**Original Research Article**

# COMPARISON OF EFFICACY OF INTRATHECAL ROPIVACAINE AND ROPIVACAINE WITH FENTANYL IN LOWER ABDOMINAL AND LOWER LIMB SURGERIES: A PROSPECTIVE RANDOMISED STUDY

**M. Ravikumar[1], R. Vijayendran[2], A. Dilli Rakesh[2], Priyanka Sekar[3], V.Arun Kumar[3]**

[1]Associate Professor, Department of Anesthesiology, Chengalpattu Medical College Hospital, Tamilnadu, India
[2]Senior Assistant Professor, Department of Anesthesiology, Chengalpattu Medical College Hospital, Tamilnadu, India
[3]Postgraduate, Department of Anesthesiology, Chengalpattu Medical College Hospital, Tamilnadu, India

## Abstract

**Background:** Fentanyl as an adjuvant may improve the quality of the spinal block of ropivacaine while maintaining its advantage of early motor recovery. This study aimed to compare the efficacy of intrathecal Ropivacaine and Ropivacaine with fentanyl in lower abdominal and lower limb surgeries. **Materials and Methods:** Sixty patients were randomly allocated to receive either intrathecal 2.5ml of 0.75%Ropivacaine +0.5ml fentanyl (25mcg) (Group I) or 3ml of 0.75% ropivacaine only (Group II). The onset, duration, sensory and motor block spread, haemodynamic parameters and side effects were recorded. Statistical Package for Social Sciences 19 software was used for statistical analysis. **Result:** The mean time for the onset of sensory blockade and maximal sensory blockage were significantly higher (p<0.05) in Group II compared to Group I patients. The mean time for the onset of motor blockade in Group-I was significantly lower (p<0.05) than in Group II. The mean time for regression of sensory blockade up to L1 level in Group I was significantly higher (p<0.05) than reported in Group II. The mean duration of motor blockade and duration of analgesia in Group I was reported to be significantly higher (p<0.05) than in Group I. The observation means heart, MAP, and oxygen saturation (SpO2) were comparable in both group patients. The observation of side effects among both group patients was found to be comparable. **Conclusion:** This study concluded that adding fentanyl as an adjuvant to ropivacaine in spinal anaesthesia produces an earlier onset of sensory and motor blockade when compared to ropivacaine only.

## INTRODUCTION

The recent trend in healthcare centres everywhere is to provide patients with cost-effective care. There is an increasing trend towards ambulatory daycare surgery and rapid discharge of patients. The operation of inguinal or incisional hernia and even simple ligation surgeries are done without much complexity nowadays and can be completed in 60-90min without many intra or postoperative complications. Hence, these have become ideal outpatient procedures, reducing hospital stay length.[1,2] For ambulatory daycare surgeries, ideal anaesthesia should be a rapid and smooth onset of action, good intraoperative analgesia, a faster recovery period free of side effects or residual effects, and early mobilisation. Spinal anaesthesia is a popular regional anaesthesia technique for such settings. It can provide rapid onset, immediate intraoperative and postoperative analgesia at minimum cost. The complication of general anaesthesia and its residual effects are avoided, and recovery is early with minimal alteration in cognitive and psychomotor function, which too helps in the early discharge of the patient.[3]

Ropivacaine is a new local anaesthetic drug belonging to the amino amide 3 group, a propyl derivative of pipecoloxylidides. Today heavy bupivacaine 0.5% is most commonly used for spinal anaesthesia.[4] Levo-bupivacaine is a new long-acting local anaesthetic with less pharmacological activity and is very similar to racemic system toxicity. Levo-bupivacaine, a pure S (-) enantiomer of bupivacaine,

297

use has progressively increased. Ropivacaine has a less systemic toxic profile, especially cardiotoxic than other local aesthetic agents.[5] Fentanyl is a pure μ-receptor agonist. It has a rapid onset of action following spinal anaesthesia due to its lipophilic nature. The intrathecal dose of fentanyl will produce minimal respiratory depression compared to other opioid analgesics. Fentanyl gives improved anaesthetic quality without many complications. An intrathecal dose of 10 to 25 mcg of fentanyl prolongs the duration of action, and the sensory block gets extended.[6,7] This study aimed to compare intrathecal Ropivacaine effects with or without fentanyl in lower abdominal and lower limb surgeries.

## MATERIALS AND METHODS

This prospective randomised controlled study was conducted in the Department of Anaesthesia with cooperation from the Department of General Surgery at Chengalpattu Medical College and Hospital, Chengalpattu, from March 2021 to March 2022. A total of 60 patients enrolled for the study were divided into two groups Group I, treated with 0.75% of ropivacaine (2.5ml) + 0.5ml fentanyl (25mcg), and Group II, treated with 0.75% of ropivacaine (3ml). Written informed consent and permission from the institutional ethical committee were obtained from all the study participants before study initiation.

**Inclusion Criteria**
Patients of the age group of 18 to 65 years of either gender, height ≥150cm and weight ≥50kg undergoing elective lower abdominal and lower limb surgeries under spinal anaesthesia, and patients with American Society of Anaesthesiologists (ASA) of class I, II were included.

**Exclusion Criteria**
Patients with allergy to local anaesthetics, infection at the injection site, spine anomaly, neurological deficit, coagulation abnormalities, contraindications to spinal anaesthesia, and patients refusing to participate in the study were excluded.

**Methodology**
Pulse-oximetry for monitoring saturation (SpO2), Non-invasive blood pressure monitoring (NIBP), and Electrocardiogram (ECG) were attached, and baseline pulse rate, blood pressure, and oxygen saturation were recorded.
In Group I, the needle trajectory was anaesthetised with 2% lignocaine with the patient in the right lateral decubitus position. A subarachnoid puncture is performed with a 25G Quincke needle in the L3-L4 intervertebral space using a midline approach. After the free flow of cerebrospinal fluid (CSF), 2.5ml of 0.75%Ropivacaine +0.5ml fentanyl (25mcg) is injected at the rate of 0.2ml/sec, and the patient is placed in dorsal decubitus.
In Group II patient was placed in the right lateral decubitus position, and the needle trajectory was anaesthetised with 2% lignocaine. A subarachnoid puncture was performed using a 25G spinal Quincke

needle in the L3-L4 intervertebral space using the midline approach. After the free flow of cerebrospinal fluid (CSF) is confirmed, 3ml of 0.75% ropivacaine is injected at 0.2ml/sec, and the patient is placed in dorsal decubitus.
The quality of motor blockade in the lower limb will be graded according to the modified Bromage scale until the return of normal motor functions and the maximum Bromage score reached is noted. Block evaluation was carried out by recording parameters such as the onset of sensory blockade, time taken for maximum sensory blockade and duration of analgesia. The motor blockage was studied by the quality of motor blockage (by Bromage scale), Heart rate, blood pressure and duration of analgesia. The onset of motor block was defined as the time from spinal injection until Bromage 3 score is registered. Duration of motor blockade was defined as the time from onset until the patient attained a slight motor recovery to Bromage 1. The surgical incision was commenced when the sensory block level was at or above the T6 dermatome and complete motor blockade (Bromage 3).
Side effects such as hypotension, bradycardia, respiratory depression, nausea, vomiting, shivering and pruritus were checked and recorded. Respiratory depression ($RR < 8$/min or $SPO2 < 90\%$) If observed, administer 100% oxygen with a closed circuit. Inj. Naloxone 0.1-0.5mg/kg I/V, repeated at a 2-3 min interval to a maximum dose of 10 mg. Nausea and vomiting, if any, were treated with Inj. Ondansetron 4 mg IV. Shivering was treated with Inj. Tramadol 25mg IV in incremental doses. Pruritus was treated with Inj. Chlorpheniramine maleate 25mg IV. The duration of surgery in each case was noted. When the patients began to experience VAS =>4, it was considered that the analgesic action of the drugs was terminated, and the rescue analgesic injection of Paracetamol 1g I/V was given.

**Statistical Analysis**
The collected data was entered in Microsoft Excel (windows 11) and analysed using the statistical package for social sciences (SPSS-19). To find an association between two categorical variables Pearson chi-square test was used. The value of P <0.05 is considered statistically significant.

## RESULTS

All the patients were male in both Group I and II. The mean age and ASA classification in both groups were comparable.
The mean time for the onset of sensory blockade and maximal sensory blockage were significantly higher (p<0.05) in Group II compared to Group I patients. The mean time for the onset of motor blockade in Group-I (Ropivacaine+ Fentanyl) was 7.63 ± 1.42 mins. The mean time for the onset of motor blockade in Group II (Ropivacaine) is 11.33 ± 1.02 mins, and the effect was statistically significant (p<0.05). The mean time (237.27 ± 42.63 mins) for regression of

298

**International Journal of Academic Medicine and Pharmacy (www.academicmed.org)**
ISSN (O): 2687-5365; ISSN (P): 2753-6556

sensory blockade up to L1 level in Group I (Ropivacaine+ fentanyl) was significantly higher (p<0.05) as compared to the reported in Group II (Ropivacaine) with a mean time of 185.1± 12.07 mins [Table 1].

The mean duration of motor blockade (294.83 ± 6.29 mins) and duration of analgesia (282.43 ± 13.74 mins) in Group I was reported to be significantly higher (p<0.05) as compared to those found in Group II with a mean duration of 275.97± 0.18 and 243.02 ± 7.59 mins respectively [Table 1]. The observations made (heart rate , MAP, and oxygen saturation (SpO2)) from baseline to 60 mins were comparable in both group patients.

**Table 1: Observation of demographic and other variables of patients in both groups**

| Parameters | Observation N (%) | | P-value |
|---|---|---|---|
| | Group I (Ropivacaine + Fentanyl) (N=30) | Group II (Ropivacaine) (N=30) | |
| Gender | | | |
| Male | 30 | 30 | NA |
| Female | 0 | 0 | |
| Age groups | | | |
| ≤ 40 years | 8 | 14 | 0.271 |
| 41-50 years | 17 | 12 | |
| 51-60 years | 5 | 4 | |
| Mean age years | 44.43±6.06 | 43.3±5.73 | 0.460 |
| ASA class | | | |
| I | 16 | 15 | 0.796 |
| II | 14 | 15 | |
| Onset of sensory Block | 4.73±1.23 | 6.9±0.96 | 0.001 |
| Onset of maximal sensory block | 4.13±0.77 | 6.1±0.71 | 0.001 |
| Onset of motor block | 7.63±1.42 | 11.33±1.02 | 0.001 |
| Duration of sensory block | 237.27±42.63 | 185.1±12.07 | 0.001 |
| Duration of motor block | 294.83±6.29 | 275.97±0.18 | 0.001 |
| Duration of analgesia | 282.43±13.74 | 243.03± 7.59 | 0.001 |

**Table 2: Observation of side effects reported among patients of both groups**

| Side effects | Ropivacaine +Fentanyl (Group I) | Ropivacaine (Group II) |
|---|---|---|
| Bradycardia | 0 | 1 |
| Hypotension | 3 | 8 |
| Nausea & vomiting | 5 | 2 |
| Pruritus | 3 | 0 |
| Shivering | 0 | 3 |
| NIL | 19 | 16 |
| P VALUE - 0.061 | | |
| Non-significant | | |
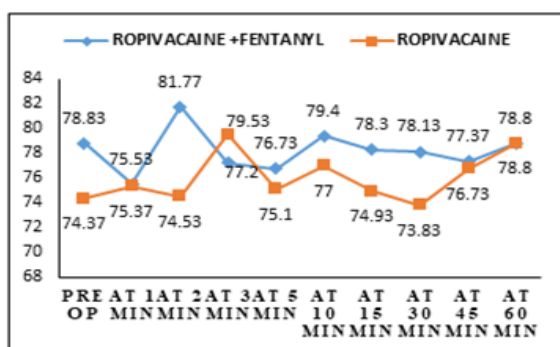


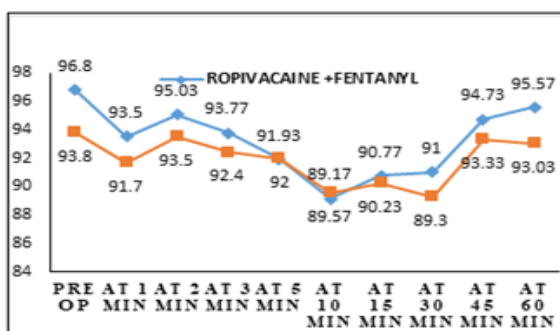**Figure 1 Distribution of Heart Rate**

Hypotension was reported in more patients (8) of Group II, and nausea and vomiting were found in more patients (5) of Group I. However, the overall observation of side effects among both group patients was comparable [Table 2].

## DISCUSSION

Neuraxial regional anaesthesia is the anaesthesia of choice for patients undergoing surgeries below the umbilical region as it provides better pain control than intravenous narcotics intraoperatively and postoperatively, earlier recovery of bowel function, less need for systemic opioids (Narcotics) and less nausea. As a result, easier breathing results from better pain control, early ambulation and spare endotracheal intubation and its side effects.[1-3]

Several local anaesthetics are available for neuraxial blockade, and the most common ones are bupivacaine, lignocaine and ropivacaine. Compared to lignocaine, bupivacaine and ropivacaine are longer-acting local amide anaesthetics. Although both agents are longer acting, ropivacaine has the advantage over bupivacaine by providing better cardiovascular and neurological stability.[8,9]



**Figure 2 Distribution of Mean arterial Pressure**

299

Adjuvants are the drugs that are added to the local anaesthetics to reduce the dose of the local anaesthetics while maintaining or prolonging the duration of the desired sensory and motor block effects. It also avoids the side effects of the adjuvants when administered intravenously alone.[1,2]

Several adjuvants have been tried and compared, and the most common one includes adrenaline and opioids. Fentanyl is a synthetic lipophilic opioid that is been used for a long time as an adjuvant. This study compares ropivacaine with fentanyl and ropivacaine alone intrathecally for lower abdominal and lower limb surgeries. The variables compared includes sensory and motor blockade, duration of analgesia, mean arterial pressure, pulse rate, oxygen saturation and adverse effects.[1,5-7] In our study, the demographic profile in both groups regarding age, gender, and ASA class showed no statistically significant difference. Mitra et al. also reported similar findings in their investigations.[10]

In our study, the statistical analysis of the data showed that the time of onset of the sensory block to T10 and the time taken to achieve the maximum sensory block was significantly faster when fentanyl was added as an adjuvant to ropivacaine than when ropivacaine alone was used. The time for two segmental regression and sensory regression to L1 was prolonged in the ropivacaine with fentanyl group. The time of onset of the pain and the time of demand for the first rescue analgesics was delayed in ropivacaine with the fentanyl group than with the Ropivacaine group. Malinowski et al. also reported similar findings in their investigation, where the onset of sensory blockade was faster in the ropivacaine and fentanyl groups. In their study, they reported that the time for two-segment regression between the two groups was 89±33 mins in the ropivacaine and fentanyl group and 98±30 mins in the levobupivacaine with fentanyl group when administered intrathecally.[11]

The time taken to achieve the maximum motor block was significantly faster with the fentanyl ropivacaine group than with the ropivacaine group. The time for complete return of the motor block was delayed in patients in the fentanyl ropivacaine group than in the ropivacaine group. McNamee et al., in their study, noted that the duration of motor block was significantly shorter in the ropivacaine + Fentanyl group (2.1 hrs) as compared to the bupivacaine+ Fentanyl group (3.9 hrs). Also noted, the duration of the motor block was significantly shorter with ropivacaine (150 mins) than bupivacaine (210 mins). The duration of motor block was significantly shorter in the ropivacaine group also compared to the bupivacaine group.[12]

We achieved prolonged postoperative analgesia with the ropivacaine fentanyl group with a highly significant P value of 0.001. However, Chung et al. reported that the time of regression of block to S1 was longer (188.56±28.2 mins) in the intrathecal bupivacaine+ Fentany group when compared to ropivacaine + Fentanyl group (162.56±20.2 mins).[13]

Baseline hemodynamic parameters were comparable in both groups. The mean Pulse Rate (PR) and mean arterial pressure (MAP) decreased significantly in both groups compared to baseline. However, there was no significant intergroup variation. There is no significant hemodynamic instability between the two groups after spinal anaesthesia. Bhat et al. also reported similar findings in their investigation, whereas comparable hemodynamic parameters were reported after 5 minutes between groups receiving Bupivacaine and Ropivacaine.[14]

No serious side effects were noted in either group during the study. The incidence of nausea was 6% in Group I and 16% in Group II. The incidence of shivering was 10% in Group II, while no patient in Group I complained of shivering. Pruritus complained to 10% of patients from Group I, but none from Group II. Intraoperative bradycardia occurred in only 3% of patients in Group II, while hypotension was reported in 26% of patients in Group II and 10% in Group I. However, there was no significant difference between the two groups with regard. No incidence of post-dural puncture headache or respiratory depression was observed in either group. McNamee et al., in their study, reported hypotension in 24% of patients with higher doses of plain ropivacaine (17.5 mg, 25 mg) for total hip arthroplasty. Hypotension was also observed when he compared ropivacaine (17.5 mg) with bupivacaine (17.5 mg) in 12% and 26% of patients for the same surgery.12 Khanna and Singh reported 20 % incidences of pruritis in both groups receiving Ropivacaine + Fentanyl and Bupivacaine + Fentanyl intrathecally.[15]

## CONCLUSION

Our study concludes that adding fentanyl as an adjuvant to ropivacaine in spinal anaesthesia produces an earlier onset of sensory and motor blockade when compared to ropivacaine alone. The sensory and motor blockade duration was also significantly longer when fentanyl was used as an adjuvant. The duration of postoperative analgesia is also significantly longer when fentanyl is added as an adjuvant to bupivacaine in spinal anaesthesia, compared to ropivacaine alone. The incidence of side effects such as hypotension, nausea, and vomiting is also significantly lower in fentanyl, as compared to ropivacaine alone.

## REFERENCES

1. McConachie I, McGeachie J, Barrie J. Regional anaesthetic techniques. In: Thomas EJ, Knight PR, editors. Wylie and Churchill Davidson's – A Practice of Anesthesia. Vol. 37. London: Arnold; 2003. p. 599-612.
2. Atkinson RS, Rushman GB, Davies NJ. Spinal analgesia: Intradural and extradural. In: Lee's Synopsis of Anaesthesia. Oxford: Butterworfh Heinemann; 1998. p. 691-716.
3. Brull R, Macfarlane AJ, Chan VW. Spinal, epidural, and caudal anesthesia. In: Miller, R.D., Ed., Miller's Anesthesia, 8th Edition, Saunders Elsevier, Philadelphia, 1684-1720.

4. Kuthiala G, Chaudhary G. Ropivacaine: A review of its pharmacology and clinical use. Indian J Anaesth 2011;55:104-10.

5. Graf BM, Abraham I, Eberbach N, Kunst G, Stowe DF, Martin E. Differences in cardiotoxicity of bupivacaine and ropivacaine are the result of physicochemical and stereoselective properties. Anesthesiology 2002;96:1427-34.

6. Bang EC, Lee HS, Kang YI, Cho KS, Kim SY, Park H. Onset of labor epidural analgesia with ropivacaine and a varying dose of fentanyl: A randomised controlled trial. Int J Obstet Anesth 2012;21:45-50.

7. Boztug N, Bigat Z, Ertok E, Erman M. Intrathecal ropivacaine versus ropivacaine plus fentanyl for outpatient arthroscopic knee surgery. J Int Med Res 2005;33:365-71.

8. Hodgson PS, Neal JM, Pollock JE, Liu SS. The neurotoxicity of drugs given intrathecally (spinal). Anesth Analg 1999;88:797-809.

9. Hiller A, Rosenberg PH. Transient neurological symptoms after spinal anaesthesia with 4% mepivacaine and 0.5% bupivacaine. Br J Anaesth 1997;79:301-5.

10. Mitra P, Roy A, Huda A. A comparative study of efficacy, potency and recovery of intrathecal 0.5% ropivacaine with fentanyl and 0.5% levobupivacaine with fentanyl in lower abdominal surgeries in patients of 18-60 years of age. Int J Sci Res 2021; 10: 2277-8179.

11. Malinovsky JM, Charles F, Kick O, Lepage JY, Malinge M, Cozian A, et al. Intrathecal anesthesia: ropivacaine versus bupivacaine. Anesth Analg 2000;91:1457–60.

12. McNamee DA, McClelland AM, Scott S, Milligan KR, Westman L, Gustafsson U. Spinal anaesthesia: comparison of plain ropivacaine 5 mg ml(-1) with bupivacaine 5 mg ml(-1) for major orthopaedic surgery. Br J Anaesth 2002;89:702–6.

13. Chung CJ, Choi SR, Yeo KH, Park HS, Lee SI, Chin YJ. Hyperbaric spinal ropivacaine for cesarean delivery: a comparison to hyperbaric bupivacaine. Anesth Analg 2001;93:157–61.

14. Bhat SN, Himaldev, Upadya M. Comparison of efficacy and safety of ropivacaine with bupivacaine for intrathecal anesthesia for lower abdominal and lower limb surgeries. Anesth Essays Res 2013;7:381-5.

15. Khanna MS, Singh IK. Comparative evaluation of bupivacaine plain versus bupivacaine with fentanyl in spinal anaesthesia in geriatric patients. Indian J Anaesth 2002;46:199-203.

301

**International Journal of Academic Medicine and Pharmacy (www.academicmed.org)**
ISSN (O): 2687-5365; ISSN (P): 2753-6556