Comparison of Ropivacaine with or without Fentanyl in Spinal Anaesthesia for Lower Limb Surgeries

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ARTICLE HISTORY
Received: May 11, 2024
Accepted: Jun 28, 2024

INTRODUCTION

Spinal anesthesia is a type of anesthesia commonly employed for surgeries involving the lower abdomen and extremities.1 Ropivacaine, a local anesthetic of the amide class, is particularly favored due to its properties comparable to bupivacaine, leading to similar sensory and motor block effects but with a shorter duration of action.2 Additionally, ropivacaine offers a more pronounced difference between its effects on sensory and motor nerves, making it beneficial when a prolonged motor block is undesirable.3,4 Despite being 40-50% less potent than bupivacaine, when used in equal amounts, ropivacaine achieves similar clinical outcomes with a better preservation of motor function.5 Although bupivacaine is the more commonly used local anesthetic, ropivacaine has gained attention.

ABSTRACT

Introduction: Spinal anaesthesia is a preferred technique used for lower limb orthopaedic surgeries. Ropivacaine with its short duration of motor blockade and provision for early ambulation along with addition of spinal additives has proven beneficial to the patient. This prospective, double-blind, randomized controlled study set out to evaluate the effects of 0.75% isobaric ropivacaine with fentanyl versus 0.75% isobaric ropivacaine during lower limb orthopaedic surgeries performed under spinal anaesthesia.

Methods: The study enrolled 74 patients, aged 18-65 years of either sex, ASA PS I and II, planned for lower limb orthopaedic surgeries. Patients were randomly allocated to receive either 2.5 ml of 0.75% isobaric ropivacaine and 0.5ml of normal saline (Group R) or 2.5 ml of 0.75% isobaric ropivacaine and 0.5ml of fentanyl (25mcg) (Group RF).

Results: The demographic profile, onset time of sensory block to T10 dermatome, time for complete motor blockade, maximum block height, duration of motor block, and haemodynamic parameters did not significantly differ between the two groups. Group R took 200.27 ± 21.28 minutes for the S2 dermatome segment regression, while Group RF took 284.59 ± 32.88 minutes (p-value<0.001). Group RF experienced analgesia for a longer duration (335.68±22.18 min) than Group R (240.00±28.28 min) (p-value<0.001).

Conclusion: Fentanyl greatly extends the duration of S2 segment regression and analgesia when combined with ropivacaine; the effects on haemodynamics and motor blockade is clinically negligible and side effects are minimal.

CONFILICT OF INTEREST : None
Acknowledgements: None
FUNDING SOURCES: None
in recent years for its equivalent spinal anesthesia capabilities and its reduced risk of neurotoxicity and cardiotoxicity when compared to bupivacaine. Studies have shown that ropivacaine leads to fewer arrhythmias and is more well-tolerated when administered intravenously, resulting in less impact on myocardial contractility and conductivity than bupivacaine. Lignocaine, another local anesthetic, is particularly suited for day surgeries due to its block (motor and sensory) and recovery properties. However, it is known to cause a high rate of transient neurological symptoms.

It has been demonstrated that prolonging the time frame of sensory analgesia during spinal anesthesia can be achieved by intrathecally administering small-dose fentanyl (10–25 mcg) in addition to local anesthetics. Without sacrificing its advantages, such as early mobilization and early voiding, the addition of this adjuvant to ropivacaine has demonstrated to increase the quality of intraoperative and postoperative analgesia and hemodynamic stability.

The application of ropivacaine as a spinal anesthetic has shown advantages in achieving sufficient effects on both sensory and motor functions, along with reducing its impact on systemic toxicity. As a result, there has been a growing preference for ropivacaine in our clinical practice. By incorporating spinal additives such as fentanyl with ropivacaine, the anaesthesiologist has a significant advantage in extending the duration of pain relief following spinal anesthesia, which in turn reduces the need for other analgesics and fewer side effects. This research seeks to determine whether the combination of ropivacaine and fentanyl in subarachnoid blocks during surgeries on the lower limbs will result in more effective block characteristics and better haemodynamics as compared to using ropivacaine alone.

**METHODS**

It was a randomized double blinded prospective interventional study conducted on 74 patients admitted to Operating rooms, postoperative ward, post-anesthesia care unit, and wards of Tribhuvan University Teaching Hospital, Maharajgunj, Nepal. All patients 18 to 65 years of age and ASA physical status of I and II planned for lower limb orthopaedic surgery under spinal anaesthesia were included in the study. Patient with a height less than 150 cm, history of hypersensitivitiy to study drugs, pregnancy, and those unable to communicate verbally were excluded from the study. After the approval from the Institutional Review Committee of Institute of Medicine (IOM) and the Ethical Review Board of Nepal Health Research Council (NHRC), this study was registered with NCT04199013 at clinicaltrials.gov registry. Patients were screened for enrollment in the study by an anaesthesiologist not involved in the study and randomly distributed in two groups using computer generated numbers that were concealed in Sequentially Numbered Opaque Sealed Envelopes (SNOSE).

During the preanesthetic examination, the participants were briefed on the objectives of the study, the voluntary nature of their involvement, the benefits and potential dangers of the procedure, and were educated on sensory and motor blockages. They were also provided with written consent. The participants were instructed to keep clear of food and drink according to the ASA’s guidelines. Their heart rate, systolic blood pressure, diastolic blood pressure, mean arterial pressure, and oxygen levels in the blood were measured at the start. The patients were then moved to the operating room, where their HR, SpO2, SBP, DBP, and MAP were recorded again. The patients in Group R received a subarachnoid injection of 2.5 ml of a 0.75% isobaric ropivacaine solution containing 18.75 mg of the drug, along with 0.5 ml of normal saline, for a total volume of 3 ml. On the other hand, the patients in Group RF received the same injection but with an additional 0.5 ml of fentanyl (25 mcg) for a total volume of 3 ml.

For fifteen minutes, patients were given 15ml/kg body eight of Ringer’s lactate solution. The skin was infiltrated with 2% lignocaine while stringent aseptic precautions were followed. A 25G Quincke spinal needle was used for the lumbar puncture, which was done in the sitting or lateral position at the L3-L4 or L4-L5 intervertebral spaces. Over the course of 15 seconds, 0.2 ml/second of the study drug was injected. The patients were immediately put in a supine position following the spinal medication injection, and this was noted as “time-zero.” The operating table was maintained in its neutral position. The loss of pinprick sensation at the T10 level in the mid-clavicular line was used to gauge the degree of sensory block. The test was performed every 2 min from “time zero” for the first 10 min, then every 5 min till loss of discrimination to pinprick till 30 min. Time to achieve a complete motor block (Modified Bromage 3) was noted every 5 min from “time zero” till 30 min. Motor block in the lower limbs was graded according to the modified Bromage (MB) scale.
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Following verification of the motor block of Modified Bromage score of 3 and the loss of pinprick sensation at T10 relative to C5-6 dermatome, the surgery was approved. Failure was defined as the inability to achieve a Modified Bromage Score of 3 within 30 minutes from “time zero” and the loss of pinprick at the T10 sensory level. These patients received general anesthesia and were not included in the analysis. Instead, the protocol analysis only reported the total number of failures.

The maximum block height and the amount of time it takes for sensory block to develop up to T10 level were measured and recorded. Up until the maximum block height was reached, the block level was recorded by pin-pricking every five minutes. The height at which the sensory block level stayed constant for two consecutive 5-minute intervals (ie. for a total of ten minutes at the same block level) was defined as the maximum block height. The time it took to reach the T10 level of sensory blockade was considered as the onset of sensory blockade.

The vitals of the patients were monitored every 5 min throughout the surgery. The patient’s heart rate, blood pressure (SBP, DBP, MAP) and oxygen saturation were recorded every 5 min for the first 30 min from “time zero” then every 30 minutes till the end of the surgery for data analysis. After the end of the procedure, the vitals were recorded every 30 min till 5 hours from “time zero”.

Time to reach Modified Bromage 0, time for S2 segment regression of sensory level, and total duration of analgesia were recorded. The time interval between “time zero” of the subarachnoid injection and the point at which patients started requesting rescue analgesics for pain relief was considered the duration of analgesia. In accordance with hospital protocol, analgesia was administered for pain management. After surgery, the time it took for the S2 segment regression was recorded using pinprick sensation over S2 dermatome regions every 30 minutes. The time span from “time zero” to the regression of the S2 segment was used to define the total duration of sensory blockade. Every 30 minutes from the time the surgery ended, the Modified Bromage Score was evaluated in order to determine the time it took to reach Modified Bromage 0.

Hypotension was defined as decrease in MAP of more than 25% from the baseline vitals. Episodes of hypotension were treated with IV fluids and Inj. Phenylephrine 50 mcg IV bolus. Bradycardia was defined as heart rate <60 beats/min and treated with IV atropine 0.6 mg.

Side effects like nausea, vomiting and pruritus were noted from “time zero” up to 180 min. If occurred, nausea, vomiting and pruritus were managed with Inj. ondansetron 8 mg IV. After completion of surgery, the patients were transferred to recovery room and monitoring of haemodynamic parameters was done.

Data collection was done in a preformed sheet. Statistical analysis was done by using Statistical Package for the Social Sciences (SPSS) software version 16.0. Biostatistician was consulted. Values were presented as mean (± standard deviation) or frequency. p value of <0.05 was considered significant. Independent t test was used for normally distributed data. Chi square test was used for categorical data. Mann-Whitney U test was used for non-normally distributed (skewed) data.

RESULTS

Our calculated sample size was 66. Assuming 10% drop out from the study a total of 74 patients were included in our study. Thus, there were 37 patients in ropivacaine group (Group R) and 37 in ropivacaine with fentanyl group (Group RF).

The result is presented in 11 sections namely demographic profile, ASA Physical status, time required to reach T10 blockade, maximum cephalad level, time required to reach Bromage 3, time required for S2 segment regression, total duration of analgesia, time required to reach Bromage 0, comparison of HR, SBP, DBP, MAP, SpO\textsubscript{2}, incidence of nausea, vomiting and pruritus between the two groups.

There was no significant difference in the demographic profile and ASA Physical status between the two study groups. (Table 1)

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Group R</th>
<th>Group RF</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>36.86±12.94</td>
<td>34.22± 13.29</td>
<td>0.388</td>
</tr>
<tr>
<td>Height (cm)</td>
<td>162.35±6.49</td>
<td>161.14± 5.08</td>
<td>0.372</td>
</tr>
<tr>
<td>Sex (Male/ Female)</td>
<td>24/13</td>
<td>25/12</td>
<td>0.806</td>
</tr>
<tr>
<td>ASA PS I &amp; II</td>
<td>29/8</td>
<td>27/10</td>
<td>0.588</td>
</tr>
</tbody>
</table>

At level T10, there was no discernible variation in the average start time of sensory blockage. The mean onset time in group R was 5.8±2.00 min, which was somewhat faster than the onset of 5.62±1.82 min in...
group RF. When it came to the start of total motor blockage (Time to Bromage 3), Group R and Group RF did not differ significantly from one another. In Group R, the average time to reach Bromage 3 was 8.51±3.51 minutes, while in Group RF, it was 8.11±2.97 minutes (p-value 0.593). S2 segment regression took 200.27±21.28 minutes in group R and 284.59±32.88 minutes in group RF, both of which had statistically significant durations (p-value <0.001). Group RF experienced a considerably longer mean duration of analgesia (335.68±22.18 min) as compared to Group R (240.00±28.28 min) (p-value<0.001). The duration of motor blockade was comparable in both the groups. The mean time to attain Bromage 0 in Group R was 169.5±17.6 min while that in Group RF was 173.5±21.4 min. (p-value 0.376). (Table 2)

Table 2: Block Characteristics

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Group R</th>
<th>Group RF</th>
<th>p-value</th>
</tr>
</thead>
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<tr>
<td>Time To Reach T10 Level Blockade (min)</td>
<td>5.89±2.00</td>
<td>5.62±1.82</td>
<td>0.544</td>
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<tr>
<td>Time To Bromage 3 (min)</td>
<td>8.51±3.51</td>
<td>8.11±2.97</td>
<td>0.593</td>
</tr>
<tr>
<td>Time for S2 Segment Regression (min)</td>
<td>200.27±21.28</td>
<td>284.59±32.88</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>Total Duration Of Analgesia (min)</td>
<td>240.00±28.28</td>
<td>335.68±22.18</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>Time To Bromage 0 (min)</td>
<td>169.5±17.6</td>
<td>173.5±21.4</td>
<td>0.376</td>
</tr>
</tbody>
</table>

*statistically significant

Table 3: Comparison of incidence of nausea/vomiting

<table>
<thead>
<tr>
<th>Nausea Vomiting</th>
<th>R (n=37)</th>
<th>Percentage (%)</th>
<th>RF (n=37)</th>
<th>Percentage (%)</th>
<th>p-value</th>
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<tr>
<td>No</td>
<td>35</td>
<td>94.6</td>
<td>34</td>
<td>91.9</td>
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<tr>
<td>Yes</td>
<td>2</td>
<td>5.4</td>
<td>3</td>
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</tbody>
</table>

The incidence of nausea/vomiting were in 2 patients in Group R and in 3 patients in Group RF and both the groups were comparable. (Table 3)

Table 4: Comparison of incidence of pruritus

<table>
<thead>
<tr>
<th>Pruritus</th>
<th>R (n=37)</th>
<th>Percentage (%)</th>
<th>RF (n=37)</th>
<th>Percentage (%)</th>
<th>p-value</th>
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<tbody>
<tr>
<td>No</td>
<td>37</td>
<td>100.0</td>
<td>31</td>
<td>83.8</td>
<td>0.033*</td>
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<tr>
<td>Yes</td>
<td>0</td>
<td>6</td>
<td>6</td>
<td>16.2</td>
<td></td>
</tr>
</tbody>
</table>

*statistically significant

There were no significant differences in Mean arterial pressure, Systolic blood pressure, Diastolic blood pressure and Heart rate between Group R and Group RF at any time during the recording. (Figure 1)

Fig 1: Comparison of Systolic blood pressure

The incidence of pruritus was only present in Group RF which was statistically significant (p-value 0.033). (Table 4)
DISCUSSION

A common anaesthetic technique for surgeries on lower limbs and abdomen is spinal anaesthesia. Its application has been viewed as beneficial in reducing intraoperative blood loss, postoperative thromboembolic event incidence, morbidity in high-risk surgical patients, and blunting the stress response to surgery.

The purpose of this study was to evaluate the block characteristic of 0.75% isobaric ropivacaine in lower limb orthopaedic surgeries with or without the addition of opioids (fentanyl) during spinal anesthesia. 25 mcg (0.5 ml) of fentanyl or 0.5 ml of NS were mixed with 2.5 ml of 0.75% isobaric ropivacaine was used.

In this study, there was no failure of spinal anaesthesia. Sufficient analgesia and anaesthesia for lower limb surgery was obtained. Therefore, the combination of ropivacaine and fentanyl showed benefits in terms of longer durations of analgesia and sensory blockade, as well as similar durations of motor blockade.

In a study by Wahedi et al18, the intrathecal plain ropivacaine failure rate for abdominal surgery was 20% using 15 mg (3 ml of 5 mg/ml solution). In a different study by Malinovsky et al19, using 15 mg of the plain ropivacaine for urological surgery resulted in 16% failure rate. When using 18.75mg of plain ropivacaine for orthopaedic surgery, Mcnamee et al20 found 98% of patients had adequate block. In contrast, all patients in study by Koltka et al.20 who used 19.5 mg of plain ropivacaine achieved a block height of T10 or higher. With the use of 18.75mg of isobaric ropivacaine, almost all the patients in the aforementioned study done by Mcnamee et al20 and Koltka et al.20 attained the desired block level of T10. We thus used the similar dose of 18.75mg of isobaric ropivacaine in our study in order to provide the minimal sensory block level required for the procedure to commence.

Comparable patient demographics applied to both groups of patients. Regarding age, height, and ASA PS, there was no discernible variation in the distribution of patients. Similar demographic features were observed in study by Seetharam et al.1

In our investigation, the Ropivacaine (R) group took 5.89± 2 minutes to achieve T10 level sensory blockade, while the Ropivacaine with Fentanyl (RF) group took 5.62±1.82 minutes, a difference that was not statistically significant. The outcomes are consistent with a study by Murali et al21 which the R group’s mean time for sensory block onset was 4.02 ± 1.03 minutes, while the RF group’s mean time was 3.54 ± 1.06 minutes, and both groups’ results were comparable.

Five cases in Group RF reached a maximum T4 sensory block level, while none in Group R had reached a comparable block level. T6 was the highest sensory block level that Group R was able to achieve. Our study’s findings were similar to those of a study conducted by Murali C.H et al21 which found that group RF’s maximum sensory block level was T4, while group R’s maximum block level was T7.

There was no discernible difference in the timing of the start of complete motor blockage between the two research groups. The mean onset time for group R was 8.51±3.51 minutes, whereas the mean time for group RF was 8.11±2.97 minutes. Both of these differences were statistically insignificant (p-value 0.593). The findings were consistent with a research by Chaudhary et al16 where the mean time for motor blockade onset was 3.50±1.17 minutes in group RF and 3.90±1.39 minutes in group R.

In our investigation, the time to regression of sensory block to S2 segment was significantly prolonged with the addition of fentanyl as a spinal additive. Group II’s S2 dermatomal regression took 200.27±21.28 minutes, whereas Group RF’s took 284.59±32.88 minutes. The group utilizing fentanyl as an additive found that the extended regression time for the S2 segment was a substantial advantage, as the values showed statistical significance with a p-value less than 0.001. The study conducted by by K Gupta et al22 found that the S1 segment regression duration in Group I (Ropivacaine) was 316.40±41.53 minutes, while Group II (Ropivacaine plus fentanyl) had a duration of 359.80±66.96 minutes with a p-value of less than 0.001. In a similar study done by M Athar et al23 the time to regression of sensory block to L1 was longer in the Group RF than Group R (245.66 ± 22.35 min vs. 187.16 ± 17.05 min; P< 0.001).

Study done by M Athar et al23 revealed that Group RF’s analgesia lasted much longer than Group R’s (313.67 ± 23.45 min in Group RF vs. 243.83 ± 21.03 min in Group R, with P < 0.001). The results of our investigation was similar to the previous mentioned study and showed that Group RF experienced considerably longer analgesia durations (335.68±22.18 min vs. 240.00±28.28 min) than Group R.

Early mobilization decreases the hospital stay, reduces incidence of nosocomial infections, is cost effective and provides more comfort to the patient. Patients
could be able to resume their daily routine activities after being discharged on the day of surgery. This will address the increasing burden on health care services and limited number of bed and facilities available in the hospital.  

When it comes to the recovery period from motor blockade, using ropivacaine has a significant advantage over using other anesthetic drugs like bupivacaine. In a research by Bhat et al., the mean duration of motor blockade was 153.57±15.65 minutes for Group B (ropivacaine) and 211±11.29 minutes for Group A (bupivacaine). The length of motor blockade in our investigation was comparable for the two study groups (169.5±17.6 min in Group R vs. 173.5±21.4 min in Group RF). A motor recovery to Bromage scale 1 was found to be faster in Group RF (242.8 ± 47.06 min) than in Group BF (268 ± 49.9 min) (P = 0.023), according to a study by Jagtap et al. Therefore, using ropivacaine provided a benefit for early mobility.

In our study, a total of 9 episodes of hypotension were recorded (5 in RF group and 4 in R group) which were managed with IV fluids and Inj. phenylephrine. Besides these episodes, there were no other major haemodynamic changes and no episode of bradycardia recorded in our study. In one study, Chhabra et al. found that when ropivacaine was added to clonidine, the incidence of bradycardia and hypotension was higher than in the group that received ropivacaine with fentanyl. Compared to 2.8% of patients in the fentanyl group, 8.6% of patients in the clonidine group experienced hypotension and bradycardia. The findings of our investigation were similar to those of a study conducted by Beohar et al., in which hypotension was experienced by 2 patients in the ropivacaine group and 4 patients in the ropivacaine plus fentanyl group. In a research comparing hyperbaric ropivacaine 0.5% and hyperbaric bupivacaine 0.5% used for spinal anesthesia, hypotension was observed to occur far less frequently in the ropivacaine group than in the bupivacaine group.

In regard to other adverse effects, pruritus was exclusively seen in the RF group. A total of 6 patients developed mild pruritus in RF group which did not cause major discomfort to the patient and was easily managed with Inj. Ondansetron 8mg IV. The results were similar to a study done by M Athar in which pruritus was exclusively seen only in 3 patients of the RF group. Intrathecal fentanyl-induced pruritus has been found to occur in 67% to 100%. It’s yet unknown exactly how opioids cause pruritus. The existence of a “itch center” in the central nervous system, medullary dorsal horn activation, and antagonistic relationships between inhibitory transmitters are some of the hypothesized mechanisms.

Both groups experienced equal rates of nausea and vomiting, which were treated with an intravenous injection of 8 mg of Ondansetron. Three patients in Group RF and a total of two patients in Group R experienced nausea and vomiting. This was comparable to a study by K Gupta et al. where nausea and vomiting were experienced by two patients in Group RF and three patients in Group R.  

CONCLUSION

When 0.75% isobaric ropivacaine and fentanyl are used together in combination as compared to the use of 0.75% isobaric ropivacaine only in spinal anesthesia for lower limb orthopaedic surgeries, the effects are similar in terms of the onset of sensory and motor blockade, the duration of motor blockade, and haemodynamics, but they prolong sensory blockade and analgesia. Thus, the use of 0.75% isobaric ropivacaine combined with fentanyl proves itself as the better combination in providing prolonged analgesia and anaesthesia for patients undergoing surgeries.

REFERENCE

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