

POSTOPERATIVE RECOVERY IN MAJOR ORTHOPAEDIC PROSTHETIC

ASSESSMENT OF REDAX DRENTECH SURGICAL® AUTOTRANSFUSION SYSTEM

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BACKGROUND

A total of 73 patients who underwent hip arthroplasty (n° = 53) and knee arthroplasty (n° = 20) were reviewed in a prospective, randomized, blind study during the months May-July 2001 (1° group) and Mars-May 2002 (2° group) in order to assess the efficacy of REDAX DRENTECH® postoperative blood salvage system.

A particular attention has been paid to the study of coagulation modifications in blood salvage through the analysis of some coagulation factors (1° group) and of fibrin degradation products (2° group).

The patients (average age of 68.8 years) who were included in the study, underwent hip or knee arthroplasty, 1° or 2° operation, with or without preoperative autotransfusion (predeposit): at the end of surgery and upon consent the REDAX® recovery system was applied to them.

In the 1° group, (43 patients), the following laboratory tests have been performed: *on blood salvage*: hemochrome, reticulocytæmia, erythrocyte lysis, hematias microscopic assay, fibrinogen assay, PT, aPTT, ATIII, determination of factors V, VII, X, bacterian composants research; *on the patient*: hemochrome and reticulocytæmia, electrolytes and residual hemoglobin, bilirubinaemia, haptoglobinaemia, leucocyte formula, coagulation indexes, determination of factors V, VII, X.

In the 2° group (30 patients) ATIII and D-dimers levels were studied *on blood salvage*, and *on the patient* during the preoperative (basal) and the postoperative phases before the reinfusion.

The average quantity of retransfused blood was 535 ml, the average hemoglobin in recovered blood from the system was 8,7 g/dl, residual (free) hemoglobin was 0,15 mg/dl. It was not possible to underline significant morphologic alterations during the microscopic and instrumental examination of the samples.

In the recovered blood, a reduction of V° and X° factors and an increase in VII° factor can be noticed. D-dimers concentration increased in circulating blood and to a even greater extent in recovered blood. ATIII decreased both in the patient and in blood salvage.

The alterations of coagulation factors and, in the second instance, of fibrin degradation products are clearly referable to the physiological activation of normal reparative processes due to biological insult related to a surgical wound.

In no patient complications referable to reinfusion or important alterations of coagulation parameters after the reinfusion occurred.

This study allows us to observe that, although some modifications of plasma components, in particular those related to the coagulation function, the reinfusion of collected blood during the postoperative phase through the REDAX[®] system is safe and risk-free. This system allows to recover a good quantity of blood that, even if it has not a high level of hematocrit, is useful during the perioperative phase and represents an important procedure within a transfusion-saving program.

MATERIALS AND METHODS

The study included 73 patients, average age of 69.8 years, who underwent hip ($n^{\circ} = 53$) and knee ($n^{\circ} = 20$) arthroplasty, 1^o or 2^o operation, and were divided into two different groups and periods: the study on the first group, 43 patients, was carried out during the months May-July 2001; the study on the second group, 30 patients, during the months Mars- May 2002.

The REDAX DRENTECH SURGICAL[®] postoperative blood salvage system was applied to all the patients at the end of surgery and upon consent.

This completely closed system is a non-wash device, which requires a battery exhaust system with adjustable suction of pressures from -25 to -100 mmHg, is equipped with a 120 micron hemocompatible filter and with a supernatant layer separation system.

In the 1^o group, the collected and reinfused within 6 hours blood quantity was determined for each patient and laboratory tests were performed both on the blood collected from the system and on the patients' blood before the surgery (basal), after the reinfusion and, only for few tests, after 5 days from surgery.

In particular, *on blood salvage*, we considered:

- a) hemochrome, reticulocyte count on blood samples taken in K2-EDTA with four different hematologic systems (ABX Pentra 120, Sysmex SE-9000, Sysmex SE-9500, Sysmex XE-2100);
- b) erythrocyte lysis indirect determination through the dosage of residual hemoglobin and of potassium, sodium and chlorine on heparin-plasma;
- c) hematias microscopic assay and leucocyte formula performed by two health professionals on 200 cells following NCCLS protocol;
- d) coagulation cascade assay through fibrinogen determination, PT, aPTT and ATIII on citrate-plasma, determination of factors V, VII, X (coagulation tests were carried out with a CA6000 and 7000 SISMEX-TOA instrumentation with BIOPOOL reagents);
- e) bacterian pollutants research with their relevant microbial load.

On the patient, we considered:

- a) hemochrome and reticulocytopenia;
- b) electrolytes and residual hemoglobin;
- c) bilirubinaemia and haptoglobinaemia;
- d) leucocyte formula;
- e) coagulation indexes and determination of factors V, VII, X.

In the second group, both ATIII and D-dimers levels have been studied, respectively *on the patient* before the surgery (basal) and *on blood salvage* at the end of the surgery.

RESULTS

1° Group

The average quantity of collected blood is 560 ml; the average quantity of reinfused blood is **535** ml. Hemochrome average values of recovered blood are the following (Figure 1):

Parameters	Average value
RBC	2.91 x 10 ⁶ /ml
Hb	8.7 g/dl
Ht	26.8 %
Plt	28.6 x 10 ³ /ml
Reticulocytes	14.8 ‰
K ⁺	4,15 mEq/l
Residual Hb	0,15 mg/dl

Figure 1

Morphologic alterations of great importance during microscopic and instrumental examination of the samples were not found. The blood is in good repair, without significant morphologic alterations. In almost all the examined cases, we verified erythroid and/or myeloid immature elements at different stages. This peculiarity is probably due to the bone marrow mechanical exposure during surgical manoeuvring. The values of factors V, VII, e X which were measured on the patient before and after surgery, on drainage blood and on reinfused blood show a reduction of factors V and X in reinfused blood with an increase of factor VII (Figure 2).

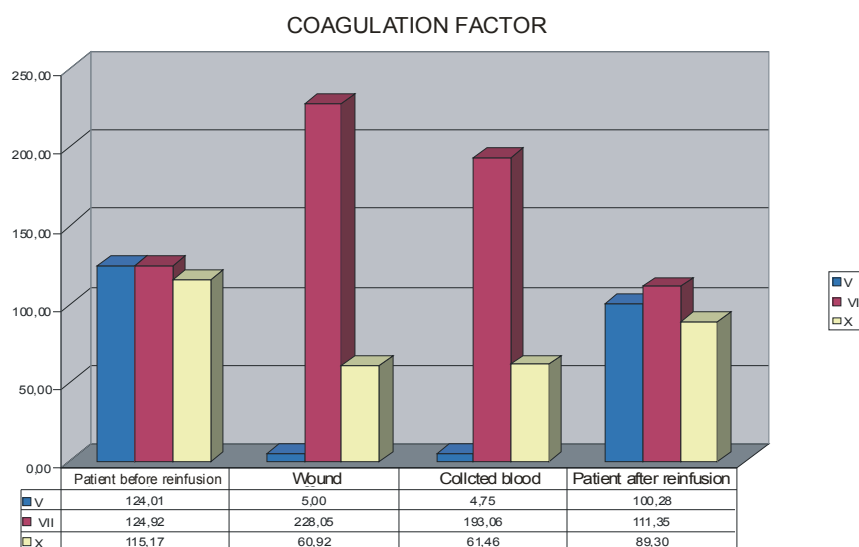


Figure 2

Coagulation factors trend

Coagulation time analysis (PT, I.N.R., aPTT) performed on 1° group patients respectively immediately after the reinfusion (4.00 pm), during the first and second day, shows a slight rise in reinfused patients compared to controls; this rise does not achieve statistical significance (Figure 3, 4, 5).

PT trend (v.n. = 70 - 100%)

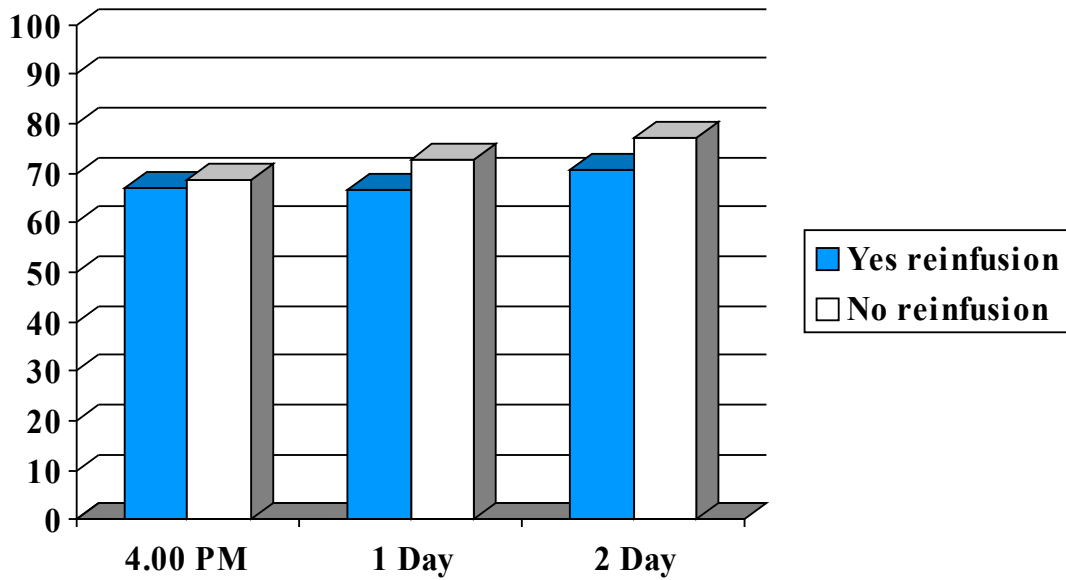


Figure 3

I.N.R. trend (v.n. = 0,90 - 1,20)

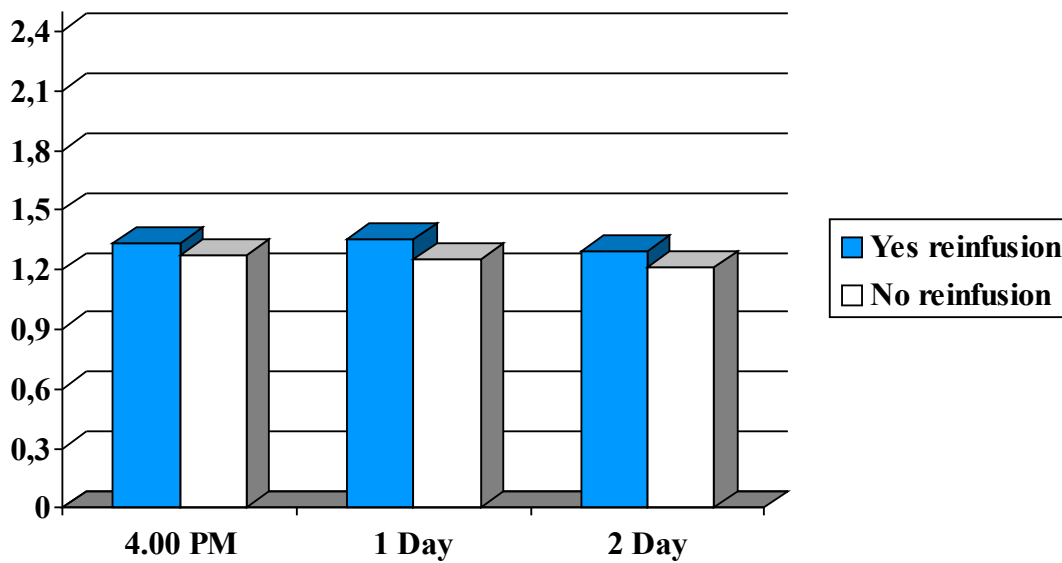


Figure 4

APPT trend (v.n. = 28 - 42")

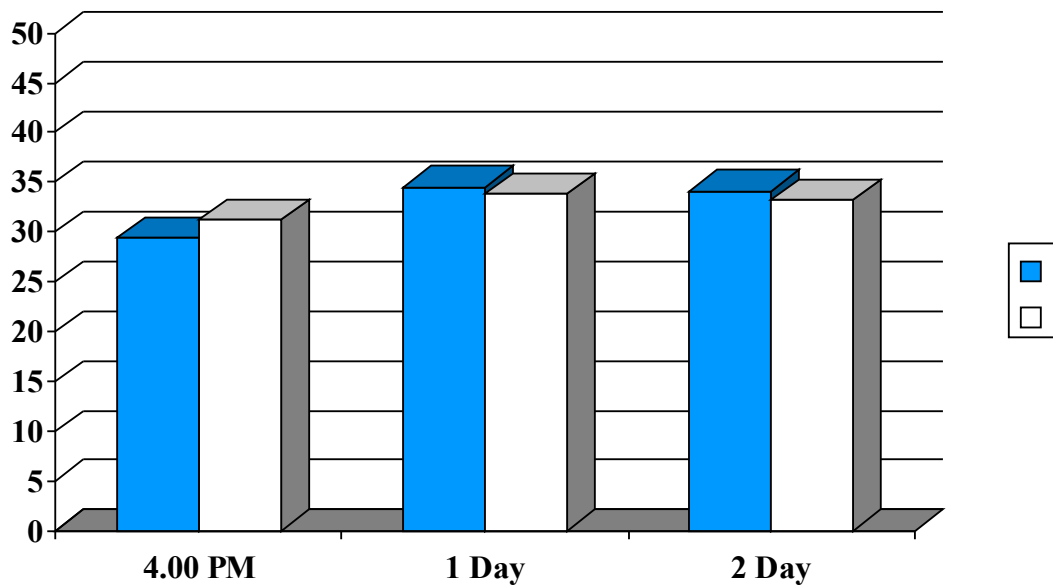


Figure 5

The supernatant layer microscopic examination confirms the presence in this portion of a great quantity of lipids and the importance of their elimination during this stage from the reinfused blood. During the control after 5 days, no alteration of examined parameters of great importance was found; on the contrary, an average increase of hemoglobin of about 1 g/dl and the settling of reticulocyte value at 25% has to be noted.

2° Group

D-dimers level is definitely on the increase in circulating blood at the end of surgery compared to basal value, as a consequence of surgical trauma; sample concentration from recovery system was difficult to determine, due both to high concentration, and to technical interferences caused by particular characteristics of recovered salvage from drainage so that it is often indeterminable using available coagulometers. In this case, the determination has been performed manually through a semiquantitative determination method (BIOPOOL reagents); the recorded values are high and present peaks that are 200 times higher than basal value (Figure 6).

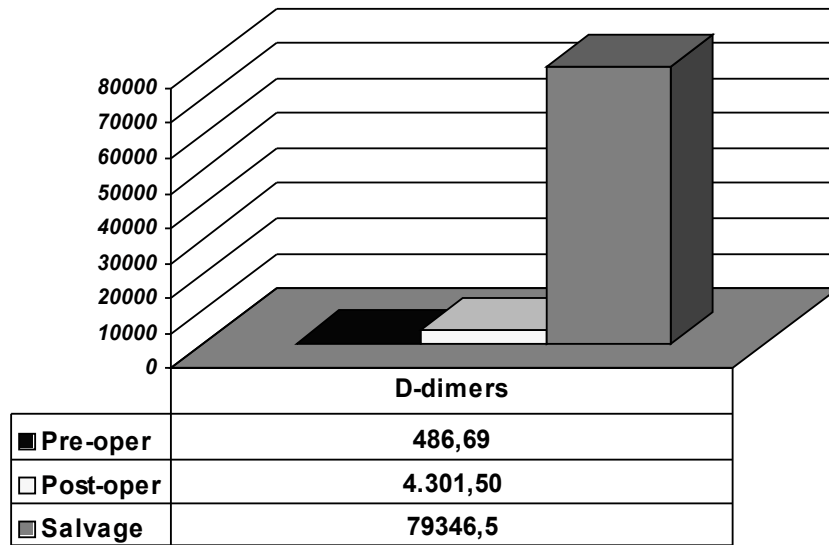


Figure 6

On the contrary, ATIII is consistently on the decrease both in the patient at the end of surgery and in recovered blood (average values: basal 81%, at the end of surgery 58%, blood salvage 37%).

DISCUSSION AND CONCLUSIONS

Non- wash postoperative blood salvage systems have been known and used for years in surgery, even if they find their wider field of application in orthopaedic prosthetic surgery in connection with operating relative aseptic characteristics and with the quantity of postoperative blood losses that is almost always higher than intraoperative losses.

Different studies have demonstrated the safety and efficacy of this method to reduce, together with other autotransfusion techniques (predeposition, preoperative hemodilution, intraoperative salvage), the use of homologous blood transfusions which is not, up to the present, risk-free for the patients.

Over the years, the collaboration between biotechnological industry and health professionals has allowed the evolution of recovery systems in pursuit of continuous improvement in the fields of safety, efficacy and simplicity of utilization. With regard to this, last generation systems envisage the complete circuit locking, blood double filtration, and the division during lipid buffy coat phase. Nevertheless, blood salvage from surgical wound is not theoretically risk-free: there is a risk of possible bacterial contamination, of the immission in circulation of microclots and/or microembolus of tissue derivation, or of the activation of coagulation and/or inflammation processes.

The aim of this study was not only to assess system reliability but also to test some of reinfused blood qualitative characteristics.

As far as the first point is concerned, we have not recorded any complication referable to blood salvage reinfusion.

From the laboratory standpoint, the obtained results show that the collected blood from REDAX DRENTECH SURGICAL[®] system is in good repair from the hematochemical standpoint. Actually, it does not present relevant alterations chargeable to hematis morphology, nor significant hemolysis marks, either direct or indirect. As far as immature forms are concerned, their presence is exclusively due to surgical action and they are not present in the control after 5 days.

The observation of significant modifications concerning coagulation cascade factors and fibrinolytic activity in blood salvage is clearly compatible with corrective homeostatic trigger processes related to surgical wound. With regard to this, other authors have observed the increase of various chemical factors and mediators of inflammation as, for example, I-L, complement fractions, some leucocyte subgroup. It can be assumed that the tissue damage determines on the one hand the inflammation activation and, on the other hand the coagulation activation, which is strictly related to the previous one, as the homeostatic system can not make a difference between accidental and surgical trauma. The observation of blood that arising from a surgical wound is fortified through some partly activated or variously “processed” factors that come from the wound itself, should not be surprising. The question that arises is if the presence of inflammation and coagulation mediators in recovered blood can or can not determine a damage to the patient when he is reinfused. Non-wash postoperative blood salvage system have been using for over 15 years on a large scale and, up to the present, no complication that can invalidate its effectiveness was found.

Numerous studies have underlined the positive aspects of postoperative salvage within a transfusion-saving program, and they have never referred to complications directly related to reinfused blood characteristics.

Krohn et al. refer to a postoperative bleeding increase in patients which underwent reinfusion with blood salvage, relating this fact, in another study to D-dimers competitive action on fibrin and to the increase of plasma activities analyzed in patients’ blood after the reinfusion^B. It is possible that these results were conditioned by some elements which were not found in other studies such as the use of wash intraoperative salvage (average 570 ml) and definitely high intraoperative average losses (1460 ml).

The increase of coagulation times that in our work do not have statistical significance, seem to depend on blood salvage reinfusion, which has increased fibrinolytic activity and antifebrin action. It is possible that beyond a certain value of intraoperative losses and beyond standard collected and reinfused volumes (< 800 ml), these coagulation alterations can make postoperative autotransfusion “ineffective”, increasing bleeding time and transfusion demand; further studies are hoped for clarify also these aspects.

It is necessary to underline also D-dimers increase among those patients who recover their blood, as it represents a sign of false positivity in a possible differential diagnosis with other postoperative coagulation diseases and in particular with embolic DVT.

KEY WORDS

Postoperative blood salvage, hip arthroplasty, knee arthroplasty.

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