A prospective study to compare early postoperative outcomes in patients undergoing total knee replacement with or without drain

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Abstract
Aim: The main aim of this study is to compare early postoperative outcomes in patients undergoing total knee replacement with or without drain.

Materials and Methods: This study was conducted on indoor patients undergoing total knee replacement at Deenanath Mangeshkar Hospital and Research Centre, Erandwane, Pune from September 2016 to December 2017 and comprised 62 patients (31 patients in each group – group 1 without drain and group 2 with drain) of both gender meeting the inclusion criteria. Patients were post-operatively followed up for one month and outcomes- percentage drop of haemoglobin, requirement of blood transfusion and wound complications noted and compared.

Results: The 2 groups were comparable in terms of pre-operative characteristics. There was no statistically significant difference in mean pre- and post-operative haemoglobin, average percentage drop of haemoglobin (20.91% in group without drain and 18.7% in group with drain), blood transfusion requirement and wound complications in the two groups.

Conclusion: There appears to be no clear benefit or drawback to the use of suction drainage after total knee replacement.

Keywords: Knee replacement, drain, haemoglobin, blood transfusion

Introduction
Total Knee Replacement (TKR) is one of the most important orthopaedic surgical advances of the twentieth century for treatment of osteoarthritis and moderate/severe rheumatoid arthritis. Primary total knee replacement can result in a considerable amount of blood loss which often requires post-operative blood transfusion [1-3]. In some studies, transfusion of blood after total knee replacement has been reported to be as high as 30% [4]. Allogeneic blood transfusion carries the risk of immunological and non-immunological adverse effects like increased rate of postoperative infections, disease transmission and high medical cost. Use of post-operative suction drainage is widely prevalent among orthopedic surgeons [5]. Merits of use of drain is that it prevents hematoma formation at the surgical site and thus bacterial colonization and subsequent infection, decreases tension over the incision (Which consequently decreases pain) and accelerate wound healing [6-7]. However, the demerits of use of the drainage system is that it increases bleeding because the tamponade effect does not occur at the surgical site, restriction in range of motion and rehabilitation in early post-operative period and can also cause retrograde infection [8]. There are literatures showing no benefits of drain in TKR [9-11]. However, in current practice drain in TKR is widely used in Indian setup. There are limited Indian literature [12] suggestive of no benefits of drain uses in TKR but that is also not conclusive. So this study was done to compare the percentage drop of haemoglobin (Hb), requirement of blood transfusion and wound complications as wound dehiscence, necrosis of wound margin and wound infection (Superficial/deep) within one month of total knee replacement with or without drain.
 Materials and Methods
Study was a prospective, observational comparative study, conducted on indoor patients undergoing total knee replacement at Deenanath Mangeshkar Hospital and Research Centre, Erandwane, Pune from September 2016 to December 2017 and comprised 62 patients (31 patients in each group – group 1 without drain and group 2 with drain) of both gender meeting the inclusion criteria.  

Inclusion criteria were patients with grade 3 and grade 4 osteoarthritis of the knee. Patients with history of infective pathology, revision arthroplasties and patients with coagulation disorder or on prior anticoagulant therapy were excluded from the study. Patient selection was done by simple randomization in two groups by using a sealed envelope technique. The approval for the study from Ethics Committee of the hospital was taken and informed consent was obtained from all patients.

After appropriate radiological and pre-operative hematological investigations the patients were posted for surgery. The surgeries were performed under regional spinal or general anaesthesia as per patient’s requirement. The standard surgical steps were followed. In cases of use of drain (Group 2 patients), wound was closed after putting suction drain (12 number Romo Vac) in lateral gutter (Intra-articular) of knee. Three doses of intravenous antibiotics (Cefuroxime 1.5 gm) was given to patients of each group, 1st dose was given 30 minutes before incision, 2nd and 3rd dose was given after 12 hrs and 24 hrs of surgery. 

Post-operative haemogram was done on day 1 and day 3. Postoperative drain output volume was measured daily. Dressing was done on post-operative day 2, 5 and earlier if soaking was present. The drain was removed 48 hours after surgery. Wound examination was done at each dressing. Complications, if any, post-operatively were noted. Patient was discharged after 4 - 6 days post-operatively according to patient condition. All the patients were followed up on day 14 and day 30. In case of any wound complication, more follow up were done accordingly. On first follow up staple removal was done and on each follow up wound was examined for dehiscence, margin necrosis and infection (Superficial/deep).

Outcome measures
1. Primary outcome- The percentage drops of haemoglobin postoperatively.

Blood transfusion was considered if
Drain collection of ≥ 500 ml (Possible ongoing loss) in 24 hrs with haemoglobin drop of ≥ 4 gm/dl or if total haemoglobin of patient drops to < 8 gm/dl.
1. Tertiary outcome- Wound complications within one month postoperatively as:
   a. Wound margin necrosis
   b. Wound Dehiscence
   c. Wound Infection (Superficial/Deep)

Statistical analysis
The description of the data was done in form of mean +/- SD for quantitative data while in the form of % proportion for qualitative (Categorical) data. P-values of < 0.05 was considered significant. For quantitative data, unpaired Student’s t-test was used to test statistical significance of difference between two independent group means. For comparison of categorical variables (i.e to examine the associations between qualitative/quantitative variables), chi-square test was used if the number of elements in each cell were 5 or higher and Fisher’s exact test, otherwise. To compare proportions between two groups Z test of proportions was used.

Observations and Results
The mean age of the patients was 65.90 years in the group 1 (Without drain) and 65.39 years in the group 2 (With drain), were comparable and also gender distribution (22 males, 9 females in group 1 and 20 males, 11 females in group 2) between two were comparable. Mean pre- and post-operative haemoglobin, average percentage drop of haemoglobin, blood transfusion requirement and wound complications are summarized in table 1.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Group 1 (Without drain) n = 31</th>
<th>Group 2 (With drain) n = 31</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean pre-operative haemoglobin (gm/dl)</td>
<td>12.242 ± 1.47</td>
<td>12.100 ± 1.46</td>
<td>.704</td>
</tr>
<tr>
<td>Mean haemoglobin post-operative day 1 (gm/dl)</td>
<td>10.532 ± 1.77</td>
<td>10.694 ± 1.57</td>
<td>.705</td>
</tr>
<tr>
<td>Mean haemoglobin post-operative day 3 (gm/dl)</td>
<td>9.787 ± 1.72</td>
<td>9.787 ± 1.27</td>
<td>1.000</td>
</tr>
<tr>
<td>Average percentage drop of haemoglobin</td>
<td>20.91 ± 10.13</td>
<td>18.7 ± 9.88</td>
<td>.514</td>
</tr>
<tr>
<td>Blood transfusion</td>
<td>3 patients (9.7%)</td>
<td>3 patients (9.7%)</td>
<td>1.000</td>
</tr>
<tr>
<td>Wound margin Necrosis</td>
<td>1 patient (3.2%)</td>
<td>0</td>
<td>.313</td>
</tr>
<tr>
<td>Wound dehiscence</td>
<td>0%</td>
<td>0%</td>
<td>1.000</td>
</tr>
<tr>
<td>Wound infection</td>
<td>1 patient (3.2%)</td>
<td>1 patient (3.2%)</td>
<td>1.000</td>
</tr>
</tbody>
</table>

(p<0.05 significant)

There was no statistically significant difference in mean pre-and post-operative haemoglobin, average percentage drop of haemoglobin, blood transfusion requirement and wound complications in the two groups as summarized in table 1.

Discussion
Drains have traditionally been used in total knee replacement but its use is controversial. Infection is one of the main complications following TKR and needs immediate consideration. Although suction drain frequently used with rational of preventing haematoma formation at the surgical site and subsequent infection, it can also lead to significant infection risk due to increased risk of ingress of skin micro-organisms into the wound through way of the drain or drain track. Recent trend in total knee replacement has inclined towards surgery done without using drains. This method has its advantage like it decreases requirement of blood transfusion and transfusion related complications. There are limited Indian literature suggestive of no benefits of drain uses in TKR but that is also not conclusive. So this study was done to compare the percentage drop of haemoglobin, requirement of blood transfusion and wound...
complications within one month of total knee replacement with or without drain. Our study had shown the average age of the patients who underwent TKR to be 65 years, comparable to study done by Keska R et al \[15\] in which average age was 68 years. Mean pre-op Hb was similar in the patients between the two groups when tested using independent t-test, 12.24 gm/dl in group 1 and 12.10 gm/dl in group 2 and is comparable to study conducted by Sharma GM et al \[12\]. In our study the mean post-operative Hb on day 1 and day 3 (as summarized in table 1) was similar in the patients between the two groups when tested using independent t-test, Adalberth G et al \[10\] study also didn’t found any statistical significant difference between their study groups (p value=0.8). Percentage drop of haemoglobin in our study was slightly more in group without drain (20.91%) than in group with drain (18.70%), but difference found statistically insignificant and comparable to results found in study conducted by Reilly et al \[10\]. Same percentage of patients (9.7%) in both groups required blood transfusion, very less than in study done by Keska R et al \[15\] (39% in patients without drain and 53% in patients with drain). This might be because we did meticulous haemostasis on deflation of tourniquet after implantation of femoral and tibial component, while Keska R et al \[15\] released tourniquet after compression dressing without doing haemostasis. In the group without drain, one patient (3.2%) developed wound margin necrosis and one patient developed superficial wound infection, both managed conservatively and healed completely. No wound complication was noticed in the group of patients with drain. No deep infection of wound was noted in patients of any group. There was no statistical difference in wound complications between the two groups and also results found comparable to that of the study conducted by Sharma GM et al \[12\] (1.69% superficial wound infection rate in both groups).

The limitations of our study were: the small sample size and the presence of confounding variables like use of local infiltration which can reduce the postoperative blood loss in both the study groups.

Conclusion
No significant difference in wound complications rate or blood loss was found between the cases with or without drain after total knee replacement, there appears to be no clear benefit or drawback to the use of suction drainage after total knee replacement.

References