

**A comparison between intrathecal nalbuphine versus fentanyl as an adjuvant with 0.5% hyperbaric bupivacaine for postoperative analgesia in patients undergoing lower segment cesarean section**

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**Abstract**

**Background:** This study aims to compare the postoperative analgesia of intrathecal nalbuphine and fentanyl as adjuvants to bupivacaine in cesarean section.

**Methods:** A prospective, randomized, double-blind, and comparative study was conducted on 90 patients of American Society of Anesthesiologists (ASA) physical status I and II of age group 20–45 years with normal coagulation profile undergoing cesarean section under spinal anesthesia. These patients were randomized into three groups with fifty patients in each group. Group I received 2 ml of 0.5% hyperbaric bupivacaine (10 mg) plus 0.4 ml nalbuphine (0.8 mg), Group II received 2 ml of 0.5% hyperbaric bupivacaine (10 mg) plus 0.4 ml fentanyl (20 µg), and Group III received 2 ml of 0.5% hyperbaric bupivacaine (10 mg) plus 0.4 ml of normal saline.

**Results:** The mean duration of effective analgesia was  $259.20 \pm 23.23$  min in Group I,  $232.70 \pm 13.15$  min in Group II, and  $168.28 \pm 7.55$  min in Group III. The mean number of rescue analgesics required was

significantly lower ( $P < 0.001$ ) in Group I as compared to Group II and III.

**Conclusion:** Both intrathecal nalbuphine 0.8 mg and fentanyl 20 µg are effective adjuvants to 0.5% hyperbaric bupivacaine in subarachnoid block. However, intrathecal nalbuphine prolongs postoperative analgesia maximally and may be used as an alternative to intrathecal fentanyl in cesarean section.

**Keywords:** Nalbuphine, Bupivacaine, Fentanyl.

**Introduction**

Subarachnoid block is the preferred anesthesia for cesarean section, being simple to perform and economical with rapid onset.<sup>1</sup> Adding adjuvant drugs to intrathecal local anesthetics improves quality and duration of sensory blockade and prolongs postoperative analgesia. Intrathecal opioids are synergistic with local anesthetics, thereby intensifying the sensory block without increasing sympathetic block.

Fentanyl is a lipophilic opioid with a rapid onset following intrathecal injection and does not migrate to the 4th ventricle to cause respiratory depression.

Various studies have shown that it improves duration of sensory anesthesia and postoperative analgesia without producing significant side effects.<sup>2</sup>

Nalbuphine when used as adjuvant to hyperbaric bupivacaine has also improved the quality of perioperative analgesia with fewer side effects. It is a mixed synthetic agonist antagonist which attenuates the  $\mu$ -opioid effects and enhances the  $\kappa$ -opioid effects.<sup>3</sup> There is no documented report of neurotoxicity with nalbuphine. Morphine, fentanyl, and other  $\mu$ -opioids come under Narcotic Act, thus their availability is a major concern while nalbuphine is easily available and with fewer side effects<sup>4</sup>

There are very few large studies that have compared intrathecal nalbuphine with intrathecal fentanyl added to hyperbaric bupivacaine in cesarean section. Therefore, we designed a randomized double-blind study to compare the effects of intrathecal nalbuphine and fentanyl as adjuvants to bupivacaine in comparison to plain bupivacaine in 100 patients undergoing cesarean section. The aim of this study was to compare fentanyl with nalbuphine as intrathecal adjuvant to 0.5% hyperbaric bupivacaine in terms of sensory and motor blockade characteristics and duration of postoperative analgesia as the primary end points and intraoperative hemodynamic changes, sedation, pruritus, and respiratory depression as the secondary end points in patients undergoing cesarean section.

#### **Material and methods**

90 patients with ASA physical status Class I or II, aged 18–45 years, posted for cesarean section in our institution were included in this study. This was a prospective randomized double-blind comparative study. Patients with contraindication for spinal anesthesia were excluded from this study.

Preanesthetic evaluation and basic laboratory investigations were done in all the patients, and they were explained in detail about the procedure of the spinal anesthesia during the preanesthetic visit. Patients were familiarized with the visual analog scale (VAS). (0 – No pain, 10 – Worst pain) a day before surgery

In the operating room, baseline blood pressure (BP) (systolic, diastolic, and mean), heart rate, respiratory rate, and peripheral oxygen saturation (SpO<sub>2</sub>) were recorded after attaching routine monitors (electrocardiogram, noninvasive BP, and pulse oximeter).

Intravenous access was secured with 18G cannula, and all patients were preloaded with 10 ml/kg of Ringer's lactate solution. The study medication (2.4 ml of the drug solution) was prepared by the anesthesiologist who did not take part in the study. Group I patients received 2 ml of 0.5% hyperbaric bupivacaine plus 0.4 ml nalbuphine (0.8 mg), Group II patients received 2 ml of 0.5% hyperbaric bupivacaine plus 0.4 ml fentanyl (20  $\mu$ g), and Group III patients received 2 ml of 0.5% hyperbaric bupivacaine plus 0.4 ml of normal saline.

The subarachnoid block was performed by the anesthesiologist who was not involved further in the study to ensure blinding. Both patients and observers were blinded to the drugs given. Patients were then immediately placed in the supine position, with a wedge under the right hip to maintain left uterine displacement. Oxygen was provided through Venturi mask at the rate of 4 l/min.

BP (systolic, diastolic, and mean), heart rate, respiratory rate, and SpO<sub>2</sub> were continuously monitored and recorded at 5, 10, 15, 20, 25, and 30 min after the injection, and subsequently every 15 min. Hypotension (defined as systolic BP of <90 mmHg or <20% of baseline BP) was treated with intravenous

fluid initially (250 ml boluses repeated twice) and intravenous ephedrine 5 mg, if required. Bradycardia (defined as heart rate of <60) was treated with 0.6 mg of intravenous atropine sulfate. Sensory block was assessed by pinprick method and motor block by Modified Bromage Scale.

The onset of sensory blockade (defined as the time from the injection of intrathecal drug to the absence of pain at the T6 dermatome) and onset of complete motor blockade (time taken from the injection to development of Bromage’s Grade 3 motor block) were recorded. The duration of sensory blockade (two segment regression from highest level of sensory blockade) was also recorded in each patient. Duration of motor blockade (time required for motor blockade to return to

Bromage’s Grade 1 from the time of onset of motor blockade) was also noted. Grades of sedation during surgery were assessed by the Modified Ramsay’s sedation scale.

Postoperatively, pain score (VAS) was assessed 1 h for first 4 h and at 12 and 24 h. The duration of effective analgesia (time from the intrathecal injection to the first rescue analgesic requirement, VAS score >3) was noted. Intramuscular diclofenac (75 mg) was administered as rescue analgesic, and total number of rescue analgesics required postoperatively in 24 h period was recorded. Patients were also assessed for side effects such as nausea, vomiting, hypotension, pruritis, and bradycardia.

Results

Table 1: Demographic Variables

Parameters	Group I (n=30)	Group II (n=30)	Group III (n=30)	P value
Age (years)	23.21±3.24	24.15±2.58	22.35± 3.21	>0.05
ASA I/II	22/8	27/3	25/5	>0.05

All groups were comparable.

Table 2: Characteristics of sensory and motor block

Parameters	Group I (n=30)	Group II (n=30)	Group III (n=30)	P value
Onset Sensory block (Mint.)	4.88±1.25	4.52±1.21	5.06± 1.24	>0.05
Onset motor block (Mint.)	6.56±1.34	6.62±1.53	7.08± 1.68	>0.05
Duration of Sensory block (Mint.)	108.23±5.24	112.54±4.65	86.32± 2.34	<0.05
Duration of motor block (Mint.)	154.23±3.21	152.34±2.40	124.12± 2.14	<0.05

As shown in Table 2, the difference in the time of onset of sensory and motor block was statistically

nonsignificant (NS) among the groups (P > 0.05). The mean duration of sensory block was 108.23 ± 5.24 min

in Group I,  $112.54 \pm 4.65$  min in Group II, and  $86.32 \pm 2.34$  min in Group III. The mean duration of motor block (time required for motor block to return to Bromage's Grade 1 from the time of onset of motor block) was  $154.23 \pm 3.21$  min in Group I,  $152.34 \pm 2.40$  min in Group II, and  $124.12 \pm 2.14$  min in Group III.

### Discussion

We conducted a randomized double-blind study to compare intrathecal nalbuphine and fentanyl as adjuvants to 0.5% hyperbaric bupivacaine with bupivacaine alone in patients undergoing cesarean section.

Nalbuphine exhibits a ceiling effect to analgesia, i.e. increase in dose increases analgesic effect only up to a certain point beyond which there is no further enhancement of analgesia with the increase in dose.<sup>5</sup> We chose 0.8 mg of nalbuphine to compare with 20  $\mu$ g of fentanyl as Culebras et al.<sup>6</sup> and Jyothi et al.<sup>7</sup> had previously observed that increasing nalbuphine dose from 0.8 to 1.6 mg and 2.4 mg did not increase analgesic efficacy.

We found that onset of sensory block was comparable in the three groups. Gomaa et al. compared intrathecal nalbuphine 0.8 mg and fentanyl 25  $\mu$ g and found that there was no statistically significant difference in onset of sensory block between fentanyl (1.64 min) and nalbuphine (1.60 min) group<sup>8</sup> Similar results were observed by Gupta et al.,<sup>9</sup> Ahmed et al.,<sup>10</sup>

### Conclusion

We conclude that both intrathecal nalbuphine 0.8 mg and intrathecal fentanyl 20  $\mu$ g are effective adjuvants to 0.5% hyperbaric bupivacaine in patients undergoing cesarean section under subarachnoid block. They increase the duration of sensory block as well as postoperative analgesia without any increase in side effects. However, intrathecal nalbuphine prolongs

postoperative analgesia maximally and may be used as an alternative to intrathecal fentanyl in cesarean section.

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