Does intraoperative cell salvage system effectively decrease the need for allogeneic transfusions in scoliotic patients undergoing posterior spinal fusion? A prospective randomized study

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ORIGINAL ARTICLE

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Abstract
Purpose To determine the safety and efficacy of intraoperative cell salvage system in decreasing the need for allogeneic transfusions in a cohort of scoliosis patients undergoing primary posterior spinal fusion with segmental spinal instrumentation.
Methods A total of 110 consecutive scoliosis patients undergoing posterior instrumented spinal fusion were randomized into two groups according to whether a cell saver machine for intraoperative blood salvage was used or not. Data included age, body mass index, perioperative hemoglobin levels, surgical time, levels fused, perioperative estimated blood loss, perioperative transfusions and incidence of transfusion-related complications. A Chi-square test and *t* tests were performed for intraoperative and perioperative allogeneic transfusion between groups. A regression analysis was performed between selected covariates to investigate the predictive factors of perioperative transfusion.
Results Perioperative allogenic blood transfusion rate was lower in the cell saver group (14.5 versus 32.7 %, $p = 0.025$). Mean intraoperative red blood cell transfusion requirement was also lower (0.21 U/pt versus 0.58 U/pt, $p = 0.032$). A multivariate analysis demonstrated that no. of fused segments (OR: 1.472; $p = 0.005$), preoperative hemoglobin level (OR: 0.901; $p = 0.001$), and the use of cell saver system (OR: 0.133; $p = 0.003$) had a trend toward significance in predicting likelihood of transfusion.
Conclusions Cell saver use significantly reduces the need for allogeneic blood in spine deformity surgery, particularly in patients with low preoperative hemoglobin or longer operation time. This study confirms the utility of routine cell saver use during PSF with segmental spinal instrumentation for scoliosis patients.

Keywords Cell salvage system · Scoliosis · Allogenic blood transfusion · Prospective randomized study

Introduction

Scoliosis patients undergoing posterior spinal fusion can experience significant intraoperative blood loss and often require perioperative blood transfusions [1, 2]. Various options for blood replacement are available to the surgeon including allogeneic blood, predonated autologous blood and intraoperative autologous cell salvage and transfusion.

Despite rigorous modern screening techniques, transfusion of allogeneic blood still carries the risk of transmission of human immunodeficiency virus (HIV) of 1 in 1,930,000, hepatitis B of 1 in 137,000, hepatitis C of 1 in 1,000,000, as well as inducing hemolytic and allergic reactions [3–5]. These risks, albeit small, have driven surgeons to seek out alternatives to minimize the number of allogeneic blood transfusions.

A machine for intraoperative blood salvage, known as a "cell saver" (CS), aspirates, washes, and filters a patient's blood during an operation, so that the blood can be returned to the patient's circulation. It can possibly obviate the need for additional predonated autologous or allogeneic red

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blood cell transfusion [6, 7]. This method is also a good alternative for patients who refuse to accept donated blood because of religious beliefs. Other advantages of using cell salvage are the lack of viral disease transmission, a reduced risk of alloimmunization, normal potassium concentration, the fact that the infused cells are at room temperature and have normal red blood cell oxygen carrying capacity and 2,3-diphosphoglycerate (2,3 DPG) levels [8, 9].

Despite these benefits, it is not clear whether use of cell saver decreases the need for other transfusions in this patient population. While some studies have found that cell saver use decreases the need for other blood transfusion in orthopedic surgery, [10–12] others have found its use to be of little or no benefit [13, 14]. In addition, there are reported complications with cell saver usage in pediatric patients, including transient hematuria, [15] concern for reinfusion of heparinized blood leading to altered hemostasis, [16] and alteration in electrolyte balance [17]. Moreover, cell salvage systems are costly, and may require additional health care personnel to operate the system during surgery. Others have estimated the cost of cell saver for spinal fusion to be $240–$512 per operative case [13, 14]. These authors concluded that cell saver was more expensive than predonated blood for autotransfusion [13, 14].

This prospective, randomized study was designed to determine the safety and efficacy of intraoperative cell salvage system in decreasing the need for allogeneic transfusions in a cohort of scoliosis patients undergoing primary posterior spinal fusion with segmental spinal instrumentation.

Methods

A total of 110 consecutive scoliosis patients undergoing posterior instrumented spinal fusion between January 2012 and June 2013 at a single hospital were prospectively randomized into one of two groups using a simple equal probability randomization scheme to be included in the study. These two groups of patients differ only according to whether a CS (Haemonetics Cell Saver 5, Haemonetics Corporation, Braintree, MA, USA) machine for intraoperative blood salvage was used or not. During the study period, a total of 55 patients were operated with the use of a machine for intraoperative blood salvage (CS group) and 55 patients without it (NCS or control group). Scoliosis patients who underwent osteotomy, growing rod extending or revision surgery, with a history of a bleeding disorder, a low platelet count (<150,000), abnormal partial thromboplastin time or international ratio test, previous thromboembolic event, or a family history of thromboembolism were excluded. No patient predonated autologous blood in preparation for surgery, no hemodilution technique was used and no intravenous procoagulant or antithrombolytic medications were administered during surgery.

All patients underwent a similar operative technique: a standard posterior subperiosteal exposure of the spine, preparation of pedicle or lamina hook sites at several levels, and Moe's bone grafting. Surgery was performed by a single senior surgeon (JXS). Blood loss was estimated by evaluating the amount of blood in the suction canister and that in the soaked lap pads. The surgery was performed with the patient under hypotensive anesthesia in which systolic blood pressure was kept to <90 mmHg. All wounds were closed over hemovac drains which were placed on continuous suction. Drains were discontinued no sooner than postoperative day 3, with output of <100 mL over 24 h.

The same blood transfusion guidelines were used for all patients. Allogenic blood transfusion was performed if hemoglobin decreased to <7.0 mg/dL or if anemic symptoms developed, such as a decrease in blood pressure to <100 mmHg systolic, tachycardia greater than 100 beats/min, or a low urine output of <30 mL/h, even after initial fluid challenge with 500 mL normal saline in patients with a hemoglobin level between 7.0 and 8.0 mg/dL [18, 19]. Erythropoietin was administered subcutaneously at the standard dose of 10,000 international units (IU) per day after surgery for a week. In addition, all patients received iron supplementation 6 mg/kg/day in 3 divided doses for 1 week after surgery.

Institutional Review Board-approved informed consent was obtained from all patients before participation in this study. The Student's t test or Chi-square test was performed to compare the following variables: age, gender, body weight index, estimated blood loss, surgical time, blood drainage after operation, baseline and postoperative hemoglobin and hematocrit values, intraoperative allogeneic transfusion and perioperative allogeneic transfusion rate. Regression analyses were conducted to identify predictors of transfusion. All statistical tests were 2-tailed, and a p value <0.05 was considered significant. All statistical analyses were conducted using SPSS version 12.0 (Chicago, IL).

Results

Patient and surgical characteristics

Descriptive analysis was performed to summarize patient and surgical characteristics (Table 1). Fifty-five (50.0 %) patients were operated with the use of intraoperative cell salvage, whereas 55 patients (50.0 %) did not use cell salvage system. There were no significant differences in

Table 1 Patient and surgical characteristics ($N = 110$)

Characteristics	Non-cell salvage system ($n = 55$)	Cell salvage system ($n = 55$)	p value
Age (years)	16.81 ± 6.97	15.53 ± 5.60	0.248
Sex			
Male/female	10/45	15/40	0.255
BMI (kg/m^2)	19.24 ± 3.08	19.56 ± 3.48	0.569
Diagnosis			0.975
Congenital scoliosis	19	18	
Idiopathic scoliosis	24	25	
Adult scoliosis	6	7	
Neuromuscular scoliosis	6	5	
No. of fused segments	10.85 ± 3.03	11.26 ± 2.70	0.427
EBL (mL)	696.76 ± 374.32	767.42 ± 362.29	0.272
Hemovac (mL)	593.70 ± 258.78	548.06 ± 201.91	0.264
Transfusion (op) (U/pt)	0.58 ± 1.07	0.21 ± 0.63	0.032
Transfusion (post-op) (U/pt)	0.22 ± 0.63	0.11 ± 0.46	0.301
Allogenic blood transfusion, n (%)	18 (32.7)	8 (14.5)	0.025
Op time (min)	208.90 ± 52.64	220.00 ± 56.62	0.244

BMI body mass index, *EBL* estimated blood loss during operation, *Hemovac* blood drainage to hemovac after operation, *transfusion* (*op*) red blood cell transfusion unit during operation, *transfusion* (*post-op*) red blood cell transfusion unit after operation, *Op time* operation time, *U blood units* U/pt units per patient

age, gender, BMI, diagnosis, number of levels fused, intraoperative estimated blood loss, blood drainage to hemovac after operation, red blood cell transfusion unit after operation and operation time between the cell salvage and no cell salvage groups. Significant differences existed in the red blood cell transfusion requirements during operation and allogenic blood transfusion rate between the 2 cohorts. In patients who had intraoperative cell salvage, the mean red blood cell transfusion requirement during operation was 0.21 U/pt compared to 0.58 U/pt in patients who did not use intraoperative cell salvage. Within the cell salvage group, the entire perioperative allogenic blood transfusion rate was 14.5 % compared to 32.7 % of the control group (no cell salvage).

Cell salvage usage and change in hematocrit level

There were no significant differences in the hemoglobin and hematocrit values between patients without allogenic transfusion in the cell salvage group and control group (no cell salvage) preoperatively (13.72 versus 13.69 g/dL, $p = 0.888$; 40.73 versus 40.51 %, $p = 0.709$). The first day after surgery, there were statistical differences in the mean hemoglobin and hematocrit level between the cell salvage group and the control group (10.44 versus 9.62 g/dL, $p = 0.010$; 30.70 versus 27.47 %, $p = 0.000$). The third day after surgery, the mean hemoglobin and hematocrit level of the cell salvage group were significantly higher than the control group (9.43 versus 8.82 g/dL, $p = 0.048$; 27.45 versus 25.77 %, $p = 0.048$). Interestingly, however, there were no statistically significant differences in the mean hemoglobin and hematocrit level in the CS and NCS groups of patients at the time of hospital discharge. (10.01 versus 9.79 g/dL, $p = 0.415$; 29.75 versus 29.22 %, $p = 0.526$) (Table 2).

Predicting allogeneic blood transfusion

A univariate analysis demonstrated that the mean number of levels fused in the patients who had allogeneic transfusion (12.65) was significantly higher ($p = 0.000$) than the patients who did not have transfusion (10.02). Also surgical time in the patients who had transfusion (230.38 min) was significantly longer ($p = 0.021$) than the patients who did not have transfusion (203.00 min). The mean preoperative hemoglobin and hematocrit values were less in patients with transfusion requirement than in those without transfusion requirement (12.75 versus 13.70 g/dL, $p = 0.000$; 37.99 versus 40.64 %, $p = 0.000$). The amount of intraoperative blood loss and drained volume was significantly greater in the former group compared with the latter group (915.38 versus 600.60 mL, $p = 0.000$; 664.61 versus 508.85 mL, $p = 0.003$). There were no significant

Table 2 Hematologic profiles

Parameters	Non-cell salvage system ($n = 37$)	Cell salvage system ($n = 47$)	p value
Hemoglobin (g/dL) (patients without transfusion)			
Baseline	13.69 ± 1.04	13.72 ± 1.03	0.888
Day 1 postoperation	9.62 ± 1.46	10.44 ± 1.37	0.010
Day 3 postoperation	8.82 ± 1.57	9.43 ± 1.17	0.048
At discharge	9.79 ± 1.44	10.01 ± 1.03	0.415
Hematocrit (%) (patients without transfusion)			
Baseline	40.51 ± 2.77	40.73 ± 2.65	0.709
Day 1 postoperation	27.47 ± 4.17	30.70 ± 3.65	0.000
Day 3 postoperation	25.77 ± 4.30	27.45 ± 3.37	0.048
At discharge	29.22 ± 4.34	29.75 ± 3.34	0.526

differences between two groups based on age, gender and BMI. Further stratifications according to curve magnitude, diagnosis and fused vertebral levels showed that cell saver could significantly decrease the allogeneic transfusion rates in those patients underwent surgery for more than 10 fused vertebral levels ($p = 0.007$) (Table 3). A multivariate analysis demonstrated that preoperative no. of fused segments (OR: 1.472; $p = 0.005$), preoperative hemoglobin level (OR: 0.901; $p = 0.001$), and the use of cell saver system (OR: 0.133; $p = 0.003$) maintained its significance in predicting likelihood of transfusion (Table 4). Nagelkerke R^2 indicated that this model explained 52.4 % of the variance of likelihood of transfusion.

Allogeneic transfusion-related complications

A total of 11 allogeneic transfusion-related complications occurred in the perioperative period. In the CS group, there were four cases of electrolyte changes. The control group showed one case of allergic reaction and six cases of electrolyte changes. No marked differences were observed in transfusion-related complications between both groups (Table 5).

Table 3 Stratification of surgical characteristics

Characteristics	Transfusion group		
	Non-cell salvage system ($n = 18$)	Cell salvage system ($n = 8$)	p
Curve magnitude, n (%)			
<80°	7 (38.9)	3 (37.5)	1.000
≥80°	11 (61.6)	5 (62.5)	
No. of levels fused, n (%)			0.007
<10	7 (38.9)	0 (0)	
≥10	11 (61.1)	8 (100)	
Diagnosis, n (%)			0.716
Congenital scoliosis	6 (33.3)	4 (50.0)	
Idiopathic scoliosis	8 (44.4)	2 (25.0)	
Adult scoliosis	1 (5.6)	1 (12.5)	
Neuromuscular scoliosis	3 (16.7)	1 (12.5)	

Table 4 Multivariate regression model predicting transfusion

Predictors	Odds ratio	95 % confidence interval		p values
		Lower limit	Upper limit	
No. of fused segments	1.472	1.125	1.927	0.005
Hemoglobin (pre)	0.901	0.849	0.957	0.001
Cell saver	0.133	0.035	0.498	0.003

Nagelkerke $R^2 = 0.524$

Hematocrit (pre) preoperative hematocrit

Table 5 Summary of possible transfusion-related complications

Transfusion-related complications	Non-cell salvage system ($n = 55$)	Cell salvage system ($n = 55$)	p value
Allergic reaction, n (%)	1 (1.8)	0 (0)	1.000
Hemolytic reaction, n (%)	0 (0)	0 (0)	–
Electrolyte changes, n (%)	6 (10.9)	4 (7.3)	0.507
Metabilic acidosis, n (%)	0 (0)	0 (0)	–
Hemoglobinuria, n (%)	0 (0)	0 (0)	–
Hematuria, n (%)	0 (0)	0 (0)	–
Acute renal failure/ insufficiency, n (%)	0 (0)	0 (0)	–

Discussion

There is conflicting evidence in the literature regarding cell salvage system usage in pediatric orthopedic surgery. McMurray et al. [10] found that cell saver usage decreased the need for donor blood transfusion in primary and revision hip arthroplasty. Nicolai et al. [6] also demonstrated that cell saver decrease the amount of other blood transfusions in children undergoing acetabuloplasty. In their meta-analysis, Huet et al. [11] found that cell savers were effective in decreasing the need for allogeneic transfusions in orthopedic surgery. Lennon et al. [20] reported the cell salvage system to be useful in decreasing allogeneic blood transfusion in a group of both pediatric and adult spinal deformity patients. It was after thorough consideration based on these studies that led to the routine usage of cell salvage systems at our hospital.

However, Siller et al. [14] examined cell saver use in spinal fusion for idiopathic scoliosis and found that blood requirements for this procedure can be met less expensively and more reliably by the use of predonated autologous blood. Weiss et al. [16] also found that the use of cell saver does not significantly reduce the need for other transfusions in scoliosis surgery. To overcome such controversies, we embarked to examine the use of cell saver in scoliosis surgery based on our institutional practice.

The disagreement among the conclusions of the aforementioned studies might be explained by the specifications of cell salvage system use and the overall perioperative blood management strategy. Our results showed differences between the groups in entire perioperative allogenic blood transfusion rate, as only 14.5 % of patients in the CS group received allogeneic blood, compared to 32.7 % of the patients in the control (NCS) group. In our study, we had a uniform perioperative blood management strategy. No patient predonated blood, no patient had hemodilution, all patients had hypotensive anesthesia, and all patient

received recombinant human erythropoietin (rhEPO) administration postoperatively. Without preoperative autodonation, patients arrive to the operating room with a higher hemoglobin level. Blood conservation techniques such as the use of hypotensive anesthesia, rhEPO also decreased the risk of allogeneic transfusion. We hypothesize that these subtle differences in blood management technique explain why the cell salvage system was efficacious in our study population.

The cost of cell saver for spinal fusion costs approximately $350 for one case, whereas one hospital day costs approximately $100 in our country. Patients who predonated blood for autotransfusion will spend at least 7 days more in the hospital before surgery for this predonation procedure. Thus, the use of cell saver led to significant cost savings: as a result of using cell saver in one patient equals to a net savings of at least $350. Obviously, multiplied by the number of cases done in 1 year, this would represent even greater savings.

Vitale et al. [21] reported that fewer fused vertebral levels and shorter operations trended toward lower allogeneic intraoperative transfusion rates. Other relevant predictors of transfusion reported in the literature for adult and pediatric spine surgery include low preoperative hemoglobin, pulmonary disease, low body weight, use of valproic acid and increased curve severity [7, 22–25]. In line with the studies of Vitale et al. [21] our study demonstrated that higher preoperative hemoglobin (OR: 0.901, $p = 0.001$) and fewer fused vertebral levels (OR: 1.472; $p = 0.005$) predicted lower allogeneic intraoperative transfusion rates. Further stratifications according to curve magnitude, diagnosis and fused vertebral levels have demonstrated that cell saver could significantly decrease the allogeneic transfusion rates, especially for those patients underwent surgery for more than 10 fused vertebral levels, suggesting that the cell salvage system may be useful especially for those patients with low preoperative hemoglobin or longer fused vertebral levels (more than 10 levels).

In the clinical setting of spine surgery, adjuvant treatment with rhEPO might result in higher perioperative hemoglobin levels and a further reduction in the exposure to allogeneic blood transfusions. In our series, all the patients in the two groups received rhEPO postoperatively. As shown in Table 2, despite the Hb and hematocrit levels in the control group were significantly lower in the first 3 days they were able to increase to the same extent as those patients in the CS group at the time of hospital discharge. We think that postoperative drop in hematocrit level was a consequence of the dilution effect caused by administration of intravenous liquids and blood loss during the surgery. After appropriate hydroelectrolyte management and the effects of rhEPO, the hematocrit level increased at the time of discharge. Therefore, our results are partially in agreement with those of previous studies involving patients with similar surgical pathologies [26, 27].

Aside from the likelihood of the use of autologous cell saver transfusions, risks associated with its use must also be considered. Complications such as haemolysis, intravascular coagulation, decreased haematocrit level and microembolization have been reported to be associated with older machines, which had rotating heads and damaged red blood cells, thus releasing free hemoglobin and causing complications. In our study, we found that transfusion-related complications such as allergic reaction, hemolytic reaction and electrolyte changes in the two groups were similar, suggesting that the use of intraoperative cell saver transfusions is safe. However, this should be interpreted with caution. The rare occurrence of these complications precludes any other reasonable study design, unless there is a multicenter effort.

This was a relatively large prospective randomized study comparing 55 control patients with 55 patients in whom intraoperative cell saver was used. Clinical characters were prospectively collected as detailed as possible. We also had a uniform perioperative blood management strategy and the same standard trigger for transfusion. The inclusion of these factors allows for a more accurate assessment of perioperative blood loss and transfusion requirements with surgery for scoliosis patients.

In conclusion this prospective single center study of consecutively recruited patients with scoliosis has identified the use of intraoperative blood salvage and autologous transfusion in spine deformity surgery significantly reduces the need for allogeneic blood during this operation. The efficacy and safety of spinal deformity surgery may be enhanced if an individualized approach is taken, considering both the patient's likelihood of requiring allogeneic blood transfusion and the risks and benefits of cell salvage system for that individual, coupled with other blood saving techniques, such as antifibrinolytic drugs, fibrin sealant, controlled hypotension, autologous platelets, etc.

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Conflict of interest None.

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