Introduction

Primary posterior spinal instrumentation and fusion surgery for scoliosis is a major spinal operation that is associated with massive intraoperative blood loss [1,2]. Over the past decades, despite significant improvements in the safety of allogeneic RBC transfusion, there remain underlying risks such as allergic reactions and the risks of bacterial, malarial, HIV and hepatitis infections [3]. Furthermore, allogeneic RBC transfusion may be related to an increased rate of operative site infections [4]. Should blood transfusion complications ensue in children and adolescents, the consequences may be serious and long-term.

In recent years, to decrease the need for allogeneic blood transfusion, alternative approaches such as the use of the cell saver, which can salvage and return the patient’s RBCs, have been widely used intraoperatively [3]. Use of the cell saver has extended to spinal deformity surgery, including surgery for scoliosis. However, there are conflicting reports about the efficacy and cost-effectiveness of intraoperative use of the cell saver. Some studies have indicated that use of the cell saver decreased RBC transfusions in scoliosis surgery [5–7], while others have demonstrated that cell saver use presented little benefit or might have been associated with increased blood loss [8–11]. In all, few studies have evaluated the intraoperative use of the cell saver in a younger age group such as ours.

Therefore, we designed this retrospective study to analyze a large series of school-aged and adolescent patients undergoing elective posterior spinal pedicle screw instrumentation and fusion surgery to determine the efficacy and cost-effectiveness of the intraoperative use of the cell saver.

Materials and Methods

The study was a retrospective review of charts and anesthesia records of patients at the People’s Liberation Army (PLA) hospital No. 306 and was approved by the institutional review board and...
Surgical approaches

The majority of the operations were performed by two authors (H.-S. Ma & J.-G. Wu) who have been dedicated to this field for more than fifteen and ten years. The patients underwent cervical and/or thoracic and/or lumbar laminectomy and arthrodesis according to the standard posterior approach. If indicated, osteotomy and hemivertebra resection were performed. Instrumentation was achieved using segmental pedicle screws, Postero-lateral vertebral plate decortication was accomplished using a high-speed burr and rongeurs, followed by autogenous iliac crest and/or rib and/or allogenic bone graft that was placed as dictated by the specific circumstances of the individual procedure. One drain was routinely placed under the muscles of the back before closure of the incision to allow continuous suction, and it was withdrawn no later than postoperative day three, when the drainage volume was less than 100 ml per day.

The decision to use or not use the cell saver was made by the surgeons, who tended to use the cell saver for cases in which major blood loss was anticipated. The “cell saver” cohort all had intraoperative cell salvage performed by an experienced technician in accordance with the manufacturer’s guidelines. The washed RBCs were infused during the intraoperative period. For cases when the cell saver blood was insufficient, complementary allogenic blood use was indicated. The intraoperative EBL was determined based on the combined volume of blood gathered in the cell saver canister, suction canisters and swab wash. The postoperative EBL was determined by measuring the amount of blood in the drainage bag. The total perioperative amount of EBL was calculated. The intra- and total perioperative blood replacement was described as % of (calculated) blood volume which was set at 70 mL/kg (weight).

According to the formal transfusion protocol of the PLA hospital No. 306, intraoperative indications for transfusion were signs of anemia such as hypotension that was inadequately responsive to fluid challenge; blood loss greater than 20% of the total blood volume; and a hemoglobin level less than 9.0 g/dl or an absolute hemoglobin level of less than 7.0 g/dl without signs of anemia. The same transfusion guidelines were followed during the postoperative period. Coagulopathy is believed to develop as a consequence of massive blood loss and massive red cell transfusion. Therefore, fluid management approaches emphasize the use of an adequate volume of FFP simultaneously with platelet transfusions. However, there was no formal protocol concerning the transfusion of FFP at our hospital. Thus, the amount of FFP transfused was determined by the combined discretion of the surgeon and the anesthesiologist.

The main anesthetic approach is summarized as follows. General anesthesia was induced by intravenous midazolam 0.1 mg/kg, fentanyl 2 µg/kg, propofol 2−3 mg/kg and vecuronium 0.1 mg/kg. The patient was intubated with an armored endotracheal tube. Anesthesia was maintained by continuous infusion of propofol and remifentanil and intermittent injections of fentanyl and vecuronium. Continuous ECG, pulse oximetry, end-tidal CO2, invasive arterial blood pressure (ABP), central venous pressure (CVP), urine output and blood-gas analysis were routinely monitored. All of the patients underwent wake-up testing, and some of the patients accepted the use of somatosensory evoked potential monitoring to avoid possible spinal neural damage when the scoliosis was corrected.

No patient donated autologous blood preoperatively, no hemodilution technique was employed, and no procoagulant medicine was administered during the operative procedures. Deliberate hypotension was achieved by modulating the anesthesia depth to maintain a mean arterial pressure (MAP) between 40 and 50 mmHg.

At our hospital, the cost for transfusion of each unit of allogenic packed RBCs is $70.49, which includes ABO and Rh blood typing, antibody screening, cross matching, packed RBCs, white blood cell filtration and administrative expenses (Table 1). The cost for the use of the cell saver is a flat rate charge of $311, which includes tubing, liner and anticoagulant solution costs. The cost for each package of FFP (200 ml), including administrative expenses, is $13. The total transfusion cost for every patient was calculated.

Statistics

The two groups were compared for preoperative baseline and perioperative factors. Because patients were not randomized by gender, age, weight, preoperative Cobb angle, preoperative Hb and Hct, EBL, duration of the operation and number of spinal

The Efficacy and Cost-Effectiveness of Cell Saver

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levels fused, we attempted to reduce the bias due to confounding by using propensity score matching [12,13].

A logistic regression model was created with a stepwise option to derive a propensity score that included parameters available about the patients and the surgical procedures. Each patient was assigned a propensity score that reflected the intraoperative EBL. The variables tested in the propensity score were gender, age, body weight, preoperative Cobb’s angle of major curvature, EBL, preoperative Hb and Hct, duration of the surgery and number of spinal levels fused. Based on the propensity score of each patient, a 1:1 matched and 0.2 caliper analysis was performed without replacement. The aim of this procedure was to attempt to mimic randomization by creating 2 groups of patients who were comparable with respect to all covariates mentioned above.

Each patient in the cell saver group was matched with the patient in the control group with the closest propensity score using an 8-1 digit match algorithm [12]. Patients who did not have close pairings were excluded from the final matched population.

Finally, the groups were compared according to perioperative parameters with the primary outcome parameters determined as intraoperative and postoperative allogeneic transfusion amount, total perioperative transfusion amount and the cost of all blood transfusion-related expenses. Categorical variables were summarized as frequencies and continuous variables as the mean ± standard error of the mean (SEM). Characteristics of the 2 groups were compared by using Student’s t-test for continuous variables and the chi-square test for categorical variables. All statistical analyses were performed using Statistical Package for the Social Sciences (IBM SPSS Statistics 19.0, Chicago, IL, USA), and the statistical significance was defined as P<0.05.

Results

After applying the exclusion criteria, a total of 247 patients initially qualified for our study. The cohort consisted of 67 patients in whom the cell saver was used and 180 patients in whom no cell saver was used. Demographic characteristics and perioperative factors regarding the patients before and after matching are presented in Table 2.

The propensity score matching produced 60 matched pairs. No match was found for 7 patients in the cell saver group because there were insufficient patients in the control group with the proper matching score. Between the two groups, matching was satisfactory in achieving balance with respect to the variables we collected, in particular for the most important factor: intraoperative EBL (Table 2). No serious complications concerning the transfusion of autologous or allogeneic blood were reported, and no blood coagulation disorders were encountered.

There were 59 patients in the control group and 58 in the cell saver group who received allogeneic RBC transfusion. A comparison of the transfusion findings and other perioperative results are presented below (Table 3).

During the intraoperative period, the amount of allogeneic RBCs transfused in the control group was significantly higher than that in the cell saver group ($260.60±48.18 vs 540.00±39.24 ml, P=0.279)$.

During the postoperative period, the amount of allogeneic RBC transfused in the control and cell saver groups was not significantly different ($3.63±0.62 vs 3.45±0.46 units, P=0.813$). The amount of FFP transfused in each group was also not significantly different ($293.33±97.13 vs 253.00±42.44 ml, P=0.503$).

When the observation period was examined in its entirety, the amount of perioperative total allogeneic RBC units transfused for each patient in the control group and the cell saver group did not significantly differ ($11.92±0.93 vs 9.85±0.78 units, P=0.101$). Moreover, the volume of FFP transfused in the two groups was also not significantly different ($913.33±117.16 vs 775.00±81.88 ml, P=0.335$).

Furthermore, there were no significant differences with regard to intraoperatively transfused crystalloids and colloids (P=0.372 and P=0.673, respectively), the duration of patient stay in the ICU (P=0.659), postoperative hospital stay (P=0.996), postoperative drainage (P=0.567), total perioperative EBL (P=0.596), intraoperative blood replacement (P=0.695), total blood replacement (P=0.812), postoperative Cobb angle of major curvature (P=0.376), discharge Hb and Hct (P=0.191 and P=0.485, respectively).

The total cost of perioperative transfusion of all blood products (including reinfused RBCs, allogeneic RBCs and FFP) was calculated for each patient. According to the costs standard of our hospital, the total expenses for blood products in the control group were slightly lower than in the cell saver group, but the marginal variance did not reach statistical significance ($899.92±72.07 vs 1056.64±58.95, P=0.095$). However, the costs of allogeneic blood products in China are relatively low (RBC/plasma $=80.49±13$) compared to the approximate costs of US (RBC/plasma $=250/75$). The packed RBC concentrate is the equivalent of 200 ml of blood in China and 500 ml in US. Therefore, assuming the cost of cell saver use is the same in China and US ($311$), under the premise of US standard the total transfusion cost for every patient was calculated. Under this standard, the total expenses for blood products in the control and cell saver groups was not significantly different ($1534.17±131.79 vs 1586.63±103.54, P=0.775$).

Discussion

This study examined perioperative blood loss and its management in school-aged children and adolescents undergoing posterior correction of scoliosis with instrumentation and fusion. For many years, instrumented posterior correction has been considered major spine surgery and has been associated with significant blood loss that often requires blood replacement. During the past decades, despite improvements in laboratory test methods and careful screening of donated blood that have decreased the incidence of blood-borne, transfusion-related infectious diseases, assurances of complete safety from transmissible diseases could not be achieved till now [14].

| Table 1. Allogeneic blood cost. |
|---|
| Expenditure | Cost ($) |
| ABO and Rh typing | 3.28 |
| Antibody screen | 14.75 |
| Cross match | 9.84 |
| Packed RBCs | 34.43 |
| White blood cell filtration | 6.89 |
| Administration | 1.31 |
| Total | 70.49 |

doi:10.1371/journal.pone.0092997.t001
The cell saver has been used clinically for decades and has been widely applied in contemporary spinal surgery. However, current reports in the literature point to conflicting points of view regarding the efficacy and cost-effectiveness of its use. Some authors have demonstrated that the cell saver did not decrease allogeneic blood transfusion requirements in spine surgery studies performed in adults. Owens et al [8] demonstrated in adult posterolateral fusion surgery patients that the use of autologous cell saver transfusion did not reduce requirements for intraoperative or postoperative allogeneic blood transfusion. Canan et al [9] indicated that the use of the cell saver for single-level posterior lumbar decompression and fusion did not significantly reduce the need for allogeneic blood transfusion and was not cost-effective. In a systematic review, Elgafy et al [10] noted that there was little support for routine use of the cell saver in major elective spinal surgery with regard to safety and efficacy considerations. Furthermore, similar findings have been reported for adolescent spinal surgery. Weiss et al [11] demonstrated that in

### Table 2. Patients’ demographic characteristics and perioperative factors, before and after propensity score matching.

| | Overall Cohort | Propensity-Matched Cohort |
|---|---|---|
| | Control | Cell saver | Control | Cell saver | P |
| Gender (Male/Female) | 65/115 | 27/40 | 23/37 | 22/38 | 0.850 |
| Age (yr) | 13.89±0.21 | 14.57±0.28 | 0.072 | 14.93±0.31 | 14.65±0.28 | 0.496 |
| Body weight (kg) | 38.09±0.77 | 43.39±1.35 | <0.001 | 42.04±1.30 | 42.13±1.28 | 0.960 |
| Pre-op hemoglobin (g/dl) | 126.85±6.00 | 130.84±1.85 | 0.049 | 128.62±1.70 | 130.01±1.99 | 0.597 |
| Pre-op hematocrit | 40.11±0.43 | 40.57±1.03 | 0.624 | 39.83±0.59 | 40.44±1.14 | 0.632 |
| Pre-op Cobb angle of major curvature(°) | 87.66±2.13 | 91.40±3.60 | 0.365 | 94.70±3.31 | 90.40±3.88 | 0.401 |
| Intraoperative EBL (ml) | 1541.94±82.72 | 2352.99±169.02 | <0.001 | 2185.83±169.82 | 2135.83±168.33 | 0.835 |
| Duration of the operation (min) | 298.96±6.14 | 337.87±8.91 | 0.001 | 328.62±8.82 | 334.67±11.01 | 0.669 |
| Number of levels fused | 10.18±0.31 | 10.03±0.494 | 0.803 | 9.92±0.537 | 9.85±0.78 | 0.101 |

### Table 3. Transfusion tally and other perioperative results for propensity-matched cohort.

| | Control | Cell saver | P |
|---|---|---|---|
| Allogeneic RBC transfusion (units) | | | |
| Intraoperative (units) | 8.28±0.54 | 6.40±0.51 | 0.012 |
| Postoperative (units) | 3.63±0.62 | 3.45±0.46 | 0.813 |
| Total perioperative (units) | 11.92±0.93 | 9.85±0.78 | 0.101 |
| FFP transfusion (ml) | | | |
| Intraoperative (ml) | 620.00±48.18 | 540.00±59.24 | 0.279 |
| Postoperative (ml) | 293.33±97.13 | 235.00±42.44 | 0.583 |
| Total perioperative (ml) | 913.33±117.16 | 775.00±81.88 | 0.335 |
| Other perioperative parameters | | | |
| Crystalloids (ml) | 1650.91±92.91 | 1547.46±70.29 | 0.372 |
| Colloids (ml) | 1422.81±93.32 | 1474.58±79.65 | 0.673 |
| Reinfused amount of RBC (ml) | | | |
| Duration of ICU stay (h) | 6.29±0.95 | 5.76±0.73 | 0.659 |
| Postoperative hospital stay (days) | 17.53±1.29 | 17.53±0.77 | 0.996 |
| Postoperative drainage (ml) | 852.92±109.34 | 769.21±87.95 | 0.567 |
| Total perioperative amount of EBL (ml) | 2889.25±215.37 | 2724.28±211.49 | 0.586 |
| Intraoperative blood replacement (%) | 77.25±6.82 | 81.38±7.98 | 0.695 |
| Total blood replacement (%) | 104.69±9.15 | 101.47±9.94 | 0.812 |
| Postoperative Cobb angle of major curvature (°) | 41.39±3.57 | 38.11±2.51 | 0.376 |
| Discharge hemoglobin (g/dl) | 104.58±2.86 | 98.73±3.39 | 0.191 |
| Discharge hematocrit | 31.87±0.96 | 30.80±1.19 | 0.485 |
patients undergoing spinal fusion for scoliosis, the use of the cell saver did not decrease the rate of allogeneic transfusion. However, apart from these negative studies suggesting that use of the cell saver is expensive and ineffective, other studies support use of the cell saver. Bowen et al [5] demonstrated that cell saver use decreased allogeneic transfusion, particularly in operations >6 hours in duration with an estimated blood loss >30% of the total blood volume in pediatric idiopathic scoliosis patients. Erse et al [6] reported that the cell saver reduced both intra- and postoperative blood transfusion in patients undergoing posterior spinal fusion for adolescent idiopathic scoliosis. A systematic review by Carless et al [7] demonstrated that the cell saver was efficacious in reducing the need for allogeneic red cell transfusion in adult elective orthopedic surgery. The preoperative Cobb angle of major curvature in our study was 93° and ranged from 50–65° in similar studies [5,6,11]. Intraoperative EBL in our study was approximately 2161 ml, while that in similar studies ranged between approximately 700 and 1100 ml [5,6,9,11,15,16]. There are several possible reasons for these findings. First, China has the largest population in the world, and with an incidence of scoliosis of approximately 1.06% [17], therefore China has a vast number of such patients. Second, China is a developing country, and economic conditions vary greatly between different provinces and different families. The poor economic conditions among scoliosis patients have limited disease prevention and early treatment, and therefore, the pathogenesis of this condition tends towards progression to a serious stage. Finally, our hospital is a high volume center of excellence that has a dedicated team of spinal surgeons and anesthesiologists who have participated in the instrumented posterior correction of scoliosis from 1999. Thus, many seriously ill patients have been transferred from other institutions to our center. Of note, the results of our study are in partial agreement with the findings of previous studies that supported the use of the cell saver as efficacious. In our study, there were less intraoperative allogeneic blood transfusions in the cell saver group (P=0.012), but during the postoperative period, there was no significant difference between the control and cell saver groups with regard to transfusion requirements (P=0.813). Finally, if we calculated overall perioperative allogeneic blood transfusions, there was no significant difference between the two groups (P=0.101). An important finding in our study is that to date, few studies have reported on the transfusion of fresh-frozen plasma, which must be transfused in adequate quantities when the patient accepted massive red cell transfusion to avoid possible coagulopathy. In our study, there were no significant differences in intra-, post- and total perioperative FFP transfusion between the control and cell saver groups. For any clinical study, baseline characteristics are one of the most important preconditions for data analysis and result reliability. Unfortunately, the baseline conditions and characteristics of age, weight, preoperative Cobb angle of major curvature and EBL, perhaps the most important factor, were significantly imbalanced or not available in some previous studies [5,6,9,11,16,18]. Therefore, their results and conclusions may be drawn into question. To our knowledge, our study investigated the largest population of this type to date. Moreover, this is the first report to use the statistical method of propensity score matching to diminish the bias between the control and cell saver groups. In our study, all patients accepted a similar anesthesia method and blood transfusion protocol. No other methods of blood management were used in any patients. Therefore, only the isolated effect of cell saver use on blood transfusion was examined. In terms of the cost-effectiveness analysis, when we calculated the total cost of perioperative transfusion of all blood products, the cost in the control group was slightly lower than that in the cell saver group, but the marginal difference was not significant (P=0.095). Therefore, from a health economics stance, we concluded that cell saver use is not cost-effective. The subjects in our study are children and adolescents, and their weights, % intraoperative blood loss and preoperative Cobb angles vary considerably. For example, one liter blood lose in a small child means exsanguination and in a large one is irrelevant. Therefore, we ranked the 120 patients from the lowest to the highest according to the three factors, respectively. Then we divided them into three groups with 40 cases in each subgroup (low, intermediate and high) to further investigate whether the cell saver could be efficacious and cost-effective in each group. The result is that cell saver was not efficacy and cost-effectiveness in any of the groups (as shown in tables S1–S3 in File S1). On the other side, cell saver decreased the need for intraoperative allogeneic RBC transfusion even though it didn’t decrease the need in post- and perioperative period. This is valuable to our clinical approaches, because use of cell saver alleviated the contradiction of massive blood demand in the operative day. There are some limitations to our study. First, the diagnoses of scoliosis encompass idiopathic scoliosis, congenital scoliosis and neuromuscular scoliosis such as cerebral palsy and muscular dystrophy, among others [19]. Second, in some patients, surgical procedures such as osteotomy and corpectomy can lead to major bleeding. Although we achieved a satisfactory balance of the baseline characteristics between the control and cell saver groups by using the propensity score matching method, the distribution of these factors was not investigated in further detail between the groups. Third, the costs of allogeneic blood products in China are relatively low compared to the US and European standards whilst the use of cell saver is comparably expensive ($300). Furthermore, the costs associated with blood transfusion comprises of more variables [20]. However, these factors were not examined thoroughly. Finally, our study design was retrospective and was performed at a single-center.

Conclusions

In posterior spinal instrumentation and fusion surgery for scoliosis in school-aged children and adolescents, the use of the cell saver decreased the need for intraoperative allogeneic red blood cell transfusion but failed to decrease total perioperative allogeneic red blood cell transfusion. From the standpoint of health economics, the use of the cell saver is not cost-effective. Therefore, there is a need for additional research to include adequately powered, high-quality randomized controlled studies to further investigate the use of the cell saver.

Supporting Information

File S1 Supporting information tables. Table S1, Main outcomes divided by weight. Table S2, Main outcomes divided by % blood loss. Table S3, Main outcomes divided by preoperative Cobb angle (*).
Acknowledgments

The authors thank Ms. Jun Fan, DongYun Ren, EnRun Li, for their assistance in reviewing the electronic medical record database, abstracting data, and proofing.

Author Contributions

Conceived and designed the experiments: YLM WWF YL HSM JGW. Performed the experiments: YLM WWF WZG WZS YL. Analyzed the data: YLM WWF YL XPW WDM. Contributed reagents/materials/analysis tools: YLM WWF YL. Wrote the paper: YLM YL WDM WWF.

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