

# Comparative Study to Assess Efficacy of Nalbuphine vs Fentanyl as an Adjuvant to Intrathecal 0.5% Hyperbaric Bupivacaine for Lower Abdominal Surgeries: A Randomized Control Trial

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**Abstract:** Intrathecal opioids are commonly used adjuvants in spinal anesthesia to prolong the action of local anesthetics. In this study, we aim to compare the efficacy of Nalbuphine with Fentanyl as an adjuvant to Bupivacaine. **Methods:** After obtaining Institutional Ethics Committee approval and informed written consent, 60 patients coming for lower abdominal surgeries were randomly allocated into two groups, Group A (Nalbuphine 1mg) and Group B (Fentanyl 25mcg), with 30 patients in each group. The sample size was calculated using a two means study. Data will be represented as mean with standard deviation. Students paired T-test, Chi-square Test, Students T-test were used for statistical analysis. The onset and duration of sensory and motor block, duration of analgesia, hemodynamic parameters, and side effects were recorded. **Results:** The onset of sensory block and motor block, the duration of sensory block, and motor block, as well as the duration of analgesia was more with Nalbuphine, with p-value statistically significant (<0.05). **Conclusion:** Nalbuphine is a better alternative to Fentanyl as an adjuvant to intrathecally administered local anesthetics as it has a faster onset of action, prolonged duration, and provides better postoperative analgesia.

**Keywords:** Nalbuphine, Fentanyl, adjuvant, bupivacaine

## 1. Introduction

Spinal anesthesia is the most commonly used technique for lower abdominal surgeries and bupivacaine is the most commonly used intrathecal local anesthetic agent. However, postoperative pain control is a major problem while using only local anesthetics as they are associated with a relatively short duration of action, and thus early rescue analgesic intervention is needed in many cases during the postoperative period. To avoid this, various additives have been used along with bupivacaine to increase their duration of action and efficacy. They increase the speed of the onset of neural block, improve the quality, and prolong the duration of the block.

Fentanyl is a lipophilic opioid with a rapid onset following intrathecal injection, without causing respiratory depression as it does not migrate to the 4th ventricle. Studies have demonstrated that it improves the duration of sensory anesthesia and postoperative analgesia without producing significant side effects. Nalbuphine is an agonist-antagonist opioid that is structurally related to oxycodone and naloxone. It has the potential to attenuate the  $\mu$ -opioid effects and enhance the  $\kappa$ -opioid receptor-mediated effects. It has been recently used intrathecally for cesarean sections, infra-umbilical surgeries, lower limb orthopedic surgeries, and for the prevention of intrathecal morphine-induced pruritis.

Very few studies have compared the effects of adding intrathecal nalbuphine (opioid agonist-antagonist) or fentanyl (opioid agonist) as an adjuvant to bupivacaine. In this perspective, randomized, double-blind study, we tried to compare fentanyl and nalbuphine as adjuvants to bupivacaine in a subarachnoid block in terms of onset and duration of sensory and motor block as the primary outcome and intraoperative and postoperative hemodynamic profile as a secondary outcome.

In our study, we aim to compare the efficacy of Nalbuphine (1mg) vs Fentanyl (25 $\mu$ g) as adjuvant to intrathecal 0.5% Hyperbaric Bupivacaine in terms of following:

- 1) Onset and duration of sensory block and motor block
- 2) Time to 1st rescue analgesia
- 3) Hemodynamic parameters
- 4) Side effects

## 2. Methods

- 1) This randomized double blinded study was conducted in government general hospital, government medical College Anantapur, during period of June 2021 to June 2022.
- 2) After obtaining Institutional Ethics Committee approval and informed written consent from all the participants, 60 patients were divided into 2 groups of 30 patients each:
  - a) Group A: Nalbuphine 1mg (0.5ml)
  - b) Group B: Fentanyl 25 $\mu$ g (0.5ml)

As an adjuvant to 2.5ml of 0.5% hyperbaric bupivacaine.

Inclusion criteria	Exclusion Criteria
20-60 years of age	<20 yrs or>60 yrs
ASA physical status of I or II	ASA physical status of III or more
Informed written consent	Patient refusal
Elective lower abdominal surgeries	Allergy to local anesthetics
	Contraindications to spinal anesthesia
	CVS, Renal or liver disorders

- The onset and duration of sensory block and motor block, time for 1<sup>st</sup> rescue analgesia, hemodynamic parameters and side effects were noted and compared.
- Sensory block was assessed by spirit swab, motor block by Modified Bromage scale and rescue analgesia was given when VAS  $\geq$ 4.
- Randomization and allocation was done by using randomly generated computer numbers.
- Statistical analysis was done using Jamovi version 1.6.23 software.
- Results were presented as means  $\pm$  standard deviation.
- p-value was calculated by using Student's-T-test; p-value <0.05 is considered statistically significant.

### 3. Statistical analysis

**Table 1:** Characteristics of Sensory and motor block

Parameter	Group	Mean	Standard Deviation	p-value
Onset of Sensory Block Min	A (n=30)	1.9	0.42	0.0052 (S)
	B (n=30)	2.25	0.3	
Onset of Motor Block Min	A (n=30)	2.9	0.53	0.0045 (S)
	B (n=30)	3.3	0.55	
Duration of Sensory Block Hrs	A (n=30)	5.65	1.06	0.025 (S)
	B (n=30)	5.05	0.55	
Duration of Motor Block Hrs	A (n=30)	3.87	0.43	0.036 (S)
	B (n=30)	3.25	0.48	
Time to 1 <sup>st</sup> rescue analgesia Hrs	A (n=30)	6.3	0.8	0.0012 (S)
	B (n=30)	5.5	0.9	
VAS	A (n=30)	4.3	1.82	0.0005 (S)
	B (n=30)	5.8	1.95	

### Hemodynamic parameters

**Table 2:** Heart Rate

GROUP	BASALHR	5MINHR	15MINHR	30MIN HR	60MINHR	90MINHR
A	78.4 $\pm$ 10.6	78.9 $\pm$ 5.3	77.6 $\pm$ 9.2	76.5 $\pm$ 9.9	73.6 $\pm$ 9.1	74.6 $\pm$ 8.8
B	78.6 $\pm$ 10.2	77.2 $\pm$ 6.8	75.5 $\pm$ 8.8	75.5 $\pm$ 9.4	71.9 $\pm$ 8.9	72.9 $\pm$ 8.4
p-value	0.42	0.388	0.295	0.223	0.178	0.125

**Table 3:** Systolic Blood Pressure

GROUP	BASALSBP	5MINSBP	15MINSBP	30MINSBP	60MINSBP	90MINSBP
A	133.5 $\pm$ 12.5	118.5 $\pm$ 10.5	115.5 $\pm$ 9.6	112.8 $\pm$ 8.2	110.6 $\pm$ 7.9	115.6 $\pm$ 7.5
B	134.9 $\pm$ 11.8	115 $\pm$ 9.8	111.3 $\pm$ 9.1	106.5 $\pm$ 8.1	109.5 $\pm$ 7.5	111.3 $\pm$ 7.7
p-value	0.728	0.395	0.162	0.061	0.354	0.145

**Table 4:** Diastolic Blood Pressure

Group	BASALDBP	5 MINDBP	15MINDBP	30MINDBP	60MINDBP	90MINDBP
A	78.5 $\pm$ 10.2	74.8 $\pm$ 9.1	71.4 $\pm$ 8.4	69.1 $\pm$ 7.9	68.9 $\pm$ 7.8	68.6 $\pm$ 8.2
B	79 $\pm$ 9.9	74.15 $\pm$ 8.6	70.3 $\pm$ 7.9	67.8 $\pm$ 7.6	67.25 $\pm$ 7.7	67.4 $\pm$ 7.9
p-value	0.485	0.458	0.389	0.288	0.423	0.457

### 4. Results

- Demographics, Hemodynamic parameters and side effects were comparable but statistically not significant.
- There was early onset of sensory and motor block, as well as prolonged duration of sensory and motor block in Nalbuphine group than Fentanyl group which is statistically significant.
- The time for 1<sup>st</sup> rescue analgesia is also more with Nalbuphine group than Fentanyl group which is statistically significant.

## 5. Discussion

- Nalbuphine<sup>1</sup> is an agonist – antagonist opioid that binds to  $\mu$  – receptors as well as  $\kappa$ - and  $\delta$ -receptors.
- Nalbuphine acts as an antagonist at the  $\mu$ -receptor, thus reducing side effects of  $\mu$  – agonists and by acting as agonist at the  $\kappa$ -receptor, it has analgesic effect.
- Fentanyl is  $\mu$ -receptor agonist and is commonly used as adjuvant in spinal anesthesia, and is more commonly associated with side effects like pruritis, urinary retention, respiratory depression.
- In this study we aim to compare the efficacy of Nalbuphine 1mg to that of Fentanyl 25 $\mu$ g as adjuvant to intrathecal 0.5% Hyperbaric Bupivacaine.
- Prabhakaraiah *et al.*<sup>1</sup> have performed similar study with Nalbuphine 0.8mg vs Fentanyl 25 $\mu$ g as adjuvant to Bupivacaine. Their study showed that the post – operative VAS scores were better in Fentanyl group than Nalbuphine group (p=0.0007).<sup>1</sup>
- Gomma *et al.*<sup>2</sup> have compared Nalbuphine 0.8mg vs Fentanyl 25 $\mu$ g as adjuvant to Bupivacaine in parturients coming for LSCS. Their study showed that the onset of motor block was rapid with Fentanyl group than Nalbuphine group (p=0.008).<sup>2</sup>
- In our study, there was rapid onset and prolonged duration of sensory and motor block in Nalbuphine group compared to Fentanyl group (p<0.05).
- The duration of post – operative analgesia was prolonged and post-operative VAS score was also less with Nalbuphine group compared to Fentanyl group (p<0.05).
- Side effects associated with opioid adjuvants were also less in Nalbuphine group compared to Fentanyl group

## 6. Conclusion

We conclude that Nalbuphine 1mg provides reliable sensory and motor block and prolongs post-operative analgesia better than Fentanyl 25 $\mu$ g as adjuvant to Bupivacaine in lower abdominal surgeries.

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