Equipment Review

Assessment of a new ultrafiltration blood processing system

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Purpose: To report our clinical experience with a new blood processing device which uses ultrafiltration. We assessed safety and efficacy by evaluating: 1) the quality and the quantity of intraoperative shed blood processed and reinfused to the patient 2) homologous blood requirements 3) clinical status of the patient post-transfusion.

Methods: With Ethics Committee approval, the ultrafiltration device was used in six consenting patients undergoing major elective spinal surgery. Blood samples for haematology and biochemistry tests were collected from patients post-induction of anaesthesia (baseline), 1 hr and 24 hr post-autotransfusion. Volumes of blood collected and processed, and all autologous and homologous transfusions were recorded. Patients were assessed postoperatively for any adverse effects.

Results: Five patients had donated blood preoperatively. One patient required homologous blood products in addition to autologous blood. In two patients, the filtration cartridge became blocked and required changing midprocessing. No patient sustained device-related complications. One patient had postoperative haematuria which resolved spontaneously within two hours.

Conclusion: The ultrafiltration device was safe and effective in reducing homologous blood requirements in six patients undergoing elective spinal surgery. Further evaluation of the ultrafiltration device will be necessary, especially in view of the blockage of the filtration cartridge.

Objectif : Décrire notre expérience clinique avec un nouveau dispositif de traitement du sang fonctionnant par ultrafiltration. Nous avons estimé sa sécurité et son efficacité en évaluant : 1) la qualité et la quantité peropératoires de sang perdu traité et reperfusé au patient 2) les besoins en sang homologue 3) l'état posttransfusionnel du patient.

Méthodes : Avec l'accord du comité d'éthique, nous avons utilisé le dispositif d'ultrafiltration chez six patients consentant soumis à une chirurgie rachidienne élective. Les patients ont fourni des échantillons destinés aux épreuves hématologiques et biochimiques après l'induction de l'anesthésie, une heure et 24 h après l'autotransfusion. Nous avons noté le volume du sang recueilli et traité ainsi que les transfusions homologues. Les effets secondaires ont été évalués en postopératoire.

Résultats : Cinq patients avaient donné du sang à la période préopératoire. Un patient a eu besoin de produits sanguins homologues en plus du sang autologue. Chez deux patients, la cartouche filtrante s'est obstruée et a dû être remplacée en cours d'intervention. Aucun patient n'a présenté de complication en rapport avec l'appareil. Un patient a souffert d'une hématurie qui s'est dissipée en moins de deux heures.

Conclusion : Le dispositif à ultrafiltration a réduit les besoins de sang homologue avec sécurité et efficacité chez six opérés pour une intervention rachidienne non urgente. Une évaluation plus complète du dispositif s'impose spécialement en raison de l'obstruction de la cartouche filtrante.

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OVER the past decade, there has been a growing demand for autologous blood products which has been fuelled by awareness of the hazards of homologous blood transfusion, in particular disease transmission.[1] Predeposited autologous blood products and intraoperative blood salvage are two techniques which minimize use of homologous blood products.

Major elective spinal surgery is associated with considerable blood loss. At our institution, preoperative blood donation and an intraoperative blood processing device are routinely used for this surgery. The usual device is a centrifuge system which relies upon the generation of centrifugal forces to separate the components of blood according to their different densities. Irrigants, anticoagulants, cell degradation products and plasma are removed, leaving a concentrated red cell product. The Autocell blood salvage device has recently been developed by Davol Incorporated, subsidiary of C.R. Bard, Inc., Cranston, RI. It uses a different technique, ultrafiltration, to separate and remove waste products. Biocompatibility testing of the Autocell device had shown no damage to whole human blood.

We assessed the safety and efficacy of the Autocell device in six adult patients undergoing major elective spinal surgery by evaluating: 1) the quality and quantity of shed blood which was processed and reinfused to the patient; 2) volume of homologous blood requirements; 3) clinical status of the patient post-transfusion.

Description of Davol Autocell ultrafiltration device

The mobile hardware system (Figure) consists of: an operator control panel with push button keys, a message display which shows volume processed and audible/visual alarm indicators and a built-in vacuum source connected to the collection reservoir by a vacuum supply line.[a] The filtration cartridge is a single-patient use component which inserts into the pneumatic interface at the top of the system hardware. The cartridge contains the fluid reservoirs, pneumatic pumps and filters needed to wash and concentrate salvaged blood. Prior to use, the filtration cartridge is primed with approximately three litres of saline. Priming removes residual glycerine and air from the system. The suction and anticoagulant assembly is similar to that of the centrifuge system. The anticoagulated shed blood is aspirated to a three litre collection reservoir which contains a 20 μm filter.

Once collected, blood is processed by either a 'standard' (150 ml·min^{-1}) or an 'extended' (250 ml·min^{-1}) wash. The 'extended' wash is used for surgery which requires more extensive cleansing of blood, such as orthopaedics. As well as 'batch' processing, the reservoir can be connected to the filtration cartridge for continuous processing. During processing, the blood passes through a series of two filters. Washed blood is delivered from the cartridge to the reinfusion bag. Irrigants, anticoagulants and cell degradation products are directed to the waste bag. After all blood is processed, 'purging' the system delivers any residual blood in the filtration cartridge to the reinfusion bag. A standard 20–40 μm filter is used during reinfusion of blood to the patient.

Method

With approval of the Ethics Committee and informed written consent, six patients underwent routine anaesthetic and surgical management. Monitoring consisted of: continuous ECG, pulse oximetry, end-tidal capnography and vapour analysis, direct blood pressure monitoring with an arterial line, central venous pressure monitoring and urinary output. Mean arterial pressure was maintained 10–20% below the patient's preoperative value by titrating inspired isoflurane. Blood loss was replaced initially with crystalloid (Normal Saline and Plasmalyte), then cell saver blood, then predonated blood, and finally homologous blood products if required.

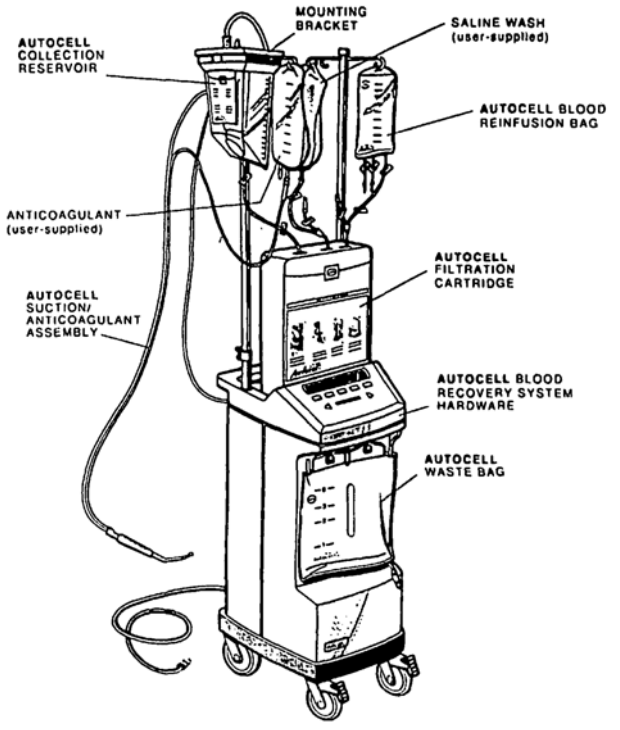

FIGURE New Davol Autocell Ultrafiltration system.

a Operator's Manual Autocell Blood Recovery System Davol Inc., 1994.

The pressure of the aspiration suction was maintained at 100 mmHg. No blood was aspirated from the surgical wound in the presence of topical haemostatic agents, antibiotics or antiseptics. The anticoagulant used was Acid Citrate Dextrose solution A (ACDA). The ratio of anticoagulant to blood volume was maintained at 1:7–1:10 by manual adjustment of the flow of anticoagulant solution by the perfusionist. Blood was processed intermittently in 'batches' following the collection of each litre, rather than continuously. All blood was reinfused to the patient through a 20–40 μm filter within six hours of collection. Blood samples for biochemistry, complement, haematology and coagulation testing were collected from the patients' arterial lines following induction of anaesthesia, and at one and 24 hr post autotransfusion. The volumes of surgical blood loss, autologous (salvaged and predonated) and homologous transfusions were recorded.

Results

The Autocell device was used in six female patients with a mean (± SD) age of 43 ± 18 yr and weight of 63 ± 12 kg. The volumes of blood lost, collected, processed and reinfused are shown in Table I. The volume of blood collected did not include the volume of ACDA. Five patients had donated blood preoperatively. All predonated blood was reinfused either intraoperatively or in the initial postoperative period. One patient required homologous blood products in addition to autologous blood.

Table II shows haemoglobin, platelet count, prothrombin time (PT) and partial thromboplastin time (PTT) preoperatively (baseline), 1 hr and 24 hr post-autotransfusion. Postoperative biochemical tests of renal function were within normal limits. Complement levels were not elevated postoperatively. This is consistent with previous studies which have shown no systemic activation of complement with the use of a cell salvage device.[2]

In two patients, the filter became blocked during processing and the filtration cartridge had to be changed. In both cases, the collection time exceeded five hours, whereas collection time had been less than four hours in the other four patients. Prolonged collection time may be associated with accumulation of clot and debris. It is likely that blockage of the filter would be less likely to occur with continuous, rather than batch, processing since there is less time for debris to accumulate.

No patient sustained device-related complications. One patient developed haematuria post-transfusion in the presence of normal coagulation studies. The haematuria settled spontaneously after two hours and there were no sequelae.

Discussion

Avoidance of homologous blood products can be achieved through rationalization of the trigger haematocrit for transfusion,[3] reduction of surgical blood loss, using controlled hypotension for example, and use of autologous blood products. The concept of autotransfusion is almost 180 years old.[4] Today it takes the form of preoperative donation, acute normovolaemic haemodilution, intraoperative and postoperative cell salvage. Intraoperative cell salvage has achieved widespread acceptance in the areas of cardiac,[4,5] vascular,[5,6] orthopaedic,[7,8] spinal,[9,10] liver transplant[11] and trauma surgery.[12] It is contraindicated in the settings of haemodynamic instability and coagulopathy, and is relatively contraindicated in the presence of malignancy, sepsis and obstetric surgery.[4] Blood should not be aspirated from the wound in the presence of topical haemostatic agents, methyl methacrylate, hydrogen peroxide, betadine, topical antibiotics and bodily fluid contaminants such as amniotic fluid and bowel contents.[b]

In this spinal surgery study, the average blood loss was 1.85 litres (range 0.4–3.5 litres). One of six patients required homologous blood products. This supports previous findings of reduction of homologous blood use when both salvaged and predonated blood are used.[7,13]

TABLE I Blood volumes

	Mean (± SD)	*Range*
Total blood loss (ml)	1850 ± 1078	400–3500
Blood Collected (ml)	1244 ± 571	330–1870
Volume Processed (ml)	698 ± 349	230–1140
% Salvaged*	58 ± 13	44–78

$$* \text{ \% Salvaged} = \frac{\text{Volume processed by device}}{\text{Volume collected in reservoir}}$$

TABLE II Perioperative haematology

	Baseline	*1 hr post-transfusion*	*24 hr post-transfusion*
Haemoglobin ($g \cdot dl^{-1}$)	95.3 ± 11.3	89 ± 17.7	80.8 ± 10.6
PT (sec)	10.5 ± 0.4	12.1 ± 1.4	12.4 ± 1.0
PTT (sec)	29.7 ± 3.1	33.6 ± 6.6	34.5 ± 8.0
Platelets ($\times 10^9 \cdot L^{-1}$)	231.3 ± 33.8	189.3 ± 56.3	161.6 ± 60.7

Values are mean ± SD
PT = Prothrombin time
PTT = Partial thromboplastin time

b Guidelines for blood salvage and reinfusion in surgery and trauma. Bethesda: American Association of Blood Banks, 1993.

With all intraoperative cell salvage devices that use a wash cycle, a dedicated operator is essential.[b] Both anaesthetists and the perfusionist quickly became familiar with the ultrafiltration device and found it easy to use.

During the post-transfusion period, one patient developed haematuria which cleared after two hours. Haematuria is due to plasma free haemoglobin in the urine. In a previous study using the Centrifuge Cell Saver in spinal surgery patients, the incidence of haematuria was 5% and it cleared within one to four hours.[9] It is not known what quantity of free haemoglobin in urine is required to cause renal damage. If haematuria is present, it is important to avoid other factors that may impair renal function, such as hypovolaemia, sepsis and nephrotoxic agents.

Evaluation of the Davol Autocell ultrafiltration device is ongoing. The Autocell device is not yet available for purchase and the anticipated cost is not known. It should be noted that in situations where it is difficult to anticipate the volume of blood loss, this device can be set up for blood collection only, without incurring the expense of processing equipment and personnel. Once sufficient blood has been collected, processing can be initiated.

In summary, we found the Autocell device to be safe and effective in minimizing homologous blood requirements in a small group of patients undergoing major elective spinal surgery. Further evaluation is needed, especially since the filtration cartridge became blocked in two patients. Future studies assessing cost-effectiveness of this device would be useful.

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