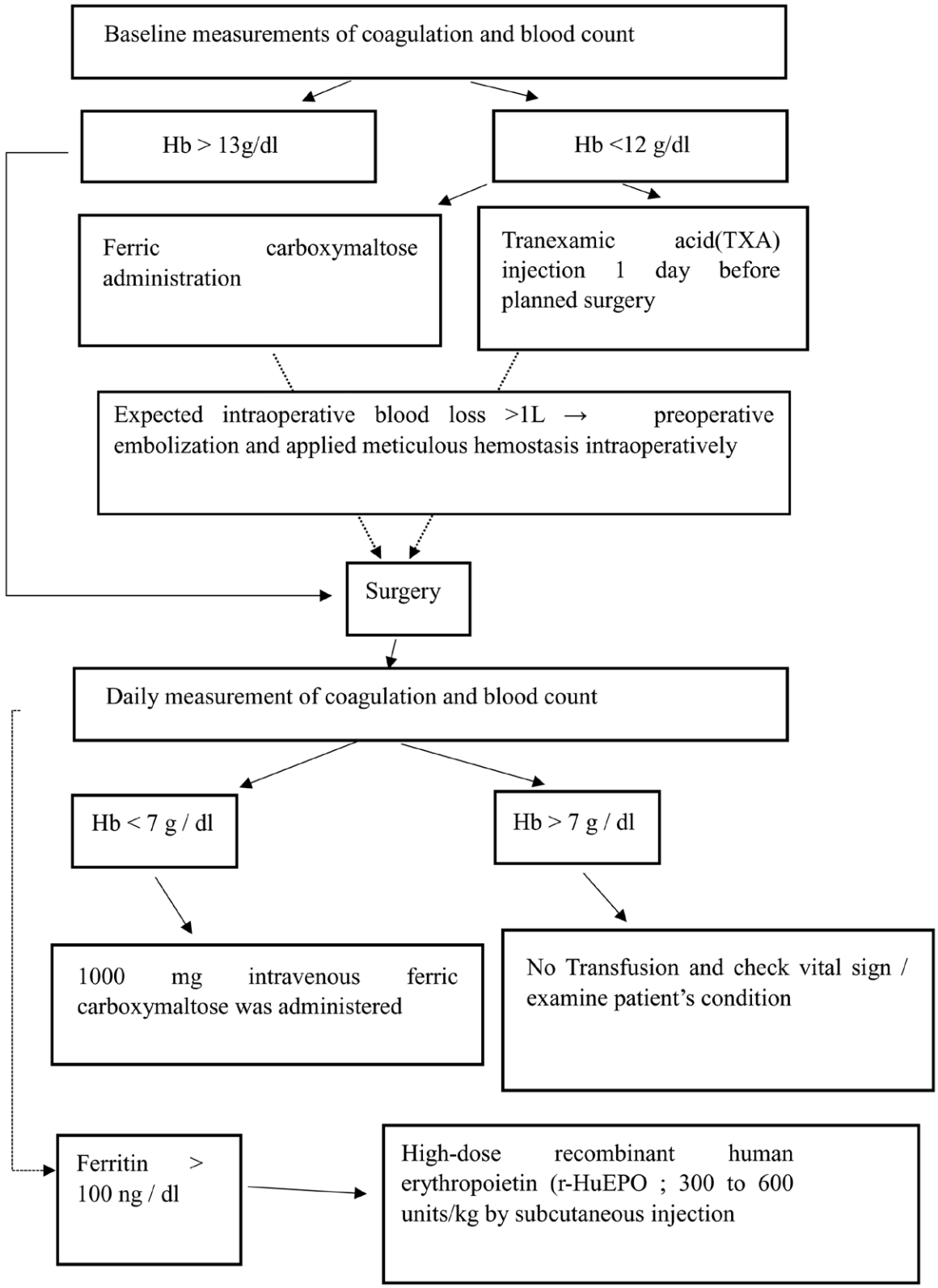


Figure 1. Flow chart of patient blood management strategy.

(86.7%). However, within the study group, only 1 out of 10 surgeries (10.0%) involved ABTs. The association between hemodynamic status did not exhibit a significant difference between the 2 groups. Hematologic profiles are detailed in Table 2. Across all surgical cases, the total blood loss ranged from 450 to 2100 cm^3, with an average of 514.3 cm^3 for the control group and 375.0 cm^3 for the study group. Out of the total patients, 21 had received neoadjuvant chemotherapy preoperatively. Among these patients, a statistically significant decrease in hemoglobin and hematocrit levels was observed in comparison to the group that did not undergo neoadjuvant chemotherapy, as shown in Table 2. A description of surgeries performed on the 25

osteosarcoma patients is presented in Table 3. The average TV was 5.13 units (range 0–14 units) in the control group, and 0.28 units (range 0–2 units) in the study group. Patient No. 17 underwent a limb salvage operation with arthrodesis using a tumor prosthesis. Despite having a slightly lower baseline hemoglobin level (11.0 g/dL), a PBM protocol was applied. However, allogeneic blood was transfused due to uncertainties about the PBM protocol during the initial study phase. Table 4 outlines the specifics of the applied PBM protocol for each patient. Notably, surgical site infections occurred in 2 patients who received ABTs within the control group.

4. Discussion

The primary objective of this study was to investigate the feasibility of employing a PBM protocol in patients undergoing surgical treatment for osteosarcoma. Concurrently, we sought to comprehensively evaluate the overall outcomes for individuals undergoing surgery due to osteosarcoma. The obtained results yielded significant statistical findings, showcasing a remarkable decrease from 86.7 to 10.0% in the proportion of patients receiving blood transfusions following the implementation of the protocol. Additionally, the aggregate TV underwent a substantial reduction, diminishing from 4.95 units (equivalent to 1.98 L) to 0.4 units (equivalent to 0.16 L) subsequent to the application of this approach. Notably, the data also imply that the implementation of the protocol did not exert any adverse influence on patient outcomes. These findings collectively suggest that the incorporation of a PBM protocol could potentially play a role in mitigating the necessity for ABTs.

Numerous reports have detailed endeavors to curtail blood transfusion usage in cancer-related surgeries,{Litton, 2013 #90}[7–9] highlighting that a more stringent blood transfusion protocol indeed diminishes the incidence of such transfusions. However, these protocols have also been observed to exert an adverse impact on patient survival rates.[8] One of these studies specifically demonstrated a reduction from 31 to 23% in the proportion of patients necessitating transfusions post-protocol implementation,[8] yet no previous investigations have been conducted on osteosarcoma patients employing a blood management protocol. For the effective management of bone tumor patients, it remains imperative to accurately gauge blood loss, anticipate transfusion necessities, and identify the contributing factors therein.

Malignant bone tumor surgery is inherently associated with substantial blood loss, making effective blood loss management a critical consideration within orthopedic cancer surgery. Compared to marginal resections for benign tumors, wide resections for malignant tumors have been linked to notably higher blood loss levels.[9] The management of patients with bone tumors, including osteosarcoma cases, necessitates a combination of high-dose chemotherapy and surgery, often involving extensive dissections. As a result, patients may experience considerable blood loss, potentially leading to the requirement for ABTs. The perioperative administration of blood transfusions can lead to immunosuppression and is correlated with adverse clinical outcomes, including heightened risks for those undergoing colorectal cancer resections.[10] A longstanding and well-known risk associated with blood transfusion dates back to 1982, when it was revealed that diseases such as HIV, hepatitis C virus, hepatitis B virus, and human T-cell lymphotropic virus could be transmitted through blood transfusions[11,12] owing to the "window period" during which an infected donor remains contagious despite negative screening tests[13] Preoperative, perioperative, and postoperative blood transfusions are recognized as independent risk factors for unfavorable postoperative outcomes, encompassing infections, prolonged HSs, and escalated medical expenditures. Furthermore, the prevention of postoperative infections in cancer patients is of paramount significance due to their heightened susceptibility to infections arising from their compromised immune state.[14]

In the realm of orthopedic surgery, the endeavor to curtail blood transfusions holds the potential to contribute significantly to the reduction of postoperative infection risks. Furthermore, it has been observed that perioperative allogeneic red blood cell transfusions correlate with heightened morbidity and mortality among patients.[15] In a study by Pulido et al, it was identified that patients who received allogeneic transfusions had a 2.1 times greater likelihood of developing periprosthetic joint

Table 1

Baseline patient characteristics and changes before and after PBM implementation.

	Control (n = 15)	Study (n = 10)	*P* value
Age (yr)	27.5 ± 11.5	36.3 ± 10.8	<.001
Gender (male: female)	8: 7	6: 4	
Body mass index (kg/m^2)	26.6 ± 2.7	25.1 ± 4.3	.863
Hemodynamic status			
Systolic BP (mm Hg)	126.0 ± 18.3	124.0 ± 21.2	.723
Diastolic BP (mm Hg)	75.9 ± 12.3	77.0 ± 8.4	.540
Heart rate (beats/min)	82.7 ± 12.1	77.1 ± 16.6	.400
Hematologic values			
Hemoglobin (g/dL)	11.2 ± 2.3	10.3 ± 1.9	.432
Platelet (×10^4/μL)	26.8 ± 7.3	27.2 ± 9.6	.655
Duration of hospital stay (d)	14.9 ± 7.5	12.8 ± 12.4	**.017**
Pathologic finding			
Conventional osteosarcoma	15 (100.0%)	10 (100.0%)	
Intraoperative blood loss (cm^3)	514.3 ± 76.6	375.0 ± 55.9	**.023**

Table 2

Preoperative chemotherapy and hematologic profile.

	No chemotherapy	Neo-adjuvant chemotherapy	*P* value
Hemoglobin (g/dL)	12.5 ± 1.4	9.8 ± 2.4	**.023**
Hematocrit (%)	41.1 ± 2.9	32.9 ± 4.3	**.021**
Platelet (×10^4/μL)	26.8 ± 7.3	23.5 ± 2.7	.863

infections in comparison to those who did not receive transfusions.[16] Drawing upon the insights gleaned from our study, we have formulated a perioperative PBM protocol aimed at mitigating these risks associated with ABTs. Presently, to the best of the authors' knowledge, no investigation has reported on the effectiveness and safety of such a PBM protocol within the context of musculoskeletal tumors, particularly among primary osteosarcoma patients.

Our study is subject to certain limitations. The relatively small patient cohort can be attributed to the limited study design and the rare nature of the disease itself. Furthermore, the inclusion of different anatomical sites and pathological findings may have influenced the quantity and interpretation of outcomes. Nevertheless, within the Pre-PBM group, a subset of patients (Patient No. 2, 3, 4, 5, 6, 11, 12, 13, 14) underwent limb salvage procedures with tumor prostheses on the distal femur, and these patients required an average of 4.6 units of allogeneic blood transfusion. Conversely, in the study group, patients who underwent the same procedures at the same surgical site (Patient No. 18, 23, 24, 25) did not necessitate blood transfusions following the protocol implementation. Moreover, there existed a statistical difference in ages between the 2 groups (Table 1) due to the limited number of patients (10) in the study group. Despite these constraints, we believe that the retrospective nature of our study potentially reinforces our findings.

In conclusion, our study demonstrates the safe applicability of a PBM approach in limb salvage surgeries for osteosarcoma patients. Thus, our findings offer a novel reference point for the

Table 3

Description of surgery and tendency of Hb in 25 patients with osteosarcoma.

Patient No.	Side	Surgical site	Neo-adjuvant chemotherapy	Surgery	Pre op Hb	Intra-op Hb	POD #1 Hb	Total amount of blood transfusion (L)
Control								
1	Right	Proximal tibia	–	LSO with TP	16.3	13.4 (1.6)	10	1.6
2	Left	Distal femur	+	LSO with TP	6.8 (0.4)	9.3 (2.8)	7.2 (2.0)	5.2
3	Right	Distal femur	+	LSO with TP	9.9	9.9 (2.0)	10.4	2.0
4	Left	Distal femur	+	LSO with TP	8.0 (0.8)	11.8 (2.1)	7.7 (0.8)	3.7
5	Right	Distal femur	+	LSO with TP	10.9	10.3 (0.8)	7.8 (0.8)	1.6
6	Right	Distal femur	+	LSO with TP	8.3 (0.8)	11.1 (0.8)	4.0 (0.8)	2.4
7	Left	Proximal humerus	+	LSO with TP	13	12.0 (1.2)	10.1	1.2
8	Left	Proximal fibula	+	LSO with TP	11.9	N/A	11.3	0
9	Left	Proximal fibula	+	Wide excision	8.8 (0.8)	N/A	11	0.8
10	Right	Proximal tibia	+	LSO with TP	10.0 (0.8)	10.3 (1.2)	11	2.0
11	Left	Distal femur	+	Wide excision	16	10.5	10	0
12	Left	Distal femur	+	LSO with TP	13.9	11.4	11.4 (1.2)	1.2
13	Left	Distal femur	–	LSO with TP	11.6 (0.8)	8.7	7.6 (0.8)	1.6
14	Right	Distal femur	+	LSO with TP	9.5 (1.2)	7.9 (2.0)	8.6 (1.2)	4.4
15	Left	Proximal humerus	–	LSO with TP	11.9	9.7 (2.0)	9.6	2
				Average	1.3	3.9	1.6	**1.98**
PBM group								
16	Left	Proximal tibia	–	LSO with TP	13.4†	N/A	11.7	0
17	Left	Distal femur	+	LSO arthrodesis using TP	11.0 (0.8)†	10.8	8.8	0.8
18	Right	Distal femur	+	LSO with TP	7.7†	10.8	10.8	0
19	Right	Pelvic ilium	+	Wide excision and pelvic recon	13.2†	11.1	10.5	0
20	Left	Proximal tibia	+	LSO with TP	8.0†	10	10.3	0
21	Right	Proximal tibia	+	LSO with TP	10.7†	N/A	10.1	0
22	Right	Proximal tibia	+	LSO with TP	8.1†	9.6	9.2	0
23	Right	Distal femur	+	LSO with TP	10.2†	10.8	10.8	0
24	Right	Distal femur	+	LSO with TP	9.8†	9.2	8.4	0
25	Right	Distal femur	+	LSO with TP	10.5†	9.1	9.5	0
				Average	0.16	0	0	**0.16**

( ) = amount of blood transfusion, Hb = hemoglobin, L = liter, LSO = limb salvage operation, POD = postoperative day, TP = tumor prosthesis.

*POD #3 Hb.

†Hb at 30 d ahead planned surgery.

Table 4

Details of applied PBM protocol.

Patient No.	Hb at 30 d ahead surgery	Pre op Hb	Ferric carboxymaltose (Ferinject®)	Tranexamic acid	Human erythropoietin (EPO; Epokine®)
16	13.4	13.4	N/A	N/A	N/A
17	11.0	11.0 (2U)	1000 mg (POD #0)	250 mg (–1*)	N/A
18	7.7	10.8	1000 mg (–11, POD #1)	250 mg (–1, POD #1)	8000 U (–10)
19	13.2	13.2	1000 mg (POD #0)	N/A	N/A
20	8.0	10.8	1000 mg (POD #1)	250 mg (–2)	8000 U (–12)
21	10.7	11.8	1000 mg (POD #0)	250 mg (–1, POD #1)	N/A
22	8.1	10.3	1000 mg (–20, –3, POD #2)	250 mg (–3, POD #1)	N/A
23	10.2	10.2	1000 mg (POD #2)	250 mg (–3, POD #1)	N/A
24	9.8	10.2	1000 mg (POD #2)	250 mg (POD #1)	N/A
25	10.5	10.5	1000 mg (POD #2)	N/A	N/A

Hb = hemoglobin, POD = postoperative day, U = unit.

*A day ahead planned surgery.

management of a restrictive allogeneic blood transfusion strategy within the context of bone tumor surgery.

Author contributions

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