Drain Vs No Drain in Primary Cemented Total Knee Arthroplasty: Prospective Randomized Controlled Trial

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ABSTRACT:

Rationale: The ancient use of closed suction drain after orthopedic methods has been withstood for the previous few decennium.

Objective: This study was carried out to estimate the efficiency of closed suction drainage following primary total knee arthroplasty.

Methods and results: sixty patients with primary Total Knee Arthroplasty were classified into two groups; D group (drain used) and ND group (no drain used). Parameters assessed were pre- and post-op Hb and HCT, visible blood loss, acute inflammatory response, early infection, ecchymosis and duration of stay.

The average age of the participants was 61.6 years (ranging from 56 to 68 years old) in D group and 62.76 (range from 56 to 67 years) in ND group. In D group Pre-operative Hb was 12.83, in ND group was 12.92. Post-operative Hb on 2nd day was 8.98 and 10.54 for D and ND groups respectively (p< 0.001). Post-operative Hb on 7th day was 9.08 and 9.47 for D and ND groups respectively (p=0.042). Visible postoperative blood loss was 656.67 for D group and 100 for ND group (p< 0.001). 14 patients in D group had blood transfusion postoperatively and only 3 in ND group (p=0.011). There were no recorded cases with infection. No significant difference was detected between the 2 groups in respect to acute inflammatory response, Ecchymosis around wound, DVT, PE and LOS.

Discussion: There are no advantage of using closed suction drain after primary TKA. The blood loss and the need for blood transfusion was significantly more when using a drain.

KEYWORDS: TKA, drain, no drain, RCT.

INTRODUCTION

Total Knee Arthroplasty (TKA) can result in a considerable amount of blood loss. Several plans to decrease the requirements for allogenic red cell transfusion have been used, like the utilize of thigh tourniquets, diathermy coagulation, Tranexamic Acid, clamping drains, adrenaline infiltration, and computer-assisted navigated TKAs [1,2,3,4]. Most bleeding in TKAs occurs in the earliest postoperative hours (37% through first two hours and 55% through the following hours). Drains in arthroplasty have been used historically for theoretically preventing hematoma formation, decreasing tension over the wound (which
consequently reduces pain), reducing the delaying of injury recovery and reducing the threat of infection [5,6]. On the other side, the drainage system surely rises bleeding due to the tamponade influence does not appear at the surgical site. Besides, it can lead to a retrograde infection [5,6,7].

The objective of this study is to evaluate and compare the difference in postoperative blood loss and inflammatory response between patients with a drain and those with no drain after primary cemented TKA. Other outcomes (infection, wound healing, pulmonary embolism (PE), deep venous thrombosis (DVT) and length of hospital stay (LOS) were also assessed.

PATIENT AND METHODS

Sixty consecutive patients, who underwent primary cemented Total Knee Arthroplasty between January 2016 to October 2017, were involved in this investigation. Inclusion criteria were participants with primary and secondary osteoarthritis of the knee. Cases with revision arthroplasties, participants with medial collateral ligament MCL or lateral collateral ligament LCL insufficiency, arthritic knees with severe bone loss and patients with bone tumours were eliminated from this current investigation. 30 participants were involved in group D (drain used) and 30 patients were in group ND (no drain used). The participants were followed up postoperatively in Out Patient Department OPD on the 7TH day and then weekly for 3 weeks. All the participants were chosen by simple randomization applying a sealed opaque envelope technique. There were no participants with a history of cardiac comorbidities. Patients on warfarin and clopidogrel were advised to discontinue it 5 days before surgery. Regarding aspirin, it has not been discontinued before operation. Well-documented informed agreement was obtained from all patients registered in this trial. Spinal, combined with epidural anaesthesia was used in all patients. The standard surgical procedures were applied. All cases were given 2-gram first generation Cephalosporin within 30 min before the procedure. Anterior midline incision with medial parapatellar approach were applied for all study patients.

All patients were anaesthetized by epidural spinal anaesthesia. A pneumatic tourniquet was applied in all the patients and was deflated before closure for hemostasis of any bleeders. A bone plug was used to close the distal femoral entry before cementing. No other strategies to decrease the blood loss were used; like tranexamic acid local or systemic, saline adrenaline infiltration, hydrogen peroxide or fibrin sprays glue. The closed suction drain was used in group D. Thick compression dressing was applied for all the cases post-operatively. Identical pain management agreements were applied in two groups. Drain removal for all the patients in group D was completed within 48 h postoperatively. Blood transfusion was used in patients with postoperative Hb ≤ 8 g/ dL [8]. The primary outcome measure assessed was haemoglobin and HCT levels on the 2nd and 7th postoperative days [9]. Postoperative visible total blood loss was assessed in both groups using a visual guide table to assess blood loss in ND group [10]. The secondary outcome measures assessed were the inflammatory response by detecting the values and trend of CRP and ESR levels in the 2nd and 7th postoperative days and weekly for the next three weeks [11]. Complications (infection, DVT, PE and wound healing) and postoperative LOS were all assessed.

Statistical analysis:
Comparisons among quantitative variables were confirmed by applying the non-parametric Mann-Whitney test (Chan, 2003a). To compare tabulated results, the Chi-square ($\chi^2$) test was carried out. Exact test was applied in lieu when the predictable frequency is lower than 5 (Chan, 2003b). P-values lower than 0.05 were believed statistically significant

RESULTS:

The average age of the participants was 61.6 years (ranging from 56 to 68 years old) in group D and 62.76 (range 56 - 67) in group ND. In D group, PCL sacrificing (PS) design was used in 25 patients and cruciate retaining (CR) in 5 patients. In ND group, PS was used in 27 patients and CR in 3 patients. There was no statistical difference between both groups ($p = 0.225$). Patellar resurfacing was performed for 4 patients in group D and for 3 patients in ND group ($p = 0.41$). Mean operative time for group D was 117 min and for group ND was 116 min.

The mean preoperative Hb, postoperative Hb and HCT levels on the 2nd and 7th days, clinical blood loss and the number of patients who had blood transfusion are shown in (Table 1).

<table>
<thead>
<tr>
<th>Variable</th>
<th>Group D (with drain)</th>
<th>Group ND (no drain)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-operative Hb</td>
<td>12.83</td>
<td>12.92</td>
<td>0.174</td>
</tr>
<tr>
<td>Post-operative Hb on 2nd day</td>
<td>8.98</td>
<td>10.54</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Post-operative HCT on 2nd day</td>
<td>27.88</td>
<td>33.31</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Post-operative Hb on 7th day</td>
<td>9.08</td>
<td>9.47</td>
<td>0.042</td>
</tr>
<tr>
<td>Post-operative HCT on 7th day</td>
<td>28.59</td>
<td>30.82</td>
<td>0.002</td>
</tr>
<tr>
<td>Visible postoperative blood loss</td>
<td>656.67</td>
<td>100</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Blood transfusion (number of patients)</td>
<td>14</td>
<td>3</td>
<td>0.011</td>
</tr>
</tbody>
</table>

There was a statistically significant variation in the postoperative blood loss (P-value < 0.001) and the need for blood transfusion (P-value; 0.011) between the two groups; both parameters were more in group D.

There was no considerable significant variation among both groups regarding the value/trend of ESR and CRP as an indicator for inflammatory response. Ecchymosis around the wound was encountered in 2 patients (6.7%) in group D and 7 patients (23.3%) in group ND with no statistically significant difference ($p = 0.145$) and resolved completely in all patients by the 4th week without any signs of wound infection. There were no cases with infection, DVT or PE encountered in this study. Mean postoperative LOS for D group was 3.03 and for ND group 2.6 days ($p = 0.775$).

<table>
<thead>
<tr>
<th>Variable</th>
<th>Group D (with drain)</th>
<th>Group ND (no drain)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ecchymosis around wound</td>
<td>6.7%</td>
<td>23.3%</td>
<td>0.145</td>
</tr>
<tr>
<td>Skin blisters</td>
<td>0%</td>
<td>10%</td>
<td>0.095</td>
</tr>
<tr>
<td>LOS (number of days)</td>
<td>3.03</td>
<td>2.6</td>
<td>0.775</td>
</tr>
</tbody>
</table>

DISCUSSION:
The use of drains in arthroplasty still debatable and must be reviewed by surgeons. McManus et al. [12] utilized radioisotope Tc-99m-marked red blood cells and recorded that a large number of red blood cells transmit to the joint space, with the tissue compartment being unable to move the cells into the system circulation once more, causing an additional decrease in hemoglobin levels. When the joint gap and muscle compartment fill with blood, the bleeding eventually stops of saturating. When a drain is applied between the joint space and the muscle space, the tamponade effect will be lost, leading to more bleeding into the drain till it is eliminated.

This study suggested that both Hb and HCT values are significantly less in patients with drain. Visible postoperative blood loss and the amount of transmitted blood in participants without drains is considerably less than in those with drains. Some researchers have reported similar findings, in a systematic review of Parker et al. [5] about the use of closed suction drain following TKA operation. The review involved 36 trials including 5,697 knees and they did not recommend to utilize surgical drain. The blood loss and the blood transfusion requirement were comparatively more with drains leading to a greater rate of transfusion. This trail provides more evidence to support the suggestion of the prospective, randomized test of drainage in knee arthroplasty confirmed by Li et al. [13] In a study on 100 knee arthroplasties. Esler et al. [14] also had similar findings concerning blood loss and the blood transfusion.

On the other hand, Adalberth et al. [15] Gaurav et al. [16], Zhang et al. [17] and Wang et al. [18] found no additional benefits of using drain after knee arthroplasty, they did not report differences in blood loss and blood transfusion between the drain and no drain groups. Using different strategies to decrease postoperative blood loss like elastic compression dressing for 4 days postoperatively in Adalberth et al. [15] or intravenous Tranexamic acid (TXA) in Gaurav et al. [16], Zhang et al. [17] and Wang et al. [18] may be a possible explanation. In a meta-analysis by Yang et al. [19] Randomized controlled trial (RCTs) reported that intravenous TXA reduced significantly the blood loss and the blood transfusion unites after knee arthroplasty.

Waugh and Stinchfield have recommended the utilize of closed suction drain in orthopaedic operations, suggesting that the mean of infection was greater in participant who did not have incorporated drains [20] Later on, many studies have questioned the effect of using drain on infection rate. In this study, infection was not encountered in any cases and consequently, no difference was detected between the 2 groups. The same results were reported in two studies by Li et al. [12] and Esler et al. [14] In the meta-analysis of Zhang et al. [17] there was also no considerable variation among using drain and non-using drain in the incidence of infection. Minnema et al. [21] in their case-control study, concluded that the use of closed suction drainage was related to the development of surgical site infection SSI after TKA and recommended that avoiding the utilize of operative drainage in patients undergoing TKA should reduce the risk of infection.

The postoperative inflammatory response was assessed by serially measuring ESR and CRP on the 2nd and 7th days postoperatively, followed by weekly until the 4th post-operative week. We found no statistically significant difference between the two groups in the behavior of ESR and CRP as indicators for the inflammatory response postoperatively. The readings of ESR and CRP were in a declining manner in both groups.
There was no significant difference between groups regarding postoperative LOS, DVT and PE. Erythema around the wound was noticed more among patients without drain with no statistically significant difference and was resolved completely in all patients by the 4th week. The best we know, the current study is the earliest clinical prospective trial that compares the difference in acute inflammatory response between TKA with drain and with no drain by detecting the postoperative behavior of ESR / CRP. The limitations of the present trial involved the low number of participants and concise follow up. Further prospective randomized controlled studies with a bigger number of patients and longer follow up are recommended.

This study suggests that there are no advantage of using closed suction drain after TKA. The blood loss and the need for blood transfusion were significantly more when using a drain. There was no significant difference in the inflammatory response, infection rate, ecchymosis around the wound, LOS, PE and DVT.

**Conflict of interests:**
The Authors has no disagreement of benefits linked to this investigation to proclaim

**Funding disclosure:**
The authors confirm that no funding was received related to this study.

**Ethical Approval:**
This study has been approved by the appropriate ethics committee (the scientific board of the department of Trauma & Orthopaedic surgery, Cairo University Hospitals). Well-documented informed agreement was obtained from all patients before participated in this trial. Specifics that might reveal the identity of the participants under the present survey have been ignored.

**Informed Consent:**
Randomization was done after obtaining a written informed consent from the study participants. The informed consent included explanation of the procedure purpose, benefits, in addition to its different risks and complications.

**References**