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Investigation of the use of drained blood reinfusion after total knee arthroplasty: A prospective randomised controlled study

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ABSTRACT

Purpose. To compare the use of a blood salvage and reinfusion system with standard allogeneic blood transfusion after total knee arthroplasty—a procedure associated with significant postoperative blood loss.
Methods. Between June 2002 and May 2004, 60 patients undergoing total knee arthroplasty were randomly allocated into a reinfusion group (n=26) or a control group (n=34). Patients in the reinfusion group had their blood reinfused from drains within 6 hours of surgery. Both groups received allogeneic blood transfusions according to specified transfusion criteria if the haemoglobin level fell below 90 g/l, or in the presence of severe anaemic symptoms. Haemoglobin levels and drain output were recorded daily for 3 consecutive days after surgery.
Results. There was no significant difference between the 2 groups in demographic data, drain output, total blood loss, and mean postoperative haemoglobin levels. Significantly more allogeneic blood was required by the control group than by the reinfusion group (p=0.022).
Conclusion. Postoperative reinfusion of drained blood reduced the need for blood transfusion after total knee arthroplasty, while having an effect on postoperative haemoglobin level equivalent to standard allogeneic blood transfusion.

Key words: *arthroplasty, replacement, knee; blood transfusion, autologous*

INTRODUCTION

Allogeneic blood transfusion is considered the standard and most effective method of compensating for blood loss during surgery. It has been reported that total blood loss after total knee arthroplasty (TKA) can be as high as 1.5 litres,[1] making postoperative allogeneic blood transfusion inevitable. However, approximately 20% of all transfusions result in adverse effects, with 0.5% being severe.[2] Adverse reactions range from febrile reactions, allergic reactions,

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and viral disease transmissions to, rarely, severe incompatibility of the ABO blood group.

Both patients and surgeons are increasingly aware of the complications associated with allogeneic blood transfusion, particularly disease transmission. Safe methods of minimising the use of postoperative allogeneic blood transfusion are needed. Studies have shown that blood salvage and postoperative reinfusion can reduce the need for allogeneic blood transfusion and thus minimise its related adverse reactions, including various types of infection. However, these studies have not been randomised and controlled.[3,4] Both Newman et al.[5] and Woolson and Wall[6] recently studied the effectiveness of postoperative blood salvage in a randomised controlled setting and found it to be effective and even more cost-effective than allogeneic transfusion.

In Hong Kong, postoperative blood salvage for TKA patients is not uncommon. However, no similar randomised controlled study has been carried out to investigate the effectiveness of postoperative salvaged blood reinfusion and its associated adverse reactions.

MATERIALS AND METHODS

Between June 2002 and May 2004, 60 patients undergoing unilateral TKA in Kwong Wah Hospital, Hong Kong were enrolled in this prospective randomised controlled trial. Inclusion criteria were unilateral TKA; no severe heart disease, immunocompromised disease, chronic renal failure, rheumatoid arthritis, or seronegative arthritis; and a low risk of deep vein thrombosis and blood dyscrasia. The nature of the study and the possible adverse reactions resulting from reinfusion were carefully explained to each patient, and informed consent was obtained together with the surgical consent. This study was approved by the Ethics Board of the Hong Kong Hospital Authority's Kowloon West Cluster.

Patients were randomly allocated into a reinfusion group and a control group. Randomisation was by sealed opaque envelopes, which were well mixed by independent personnel and consecutively assigned a case number from 1 to 60. All surgeries were performed by specialists of the joint and reconstruction team using an identical surgical approach and technique. Two kinds of cemented tricompartmental knee prostheses were used, selection of which was based on surgeon preference and availability.

Near the end of each operation, the corresponding envelope was opened, and the surgeon was informed at the time of drain insertion to achieve a single-blind effect. Total intra-operative blood loss was recorded.

Table 1
Transfusion criteria according to Claudio[8]

Haemoglobin level (g/l)	Units of transfusion
81–90	1
71–80	2
61–70	3
50–60	4

Within 6 hours of surgery, patients in the reinfusion group had their blood reinfused from drains using a 40 μm blood filter between the collection bag and the intravenous site. Drain outputs were recorded at postoperative 6 hours and then daily until removal. All patients had their drains removed on postoperative day 2 or 3.

The reinfusion system used, DONOR (Van Straten Medical, Nieuwegein, the Netherlands), is an integrated, closed system designed for the collection and reinfusion of drained wound blood. It consists of an 800 ml chorine-free, pre-evacuated collection vessel, a vacuum regulator, and a 40-μm integrated filter for salvaged blood. This reinfusion system was found to be very easy to use by both operating theatre and ward personnel, particularly on tubing connections. The 40-μm filter effectively reduces more than 90% of lipid particles and nearly 80% of leukocytes from salvaged blood,[7] offering prophylactic protection against the clinical sequalae of reinfusion, such as fat embolism syndrome, febrile reactions, and pulmonary dysfunction. In addition, the system does not induce haemolysis. Cannulation of the reinfusion bag was performed by trained nursing staff. Any adverse reactions were recorded and the procedure was stopped if reactions were severe, as in conventional transfusion procedures. Both groups had their haemoglobin levels and drain output checked daily for 3 consecutive mornings. Allogeneic blood transfusions were given to both groups of patients according to the designated transfusion criteria (Table 1), or on the authority of the lead physician if the patient experienced severe anaemic symptoms. All demographic data, postoperative drain output, blood loss, haemoglobin levels, and allogeneic blood transfusion needed were compared between the 2 groups using the Chi squared test and student's *t* test, with 95% confidence interval. The sample size of the study was estimated with reference to the difference in transfusion requirement between the 2 groups (more than 50%) in a previous study.[9] It was then calculated to achieve a power of 0.9 (1-beta) using

Table 2
Preoperative comparison of the reinfusion and control groups

	Reinfusion group (n=26)	Control group (n=34)	p value
Mean age (range) [years]	72 (57–84)	69.4 (55–78)	0.83
Operating side (right/left)	14/12	18/16	0.944†
Pre-morbid condition* (yes/no)	14/12	22/12	0.306†
Sex (male/female)	6/20	12/22	0.306†
Prosthesis used (press fit condylar/Osteonic)	20/6	27/7	0.817†
Mean haemoglobin level (range) [g/l]	124 (104–154)	128 (96–147)	0.836

* Diabetes, hypertension, and ischaemic heart disease
† Chi squared test

Table 3
Comparison of postoperative results between the reinfusion and control groups

	Reinfusion group (n=26)	Control group (n=34)	p value
Mean total operative blood loss (range) [ml]	273 (100–600)	280 (100–800)	0.84
Mean total drain output volume (range) [ml]	638.5 (0–860)	683.2 (10–1930)	0.632
Mean haemoglobin level (range) [g/l]			
Immediately postoperative	101 (84–128)	104 (87–137)	0.332
Day 3	98 (77–130)	101 (77–130)	0.401
Grouped median units of allogeneic transfusion	0.15 (0–1)	0.46 (0–4)	0.033*
Patients requiring allogeneic transfusion (yes/no)	4/22	13/21	0.05†
Reinfusion volume (range) [ml]	425.2 (180–620)	N/A	
Febrile complications (yes/no)	2/24	1/33	0.403†

* Non-parametric Mann-Whitney *U* test
† Chi squared test

2-tail Chi squared test with 95% confidence intervals. The study followed the principle of 'intent to treat'.

RESULTS

There was no significant difference between the reinfusion and control groups in terms of patient age and weight, side of operation, type of prosthesis used, or mean preoperative haemoglobin level (124 g/l in the reinfusion group and 128 g/l in the control group) [Table 2]. Although patients with severe premorbid conditions were excluded, many of the patients had stable, controlled disease, such as diabetes, hypertension, and ischaemic heart disease. Nonetheless, the 2 groups were equivalent in terms of past health status. Postoperative total drain output and total operative blood loss were not statistically different between the 2 groups (Table 3).

As shown in Table 3, significantly more patients in the control group required allogeneic transfusions (Chi squared test, p=0.05). Furthermore, of the patients who received transfusions, those in the control group required significantly more blood than those in the reinfusion group (non-parametric Mann-Whitney *U* test, p=0.033). No significant difference was found between the 2 groups' mean postoperative haemoglobin levels, which were recorded for 3 consecutive postoperative days. All transfusions required in both groups were performed within these 3 days, with post-transfusion haemoglobin levels taken into account. The haemoglobin level was representative on day 3, as it was the resultant haemoglobin level after either reinfusion or allogeneic blood transfusion; there was no significant difference between the 2 groups.

There was also no significant difference between the 2 groups in febrile complication rate. Fevers that did occur subsided in one to 2 days with no serious consequences. No patients suffered from deep vein thrombosis requiring heparin prophylaxis or postoperative treatment. All reinfusions were finished within 6 hours of surgery, in reference to the recovery room arrival time.

One patient in the reinfusion group had a tubing blockage after transfusion of approximately 180 ml. The procedure was subsequently stopped and the drained blood discarded. All other patients were processed uneventfully.

DISCUSSION

Although many studies investigating the use of drained blood reinfusion after surgery have been published and many local centres have adopted a similar blood management programme, there has been no randomised controlled research to quantify the effectiveness of its use after TKA in Hong Kong Chinese population. This study showed that a significant reduction in the use of allogeneic blood transfusions could be achieved in patients undergoing TKA by postoperatively reinfusing the drained blood using a reinfusion filtration system.

In our series, 15.8% of patients with drained blood reinfusion required further allogeneic blood transfusion; whereas in the control group, nearly 40% of patients needed subsequent transfusions. That means nearly 85% of the reinfusion group did not require allogeneic blood transfusion after TKA. These results were comparable to those found in the literature,[8] although some studies have demonstrated even a lower rate of transfusion in reinfusion groups.[6] This may be due to a difference in the transfusion threshold.

Both groups of our patients were very similar in terms of demographic data and preoperative investigation results. Although surgeries were carried out by different surgeons, the approach and technique were the same, and the patients were supervised by the same consultant. Intra-operative blood loss was not significantly different. A pneumatic tourniquet was used in all patients; it was released and haemostasis was achieved before wound closure. It was very unlikely that outcomes were affected by these surgical details.

The transfusion criteria used was based on the study presented by Claudio[8] in 2000. It was a restrictive but safe transfusion strategy: transfusion was commenced when the haemoglobin level was below 90 g/l; a decrease of 10 g/l of haemoglobin level required one extra unit of blood transfused.

It is very difficult to create a double-blind setting because patients and nursing staff are able to see the reinfusion system. However, blinding the surgeon before drain insertion helped to reduce the bias of 'over-enthusiastic haemostasis' in the reinfusion group, and vice versa. Subsequent investigation, such as taking blood and charting drains, were carried out by independent personnel. Although inter-observer differences may arise in the charting of drain output by nursing staff, they are unlikely to affect outcomes. There may have been over-reinfusion in the treatment group because all drained blood was transfused, regardless of the patient's immediate postoperative haemoglobin level. This may have elevated the overall mean postoperative haemoglobin level by comparison. Although the transfusion criteria were used as a reference and we encouraged individual ward surgeons to follow the guidelines as closely as possible, it was unethical to withhold transfusions when required, such as in the presence of severe anaemic symptoms.

The expense for each unit of allogeneic blood transfused was around £125 (US$228.4).[9] The total cost of the reinfusion system used in this study, including replacement drain bottle, was less than HK$1000 (US$128.5). Because the procedures for setting up this reinfusion system are similar to those for standard allogeneic blood transfusions, it requires no additional medical personnel. The system is more cost-effective than conventional allogeneic blood transfusion.

The potential risk of reinfusing drained blood after surgery has been investigated. Some studies have reported that drained blood consists of decreased platelet counts, pH levels, and clotting factors, as well as an increase in fibrins degradation products.[9,10] Hand et al.[11] identified low levels of methyl methacrylate monomers in the filtered blood, although it was not clinically significant. Contra-indications to the use of unwashed shed blood have been formulated by the American Association of Blood Banks,[12] which suggests that various cytokines are activated in the drained blood and may pose problems for some patients if cytokines rise to a higher level more than 6 hours after bleeding.[13] In the present study and most of the previous studies, reinfusion was completed within 6 hours of surgery. No serious complications were detected in our series, including deep vein thrombosis, pulmonary embolism, or other coagulopathies.[14] However, our sample size might be too small to detect adequate complications.

In view of the very small risk of metabolic disturbance when using shed unwashed blood, some studies have advocated the use of temporary drain clamping following TKA to reduce blood loss.[14] As no significant differences were found between the 2 groups, such practice is of no clinical benefit. The complications associated with allogeneic blood transfusion include acute haemolysis (especially incompatibility of the ABO blood group mainly due to human error), transmission of infection such as viruses and bacteria, circulatory overload, immunosuppression, hypothermia, embolism, potassium intoxication (especially after prolonged blood storage), hypercalcaemia, and citrate intoxication. Reducing the use of allogeneic blood by abiding to strict guidelines has been stressed repeatedly.

In the present study, reinfusion of operative drained blood significantly reduced the requirement for allogeneic blood transfusion. Nearly 85% of patients in the reinfusion group required no allogeneic blood transfusion. Blood loss during TKA can be restored by drained blood reinfusion, which is as good as allogeneic blood transfusion. In addition, it is more cost-effective and therefore we believe that using a reinfusion system in blood management is worthwhile.

CONCLUSION

Postoperative drained blood reinfusion was effective in reducing allogeneic blood transfusion after TKA. The reinfusion process is safe and its use is more cost-effective than allogeneic blood transfusion.

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