

Cell Salvage Using the Autotransfusion Device CATSmart®: A Randomized Controlled Bicentric Trial Evaluating the Quality of Two New Flex Wash Programs

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Keywords

Intraoperative cell salvage · Autotransfusion · Transfusion · Washing program · Flex wash · CATSmart®

Abstract

Background: The use of cell salvage and autologous blood transfusion is an important and widespread method of blood conservation during surgeries with expected high blood loss. The continuous autotransfusion device CATSmart® (Fresenius Kabi, Germany) contains two new washing programs on the device called Flex wash 3 and Flex wash 5. To the best of our knowledge, there are no published clinical data regarding the performance of the two new washing programs. **Methods:** In total, 69 patients undergoing cardiac or orthopedic surgery were included in this randomized, controlled, bicentric trial to validate the red cell separation process and washout quality of Flex wash 3 compared to Flex wash 5. After washing, the primary quality target was to determine hematocrit value, recovery rate, albumin, and total protein elimination rate in the packed red cells (PRCs). The secondary objective was to assess the elimination of heparin by measuring the factor anti-Xa activity by a 1- and 2-stage assay in PRC after washing. **Results:** In the whole cohort of patients, hematocrit was 16.00% [9.15%; 21.30%] (median [Q1; Q3]) in the wound blood and 69.90% [51.10%; 80.90%] in the PRC resulting in a

recovery rate of 63.92% [47.06%; 88.13%]. The albumin elimination rate was 98.77% [97.94%; 99.27%], and the total protein elimination rate was 98.85% [97.76%; 99.42%]. The heparin elimination rate was 99.95% [99.90%; 99.97%] in the 1-stage assay and 99.70% [99.41%; 99.87%] in the 2-stage assay. There was no difference between Flex wash 3 and Flex wash 5 washing procedure regarding the recovery rate 63.75% [46.64%; 78.65%] versus 67.89% [47.20%; 92.69%] ($p = 0.85$), albumin elimination rate 98.74% [97.67%; 99.27%] versus 98.78% [98.10%; 99.28%] ($p = 0.97$), protein elimination rate 98.79% [97.94%; 99.47%] versus 98.92% [97.58%; 99.42%] ($p = 0.88$), and anti-Xa elimination rate in the 1-stage assay 99.94% [99.79%; 99.97%] versus 99.95% [99.92%; 99.97%] ($p = 0.24$) and in 2-stage assay 99.66% [99.20%; 99.86%] versus 99.77% [99.47%; 99.90%] ($p = 0.23$). **Conclusions:** The two new washing procedures, Flex wash 3 and Flex wash 5, enable sufficient and comparable red cell separation and washout quality of albumin, total protein, as well as heparin.

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Introduction

Red blood cell (RBC) transfusion is often required in surgery with significant blood loss. However, side effects of allogenic RBC transfusion, e.g., non-infectious severe

hazards of transfusion [1, 2], procedural errors [1], or infectious short- and long-term complications, lead to increased mortality [1–4].

Thus, the development of intraoperative cell salvage (ICS) and autologous blood cell transfusion is a crucial method to reduce the need for homologous RBC transfusion [5]. Cell salvage collects wound blood (WB) from the surgical field, followed by filtering and washing to produce an autologous blood concentrate for the transfusion of RBCs. In the past, it has been shown that using ICS reduces the need for allogenic RBC transfusion [6]. CATSmart[®] is one system among others used for ICS. The system has been shown to produce high-quality packed red cells (PRCs) for transfusion regarding hematocrit (Hct) and elimination rates of protein, albumin, and potassium [7]. There are three washing programs, called emergency wash, low volume wash, and smart wash, that are different in the ratio of washing solution/PRCs (emergency wash ratio 1.0, low volume wash ratio 7.0, and smart wash ratio 7.5) and the maximum PRC flow (emergency wash 100 mL/min, low volume wash 25 mL/min, and smart wash 28 mL/min) [8, 9]. According to the operating instructions by the manufacturer, low volume wash is especially designed to process even small blood volumes containing a minimal RBC volume of 35–50 mL. Smart wash ensures optimal balance between PRC output rate and washout performance and is recommended for highly contaminated or damaged blood. Emergency wash allows the fastest blood processing for quick access to washed PRC with a maximum blood flow [9].

The latest update to the device provides two new washing programs with a flexible washing solution/PRC ratio called Flex wash 3 and Flex wash 5. Flex wash is recommended for use in standard or routine cases where highly contaminated or damaged blood processing or low volume blood loss is not factor. According to the operation instructions, the processing of shed blood is faster and the usage of saline for washing is lower compared to smart wash [9]. The washing programs are CE certified and have been released based on the results of an *in vitro* laboratory test. The Flex wash programs differ in the wash ratio and maximum PRC production rate; i.e., Flex wash 3 has a 3:1 wash ratio that uses three-part saline to one-part PRC at a maximum PRC flow rate of 35 mL/min, and Flex wash 5 has a 5:1 wash ratio and at a maximum PRC flow rate of 35 mL/min [9]. To obtain a consistent quality, the flow rate of the PRC varies according to Hct so that the number of RBCs at any given time is constant. For this purpose, the actual flow of PRC is monitored and compared to the programmed PRC flow. In case of deviation, the blood flow is adapted until a constant and optimum cell throughput is reached. Thereby, differences in shed blood are compensated and a constant PRC Hct and PRC flow are

achieved. The entire washing process is sensor controlled: the PRC sensor in the washing chamber includes a camera that is directed at the washing chamber and optically measures the fill level of the washed PRC. The lines near the pumps for shed blood and washing solution leading to the washing chamber are equipped with ultrasonic sensors for monitoring of blood and saline supply. Additionally, there are ultrasonic sensors monitoring Hct in the shed blood and PRC, to control the washing process during usage. With the two new Flex wash programs, no unexpected events have yet been reported. The advantage of the Flex wash programs in a clinical setting could be less wastage and changeover of saline washing solution in addition to a faster washing process and PRC flow compared to smart wash or low volume wash. So far, there has yet to be data on the two new washing programs, Flex wash 3 and 5, in the clinical setting. The aim of the study was to show the non-inferiority of the new Flex wash programs compared to historical data regarding quality parameters in the PRC of other presently available washing programs. The advantage of Flex wash programs may be a faster production of PRC with less usage of saline. This may result in a faster availability of autologous blood for the patients in addition to less workload for the staff, ensuring more time for patient care. We therefore investigated the red cell separation process and the washout quality of the new Flex wash 3 and 5 programs *in vivo* in two independent cohorts of patients undergoing cardiac and orthopedic surgery.

Materials and Methods

Two prospective cohorts were assessed in the University Hospital Essen (UKE) and the Marienhospital Bottrop (BOT) between June 2021 and May 2022. Center UKE allocated only cardiac surgery patients, and Center BOT only orthopedic surgery patients because the centers are specialized for these specialties. The cardiac and orthopedic surgery was chosen because of the different volumes and characteristics of blood loss. We assumed that in elective orthopedic procedures a significant blood loss is less common than in more complex, acute cardiac surgery; therefore, the shed blood would contain more damaged tissue cells. This study protocol was reviewed and approved by the Ethics Committee of University Duisburg/Essen (approval reference 19-8917-BO) for the study center in Essen and from the Ethics Committee of Medical Chamber Westphalia-Lippe (approval reference 2021-358-b-s) for the study center in Bottrop. Written informed consent was obtained from all participants. Adult patients undergoing elective cardiac or orthopedic surgery with an estimated intraoperative blood loss of more than 500 mL were enrolled in this study. Exclusion criteria were patients with malignancy, pregnancy, and subjects who refused transfusion of blood products. Initially, 271 patients were included in total in both study centers. However, 202 patients had to be excluded due to implementation failures (200 patients did meet exclusion criteria of <100 mL PRC volume,

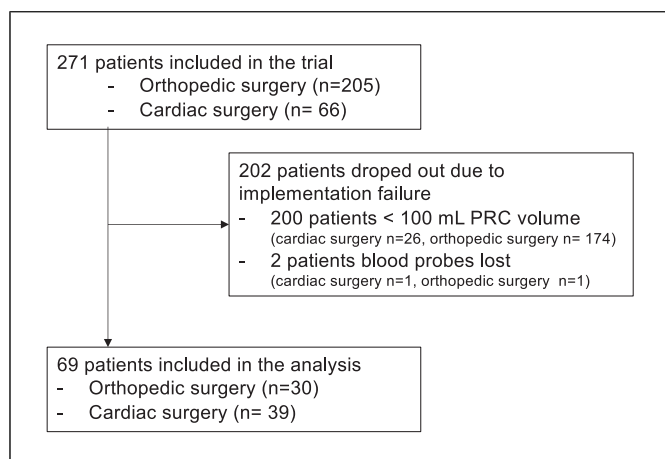


Fig. 1. Study flowchart.

and blood probes of another two patients were lost), resulting in a cohort of 69 patients being included in the final analysis (shown in Fig. 1).

Outcome

The primary objective was to evaluate the performance of the two new washing procedures, which was assessed by the Hct and RBC recovery rate and elimination rates of albumin and total protein in the PRCs after washing. The secondary aim was to measure heparin elimination using anti-Xa activity in the PRC and WB to check the remaining heparin content after washing.

Procedures

Patients were randomized by a sealed envelope system for each center to the Flex wash 3 or Flex wash 5 group before surgery. The CE-certified autotransfusion device collected and processed WB (CATSmart[®], Fresenius Kabi AG, Germany). WB was collected in the sterile reservoir, separated by centrifugation, and washed using either the Flex wash 3 or the Flex wash 5 washing program. This procedure results in PRCs in a sterile bag for transfusion. During the washing process, all plasma and non-red cellular components of the WB are removed, as well as products of cell and tissue damage and anticoagulants. Blood samples before and after washing were collected and analyzed in the central laboratory of the two centers to characterize the Hct values and elimination rates. Blood reservoirs were manually homogenized before sampling. The volume of the PRC after washing had to be a minimum of 100 mL; otherwise, patients were excluded from further analysis. The initial 10–20 mL flowing in the PRC bag is a normal saline solution required for priming the whole washing chamber and tubes within the system. This priming solution dilutes the obtained PRC volume leading to false low Hct values and recovery rates. A minimum of 100 mL PRC volume negates this systematic influence and leads to more accurate values of PRC. The RBC recovery rate was calculated from the volume (Vol) and Hct of the collected WB and the prepared washed PRC concentrate (PRC) [10]: recovery rate (%) = $((\text{Vol PRC} \times \text{Hct PRC}) / (\text{Vol WB} \times \text{Hct WB})) \times 100$.

Washing efficiency can be evaluated by measuring substances present in the plasma of the collected WB that are eliminated together, e.g., heparin, total protein, or albumin. The advantage of total protein is that this parameter is only affected by the washout and not by cell damage like other parameters,

e.g., free hemoglobin or potassium. Elimination of the hemolytic plasma and contaminants occurs first by displacement of most of the supernatant during centrifugation and second by diluting the remaining supernatant during cell washing. Therefore, not just concentrations but absolute amounts in starting material and product must be compared [11]: elimination rate (%) = $100 - 100 \times ((C_{\text{PRC}} \times \text{Vol}_{\text{PRC}} \times (1 - \text{Hct}_{\text{PRC}} / 100)) / (C_{\text{WB}} \times \text{Vol}_{\text{WB}} \times (1 - \text{Hct}_{\text{WB}} / 100)))$, while C = concentration in the supernatant, Vol = volume.

Anti-Xa was measured with the Atellica[®] Coag 360 Analyzer (Siemens Healthineers, Erlangen, Germany) by a 1-stage heparin assay (Siemens INNOVANCE[®] Heparin, Erlangen, Germany) as well as a 2-stage heparin assay (BIOPHEN[™] ANTI-Xa, Hyphen BioMed, Neuville-sur-Oise, France). The 1-stage heparin assay depends on the patient's endogenous antithrombin III (ATIII) levels. In contrast, the 2-stage heparin assay is independent of endogenous ATIII levels and works under the condition of a lack of endogen ATIII in the sample. The instrument controls were performed according to the product inserts (the manufacturer's quality control). The 1-stage heparin assay is accredited according to DIN EN ISO 15189:2014. In case of a laboratory value below the detection limit, the next smaller value has been inserted (e.g., albumin <0.2 g/dL was processed as 0.19 g/dL).

Statistics

All statistical analyses were performed using SPSS 29.0 software (SPSS, Inc., Chicago, IL, USA) and Microsoft Excel V16.73 (Microsoft, Redmond, WA, USA). Descriptive statistics were calculated on all measures to determine the characteristics of the sample, check normality assumptions, and ensure adequate variability. Data were tested by the Shapiro-Wilk test and showed no normal distribution; thus, analysis was performed with nonparametric tests. All results are presented as median, first quartile (Q1) and third quartile (Q3), or incidence (n, %). The Mann-Whitney U test calculated differences in continuous variables. A p value of ≤ 0.05 was considered to be statistically significant. The study was stopped after reaching >70 patients due to feasibility reasons. We interpreted the effects by also taking the effect sizes into account; therefore, Cohen's d was calculated.

Results

Enrolment

A total of n = 69 patients were analyzed, n = 39 (56%) in cardiac surgery and n = 30 (44%) in orthopedic surgery (shown in Fig. 1). A high dropout rate was caused by a PRC volume <100 mL, most likely resulted from diluted shed blood in the orthopedic patient group.

Red Cell Separation Performance

In the whole cohort of patients, Hct was 16.00% [9.15%; 21.30%] (median [Q1; Q3]) in the WB and 69.90% [51.10%; 80.90%] in the PRC resulting in a recovery rate of 63.92% [47.06%; 88.13%]. There was no difference between the Flex wash 3 and Flex wash 5 washing procedures regarding the recovery rate 63.75% [46.64%; 78.65%] versus 67.89% [47.20%; 92.69%] (p = 0.85) or Hct in the PRC 71.70% [61.70%; 76.50%] versus

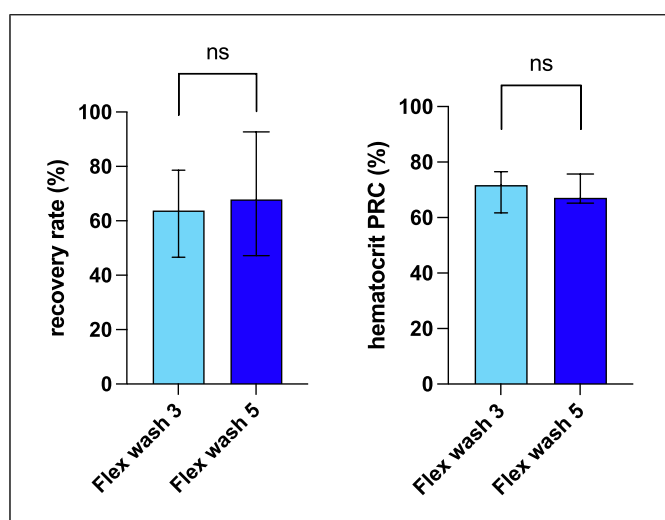


Fig. 2. Recovery rate (%) and Hct (%) in PRC differentiated for Flex wash 3 and 5. Presented as median [Q1; Q3]. PRC, packed red cell.

67.10% [65.18%; 76.68%] ($p = 0.80$) (shown in Fig. 2). Significant differences have been reported for the recovery rate in the two study centers: 76.28% [55.87%; 103.43%] (UKE) versus 51.11% [35.54%; 74.52%] (BOT) ($p = 0.03$) (shown in online suppl. Table 1; for all online suppl. material, see <https://doi.org/10.1159/000536322>). The volume of WB was 1,705 mL [1,420 mL; 2,411 mL] (UKE) versus 1,427 mL [1,131 mL; 1,658 mL] (BOT) ($p = 0.06$), resulting in a higher PRC volume: 289 mL [170 mL; 406 mL] (UKE) versus 145 mL [113 mL; 211 mL] (BOT) ($p < 0.001$) with a Hct 73.50% [64.90%; 76.70%] (UKE) versus 66.10% [61.75%; 72.48%] (BOT) ($p = 0.07$).

Washout Quality of Albumin and Total Protein

The albumin elimination rate was 98.77% [97.94%; 99.27%], and the total protein elimination rate was 98.85% [97.76%; 99.42%]. There was no difference between the Flex wash 3 and Flex wash 5 washing procedures regarding the albumin elimination rate of 98.74% [97.67%; 99.27%] versus 98.78% [98.10%; 99.28%] ($p = 0.97$) and total protein elimination rate of 98.79% [97.94%; 99.47%] versus 98.92% [97.58%; 99.42%] ($p = 0.88$) (shown in Table 1). There was a statistically significant difference between the elimination rates of albumin between the centers (shown in online suppl. Table 1).

Washout Quality of Heparin

The heparin elimination rate was 99.95% [99.90%; 99.97%] in the 1-stage assay and 99.70% [99.41%; 99.87%] in the 2-stage assay. Again, there was no difference between the Flex wash 3 and Flex wash 5 washing procedures regarding the heparin elimination rate in the 1-stage assay 99.94% [99.79%; 99.97%] versus 99.95% [99.92%; 99.97%] ($p = 0.24$) and the 2-stage assay 99.66% [99.20%; 99.86%] versus 99.77% [99.47%; 99.90%] ($p = 0.23$) (shown in

Table 1). There was a statistically significant difference between the elimination rates of the 2-stage assay between the centers. However, it seems not clinically relevant due to elimination rates >99% in both centers (shown in online suppl. Table 1).

Discussion

ICS has undergone impressive development over recent years [12]. ICS is recognized to reduce the need for allogenic blood products and is recommended for procedures with an estimated higher blood loss [5, 6, 13]. It has been shown that using ICS is a feasible method to reduce the need for RBC transfusion [6, 14], benefitting patient outcomes [15–17]. One improvement option could be the implementation of new washing programs like Flex wash 3 and Flex wash 5, by reducing the ratio washing solution/PRC.

In case of using new washing programs, there should be no concerns about the quality of the PRC; in the best case, the washing programs are more suited to specific situations resulting in a higher quality of PRC compared to existing programs. First, in all cases a Hct >50% in the PRC and total protein or albumin elimination rate >90% can be achieved. Our data show that both Flex wash 3 and Flex wash 5 can be used without concern.

Differences between both centers have been detected. There was a higher recovery rate and Hct in the PRC in the Center UKE. The characteristics of single patients included in this trial were not the aim of this study unfortunately. In general, we can state cardiac surgery in the Center UKE was various, e.g., coronary artery bypass grafting, valvular reconstructions or replacements, aortic graft replacements, or a combination of both. All procedures were performed using cardiopulmonary bypass and high levels of heparin. Suctioned blood from major vessels was collected immediately without any further addition of damaged tissues or cells and processed immediately after extravasation. Orthopedic procedures in the Center BOT included hip and knee replacements which resulted in less blood loss as compared to cardiac surgery. The recovered blood was sampled over a longer period during the whole operation and processed in the washing chamber after a longer interval than in the cardiac surgery group. The total volumes of blood recovered were therefore less. Additionally, the WB was associated with a higher content of damaged tissue, e.g., fat, bone, and muscle cells. This may explain the higher quality of the PRC regarding Hct and recovery rate in the Center UKE. The different compositions of the WB explain the higher elimination rate of albumin in the Center BOT, where a higher amounts of albumin were detected in the WB (median [Q1; Q3]), albumin WB (g/dL), 1.51 (1.19; 2.05) BOT

Table 1. Recovery rates and elimination rates differentiated for Flex wash 3 and 5, presented as median [Q1; Q3]

	Total, <i>n</i> = 69	Flex wash 3, <i>n</i> = 35	Flex wash 5, <i>n</i> = 34	<i>p</i> value (fw3 vs. fw5)	Cohen's <i>d</i>
Elimination rate total protein, %	98.85 [97.76; 99.42]	98.79 [97.94; 99.47]	98.92 [97.58; 99.42]	0.88	0.082
Elimination rate albumin, %	98.77 [97.94; 99.27]	98.74 [97.67; 99.27]	98.78 [98.10; 99.28]	0.97	-0.069
Elimination rate heparin 1-stage assay, %	99.95 [99.90; 99.97]	99.94 [99.79; 99.97]	99.95 [99.92; 99.97]	0.24	-0.408
Elimination rate heparin 2-stage assay, %	99.70 [99.41; 99.87]	99.66 [99.20; 99.86]	99.77 [99.47; 99.90]	0.23	-0.326

fw3, Flex wash 3; fw5, Flex wash 5.

versus 1.04 (0.89; 1.32) UKE. Comparison of the two centers showed a difference in the heparin elimination only in the 2-stage assay. The 2-stage assay works in the absence of endogenous ATIII by addition of exogenous ATIII. The difference between the centers could be explained by a lack of endogenous ATIII in the patients of UKE because of supposed higher volume turnover in the UKE group. However, this was not the aim of this study and is only speculation.

Alberts et al. investigated the wash program performance by comparing CATSmart[®] to the C.A.T.S. plus system, the former system for ICS released in 2004. C.A.T.S. plus may still be in use but is no longer available on the market. The advantage of CATSmart[®] is a higher resolution camera that monitors blood and saline flow in the device and automatically adjusts flow rates into the device, thus optimizing the separation and washing process. Through an in-line sensor, Hct of shed blood and PRC can be monitored. For the CATSmart[®] device, they found a Hct in the PRC of 59.63% and a recovery rate of 85.41%, remaining slightly under the values we could measure. Elimination rates of total protein and albumin were 97.1% and 97.5%, similar to our data [7].

In an experimental study with banked donor blood, Seyfried et al. could demonstrate similar high-quality values for recovery rate, total protein, albumin, and heparin elimination rates (87.4%, 99.1%, 99.2%, and 99.94%, respectively) in the smart wash program using the CATSmart[®] device as we found in our collective the Flex wash programs [18]. A further investigation of the washout quality of CATSmart[®] found similar Hct concentrations in WB and PRC using smart wash program as in our collective (12% WB, 78.5% PRC). Other similar removal ratios to ours for albumin and for anti-Xa activity (97.9%, 99.9%) were presented. Further matching parameters have not been reported [19].

Compared to the discussed data about the performance of the established washing programs, Flex wash 3 and 5 are at least equal regarding the recovery and elimination rates of

the studied parameters. The advantage of the new washing programs is a reduction of washing solution, which may be more user-friendly, and a reduction of cost and waste combined with a higher PRC flow.

Limitation

The present investigation was performed at two medical centers with a restricted number of included patients. Further multicenter studies with a larger cohort are warranted to prove the effectiveness of this trial. In future studies, a direct comparison of different programs should be addressed.

Conclusion

CATSmart[®] system and its new Flex wash washing programs provide a high-quality product for Hct, protein, albumin, and heparin elimination across the range of tested usage in cardiac or orthopedic surgery.

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Statement of Ethics

We comply with the guidelines for human studies and confirm that the research was conducted ethically in accordance with the World Medical Association Declaration of Helsinki. This study protocol was reviewed and approved by the Ethics Committee of University Duisburg/Essen (approval reference 19-8917-BO) for the study center in Essen and from the Ethics Committee of Medical Chamber Westphalia-Lippe (approval reference 2021-358-b-s) for the study center in Bottrop. Written informed consent was obtained from all participants.

Conflict of Interest Statement

The authors have no conflicts of interest to declare.

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Author Contributions

Sven Arends and Michael Nosch: conception of the work, acquisition, analysis and interpretation of data, and drafting the manuscript. Michael Thomas: acquisition, analysis and interpretation of data, and reviewing the work critically for important intellectual content.

Thomas Droll: acquisition of data and reviewing the work critically for important intellectual content. Denise Zwanziger: conception of the work, acquisition and analysis of data, and reviewing the work critically for important intellectual content. Thorsten Brenner: conception of the work, analysis and interpretation of data, and reviewing the work critically for important intellectual content. Ali Haddad: conception of the work, acquisition, analysis and interpretation of data, and reviewing the work critically for important intellectual content. All authors gave final approval of the manuscript to be published.

Data Availability Statement

The dataset supporting the conclusions of this article is available from the corresponding author upon request.

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