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ORIGINAL

EVALUATING THE SURGICAL EFFICACY AND COST-EFFECTIVENESS OF INTRAOPERATIVE CELL SAVER UTILIZATION IN THE TREATMENT OF LUMBAR DEGENERATIVE SCOLIOSIS

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ABSTRACT

Objectives: To evaluate the cost-effectiveness and surgical efficacy of intraoperative cell saver use in lumbar degenerative scoliosis surgery. **Methods:** 50 lumbar degenerative scoliosis patients who underwent instrumentation, fusion and correction with a posterior approach were analyzed. Patients were formed as cell saver (CS group, n: 26) and non-cell saver (NCS group, n: 24). Between groups, instrumentation- osteotomy levels, and cost effectiveness assessment were performed. **Results:** The number of instrumentation levels is 5.07 ± 1.89 in group CS, 3.6 ± 1.88 in group NCS ($p = 0.004$); the number of osteotomy levels was 2.84 ± 1.51 in group CS and 1.83 ± 0.91 in group NCS ($p = 0.007$). Cost effectiveness analysis was evaluated; In CS, the total cost was found to be 42010.4 ± 27700 \$, while the group NCS was 17105 ± 18220.6 \$ ($p = 0.001$). **Conclusion:** The use of cell saver is not routinely required in lumbar degenerative scoliosis surgery. Despite its high cost, it may be useful in cases where instrumentation-osteotomy levels are high.

KEYWORDS: Cell saver; scoliosis; cost-effectiveness; transfusion

1. INTRODUCTION

Intraoperative blood loss is a common problem in lumbar degenerative scoliosis (LDS) surgery. Intraoperative mean blood loss in major spine surgery is 650-2839 ml (Elgafy, Bransford, McGuire, Dettori, & Fischer, 2010). Morbidity and mortality increase in patients with 500 ml or more blood loss after non-cardiac surgery (Huang & Ou, 2015). Various blood transfusion options are

available, including allogeneic blood, predonated autologous blood, and use intraoperative cell saver (CS). Allogenic blood transfusion is an effective and popular method for blood loss. Allogenic blood transfusion can transmit infectious diseases such as HIV, hepatitis, CMV, and may produce allergic and hemolytic reactions (Elgafy et al., 2010). These risks have prompted surgeons to look for alternatives to minimize allogeneic blood transfusions.

Perioperative antifibrinolytic agents such as recombinant factor VIIa, aprotinin, tranexamic acid and aminocaproic acid as well as alternative methods such as reducing abdominal pressure, hypotensive anesthesia, normovolemic hemodilution, topical hemostatic agents and intraoperative CS are performed to reduce blood loss and allogeneic blood transfusion (Bible, Mirza, & Knaub, 2018).

The use of intraoperative autotransfusion systems (Medtronic Autologous; Medtronic Inc., ABD), such as CS, has become popular in spinal surgery. Blood is collected from the surgical field by aspiration, anticoagulated with heparin and filtered. It is then centrifuged to separate the red blood cells from the white blood cells, and then it is washed. After these procedures are completed, the collected blood is transferred to the patient again. Thus, patients can avoid the risks associated with allogeneic transfusion. There is no consensus on the use of CS in spine surgery. In our study, we aimed to reveal the effect of CS use on clinical efficacy and cost in LDS surgery.

2. Methods

After receiving the approval of the local ethics committee, 50 patients with LDS who were operated with posterior intervention in a single center between May 2013 and May 2018 were retrospectively analyzed. There were two groups as group CS with 26 patients who received CS and group non-cell saver (NCS) with 24 patients who did not receive CS.

Patients who are older than 18 years of age and had not previously undergone a spinal surgery were included in the study. Patients who had previously undergone fusion due to infection, tumor or trauma were excluded from the study. The patients age, gender, pre- and post-operative hematocrit platelet / calcium / albumin levels, number of fused segments, number of corpectomy, osteotomy / transforaminal lumbar interbody cage (TLIF) levels, estimated blood loss, allogeneic blood transfusion and fresh frozen plasma (FFP) transfusion needs were recorded.

The operations were performed by the same surgeons who had previous experience with spine surgery. All the surgical procedures were operated under the normovolemic hemodilution and hypotensive anesthesia. The iliac wing graft was not utilized in the surgery of any of the patients. Following the operation, the patients were transferred to the intensive care unit for close

follow-up and were monitored for 24 hours.

Allogeneic blood transfusion was performed after the infusion of 500mL normal saline in the event that symptoms of anemia such as a hemoglobin level <7.0 g/dL or a hemoglobin value between 7.0 and 8.0 g/dL, and tachycardia >100 beats/min, systolic blood pressure <100 mmHg, or urine output <30 mL/h may occur (Ovadia, Luger, Bickels, Menachem, & Dekel, 1997; Parker, Roberts, & Hay, 2004). In our study, the cost of the CS system establishment, infusion of autologous blood and the allogeneic blood transfusion were provided from the invoicing representatives of the institution. The cost efficiency analysis of CS was conducted.

3. Statistics

Measures of central tendency and diffusion, paired t-test, Mann-Whitney U test and chi-square test were utilized to compare the data as the statistical analysis. SPSS 20.0 package software was used for the statistical analysis and $p < 0.05$ was considered statistically significant.

4. Results

The mean age of the participants included in the study was 55.3 ± 11.2 (30-76). The mean age was 57.3 ± 11 in group CS whereas it was 53.2 ± 11.2 ($p > 0.05$) in group NCS. There were 35 females and 15 males. 11 male patients were in group CS and 4 patients were in the group NCS ($p = 0.048$) while 15 female patients were in group CS and 20 female patients were in group NCS ($p = 0.048$). The number of instrumentation levels was 5.07 ± 1.89 in group CS and 3.6 ± 1.88 in the group NCS ($p = 0.004$); The number of osteotomy levels was 2.84 ± 1.51 in group CS and 1.83 ± 0.91 in the group NCS ($p = 0.007$). The number levels with the usage of TLIF cage was 1.19 ± 1.16 in group NCS and 1.12 ± 0.89 in group NCS ($p > 0.05$). 4 patients who underwent corpectomy were in the group CS and 1 patient was in group NCS ($p > 0.05$). (Table 1).

Table 1. General characteristics of the cases

	CELL SAVER (+) (N=26)	CELL SAVER (-) (N=24)	P
AGE*	57,3±11,0	53,2±11,2	0,17
MALE	11	4	0,048
FEMALE	15	20	0,048
TLIF CAGE LEVELS*	1,19±1,16	1,12±0,89	0,97
INSTRUMENTATION LEVELS*	5,07±1,89	3,6±1,88	0,004
OSTEOTOMY LEVELS*	2,84±1,51	1,83±0,91	0,007
CORPECTOMY	4	1	0,13

*mean±SD

While the preoperative hematocrit value was measured as $39.0 \pm 3.39\%$ in group CS, it was measured $39.0 \pm 4.1\%$ ($p>0.05$) in group NCS. In the postoperative period, it was $28.8 \pm 6.5\%$ in group CS and 30.2 ± 3.4 ($p>0.05$) in group NCS. While the preoperative platelet value was $276.0 \pm 66.1 / \text{mm}^3$ in group CS and $277.7 \pm 60.5 / \text{mm}^3$ in group NCS ($p>0.05$), it was

$162.7 \pm 49.6 / \text{mm}^3$ in group CS and $188.1 \pm 48.9 / \text{mm}^3$ in group NCS ($p=0.05$) in the postoperative period. While the preoperative calcium value was $9.64 \pm 0.59 \text{ mg/dl}$ in group CS and $9.6 \pm 0.43 \text{ mg/dl}$ in group NCS, these values were found to be $7.30 \pm 0.61 \text{ mg/dl}$ and 7.30

$\pm 0.61 \text{ mg/dl}$ in the postoperative period, respectively ($p>0.05$). While the preoperative albumin value was $4.05 \pm 0.45 \text{ g/dl}$ in group CS and $4.28 \pm 0.32 \text{ g/dl}$ in group NCS, it was $2.69 \pm 0.38 \text{ g/dl}$ in group CS and $2.56 \pm 0.72 \text{ g/dl}$ in group NCS in the postoperative period. ($p>0.05$) (Table 2).

Table 2: Comparison of the laboratory findings of the cases

	CELL SAVER (+) (N=26)	CELL SAVER (-) (N=24)	P
PREOP HEMATOCRIT VALUE	39,0±3,39	39,0±4,1	0,86
POSTOP HEMATOCRIT VALUE	28,8±6,5	30,2±3,4	0,52
PREOP PLATELET VALUE	276,0±66,1	277,7±60,5	0,62
POSTOP PLATELET VALUE	162,7±49,6	188,1±48,9	0,05
PREOP CALCIUM VALUE	9,64±0,59	9,6±0,43	0,92
POSTOP CALCIUM VALUE	7,30±0,61	7,4±0,84	0,74
PREOP ALBÜMIN VALUE	4,05±0,45	4,28±0,32	0,32
POSTOP ALBÜMIN VALUE	2,69±0,38	2,56±0,72	0,61

**mean ± SD*

While the average blood loss in surgery is $1283 \pm 787 \text{ ml}$ (350-3200 ml), it was found to be $1487.1 \pm 832 \text{ ml}$ in group CS and $1062.0 \pm 685 \text{ ml}$ in group NCS ($p>0.05$). It was observed that the allogeneic blood transfusion needs were $2.1 \pm 1.8 \text{ Unit}$ in group CS and $2.0 \pm 2.02 \text{ Unit}$ in group NCS ($p>0.05$). While the FFP requirements were $0.57 \pm 1 \text{ Unit}$ in group CS and $0 \pm$

0.7 Unit in group NCS ($p=0.02$) (Table 3). When the cost analysis was conducted, it was determined that the cost per-patient was $553.2 \pm 192.3 \$$ in group CS and $184.8 \pm 184.2 \$$ in group NCS ($p=0.001$). Considering the total cost, the cost of the group CS was $42010.4 \pm 27700 \$$ and $17105 \pm 18220.6 \$$ in group NCS ($p=0.002$) (Table 3). Mortality, infection, allergic and hemolytic

reactions related to the transfusion were not observed in any of the patients.

Table 3: Blood requirements and cost analysis of the cases

	CELL SAVER (+) (N=26)	CELL SAVER (-) (N=24)	P
ALLOGENEIC BLOOD REQUIREMENT	2,1±1,8	2,0±2,02	0,64
FFP REQUIREMENT	1,03±1,3	0,37±0,76	0,02
COST PER-PATIENT	553.2 ± 192.3	184.8 ± 184.2	0,001
TOTAL COST	114268,3±75344	46525,6±49560	0,002

5. Discussion

Intraoperative CS is seen as an approach of minimizing the number of allogeneic blood transfusion by collecting the blood emerging during the surgery and transferring it to the patient following a series of procedures (Roger Kirk Owens et al., 2013). However, it has been claimed that minimizing the complications associated with the allogeneic blood transfusion is beneficial in terms of transferring the blood back to the patient in a safe and effective manner (Choi, Hyun, Kim, Jahng, & Kim, 2019). In a randomized prospective single-center study conducted in 110 scoliosis patients, it was determined that the usage of CS minimizes the requirement for the allogeneic blood transfusion significantly (Liang et al., 2015). Lennon et al (LENNON et al., 1987) reported that the usage of intraoperative CS in patients with spinal deformity was beneficial in terms of minimizing the amount of allogeneic blood transfusion. In other studies, conducted in pediatric patients and patients with adolescent scoliosis, it has been highlighted that CS minimizes the incidence of allogeneic transfusion (Bowen, Gardner, Scaduto, Eagan, & Beckstead, 2010; Miao et al., 2014). As a result of their literature review on the usage of CS in adolescent idiopathic scoliosis surgery, Stone et al (Stone, Sardana, & Missiuna, 2017) shared their conclusion that CS causes a decrease in the incidence of allogeneic blood transfusion and therefore its use in adolescent scoliosis surgery would be beneficial.

It was found in another study conducted in fusion surgeries with lumbar instrumentation that the usage of CS led to a decrease in the need for allogeneic blood transfusion (Djurasovic et al., 2018). In our study, it was found that there was no significant difference between the groups in terms of the requirement of allogeneic blood transfusion. (2.1 ± 1.8 U, 2.0 ± 2.02 Unit $p > 0.05$). Similarly, there are studies reporting that the usage of CS does not minimize the requirement of the allogeneic blood transfusion. According to Weiss et al (Weiss, Skaggs, Tanner, & Tolo, 2007), the usage of CS in scoliosis surgery did not significantly minimize the need of blood transfusion. It was concluded in another study on patients undergoing single-level posterior lumbar decompression and fusion surgery that CS did not significantly minimize the need of allogeneic blood transfusion (Canan et al., 2013). Comparable results

were achieved in group of patients who underwent short segment (<3) lumbar laminectomy and fusion surgery (Kelly et al., 2015). Gause et al (Gause et al., 2008) stated that the intraoperative CS does not minimize the need for allogeneic blood transfusion, on the contrary it may be associated with high blood loss.

FFP transfusion was performed in addition to blood transfusion to prevent the development of coagulopathy in the patients. Miao et al.¹⁰ discovered no significant difference when the levels of fresh frozen plasma transfused to patients during scoliosis surgery were compared. While in our study, the requirement of FFP was found to be significantly higher in group CS (p=0.02). Furthermore, the platelet value of the patients in the CS group decreased in the postoperative period, according to our study (p=0.05). In the study of Akgül et al (Akgul et al., 2014) on the effectiveness of CS use in scoliosis surgery, no significant difference was reported between platelet values in the postoperative period.

Owens et al.⁶ recommended the usage of CS in surgeries where the TLIF cage and multilevel fusion is utilized. In comparable studies, the usage of CS in multi-level fusion surgery was recommended, but it was reported that there was no significant benefit in the short segment fusion and laminectomy surgery (Gum et al., 2017). According to our study, the number of fusion (p=0.004) and osteotomy (p=0.007) levels in the CS group was found to be significantly higher in the CS group. However, no significant difference in TLIF cage levels was discovered.

It was reported that the studies on the cost-effectiveness of CS usage in spinal surgery have produced various results. Savvidou et al (Savvidou, Chatziioannou, Pilichou, & Pneumaticos, 2009) addressed that the usage of CS minimizes the cost of transfusion in adult lumbar fusion surgery compared to the usage of only the allogeneic blood transfusion. In a study conducted in adult spinal deformity patients, the usage of CS was reported to provide cost savings when used above five or more levels in adult spinal deformity surgery even though its use did not minimize the need for allogeneic transfusion.¹⁹ According to Kelly et al (Kelly et al., 2015) the CS was reported to have no significant benefit on cost-effectiveness in the short segment lumbar laminectomy and fusion surgery (≤ 3 levels). According to Canan et al (Canan et al., 2013) the usage of intraoperative CS in single-level instrumented lumbar fusion surgery was reported to be non-cost-effective. When cost analysis was carried out in our study, it was discovered that the cost per patient in the group CS was significantly higher than in the group NCS (p=0.001). Considering the total cost, the group CS was similarly found to be significantly higher than the group NCS (p=0.002). Considering our study, it is seen that there are some limitations. The study's limitations include that it is retrospective, that the number of patient groups is low, that the usage of CS on a patient group is decided by the

surgeons, and that the usage of CS is chosen based on the extent of the surgery. Prospective studies to be performed by standardizing the use of CS is thought to reduce the need for allogeneic blood transfusion of intraoperative CS in LDS surgery.

Conclusion

The routine usage of CS in the LDS surgery is seen to be unnecessary due to its high cost. However, it was previously considered to be useful in cases with high instrumentation and osteotomy levels. If CS is used in LDS surgery, the need for FFP may increase, and the risk of postoperative thrombocytopenia should be considered.

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