To study the efficacy of ropivacaine (0.75%) with or without butorphanol as an adjuvant in single shot epidural anaesthesia in lower limb orthopedic surgeries

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Abstract
Objectives: To evaluate the efficacy of Butorphanol as an adjuvant to Ropivacaine (0.75%) Plain in Single Shot Epidural Anaesthesia on: Onset of Sensory & Motor Block; Duration of Sensory & Motor Block; The Hemodynamic Changes Intra operatively & Post operatively; Duration of post-operative analgesia, Side Effects / Complications if any.

Material and Methods: 60 adult patients of ASA I/II, posted for elective lower limb surgeries in orthopaedics were divided in to two groups randomly.
Group R (n = 30) were given a single shot dose of epidural Ropivacaine 0.75% 20ml and Normal saline equivalent to 15µg/kg of Butorphanol.
Group B (n = 30) were given a single shot dose of epidural Ropivacaine 0.75% 20ml with 15ug/kg Butorphanol as an adjuvant.

Results: The mean onset time to achieve desired sensory block was rapid in the Group-B compared to Group-R. The mean time to achieve motor block was faster in Group-B compared to Group-R. The hemodynamic parameters were comparable at all the time among both the groups. Total duration of analgesia was significantly prolonged in Group-B compared to Group-R. No major side effects were observed in either of the group.

Conclusion: Epidural 0.75% Ropivacaine with Butorphanol showed better clinical profile as compared to 0.75% Ropivacaine plain for lower limb orthopedic surgeries in single shot epidural anaesthesia.

Keywords: Single Shot Epidural Anaesthesia, Ropivacaine 0.75%, Butorphanol

1. Introduction
Recent trends suggests that regional anaesthesia is replacing general anaesthesia in all most all the surgeries below umbilicus mainly because its benefits such as avoidance of poly pharmacy, airway manipulation, misplacement of endotracheal tube, hypo or hyper ventilation, vomiting, pulmonary aspiration. Also it reduces surgical stress and attenuates in plasma catecholamines and other hormones. Along with this the main advantage of regional anaesthesia is that it provides intra and postoperative pain relief with full preservation of mental status & normal reflexes, unlike general anaesthesia.

When it comes to regional anaesthesia & pain relief, epidural anaesthesia is preferred to spinal anaesthesia as

- The duration of anaesthesia can be achieved longer than with spinal anaesthesia.
- Longer duration of post-operative analgesia.
- Less chances of spinal anaesthesia such as headache, arachnoiditis & meningitis.
- GI complaints like nausea & vomiting are minimal.
- Less chances of cardiac disturbances like severe bradycardia & hypotension.

Drugs commonly used for epidural analgesia:
1. Local anesthetics
2. Opioids
3. Local anesthetic-opioid combinations
4. Other Adjuvants: A variety of adjuvants are used for epidural infusion to enhance analgesia while minimizing side effects, like Clonidine, Epinephrine, Ketamine, Sodium bicarbonate etc.

Among local anaesthetics, Ropivacaine is a synthetic local anaesthetic agent which is more potent & much less cardio toxic when compared to commonly used bupivacaine.

Butorphanol is an agonist - antagonists (K analgesics) kind of opioid which is said to have less respiratory depression compared to other opioids and no or minimal adverse effects.

On the basis of these evidences, a study was undertaken to compare the efficacy of ropivacaine (0.75%) with or without butorphanol as an adjuvant in single shot epidural anaesthesia on the onset and duration of sensory and motor blockade, hemodynamic stability, duration of analgesia, and side effects in patients undergoing elective lower limb orthopedic surgeries.

2. Material and Methods
The study was conducted in Department of Anaesthesiology, Dhiraj Hospital, S.B.K.S. Medical Institute and Research Centre during 2013 to 2014.

After consent of the ethical committee, this study was conducted on sixty adult patients of ASA class I and II, posted for elective lower limb surgeries in orthopaedics. All the patients in the study were explained clearly about the purpose and nature of the study in the language they could understand. They were included in the study only after obtaining a written informed consent.

Patients were randomly divided into two groups of 30 each.
Group R (n = 30) were given a single shot dose of epidural ropivacaine 0.75% 20ml and normal saline equivalent to 15µgm/kg of butorphanol.
Group B (n = 30) were given a single shot dose of epidural ropivacaine 0.75% 20ml with 15ug/kg butorphanol as an adjuvant.

2.1 Inclusion criteria
i. Patients in the age range 18-55 years.
ii. Weight between 50-70kg.
iii. Height above 5feet.
iv. ASA risk category I and II.
v. No known history of allergy, sensitivity or other form of reaction to local anesthetics.
vi. Patient willing to sign informed consent.

2.2 Exclusion criteria
i. Patient refusal.
ii. Patients with spine deformity.
iii. Patients with local skin infections at site of injection.
iv. Known allergy to the trial drugs.
v. Patients with incomplete effect who required supplementation with General anaesthesia.
vi. ASA III or more.

2.3 Preoperative Management

2.3.1 Preoperative assessment
All the patients posted for the planned surgery were undertaken for pre-anesthetic checkup and following data’s were evaluated:
- History
- Clinical examination
- Systemic examination
- Investigations

2.3.2 In the recovery room
- The patients were assessed on the morning of the procedure 30minutes prior to the surgery for the vital parameters.
- An intravenous line was secured in the recovery room itself with 18G vein flow & Inj. Ringers lactate infusion was started at the rate of 10ml/kg.

2.4 In the operation theatre
- On the arrival of the patient in the operation theatre, the patient was shifted on the o-t table and multi-parameter monitor was attached to the patient and vital parameters were noted down:
  - Pre-medications were administered intravenously in the form of:
    - Inj. Onodansetron 4mg
    - Inj. Glycopyrrolate 0.2mg
  - Following to this, patient was taken up for the epidural injection.

2.4.1 Epidural procedure
- The patient was given the position for this procedure in either of the two ways, that is lateral position or sitting position according to the patient’s condition & comfort.
- An autoclaved epidural tray was used.
- With all aseptic precautions, a skin wheal was raised at L₃ -L₄ or L₄ - L₅ interspace with 2cc of 1% lignocaine.
- The epidural space was identified using a18G TOUHY needle with loss of resistance to saline technique.
- A mixture of 20ml ropivacaine (0.75%) plain with normal saline equivalent to 15µgm/kg of butorphanol for Group-R and 20ml ropivacaine (0.75%) plain with injection butorphanol 15µgm/kg for Group-B were prepared.
- 2cc of the prepared solution was injected as a test dose and observed for any intravascular or intrathecal injection. Then injection of the remaining solution was given after negative aspiration for CSF and blood.
- Patient was given supine position immediately.

2.4.2 Sensory block assessment
- The onset of sensory block was considered from the time of epidural injection till the level of T₁₀ was achieved.
- The duration of sensory block was considered from attainment of level of T₁₀ and till it regressed below L₅.

2.4.3 Motor block assessment:
- The onset time of motor block was considered from the time of epidural injection till bromage scale 3 was achieved.
- The duration of motor block was considered as the time since Bromage scale 3 was achieved & up till the bromage scale went below 1.

2.4.4 Hemodynamic assessment:
  - Monitoring of vitals
    - HR, BP, RR & SpO₂ were recorded immediately after the epidural injection & following that after 2, 5, 10, 15 & 30mins for first half hour & than every 30mins till the end of the procedure. Post-operatively every 1hourly for first 3 hours and every 2hourly for next 6hours.
    - In any phase, if the arterial blood pressure (BP) decreased more than 20% below the pre-operative value, it was considered to be significant hypotension and Inj. Mepheneteramine in 6 mg increments was given intravenously.
    - If anytime SpO₂ had fallen below 90%, O₂was started at 3-4 lit/min.

2.4.5 Complications
- All patients were monitored for side effects/complaint of the procedure & the drugs used for epidural anaesthesia both intra-operatively as well as post-operatively.
  - These include:
    - Nausea, Vomiting
    - Sedation
    - Pruritus
    - Dizziness, Confusion.

2.5 Post-operative management
- With stable hemodynamic, patients were transferred to the recovery room. Patients were constantly monitored haemodynamically as described.
2.5.1 Post-Operative Analgesia

The intensity of post-operative pain was assessed employing the visual analogue score (VAS). When VAS≥3, Rescue analgesic (Inj. Diclofenac IM) were administered.

Post-operative analgesia was considered as the time between the epidural injection and the requirement of analgesic for the first time or patient’s first complaint of pain (VAS≥3).

2.6 Statistical Methods

- Data were collected, tabulated, coded & then analyzed using GRAPHPAD PRISM computer software version 6.0
- Numerical variables were presented as Mean & Standard Deviation (SD). While categorical variables were presented as percentage (%).
- As regard numerical variables; unpaired student-t test was done.
- The inferences based on ‘p’ value were made as : p>0.05: Not Significant; p<0.05: Significant; p<0.001: Strongly Significant

3. Observation and Results

Demographic data was comparable among both the groups in terms of age, sex, height, weight & ASA grade.

Table 1: Demographic Data

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Group – R (n = 30)</th>
<th>Group – B (n = 30)</th>
<th>Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>37.77 ± 2.098</td>
<td>36.53 ± 1.668</td>
<td>P = 0.6471; not significant</td>
</tr>
<tr>
<td>Sex (M/F)</td>
<td>25/05</td>
<td>27/03</td>
<td>No significance</td>
</tr>
<tr>
<td>Height (cm)</td>
<td>161.5 ± 1.255</td>
<td>161.8 ± 1.146</td>
<td>0.8605; not significant</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>56.60 ± 0.6637</td>
<td>56.30 ± 0.6884</td>
<td>0.7548; not significant</td>
</tr>
<tr>
<td>ASA grade</td>
<td>I 16</td>
<td>II 17</td>
<td>Not significant</td>
</tr>
<tr>
<td>II 14</td>
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Fig 1: Chart showing Comparison of Onset of Sensory Block & Motor Block

The onset of the sensory block was faster in Group-B (9.56±0.2072min) compared to Group-R (13.83±0.2499min). As well as the onset of motor block was also rapid in Group-B (13.03±0.2273min) patients compared to Group-R (17.17±0.2586min) patients. Hence it was clinically as well as statistically significant. (p<0.0001)

Fig 2: Chart showing Comparison of Duration of Sensory Block & Motor Block

The duration of the sensory block was longer in Group-B (338.3±1.55min) compared to Group-R (233.5±3.164min). As well as the duration of the motor block was also longer in Group-B (264.5±3.615min) patients compared to Group-R (194.2±3.181min) patients. Thus it was clinically as well as statistically significant. (p<0.0001)
Total duration of analgesia was significantly longer in Group-B (408±4.198min) compared to Group-R (275±3.356min) (p<0.0001).

4. Discussion
4.1 Demographic Data
The demographic data in terms of age, sex, weight, height and ASA grade were comparable in both the groups of our study (Table no.1).

Binay et al, 2012, used butorphanol-bupivacaine mixture in lower limb orthopedic surgeries and stated that the wide variability in the age of the patients (18-75yrs) in their study was a confounding factor in relation to perception of pain as pain perception varies with age.15 However this was not observed in our study as the demographic data (age: 18-55yrs) did not have extreme variability.

4.2 Sensory and motor blockade
In the present study the onset of sensory blockade was faster in Group-B (9.56±0.20min) compared to Group-R (13.83±0.24min).

Sara et al, June 2011, stated that the onset time for sensory block to T1 varied between 10 and 25mins (15.66±6.91min) with 0.75% ropivacaine plain epidurally, which was comparable to our study (13.83 ± 0.24min).17 Also paralleling our findings, Binay et al, 2011, conducted a study in lower orthopedic patients with epidural bupivacaine & butorphanol mixture & observed that onset of sensory block was 8.6±1.40min.12

Bhawna et al, studied 15ml of 0.75% ropivacaine with fentanyl and found that the mean onset time of sensory analgesia at T1 dermatome was (12.4±6.9min)18 which was also similar to our study Group-R. In the present study the onset of motor blockade was shorter in Group-B (13.03 ± 0.22min) compared to Group-R (17.17±0.25min).

Sara et al, June 2011, found that a greater intensity of motor block was achieved with 0.5% bupivacaine at an earlier stage but within 30mins the difference in motor block between 0.5% bupivacaine & 0.75% ropivacaine was not significant which suggested that ropivacaine 0.75% also produced efficient motor block,19 in conjunction to the present study.

Binay et al, 2011, observed onset of motor blockade 10.1±1.7min with bupivacaine-butorphanol combination in epidural blocks12 which was slightly faster than our study. In the present study the duration of sensory blockade was longer in Group-B (338.3±4.15min) compared to Group-R (233.5±3.16min). Also the duration of motor blockade was longer in Group-B (264.5±3.61min) compared to Group-R (194.2±3.18min).

Binay et al, 2011, observed total duration of sensory blockade 167.0±23.8 min20 which was much longer than our study group.

Bhawna et al, observed total duration of sensory blockade as 130.6±10.2 min14 which was again much shorter than that in the present study. They also suggested that the potency of ropivacaine may be altered by co-administration with other anaesthetics and opioid analgesic.

Manpreet et al, 2011, studied addition of butorphanol & sufentanil to bupivacaine for subarachnoid block and reiterated that the addition of butorphanol significantly prolonged the duration of sensory block. They also found that 90% of patients achieved a bromage scale of 3 in butorphanol group & the duration of motor block was prolonged.21 However, as compared to present study, the duration of both sensory block (170.87±22.21min) and motor block (132.20±20.8min) was lower in our study. This could be attributed to the separate routes of central neuraxial blockade used in both studies.

Vaghadia et al, observed that opioids like butorphanol increases the sensory block and delays the time of two-segment regression of the sensory level.16,17 Vinita et al, also added butorphanol to hyperbaric bupivacaine and concluded that butorphanol intensifies the sensory blockage and increases the duration of sensory blockade without increasing the intensity of motor blockade & requirement of rescue analgesia which was similar to study.16

Singh et al, conducted a study on 80 ASA I & ASA II patients undergoing lower limb surgeries where 25mg of butorphanol and 25mg of fentanyl were added to epidural bupivacaine and they found that this combination doesn’t prolong the motor block significantly.19 However in our study the motor block was significantly prolonged with the addition of butorphanol in the Group-B in comparison to Group-R.

Sara et al, observed total duration of motor blockade of 144.67±34.61min with 0.75% plain ropivacaine which was comparatively lower than our study.15 Thus combination of local anaesthetics and opioids may effectively inhibit multiple areas of neuronal excitability, thus enhances the potency of surgical anaesthesia.20

One patient in Group-B did not have satisfactory anaesthesia. This may be due to lower pain threshold of the patient or may be due to improper placement of portion of the drug in the epidural space. An important factor for a sufficient epidural analgesia is the exact epidural positioning of the epidural needle in the area of the spinal cord segments, which are affected by the operation,21 hence this patient wasn’t included in our study.
Does adrenaline improve epidural bupivacaine and fentanyl analgesia after abdominal surgery?

The use of opioids in conjunction with local anaesthetic for spinal anaesthesia has been associated with decreased pain scores and reduced analgesic requirement in the post-operative period.\(^{20,21}\) Results of previous studies have demonstrated that intrathecal opioids not only enhance analgesia when added to sub therapeutic doses of local anaesthetics but also do not prolong recovery.\(^{20}\)

In the present study, butorphanol along with ropivacaine not only provided adequate anaesthesia & analgesia but also significantly prolonged its duration. The time for first request of analgesic (duration of analgesia) with the use of epidural ropivacaine & butorphanol was 408±4.19min which was significantly higher as compared to 275.0±3.35min in Group-R. (P < 0.0001)

VAS was significantly higher value in Group-R than Group-B. There was significantly prolonged duration of analgesia in all the patients enrolled in the butorphanol group over ropivacaine alone group.

Sara et al, reported duration of analgesia between 5 and 7.5hrs (352.00±41.63) with epidural ropivacaine 0.75% which was longer than our study in which the duration of analgesia with plain ropivacaine 0.75% was 275.0±3.35min.\(^{11}\)

Gupta et al, studied epidural butorphanol & tramadol with bupivacaine for post-operative analgesia & found that the duration of analgesia was 6.25±1.58hrs which was consistent with the findings of our study.\(^{27}\)

Abbud et al\(^a^{18}\) & Dhimar et al\(^a^{29}\) found an analgesia lasting 5.53±0.86hrs and 8hrs respectively with epidural butorphanol which is similar to our study.

Our results were comparable to Dahlgren et al\(^a^{28}\) and Courtney et al\(^a^{29}\) who demonstrated that the addition of butorphanol to bupivacaine in central neuraxial blockade significantly prolonged the duration of analgesia compared to bupivacaine alone.

Gunion et al reported that opiate analgesics provide effective pain relief and are widely used for control of mild to severe pain.\(^{31}\)

We can safely state that the duration of analgesia in the butorphanol group was significantly prolonged compared with the control group and it has the potential to limit the requirement of post-operative analgesics and its related side effects.

### 4.4 Haemodynamic parameters & side effects / complications:

In this study all the haemodynamic parameters (Pulse, Blood pressure, Respiratory rate & SpO2) of both the groups were comparable at all the time intervals and were clinically & statistically insignificant. This might be an explanation for the increased cardiac index by butorphanol.\(^{22}\)

A low incidence of side effects was observed in our study. Three patients (10%) had hypotension, two patients (6.66%) had bradycardia and two patients (6.66%) had sedation in the butorphanol group. (Table no.2)

Three patients who had hypotension required small doses of iv Mephentermine in addition to crystalloidal bolus.

Sara et al, also noted that vital signs were stable in all patients throughout the study period. They also mentioned that hypotension was the most common side effect and the decrease in blood pressure was transient, quickly resolved by increasing crystalloidal infusion and a single bolus dose of 6mg mephentermine which was similar to our study.\(^{13}\)

Binay et al, observed hypotension in two patients (5%) in the butorphanol treated group requiring treatment with a single bolus dose of 6mg ephedrine in addition to crystalloidal bolus.\(^{22}\)

Two patients who had bradycardia required single bolus of iv atropine 0.6mg.

Mephentermine is common side effect of epidural opioids is pruritus which is related to cephalad migration of opioids in the CSF. None of our patients in either group had complained of pruritus.

In correlation with our study both Bhawna et al\(^{14}\) and Gupta et al\(^{27}\) noted no incidence of nausea, vomiting, head-ache, post-epidural shivering, and urinary retention.

Sedation is a reported side effect of neuraxially administered butorphanol.\(^{33}\)

In our study none of the patient had Ramsey score above 2. However score of 2 were noted in two patients in Group-B, which didn’t require any treatment.

Gupta et al,\(^{27}\) observed sedation in 28(93.33%) patients out of 30 compared to 2 (6.66%) patients out of 30 in our study. However they mentioned that mild sedation in epidural butorphanol group was considered desirable rather than a side effect in their patients.

### 5. Conclusion

In the present clinical study epidural addition of butorphanol to ropivacaine 0.75% ensures faster attainment as well as longer duration of both sensory and motor blockade, maintains intra-operative as well as post-operative haemodynamic parameters, prolongs the duration of analgesia, without causing significant side effects & thus, it also establishes a good safety profile of epidurally administered butorphanol in humans.

### References

17. Tiwari CS, Agnihotri VM. Intrathecal pentazocine 1.5mg/kg, produced sufficient analgesia and motor block in 60 patients undergoing various surgical procedures below umbilicus. *Indian J Anaesth* 1997; 40:30-6.
20. Tiwari CS, Agnihotri VM. Intrathecal pentazocine 1.5mg/kg, produced sufficient analgesia and motor block in 60 patients undergoing various surgical procedures below umbilicus. *Indian J Anaesth* 1997; 40:30-6.

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