



Filters in autologous blood retransfusion systems affect the amount of blood cells retransfused in total knee arthroplasty A pilot study

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A pilot study was undertaken to evaluate whether filters integrated in postoperative retransfusion systems affect the amount of blood cells retransfused after total knee arthroplasty. Twenty-two consecutive patients received either the Donor retransfusion system (n=12 patients) or the Bellovac ABT retransfusion system (n=10). Both systems differ with respect to the type of filter, a Pall Lipiguard filter and a Sangopur filter, respectively. At the beginning of the retransfusion, blood samples were taken before and after the filter. The filter of the Donor system significantly decreased the amount of leukocytes and erythrocytes, whereas the filter of the Bellovac system did not. As a result the haemoglobin level of retransfused blood with the Donor system was significantly lower than with the Bellovac system.

It can be concluded that the type of filter integrated in two postoperative autologous blood retransfusion systems significantly affected the amount of blood cells retransfused in patients undergoing total knee arthroplasty.

Keywords : arthroplasty ; retransfusion ; filter ; blood cells.

INTRODUCTION

Blood loss during orthopaedic procedures may be extensive and may require transfusion of allogeneic blood. One of the alternatives to allogeneic

blood transfusion is postoperative re-infusion of drained blood. In the Netherlands several postoperative cell saving systems are widely used in patients undergoing total knee arthroplasty (TKA). Currently, the Bellovac ABT retransfusion system is the system most used in the Netherlands, while the Donor retransfusion system is gaining popularity. Both the Bellovac and Donor systems are based

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on the same principle, namely postoperative collection of blood, filtration of shed blood and retransfusion of filtered autologous blood. Although both systems have the same principles, they differ with respect to the type of filter, suction pressure and handling procedures. The filter of the Donor retransfusion system is a Pall Lipiguard filter, and the filter of the Bellovac system is a Sangopur filter. In a recently published randomised study, So-Osman *et al* concluded that the Donor system and the Bellovac system were equal in efficacy and safety (10). Except for the amount of leukocytes, shed blood samples before and after filtering in both systems were comparable with regard to the amount of thrombocytes and the haemoglobin (Hb) level, but erythrocyte counts were not made.

This pilot study was designed to evaluate the filters integrated in the Donor and the Bellovac system with respect to the retransfused blood cells in patients undergoing TKA. The primary objective was to compare differences in the amount of leukocytes and erythrocytes after filtering in both postoperative retransfusion systems.

MATERIALS AND METHODS

From November 2006 to February 2007 all patients scheduled for elective TKA for primary osteoarthritis (OA) in our clinic were included in this prospective non-randomised observational pilot study. Patients with haematological diseases, coagulation disorders or with known malignancy or infection on admission and those with previous surgery to the joint were excluded. Other alternatives to allogeneic blood transfusions were not allowed. Known rheumatoid arthritis and former arthroscopy of the knee with meniscectomy were not exclusion criteria. After oral and written study information was given, informed consent was obtained.

Twenty-two patients were enrolled in the study. The first 12 patients were assigned to receive the Donor retransfusion system (van Straten Medical, Nieuwegein, the Netherlands) and the next ten consecutive patients were assigned to receive the Bellovac ABT retransfusion system (AstraTech AB, Mölndal, Sweden). The Donor retransfusion system is a closed wound drainage system which consists of an 800ml collection container for shed blood and a retransfusion system with an integrated Pall Lipiguard filter. This depth filter consists of a polyester screen media consisting of a cascade with variable pore

size with the least size of 40 microns. The Donor system has a continuous pre-evacuated vacuum pressure of -150 mmHg during collection of shed blood. The Bellovac system consists of a suction bellow connected to a 500 ml collection bag for postoperative shed blood and a retransfusion system. Blood coming out of the wound first passes a filter of 200 microns before entering the collection bag and passes a Sangopur filter during retransfusion. The Sangopur filter consists of a gradual screen filter with a pore size of 80 and 40 microns. The vacuum pressure of the Bellovac system is intermittent with a maximum suction pressure of -90 mmHg.

All patients received an uncemented Scorpio TKA (Stryker Netherlands, Waardenburg, the Netherlands). Operations were done by three different surgeons, all experienced in joint replacement and using a standard medial parapatellar arthrotomy. A tourniquet was used during surgery and was released after wound closure. One deep drain was placed at the end of surgery, and was connected to the retransfusion system after closure of the wound. Collection and retransfusion of postoperatively shed blood was in accordance to product guidelines by which all retransfusion occurred within six hours after surgery. The minimum amount of collected shed blood had to exceed 150 ml after which retransfusion occurred. The amount of collected and retransfused blood was recorded.

At the beginning of the retransfusion blood samples were taken out of the collection container (Donor) or bag (Bellovac) (T_1 , see table II), and out of the retransfusion line connected to the patient during retransfusion (T_2 , see table II). Once the blood samples had been taken, they were passed to the department of clinical chemistry and haematology for analysis. The following laboratory parameters were assessed: Hb, free Hb, haematocrit (Ht), mean corpuscular volume (MCV), erythrocytes, leukocytes, and thrombocytes using a Sysmex XE-2100 (Goffin-Meyvis, Etten-leur, the Netherlands).

Blood Hb levels were measured preoperatively and after surgery on Day 1 and 3 according to standard measurements in hospital policy by taking intravenous blood samples. Furthermore all allogeneic blood transfusions given to our population were in accordance with hospital policy (flexinorm, CBO consensus guidelines, 2004) that is based on the Hb transfusion trigger depending on the American Society of Anaesthesiologist (ASA) classification and age. All allogeneic blood transfusions were recorded.

All complications, including possible transfusion reaction which occurred during admission were recorded.

Patients who used anticoagulation (acenocoumarol or acetylsalicylate) stopped their intake seven days pre-operatively. All patients received low-molecular-weight heparin (nadroparine) for thrombo-embolic prophylaxis starting just before surgery and continuing six weeks postoperatively. The rehabilitation program conformed to standard hospital policy and discharge out of the hospital was planned at Day 5 after surgery.

The results were analysed statistically with the paired t-test for all blood sample measurements within the patients to analyse the effect of the filter. Different filtering rates, defined as the level before filtering minus the level after filtering, between both groups were analysed with Student's test. A p-value less than 0.05 was considered indicative of a significant difference.

RESULTS

Twenty-two consecutive patients undergoing elective TKA were enrolled in the study. Their average age was 67 years (range 49-82). The proportion of females among the patients was perceptibly higher than the males in both groups. Details of the patient characteristics are presented in table I. All patients were ASA 2 or 3 category and both groups were similar in terms of gender, age and preoperative Hb levels.

In three patients blood samples were not taken out of the retransfusion system. In two of those three patients the amount of shed blood in the collection device six hours after surgery did not exceed 150 ml (one patient in both groups). In the third patient (Bellovac group) 200 ml of shed blood was collected but neither blood samples, nor retransfusion of shed blood took place, because the nurse was not familiar with the procedure. In total 19 blood samples were taken out of the collection device and out of the retransfusion line.

The average amount of collected blood was 449 ± 242 (SD ; range, 40-800) ml in the Donor

group and 334 ± 167 (SD ; range, 40-600) ml in the Bellovac group (NS). As a result a little more blood was retransfused, after taking the blood samples, to the patients in the Donor group compared to the patients in the Bellovac group (445 ml versus 322 ml), although this difference was not statistically significant.

Blood sample analysis for both postoperative retransfusion systems is shown in table II. Filtering shed blood with the filter in the Donor group showed a significant decrease in the amount of leukocytes by 56% (from 6.9 to $3.0 \cdot 10^9/l$), whereas after filtering with the filter in the Bellovac group this was only 3% (from 6.7 to $6.5 \cdot 10^9/l$). This filtering rate for leukocytes was significantly different between both groups ($p < 0.001$). Furthermore, the amount of erythrocytes in blood samples after filtration using the Donor filter was decreased by 16% (from 3.5 to $3.0 \cdot 10^{12}/l$), whereas it was not after filtration using the Bellovac filter (from 3.4 to $3.5 \cdot 10^{12}/l$). Again, this filtering rate for erythrocytes between both groups was significantly different ($p=0.003$). The same counted for the filtering rate for thrombocytes between both groups, in which the Pall Lipiguard filter of the Donor system decreased the amount of thrombocytes from 42 to $26 \cdot 10^9/l$ (38%).

The Hb level of blood samples in the Donor retransfusion system decreased from 10.5 ± 1.8 g/dl to 8.9 ± 2.0 g/dl (NS), whereas the Hb level in the Bellovac system remained unchanged after filtering, i.e. from 10.8 ± 1.9 g/dl to 11.0 ± 2.5 g/dl (NS). On average, the filter in the Donor system caused a decrease in Hb of 1.6 g/dl, whereas there was no decrease in Hb using the filter in the Bellovac system. This difference in filtering rate for Hb between both groups caused by the difference in type of filter was significant ($p = 0.004$).

Table I. — Patient characteristics in both retransfusion groups

	Donor (n=12)	Bellovac ABT (n=10)
Male / female	4 / 8	3 / 7
Age (yrs)	67 (49-82)	67 (55-79)
Preoperative Hb (g/dl)	14.0 ± 1.9 (11.8-17.1)	13.9 ± 1.5 (11.9-17.1)

Values are presented as mean \pm standard deviation (range).

Table II. — Data of blood samples from patient and shed blood before and after filtering

	Donor system (n 11)			Bellovac system (n=8)			p-value
	T ₁ Mean ± SD (Range)	T ₂ Mean ± SD (Range)	Filtering rate Mean ± SD	T ₁ Mean ± SD (Range)	T ₂ Mean ± SD (Range)	Filtering rate Mean ± SD	
Haemoglobin (g/dl)	10.5 ± 1.8 (8.1-13.7)	8.9 ± 2.0 (6.6-12.2)	1.6 ± 1.0	10.8 ± 1.9 (6.9-13.0)	11.0 ± 2.5 (7.1-14.3)	-0.2 ± 1.4	0.004
Free Hb (g/dl)	0.16 ± 0.08 (0.0-0.5)	0.16 ± 0.07 (0.2-0.3)	0.0 ± 0.07	0.16 ± 0.05 (0-0.1)	0.16 ± 0.05 (0.2-0.3)	-0.01 ± 0.05	0.522
Haematocrit (l/l)	0.32 ± 0.05 (0.20-0.41)	0.28 ± 0.06 (0.21-0.38)	0.05 ± 0.03	0.33 ± 0.06 (0.21-0.38)	0.33 ± 0.07 (0.22-0.44)	0 ± 0.03	0.003
MCV (fl)	93 ± 4.3 (88-101)	93 ± 4.5 (88-101)	0 ± 0.63	96 ± 5.3 (87-104)	96 ± 5.3 (88-104)	0.1 ± 0.8	0.297
Erythrocytes (10E ¹² /l)	3.5 ± 0.6 (2.8-4.6)	3.0 ± 0.7 (2.3-4.2)	0.5 ± 0.3	3.4 ± 0.7 (2.2-4.3)	3.5 ± 0.8 (2.2-4.6)	-0.1 ± 0.4	0.003
Leukocytes (10E ⁹ /l)	6.9 ± 1.8 (2.9-9.3)	3.0 ± 1.8 (0.4-5.3)	4.3 ± 2.0*	6.7 ± 2.2 (2.4-9.7)	6.5 ± 2.2 (2.3-9.1)	0.2 ± 0.7	< 0.001
Thrombocytes (10E ⁹ /l)	42 ± 16 (25-64)	26 ± 10 (15-41)	16 ± 11	45 ± 13 (27-65)	45 ± 12 (28-67)	0 ± 4	<0.001

T₁ = Sample of collection device before filtering ; T₂ = sample of retransfusion line after filtering (Pall Lipiguard filter in the Donor system, Sangopur filter in the Bellovac system) at beginning of retransfusion ; filtering rate = difference between T₁ and T₂, defined as the level before filtering minus the level after filtering, in which a negative value means a increase of that value ; SD = standard deviation ; * = significant difference within patients ; p-values are analysing different filtering rates between both groups.

Among all blood samples the free Hb content remained under the critical level of 0.6 g/dl. The MCV of blood samples in the collection device as well as in blood samples after filtering had normal levels and was comparable to the MCV in blood samples taken from the patient.

Preoperative Hb levels in both groups did not differ, i.e. 14.0 ± 1.9 g/dl in the Donor group and 13.9 ± 1.5 g/dl in the Bellovac group (NS). On the first day after surgery, Hb levels had decreased in both groups, to 11.9 ± 1.5 g/dl in the Donor group and to 11.6 ± 2.1 g/dl in the Bellovac group (NS). At Day 3 after surgery, Hb levels further decreased to 10.8 ± 1.1 g/dl and 11.2 ± 2.4 g/dl in the Donor group and Bellovac group, respectively (NS). No patient in the Donor group received allogeneic blood transfusions compared to one patient in the Bellovac group who received two erythrocyte concentrates. No visible side-effects, allergic or haemolytic reaction occurred after retransfusion. In the Donor group one patient was readmitted one week after discharge because of a possible wound infection. Micro-organisms were not found in cul-

tures. After clinical improvement oral antibiotics were stopped and the patient was discharged. In the Bellovac group one patient showed a small dehiscence of the wound, without clinical signs of infection. Due to observation of the wound the hospital stay was prolonged. No thrombo-embolic events occurred in the population.

DISCUSSION

This pilot study evaluated whether the type of filter integrated in two postoperative retransfusion systems affected the amount of blood cells retransfused in patients undergoing TKA. We have shown that patients treated with a retransfusion system received autologous shed blood with different constituents depending on the type of filter. This was shown by a significant reduction in the amount of leukocytes when using the filter as integrated in the Donor system. This reduction is in accordance with the result described in literature (2,10). Although both systems have filters with similar minimum

pore size, filtering shed blood using the filter as integrated in the Bellovac system had no influence upon the amount of leukocytes retransfused. In the past, a few studies have been published in which the authors concluded that retransfusion of autologous shed blood alters the activity of the polymorphonuclear leukocytes (4,5). Although a positive effect of retransfusion is described (9), the clinical effect of retransfusion of activated leukocytes is still unknown (8).

Whereas the reduction of leukocytes was expected to occur using the Donor system, the reduction of both erythrocytes and thrombocytes was surprising as the average size of both blood cells is only 7.8 and 3.0 microns, respectively (6). Though erythrocytes pass through, the Lipiguard filter partly functions as a sponge as erythrocytes obviously are absorbed in this sponge since their concentration in the retransfused blood is reduced. Thereby, their primary function to recover blood is hampered. While So-Osman *et al* concluded that the Donor and Bellovac systems were equal (10), our study showed significant differences in filtering rates for leukocytes, erythrocytes and thrombocytes between both retransfusion systems caused by the type of integrated filter.

As a result of the difference in the amount of erythrocytes, there was a difference in the Hb level in the blood samples in both systems. The filtering rate for Hb level, defined as the Hb level before filtering minus the Hb level after filtering, was significantly different in the Donor system compared to the filtering rate for Hb level in the Bellovac system. Therefore, it might be suggested that retransfusion of shed blood filtered by the Sangopur filter in the Bellovac system, causes a bigger increase in Hb level in systemic blood samples of the patients. Nevertheless, the systemic Hb levels were slightly lower at Day 1, but were higher at Day 3 after surgery in patients treated with retransfused blood from the Bellovac system compared to the Donor system. However, conclusions about differences in systemic Hb level after retransfusion in both systems can not be made because of small sample size. In addition, this study was not designed to evaluate differences regarding the need for allogeneic blood transfusions in both systems.

The filter in the Bellovac retransfusion system appears beneficial because of an increased rate of retransfused blood cells. However, this interpretation is doubtful. The filter is supposed to reduce the amount of potential emboli sources by reducing emulsified fat, cell aggregates and debris. In our study none of the patients experienced any thrombo-embolic complications. However, no measurements were performed to objectivate possible effects.

Not only the kind of filter but also the suction drainage of Bellovac and Donor system differs. The American Association of Blood Banks (AABB) recommends a suction level for closed wounds no higher than 100 mmHg, because if the vacuum suction is set too high, red blood cells will be lysed (11). In our study we have not found indications of haemolysis in both retransfusion systems, as shown by the low free Hb and normal MCV levels. Although suction pressure does not seem to be clinically relevant regarding haemolysis, it might be relevant regarding collecting shed blood volumes, since the calculated true Hb (volume * Hb concentration) in retransfused blood might be different in both systems, because there was a trend towards collecting more shed volume in the Donor system. However, the study of So-Osman *et al* showed opposite results by which the Bellovac system collected and reinfused more shed blood volume compared to the Donor system (10).

Though several studies have shown the efficacy of different postoperative blood cell saving systems after TKA (1,3,7,12), larger sufficiently powered studies are necessary to compare retransfusion systems regarding presumed differences in shed volumes, systemic Hb level after retransfusion and differences in need for allogeneic blood transfusions.

In summary, using either a Donor retransfusion system or a Bellovac retransfusion system, blood with different amounts of blood cells was retransfused to the patient. The filter integrated in the Donor system significantly decreased the amount of leukocytes and erythrocytes. As a result the Hb level of retransfused shed blood with the Donor system was significantly lower than with the Bellovac system. It can be concluded that the type of filter integrated in two postoperative autologous

blood retransfusion systems significantly affected the amount of blood cells retransfused in patients undergoing TKA.

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