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ORIGINAL PAPER

Conventional drainage versus four hour clamping drainage after total knee arthroplasty in severe osteoarthritis: a prospective, randomised trial

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Abstract Total knee replacement in severe osteoarthritis usually requires extensive soft tissue releases often associated with considerable bleeding. In a prospective, randomised trial we compared postoperative conventional suction drainage versus four hour clamping drainage in 60 patients undergoing total knee arthroplasty for severe osteoarthritis. We compared blood loss, number of transfusions, postoperative complications and knee function and found significantly less postoperative blood loss through the drains ($p<0.001$), and fewer blood transfusions ($p=0.09$) were needed in the clamped group. We conclude that clamping drainage after total knee arthroplasty in severe osteoarthritis reduces blood loss through the drains and the need for blood transfusions.

Résumé La prothèse totale du genou dans les gonarthroses sévères nécessite souvent une résection tissulaire importante, celle-ci étant souvent associée à un saignement important. Nous avons réalisé une étude prospective randomisée comparant le drainage conventionnel post-opératoire versus clampage du drain durant 4 heures chez 60 patients ayant bénéficié d'une prothèse totale du genou pour une gonarthrose importante. Nous avons comparé les pertes sanguines, le nombre de transfusion, les complications post-opératoires, la fonction du genou. Nous avons observé qu'il y avait beaucoup moins de pertes sanguines dans les drains ($p<0.001$) et beaucoup moins de transfusions ($p=0.009$) dans le groupe des patients dont le drain avait été clampé pendant 4 heures. Nous pouvons conclure que le clampage du drain après prothèse totale du genou dans les gonarthroses sévères permet de réduire les pertes sanguines et le nombre de transfusions.

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Introduction

The use of closed suction drainage after total knee arthroplasty (TKA) is still somewhat controversial. While a greater need for postoperative blood transfusion has been reported with closed suction drainage as compared to no drainage in total joint replacement [5, 16], there are concerns with respect to wound problems if no drainage is used [8, 10]. Still, blood transfusions represent additional costs, a risk of transfusion-transmitted viral disease, bacterial contamination, post-transfusional immunosuppression as well as serious acute and delayed non-infectious transfusion reactions [4, 6]. Thus, it is of interest to determine if it is possible to reduce blood loss while still using drainage. This applies especially to TKA in severe osteoarthritis (OA), which often requires extensive soft tissue releases and/or large bone cuts with increased risk of developing postoperative haematoma.

Clamping drainage produces temporary haemostasis by creating an intra-articular tamponade [9], which when released allows for removal of the blood through drains, preventing wound haematoma. There is some ambiguity with respect to clamping in the literature [9, 13–15, 17, 18]. While some authors [14] have reported significant reduction in blood loss through drains, others [9] have found no

difference, either in calculated blood loss or transfusions. However, these reports did not take into account the severity of OA.

The aim of our study was to investigate whether clamping closed suction drainage for four hours was advantageous after TKA in radiographically severe OA.

Patients and methods

In a prospective, randomised trial we analysed 60 radiographically severe knee OA patients admitted for TKA. The OA grade was assessed according to Burnett's radiographic atlas [3]. The evaluation is based on a number of radiographic changes and graded in stages from 0 to 21 (the higher the grade, the more severe the OA). Only patients with a score ≥14 were included in the study.

Just before surgery an envelope was extracted randomly dividing patients into two postoperative drainage groups: clamped (n=30), where drains were clamped for the first four postoperative hours and non-clamped (n=30).

Patients with coagulation disorders and/or on anticoagulant treatment were excluded.

The implant used was the PFC Sigma PS (DePuy Orthopaedics Inc., Warsaw, IN, USA) prosthesis inserted through the conventional anterior approach. Spinal/epidural anaesthesia was used and two experienced surgeons performed all of the cases without use of a tourniquet. The bone cement and cementing technique was the same in all cases. Duration of surgery was recorded.

The surgeons were blinded to the patient grouping until the wound was closed. The same external 3.2-mm diameter drain and closed suction drainage system were used. A single drain was used which was placed subfascially and pulled through the skin laterally/proximally. Drains were removed after 48 hours.

All patients had antithrombotic prophylaxis with low molecular weight heparin (Enoxaparin, Aventis Pharma International) subcutaneously: 0.2 ml 12 hours before the operation and 0.2 ml perioperatively, and thereafter 0.4 ml once a day, until discharge from hospital. Further, an elastic compression bandage was applied on both legs. Antibiotic prophylaxis was given at the start of surgery and continued for a period of two days, as the drains were used.

The indications for blood transfusion were haemoglobin ≤8.5 g/dl, haematocrit ≤25, and/or clinical criteria were syncope, dyspnoea, tachycardia, hypotension, angina pectoris, transient ischaemic attack [11]. The decision about blood transfusion was made by an anaesthetist blinded to the randomisation.

The perioperative blood loss was not measured. However, the haemoglobin, red blood cells and haematocrit value one hour before surgery and on the first postoperative day were recorded to calculate total blood loss (VL). The calculations were performed on the first and the third postoperative days using the formula [2] VL (ml) = EBV × ln (Hto/Htmin), in which Hto = initial haematocrit level and Htmin = last haematocrit level. Estimated blood volume (EBV) was calculated using the formulas [7]: EBV (ml)= W × 70 for men or EBV=W × 65 for women, in which W= weight (kg). Blood loss for the third day was not calculated for patients having received blood transfusions.

The external blood loss through drains was recorded 0–6, 6–24 and 24–48 hours postoperatively as well as the need for blood transfusions.

All of the patients had the same rehabilitation program. Active range of motion (ROM) was recorded on the third and the sixth postoperative days as well as the incidence of pyrexia >−37.5°C. The status of bandage bleeding was investigated, i.e. excessive bleeding through the wound, and dressing reinforcement was recorded.

The study was approved by the Ethics Committee of the institution.

Statistics

The primary effect variable, used for power calculation analysis, was the blood loss through drains after the TKA. With an assumption of a difference in means of 70 ml, and a SD of 70 ml for both groups, and aiming at a power of 0.95 and a risk of 0.05 for type 1 error, 27 patients were required in each group.

The t-test was used to calculate the differences, including 95% confidence intervals (CI), between the numerical variables in the groups. Fisher's exact test was used to compare the requirement of the blood transfusion proportions and incidence of pyrexia between the groups. Statistical Package for the Social Sciences (SPSS) software was used for calculation and $p<0.05$ was considered statistically significant.

Results

There were 23 women and seven men with a mean age of 67 (SD: 7) years and mean body mass index (BMI) of 32 (SD: 6) kg/m^2 in the clamped group and 27 women and three men with a mean age of 70 (SD: 7) years and BMI of 31 (SD: 5) kg/m^2 in the non-clamped group. These parameters did not statistically differ significantly between the groups. Comparisons of blood parameter data are presented in Table 1. EBV in the clamped group was 5,607 (SD: 1,100) ml and in the non-clamped group 5,500 (SD: 842) ml. The means of calculated blood loss volume on the first and the third postoperative days for the clamped group were 1,470 ml (SD: 555) and 2,014 ml (SD 790) and

Table 1 Haemoglobin (Hb, g/dl), red blood cells (RBC, $*10^{12}$/l) and haematocrit (Hct)

	Clamped	Non-clamped	*p* value
Hb preoperatively	13.5 (1.4)	13.3 (1.6)	0.6
Hb the first day after TKA	10.4 (1.4)	9.9 (1.9)	0.25
RBC preoperatively	4.5 (0.7)	4.4 (0.6)	0.13
RBC the first day after TKA	3.3 (0.4)	3.3 (0.6)	0.36
Hct preoperatively	39.4 (3.6)	38.8 (4.7)	0.57
Hct the first day after TKA	30.4 (4.1)	29 (5.6)	0.27

Mean (SD) changes preoperatively and the first day after the total knee arthroplasty (TKA)

for the non-clamped group 1,627 ml (SD: 752) and 2,160 ml (SD: 532), respectively. There were no significant differences between the groups with respect to estimated blood volume prior to the operation or the total calculated blood loss from the circulation. However, there was a significant increase in blood loss through drains in the non-clamped group (Table 2). The mean duration of surgery was 96 min in the clamped and 92 min in the non-clamped group (p=0.2). The mean hospital stay was 8.2 days for both groups, and there were no significant differences in the incidence of pyrexia (clamped 17 and non-clamped 10, p=0.12) or in ROM (Table 3).

One case of prolonged wound healing was observed in a knee with a non-clamped drain. No differences in bandage bleeding were recorded.

Transfusions were performed for six patients in the clamped group compared to 13 patients in the non-clamped group (p=0.09). Clamped group patients were transfused with 13 blood units compared to 32 blood units in the non-clamped group (p=0.07). On average the non-clamped group had 0.6 (95% CI: 0.41–1.241) more blood units.

Discussion

There are numerous reports in the literature on drainage options after TKA but there is no consensus. Our material represents severe OA patients. Knee surgery in such

Table 2 Postoperative haemorrhage fluid loss through drains (ml) between 0–6, 6–24 and 24–48 hours after the surgery

	Clamped	%	Non-clamped	%	*p* value
0–6 h	109 (65)	31	265 (88)	45	<0.001
6–24 h	144 (66)	40	188 (85)	32	0.27
24–48 h	102 (68)	29	133 (84)	23	0.12
Total 0–48 h	354 (151)	100	586 (175)	100	<0.001

Means (SD)

Table 3 Active postoperative knee range of motion (°) at the third and sixth day after the surgery

	Clamped	Non-clamped	*p* value
Third day			
Flexion	82 (11.5)	82 (15)	0.9
Extension	179 (1.7)	180 (0.9)	0.8
Sixth day			
Flexion	90 (9.5)	89 (13.3)	0.7
Extension	180 (0.9)	180 (0)	0.3

Means (SD)

patients usually requires larger bone cuts and more excessive soft tissue release, subsequently inducing more blood loss. It is known that postoperative haematoma is associated with greater infection risk [10]. Although drainage is meant to reduce the local haematoma, it has been claimed to increase the total blood loss and need for transfusions [12]. As this should be more apparent in patients with severe OA, alternative methods to reduce postoperative blood loss such as clamping of the drain may be an option. One of the first studies analysing this method was published in 1984 [17] in which it was observed that intermittent clamping drainage was associated with less blood loss through the drains as compared to continuous suction drainage. A few other studies have since been published comparing different clamping techniques [9, 13–15, 17, 18], also reporting a decrease in blood loss with clamping. However, none of these reports focused on patients with severe OA where increased blood loss is to be expected. Compared to some other studies [9, 14, 15], we experienced less blood loss than expected considering that our patients had severe joint destruction and that we did not use a tourniquet. Although we did not find a difference in calculated total blood loss from the circulation there was a significant difference in mean blood loss through drains (354 ml in the clamped group and 586 ml in the non-clamped group), which indicates accumulation of a haematoma in the knee.

The duration of clamping drainage is still being debated with suggestions ranging from one to 24 hours. As it was reported [14] clamping for a period of four hours postoperatively could be expected to reduce bleeding. A longer clamping period has also been reported to be associated with a number of different problems such as delayed wound healing with skin edge necrosis, haematoma and deep venous thrombosis [18]. A different clinical practice of drainage periods exists in different institutions and it varies from 24, 48 and up to 72 hours postoperatively. It also has been reported that leaving drains for more than 24 hours may increase the risk of infection due to bacterial colonisation of the drain which increases with drainage period [19]. However, other authors reported that suction

drainage culture is not useful in detecting postoperative infection for aseptic orthopaedic surgery [1] and thus is not a risk factor for future infection manifestation. In our study we used four hour clamping and we did not observe any wound problems in the clamped group. Our results suggest that a four hour clamping period is optimal and can be used in routine TKA in severe OA cases.

Our study did not show a statistically significant reduction in the number of transfused patients in the clamped group (p=0.09) and neither did the differences in transfused units of blood between the groups (p=0.07) reach significant levels. However, these results should be interpreted with caution from the statistical point of view. The t-test was used to compare the numeric means of transfused blood units between the groups. As the majority of patients did not need any transfusion, the large number of 0 values affected the results of the t-test. Thus, to prove the significance we would have needed a larger patient group. However, we consider the observed differences between the groups in transfused blood units (14 vs 32) and proportion of patients needing transfusion (6 vs 13) to be clinically and economically important.

We conclude that in patients with severe OA undergoing TKA four hour clamping of the drain reduces postoperative blood loss.

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