

# A COMPARATIVE STUDY OF NALBUPHINE AND FENTANYL WITH BUPIVACAINE IN SPINAL ANAESTHESIA FOR LOWER ABDOMEN AND LOWER LIMB SURGERIES

## Anaesthesia

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### Abstract:

**Background:** Opioid analogues have been used as additive to Bupivacaine in spinal anaesthesia to improve the onset of action, quality of intraoperative and postoperative analgesia and to prolong the duration of block. Fentanyl is a potent synthetic opioid agonist and Nalbuphine is a synthetic opioid agonist-antagonist analgesic. In the present study we aim to compare the effects of adding Nalbuphine or Fentanyl as an adjunct to Bupivacaine in Spinal Anaesthesia.

**Materials and methods:** In present study we included 150 patients, belonging to ASA grade I and II of age group 18-60 yrs, scheduled for lower abdomen and lower limb surgeries under spinal anaesthesia which were randomly divided into three groups. Group I received 2.5ml, 0.5% Bupivacaine Heavy and 0.5ml Normal Saline, Group II received 2.5ml, 0.5% Bupivacaine Heavy and 1mg Nalbuphine prepared into 0.5ml and Group III received 2.5ml, 0.5% Bupivacaine Heavy and 10mcg Fentanyl prepared into 0.5ml. Baseline observations were started before intrathecal drug injection. After intrathecal drug injection, data recording was performed during the intraoperative period at 5 min interval till 15 min and at 15 min interval till 180 minutes. The primary outcomes studied were onset of sensory and motor block, duration of pain relief. Hemodynamic variables and side effects were also taken into consideration.

**Results:** The results showed that mean time to achieve sensory block was lower in Fentanyl group. Mean time to achieve motor block was lower in Nalbuphine group. Median of Maximum level of sensory block was same in both the groups. Fall in Systolic Blood Pressure (SBP), Diastolic Blood Pressure (DBP) and Mean Arterial Pressure (MAP) were more in Fentanyl group which was easily controlled with small bolus dose of Ephedrine. Overall duration of analgesia was significantly longer in Fentanyl group.

**Conclusion:** Fentanyl is a better choice as an adjunct to Bupivacaine in Spinal Anaesthesia than Nalbuphine in terms of onset of block and duration of analgesia without any significant hemodynamic disturbances and side effects.

**Key words:** Spinal Anaesthesia, Nalbuphine, Fentanyl, Bupivacaine.

## Introduction

Central neuraxial opioids, intrathecal as well as epidural, offer the perceived benefit of selective analgesia without sensory or motor blockade. Opioid analogues have been used as additive to Bupivacaine in spinal anaesthesia to improve the onset of action, quality of intraoperative and postoperative analgesia and to prolong the duration of block.<sup>1,2,3,4</sup>

Nalbuphine hydrochloride is a synthetic opioid agonist-antagonist analgesic of the phenanthrene series. It is agonist on kappa and antagonist on mu opioid receptors. Fentanyl is a potent synthetic mu-opioid agonist. It is a narcotic analgesic, Morphine type, 100 times more potent than Morphine.

In the present study, we compared the effects of adding them as an adjunct with Bupivacaine in spinal anaesthesia.

The primary outcomes studied were effect on onset of sensory and motor blockade, maximum level of sensory and motor blockade, duration of pain relief. Hemodynamic variables and side effects were also recorded.

## Materials and Methods

After approval from the ethics committee and written informed consent, 150 ASA physical status I-II patients of either sex with an age range of 18-60 years scheduled for elective or emergency surgery were included in the study. Patients using  $\alpha$ 2-adrenergic receptor antagonists, calcium channel blockers, angiotensin-converting enzyme inhibitors, showing dysrhythmias in the electrocardiogram, and patients who had a history of lowback surgery were excluded from the study. The patients were randomly divided into 3 groups of 50 individuals each using lottery method. All patients received a coded intrathecal drug volume of 3.0 ml. The dose of hyperbaric 0.5% Bupivacaine, 12.5 mg, was identical in all study groups. The active study groups (Groups II and III) received Nalbuphine (Nalfy from Glenmark pharmaceuticals), 1mg prepared into 0.5ml and Fentanyl (Fendrop from Sun pharma) 10mcg prepared into 0.5ml respectively added to Bupivacaine in the same syringe; the control group (Group I) received 0.5ml of saline added to Bupivacaine. Before surgery, all patients were explained about 10-point VAS to assess pain intensity. All patients had spinal anaesthesia according to a standard

protocol. An oral 0.25mg Alprazolam premedication was given night before surgery and at 6 a.m. in the morning of surgery. After hydration with 15 ml/kg bd.wt of Ringer's lactate solution, a midline spinal puncture was performed at L3/4 with the patient in the sitting position using a 25-gauge Quincke spinal needle (BD). The L3/4 interspace was identified by a line between the upper borders of the iliac crest passing through the spinous process of L4 or the interspace between L4 and L5. After giving the drug, the patients were placed in the supine position for surgery. During surgery, additional IV fluids (crystalloids, colloids, and blood) were administered as peri-operatively dictated by blood loss and hemodynamic instability. Blood loss  $\geq$  500 ml was replaced with maximally 1000 ml of Hetastarch. Hemodynamic instability was defined as a 30% reduction in mean arterial blood pressure (BP) from baseline value and was treated with 300 ml of additional fluids or, if not responsive within 5 min, with IV ephedrine (3-mg bolus). If, intra-operatively, a need for additional sedation was expressed, IV Midazolam was given intermittently (1-mg bolus). Baseline observations were started before intrathecal drug injection. Heart rate, electrocardiogram, non-invasive arterial BP, and peripheral oxygen saturation were monitored intra-operatively. After intrathecal drug injection, data recording was performed during the intra-operative period at 5 min interval till 15 min and at 15 min interval till 180 minutes. Then the level of sensory and motor blockade was assessed. To evaluate the extension of the sensory block, the number of dermatomal segments above the lumbar injection site was assessed.

The intensity of pain was assessed using a 10-point VAS. Duration of pain relief was defined as the time from intrathecal injection to the first request for supplemental analgesia by IM Tramadol (50mg). Lower limb motor blockade was graded according to the Modified Bromage scale. Sedation was scored on a 6-point scale (Ramsay sedation score) ranging from 1 to 6 (1 anxious agitated or restless to 6 no response to light glabellar tap or loud auditory stimulus). All data collection was performed by persons not involved in patient care. Complete recovery from the Nalbuphine or Fentanyl-induced sensory and motor block was documented in all patients.

Monitored parameters were onset of sensory block, onset of motor block, period of complete and effective analgesia and vitals such as spO<sub>2</sub>, Heart rate, SBP, DBP, and MAP. Specific side effects such as Nausea, vomiting, sedation, respiratory depression, pruritus and urinary retention etc. if

any were also taken into consideration.

### Statistical Analysis

The statistical analysis was done using SPSS (Statistical Package for Social Sciences) Version 15.0 statistical analysis software. The values were represented in Numbers (%) and Mean±standard deviation (SD). The statistical tests used were Chi square test, Student “t” test and one-way analysis of variance (ANOVA) with Bonferroni correction, where appropriate.

### Effect size analysis

The effect size of the study was calculated duration of effective analgesia in Group I (minimal dose) as compared to Group III (maximal dose)

Effect size (d) = 3.023(Large size)

Power = 1.000(Considering the difference between two groups to be 129 min, within group standard deviation to be 42.5, no. of samples to be 50 and alpha error to be 5%).

Both the effect size and power indicated that the findings of the study could be extended to population.

Power of the test was calculated using Power and Sample Size calculator downloaded from Vanderbilt University website.

### Results

A total of 150 subjects were enrolled and divided into three groups of 50 each. In Group I (control) we used Normal saline with Bupivacaine, In Group II Nalbuphine with Bupivacaine and in Group III Fentanyl with Bupivacaine. Statistically, there was no significant intergroup difference regarding age, gender distribution and baseline hemodynamic parameters.

### Onset of sensory block

The mean time to achieve sensory block up to T8 level was 4.78±2.16 minutes in Group I, 3.58±1.33 minutes in Group II and 3.24±1.04 minutes in Group III. (Table 1, Figure 1). Statistically, there was a significant intergroup difference

(p value < 0.001).

In Group I, there was 1 and in Group II there were 2 patients who could not achieve the sensory block up to T8 level till 15 minutes.

### Onset of Motor Block

The mean time to achieve Grade III motor block was 8.87±3.68 minutes in Group I, 5.64±2.60 minutes in Group II and 6.08±3.23 minutes in Group III (Table 2, Figure 2).

The mean time to achieve Grade III motor blockade was minimum in Group II and maximum in Group I showing a significant intergroup difference (p value < 0.001). There were 3 patients in Group I who did not achieve Grade III motor block till 15 minutes.

It means that Grade III motor block was achieved earliest in the patients receiving Nalbuphine followed by the patients receiving Fentanyl.

### Median Level of sensory block

Median Level of sensory block was T6 in all 3 Groups after 15 minutes of intrathecal injection but it ranged from T4-T10 in Groups I and II whereas it ranged from T4-T6 in Group III which shows that level of sensory block was consistently higher in patients receiving Fentanyl than patients receiving Nalbuphine.

### Duration of Analgesia

The mean duration of complete analgesia was found to be 129.3±10.2, 183.4±20.1 and 190.9±30.3 min. in Groups I, II and III respectively (Table 3, figure 3).

The mean duration of effective analgesia was found to be 151.3±40.1, 242.4±41.4 and 280.3±45.1 min. in Groups I, II and III respectively (Table 3, figure 3).

Group I had significantly shorter duration of complete as well as effective analgesia as compared to Groups II and III (p value < 0.001).

A significant difference was observed between Groups

II and III for the mean duration of effective analgesia ( $p$  value  $< 0.001$ ) with Group III showing significantly longer duration as compared to Group II.

It means that the longest duration of both complete and effective analgesia was experienced by the patients receiving Fentanyl, followed by the patients receiving Nalbuphine (Figure 3).

### **Pulse Rate**

There was no statistically significant intergroup difference observed among the three study groups regarding pulse rate throughout the study period ( $p$  value  $> 0.05$ ).

At most of the times the mean value in all the three groups remained between 80 to 90 beats per minute.

### **SpO<sub>2</sub>**

At most of the times the mean value of SpO<sub>2</sub> in all the three groups remained above 99%. There was no significant intergroup difference ( $p$  value  $> 0.05$ ).

### **Systolic Blood Pressure (SBP)**

In Group I, the mean of SBP ranged from  $115.5 \pm 2.1$  (at 120 minute) to  $130.4 \pm 12.3$  (baseline) mmHg whereas in Group II, it ranged from 106(at 150 minute) to  $131.9 \pm 11.0$  mmHg and in Group III, the mean value ranged from  $108.4 \pm 12.6$  (15 minute) to  $128.1 \pm 11.2$ (baseline)mmHg.

Statistically significant intergroup differences were observed from 5 min to 90 min time interval except at 60 min. At all these occasions the mean value was maximum in Group I followed by Group II and then Group III. From 105 min onwards no significant difference was observed amongst groups.

It means that fall in SBP was maximum in patients receiving Fentanyl followed by patients receiving Nalbuphine.

### **Diastolic Blood Pressure (DBP)**

In Group I, the mean DBP ranged from  $71.1 \pm 9.6$ (at 30

min) to  $83(135 \text{ min})$ mm Hg whereas in Group II, it ranged from 48(at 150 min) to  $81.6 \pm 10.0$  mm Hg(135 min) and in Group III the mean value ranged from 48(150 min) to  $77.9 \pm 7.5$ (Baseline)mm Hg.

Statistically significant intergroup differences were observed from 0 min to 90 min time interval. At all these occasions the mean value was maximum in Group I followed by Group II and then Group III. From 105 min onwards no significant difference was observed amongst groups.

It means that fall in DBP was maximum in patients receiving Fentanyl followed by patients receiving Nalbuphine.

### **Mean Arterial Pressure (MAP)**

In Group I, MAP ranged from  $82.5 \pm 9.4$ (at 30 min) to  $99(135 \text{ min})$ mm Hg whereas in Group II, it ranged from 63(at 150 min) to  $95.5 \pm 8.3$ mm Hg (Baseline) and in Group III the mean value ranged from 70(150 min) to  $91.6 \pm 8.9$ (Baseline) mm Hg.

Statistically significant intergroup differences were observed from 0 min to 75 min time interval. At all these occasions the mean value was maximum in Group I followed by Group II and then Group III. From 90 min onwards no significant difference was observed amongst groups. It means that fall in MAP was maximum in patients receiving Fentanyl followed by patients receiving Nalbuphine.

### **Respiratory Rate**

Mean respiratory rate in Group I ranged from  $14.6 \pm 2.0$ (60 min) to 20/min (135 min). In Group II, it ranged from 12(150 min) to  $16.1 \pm 2.0$ (0 min) and in Group III, it ranged from 12(150 min) to  $16.1 \pm 3.8$ (0 min). Statistically, no significant intergroup difference was observed ( $p > 0.05$ ) at any time interval.

### **Side Effects**

No significant difference was observed among different groups for any of the side effects.

Pruritus was observed in 2 patients in Group I, in 4 patients

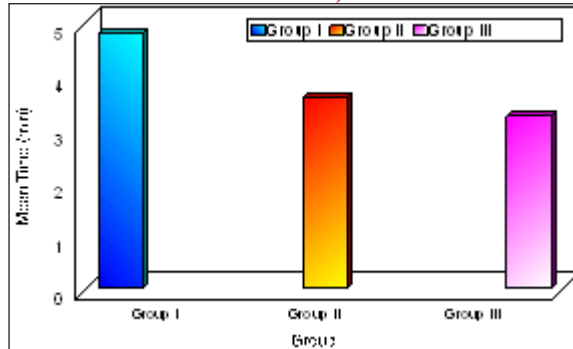
in Group II and in 5 patients in Group III. Nausea and Vomiting was observed in 1 patient in Group I, 3 patients in Group II and 2 patients in Group III. Two patients in Group III suffered from hypotension.

**Table- 1:**  
**Time to achieve sensory block up to T8 level (in minutes)**

S.N.	Group	Mean Time	SD	Range
1.	Group I (n=49)	4.78	2.16	2 – 10
2.	Group II (n=48)	3.58	1.33	2 – 10
3.	Group III (n=50)	3.24	1.04	1 – 5

F=12.746; p<0.001

**Figure – 1:**  
**Time to achieve sensory block up to T8 level (in minutes)**

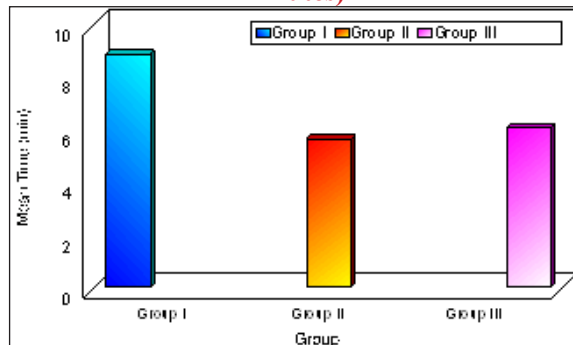


**Table – 2:**  
**Time to achieve Motor block up to Grade III (in minutes)**

S.N.	Group	Mean Time	SD	Range
1.	Group I (n=47)	8.87	3.68	4-15
2.	Group II (n=50)	5.64	2.60	3-15
3.	Group III (n=50)	6.08	3.23	3-15

F=14.483; p<0.001

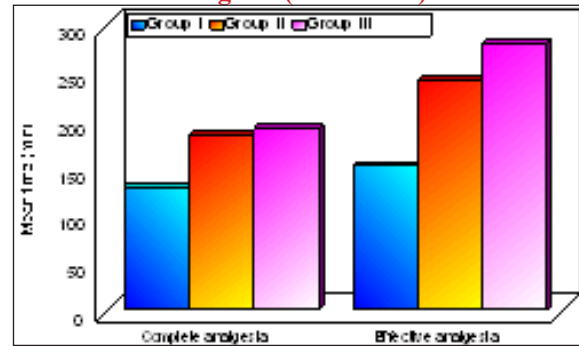
**Figure – 2:**  
**Time to achieve Motor block up to Grade III (in minutes)**



**Table– 3:**  
**Duration of Complete Analgesia and Effective analgesia (in minutes)**

S. N.	Variable	Group I (n=50)			Group II (n=50)			Group III (n=50)			Significance	
		n	Mean	SD	n	Mean	SD	n	Mean	SD	F	“p”
1.	Complete analgesia	50	129.3	10.2	50	183.4	20.1	50	190.9	30.3	118.8	<0.001
2.	Effective analgesia	50	151.3	40.1	50	242.4	41.4	50	280.3	45.1	123.1	<0.001

**Figure -3:**  
**Duration of Complete Analgesia and Effective analgesia (in minutes)**



**Discussion**

The present study was designed to compare the effects of adding Nalbuphine or Fentanyl as an adjunct to Bupivacaine in Spinal Anaesthesia.

In Group I (control) we used Normal saline with Bupivacaine, In Group II Nalbuphine with Bupivacaine and in Group III Fentanyl with Bupivacaine.

**Onset of sensory block**

Mean time for onset of sensory block in Group I, II and III were 4.78±2.16 minutes, 3.58±1.33 minutes and 3.24±1.04 minutes respectively (p<0.001). Onset of sensory block was faster in Group III.

Uma Srivastava et al<sup>5</sup> used intrathecal Fentanyl with Lignocaine heavy and concluded that it not only speeded up the onset and increased the duration of sensory block but also prolonged the postoperative analgesia without affecting the recovery of motor block. This finding is consistent with the present study.

Singh H et al<sup>1</sup> used intrathecal fentanyl with bupivacaine to

prolong sensory blockade and they concluded that fentanyl prolonged the duration of bupivacaine induced sensory block and reduced the analgesic requirement in the early postoperative period following bupivacaine spinal block. Even in our study Fentanyl prolonged the sensory blockade and period of effective analgesia.

Shende D et al<sup>6</sup> studied the influence of intrathecal fentanyl on subarachnoid block for Caesarean section and they concluded that adding fentanyl to hyperbaric bupivacaine for spinal anaesthesia markedly improves intra-operative anaesthesia for Caesarean section. In the present study it was observed that sensory block up to T8 level was achieved earlier in patients receiving Fentanyl than in patients receiving Nalbuphine with bupivacaine or bupivacaine alone.

### Onset of Motor Block

Mean time for onset of motor block of Grade III in Group I, II and III were 8.87±3.68 minutes, 5.64±2.60 minutes and 6.08±3.23 minutes respectively (p<0.001). Onset of motor block was faster in Group II.

### Duration of Analgesia

**Complete analgesia:** It refers to the time from intrathecal injection to the first complaint of pain by the patient.

**Effective analgesia:** It refers to the time from intrathecal injection to the administration of analgesic supplement i.e. i.m. tramadol (VAS ≥ 4).

Mean time of complete and effective analgesia was more in Group III followed by Group II and then by Group I, it means that Fentanyl provided longer duration of analgesia than Nalbuphine (p<0.001).

Jaishri bogra et al<sup>2</sup> studied the synergistic effect of intrathecal fentanyl and bupivacaine in spinal anaesthesia for caesarean section and they concluded that fentanyl potentiate and reduce the dose of bupivacaine and in our study it was found that period of complete and effective analgesia was prolonged with Fentanyl.

Hadzilia S et al<sup>7</sup> studied the effect of intrathecal Fentanyl added to Lidocaine for open prostatectomy surgery

and concluded that addition of intrathecal Fentanyl 10mcg to 3.5ml 2% Lidocaine improves the quality of anaesthesia and delays the analgesic requirement during the early postoperative period in patients undergoing open prostatectomy which is a consistent finding with the present study where bupivacaine was used instead of lidocaine.

Unlugenc H8 did a double blind comparison of intrathecal ketamine (0.05mg/kg) and fentanyl (25mcg) combined with plain bupivacaine (10mg) 0.5% for caesarean delivery and concluded that fentanyl provided prolonged analgesia than ketamine but onset of sensory and motor block was faster in ketamine group. Comparing drug and dose of Fentanyl was different in the present study but the finding of prolongation of analgesia correlates with the above mentioned study.

Xavier Culebras et al<sup>4</sup> Compared between Intrathecal Nalbuphine and Morphine regarding postoperative analgesia and adverse Effects, in caesarean delivery and they found 0.8 mg of intrathecal nalbuphine improves intraoperative analgesia and prolong postoperative analgesia, without increasing the risk of side effects. But on comparing Nalbuphine with Fentanyl in the present study it was found that fentanyl improves the onset of sensory block, prolonged the duration of effective analgesia and reduces the supplement analgesic requirement in the postoperative period.

B N Biswas et al<sup>9</sup> compared the effects of adding 12.5mcg Fentanyl to 2.0ml Bupivacaine and concluded that duration of effective analgesia was prolonged to 248 minutes in comparison to 150 minutes when Bupivacaine was used alone. Even in the present study Fentanyl pronged the period of effective analgesia.

### Mean Arterial Pressure

Statistically significant intergroup differences were observed from 0 min to 75 min time interval. At all these occasions the mean value was maximum in Group I followed by Group II and then Group III. From 90 min interval onwards no significant difference was observed amongst groups.

It means that fall in MAP was observed maximum in patients receiving Fentanyl followed by patients receiving Nalbuphine.

In a study done by Fontes S et al<sup>10</sup> they concluded that adding Fentanyl (15mcg) to spinal bupivacaine(10mg) resulted a significant MAP reduction at 5 minutes after spinal injection. This was not observed when lower dose of bupivacaine (7mg) was used. This is consistent with the present study. However, the doses were different in our study in which we used 10mcg Fentanyl with 12.5mg Bupivacaine.

### Side Effects

No significant difference was observed among different groups for any of the side effects.

Pruritus was observed in 2 patients in Group I, in 4 patients in Group II and in 5 patients in Group III. Nausea and Vomiting was observed in 1 patient in Group I, in 3 patients in Group II and in 2 patients in Group III. Two patients in Group III suffered from hypotension.

Catherine O hunt et al<sup>3</sup> studied the perioperative analgesia with subarachnoid fentanyl for caesarean section and they concluded that fentanyl improves the quality of blockade but higher doses cause the pruritus and in the present study also fentanyl produced pruritus but it was not found to be significant.

Hea jo yoon et al<sup>11</sup> compared intrathecal Nalbuphine with Morphine and concluded that incidence of pruritus were significantly lower in Nalbuphine than Morphine. In our study there were lesser no. of patients who complained of pruritus receiving Nalbuphine than the patients receiving Fentanyl but it was not found to be significant.

M S Khanna et al<sup>12</sup> concluded that incidence of pruritus and respiratory depression were more prevalent in patients receiving 25mcg of Fentanyl with 2.5ml Hyperbaric Bupivacaine in comparison to control group receiving 2.5ml Hyperbaric Bupivacaine and Normal saline. It is a consistent finding with the present study in which some of the patients in both the groups complained of pruritus.

### Conclusion

Mean time to achieve sensory block was lower in Fentanyl group. Mean time to achieve motor block was lower in Nalbuphine group. Median of Maximum level of sensory

block was same in both the groups. Fall in Systolic Blood Pressure; Diastolic Blood Pressure and Mean Arterial Pressure were more in Fentanyl group which was easily controlled with small bolus dose of Ephedrine. Overall duration of analgesia was significantly longer in Fentanyl group.

In our opinion Fentanyl is a better choice as an adjunct to Bupivacaine in Spinal Anaesthesia than Nalbuphine in terms of onset of block and duration of analgesia without any significant hemodynamic disturbances and side effects.

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