ISSN: 2581 – 3633
PubMed - National Library of Medicine - ID: 101745081

International Journal of Medical Science and Advanced Clinical Research (IJMACR)

Available Online at:www.ijmacr.com

Volume – 8, Issue – 3, June - 2025, Page No.: 178 – 187

Comparison of Efficacy of Intrathecal Isobaric Ropivacaine-Fentanyl and Ropivacaine-Nalbuphine for Post-Operative Analgesia in Lower Limb Orthopaedic Surgery

[1]Dr.Dhara Kakadiya, Assistant Professor, Department of Anesthesia, Gujarat Cancer and Research Institute

[2]Dr. Prayut Prajapati, Previous Resident, Department of Anesthesia, Gujarat Cancer and Research Institute

[3]Dr.Gosai Neeta D., Professor, HOD, Department of Anesthesia, Gujarat Cancer and Research Institute

[4]Dr. Bijal.Shah, Associate Professor, Department of Anesthesia, Gujarat Cancer and Research Institute

Corresponding Author: Dr. Bijal.Shah, Associate Professor, Department of Anesthesia, Gujarat Cancer and Research Institute.

How to citation this article: Dr. Dhara Kakadiya, Dr. Prayut Prajapati, Dr.Gosai Neeta D., Dr. Bijal.Shah, "Comparison of Efficacy of Intrathecal Isobaric Ropivacaine-Fentanyl and Ropivacaine-Nalbuphine for Post-Operative Analgesia in Lower Limb Orthopaedic Surgery", IJMACR- June - 2025, Volume – 8, Issue - 3, P. No. 178 – 187.

Type of Publication: Original Research Article

Conflicts of Interest: Nil

Abstract

Background: Spinal anesthesia is commonly used for lower limb orthopedic surgeries due to its ability to provide effective intraoperative and postoperative analgesia. The addition of intrathecal adjuvants like opioids can enhance the duration of analgesia. This study aimed to compare the efficacy of fentanyl citrate and nalbuphine hydrochloride as adjuvants to isobaric ropivacaine for spinal anesthesia in lower limb orthopedic surgeries.

Methods: This prospective, randomized study included 100 patients (ASA PS I/II, aged 18-65 years) scheduled for elective lower limb orthopedic surgeries under spinal anesthesia. Patients were randomized into two groups: Group RF (fentanyl 25 mcg + ropivacaine 22.5 mg) and Group RN (nalbuphine 1 mg + ropivacaine 22.5 mg). Intraoperative hemodynamics, onset and duration of sensory and motor block, duration of analgesia, and postoperative pain scores (VAS) were assessed. The need for rescue analgesia and side effects were also recorded.

Results: The two groups were comparable in terms of demographic data, ASA grade, and surgery duration. Group RF had a significantly faster onset of sensory and motor block compared to Group RN ($p < 0.05$). Duration of sensory block was shorter in Group RF (254.22 ± 7.89 mins) compared to Group RN (296.98 ± 8.31 mins) ($p < 0.0001$). Duration of motor block was also shorter in Group RF (153.18 ± 4.76 mins) than in Group RN (190.2 ± 5.82 mins) ($p < 0.0001$). Postoperative analgesia was significantly longer in Group RN (299.7 ± 7.72 mins) than in Group RF

(274.38 ± 9.79 mins) ($p < 0.0001$). The need for rescue analgesia was earlier in the fentanyl group. Both groups had comparable intraoperative hemodynamic stability. Common side effects included nausea, pruritus, and hypotension, with no significant differences between the groups.

Conclusions: Both fentanyl and nalbuphine, when combined with ropivacaine for spinal anesthesia, provided effective intraoperative and postoperative analgesia. Nalbuphine provided a longer duration of analgesia, while fentanyl offered a quicker onset and shorter motor block duration. Both drugs were well-tolerated, with no significant differences in adverse effects. These findings suggest that nalbuphine may be a preferable choice when prolonged analgesia is desired, whereas fentanyl may be more suitable for faster recovery of motor function.

Keywords: Fentanyl, Nalbuphine Hydrochloride, Isobaric Ropivacaine, Lower Limb Orthopedic Surgeries, Isobaric Ropivacaine

Introduction

Spinal anesthesia is often preferred over general anesthesia due to its ability to reduce stress responses and provide effective postoperative pain relief. However, spinal anesthesia offers temporary analgesia, which is why intrathecal adjuvants like opioids are used to extend pain relief duration. These opioids enhance the sensory block without increasing the sympathetic block, improving the overall quality of spinal anesthesia. [1]

Ropivacaine, a long-acting local anesthetic, is considered safer than bupivacaine due to its lower cardiotoxicity and neurotoxicity. It also provides better sensory-motor differentiation, allowing for faster motor recovery. Fentanyl, a synthetic opioid, primarily acts on mu-receptors to provide potent analgesia with fewer side effects compared to morphine. Nalbuphine, a synthetic opioid with agonist-antagonist properties, acts on kappa-receptors and has a favorable safety profile, minimizing common opioid side effects like nausea and pruritus. [2]

This study aims to compare the efficacy of fentanyl citrate and nalbuphine hydrochloride when combined with isobaric ropivacaine for spinal anesthesia in lower limb orthopedic surgeries. The goal is to assess intraoperative hemodynamic stability, postoperative pain management, the need for rescue analgesia, and the incidence of side effects. Both fentanyl and nalbuphine are expected to provide prolonged analgesia, maintain stable vital signs, and reduce opioid-related side effects compared to traditional anesthetic techniques. [3]

By examining these drug combinations, the study will help identify the most effective adjuvant to improve patient outcomes and minimize complications during and after spinal anesthesia.

Methods

After obtaining Institutional Ethical Committee Permission and Informed Consent from Patients, of 100 Patients of American Society of Anesthesiologists Physical Status (ASA PS) I and II and aged between 18 to 65 years scheduled to undergo Elective Orthopaedic Surgery under Subarachnoid Block were included in this study.

Patients Refused to block, Allergy to Local Anaesthetic drugs and opioids, having contraindication for Spinal Anaesthesia and Pregnant patients were excluded from study. All the patients were fasted overnight for 8 hours. Pre-medication given in the form of Tablet Lorazepam 1mg at 10 pm the night before surgery. No intravenous fluid was given till arrival to operating theatre.

Psychological counselling was done and procedure explained to all the patients in advance. All patients were made familiar with the concept of Visual Analogue scale for pain (VAS), which consisted of 10cms line, with 0 equalling "No pain" and 10 equalling "Worst possible pain."

On arrival in the operating room an IV access was secured using an 18G cannula in the forearm vein. Preloading was done with 10ml/kg Ringer's lactate and further fluid adjusted as per the blood loss and maintenance during surgery. Patient is given Inj. Ondansetron 0.15mg/kg IV as Antiemetic medication. A fall of mean arterial pressure to less than 70mm hg was treated with rapid infusion 0f 500 ml RL and 6 mg of Injection Mephentermine intravenously if there is no response to fluid administration.

Bradycardia (Heart rate less than 50/minute) is treated with intravenous Atropine sulphate 0.6mg

Standard monitoring including continuous electrocardiogram, Heart rate, Oxygen saturation, noninvasive automated blood pressure measurements and visual assessment of Respiratory rate done and baseline values were noted. In all the patients, under strict aseptic and antiseptic precautions, lumber puncture was performed in left lateral position, after giving local anaesthesia with 24G hypodermic needle, using a 23 G Quincke's spinal needle with bevel in direction to separate the dura fibers, positioned midline at the L3-L4 interspace, after getting free flow of CSF and study drug injected. After completion of injection, patients were immediately returned to the supine position. O2 with venti-mask 4-6 L/min started with maintenance of IV fluid via intravenous line in both groups.

Monitoring

Vital Parameters like HR, BP, MAP, SPO2 and RR were measured at 0, 5, 10, 20, 30, 60, 120, 180, 240, 300 and 360 mins. The onset of sensory block and time to reach highest sensory level were noted. It is assessed by soft touch & pinprick method using a 24G hypodermic needle along the mid-clavicular line bilaterally every 2 mins till the level had stabilized for four consecutive tests. The onset of motor block is defined as the time required to achieve Modified Bromage scale III. The duration of motor blockade is the time to achieve Modified Bromage scale 0 from Modified Bromage III. Motor blockade was assessed by Modified Bromage Scale.

- Bromage 0: No motor block.

Bromage I: Inability to raise extended leg, able to move knees and feet.

Bromage II: Inability to raise extended leg and move knee, able to move feet.

- Bromage III: Complete block of motor limb.

The Duration of analgesia is considered as time interval between the injections of local anaesthetic drug intrathecally for spinal anaesthesia to the first rescue analgesic on patient demand (VAS≥4).

Pain was assessed using Visual Analogue Scale between 0 and 10. VAS was assessed immediately postoperatively and every 30 minutes till the rescue analgesia is given (0 = No pain, 10 = Most severe pain). Injection Diclofenac 75mg IV Infusion was given as rescue analgesic when VAS ≥ 4.Patients were monitored for respiratory depression (RR<8) and Oxygen desaturation (SPO2<90%) treated with 100% oxygen supplementation and respiratory support if needed.

Statistical Analysis

Data was compiled using Microsoft Excel. Statistical Analysis was carried out using GraphPad Prism Version 7.03.Results on Continuous measurements are presented on Mean±Standard Deviation and Categorial measurements in Number(%).Demographic data was analysed using Student's t-test assuming equal variance for both the study groups. Unpaired t-test has been used to find the significance of HR, SBP, DBP, MAP, RR, Onset, Regression and Duration of Sensory block, Onset and Duration of Motor block, Duration of Analgesia and VAS score. Categorial Data was compared between two groups by Chi- Square test. P value < 0.05 was considered statistically significant.

Results

100 patients belonging to ASA grade I and II, of either sex, in age group between 18- 65 years, posted for elective lower limb orthopaedic surgeries under Spinal anaesthesia were selected for the study. They were randomly allocated to two groups with 50 patients in each group.

Following perioperative parameters were recorded in the study.

- Age, Sex, Weight, Height, ASA Grade, Duration of surgery.
- Intraoperatively: HR, SBP, DBP, MBP, SPO_2, RR.
- Characteristics of sensory blockade.
- Characteristics of motor blockade.

Intraoperative & Postoperative complications

Post Operative Analgesia.

Table 1 shows that the mean age of patients in group RF was 33.3 ± 15.2 (Range: 18-65yrs) and in group RN was 33.12± 17.25 (Range: 18-65yrs). Both groups were age matched (p=0.956). Both groups were also comparable with respect to sex distribution(p=0.6769), weight (p=0.6867), Height (p=0.0765), ASA Grading (p=0.4122) and Duration of surgery (p=0.9941). Mean heart rate, SBP, DBP, MBP and RR between GROUP RF and GROUP RN is comparable at baseline, 0 min,5 mins,10 mins, 20 mins, 30 mins, 60 mins,120 mins,180 mins, 240 mins, 300mins and 36 mins and there is no statistical difference between them (p value > 0.05).

Comparison of Sensory Block Characteristics between Both Groups

Table 2 & Figure 72shows that mean onset of sensory block in Group RF was 4.41±0.63 mins and in Group RN was 4.93 ± 0.95 mins (p=0.0018).Onset was significantly earlier in RF group than RN group. The mean onset of sensory block to highest sensory level in Group RF was 7.52 ± 1.11 mins and in Group RN was 8.36 ± 1.04 mins (p=0.0002) which was significantly less in RF group than RN Group. Duration of sensory block (sensory regression to S2 level) was significantly longer in Group RN 296.98 ± 8.31mins as compared to Group RF 254.22±7.89 mins (p=<0.0001).

Table 3 & Figure 3 shows that the mean time to onset of motor blockade in Group RF was 6.58 ± 1.12 mins and in Group RN was 7.06 ± 1.15 mins (p=0.0376). The duration of motor blockade (Time to reach Grade 0 Bromage) was 153.18 ± 4.76 mins in group RF and was 190.2 ± 5.82 mins in Group RN (p<0.0001). Both Time to onset of motor blockade and duration of motor blockade were significantly lesser in RF Group than RN Group. Thus Group with Fentanyl have early onset of motor block and also shorter duration of block compared to Nalbuphine group.

Figure 4: Comparison of Postoperative VAS Score between Both Groups

Table 9 and Figure 9 shows that Patient receiving Nalbuphine had lower VAS pain scores till 300 mins

than patient's who received fentanyl. This difference in VAS scores was statistically significant after 300 mins (VAS >4) for RN group and after 270 mins (VAS >4) for RF group.

We can see from Table 5 and Figure 5 that the patients in the Fentanyl group requested rescue analgesia earlier 274.38 ± 9.79 mins than patients in the Nalbuphine group 299.7 ± 7.72 minutes. ($p<0.0001$).Thus the total duration of analgesia is more in Nalbuphine group than Fentanyl group.

Four Patients in Group RF and three Patients in Group RN had hypotension which was treated with rapid infusion of IV fluid Ringer Lactate 500 ml. Three Patients in Group RF had pruritus were treated with Inj. Promethazine 25 mg IM, while none of the patient's in Group RN had pruritus.5 Patients in RF and 4 Patients in RN had Nausea which was treated with Inj. Ondansetron 0.15mg/kg IV. None of the patients in both groups had Bradycardia, Respiratory depression, Sedation and urinary retention

Discussion

In this modern era Subarachnoid block is a very well accepted and an excellent anesthetic technique with a high success rate and a good safety profile. Hence, There is always a search process for a drug which is safer, efficacious and less toxic with an early recovery profile, which provides an early mobilization. In order to further improve the safety issues, newer local anesthetic drugs are being investigated. In order to improve the outpatient care, drugs should provide short acting and adequate anesthesia, post op analgesia without compromising the early ambulation and discharge.[3]

In this study, we compared nalbuphine with fentanyl as an adjuvant to 0.75% isobaric ropivacaine in the subarachnoid block in 100 patients in two groups (n = 50 each) undergoing lower limb elective orthopedic surgeries. In our study we used Intrathecal fentanyl citrate 25 mcg with 0.75% Isobaric Ropivacaine hydrochloride 22.5 mg in GROUP RF and Intrathecal Nalbuphine 1 mg with 0.75% isobaric Ropivacaine hydrochloride 22.5 mg in GROUP RN. Baseline parameters, demographic profile, and duration of surgery were statistically comparable in both the groups. The primary outcome measure of our study was the duration of analgesia, and secondary outcome measures were onset and duration of sensory and motor block, time for regression to S2 from the highest sensory block, hemodynamic parameters, and observation for adverse effects.

Hemodynamic Changes

In the present study there is no statistical difference between Group RF and Group RN with respect to intraoperative Heart rate, Systolic blood pressure, Diastolic blood pressure, Mean blood pressure, Respiratory Rate ($p>0.05$). Malaviya et al[4] compared intrathecal fentanyl(25mcg) and Nalbuphine (1 mg) with Ropivacaine for lower limb orthopaedic surgeries and intraoperative haemodynamic parameters were comparable among both the groups which is similar to our study. K Vijayendra kumar Babu, G Prasanna Kumar, G Harinath[5] Evaluated Efficacy of Intrathecal Fentanyl Versus Intrathecal Nalbuphine as Adjuvants to 0.75% Ropivacaine for Post-operative Pain Relief in Cesarean Section, in which Intra operative hemodynamic parameters, Oxygen saturation were comparable between two groups similar to our study. Mostafa et al [6] compared intrathecal nalbuphine and intrathecal fentanyl with bupivacaine in cesarean section and observed no statistically significant

difference was there regarding the hemodynamics and oxygen saturation, these findings are relatable with our study.

Onset of Sensory Block

There is statistical significance (p value 0.0018) between GROUP RF and GROUP RN in terms of Onset and achievement of highest level of sensory block. GROUP RF has a faster onset of sensory block (4.41±0.63 mins) than GROUP RN (4.93 ± 0.95 mins) and time to reach the highest sensory level was faster in RF (7.52 ± 1.11 mins) than GROUP RN (8.36 ± 1.04 mins) (p value 0.0002). This in accordance with the study by Naaz et al[7] where Fentanyl 25 mcg with Bupivacaine 12.5 mg produced early onset of sensory block than Nalbuphine 0.8mg and1.2mg with Bupivacaine 12.5mg.

Duration of Sensory Block

In our study the duration of sensory blockade (Time to sensory regression to S2 level) was significantly longer in RN group (296.98 ± 8.31 mins) as compared to RF group (254.22 ±7.89 mins) (p<0.0001).This finding is in accordance with study of K Vijayendra kumar Babu , G Prasanna Kumar, G Harinath[5] They observed time required for sensory regression to S2 level was significantly prolonged in Nalbuphine group (263.63 ± 44.88 mins) as compared to fentanyl group (180.75 ± 34.27 mins) for Post-operative Pain Relief in Cesarean Section.

Onset of Motor Block

In our study, The onset of motor block in GROUP RF (6.58 ± 1.12 mins) is faster than the GROUP RN (7.06±1.15 mins) and the difference is statistically significant (p value 0.0376). This is in accordance with Malaviya et al[8] who stated faster onset of Motor block in fentanyl group (6.97±0.95 mins) than in Nalbuphine group (7.14±1.03 mins) lower limb orthopaedic surgery. Naaz et al [7] found that Fentanyl group took less time to reach complete motor block (5.4±12.96 mins) than Nalbuphine 0.8mg group (7.4±3.13 mins) and Nalbuphine group 1.2mg (10.4±4.5 mins) with Bupivacaine 12.5mg.

Duration of Motor Block

In current study the duration of motor blockade was significantly longer in RN group (190.2 ± 5.82 mins) as compared to RF group (153.18 ± 4.76 mins) (p<0.0001).This finding is in accordance with study of Gupta K[10] et al who found longer duration of motor block in Nalbuphine group (182.26 ± 29.63 mins) than fentanyl group (141.63 ± 18.05 mins) Nirmal A, Singh Y, Mathur SK, Patel S[9] in a prospective, randomized, double blind study of Comparison between intrathecal nalbuphine 200mcg and butorphanol 100mcg as adjuvants to isobaric ropivacaine 0.75% 2.5 ml in elective lower limb orthopedic surgeries found duration of motor block was (226.63 ± 32.48 mins) in Nalbuphine Group.

Duration of Analgesia and VAS Score

In our study we noticed that Fentanyl and Nalbuphine both provided adequate postoperative analgesia at 30mins, 60mins, 90mins, 120mins, 180 mins and 240 min. The total duration of analgesia in Group RN (299.7 ± 7.72 mins) was significantly longer than Group RF (274.38 ± 9.79 mins) (p<0.0001) and the patient's in the Fentanyl group requested 1st rescue analgesic earlier than Nalbuphine group.

There is statistically significant increase in VAS score (4.2±0.9) after 270 mins (p<0.0001) and VAS score (4.24±0.87) after 300 mins (p<0.0001) in RF and RN group respectively.

This findings of our study coincides with Malaviya et al[8] who concluded that Nalbuphine group had longer duration of analgesia (318.2 ± 14.14 mins) than fentanyl group with Isobaric Ropivacaine (275.6 ± 18.76 mins).They found VAS score <4 up to 240 mins in both groups, statistically significant difference in the number of patients having VAS ≥4 in Group F versus Group N at 270 mins and 300 mins respectively. (P < 0.001) K Vijayendrakumar Babu, G Prasanna Kumar, G Harinath[5] had observed time to first request of analgesia was significantly prolonged in Nalbuphine group.(RF vs RN: 233 ± 36.82 vs. 312.38 ± 65.48 mins) P < 0.01 and was considered statistically significant. Sapate et al.[11] used intrathecal nalbuphine (0.5 mg) with 0.5% spinal bupivacaine (3 mL) for lower abdominal surgeries in elderly patients in a randomized control study and concluded that nalbuphine provided better quality of SAB as compared to bupivacaine alone and also enhanced the postoperative analgesia.

Side-Effects

Regarding the perioperative side effects, we found in our study 5 patients in Fentanyl group and 4 patients in Nalbuphine group had Perioperative Nausea. In Fentanyl group 4 patients and in Nalbuphine group 3 patients had intraoperative Hypotension, Fentanyl group experienced pruritus in 3 patients while none of the patient's in Nalbuphine group had this side effect. The incidence of other adverse effects such as shivering, and postoperative sedation was minimal in both the groups and found to be statistically insignificant This is in favour of findings of Malaviya et al[8],Gupta K[10] et al and Gurunath BB. [12]

Conclusion

We can conclude from our study findings that combination of Intrathecal Isobaric Ropivacaine-Nalbuphine significantly prolongs the duration of sensory block, duration of motor block, and duration of postoperative analgesia in comparison to Intrathecal isobaric Ropivacaine-Fentanyl in elective orthopedic lower limb surgeries under subarachnoid block, with stable haemodynamics and minimum non-significant adverse effects.

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Legend Tables

Table 1: Demographic Data of Both Groups

Variables	Group RF (n=50)	Group RN (n=50)	P value
Age (years)	33.3 ± 15.2	33.12± 17.25	0.956
Sex (Male/Female)	33/17	31/19	0.6769
Height (cm)	167.66 ± 4.91	166.02 ± 4.21	0.0765
Weight (kg)	62.82 ± 9.99	62.16 ± 9.63	0.6867
Duration of Surgery (Min)	102.26 ± 29.05	102.3 ± 24.53	0.9941
ASA I/II	33/17	28/22	0.4122

Data is presented as mean±SD except for sex distribution and ASA Grading

Table 2: Comparison of Sensory Block Characteristics Between Both Groups

Time in minutes (min)	Group RF (n=50)	Group RN (n=50)	P value
Time of onset of the sensory blockade (min)	4.41±0.63	4.93 ± 0.95	0.0018
Time from injection to highest Sensory level(min)	7.52 ± 1.11	8.36 ± 1.04	0.0002

Duration of sensory block (min) (REGRESSION TO S2)	254.22 ±7.89	296.98 ± 8.31	<0.0001*

Data is presented as mean±SD. (* p <0.05)

Table 3: Comparison of Motor Block Characteristics between Both Groups

Time in minutes (min)	Group RF (n=50)	Group RN (n=50)	P value
Time To Onset Of Motor blockade (Min)	6.58 ± 1.12	7.06 ± 1.15	0.0376
Duration of Motor blockade (Time To Reach Grade 0 Bromage (Min)	153.18 ± 4.76	190.2 ± 5.82	<0.0001

Data is presented as mean±SD

Table 4: Comparison of Postoperative VAS Score between Both Group

VAS Score	Group RF (n=50)	Group RN (n=50)	P value
0 min	0	0	N/A
30 mins	0	0	N/A
90 mins	0	0	N/A
60 mins	0	0	N/A
120 mins	0	0	N/A
150 mins	0	0	N/A
180 mins	1.2±0.8	1.14±0.81	0.8992
210 mins	1.5±0.8	1.66±0.63	0.3916
240 mins	2.7±0.8	2.52±0.61	0.2060
270 mins	4.2±0.9	3±0.61	<0.0001
300 mins	2.4±0.7	4.24±0.87	<0.0001
330 mins	2.8±0.6	2.9±0.54	0.4848
360 mins	3.3±0.7	3.08±0.75	0.0914

Table 5: Comparison of Total Duration of Analgesia between Both Groups

Time in minutes (min)	Group RF (n=50)	Group RN (n=50)	P value
Total Duration of Analgesia	274.38 ± 9.79	299.7 ± 7.72	<0.0001*

Table 6: Intraoperative and Post-Operative Side Effects

Side effects	Group RF (n=50)	Group RN (n=50)
Nausea	5(10%)	4(8%)
Vomiting	0	0
Hypotension	4 (8%)	3(6%)

Bradycardia	0	0
Pruritus	3(6%)	0
Respiratory Depression	0	0
Shivering	1(2%)	1(2%)
Sedation	0	0
Urinary retention	0	0