A prospective randomised controlled trial of autologous retransfusion in total knee replacement

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We undertook a prospective randomised controlled trial to investigate the efficacy of autologous retransfusion drains in reducing the need for allogenic blood requirement after unilateral total knee replacement. We also monitored the incidence of post-operative complications. There were 86 patients in the control group, receiving standard care with a vacuum drain, and 92 who received an autologous drain and were retransfused post-operatively. Following serial haemoglobin measurements at 24, 48 and 72 hours, we found no difference in the need for allogenic blood between the two groups (control group 15.1%, retransfusion group 13% ($p = 0.439$)). The incidence of post-operative complications, such as wound infection, deep-vein thrombosis and chest infection, was also comparable between the groups. There were no adverse reactions associated with the retransfusion of autologous blood.

Based on this study, the cost-effectiveness and continued use of autologous drains in total knee replacement should be questioned.

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Although it has been reported that 'there is no conclusive evidence for or against the use of drains in joint arthroplasty',¹ there remains controversy regarding the best method of blood conservation. The risks associated with allogenic blood transfusion are well documented²⁻⁴ and numerous strategies have been employed to conserve blood following total joint arthroplasty.

Autologous retransfusion drains have become increasingly popular and their use has been supported by a number of studies.⁵⁻¹³ Alternative autologous strategies, including pre-operative donation¹⁴ and intra-operative cell salvage (processed blood),¹⁵ have distinct disadvantages, making their routine application undesirable. Techniques directed towards reducing blood loss, such as fibrin sealants, drain clamping and compression bandaging, have been reported to be successful in some studies,¹⁶⁻¹⁸ although not as part of large, prospective, randomised controlled trials.

Although evidence supports the notion of a reduced allogenic blood requirement with the retransfusion of collected blood,⁵⁻¹³ some studies have called this into question.^{15,19-21} Table I outlines some prospective, randomised controlled trials in the literature that have studied autologous drains and compared them with standard vacuum drainage in total knee replacement (TKR).

In order to clarify this debate further, we report the outcome of a prospective, randomised controlled trial comparing the use of allogenic blood and the incidence of peri-operative complications after uncomplicated TKR when using either standard vacuum drainage (blood discarded) or autologous retransfusion drains.

Patients and Methods

We undertook this trial with the approval of our local ethics committee. The study was conducted in a large district general hospital.

Between May 2005 and December 2005, 178 patients were entered into the study. In a pre-assessment clinic patients were randomly assigned into two groups (standard drain or autologous retransfusion) by sealed envelope after a full discussion about the trial and after providing specifically-designed information leaflets. All patients aged over 55 years with osteoarthritis and/or inflammatory arthritis of the knee, and awaiting TKR, were considered for the study. Patients with bleeding disorders and Jehovah's Witnesses were excluded. Intra-operatively, patients requiring a more complex procedure, such as the insertion of stemmed implants and augments, were excluded. Patient demographics, including gender, age and pre-operative diagnosis, are shown in Table II. There were 86 patients in the control

Table I. Published prospective randomised controlled trials assessing the efficacy of autologous retransfusion drains compared with standard vacuum drainage in patients undergoing unilateral total knee replacement

Authors	Number of patients			Patients needing allogenic blood (%)		Reduction of allogenic blood usage (%)
	Control group	Study group	Autologous drain	Control group	Study group	
Majkowski et al ⁵	20	20	Solcotrans	95	35	64
Hedde et al ⁸	40	39	Solcotrans	67.5	25.7	62
Newman et al ⁷	35	35	Dideco 797	80	9	86
Steinberg et al ⁶	171	194	SureTrans	52	18.6	65
Cheng et al ²⁵	34	26	DONOR	62	18	44
Abuzakuk et al ²¹	52	52	Bellovac	23	25	0
This study	86	92	Bellovac	15.1	13	2

Table II. Patient demographics

	Control group	Study group
Mean age in yrs (range)	70.4 (57.9 to 87.1)	70.3 (55.2 to 88.5)
Gender (men:women)	39:47	43:49
Pre-operative diagnosis (OA:RA)*	3:83	5:87

* OA, osteoarthritis; RA, rheumatoid arthritis

group (standard vacuum drain) and 92 in the study group (autologous retransfusion drain).

Surgical technique and post-operative management. All patients received a cemented total condylar knee replacement. The implants used were the press-fit condylar (PFC) (Depuy, Leeds, United Kingdom), Freeman-Samuelson (Finsbury Orthopaedics, Leatherhead, United Kingdom) or Natural Knee II (NKII; Zimmer Ltd, Swindon, United Kingdom). The surgical technique, particularly the retention or substitution of the posterior cruciate ligament (PCL), varied between four teams, as did the techniques of anaesthesia, but the principles were similar. The PCL was preserved in 15 patients (17.4%) in the control group and 18 (19.6%) in the study group. Before inflation of a pneumatic tourniquet, all patients received one 1.5 g dose of intravenous cefuroxime and two further 750 mg post-operative doses at eight-hourly intervals. The tourniquet was released before closure and one deep drain was inserted within the joint space. The drain was connected either to a standard vacuum chamber or to the Bellovac ABT autotransfusion system (Astra Tech, Mölndal, Sweden). The negative pressure in the standard vacuum drains was 100 mmHg and in the Bellovac system 90 mmHg. The Bellovac consisted of a blood collection suction bellows connected to an autologous transfusion bag with a 200 mm filter, and a one-way valve. The transfusion bag was connected to a transfusion set with a 40 mm filter. The drain was opened 20 minutes after tourniquet release. The shed blood was returned to the patient after collecting up to 500 ml and no later than six hours after surgery. A maximum of 1200 ml was retransfused. Blood collected

into the vacuum drains of the control group was discarded.

Thromboprophylaxis was continued until the patient was discharged and comprised one daily 2.5 IU dose of fragmin (a low-molecular-weight heparin (LMWH)) and anti-embolism stockings. During the post-operative period individual teams made their own decisions about the use of antibiotics for potential wound infections or the discontinuation of LMWH for persistent wound drainage.

Transfusion criteria. We standardised the transfusion criteria in order to allow an accurate comparison between the two groups. Allogenic blood was transfused if the haemoglobin level fell below 8 g/dl, or if the patient developed clinical signs of anaemia, such as tachycardia and postural hypotension, in the presence of a haemoglobin level of 8 g/dl to 10 g/dl. All drains were removed 24 hours after surgery and the volume of blood collected was recorded. Haemoglobin measurements were taken at 24, 48 and 72 hours, and the overall length of stay in hospital was noted. The use of allogenic blood transfusions and post-operative complications, including wound infection, thromboembolic events and returns to the operating theatre, were also recorded.

Statistical methods. The sample size was calculated based on a reduction in transfusion requirement of 50% between the two groups, with a power of 90% at the 5% significance level. Statistical analysis was performed using a one-way analysis of variance (ANOVA) for the assessment of change in haemoglobin levels over time. Student's *t*-test was used to analyse differences in drainage between the two groups. Chi-squared analysis was used to assess the allogenic blood transfusion requirements and the length of stay between the groups. All analyses were undertaken using SPSS version

Table III. Pre- and post-operative haemoglobin levels and use of allogenic blood for control and study groups

	Control group	Study group	p-value
Mean (SD) pre-operative haemoglobin (g/dl)	13.4 (1.33)	13.2 (1.22)	0.864*
Mean (SD) post-operative haemoglobin (g/dl)			
24 hours	10.4 (1.59)	10.5 (1.49)	0.998†
48 hours	10.2 (1.49)	10.5 (1.48)	0.951†
72 hours	10.8 (1.58)	11.0 (1.40)	0.968†
Mean (SD) change in haemoglobin (g/dl)	2.6 (0.8)	2.2 (0.7)	0.354†
Use of allogenic blood (number of patients/total units of blood transfused)	13/26	12/22	0.439*

* chi-squared test

† analysis of variance

Table IV. Length of stay and peri-operative complications for control and study groups

	Control group	Study group	p-value (chi-squared test)
Mean length of stay in days	7.0 (3 to 16)	6.6 (3 to 14)	0.54
Complications			
Wound infection	2	3	-
Deep-vein thrombosis	2	1	-
Persistent wound drainage (no infection)	1	2	-
Other infections*	2	2	-
Returns to operating theatre	0	1	-

* urinary tract and chest

11.0 for Windows (SPSS Inc., Chicago, Illinois). A p-value < 0.05 was considered statistically significant.

Results

The mean drainage volumes between the two groups were comparable, being 638 ml (86 to 1470) in the control group and 659 ml (100 to 1900) in the study group. This difference was not significant (Student's *t*-test, $p = 0.468$). Of the 92 patients in the study group, 84 (91.3%) were retransfused with a mean of 481 ml of blood (200 to 1110). There were five patients who were not retransfused because of low drainage volumes (< 100 ml) and three patients who were not retransfused because of technical difficulties such as problems with the tubing and filter system. These patients were included in the study based on an 'intention to treat' principle. There were no retransfusion-associated complications.

Table III shows the changes in haemoglobin levels and the use of allogenic blood in both groups. The difference between the mean change in haemoglobin level for the two groups was insignificant (ANOVA, $p = 0.354$). There were 13 patients (15.1%) in the control group who required an allogenic transfusion, compared with 12 (13%) in the study group. This difference was not significant (chi-squared test, $p = 0.439$).

The mean overall length of stay was comparable between the two groups (control group 7 days (3 to 16), study group 6.6 days (3 to 14) ($p = 0.54$)). Peri-operative complications and returns to theatre were also comparable (Table IV). There was one patient in the study group who was returned

to the operating theatre for re-suturing of a wound dehiscence.

Discussion

Significant complications after allogenic blood transfusions have been well reported in the literature.²⁻⁴ However, the best method of reducing the need for transfusion after TKR remains contentious. This study has re-examined the potential benefits of autologous retransfusion compared with standard vacuum drainage after a unilateral TKR.

Autologous retransfusion has gained popularity among patients exposed to the concept, certainly in this study, and by the orthopaedic community as a whole.⁵⁻¹³ A recent study recommended its use when combined with tranexamic acid in revision hip surgery.²² Initial concerns about the safety of unwashed filtered blood²³ have been tempered by more recent studies^{5,7,13} suggesting that autologous retransfusion remains safe provided certain protocols are followed. These include abiding to maximum transfusion volumes and retransfusing the blood within six hours of surgery, thereby minimising any haematological or immune reactions.²⁴ There were no retransfusion-associated complications in our study using this protocol.

Newman et al,⁷ in a prospective randomised trial, reported a reduced frequency of febrile episodes with retransfusion compared with allogenic transfusion after standard vacuum drainage. Despite this finding, only 70 patients were studied and a large percentage (80%) of the control group required allogenic blood. Additionally, the long-term sequelae of these febrile episodes were not

reported. We found no difference in the incidence of peri-operative complications and returns to theatre between our two groups. This direct analysis has rarely been documented in similar studies.^{5,7,8,21}

Traditionally, blood collected in a vacuum drain is discarded and decisions about transfusion are individualised, taking into account local protocols and patient comorbidities. There is therefore a widespread discrepancy in the literature with respect to transfusion triggers and the use of allogenic blood. The rate of allogenic transfusion in this study was low and comparable between the groups (15.1% control group, 13% retransfusion group). This is in contrast to the published literature (Table I).^{5-8,21,25} The studies, which support the use of autologous drains, each report more than 50% allogenic blood requirement in their control groups. Majkowski et al⁵ reported a 95% allogenic blood requirement in their control group, although their randomised study only included 40 patients. We can only speculate, but our reduced transfusion rate with standard suction drainage (15.1%) may relate partly to the transfusion criteria we used. We have shown that with more structured transfusion protocols, patients can be safely shielded from allogenic blood without the need for additional blood conservation strategies.

The need for a drain in TKR has been repeatedly questioned.^{1,20} Although debate continues, the potential benefits of an autologous drainage unit can only be assessed within the remit of a randomised study which includes a treatment arm that uses no drain. Adalberth et al²⁰ prospectively randomised 90 patients into three such groups (no drain, standard vacuum drain, autologous reinfusion drain). They found no difference in the need for allogenic blood transfusion between the groups. A larger study of this nature is clearly required to clarify this further.

Our study therefore confirms the safety, but casts doubt over the efficacy, of retransfusion drains in reducing the need for allogenic transfusion compared with standard suction drainage after TKR.

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Supplementary Material

A further opinion by Dr M. Dunbar is available with the electronic version of this article on our website at www.jbjs.org.uk

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