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ORIGINAL PAPER

Autotransfusion drains in total knee replacement. Are they alternatives to homologous transfusion?

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Abstract We prospectively randomised 104 consecutive patients undergoing primary cemented total knee arthroplasty into two groups of 52 patients each, with one group to receive a standard suction drain (Redivac) and the other, an autologous transfusion drain (Bellovac). Randomisation was achieved using the software programme MINIM, which was set to randomly allocate patients to either of the two groups based on their age, sex and body mass index (BMI). All procedures were performed under pneumatic tourniquet. Drains were released in the recovery room 20 min after surgery and removed 24 h following surgery. Blood collected in the standard suction drain (control group) was discarded, while blood collected in the autologous transfusion drains (study group) was transfused unwashed back to the patient within 6 h of collection. Thirteen patients (25%) in the study group had two or more units of homologous blood transfused in addition to the blood collected postoperatively and re-transfused (average: 438 ml). Twelve patients (23%) in the control group had two or more units of homologous blood transfused. No sepsis, transfusion reactions or coagulopathies were associated with the autologous blood transfused in the study group. The use of the autologous transfusion system (Bellovac) proved to be safe but failed to reduce the need for postoperative homologous blood transfusion following uncomplicated total knee arthroplasty.

Résumé Nous avons étudié, de façon prospective randomisée, 104 patients consécutifs ayant bénéficié d'une prothèse totale du genou cimentée. Chaque patient a reçu soit un drain aspiratif standard (Redivac) soit un drain permettant une retransfusion (Bellovac). 52 patients ont été randomisés dans chaque groupe à l'aide d'un programme software avec une excellente concomitance entre l'âge, le sexe et le BMI. Toutes les interventions ont été réalisées avec garrot. Les drains ont été mis en aspiration en salle de réveil, 20 minutes après la fin de l'acte chirurgical. Ces drains ont été ôtés 24 heures après la chirurgie. Le sang collecté dans le drain standard a été rejeté alors que le drain Bellovac a permis de récupérer le sang, le retransfuser sans lavage six heures après l'intervention. 39 patients (25%) dans le groupe standard ont eu deux, ou plus de deux, unités sanguines de transfusion en plus du sang récupéré dans le drain (438 ml en moyenne). 12 patients (23%) dans le groupe contrôle ont eu deux, ou plus de deux, transfusions. Il n'y a pas eu d'infection, de réaction sanguine après ré-infusion du sang du redon. L'utilisation d'un système de réutilisation du sang de type Bellovac n'entraîne pas de problèmes particuliers mais il ne permet pas de diminuer la nécessité de transfusions post-opératoires après une prothèse totale du genou standard sans complication.

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Introduction

The use of autologous transfusion drain systems in total joint arthroplasty has been the focus of many published studies [1, 2, 4, 5, 7, 9–11, 13, 15, 16, 18, 19]. A few studies have shown that more than 70% of patients required a blood transfusion following total knee arthroplasty [18, 19].

The use of homologous blood transfusion has potential health risks, among which are the transmission of blood-borne infections, allergic reactions, immunomodulatory effects and human error in administering the blood [3]. The search for alternatives to the use of homologous blood

Table 1 Randomisation schedule according to the MINIM programme

Confounders		Autotransfusion drain group (n=52)	Standard drain group (n=52)
Age (years)	40–60	8	9
	60–75	25	24
	75–90	19	19
Sex	Male	21	31
	Female	22	30
Body mass index (BMI)	<20	1	2
	20–30	30	28
	>30	21	22

has become a primary research topic among orthopaedic surgeons, and many methods have been tried – with variable success – including the pre-operative donation of blood, erythropoietin injections, perioperative blood salvage [8] and autologous transfusion drains.

Recent technical developments have facilitated autologous blood transfusion, and the idea of reinfusing blood collected in the drain following total joint arthroplasty is becoming increasingly attractive to many surgeons. Most surgeons perform total knee replacement under tourniquet control. In this case, no blood is lost during the actual surgery, although the blood loss following surgery can be considerable. Reinfusion of the collected blood is desirable, but much controversy exists in the literature regarding the effectiveness of reinfusion drain systems.

Simpson et al. [18] reported a reduction of over 50% in the use of homologous blood in a study group of 12 patients where reinfusion drain systems were used in a total knee replacement. Newman et al. [15] in a randomised controlled study of 70 patients undergoing total knee arthroplasty found that the need for homologous blood transfusion was reduced by 80% when autologous reinfusion drains were used. However, other investigators have failed to achieve such good results using these drains, while still others have even questioned the use of drains at all in total joint arthroplasty [1, 5, 14, 17].

This prospective randomised controlled trial was designed to study the Bellovac drainage reinfusion system (Astra, Mölndal, Sweden) in total knee replacement. The aim was to evaluate the use of such systems in knee replacement and to determine whether such systems can be used as alternatives to homologous blood transfusion following primary uncomplicated total knee arthroplasty.

Materials and methods

Study design and statistical methods

This was a prospective, randomised controlled trial. A total of 104 consecutive patients undergoing primary total knee arthroplasty were selected. Fifty-two patients were allocated to each group. The sample size was chosen in order to detect a reduction in the percentage of patients requiring transfusion from 30 to 10% with 80% power at the 5% significance level.

All patients undergoing primary uncomplicated total knee replacements were included in the study. Patients undergoing revision total knee replacement and primary total knee arthroplasty with previous surgery were excluded.

Randomisation process

Patients were randomised to receive the autologous reinfusion drain or standard suction drain using the software programme MINIM [6]. This is a special computer programme which, after the confounders of the patients were entered into the programme at the time of surgery, allocated the patients to either of the groups and advised on which drain to be used. This means that each time a patient was entered into the trial, the programme allocated him/her to an 'arm', which resulted in the control and the study group being equally matched for those confounding factors when the analysis was performed. The programme uses the minimisation method to achieve a good balance of patient demographics [in this study: age, body mass index (MBI) and sex] (Table 1).

We used the minimisation method because we anticipated the confounders to be important and, therefore, a balance between the groups was necessary.

Surgical methods

The procedures were performed under pneumatic tourniquet. The surgical exposure and technique as well as the post-operative management were identical in all patients, and all components were fixed with Palacos gentamicin bone cement. The tourniquet was released after the wound had been closed, and a pressure bandage was then applied. The same surgeons performed all of the procedures, and the closure technique was standardised. One deep drain was inserted at the end of the operation. The drain was opened in the recovery room 20 min after the tourniquet was released. The amount of blood loss (including that in the dressing) was noted 24 h after surgery when the drain was removed regardless of the amount drained.

The collected blood of the patients of the control group was discarded. However, if the blood collected in the reinfusion drain was more than 150 ml, it was transfused back into the patient unwashed, and a new bag was then attached to the drain. The process was repeated if the amount of blood collected again exceeded 150 ml.

All patients followed a similar physiotherapy programme. Mobilisation started as soon as the drain and dressings were removed.

Table 2 Patient demographics

Demographic characteristics	Autotransfusion drain group[a] (n=52)	Standard drain group[a] (n=52)
Pre-operative Hb[b] – mean (g/dl)	13.6 (±1.5)	13.5 (±1.2)
Post-operative Hb (day 2) − mean (g/dl)	10.8 (±1.6)	10.1 (±1.3)
Post-operative Hb (day 5) – mean (g/dl)	10.6 (±1.5)	10.1 (±1.3)
Hospital stay – mean (days)	8.1 (±2.4)	8.3 (±2.8)
Average unit of homologous transfusions	2.3	2.3
Blood drainage following surgery – mean (ml)	673 (±355)	867 (±434)
Number of patients requiring homologous blood transfusions	13	12
Autologous blood re-infused – mean (ml)	439 (±318)	0

[a]Standard deviation, where appropriate, is given in parenthesis
[b]Hb, Haemoglobin

All patients received 20 mg enoxaparin sodium daily starting on day 1 post-operatively. Foot pumps and TED anti-embolism stockings were also used for thrombo-embolic prophylaxis, and these were continued until the patient was discharged.

A haemoglobin check was performed on days 2 and 5 post-operatively. A homologous blood transfusion was give if the haemoglobin count on these days was less than 9 g/dl. Wound problems and knee range of motion were all recorded over the period of hospital stay.

Results

Patient's disposition and characteristics

Demographic characteristics were well matched between the two 'arms' of the study (Table 2). Forty-three males and sixty-one females with an average age of 68.5 years and average BMI of 28.8 were studied.

Fifty-two patients were allocated to each group. The average operating time for the two groups was 86 minutes.

Homologous blood transfusion requirement

In the study group, 43 patients received reinfusion of the drained blood within the first 24 h following surgery; the mean volume transfused was 438 ml. Thirteen patients (13/52) had homologous blood transfusion in addition to the reinfused blood; the mean volume transfused was 2.3 units. In the standard suction drain group, 12 patients (12/52) required homologous blood transfusion following surgery; the mean volume transfused was 2.3 units.

Problems with drains

Nine patients in the autologous drain group had no reinfusion of drained blood for various reasons. Two patients developed raised temperature following transfusion, which was treated; however, no allergic reaction appeared.

In three patients less than 150 ml of blood drained into the autologous drain within 6 h and, therefore, reinfusion was not possible. Four patients had no reinfusion due to technical problems with the autologous drain. Only two of this group of patients required homologous transfusion for low haemoglobin following surgery.

Statistical analysis

There was no statistical significance in the number of homologous blood transfusions required in the two groups. However, there was a statistically significant greater fall in the haemoglobin of the control group on day 2, 10.1 g/l compared with 10.8 g/l in the study group (t=2.49, df=102 p=0.014). This had no clinical significance.

The average operative time and hospital stay were the same in both groups. No wound problems were noted, and all patients achieved a flexion of 90° before discharge from the hospital.

Discussion

The use of drains in total joint arthroplasty continues to be a controversial topic in orthopaedic literature, and many studies have reported considerable doubt with respect to the benefits of their usage [1, 5, 12]. However, other studies have shown a significant reduction in the rate of homologous blood transfusion following the use of autologous drain reinfusion systems.

Groh et al. [9] retrospectively reviewed 25 consecutive patients who had total knee replacements in which the Solcotrans re-infusion system was used, and compared these to controls who had standard suction drains. Only two patients in the Solcotrans' group required homologous transfusion compared to ten patients in the control group. Sinha et al. [19] studied 100 patients with total knee

replacements in which 50 patients had autologous reinfusion drains and the other 50 had standard suction drains. Homologous blood transfusion was reduced by 80% in the study group. Healy et al. [11] prospectively randomised 128 patients undergoing total hip and knee replacements and spinal fusions into three groups: two groups were given autologous reinfusion drain systems while the third group used a standard suction drain. Homologous blood transfusion was reduced by 60% in the autologous reinfusion drain groups. Newman et al. [15] studied 70 patients undergoing primary total knee replacements within the framework of a randomised, controlled trial. Three patients in the autologous reinfusion drain group required homologous blood transfusion compared to 28 patients in the control group.

Contrary to the above mentioned results in which the use of the autologous drainage system was shown to be advantageous, Faris et al. [7] reported that the drainage available from unilateral total knee arthroplasty is insufficient to influence post-operative haemoglobin.

Adalberth et al. [1] prospectively randomised 90 patients undergoing total knee arthroplasties into three groups: group one had no drains, group two had autologous reinfusion drained and the third group had standard suction drain. Based on their observations that the number of units of homologous blood required in the three groups did not differ, these investigators concluded that there were no benefits from using the post-operative drainage system in total knee arthroplasties. Ritter et al. [17] in a prospective randomised trial compared the use of the Solcotrans autologous reinfusion drain system with the use of no drains in 415 patients undergoing total hip and knee replacements. They concluded that the use of drainage system in total hip and knee replacements was unnecessary.

Marks et al. [14] reviewed 144 patients who had primary total hip and knee arthroplasties. The patients were divided into two groups: the control group (n=88) included patients who either received a disposable drainage system or the Solcotrans system and had inadequate drainage for autotransfusion; the study group (n=56) included patients who had Solcotrans reinfusion drain systems. The conclusions of the investigators was that the Solcotran drain system failed to reduce the need for homologous blood transfusion following surgery in the post-operative period. In addition, these investigators were unable to explain the discrepancy between their results and those of other studies that did show reduced usage. However, they did suggest that releasing the tourniquet before closing the wound could have had an effect. Our results match these in that the drain in our study was released in the recovery room 20 min after surgery.

We observed that seven of the 13 patients in the study group who required homologous blood transfusion received it after day 5 when their haemoglobin eventually fell below 9 g/dl. In the control group, only one patient required homologous blood transfusion on day 5, while all of the others required homologous transfusions on day 2 following surgery. This is a direct result of the haemoglobin level in the patients of the study group being significantly higher on day 2 than in patients of the control group and suggests that autologous reinfusion prevents a rapid fall in the haemoglobin level during the early post-operative period. However, by day 5 this benefit has disappeared.

The point at which to administer a blood transfusion is controversial; in this study, the trigger haemoglobin value for transfusion was 9 g/dl. This value is typical of those reported elsewhere. We agree that this is currently considered to be a high trigger value for transfusion and clinical symptoms of anaemia should always be considered in the decision of transfusion.

We agree with Faris et al. [7] and others that the use of autologous blood collected in the drains is safe and does not result in adverse reactions, but we failed to show that such systems reduce the need for post-operative homologous transfusions.

Staff need to be trained on the use of these drainage systems. In addition, the practical application of the drainage system is time-consuming as nurses have to observe the amount of blood drained and – when a sufficient amount has been collected before the 6-h limit – to start the reinfusion process.

Conclusion

This randomised, controlled trial failed to show the benefits of autologous re-infusion drain systems (Bellovac) and also failed to show that such systems can be used as an alternative to homologous blood transfusion following primary total knee arthroplasty.

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