A prospective comparison of clamping the drain or post-operative salvage of blood in reducing blood loss after total knee arthroplasty

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We undertook a prospective, randomised study in order to evaluate the efficacy of clamping the drains after intra-articular injection of saline with 1:500 000 adrenaline compared with post-operative blood salvage in reducing blood loss in 212 total knee arthroplasties. The mean post-operative drained blood volume after drain clamping was 352.1 ml compared to 662.3 ml after blood salvage (p < 0.0001). Allogenic blood transfusion was needed in one patient in the drain group and for three in the blood salvage group. Drain clamping with intra-articular injection of saline with adrenaline is more effective than post-operative autologous blood transfusion in reducing blood loss during total knee arthroplasty.

Patients undergoing total knee arthroplasty (TKA) require blood transfusion. Although the incidence is low, serious complications involving homologous blood transfusions, such as viral infections and graft versus host disease, have been reported. Blood transfusion also involves additional cost so a reduction in its use is important in the peri-operative period. There are two current methods for avoiding homologous blood transfusions. One is by autologous blood transfusion, including pre-operative autologous donation, intra-operative autologous donation, intra-operative autologous transfusion and post-operative blood salvage. The other is a reduction in blood loss using techniques such as hypotensive anaesthesia, drain clamping, use of fibrin tissue adhesive, compression bandaging and cryotherapy.

When a TKA is performed with the use of a tourniquet, most blood loss occurs after surgery. Among the various management strategies to deal with post-operative bleeding, several papers have described the efficacy of the post-operative collection and reinfusion of shed blood. Recently, drain clamping has received increasing attention.

In 1988, Sakihara et al reported a method of reducing post-operative bleeding whereby saline was injected through a drain tube after wound closure and the tube was then clamped for one hour. Since then further papers addressing drain clamping in TKA have been published in the English literature (Table I). In 1997, Ryu et al showed that infusion of saline with adrenaline reduced post-operative bleeding in comparison with saline alone. Yamada et al compared one-hour and 24-hour drain clamping after TKA. They concluded that the haemostatic effects were similar for each but that there were significantly more complications after 24-hour clamping. They recommended clamping for one hour to minimise complications. Meanwhile, Kiely et al clamped drains for two hours without infusion of saline and reported no significant differences in blood loss and post-operative haemoglobin levels between the clamping group and controls. Consequently, the efficacy of drain clamping in post-operative management and the effect of the additional use of adrenaline on the reduction of bleeding, has not been clarified. No study has compared

Table I. Studies of drain clamping in total knee arthroplasty (TKA)

<table>
<thead>
<tr>
<th>Authors</th>
<th>Number of TKA</th>
<th>Clamp time (hrs)</th>
<th>Volume of saline (ml)</th>
<th>Adrenaline concentration</th>
<th>Mean intra-operative volume of blood loss (ml)</th>
<th>Mean post-operative volume of drained blood (ml)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ryu et al</td>
<td>116</td>
<td>20</td>
<td>50</td>
<td>1:200 000</td>
<td>-</td>
<td>207</td>
</tr>
<tr>
<td>Yamada et al</td>
<td>22</td>
<td>1</td>
<td>50</td>
<td>1:200 000</td>
<td>215</td>
<td>247</td>
</tr>
<tr>
<td>Kiely et al</td>
<td>31</td>
<td>2</td>
<td>0</td>
<td>1:200 000</td>
<td>-</td>
<td>806</td>
</tr>
<tr>
<td>Current study</td>
<td>106</td>
<td>0.5</td>
<td>30</td>
<td>1:500 000</td>
<td>-</td>
<td>352</td>
</tr>
</tbody>
</table>
drain clamping with other post-operative measures to control post-operative bleeding. The object of this prospective, randomised study was to evaluate the efficacy of drain clamping after intra-articular injection of saline with adrenaline, as compared with re-infusion of blood collected post-operatively, in reducing blood loss in TKA.

**Patients and Methods**

This was a prospective, randomised study. All patients undergoing TKA between April 1999 and July 2001 were enrolled. Those with rheumatoid arthritis, revision TKA and simultaneous bilateral TKA were excluded. Patients were alternately assigned to one of two groups. In the first, drain clamping was performed after injection of saline with adrenaline (1:500 000) into the knee joint. A 16-gauge plastic needle was connected to the drain tube and a retrograde injection of saline with adrenaline was performed. In the second, post-operative blood salvage was used. The number of patients, the ratio of men to women, the age at operation, diagnosis and comorbidity were comparable and are described in Tables II and III. Predonation of autologous blood was not carried out for any patient.

We operated on six knees under a general anaesthetic, and the remaining 206 knees under spinal anaesthesia. All TKAs were unilateral using a medial parapatellar approach and a tourniquet. The tourniquet was not released before skin closure. For bony resection, an intramedullary alignment jig was used for the femur with an extramedullary device for the tibia. In 68 the patella was resurfaced and in 144 it was not. The posterior cruciate ligament was resected in 52 TKAs and retained in 160. The types of implant used were: Scorpio (Howmedica Osteonics Corp., Mahwah, New Jersey) in 75 knees, PFC Sigma (Depuy Orthopaedics Inc., Warsaw, Indiana) in 69, 7000 series (Howmedica Osteonics Corp.) in 30, LCS (Depuy; Johnson and Johnson) in 14, Advance (Wright Medical Technology Inc., Arlington, Tennessee) in 13 and Interax (Howmedica Osteonics Corp.) in 11. Hybrid fixation was used in 175 TKAs and full cementation in 37.

**Post-operative management.** In the drain clamping group, immediately after wound closure 30 ml saline containing 1:500 000 adrenaline was injected through a 3.2-mm diameter Port-VAC (Howmedica International SdeRL, Limerick, Ireland) drain. The drain tube was attached to a Y-connector which had a tube of 6.4 mm in diameter leading to the bellows. This tube was clamped and closed completely for 30 minutes, then the clamp was partially released until saline and blood started to flow out. If the flow of saline and blood ceased, the clamp was further opened until saline and blood flowed once again. Finally the clamp was fully opened. Shed blood was not re-infused. During release of the clamp, the volume of blood drained and the patient’s general condition were carefully monitored.

In the blood salvage group, the ConstaVac blood conservation system 2 (Stryker Instruments, Kalamazoo, Michigan) was used. Blood was collected through a drainage tube of 4.8 mm in diameter. In all TKAs in this group, a battery pump was used for the evacuation of blood, and a low suction pressure was chosen. The blood passed through a 200 µm filter on its way to the 800 ml sterile reservoir in order to remove gross debris. In the reservoir, blood was not mixed with a citrate anticoagulant but was re-infused into the patient within six hours of surgery. After re-infusion of the salvaged blood, the suction switch was turned off, while the drain remained in place for 48 hours.

In both groups, only one drain was placed deep to the fascia in the knee joint. A superficial drain was not used for any TKA. In both groups, the drains were removed at 48 hours and the volume of remaining fluid was measured. Continuous passive motion began after removal of the drains. For the prevention of deep-vein thrombosis, an arteriovenous impulse system (Novamedix, Andover, Hampshire, UK) was used in all patients.

**Assessment.** We reviewed the patient's notes, and recorded the volume of drained blood, the rate of allogenic blood transfusion, and the pre- and post-operative haemoglobin levels. The haemoglobin level was measured before surgery and at one day, one week and one month after the procedure. The re-infusion rate of retrieved blood and the volume of re-infused blood was evaluated in the blood salvage group. The operation time and the pre- and post-operative ranges of movement were also recorded, while alignment in the coronal plane was assessed on a standing anteroposterior radiograph.

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**Table II. Patient profiles**

<table>
<thead>
<tr>
<th>Group</th>
<th>Number of patients</th>
<th>Men:women</th>
<th>Mean age at operation in yrs (SD)</th>
<th>Osteoarthritis</th>
<th>Osteonecrosis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drain clamping</td>
<td>106</td>
<td>13:93</td>
<td>72.8 (6.4)</td>
<td>102</td>
<td>4</td>
</tr>
<tr>
<td>Blood salvage</td>
<td>106</td>
<td>10:96</td>
<td>72.6 (6.1)</td>
<td>103</td>
<td>3</td>
</tr>
</tbody>
</table>

**Table III. Associated comorbidities**

<table>
<thead>
<tr>
<th>Group</th>
<th>Heart disease</th>
<th>Diabetes mellitus</th>
<th>Hemiplegia</th>
<th>Parkinson’s disease</th>
<th>Hepatitis</th>
<th>Asthma</th>
<th>Pigmentary degeneration of the retina</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drain clamping</td>
<td>10</td>
<td>8</td>
<td>1</td>
<td>2</td>
<td>2</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>Blood salvage</td>
<td>12</td>
<td>8</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>
Data analysis. One-way analysis of variance (ANOVA) was used to analyse the difference in post-operative blood loss and the change in haemoglobin levels over time. A chi-squared analysis was used to assess the difference in the rates of patients requiring allogenic blood transfusions. All differences were considered to be significant when \(p < 0.01\). Statistical analysis was performed on a personal computer using Statview 4 (Abacus Concepts, Inc., Berkeley, California).

Results

The mean post-operative volume of drained blood was 352.1 ml (SD 130.7; 100 to 770) in the clamping group and 662.3 ml (SD 333.6; 15 to 1540) in the blood salvage group. This difference was significant (\(p < 0.0001\)). Allogenic blood transfusion was required for one patient (0.9%) in the clamping group and for three (2.8%) in the blood salvage group although this difference was not significant (\(p = 0.62\)).

The change in haemoglobin level over time was compared for the 208 patients who did not receive banked blood. The mean pre-operative haemoglobin level was similar for both groups. By the first post-operative day the haemoglobin level had decreased to 82% of its pre-operative level in the drain clamping group and to 83% for blood salvage. By one week after surgery, these values had declined to 75% and 77%, respectively. Thereafter, the haemoglobin level gradually recovered (Table IV). The post-operative reduction in haemoglobin level for the two groups is shown in Table V. No significant difference was found between them at any time after operation.

In the blood salvage group drained blood was re-infused in 76 patients (71.7%). No adverse reaction which required cessation of the blood transfusion was seen. The mean volume of blood re-infused was 415.1 ml (SD 133.8; 80 to 680), equivalent to 72.7% of the total volume of drained blood.

Alignment on the coronal plane and the range of movement were similar for both groups with no significant difference found (Tables VI and VII). One patient with a non-fatal pulmonary embolism and one with an acute myocardial infarction were seen in the blood salvage group. In the
clamping group, there were three patients with a non-fatal pulmonary embolism. Post-operatively, no specific complications, such as haemolysis or infection, were seen in either group. No revision arthroplasty has been performed in either group.

Discussion

Drain clamping and post-operative blood salvage are the most commonly used methods for management for post-operative bleeding in TKA. In this prospective study, we examined both methods for efficacy and safety.

The rate of allogenic blood transfusion in TKA was reported as 8% by Keating et al and 13% by Bierbaum et al, even though approximately half of their patients donated blood pre-operatively. In our study, only 2.8% of the patients in the blood salvage group and 0.9% in the drain clamping group required allogenic blood transfusion. Compared with the results of previous studies, our rate of allogenic blood transfusion was very low in both groups. Consequently, both methods appear to reduce post-operative blood loss successfully.

Several papers have reported that the salvage of unwashed red blood cells after TKA is of benefit in unilateral TKA where the volume salvaged varies between 152 and 883 ml (Table VIII). Our salvage volume of 415.1 ml is similar to these amounts. In post-operative autologous transfusion, tissue debris, plasma-free haemoglobin, phospholipids, methylmethacrylate and other potentially toxic substances can be suctioned from the wound and transfused with the blood. As a result, post-operative autologous blood transfusion has potential dangers.

In contrast, the drain clamping method is easier than post-operative autologous blood transfusion and has, potentially, a lower risk of complications. The addition of adrenaline may further increase its ability to control bleeding; we observed no adverse effects of its use in our study.

We found no significant difference between our two groups either in their pre-operative condition or post-operative results. Only one patient (0.9%) in the drain clamping group required allogenic blood transfusion while three (2.8%) received allogenic blood transfusion in the blood salvage group. Consequently, blood salvage did not lead to a reduction in post-operative blood loss. Cost analysis revealed that drain clamping was financially more efficient than post-operative blood transfusion. In Japan, the ConstaVac Blood Conservation System 2 costs 25 200 yen and the Port-VAC costs 6120 yen, making blood conservation four times more expensive. When the additional cost and trouble required for the use of the blood salvage system is taken into account, it appears that drain clamping is more efficient post-operatively than blood salvage.

However, some technical issues still remain with the drain clamping method. In previous studies, the concentration of adrenaline, the volume of saline used and the clamp time employed were different, so optimum levels for these parameters need to be established. In spinal surgery, in order to reduce bleeding, infiltration of the paraspinal soft tissues with 200 to 300 ml of 1:500 000 adrenaline has been widely used. In TKA, Ryu et al and Yamada et al used saline containing 1:200 000 adrenaline when drain clamping. Meanwhile, Olzewska et al reported the effective use of 1:100 000 adrenaline saline irrigation during routine arthroscopic knee surgery for control of bleeding.

Our concentration of adrenaline was 1:500 000, approximately the centre of the reported range. Lower concentrations of adrenaline in saline are preferable in order to protect the systemic circulation. Our choice of a 1:500 000 concentration appeared to be reasonably successful in terms of both efficacy and safety.

The volume of injected saline in the previous reports has varied from 0 to 50 ml. During our operation for TKA the knee joint was incised and a soft-tissue release performed in order to correct any deformity in the majority of patients. During our study, small amounts of saline leaked through the skin incision at the time of the injection in some of our patients even with a 30 ml volume. We therefore considered 30 ml to be a sufficiently large volume to raise the intra-articular pressure; further increases in saline volume were not thought to be of additional benefit.

Debate still surrounds the length of time for which the drain should be closed. Larsson, Lewis and Liljedahl reported that when the tourniquet was released, reactive blood flow increased with the peak flow appearing within five minutes. During this period, it is important to decrease bleeding by the use of both a high intra-articular pressure of saline and the vasoconstrictive effects of adrenaline.
Although the period of time for the drain to be closed remains controversial, between one and 24 hours has been reported previously.\textsuperscript{10-13} In general, the longer the duration of complete closure, the greater the risk of haematoma. Consequently, we felt that the period of complete drain closure should be kept to a minimum.

It is also important to maintain the intra-articular pressure sufficiently high for several hours after the drain is opened. However, there have been no discussions in earlier studies as to how the clamp should be released. If it is fully opened immediately, the intra-articular pressure rapidly declines and bleeding increases. Therefore, we recommend that the clamp is opened gradually. We believe this is important in reducing bleeding and avoiding an excessive accumulation of blood in the joint. It may also be important in reducing the influence of haemodynamics. For example, a case of transient hypotension upon release of the drain was reported by Kiely et al.\textsuperscript{13}

Based on our own results, we recommend injection into the drain tube of 30 ml saline containing 1:500 000 adrenaline and complete drain closure for 30 minutes, followed by gradual release of the clamp. Both techniques used in our study are commonly employed methods for managing blood loss after TKA in our country. Although drain clamping appeared to be advantageous over blood salvage, our evaluation was limited to the early post-operative haemodynamics and complications. The precise efficacy of these techniques could not be clarified as we made no comparison between our treatment groups and groups with other conventional post-operative techniques. Further studies, including the subsequent clinical results of our two study groups, are required.

No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article.

References