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ORIGINAL STUDY

Postoperative autologous blood salvage drains – Are they useful in primary uncemented hip and knee arthroplasty ? A prospective study of 186 cases

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There are nearly 43,000 hip replacements and 33,000 knee replacements performed each year in the United Kingdom. Many of these require a blood transfusion. However, there has been increased public concern about the safety of blood transfusion and various techniques are used to decrease the need for allogenic transfusion. Postoperative blood salvage and reinfusion is one of them.

We studied 186 consecutive patients who underwent unilateral uncemented hip or knee arthroplasty. Ninety-four had re-infusion drains and 92 had suction drains. We have compared the allogenic transfusion requirements for the two groups. We have analyzed patient and operative factors to determine whether they are predictive for risk of allogenic blood transfusion. Cost analysis was performed to determine whether the use of a re-infusion drain is a cost effective technique.

Re-infusion drains significantly decreased the requirements for allogenic blood transfusion (p = 0.001). Twenty-one percent of the re-infusion drain group and 45.7% of the suction drain group required allogenic blood transfusion. The only preoperative factor that determined whether the patient required allogenic blood transfusion was pre-operative haemoglobin. We found that age, gender, type of surgery (hip replacement or knee replacement) and whether the patient had tourniquet or not (in knee replacement) did not alter the requirements for allogenic blood transfusion. The mean transfusion costs were slightly less for re-infusion drain group (£ 182.70 per patient for re-infusion drain group and £ 196.75 per patient for suction drain group, p = 0.009). The hospital stay was also significantly reduced (11.0 days for re-infusion drain group as opposed to 12.6 days for suction drain group (p = 0.0248).

Based on these findings, re-infusion drains appear as a cost effective means of reducing the requirement for allogenic blood transfusion following primary hip and knee arthroplasty.

INTRODUCTION

There are approximately 43,000 hip replacements and 33,000 knee replacements performed each year in the United Kingdom. Many of these require at least one unit of blood transfusion (*22, 38, 40*). Hays and Mayfield have shown that patients

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who are undergoing uncemented prosthetic implantation may loose more blood than those who undergo a cemented prosthesis implantation (*21*). This potentially places them at an increased risk of requiring a blood transfusion.

There has been increased public concern about the safety of blood transfusion. Apart from the risk of incompatible blood transfusion (*39*), other main concerns include transmission of viruses - HIV, Hepatitis B, Hepatitis C, HTLV (*39*), EBV, CMV, West Nile Virus, Human Herpes Virus, Hepatitis A Virus and vCJD prions. In the United Kingdom, blood is collected from voluntary, unpaid donors after careful questioning and selection and all donations are screened for hepatitis B surface antigen and antibodies to HIV-1 and HIV-2, hepatitis C virus, and syphilis in order to minimize the risks of disease transmission (*39*). A study in the US showed that HIV and HTLV viruses could be transmitted through blood transfusion in spite of screening (*7, 31*). Recent UK estimates suggest the risk for hepatitis B virus is 1 in 50,000 to 170,000 ; for hepatitis C virus is < 1 in 200,000 ; and for HIV is < 1 in 2 million units (*39*). A recent study in France also showed a marked reduction in the risk of transfusion-transmitted viral infections between 1992 and 2002, with a further reduction following the implementation of nucleic acid testing : the current overall residual risk is 1 in 325 000 donations, and more specifically 1 in 2.5 million donations for HIV and 1 in 6.65 million donations for HCV (*36*).

There are many strategies for reducing the transfusion requirements of patients undergoing surgery. Various pharmaceutical agents have been used in an attempt to decrease the blood transfusion requirements during major joint arthroplasty. These include recombinant erythropoetin (*11, 13, 38*), fibrin sealant (*27*), tranexamic acid (*23*), aprotinin and epsilon amino caproic acid (*20*). Hemodilution is another method proposed to decrease the requirements of blood transfusion (*32*).

Autologous blood transfusion can supplement blood transfusion and decrease the need for allogenic blood transfusion. Autologous blood transfusion is also associated with lower risk of infection than allogenic transfusion (*29, 30, 40*). The different types of autologous blood transfusion include preoperative autologous blood donation, per-operative blood salvage and re-transfusion and post-operative blood salvage and re-transfusion.

Although preoperative autologous blood donation decreases the exposure to allogenic blood (*16*), its popularity is declining (*18*) mainly because of the wastage of the predonated blood and the high costs associated with collection and storage of blood (*4, 12*). Per-operative blood salvage requires expensive equipment and specially trained personnel and has been shown to be not cost effective for primary hip arthroplasty (*19*). The use of a post-operative autologous transfusion drain requires little additional specialist equipment, no additional personnel, and minimal training of existing nursing and medical staff and therefore minimal initial investment.

The aim of our study was to determine if re-infusion drain was safe and whether it decreased the exposure of patients to allogenic transfusion. We also performed cost analysis to determine whether the use of the re-infusion drain is cost effective. We have also analyzed patient and operative factors to determine whether there were any factors that were predictive for allogenic transfusion.

MATERIALS AND METHOD

All patients who underwent primary elective unilateral uncemented hip or knee arthroplasty at our institution between 1st March 2002 and 30th November 2002 were entered into the study. During the first four months of the study (Group A) conventional closed suction drains were used (Bellovac in total knee arthroplasty and Endovac in total hip arthroplasty [Astra, Molndel, Sweden]). During the second four months of the study (Group B) a postoperative autologous blood drainage transfusion system (CellTrans, Summit Medical Limited, UK) was used. This is a closed suction drainage system that allows blood drained from the wound post operatively to be collected into a transfusion bag. The collected blood can then be re-infused through a filter (Pall Lipigaurd filter, Pall Corporation, USA) directly into the patient. Pre-donation and intraoperative salvage of autologous blood was not used in either group.

Patients had been allocated an admission date by hospital administrative staff based on the time that they were placed on the orthopaedic waiting list. The

opportunity to perform the study was facilitated by a change in hospital policy at our institution. All patients had given informed consent to undergo surgery and to receive either allogenic blood and/or autologous blood as required.

Patient demographics, underlying disease state, type of operation, tourniquet applied or not, haemoglobin levels, transfusion requirements, complications and duration of inpatient stay were all documented and recorded. In both groups either one or two wound drains were inserted depending on the preference of the operating surgeon.

The indications for donated allogenic blood transfusion were the same for both groups. During the operative period the decision to transfuse was made by the attending anaesthetist. In the postoperative period, the decision to transfuse allogenic blood was made by the attending surgeon. In both cases the decision to transfuse was made in accordance to the hospital transfusion protocol.

Transfusion Protocol :

1. Peri-operative transfusions should be considered to relieve symptoms of acute blood loss when crystalloid infusions have failed to correct intravascular volume depletion. Volume of transfused blood required should depend on :
   a. Intra-operative blood loss (> 1500 milliliters).
   b. Pre-operative haemoglobin / weight of patient.
   c. Patients risk of myocardial and/or cerebral ischaemia.
2. Post-operative blood transfusions should be considered if :
   a. Post-operative haemoglobin level is < 8 g/dl.
   b. Post-operative haemoglobin level is < 10 g/dl and the patient is symptomatic.

In Group A, wound drainage was carried out with standard closed suction drainage and the blood discarded. In Group B, blood collection was carried out in the theatre recovery room, and the elective orthopaedic ward, by trained nursing staff. All blood salvaged within the first six hours was re-infused, filtered but unwashed directly from the collection bag attached to the drain, intravenously. This could be repeated by further collections up to twelve hours post operatively. If less than 100 ml of blood was salvaged in any six hour period, the blood was discarded and no further blood was re-infused. Any drainage after twelve hours was discarded.

To enable cost analysis to be performed, the cost of allogenic blood, laboratory services and disposables was calculated. This was done using the costs in GB pounds as they were at the time of the study. The cost of disposables for suction drain group was calculated as the sum of the costs of the drains and standard blood giving sets used ; for the re-infusion drain group, this cost was calculated as the sum of the costs of the autologous blood salvage drain, additional autologous giving sets, additional autologous blood collection bags and standard blood giving sets used. The cost of allogenic blood, and laboratory services were calculated using the prices quoted by the transfusion service within our institution at the time that this study was performed. Calculations were made based on all patients being cross-matched two units of donated blood prior to surgery.

Statistical analysis was performed using GraphPad InStat version 3.00 for Windows 95, GraphPad Software, San Diego California USA. We used Fisher's Exact test for binary measurements and unpaired t-test with Welsh correction for continuous measurements, which followed normal distribution. Mann Whitney test was used for continuous measurements which did not follow a normal distribution. A value of $p < 0.05$ was considered significant.

Whether the values followed a normal distribution or not was determined using the Kolmogrov and Smirnov method.

Logistic regression analysis was performed to determine if any of other factors including age, sex and joint replaced affected whether the patient received blood transfusion or not. The logistic regression analysis was performed using the StatsDirect Software version 2.3.5.

RESULTS

The 186 consecutive patients who underwent primary unilateral uncemented hip or knee arthroplasty between 1st March and 30th November 2002 were included in the study. They were 71 (38.2%) males and 115 (61.8%) females. The mean age was 68.9+/-10.9 years (range : 27 to 91). Ninety-three underwent total knee replacement (TKR) and 93 total hip replacement (THR). All implants used were uncemented.

The two groups were similar in all respects. Ninety-two consecutive patients underwent operation with conventional closed suction drains and 94 consecutive patients had autologous drains. In the suction drain group, 47 patients (51%) underwent TKR and 45 (49%) underwent THR. In the re-infusion drain group 46 patients (49%) had TKR and

Table I. — Demographic and operative details

	Re-infusion drain	Suction drain
Number	94	92
Total Knee Replacement	46 (49%)	47 (51%)
Total Hip replacement	48 (51%)	45 (49%)
Males	37 (39%)	34 (37%)
Females	57 (61%)	58 (63%)
Mean age	68.9 years	68.8 years

48 (51%) had THR. There were 34 males (37%) and 58 females (63%) in the suction drain group as opposed to 37 males (39%) and 57 females (61%) in the re-infusion group. The mean age in the suction group was 68.8 years (range : 27 to 91) as compared to a mean age of 68.9 years (range : 34 to 88) in the re-infusion drain group (table I).

There was no significant difference in the mean preoperative haemoglobin levels of the two groups (Group A : 13.1+/-1.5 g/dl and Group B : 13.1+/-1.4 g/dl) (p = 0.936).

A mean of 333 ml (range 0 to 1,300) of postoperatively salvaged blood was re-infused in Group B. Thirty three patients in Group B had less than 100 milliliters of blood collected and did not receive any transfusion. If this subset is excluded, then 61 patients received a mean volume of 512 ml of salvaged blood.

A total of 164 units of allogenic blood were transfused. Group A received 113 units and Group B received 51 units. Forty-two (46%) patients in Group A and 21 (22%) in Group B received allogenic blood transfusions. This difference was statistically significant (p = 0.001). Analysis performed without controlling for other peri-operative factors showed that patients, in whom closed suction drains were used, were approximately three times as likely to receive an allogenic blood transfusion compared with those, in whom postoperative autologous blood transfusion drains were used (Odds ratio 2.92, 95% confidence interval : 1.546 to 5.514).

There was a statistically significant difference in the mean amount (units of packed red cells/patient) of allogenic blood transfused between the re-infusion drain group (0.54 units) and the suction drain group (1.23 units) (p = 0.003). This was mainly due to the difference in the percentage of people who received allogenic transfusion between the two groups. On comparison of only those patients who received allogenic blood, there was no significant difference in the number of units of allogenic blood transfused between the re-infusion drain group (2.43 units) and the suction drain group (2.69 units) (p = 0.264).

There was a small difference in the haemoglobin drop at 24 hours following surgery between the two groups with the re-infusion drain group dropping their haemoglobin level by 3.02 g/dl (23.3%) and the suction drain group by 3.36 g/dl (25.6%). However, this difference was not significantly significant (p = 0.07).

The mean transfusion and laboratory costs incurred were £ 176.53 for suction drain group and £ 116.91 for re-infusion drain group. The mean costs of disposables for the two groups were £ 20.20 and £ 65.80 respectively. Therefore the estimated overall cost was £ 196.75 by patient for suction drain group and £ 182.70 by patient for re-infusion drain group. The difference in the cost was statistically significant. (p = 0.009).

The mean length of postoperative in-patient stay was 12.6 days for the suction group and 11.0 for the re-infusion drain group. This difference is statistically significant (p = 0.0248). These findings are summarized in table II.

There were no transfusion or wound related complications during the in-patient period in the suction drain group as compared to 2 cases of wound haematoma in the re-infusion drain group. In one patient this was attributed to postoperative anticoagulation required for treatment of a myocardial infarction. In the other case it was not felt to be attributable to a problem with the drain as it occurred following a fall after the drain had been removed.

Age, gender, operation (TKR/THR) and the use of a tourniquet in TKR did not significantly affect the requirement for allogenic blood transfusion. The preoperative haemoglobin was significantly lower (12.37 g/dl) in those that required an allogenic transfusion than in those that did not receive allogenic blood transfusion (13.43 g/dl) (p < 0.0001). These findings are summarized in table III.

Table II. — Re-infusion drain versus suction drain

	Re-infusion Drain	Suction Drain	p value
Number	94	92	
Number of patients transfused	21 (22.3%)	42 (45.7%)	0.001
Mean number of units transfused	0.54	1.23	0.003
Number of units in only transfused	2.43	2.69	0.264*
Preoperative haemoglobin (g/dl)	13.06	13.08	0.936
Drop in haemoglobin (g/dl)	3.02	3.36	0.07*
Percentage drop in haemoglobin	23.3%	25.6%	0.09*
Costs with cross-match	£ 182.70	£ 196.75	0.009*
Mean hospital stay (days)	11.0	12.6	0.0248

* - Mann Whitney test was used, as the data was non-parametric.

Table III. — Other factors determining allogenic blood transfusion requirements

		No transfusion	Allogenic transfusion	p value
Number		123	63	
Age		67.8	71.0	0.0647
Sex	Male	49 (69%)	22 (31%)	0.5287
	Female	74 (64%)	41 (36%)	
Pre-op haemoglobin (g/dl)		13.43	12.37	< 0.0001
Haemoglobin drop (g/dl)		3.16	3.25	0.7006
Percentage drop in haemoglobin		23.61	26.03	0.0408
Operation	THR	60 (64.5%)	33 (35.5%)	0.7568
	TKR	63 (67.7%)	30 (32.3%)	
TKR	Tourniquet	40 (64.5%)	22 (35.5%)	0.4808
	No Tourniquet	23 (74.2%)	8 (25.8%)	

Stepwise logistic regression analysis was also performed to confirm the above findings. The best fit was obtained when only preoperative haemoglobin and type of drain were used as determinants.

DISCUSSION

Techniques for using autologous blood to reduce allogenic blood requirements in orthopaedic surgery have been slow in becoming part of widespread surgical practice (*43*). With the well recognized risks (*39*) and increasing costs of allogenic transfusion, health care providers are under pressure to reduce the employment of allogenic blood.

People have considered various factors to predict the requirement of blood transfusion preoperatively. In this study we have found that age, sex, type of surgery (hip or knee replacement), and tourniquet usage (in knee replacement) did not have any value in predicting the requirements of allogenic blood transfusion. However, pre-operative haemoglobin altered the requirements of allogenic blood significantly. This is consistent with the findings of various other studies (*5, 8, 34*).

Unlike most other techniques for maximizing the use of the patients' own blood, post-operative blood salvage requires no specialised personnel or additional sophisticated equipment. The costs of introduction of this system are therefore minimal.

There have been various concerns regarding the safety of re-infusing salvaged blood. Increased fibrinolytic activity in the closed wound and systemic circulation has been observed after re-infusion of postoperatively salvaged blood (*26*) and Southern *et al* found significantly increased levels of cytokines in the drainage blood serum (*42*). Clements suggested that the red cells should be washed before re-infusion (*6*). However a number of studies have suggested that re-infusion of filtered but unwashed blood is safe. Dalen-Tore demonstrated that despite incubation and complement activation, maximum erythrocyte haemolysis after 24 hours of incubation was less than 1%, and felt that filtered drain blood should be considered acceptable for re-infusion (*9*). The erythrocytes collected post-operatively from drains have been found to have a similar life span as normal erythrocytes (collected from intravenous blood) (*45*). Jensen *et al* analyzed the concentration of bioactive substances in the venous blood before and after re-infusion and found that there was no change in the coagulative capacity or the concentration of bioactive substances of patients (*24*). Bengsten *et al* found that there was no systemic activation of complement system or clinical complications after re-infusion of postoperatively salvaged blood (*3*). Dalén *et al* found no additional increase in temperature during the first two hours after an autologous retransfusion (*10*). However, Faris *et al* noted febrile reactions in nearly a fifth of the patients who had re-infusion of blood that was collected between 6 hours and 12 hours postoperatively (*14*). In our study re-infusion of unwashed, filtered autologous blood was well tolerated by patients. No re-infusions had to be stopped because of pyrexial episodes or other adverse transfusion reactions. This is in keeping with the findings of previous authors (*2, 14, 17*). The re-infusion of post-operatively salvaged blood appears to be safe but additional studies are required to determine the postoperative duration for which it is safe to continue collecting and re-infusing blood, and to determine the volume of blood that can be safely re-infused.

Previous studies have been contradictory regarding the efficacy of re-infusion of postoperatively salvaged blood. Numerous studies have demonstrated the efficacy of the post operative blood salvage in reducing the requirements for allogenic transfusion (*1, 17, 33, 35*) whereas others have found no significant decrease in the requirements of allogenic blood when the re-infusion drains were used (*28*). Pitsaer demonstrated that postoperative blood salvage was particularly useful in patients of small stature, and therefore with a small circulating volume and recommended its use in all patients weighing less than 70 kg (*37*). Umlas *et al* questioned the use of post operative blood salvage systems based on his observation that 6 hour wound drainage represented only 8.7 and 16.8 percent of the overall red cell loss for hip and knee replacement, respectively (*44*). Keating *et al* and Slagis *et al* found that post operative blood salvage and re-infusion was not cost effective because of the small quantities of blood collected (*25, 41*). There is evidence that when pre-operative donation or intra-operative cell salvage have also been used post-operative blood salvage is not effective (*1*). Our study demonstrates that the introduction of a post-operative autologous blood transfusion drain is an effective means of reducing the allogenic transfusion requirement of patients undergoing primary elective uncemented total hip or knee arthroplasty. One of the reasons that the autologous re-infusion drain was effective in our study may be that all the patients received uncemented prostheses, whereas in previous studies a variety of cemented and uncemented designs have been used. It may be that the post-operative bleeding following implantation of an uncemented prosthesis is greater than with cemented prosthesis.

The cost analysis performed using estimated costs at the time at which the study was performed showed a small, but significant reduction in cost with the autologous transfusion drain. We have not included cost of inpatient stay in our cost analysis. The inpatient stay for the group in whom salvage drains were used was significantly less than those in whom suction drains were used and inclusion of

inpatient stay costs would have increased the cost difference between the two groups. Whilst we accept that our cost analysis is a rather crude estimation from which limited conclusions can be drawn, we believe it is sufficient to demonstrate that the overall cost to the health care provider is unlikely to increase with the introduction of this system.

Some authors argue that cost-benefit analysis studies potentially underestimate the benefit of autologous transfusion systems, as allogenic transfusions are associated with an increased risk of infection (*15, 33*). However there may also be potential long term or rare complications of re-infusion of unwashed, filtered blood that have not yet been recognized.

CONCLUSION

In summary, the use of a postoperative autologous blood re-infusion drain was a cost effective means of reducing the requirement for allogenic blood transfusion following primary elective uncemented hip or knee arthroplasty. Although there were no drain or transfusion related complications in this study, a larger study with longer patient follow-up is required to determine the safety of postoperative autologous transfusion drainage systems.

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