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TO COMPARE CLINICAL EFFICACY OF INTRATHECAL NALBUPHINE VS FENTANYL AS ADJUVANT TO 0.5% HYPERBARIC LEVOBUPIVACAINE IN LOWER ABDOMINAL SURGERIES

Anaesthesiology

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ABSTRACT

Introduction Spinal Anaesthesia is widely used for lower abdominal surgeries due to its rapid onset and effective analgesia. However, limited duration of postoperative pain relief remains a concern. The addition of intrathecal adjuvants such as opioids enhances the quality and duration of analgesia. Nalbuphine, a κ-opioid receptor agonist and μ-antagonist, and fentanyl, a potent μ-opioid receptor agonist, are commonly used adjuvants. Their comparative clinical efficacy with hyperbaric levobupivacaine requires further evaluation.

Primary Objective:

- To estimate and compare clinical efficacy of intrathecal nalbuphine vs fentanyl as adjuvant to 0.5% hyperbaric levobupivacaine for intraoperative anaesthesia and post-operative analgesia.

Secondary Objectives:

- To compare the estimated haemodynamic changes, onset and duration of sensory and motor block and Visual Analog Scale(VAS) in both groups.

Methods

This prospective, randomized comparative study was conducted in patients undergoing lower abdominal surgeries under spinal Anaesthesia. Participants were divided into two groups: Group N received intrathecal nalbuphine with 0.5% hyperbaric levobupivacaine, and Group F received intrathecal fentanylwith the same local anesthetic. Parameters assessed included onset and duration of sensory and motor block, duration of postoperative analgesia, hemodynamic variables, and incidence of adverse effects. Pain was evaluated using the Visual Analog Scale (VAS).

Results Both groups provided effective intraoperative Anaesthesia. Nalbuphine demonstrated a longer duration of postoperative analgesia and stable hemodynamic profile, whereas fentanyl showed a faster onset of sensory blockade. The incidence of adverse effects such as pruritus and nausea was lower in the nalbuphine group. Overall, nalbuphine provided comparable or superior analgesic efficacy with fewer side effects

Conclusion Intrathecal nalbuphine is an effective and safe alternative to fentanyl as an adjuvant to hyperbaric levobupivacaine in lower abdominal surgeries, offering prolonged postoperative analgesia with a favorable side effect profile.

KEYWORDS

Spinal Anaesthesia, Nalbuphine, Fentanyl, Levobupivacaine, Intrathecal Adjuvant, Postoperative Analgesia.

INTRODUCTION

Spinal Anaesthesia remains a widely accepted gold-standard anaesthetic technique for surgeries performed below the level of umbilicus. Conventional local anaesthetics like lidocaine, bupivacaine, tetracaine, and chloroprocaine have been extensively used, while newer agents like levobupivacaine and ropivacaine have demonstrated favorable results in terms of improved quality and intensity of sensory and motor blockade. Despite these developments, achieving prolonged and effective postoperative analgesia remains a major challenge, which has led to use of intrathecal adjuvant in combination with shorter-acting local anaesthetic to enhance the duration of analgesia during spinal Anaesthesia.

Nalbuphine is a synthetic, highly lipid-soluble opioid analgesic that acts as a κ-opioid receptor agonist and a μ-opioid receptor antagonist, offering effective analgesia, particularly for visceral pain. When administered intrathecally as an adjuvant to hyperbaric bupivacaine, nalbuphine enhances the quality of perioperative analgesia while being associated with fewer adverse effects. As a mixed agonist–antagonist opioid, it reduces μ-opioid–mediated side effects while augmenting κ-opioid–mediated analgesic effects.

Fentanyl is a potent synthetic opioid analgesic with pharmacological actions similar to morphine but with significantly greater analgesic potency. It is estimated to be 50–100 times more potent than morphine, with as little as 100 micrograms producing analgesia comparable to approximately 10 mg of morphine. Aim of this study is to compare the clinical efficacy of intrathecal nalbuphine and fentanyl when used as adjuvants to 0.5% hyperbaric levobupivacaine in patients undergoing lower abdominal surgeries focusing on the quality of spinal Anaesthesia achieved with each adjuvant, including the onset and duration of sensory and motor blockade, as well as the adequacy of intraoperative analgesia.

MATERIALS AND METHODS

Study design :

Prospective, randomized, comparative analytical study conducted in Department of Anaesthesiology at a tertiary care centre. Patients undergoing elective lower abdominal surgeries were enrolled and randomly allocated into two groups using a computer-generated randomization method to ensure unbiased distribution. Group N received intrathecal nalbuphine (0.4 mg) as an adjuvant to 0.5% hyperbaric levobupivacaine, while Group F received intrathecal fentanyl (20 mcg) with the same local anaesthetic.

Inclusion Criteria:

Age 25-55 years, BMI -18.5 – 23, Surgery- Elective, Patients who have given valid informed consent, ASA I & II.

Exclusion Criteria:

Unwilling patient, known hypersensitivity to any of the known drug, Bleeding diathesis or coagulopathy, On anticoagulant or antiplatelet therapy, spinal deformity or puncture site infection, Raised intracranial tension.

OBSERVATION & RESULTS

60 patients scheduled for elective lower abdominal surgeries under spinal Anaesthesia were recruited: Group N (n=30): 0.4 mg nalbuphine + 2.5 ml of 0.5% hyperbaric levobupivacaine, and Group F (n=30): 20 μg fentanyl + 2.5 ml of 0.5% hyperbaric levobupivacaine. Mean age was 42.17 ± 6.93 years in Group N and 41.62 ± 7.24 years in Group F, with no statistically significant difference. The distribution across age categories (25–34, 35–44, and 45–55 years) was comparable between the groups Mean weight (63.86 ± 6.13 kg vs 64.52 ± 5.84 kg), mean height (167.21 ± 4.93 cm vs 166.67 ± 5.16 cm), and mean BMI (21.23 ± 1.15 vs 21.46 ± 1.28 kg/m²) were statistically comparable.

Onset of sensory block to T6 was significantly faster in Group F (3.88 ± 0.73 min) compared to Group N (5.12 ± 0.94 min), indicating a quicker onset with fentanyl.

Similarly, time to achieve maximum sensory block was shorter in Group F (6.52 ± 1.07 min) than in Group N (8.96 ± 1.25 min). However, regression characteristics favored Group N. The two-segment regression time was significantly longer in Group N (118.68 ± 11.21 min) compared to Group F (110.27 ± 9.63 min). Furthermore, regression of sensory block to T10 was markedly prolonged in Group N (165.86 ± 15.43 min) versus Group F (142.92 ± 13.14 min).

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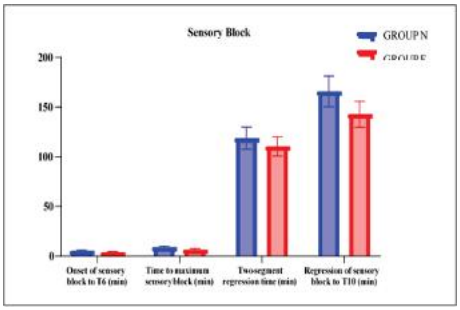


At 5, 10, and 15 minutes, all patients (100%) in both groups had an effective sensory block. However, from 60 minutes onward, statistically significant differences were observed. At 60 minutes, 96.7% of patients in Group N compared to 80.0% in Group F maintained sensory block. At 120 minutes, 83.3% of patients in Group N maintained sensory block compared to only 50.0% in Group F.

Comparison of Motor Block Characteristics (Modified Bromage Scale Parameters) Duration of Analgesia, Pain Scores (VAS), and Total Rescue Analgesic Requirement between Groups

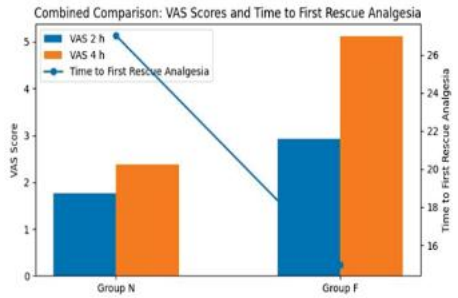
Parameter	GROUP N [n=30]	GROUP F [n=30]	p-value
Onset of motor block (min)	9.55 ± 1.37	6.79 ± 1.14	t=8.482 **p<0.0001***
Duration of motor block (min)	184.63 ± 14.95	148.21 ± 13.14	t=10.02 **p<0.0001***
Time to first rescue analgesia (min)	278.48 ± 44.12	170.61 ± 32.85	t=10.74 **p<0.0001***
VAS at 2 hours	1.76 ± 0.64	2.92 ± 0.86	t=5.927 **p<0.0001***
VAS at 4 hours	2.38 ± 0.78	5.12 ± 0.93	t=6.013 **p<0.0001***
Total paracetamol in 24 hours (g)	1.82 ± 0.63	2.95 ± 0.76	t=6.270 **p<0.0001***

The onset of motor block was significantly faster in Group F (6.79 ± 1.14 min) compared to Group N (9.55 ± 1.37 min), indicating earlier motor blockade with fentanyl. However, the duration of motor block was significantly prolonged in Group N (184.63 ± 14.95 min) compared to Group F (148.21 ± 13.14 min).

The baseline pre-operative SBP was comparable between Group N (126.48 ± 8.93 mmHg) and Group F (125.86 ± 9.15 mmHg) [26]. Although a gradual decline in SBP was observed after spinal Anaesthesia in both groups, the trends were similar and remained hemodynamically stable throughout the intra-operative period. The baseline (pre-operative) HR was comparable between Group N (82.48 ± 7.13 beats/min) and Group F (83.64 ± 7.37 beats/min) with no statistically significant difference. Following spinal Anaesthesia, both groups showed a gradual decline in HR. The pre-operative SpO_2 values were comparable in Group N (99.13 ± 0.61%) and Group F (99.08 ± 0.73%). Oxygen saturation remained consistently above 99% in both groups throughout the intra-operative period, with minimal variation. The mean urine output in Group N was 252.74 ± 54.25 mL, while in Group F it was 246.82 ± 51.84 mL.

Duration of analgesia and post-operative pain scores showed a highly statistically significant difference between the two groups.

The time to first rescue analgesia was significantly prolonged in Group N (278.48 ± 44.12 minutes) compared to Group F (170.61 ± 32.85 minutes), indicating longer-lasting analgesia with intrathecal nalbuphine.



Pain scores assessed by VAS were significantly lower in Group N at both 2 hours (1.76 ± 0.64 vs 2.92 ± 0.86) and 4 hours (2.38 ± 0.78 vs 5.12 ± 0.93) compared to Group F.

Furthermore, the total paracetamol requirement over 24 hours was significantly less in Group N (1.82 ± 0.63 g) than in Group F (2.95 ± 0.76 g).

The incidence of adverse events was largely comparable between Group N and Group F . Hypotension occurred in 4 patients (13.3%) in Group N and 5 patients (16.7%) in Group F, while bradycardia was observed in 2 patients (6.7%) in Group N and 3 patients (10.0%) in Group F, indicating no statistically significant difference. Nausea and vomiting were reported in 1 patient (3.3%) in Group N compared to 4 patients (13.3%) in Group F, which was also not statistically significant. However, sedation was significantly more common in Group N, occurring in 5 patients (16.6%) compared to 1 patient (3.3%) in Group F, indicating a statistically significant difference. Pruritus occurred only in Group F in 1 patient (3.3%) and was absent in Group N. No cases of respiratory depression, post-dural puncture headache, or seizures were observed in either group.

DISCUSSION

Opioids such as fentanyl are widely used as intrathecal additives because of their synergistic analgesic effect and rapid onset of action. Nevertheless, fentanyl is associated with dose-related adverse effects including pruritus, nausea, vomiting, and potential respiratory depression. Nalbuphine, a mixed κ-opioid receptor agonist and μ-opioid receptor antagonist, has emerged as a potential alternative intrathecal adjuvant.

In the present study, the onset of sensory block to T6 and time to achieve maximum sensory block were significantly faster in the fentanyl group compared to the nalbuphine group. This rapid onset with fentanyl can be attributed to its high lipid solubility, which facilitates rapid diffusion into spinal cord tissues and quick interaction with μ-opioid receptors. Further, the present study showed significantly prolonged two-segment regression time and delayed regression to T10 in the nalbuphine group. Prolonged sensory block with nalbuphine may be explained by its κ-opioid receptor agonism, which provides sustained spinal analgesia without rapid cephalad migration.

A major finding of the present study was significantly prolonged time to first rescue analgesia in the nalbuphine group (278.48 ± 44.12 min) compared to fentanyl (170.61 ± 32.85 min), with significantly lower VAS scores at 2 and 4 hours and reduced 24-hour paracetamol consumption. The present study demonstrated stable intraoperative and postoperative systolic and diastolic blood pressure, heart rate, oxygen saturation, and urine output in both groups, with no statistically significant intergroup differences.

In terms of adverse effects, the overall incidence of complications such as hypotension, bradycardia, nausea, vomiting, and sweating was low and comparable between groups. Notably, pruritus was observed only in the fentanyl group, whereas sedation was slightly higher in the nalbuphine group. Importantly, no cases of respiratory depression, post-dural puncture headache, or seizures were reported in either group, reinforcing the safety of both agents at the studied doses. The comparatively lower incidence of opioid-related side effects such as pruritus with nalbuphine may be attributed to its mixed κ-agonist and μ-antagonist activity.

CONCLUSION

Both intrathecal nalbuphine and fentanyl proved to be effective

adjuvants to hyperbaric levobupivacaine for spinal Anaesthesia. Hemodynamic parameters—including systolic blood pressure, diastolic blood pressure, heart rate, oxygen saturation, and urine output—remained stable and comparable throughout the intraoperative and postoperative periods in both groups. This indicates that both nalbuphine and fentanyl, at the studied doses, are safe intrathecal adjuvants with minimal cardiovascular and respiratory compromise.

While intrathecal fentanyl offers the advantage of rapid onset of sensory and motor block, intrathecal nalbuphine provides significantly prolonged sensory and motor blockade, superior and longer-lasting postoperative analgesia, reduced analgesic consumption, and a favorable side-effect profile with comparable hemodynamic stability. Therefore, intrathecal nalbuphine (0.4 mg) appears to be a highly effective and safe alternative to intrathecal fentanyl (20 μg) as an adjuvant to 0.5% hyperbaric levobupivacaine in lower abdominal surgeries, particularly when prolonged postoperative analgesia is desired. Based on the overall findings, nalbuphine may be considered the preferred intrathecal adjuvant in procedures where sustained analgesia and reduced postoperative analgesic requirement are important clinical objectives, whereas fentanyl may be selected when rapid onset of Anaesthesia is the primary consideration.

REFERENCES

1. Bembenick KN, Nguyen A, Jackson C, Shekoohi S, Kaye AJ, Kaye AD, Siddaiah H. Neuraxial Anaesthesia for vaginal delivery. In Pharmacology, Physiology, and Practice in Obstetric Anaesthesia 2025 Jan 1 (pp. 163- 173). Academic Press.
2. Capdevila X, Aveline C, Delaunay L, Bouaziz H, Zetlaoui P, Choquet O, Jouffroy L, Herman-Demars H, Bonnet F. Factors determining the choice of spinal versus general Anaesthesia in patients undergoing ambulatory surgery: results of a multicenter observationnal study. Advances in Therapy. 2020 Jan;37(1):527-40.
3. Athar M, Moied Ahmed S, Ali S, Doley K, Varshney A, Hussain Siddiqi M. Levobupivacaine or ropivacaine: A randomised double blind controlled trial using equipotent doses in spinal anaesthesia. Colombian Journal of Anestesiology. 2016 Apr;44(2):97-104.
4. Gupta K, Rastogi B, Gupta PK, Singh I, Bansal M, Tyagi V. Intrathecal nalbuphine versus intrathecal fentanyl as adjuvant to 0.5% hyperbaric bupivacaine for orthopedic surgery of lower limbs under subarachnoid block: A comparative evaluation. Indian Journal of Pain. 2016 May 1;30(2):90-5.
5. Gunion MW, Marchionne AM, Anderson CT. Use of the mixed agonist– antagonist nalbuphine in opioid based analgesia. Acute pain. 2004 Jun 1;6(1):29-39.
6. Schmauss C, Doherty C, Yaksh TL. The analgetic effects of an intrathecally administered partial opiate agonist, nalbuphine hydrochloride. European journal of pharmacology. 1982 Dec 17;86(1):1-7.