PROSPECTIVE STUDY OF EFFICACY OF LOCAL INfiltrATION ANALGESIA AND EPIDURAL ANALGESIA IN PATIENTS UNDERGOING TOTAL KNEE REPLACEMENTS

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ABSTRACT

BACKGROUND
Aims- Multiple studies have been done regarding post-operative analgesia after knee surgeries including intravenous opioids, epidural analgesia and nerve blocks. Hence, we compared the efficacy of Local Infiltration Analgesia (LIA) technique over Epidural Analgesia (EA) technique in patients undergoing TKR surgeries.

MATERIALS AND METHODS
72 patients of either sex, aged > 50 years, belonging to ASA I to III, posted for unilateral TKR for varus deformity were randomised into two groups. Patients in Group 1 received LIA and Group 2 EA. Parameters assessed were: Pain on VAS scale, Range of Movements (ROM), ambulation with support, patient satisfaction at 6 hrs., 24 hrs., 48 hrs., 72 hrs. and 96 hrs. Post-operatively.

RESULTS
Statistical analysis of the univariate and multivariate factors was performed using paired ‘t’, Chi-square test, Fisher’s test as applicable. The pain was significantly more in LIA group than in EA group at 6 hrs., 24 hrs., 48 hrs., 72 hrs. and 96 hrs. intervals. The ROM was significantly observed more in LIA group than in EA group at 48 hrs. and 72 hrs. However, there was no significant difference at 96 hrs. between both groups. Ambulation with support was possible only in LIA group. Rescue analgesia was needed only in LIA group (13.9% vs 0%). Patients of EA group were more satisfied at the end of 4 days (86.1% vs 69.4%).

CONCLUSION
Local infiltration analgesia provides simple, safe comparable analgesic efficacy and earlier ambulation than epidural analgesia post-operatively after total knee replacement surgery.

KEYWORDS
Total Knee Replacement, Local Infiltration Analgesia, Epidural Analgesia, Ropivacaine, Ketorolac, Adrenaline.


BACKGROUND
Total Knee Replacement (TKR) is associated with moderate-to-severe post-operative pain.1-2 Multiple techniques of post-operative pain control have been used after knee surgeries including intravenous opioids, Epidural Analgesia (EA) and femoral nerve block. Parenteral opioids contribute to increased morbidity, hospital costs and patients may be at significant risk for opioid related adverse effects.3-5 Femoral block and oral medication is also commonly practised in orthopaedic departments. Each technique offers several side effects6-7 and therefore the search for other methods continues. The most common method used for pain relief is epidural analgesia,8 but it has several major negative side effects.

Multiple studies have documented the efficacy of Local Infiltration Analgesia (LIA) for TKR.9,10 Many authors have described methods using bupivacaine, ropivacaine or bupivacaine and morphine as either a single intra-articular injection or a continuous intra-articular infusion.11-15 It significantly improves post-operative pain relief and may even reduce opioid consumption after TKR.10,11,16-18 Placement of an intra-articular catheter allows prolonged site specific regional analgesia. This may be beneficial since studies have shown that the duration of analgesic effect for local infiltration is typically 8 – 12 hrs.11,18 and possibly as long as 24 hrs.17,19

Hence, we aimed to compare the efficacy of LIA and EA using ropivacaine as local anaesthetic, ketorolac and adrenaline as adjuvant in patients undergoing unilateral total knee replacement for varus deformity with respect to post-operative pain relief (first 3 - 4 days), range of movement, ambulation, requirement of rescue analgesia and patient satisfaction.

MATERIALS AND METHODS
This prospective randomised study was conducted after obtaining approval from the Institutional Review Board. This prospective randomised study was carried out in patients undergoing unilateral TKR for varus deformity at our Institution from August 2012 to March 2014. Patients of either sex aged > 50 years, belonging to American Society of Anaesthesiologists (ASA) I to III were included in the study. Patients who refused to give consent with significant
systemic diseases, coagulation disorders, contraindications for EA and those patients with valgus knee were excluded from the study. Procedure was explained to the patients and written informed consent was obtained.

Patients were randomly allocated by paper envelop method into two groups of thirty six each. Patients in Group 1 received LIA and Group 2 received EA. The sample size was estimated based on a pilot study carried out in 10 patients, where it was found that mean VAS scores at 6 hours for the LIA group and the EA group were 2.3 and 1.9 respectively with Standard Deviation (SD) of 0.79. Based on these figures with alpha error= 0.05, power of study= 0.85 and using formula n= $2(Z_{a/2}Z_{p} / \text{standard error})^2$ we got the required sample size of 72 cases. In our Institution during the study period, only 80 to 100 cases satisfying the inclusion criteria were expected. So all the cases satisfying the inclusion criteria were included in the study till the required sample size 72 cases were enrolled. 72 covers were prepared containing a sheet marked as LIA group in 36 covers and EA group in 36 covers. The patients were asked to pick a cover and were included in groups as per the entry in the sheet in the cover picked up. No pre-emptive analgesia was given and TKR was performed using standard techniques. All patients were operated by single surgeon.

Group 1 patients received LIA mixture containing 300 mg ropivacaine (250 mg in patients less than 55 kg), 30 mg of ketorolac, 500 µg of epinephrine diluted to 130 - 150 mL (Based on weight of patients) and injected over a period of 45 - 60 minutes as follows: LIA mixture of 30 - 50 mL was first injected into posterior capsule of knee joint after making bone cuts followed by another injection of 35 – 50 mL into the deep tissues around medial and lateral collateral ligaments after fixation of components and tourniquet release (Figure 1). The last infiltration of 35 – 50 mL was into the subcutaneous tissue and adjoining anteromedial/ anterolateral capsule of knee joint.

Before wound closure, a 19-G catheter was placed medially on raw bone medial to femoral component, inserted using Tuohy needle through vastus medialis obliquous and exiting subcutaneously away from incision, approximately 3 inches away from joint and fixed to skin. The catheter was fitted with an antibiotic filter and packed in a separate sterile dressing. At 20 – 24 hrs. post-operatively, the surgical field was reinjected with approximately 20 mL of LIA mixture through the catheter and the catheter removed.

Group 2 patients were put on continuous EA pump (Fitted with antibacterial filter) containing 2000 mg of ropivacaine, 400 µg of fentanyl at the rate of 5 mL/hr (600 mg ropivacaine and 80 µg of fentanyl/day). Epidural pump was removed on 4% post-operative day at the nadir of action of low molecular weight heparin.

Standard post-operative protocols were followed for all patients. Post-operatively, all patients were given a combination of trypsin-chymotrypsin 10 mg thrice daily, omeprazole 20 mg once daily for first 5 days. All patients received low molecular weight heparin for 1 week and started 24 hrs. post-operatively.

Parameters assessed were: Pain on Visual Analogue Scale (VAS), Range of Movements (ROM) and ambulation with support (knee brace and walker) at 6 hrs., 24 hrs., 48 hrs., 72 hrs. and 96 hrs. The need for rescue analgesia (opioids) and overall patient satisfaction was also assessed. VAS is a most common method for measuring pain and pain relief in clinical practice. 1 - 2= no pain, 3 - 4= mild pain, 5 - 6= moderate pain, 7 - 8= severe pain and 9 - 10= intolerable pain.

The information collected regarding all the selected cases were recorded in a master chart. Data analysis was done with the help of computer using Epidemiological Information Package (EPI 2010) developed by Centre for Disease Control, Atlanta. Using this software range, frequencies, percentages, means, standard deviations, Chi-square and 'P' values were calculated. Paired 't' test was used to test the significance of difference between quantitative variables and Fisher’s test, Chi-square tests for qualitative variables. A P value less than 0.05 is taken to denote significant relationship.

RESULTS
Demographic profiles were evenly distributed between both the groups with respect to age, sex and side of operation (Table 1). Pain scores were recorded for the first 4 post-operative days. There was a significant difference in average pain score in the LIA group compared to EA group. VAS scores on post-operative day 1, 2, 3, 4 in both the groups were (2.1 vs 1.6), (1.9 vs 1.2), (1.3 vs 0.8), (0.9 vs 0.6) respectively (Table 2). The ROM was more after 48 and 72 hrs. in EA group compared to LIA group and was statistically significant (P = 0.0071, 0.0298) respectively. However, at 96 hours, ROM was found statistically insignificant (P = 0.0686). Ambulation with support (knee brace and walker) was possible only in LIA group. Almost all the patients in LIA group were ambulated by 96 hrs. Ambulation was possible for 8.3%, 44.4%, 72.2%, 86.1% patients at 24 hrs., 48 hrs., 72 hrs. and 96 hrs. respectively. Ambulation in EA group was not possible till the end of 96 hrs. (Figure 2) and was statistically significant. Rescue analgesia was needed in 13.9% patients of LIA group. None of the patients in EA group required rescue analgesia and this was statistically significant (Figure 3) (P value = 0.0269). More number of patients in EA group were fully satisfied at the end of 4 days compared to LIA group (86.1% vs 69.4%). In LIA group 16.7% of patients were poorly satisfied as compared to nil patients in EA group. Rest of the patients in both groups were fairly satisfied and was found statistically significant (Figure 4).

<table>
<thead>
<tr>
<th>Demographic Profile</th>
<th>LIA Group Mean/SD</th>
<th>Epidural Group Mean/SD</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age group in years</td>
<td>66.8/7.9</td>
<td>65.1/9.3</td>
<td>0.4131</td>
</tr>
<tr>
<td>Sex M/F (n)</td>
<td>2/34</td>
<td>4/32</td>
<td>0.3369</td>
</tr>
<tr>
<td>Side Left/ Right (n)</td>
<td>18/18</td>
<td>16/20</td>
<td>0.4068</td>
</tr>
</tbody>
</table>

Table 1. Comparison of Demographic Profile between Two Groups. SD= Standard Deviation

<table>
<thead>
<tr>
<th>Pain Score (VAS) at</th>
<th>LIA Group</th>
<th>Epidural Group</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>6 hours</td>
<td>2.47</td>
<td>0.77</td>
<td>0.0042</td>
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<tr>
<td></td>
<td>2.14</td>
<td>0.8</td>
<td>0.64</td>
</tr>
<tr>
<td>48 hours</td>
<td>1.92</td>
<td>0.6</td>
<td>0.0029</td>
</tr>
<tr>
<td></td>
<td>1.31</td>
<td>0.71</td>
<td>0.0073</td>
</tr>
<tr>
<td>96 hours</td>
<td>0.94</td>
<td>0.63</td>
<td>0.0414</td>
</tr>
</tbody>
</table>

Table 2. Comparison of Pain Score (VAS) at various Time Intervals
<table>
<thead>
<tr>
<th>Authors</th>
<th>Group 1-LIA</th>
<th>Group 2</th>
<th>Observation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kerr DR, et al</td>
<td>325</td>
<td>Epidural</td>
<td>In LIA group pain control was satisfactory, no morphine was required in two-thirds of patients</td>
</tr>
<tr>
<td>Bush CA, et al</td>
<td>64</td>
<td>Peri-articular injection containing ropivacaine, ketorolac, epimorphine and epinephrine</td>
<td>Peri-articular analgesia significantly reduce the requirement for rescue analgesia and improve patient satisfaction with no apparent risks</td>
</tr>
<tr>
<td>Anderson KV, et al</td>
<td>40</td>
<td>Wound infiltration with intra-articular infusion using ropivacaine and ketorolac</td>
<td>Peri-articular and intra-articular analgesia provided superior pain relief and reduced morphine consumption compared with continuous epidural infusion</td>
</tr>
<tr>
<td>Spreng UJ, et al</td>
<td>102</td>
<td>Ropivacaine 150 mg adrenaline 0.5 mg</td>
<td>Epidural Analgesia LIA reduced opioid consumption, facilitated faster mobilisation and early discharge from hospital, but verbal pain scores were lower in EDA group</td>
</tr>
<tr>
<td>Martin Thorsell, et al</td>
<td>85</td>
<td>Ropivacaine 300 mg adrenaline 0.5 mg</td>
<td>Epidural Analgesia LIA offers equal pain relief as that of epidural anaesthesia, but also faster mobilisation and more patient satisfaction than epidural anaesthesia</td>
</tr>
<tr>
<td>Essving P, et al</td>
<td>40</td>
<td>200 mg ropivacaine, 30 mg ketorolac and 0.5 mg epinephrine</td>
<td>Saline Injected Excellent pain relief and earlier discharge in LIA group compared to control group</td>
</tr>
<tr>
<td>B. Garcia-Benitez, et al</td>
<td>90</td>
<td>Epidural Analgesia</td>
<td>Peri-articular infiltration with analgesic cocktail before incision closure is a good treatment option for post-operative pain in TKR</td>
</tr>
</tbody>
</table>

Table 4. Comparison of Present Study Results with Other Studies
DISCUSSION
Post-operative pain control after TKR offers a clinical challenge. Pain contributes to immobility related complications, prolonged hospital stay and interferes with optimal post-operative knee rehabilitation. Arthrofibrosis and diminished range of movements are closely related to degree of post-operative pain.[20,21]

The most common method used is epidural analgesia that offers good pain relief,[43] has several complications such as motor weakness, urinary retention and hypotonia. Even complications such as epidural haematoma, spinal infection have recently led to questioning of its routine use, specifically in older women.[22] Continuous epidural analgesia using pump has inherent disadvantages- hypotension, urinary retention.[23,24] Epidural catheter complications, DVT, delayed ambulation, need to use anticoagulants, more expensive equipment and prolonged hospital stay.[10,25,26] LIA overcomes some of these disadvantages. It is cheaper, allows early mobilisation and ambulation, thereby obviating requirement of anticoagulants, preventing systemic complications and early discharge from hospital. It also decreases blood loss and need for rescue analgesia.[11] Multiple studies have been done with LIA by either using single shot injection intraoperatively,[11,16-18] continuous intra-articular injection for 24 - 48 hrs. after surgery.[27-29]

The benefits of the LIA technique are good post-operative pain control, fast mobilisation and early discharge from hospital.[27-32] It reduces opioid consumption post-operatively after total knee replacement.[25,17,18] It also decreases blood loss.[11]

Our analysis revealed that after TKR, EA group had significantly less intensity of pain than LIA group at 1 - 4th post-operative day. Use of continuous epidural pump post-operatively had more beneficial effect on pain scores in EA group compared to LIA group.

The ROM was significantly more at 48 hrs. and 72 hrs. in epidural analgesia group than LIA group. However, there was no significant difference between both groups at the 4th post-operative day. Ambulation with support was possible only in LIA group. Ambulation in epidural analgesia group was not possible by 96 hours.[19,20,33] We found that the patients in the LIA group could get in and out of bed without personal assistance and could walk with walker support from 48 hrs. onwards. Hence, LIA can be a part of fast-track arthroplasty surgery. In present study blood loss was less in LIA group, but it was not calculated and proved statistically. Both group’s patients were discharged after stitch removal on 11th post-operative day. Rescue analgesia was required in 13.9% patients of LIA group, whereas none of the patients in epidural analgesia group required rescue analgesia. No post-operative complications like DVT, hypotension or urinary retention were observed in both the groups.

In EA group though patients were more satisfied with respect to pain, early ambulation was not possible in contrast to LIA group. However, range of movements were similar in both the groups at the end of 96 hrs.

Limitations
The study was limited to only 72 patients. Larger number of enrolled cases are required to assess the risk of infections associated with LIA-injection of high volumes of non-physiological fluids both in interstitial spaces and intra-

articularly through catheter. The study duration was limited to 96 hrs. post-operatively. Use intra-articular ketorolac, as adjuvant has negative effect on bone healing[34,35,36] and may increase the risk of endoprosthetic loosening.[25] Longer duration of study period is required to assess long-term complications like endoprosthetic loosening.

CONCLUSION
Local infiltration analgesia is a better alternative to epidural analgesia. In LIA group the advantages noted were early ambulation, lesser blood loss, less expensive, no urinary retention or hypotension. However, pain relief was more satisfactory in epidural analgesia group. In LIA group, rescue analgesia was not required in more than two-third patients and more than two-third patients were fully satisfied. More than two-third patients were ambulated with walker by 72 hrs, whereas none were ambulant by 96 hours in EA group.

REFERENCES


