# Evaluation Of Blood Processed By Cell Saver In Pediatric Scoliosis

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# Abstract

Introduction We study the hematological and microbiological characteristics from the autologous blood processed through the intraoperative cell saver used in our centre (Orthopat®) during the correction of pediatric scoliosis, which is known to be a potentially bleeding surgery.

Material and methods Descriptive analysis of 31 patients undergoing pediatric scoliosis surgery. All of them received blood processed by cell saver intraoperatively. The variables collected were: demographic data, volume of the autogenous red blood cell (RBC) concentrate, blood count, biochemistry, blood culture, preoperative and postoperative blood tests of the patients, incidence of fever during reinfusion of RBC concentrate, postoperative surgical site infections and length of hospital stay.

Results Average volume obtained 288.06ml (sd 154.68). Hematocrit 70.38% (ds 10.03) in accordance with cell-saver commercial data (75%). Of the blood samples obtained, 42.86% had blood cultures that were positive for aerobes and 48.28% for anaerobes. The relation between postoperative infections and contamination of blood concentrates was not statistically significant. When comparing the pre-surgery and post-surgery analytical samples, statistically significant differences ($p < 0.05$) were found in the following: hemoglobin and hematocrit decreased in the postoperative period, while coagulation parameters show a tendency to coagulopathy.

Conclusion Our cell saver obtains RBC concentrates with a percentage of hematocrit in agreement with available information. The reinfusion of them is safe from an infectious and biochemical point of view, but its immunological implications are not clear. This surgery continues to result in a significant loss of blood. Measures taken to avoid allogenic transfusions remain necessary and should be enhanced.


# Background

The use of blood products transfusion has changed dramatically during the last decades. Liberal transfusion triggers have been replaced by more restrictive transfusion guidelines. This change results from an increased awareness of existing relations between allogenic transfusions and adverse reactions, and of the need to avoid overusing blood bank resources. For these reasons, new blood saving techniques have emerged in recent decades. For instance, the collection of blood from the surgical field by a device capable of processing it, such as the cell saver, so as to obtain reinfusion bags with high hematocrit percentages. Such autologous transfusion is considered to be safe as far as infection transmission and the generation of immunological problems are concerned. Futhermore, it reduces the risk of receiving allogeneic transfusions in surgeries with moderate-high bleeding, such as scoliosis surgery. Its use in pediatric surgeries is still a controversial issue, while research on its efficacy and the quality of the blood obtained in these interventions is very scarce[1,2].

The cell saver available for the study is the Orthopat ®, with a pediatric hood. Two hundred mililitres of products from the surgical field are necessary to start processing blood. According to the commercial data sheet, the material available for reinfusion has around 70% hematocrit. It is expected to be free of

activated coagulation factors, anticoagulant, leukocytes, platelets, cell stroma, free hemoglobin, intracellular enzymes and potassium.

However, the effectiveness of the red cell washing process is not yet fully clear, as other blood components could be found. The product to be reinfused might be affected by bacterial contamination at different stages of the process. The results of M. Muñoz et al.[3] on experimental models with cell saver OrthoPAT® show that 70-95% of the content of leukocytes, platelets, cytokines and potassium is eliminated, while 80% of red blood cells is preserved.

In this work, we study the hematological and microbiological characteristics from the autologous blood processed through the intraoperative cell saver used in our centre (Orthopat®) during the correction of pediatric scoliosis, which is known to be a potentially bleeding surgery. Regarding the hematological study, we test the effectiveness of the cell saver for obtaining high concentrations of functioning red blood cells, which according to the commercial data for adult patients should be 70%. Furthermore, we evaluate the hemolysis index of the blood samples as well as the possible analytical parameters derived from the red blood cell rupture, in cases where their measurement is technically possible.
In recent decades there have been great advances in the management of surgical bleeding, which has markedly decreased. We nonetheless compare pre- and post-operative blood tests of patients after reinfusion in order to check whether differences continue to be significant with the available blood saving methods.
On the other hand, we determine the microbiological characteristics of the blood obtained by the cell saver (Orthopat®). The appearance of fever after the reinfusion of the processed blood, as well as possible surgical site infections (SSI) during the postoperative one-month follow-up period, are monitored and their relation to positive blood cultures is studied.

# Methods

This is a prospective observational study of 31 patients undergoing surgery for pediatric scoliosis. The main aim is to determine the effectiveness of the intraoperative Orthopat® cell saver with a pediatric hood by analyzing the hematological and microbiological characteristics of the obtained blood. The study was approved by the Ethics Committee of Niño Jesús Children's University Hospital in February 2019. The data collection began immediately after the approval, and continued until November 2019.

All patients included in the study suffered from pediatric scoliosis, and underwent posterior dorsal fusion surgery, during which the intraoperative cell saver was used. The parents/legal tutors of all participants signed a prior informed consent, as also did the patients themselves if they were over 12 years old.

Patients for which the use of the cell saver was contraindicated (oncological patients, presence of infection...) were excluded from the study. Some cases were discarded due to loss of blood samples, inability to monitor infections during follow-up and cancelled surgeries.

The patients were anesthesized folllowing the general anesthetic method of the Anesthesiology Department of our center. Perfusion of 10 mg / kg / h of tranexamic acid with an initial bolus of 15-20 mg / kg and preoperative antibiotic prophylaxis with 30 mg / kg up to 2g of cefazolin were administered. The blood was vacuumed from the surgical field with a negative pressure of less than 150 mmHg. It was subsequently mixed with heparinized physiological serum (30U / ml) to be stored in the cell saver reservoir until the centrifuge hood was filled with 200ml. Then the blood began to be processed at a speed of 8000 rpm and was finally washed with 500 ml of physiological serum to obtain the red blood cell concentrates.

The variables considered in the study were patient age, weight, volemia, volume of blood from the cell saver, type of scoliosis (idiopathic, neuromuscular, associated with syndromes or hemivertebrae), and hematocrit, hemoglobin, platelets, leukocytes and basic biochemistry of the patient's preoperative and postoperative blood tests. It is important to mention that the postoperative blood sample was taken upon arrival of the patient to the Postoperative Recovery Unit after the autologous blood was transfused in the operating room. From the autologous blood we analyzed: Hematocrit, hemoglobin, platelets, leukocytes and ions, as well as blood cultures and hemolysis index, which is a colorimetric test for semiquantitative determination of hemolysis in human serum and plasma in Beckman Coulter AU analyzers®. Patient samples are diluted in the lithium hydride reagent and the absorbency is measured in 6 wavelengths. If a sample has one or more chromogens in a potentially interfering concentration, the corresponding indicators will be generated and communicated with the results of the analyzes performed on that sample.
These indicators characterize the type of chromatic substance (hemoglobin) and the approximate concentration of the interference by concentration sections. The samples were taken at the time of reinfusion of the obtained blood to the patient with the greatest possible asepsis. The appearance of fever (> 38 $^{o}$C) was monitored during the reinfusion of autologous blood. Moreover, days of hospital stay after surgery and surgical site infection (SSI) during a follow-up period of one month were recorded. For them, the most widely used definition of SSI has been provided by CDC[4]. According to it, SSIs are classified by depth and tissue spaces involved.

The statistical analysis of the quantitative variables is given in terms of means, medians, standard deviations, minimum and maximum values. Qualitative variables are expressed as absolute frequencies and percentages. The mean values of pre and postoperative blood tests were compared with the Wilcoxon test. To establish the relationship between two quantitative variables, Pearson's correlation coefficient was used. All tests have been considered significant

# Results

The demographic results and the volume obtained after blood processing are shown in Table 1. Regarding the sex of the patients 23 (74.19%) of them were girls and 8 (25.8%) boys. The type of surgery is shown in Table 2, observing a majority of scoliosis of idiopathic origin. Table 3 shows the hematological characteristics of the blood obtained from the cell saver.

The hemolysis index is 5.48 (ds 1.73), its maximum value is 6. The average volume recovered of red blood cells is 288.06 ml (ds 154.68) with a minimum value of 50 ml and a maximum of 700 ml. The correlation between the volume processed and the hematocrit of the recovered blood: Pearson, $r = 0.4426$; $p = 0.0126$. Therefore, the greater the volume of blood recovered, the greater hematocrit is obtained in the processed red blood cell concentrate.

Regarding the possible predictors of the volume recovered, we found only a relationship in the preoperative hematocrit: Pearson 0.42, p 0.02. According to the statistical regression model, the coefficient is 7.02 ($p < 0.001$, 95% CI 5.69-8.35). This indicates that an increase of 1% in preoperative hematocrit predicts 7.02 ml more in red blood cells concentrates obteined through the cell saver.

Microbiological characteristics of recovered autologous blood:

The blood culture of the blood from the cell saver was positive in 12 cases (42.86%) of a total of 28 samples analyzed since three did not reach the microbiology laboratory. The types of bacteria found are shown in Tables 4 (aerobic germs) and 5 (anaerobic germs). All correspond with non-pathogenic bacteria from cutaneous flora. Clarify that there are species that appear in both tables since it can be an aerobic or anaerobic facultative bacteria. Any patient had fever during the infusiono f autologous blood. Four of them (12.90%) presented infectious complications in the first postoperative month. All cases were infection associated with surgical wound, just one of them required emergency surgery. Only two patients with infectious complications presented positive blood culture in the blood from cell saver. Chi-square does not show statistical significance to relate infectious complications with contamination of blood bags ($p > 0.05$).

In the comparative study of the analytical samples of the pre-surgery and post-surgery patients, significant differences were found ($p < 0.05$) in the value of: Hemoglobin, hematocrit, with both decrease in the postoperative period, prothrombin time, INR, time of cephalin, fibrinogen, with a decrease in the postoperative period and tendency to coagulopathy. All analytical parameters are shown in table 6.

# Discussion

Our main objective has been to analyze the characteristics of the blood processed by the cell saver in pediatric scoliosis surgery. It is a blood saving technique which is increasingly used in major orthopedic surgery to avoid risks of allogeneic transfusions, such as transmission of viral diseases, risks associated with the storage of blood bags, blood group identification errors and potential decrease of immunomodulation5,6. It constitutes one aspect of the multidisciplinary approach to "patient blood management" 7,8, together with preoperative optimization, administration of tranexamic acid, ensuring a careful surgical technique with hemostasis, posterior surgical approach and lower transfusion triggers9.

Our results reveal that the percentage of hematocrit obtained, which is 70.38%, is similar to that described by the technical data provided by OrthoPat® for adult patients, namely, 75%. In agreement with previous studies 10-12, the blood from the cell saver presents much higher levels of hematocrit than patient blood

(30-45%) and also higher than that present in red blood cell concentrates from donors (50-65%), which is quite variable. However, leukocytes are not completely eliminated from our sample, in fact their quantity is similar to the levels found in patient postoperative analysis. Several studies13,14 have further analyzed the presence of different types of white cells and inflammatory molecules in the collected blood and their relationship with postoperative infection or days of admission. Nevertheless, no relationship or differences have been established. What seems to be clearer is the lower immunomodulatory response of autologous blood with respect to allogeneic blood transfusion15.

Immunomodulation seems to be especially important in cancer patients. The use of cell saver in these cases is still controversial because of the risk of cancer cell spreading. On the other hand, the transfusion of autologous blood would reduce the risk of immunosuppression caused by allogeneic blood transfusion16,17.

There is no agreement on potential effects of the presence of leukocytes in the processed blood. Special filters for their elimination increase the cost and affect the flow conditions during retransfusion, resulting in the activation of the complement system. In the case of immunosuppressed or cancer patients, leucodepletion of these concentrates could be considered for safety reasons during major orthopedic surgery18,19.

The amount of platelets in autologous blood is, despite its great variability, consistently smaller than that found in pre and postoperative blood samples of the patient. These platelets levels are consistent with previous studies20,21. They suggest that the processing of platelets by the cell saver is more efficient than in the case of leukocytes. According to M. Muñoz et al.3, the processing of platelets in a postoperative recovery model with OrthoPAT® would in fact reach 88%. The importance of reinfusion of processed platelets is not clear, but it may not be functional due to the discontinuous centrifugation of this device.

The hemolysis index is close to the maximum, which indicates that in the blood from the cell saver there is a high level of red blood cell breakdown. In experimental models of processed blood3 the concentration of free hemoglobin in plasma was reduced by 96% with the OrthoPAT® cell saver. As for the ions, potassium deserves special attention since a rapid reinfusion of high levels can have serious consequences. Its elimination in experimental models is around 97%3. None of our patients showed ECG abnormalities or significantly increased concentrations of this ion in the subsequent gasometric controls, despite the fact that some cases presented high concentrations of around 8 mEq x l-1. Nevertheless, the total amount of potassium in the autologous blood transfused to the patient is unlikely to be harmful. The levels of sodium and chlorine that ensure homeostasis for cell preservation are found to be similar to those in the patient blood.

The volume of red blood cells from the cell saver is directly related to the hematocrit thereof. The minimum volume obtained is 50ml, which corresponds to a 17 kg patient undergoing neuromuscular scoliosis. For this type of patients, with weights less than 25 kg, it might be advisable to process blood

with continuous processing devices, in order to obtain the largest possible reinfusible volumes and increased hematocrit concentrations22,23.

According to the microbiological analysis of the samples of autologous blood, despite surgical asepsis and antibiotic prophylaxis, it is inevitable that bacterial contamination will appear in almost half of the cases (42.86%). These data are consistent with previous publications24-29 in which the contamination exceeds 40%. However, the reinfusion of this contaminated blood did not cause a higher incidence of fever or SSI, in agreement with the findings of the previously mentioned studies. As the isolated bacteria come from skin and environmental flora, no pathogenic germ has been found, which indicates good asepsis procedures and correct antibiotic prophylaxis of our patients. Many factors may be responsible for contamination of the blood processed, including a prolonged exposure of a wide surgical field, which is characteristic of scoliosis surgery, complex and multiple instrumentation, many professionals working in the surgical field, including the replacement of team members, as well as multiple manipulations of vascular access and fluid administration among others.

Concerning immunocompromised patients, the use of a cell saver could contribute to the development of infections. To prevent this risk, adding antibiotics to the samples of processed blood in addition to applying leucodeplection should be considered as additional measures30,31. Another very different case is the immunocompetent patient, as are the majority of patients undergoing pediatric scoliosis. With careful aseptic techniques, adequate antibiotic prophylaxis and not exceeding the storage time of the blood concentrates (6 hours at room temperature or refrigerated at 4 °C for 24 hours), it continues to be a safe technique. The ranges of SSI in pediatric scoliosis can vary from 0.5% to more than 25% depending mainly on whether or not of the scoliosis is of neuromuscular origin32,33. The latter consitutes a risk factor, together with the length fo the stay, surgical instrumentation, the surgical intervention of the sacrum, the incorrect administration of antibiotic prophylaxis or the persistence of postoperative spine curvature34.

Pediatric scoliosis surgery remains one of the surgeries with the highest bleeding rates35. In the present study, analytical differences between the preoperative and the immediate postoperative period have been observed. The implication is that one should continue applying and introducing new blood-saving measures. The analysis of preoperative hemoglobin revealed that 25% of the patients had a value of less than 13 g / dl, with a minimum of 10.4 g / According to this results, there are patients (<25%) with preoperative hemoglobin around or below the limit to be considered anemic. Following the multidisciplinary approach of “Patient Blood Management”, preoperative anemia should be optimized to reduce days of stay and perioperative transfusions 36-38. One of the goals of our center in this regard is that no anemic patient without prior optimization should undergo such surgery. As the associated blood loss is considerable, and it is a programmed surgery, its date could be delayed until the patient's condition improves. In addition, we observe how the preoperative hematocrit is directly related to the volume of autologus blood obtained. Our results show that scoliosis surgery continues to cause coagulopathy and a decrease in hemoglobin level (pre-surgery 13.68 g / dl, post-surgery 10.90 g / dl). To prevent such undesired effects, it is necessary to reduce bleeding by means of pharmacological agents (tranexamic

acid), maintenance of low arterial pressure, hemodilution with fluid therapy, intraoperative techniques applied by surgeons to improve hemostasis, the use of cell saver and restrictive transfusion triggers to contribute to the reduction of transfusion ratios. These measures are reviewed and carried out according to the latest guidelines on blood management in pediatric scoliosis surgery39,40.

The main limitation of our study is the small sample size. To obtain stronger results, it would be necessary to expand it. Moreover, it is a heterogeneous group of patients in terms of weight and origin of their scoliosis, among other factors. For instance, neuromuscular scoliosis is associated in most cases with increased morbidity and a higher risk of bleeding. In addition, other influential factors in bleeding such as the number of fusion levels or Cobb angle are not considered. We should also stress that this is a prospective study conducted in a single center.

From our results we conclude that, in the pediatric patient, the cell saver used in this study obtains red blood cell concentrates with a percentage of hematocrit which is in agreement with commercial information. The reinfusion of this product seems safe from an infectious and biochemical point of view. Its implications at the immunological level are not fully clarified either in the previous literature or in our study. Broader studies that are specifically focused on this last aspect would be helpful in this regard.

# Conclusions

Pediatric spinal fusion has a specific set of risk factors for transfusion and different perioperative requirements. A deeper knowledge of blood management techniques is improving surgical planning, as well as limiting the risks associated with transfusion, maintaining hemostasis and optimizing results in these patients. This surgery still entails an important loss of blood with repercussions for the early recovery of patients. Blood saving measures taken by the surgical team are necessary. Improving outcomes, including the reduction of perioperative risks, depends critically on them.

# List Of Abbreviations

Sd – standard deviation RBC – red blood cell SSI – surgical site infection CDC – Centers for disease Control and Prevention INR – International Normalized Ratio

# Declarations

### Ethics approval and consent to participate

The parents / guardians of the participants were asked to sign an informed consent document once they had been informed verbally and through an information sheet to parents / guardians and had been able to express and solve any doubts regarding their participation in the present study.

This study is approved by the Ethics comitted of our Hospital: CEIm Hospital Infantil Universitario Niño Jesús; which is officially listed by the Ministery of our country:

https://www.aemps.gob.es/investigacionClinica/medicamentos/docs/listado-comites-investigacion-clinica.pdf

### Consent for publication

Not aplicable, there is not individual data.

### Availability of data and material

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

### Competing interests

The authors declare that they have no competing interests.

### Funding

No sources of financial assistance or potential conflicts of interest.

### Details of authors' contributions:

Elena García, EG: Study design, patient recruitment, data analysis and writing up of the first draft of the paper.

Pilar del Rey: PR: Study design, patient recruitment and data collection.

Ernesto Martínez: EM: Study design, patient recruitment and data collection.

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# Tables

TABLE 1. Demographic variables.

| | Average | SD | Median | Min | Max |
|---|---|---|---|---|---|
| Age (Years) | 14.94 | 2.97 | 15 | 4 | 20 |
| Weight (kg) | 50.58 | 16.2 | 52 | 17 | 92 |
| Volemic status (ml) | 3540.65 | 1134.03 | 3640 | 1190 | 6440 |
| Days of stay | 4.68 | 1.83 | 4 | 3 | 9 |

*SD: standard deviation, Min: minimum value, Max: máximum value.*

TABLE 2. Type of scoliosis.

| Type of scoliosis | Frequency | Percentage (%) |
|---|---|---|
| Idiopatic | 21 | 67.74% |
| Neuromuscular | 7 | 22.58% |
| Hemivertebrae | 1 | 3.23% |
| Secondary to syndrome | 2 | 6.45% |
| TOTAL | 31 | 100% |

TABLE 3. Hematological characteristics of cell saver – blood.

| | Average | SD | Median | Min | Max |
|---|---|---|---|---|---|
| HTO (%) | 70.38 | 10.03 | 71.90 | 34.20 | 81.80 |
| Platelets ($10^3$ x $\mu l^{-1}$) | 50.23 | 59.04 | 38 | 13 | 295 |
| Leukocytes($10^3$ x $\mu l^{-1}$) | 14.36 | 5.47 | 14.48 | 3.17 | 25.89 |
| Neutrophils ($10^3$ x $\mu l^{-1}$) | 8.93 | 4.26 | 8.13 | 1.25 | 19.20 |
| Lymphocytes ($10^3$ x $\mu l^{-1}$) | 2.91 | 1.47 | 2.66 | 0.48 | 6.56 |
| $K^+$ (mEq x $l^{-1}$) | 5.06 | 1.59 | 4.40 | 2.9 | 8.8 |
| $Na^+$ (mEq x $l^{-1}$) | 141.27 | 4.16 | 144 | 128 | 144 |
| $Cl^-$ (mEq x $l^{-1}$) | 121.03 | 7.07 | 120 | 102 | 141 |

*SD: standard deviation, Min: minimum value, Max: máximum value, HTO: Hematocrit, $K^+$: potasium, $Na^+$: Sodium, $Cl^-$: chlorine*

TABLE 4. Bacteria found in aerobic positive blood cultures.

| | Frequency | Percentage (%) |
|---|---|---|
| S. epidermidis, S. capitis, S. viridans | 1 | 8.33% |
| S. hominis | 3 | 25% |
| S. saprophyticus | 1 | 8.33% |
| S. capitis | 3 | 25% |
| S. epidermidis | 4 | 33.33% |
| Total | 12 | 100% |

*S: Staphyloccocus*

TABLE 5. Bacteria found in anaerobic positive blood cultures.

| | Frequency | Percentage (%) |
|---|---|---|
| Corynebacterium species | 1 | 7.14% |
| S. hominis | 1 | 7.14% |
| S. epidermidis, S. capitis, S. viridans | 1 | 7.14% |
| S. hominis | 2 | 14.28% |
| S. saprophyticus | 1 | 7.14% |
| S. capitis | 2 | 14.29% |
| S. epidermidis MR | 4 | 28.57% |
| Total | 14 | 100% |

*S: Staphyloccocus; MR: Methicillin-resistant*

TABLE 6. Blood tests pre and postsurgery from patients under scoliosis surgery.

| | Preoperatative blood test | | Postoperative blood test | | P value |
|---|---|---|---|---|---|
| | Average | SD | Average | SD | |
| HTO (%) | 41.19 | 3.64 | 32.56 | 4.25 | 0.000 |
| Hb (g/dl) | 13.68 | 1.36 | 10.90 | 1.37 | 0.000 |
| Platelets ($10^3$ x $\mu l^{-1}$) | 238.65 | 64.28 | 210.66 | 67.84 | 0.256 |
| Leukocytes ($10^3$ x $\mu l^{-1}$) | 6.86 | 1.64 | 14.84 | 6.56 | 0.000 |
| $K^+$ (mEq x $l^{-1}$) | 4.12 | 0.37 | 4.27 | 0.36 | 0.084 |
| $Na^+$ (mEq x $l^{-1}$) | 138.93 | 1.96 | 138 | 3.13 | 0.139 |
| $Cl^{-1}$ (mEq x $l^{-1}$) | 105.14 | 1.96 | 109.59 | 3.68 | 0.000 |
| Glu (mg/dl) | 88.67 | 5.51 | 144.96 | 39.27 | 0.179 |
| Fibrinogen | 321.28 | 89.2 | 242.26 | 74.58 | 0.004 |
| Cephaline time (seg) | 26.98 | 3.17 | 25.06 | 4.36 | 0.000 |
| Prothrombine time (seg) | 94.24 | 12.34 | 70 | 13.46 | 0.000 |

*SD: standard deviation, HTO: Hematocrit, Hb: hemoglobine, $K^+$: potasium, $Na^+$: Sodium, $Cl^-$: chlorine, Glu: glucose*