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Original Article

# A Study of Intrathecal Nalbuphine and Intrathecal Fentanyl as Adjuvants to 0.5% Hyperbaric Bupivacaine

**S Sreenivasarao[1], G Sarada[2], S Ramya Krishna[2], R Suresh[2]**

[1]Associate Professor, Department of Anaesthesia, AC Subba Reddy Government Medical College, Nellore, Andhra Pradesh, India, [2]Assistant Professor, Department of Anaesthesia, AC Subba Reddy Government Medical College, Nellore, Andhra Pradesh, India

## Abstract

**Background:** We want to compare the effects of intrathecal nalbuphine and intrathecal fentanyl as an adjuvant to 0.5% hyperbaric bupivacaine in cases posted for surgeries below the umbilicus.

**Methods:** It was a prospective, randomized, double-blind, and comparative study conducted on 60 patients undergoing elective surgeries under subarachnoid block at the Department of Anesthesiology, ACSR GMC, Nellore from June 2021 to May 2022. Sixty patients were divided into two groups Group 1 (nalbuphine) and Group 2 (fentanyl) according to adjuvant added intrathecally to 0.5% hyperbaric bupivacaine.

**Results:** In our study, the mean time of onset of sensory block at T10 and motor block in Group1 (nalbuphine) was earlier than Group 2 (fentanyl) and meantime for the sensory block to reach T6 in Group 1 was also earlier than Group 2 (fentanyl) with $P < 0.001$. The mean time for 2 segments regression in Group 1 was 136.784 ± 11.857 min and in Group 2 (fentanyl) was 85.983 ± 4.450 min with ($P < 0.001$) thus showing two-segments regression which is prolonged in Group 1. Duration of motor, sensory block, and time for rescue analgesia was also significantly prolonged in Group 1 (nalbuphine) compared to Group 2 (fentanyl). The adverse events in Group 1 (nalbuphine) were lesser as compared to Group 2 (fentanyl) and were statistically significant. Fall in pulse rate, systolic blood pressure, diastolic blood pressure, and mean arterial pressure was observed in both the groups following institution of spinal anesthesia.

**Key words:** Local anesthetic, Intrathecal adjuvants, Hyperbaric bupivacaine, Nalbuphine, Fentanyl, Visual analog scale

## INTRODUCTION

Hyperbaric Bupivacaine, the local anesthetic does not have the advantage of prolonged analgesia as a single agent. Due to the early arising post-operative pain, the role of various adjuvants has been proposed and evaluated.[1]

Adjuvant drugs are pharmacological agents possessing little pharmacological effect by themselves but enhance or potentiate the action of other drugs when given at the same time. Adjuvant drugs modify LA effects and reduce side effects.

Perioperatively these drugs affect:

- Latency, that is, time of onset of LA block
- Duration of analgesia, that is, duration of sensory and motor block
- Quality of analgesia, that is, complete and incomplete analgesia.

Postoperatively adjuvant drugs affect:

- Analgesic gap, that is, the time interval between subsequent doses administered
- Quality of analgesia, that is, patient satisfaction and care provider's impression of pain relief.

Knowledge and use of adjuvant drug therapy have rendered neuraxial analgesia more effective in the management of both acute and chronic pain conditions.[2] Among various

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**Corresponding Author:** Dr. R Suresh, Assistant Professor, Department of Anaesthesia, AC Subba Reddy Government Medical College, Nellore, Andhra Pradesh, India.

adjuvants, intrathecal opioids have provided an effective prolongation of post-operative analgesia after orthopedic surgical procedures.[3,4]

### Aim

The aim of this study was to study the effects of intrathecal nalbuphine and intrathecal fentanyl as adjuvants to 0.5% hyperbaric Bupivacaine in the lower abdominal and lower limb surgeries.

### Objectives

The objective of this study were as follows:

a) To compare the onset and duration of sensory block.
b) To compare onset and duration of motor block.
c) To compare hemodynamic variables intraoperatively.
d) To compare adverse effects.

### Source of Data

It was a prospective, randomized, double-blind, and comparative study, which was conducted on 60 patients undergoing elective lower abdominal and lower limb orthopedic surgeries under subarachnoid block at the Department of Anesthesiology, ACSR GMC, Nellore from June 2021 to May 2022. The study was conducted over 12 months.

### Sample Size Calculation

$$N = 2(z\alpha+z1\text{-}\beta)^2\ s^2/d^2$$

$Z\alpha = 1.96$ at confidence interval of 95%
$Z1\text{-}\beta$ = Power = 0.84 at 80% power
S = Standard deviation
D = Difference between 2 means.

### Inclusion Criteria

The following criteria were included in the study:

- Patients aged 18–60 years
- American Society of Anesthesiologists (ASA) physical status Grades 1 and 2
- Patients undergoing elective lower abdominal and lower limb surgeries
- Patients with signed consent.

### Exclusion Criteria

The following criteria were excluded from the study:

- Patients who are not willing to participate in the study.
- Patient aged below 18 and above 60 years.
- ASA physical status Grades 3 and above
- Contraindication to spinal anesthesia such as infection at the site of injection, bleeding disorders, and systemic anticoagulation.

## PATIENTS AND METHODS

A total of 60 patients were randomly taken for this study and categorized into Group 1 and Group 2.

Group 1 patients received 12.5 mg of 0.5% hyperbaric bupivacaine with 1 mg Nalbuphine diluting it to 3 mL total volume and Group 2 patients received 12.5 mg of 0.5% hyperbaric bupivacaine with 25 μg Fentanyl diluting it to 3 mL total volume. After complete pre-anesthetic check-up and investigation and due consent from 60 patients of either gender, aged between 18 and 60 years, ASAs physical status Grades 1 and 2, we designed a prospective, randomized, and double-blinded study. The selected patients were randomized into two comparable groups of 30 patients each by a computer-generated random number table. Patients of Group 1 were given 12.5 mg (2.5 mL) of 0.5% hyperbaric bupivacaine with intrathecal fentanyl 25 μg, making intrathecal drug volume to 3 mL, and patients of Group 2 were given 12.5 mg (2.5 mL) of 0.5% hyperbaric bupivacaine with preservative-free intrathecal nalbuphine 1 mg, making intrathecal drug volume to 3 mL for each patient. To ensure double blindness in the study, preparation of intrathecal drugs was done by an independent anesthesiologist not involved in the study and the drug mixture was to be administered by another anesthesiologist who will be blinded and performing spinal anesthesia. None of them were further involved in the data collection of the study. Post-operative data were recorded by a post-operative resident, who was unaware of the group allocation. All enrolled patients remained fasting overnight before surgery and were premedicated with Tablet Alprazolam 0.5 mg on the night before surgery. Before the commencement of anesthesia, patients have explained the methods of sensory and motor blockade assessments. All patients have explained the visual analog scale (VAS) scoring system. After the patient was wheeled into the operation theatre, a peripheral intravenous (IV) access with an 18G IV cannula was secured and Lactated Ringer's infusion was started to replenish the overnight fasting at a rate of 10 mL/kg, standard monitoring for heart rate (HR), non-invasive blood pressure, electrocardiogram, and pulse oximetry (spO2) was commenced and recorded at 3 min intervals throughout the surgery.

Spinal anesthesia would be performed on all patients in the sitting position. Under strict aseptic precautions, using a 25G Quincke needle mid-line spinal puncture was performed at the L3–L4 level. After observing the free flow of cerebrospinal fluid, a total volume of 3 ml of spinal solution was administered to each patient over

approximately 10–15 s. Patients were moved to the supine position immediately after administering the spinal block.

Sensory and motor block characteristics were assessed in the normal lower limb at every 2 min interval until no pinprick sensation was achieved. All time intervals were calculated from the time of the end of intrathecal injection. The onset of sensory block, defined as time to reach sensory block at T10, time taken to reach sensory block at T6, time taken to achieve maximum sensory block, and time taken to two dermatome regressions of sensory analgesia were recorded.

Grading for the motor block was done according to the Bromage scale, onset of the motor block was defined as the time taken to achieve Bromage scale 3. Time taken to achieve complete motor blockade was also noted. The surgical anesthesia was considered to be achieved when the levels of sensory block reached to T6 thoracic dermatome level with the attainment of complete motor block (Bromage-3). For recovery of a block, time to two dermatome regressions and time to complete motor recoveries were recorded. The duration of effective analgesia was taken as the time from the completion of spinal injection to the time of administration of the first rescue analgesic reflected on VAS 10: 0 where 0 = No pain to 10 = Worst possible pain. Patients with VAS score ≥3 received Inj. Diclofenac sodium 75 mg intravenously for rescue analgesia. The VAS score of >3 constituted the end point of the study. Postoperatively, the sensory and motor block levels were assessed at 15 min intervals until normal sensations returned.

Hemodynamic variables in the form of systolic blood pressure (SBP), diastolic blood pressure (DBP), and HR were noted every 5 min up to 30 min and then every 15 min up to 90 min irrespective of the duration of surgery. Hypotension (SBP < 100 mm Hg or >20% fall from the baseline value) was treated by Injection of Ephedrine 6 mg IV and an extra bolus of 100 ml of Ringer lactate. Bradycardia (HR < 50 beats/min or >20% decrease from the baseline value) was treated with Inj Atropine 0.6 mg IV. Intraoperative nausea was treated with Inj. Ondansetron 4 mg IV. Sedation was assessed by a categorical scale as used by Mostafa *et al.* and graded as 1 – Awake and alert, 2 – Awake but drowsy, responding to a verbal stimulus, 3 – Drowsy but arousable, responding to physical stimulus, and 4 – Unarousable, not responding to physical stimulus.

### Statistical Analysis

Data were entered in Microsoft Excel and analyzed in SPSS software. Descriptive statistics such as mean and standard deviation were used to summarize numerical data when normally distributed and median and interquartile ranges when non-normally distributed. Categorical data were summarized as count and percentage. Chi-square test and Z-test were applied to identify the difference in success or failure rate of the two methods. Unpaired *t*-test was used to test the difference in secondary objectives. $P < 0.05$ was considered statistically significant.

## OBSERVATIONS AND RESULTS

### Comparison of Demographic Parameters

The below Table 1 shows that there was no significant difference in age ($P = 0.190$).

The below Table 2 shows that there was no significant difference in weight ($P = 0.060$).

The below Table 3 shows that there was no significant difference in Weight (p-value-0.654).

The below Table 4 shows that there was no significant difference in gender (p-value-0.805).

The below Table 5 shows that there was no significant difference in Age (p-value-0.190).

Inference: Both groups are comparable concerning demographic parameters.

**Table 1: Comparison of age distribution**

| Age distribution | Group 1 (nalbuphine) | Group 2 (fentanyl) | *P*-value |
|---|---|---|---|
| Mean age in years | 42.03±11.18 | 42.16±12.95 | 0.190 |

**Table 2: Comparison of weight distribution**

| Weight distribution | Group 1 (nalbuphine) | Group 2 (fentanyl) | *P*-value |
|---|---|---|---|
| Mean weight in kg | 59.1±6.66 | 58.5±6.98 | 0.060 |

**Table 3: Comparison of height distribution**

| Height distribution | Group 1 (nalbuphine) | Group 2 (fentanyl) | *P*-value |
|---|---|---|---|
| Mean weight in centimeters | 167±6.74 | 165.6±9.14 | 0.654 |

**Table 4: Comparison of gender distribution**

| Gender | Group 1 (nalbuphine) | Group 2 (fentanyl) | *P*-value |
|---|---|---|---|
| Male | 12 | 11 | 0.805 |
| Female | 18 | 19 | |

### Comparison of Study Parameters

In the present study, the mean time of onset of sensory block at T10 in Group 1 was 1.546 ± 0.567 min and with Group 2 was 4.263 ± 0.688 min with $P \leq 0.001$ (Table 6).

This shows that the onset sensory block at T10 was earlier in Group 1 compared to Group 2 and was statistically significant.

In the present study, mean time for a complete sensory block at T6 in Group 1 was 5.483 ± 1.941 min and with Group 2 was 8.406 ± 1.378 min with $P < 0.001$ (Table 7).

This shows that the time taken for complete sensory block to reach T6 was earlier in Group 1 compared to Group 2 and was statistically significant.

In the present study, the mean time of onset of motor block in Group 1 was 1.983 ± 1.541 min and in Group 2 was 3.547 ± 0.961 min with $P < 0.001$ (Table 8).

This shows that the onset of motor block was earlier in Group 1 compared to Group 2 and was statistically significant.

In the present study, meantime for two segments regression in Group 1 was 136.784 ± 11.857 min and in Group 2 was 85.983 ± 4.450 min with ($P < 0.001$) (Table 9).

This shows that the mean time for two segments regression is prolonged in Group 1 compared to Group 2 and was statistically significant.

In the present study, the duration of motor block in Group 1 was 239.430 ± 12.377 min and in Group 2 was 179.070 ± 8.306 min with ($P < 0.001$) (Table 10).

This shows that the mean time for the duration of motor block in Group 1 is prolonged as compared to Group 2 and was statistically significant.

In the present study, the duration of sensory block in Group 1 was 409.913 ± 18.400 min and in Group 2 was 229.453 ± 6.980 min with ($P < 0.001$) (Table 11).

This shows that the mean duration of sensory block in Group 1 is prolonged as compared to Group 2 and was statistically significant.

In the present study, rescue analgesia time in Group 1 was 396.580 ± 18.004 min and in Group 2 was 221.483 ± 10.175 min with ($P < 0.001$) (Table 12).

This shows that the mean time for rescue analgesia, in Group 1, is prolonged as compared to Group 2 and was statistically significant.

**Table 5: Comparison of ASA grading distribution**

| ASA Grades | Group 1 (nalbuphine) | Group 2 (fentanyl) | *P*-value |
|---|---|---|---|
| ASA 1 | 16 | 18 | 0.19 |
| ASA 2 | 14 | 12 | |

**Table 6: Comparison of onset of sensory blockade at T10**

| Time of onset of Analgesia at T10 | Group 1 (nalbuphine) | Group 2 (fentanyl) | *P*-value |
|---|---|---|---|
| Time in minutes | 1.546±0.56 | 4.263±0.688 | <0.001** |

**Significant *p* value <0.001

**Table 7: Comparison of time for complete sensory blockade at T6**

| Time of complete sensory block at T6 | Group 1 (nalbuphine) | Group 2 (fentanyl) | *P*-value |
|---|---|---|---|
| Time in minutes | 5.483±1.941 | 8.406±1.378 | <0.001** |

**Significant *p* value <0.001

**Table 8: Comparison of onset of motor blockade**

| Onset of motor block (Bromage scale 3) | Group 1 (nalbuphine) | Group 2 (fentanyl) | *P*-value |
|---|---|---|---|
| Time in minutes | 1.983±1.541 | 3.547±0.961 | <0.001** |

**Significant p value <0.001

**Table 9: Comparison of time for two segments regression of sensory block**

| Two segment regression | Group 1 (nalbuphine) | Group 2 (fentanyl) | *P*-value |
|---|---|---|---|
| Time in minutes | 136.784±11.857 | 85.983±4.450 | <0.001** |

**Significant p value <0.001

**Table 10: Comparison of duration of motor block**

| Duration of motor blockade | Group 1 (nalbuphine) | Group 2 (fentanyl) | *P*-value |
|---|---|---|---|
| Time in minutes | 239.430±12.377 | 179.070±4.8.306 | <0.001** |

**Significant p value <0.001

**Table 11: Comparison of duration of sensory block**

| Duration of sensory blockade | Group 1 (nalbuphine) | Group 2 (fentanyl) | *P*-value |
|---|---|---|---|
| Time in minutes | 409.913±18.400 | 229.453±6.980 | <0.001** |

**Significant p value <0.001

**Table 12: Comparison of rescue analgesia time**

| Rescue analgesia | Group 1 (nalbuphine) | Group 2 (fentanyl) | *P*-value |
|---|---|---|---|
| Time in minutes | 396.580±18.004 | 221.483±10.17 | <0.001** |

**Significant p value <0.001

In the present study, no adverse events were seen in Group 1 and nine patients experienced adverse events in Group 2 (Table 13).

This shows that the adverse events in Group 1 are lesser as compared to Group 2.

A fall in HR was observed in both the groups following institution of SAB. After SAB till 30 min, there was a fall in the pulse rate in Group 1 of 9% and in Group 2 of 10% (Table 14).

Fall in mean arterial pressure (MAP) was observed in both the groups following institution of SAB. After SAB till 30 min, there was significant fall in the MAP in Group 1 of 8% and in Group 2 of 13% (Table 15).

**Table 13: Comparison of adverse events**

| Incidence of adverse effects | Group 1 (nalbuphine) | Group 2 (fentanyl) |
|---|---|---|
| Nausea | 0 | 3 |
| Vomiting | 0 | 3 |
| Shivering | 0 | 3 |

**Table 14: Comparison of pulse rate**

| Pulse rate (beats/min) | Group 1 (nalbuphine) | Group 2 (fentanyl) | *P*-value |
|---|---|---|---|
| Baseline | 75.735±9.150 | 82.382±7.007 | 0.001 |
| 5 min | 73.229±8.306 | 80.882±7.014 | 0.001 |
| 10 min | 72.347±6.908 | 79.588±6.774 | <0.001 |
| 15 min | 71.823±6.229 | 78.176±6.474 | <0.001 |
| 20 min | 70.471±6.407 | 76.647±6.508 | <0.001 |
| 25 min | 70.265±5.853 | 75.853±5.919 | <0.001 |
| 30 min | 69.088±5.328 | 74.500±5.701 | <0.001 |
| 45 min | 68.294±5.012 | 72.765±5.522 | 0.001 |
| 60 min | 67.706±5.300 | 70.971±5.000 | 0.011 |
| 75 min | 68.324±5.574 | 69.147±4.943 | 0.521 |
| 90 min | 67.294±5.530 | 67.882±4.740 | 0.639 |

**Table 15: Comparison of mean blood pressure**

| MAP (in mmHg) | Group 1 (nalbuphine) | Group 2 (fentanyl) | *P*-value |
|---|---|---|---|
| Baseline | 92.980±10.405 | 95.647±10.100 | 0.287 |
| 5 min | 91.137±9.876 | 86.206±8.820 | 0.033 |
| 10 min | 90.274±9.591 | 82.255±6.924 | <0.001** |
| 15 min | 89.235±9.235 | 81.863±6.727 | <0.001** |
| 20 min | 88.333±8.657 | 82.314±6.250 | 0.002** |
| 25 min | 87.059±8.182 | 83.157±5.263 | 0.022* |
| 30 min | 85.529±7.826 | 83.275±4.889 | 0.159 |
| 45 min | 84.804±7.328 | 84.431±3.738 | 0.793 |
| 60 min | 82.853±7.019 | 84.823±4.226 | 0.165 |
| 75 min | 81.961±6.517 | 85.510±4.519 | 0.011* |
| 90 min | 80.275±6.141 | 86.000±4.136 | <0.001** |

MAP: Mean arterial pressure, **Significant p value <0.001

## DISCUSSION

Nalbuphine has been used successfully over the last decade for the said purpose and has further widened the scope in regional anesthesia. The faster onset of action of local anesthetics, rapid establishment of both sensory and motor blockade, prolonged duration of analgesia into the post-operative period, dose-sparing action of local anesthetics, and stable cardiovascular parameters makes these agents a very effective adjuvant in regional anesthesia.

The following results were found:

The groups were comparable in age, gender, weight, height, and ASA grade.

Patients in Group 1 (nalbuphine) had earlier onset of sensory and motor block compared to Group 2 (fentanyl).

In present study, mean time of onset of sensory block at T10 in Group 1 (nalbuphine) was 1.546 ± 0.567 min and with Group 2 (fentanyl) was 4.263 ± 0.688 min with a ($P < 0.001$) (Table 16).

This shows an earlier onset of sensory block in Group 1.

### Time to Complete Sensory Block at T6

Group 1 (nalbuphine) was 5.483 ± 1.941 min and with Group 2 (fentanyl) was 8.406 ± 1.378 min with a ($P < 0.001$), thus showing that time taken for sensory block to reach T6 is earlier in Group 1 compared to Group 2 (Table 17).

### Time for 2 Segments Regression

In the present study, mean time for two segments regression in Group 1 (nalbuphine) was 136.784 ± 11.857 min and in

**Table 16: Comparison of onset of sensory block with other studies**

| Onset of sensory block | Group 1 (nalbuphine) | Group 2 (fentanyl) |
|---|---|---|
| Gupta *et al.* (2016)[7] (*n*=68) | 4.3±0.79 | 3.91±2.25 |
| Present study (*n*=60) | 1.546±0.56 | 4.263±0.688 |

**Table 17: Comparison of time to complete sensory block with other studies**

| Complete sensory block at T6 | Group 1 (nalbuphine) | Group 2 (fentanyl) |
|---|---|---|
| Mohamed *et al.* (2021)[5] (*n*=135) | 4.02±0.74 | 3.64±0.73 |
| Naaz *et al.* (2017)[6] (*n*=90) | 9.8±4.15 | 8.1±3.84 |
| Gupta *et al.* (2016)[7] (*n*=68) | 7.13±3.81 | 7.4±2.72 |
| Present study (*n*=60) | 5.483±1.941 | 8.406±1.378 |

Group 2 (fentanyl) was 85.983 ± 4.450 min with $P < 0.001$ thus showing two segments regression which is prolonged in Group 1.

### Duration of Sensory Blockade and Time to Rescue Analgesia

The duration of sensory blockade was taken as the time from the completion of spinal injection to the regression of sensory level till L4. Patients with VAS score ≥3 received diclofenac 75 mg intramuscularly for rescue analgesia. The VAS score of ≥3 constituted the end point of the study.

In present study, duration of sensory blockade in Group 1 (nalbuphine) was 409.913 ± 18.400 min and in Group 2 (fentanyl) was 229.453 ± 6.980 min with $P < 0.001$ (Table 18).

In the present study, rescue analgesia time in Group 1 (nalbuphine) was 396.580 ± 18.004 min and in Group 2 (fentanyl) was 221.483 ± 10.175 min with ($P < 0.001$) (Table 19).

This shows that the mean duration of sensory blockade and rescue analgesia time in Group 1 is prolonged as compared to Group 2 and was statistically significant.

### Onset of Motor Block

In the present study, mean time of onset of motor block in Group 1 (nalbuphine) was 1.983 ± 1.541 min and in Group 2 (fentanyl) was 3.547 ± 0.961 min with ($P < 0.001$).

Mohamed *et al.*, in 2021,[5] conducted a double-blinded randomized controlled study using 135 patients who had given their consent. They were randomized into three comparable groups of groups of 45 patients each. The study showed that onset of motor blockade was earlier in Group N (nalbuphine).

**Table 18: Comparison of duration of sensory block with other studies**

| Duration of sensory blockade | Group 1 (nalbuphine) | Group 2 (fentanyl) |
|---|---|---|
| Mohamed *et al.* (2021)[5] (*n*=135) | 240.2±19.61 | 225.1±4.9 |
| Naaz *et al.* (2017)[6] (*n*=90) | 450±109.38 | 441±119.69 |
| Present study (*n*=60) | 409.913±18.400 | 229.453±6.980 |

**Table 19: Comparison of time to rescue analgesia with other studies**

| Onset of sensory block | Group 1 (nalbuphine) | Group 2 (fentanyl) |
|---|---|---|
| Gupta *et al.* (2016)[7] (*n*=68) | 318.64±21.92 | 278.74±29.67 |
| Present study (*n*=60) | 396.580±18.004 | 221.483±10.17 |

### Duration of Motor Block

In our study, duration of motor block in Group 1 (nalbuphine) was 239.430 ± 12.377 min and in Group 2 (fentanyl) was 179.070 ± 8.306 min with ($P < 0.001$). This shows that the mean time for duration of motor block in Group 1 is prolonged as compared to Group 2 and was statistically significant.

### Adverse Events

In the present study, emphasis was made on opioid-related side effects such as hypotension, bradycardia, respiratory depression, nausea, vomiting, shivering, urinary retention, and pruritus, nine patients had adverse effects in Group 2 (three had nausea, three had vomiting, and three had shivering). This shows that the adverse events in Group 1 (nalbuphine) are lesser as compared to Group 2 (fentanyl).

### Hemodynamic Parameters

After spinal till 30 min, there was a fall in the pulse rate of 9% in Group 1 (nalbuphine) and 10% in Group 2 (fentanyl). This fall in HR is non-significant as the cutoff is taken as 20%. Fall in SBP was observed in both the groups following institution of spinal anesthesia. After spinal till 30 min, there was a fall in the SBP of 6% in Group 1 (Nalbuphine) and of 15% in Group 2 (fentanyl). This fall is non-significant as the cutoff is taken as 20% fall. Fall in DBP was observed in both the groups following institution of spinal anesthesia. After spinal till 30 minutes, there was a fall in the DBP of 9% in Group 1 (Nalbuphine) and of 11% in Group 2 (fentanyl). This fall is non-significant as the cutoff is taken as 20% fall. Fall in MAP was observed in both the groups following institution of spinal anesthesia. After spinal till 30 min, there was a fall in the SBP of 8% in Group 1 (nalbuphine) and of 13% in Group 2 (fentanyl). This fall is non-significant as the cutoff is taken as 20% fall.

## CONCLUSION

We concluded that nalbuphine is a better adjuvant than fentanyl in spinal anesthesia as far as prolonged post-operative analgesia, stable cardiorespiratory parameters, and quality of intraoperative block, and patient comfort is concerned.

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