

# Study of post operative analgesic efficacy of intrathecal fentanyl compared to nalbuphine with bupivacaine in spinal anaesthesia for lower abdominal surgeries at a tertiary hospital

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## Abstract


**Background:** Inadequate pain control can have several adverse effects in patients undergoing surgery. Acute postoperative pain is considered a risk factor for chronic pain and may also lead to increased morbidity and prolonged hospital stay. Present study was aimed to study post operative analgesic efficacy of intrathecal fentanyl compared to nalbuphine with bupivacaine in spinal anaesthesia for lower abdominal surgeries at a tertiary hospital. **Material and Methods:** Present study was single-center, comparative, interventional study, conducted in patients with ASA physical status Class I or II, aged 21–60 years, posted for elective lower abdominal surgeries. In the operating room, 60 patients were randomized by computer-generated random numbers into 2 groups of 30 patients each as Group N - received 2 ml of 0.5% hyperbaric bupivacaine plus 0.4 ml nalbuphine (0.8 mg) and Group F - received 2 ml of 0.5% hyperbaric bupivacaine plus 0.4 ml fentanyl (20 µg). **Results:** In present study, 60 patients randomly allocated into two groups as Group N (n=30) and Group F (n=30). We compared various parameters such as Age (years), Weight (kg), BMI (kg/m<sup>2</sup>), Gender, ASA status and Duration of surgery (min) were comparable, difference was not significant statistically. While time to reach t10 (min), duration of motor block (min) and first request for analgesia (minutes) was less in group N and difference was statistically significant. Post-operative analgesia was calculated on basis of VAS scores. We noted in less post-operative VAS scores at 3,4,6,12,18 and 24 hours in group N and difference was statistically significant. **Conclusion:** In present study, nalbuphine as an adjuvant to hyperbaric bupivacaine 0.5% for spinal anaesthesia provides excellent post-operative analgesia with a longer duration of effective analgesia in comparison to intrathecal hyperbaric bupivacaine plus 0.4 ml fentanyl. **Keywords:** nalbuphine, fentanyl, adjuvant, bupivacaine, spinal anaesthesia, post-operative analgesia

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## INTRODUCTION

Inadequate pain control can have several adverse effects in patients undergoing surgery. Acute postoperative pain is considered a risk factor for chronic pain and may also lead to increased morbidity and prolonged hospital stay.<sup>1</sup> Spinal anaesthesia is a simple method requiring small dose of local anesthetic agent to establish dense, immediate and reliable motor blockade, but precipitous hypotension and difficulty in controlling the level of analgesia are major disadvantages of spinal block.<sup>2</sup> Bupivacaine is one of the most commonly used drugs for subarachnoid block. However, use of bupivacaine alone for subarachnoid block

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provides limited duration of blockade (ranging from 60 to 120 min) and shorter postoperative analgesia. Intrathecal adjuvants are used with local anesthetics to prolong the duration and provide postoperative pain relief while minimizing the dose of local anesthetic.<sup>3</sup> Nalbuphine, a derivative of 14-hydroxymorphine is a strong analgesic with mixed  $\kappa$  agonist and  $\mu$  antagonist properties. Nalbuphine has the potential to maintain or even enhance  $\mu$ -opioid based analgesia while simultaneously mitigating the  $\mu$ -opioid side effects.<sup>4</sup> Fentanyl, a 4-anilido-piperidine compound is highly lipid soluble opioid agonist that acts on  $\mu$  (mu) receptor and principally responsible for supra spinal and spinal analgesia along with side effects like nausea, vomiting, pruritus, sedation and respiratory depression. However various studies have stated that it improves the quality of sensory anaesthesia and extends post-operative analgesia duration.<sup>5</sup> Present study was aimed to study post operative analgesic efficacy of intrathecal fentanyl compared to nalbuphine with bupivacaine in spinal anaesthesia for lower abdominal surgeries at a tertiary hospital.

### MATERIAL AND METHODS

Present study was single-center, comparative, interventional study, conducted in Department of Anaesthesia, Kamineni Institute of Medical Sciences and Research Centre, Lb Nagar Hyderabad, India. Study period was of 2 years ( from July 2019 to June 2021).

**Inclusion criteria:** patients with ASA physical status Class I or II, aged 21–60 years, posted for elective lower abdominal surgeries

**Exclusion criteria:** contraindication to regional anaesthesia (coagulopathy or localized infection); history of allergic reaction to bupivacaine, nalbuphine, or fentanyl; history of opioid or substance abuse; severely hypovolemic patients, those with raised intracranial pressure, sepsis. major spine deformity/ surgery; or neurological deficit of lower limbs. demyelinating disorder, Patient refusal for regional anaesthesia; After obtaining the hospital ethical committee approval and written informed consent, patients were included in

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 anaesthesia 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, 60 patients were randomized by computer-generated random numbers into 2 groups of 30 patients each.

Group N - received 2 ml of 0.5% hyperbaric bupivacaine plus 0.4 ml nalbuphine (0.8 mg)

Group F - received 2 ml of 0.5% hyperbaric bupivacaine plus 0.4 ml fentanyl (20  $\mu$ g),

Baseline blood pressure (BP) (systolic, diastolic, and mean), heart rate, respiratory rate, and peripheral oxygen saturation (SpO<sub>2</sub>) were recorded. Intravenous access was secured with 18G cannula, and all patients were preloaded with 10 ml/kg of Ringer’s lactate solution. Under all aseptic precautions, part was cleaned and draped. 25 G Quinckes needle was inserted in L3-L4 space with patients in sitting position and the drug combination was then be given slowly depending on the group, after confirming free of cerebrospinal fluid. Standard intra-operative and post-operative care was provided. Postoperatively, pain score (VAS) was assessed at 1,2,3,4,6, 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. Data was collected and compiled using Microsoft Excel, analysed using SPSS 23.0 version. Frequency, percentage, means and standard deviations (SD) was calculated for the continuous variables, while ratios and proportions were calculated for the categorical variables. Difference of proportions between qualitative variables were tested using chi- square test or Fisher exact test as applicable. P value less than 0.5 was considered as statistically significant.

### RESULTS

In present study, 60 patients randomly allocated into two groups as Group N (n=30) and Group F (n=30). We compared various parameters such as Age (years), Weight (kg), BMI (kg/m<sup>2</sup>), Gender, ASA status and Duration of surgery (min) were comparable, difference was not significant statistically. While time to reach t10 (min), duration of motor block (min) and first request for analgesia (minutes) was less in group N and difference was statistically significant.

**Table 1:** Demographic data and other parameters

Parameter	Group N (n = 30)	Group F (n = 30)	value
Age (years)	41.73 ± 11.25	42.49 ± 10.97	0.057
Weight (kg)	58.13 ± 10.23	59.70 ± 11.46	0.061
BMI (kg/m <sup>2</sup> )			

Gender			0.082
Male	9	10	
Female	21	20	
ASA status			0.23
I	11	12	
II	19	18	
Duration of surgery (min)	106.2 ± 41.69	108.8 ± 37.44	0.53
Time to reach T10 (seconds)	5.13 ± 0.73	6.73 ± 0.97	<0.0001
Duration of motor block (seconds)	116.67 ± 32.99	100.87 ± 24.74	<0.0001
First request for Analgesia (minutes)	245.17 ± 54.62	173.8 ± 15.34	<0.0001

Post-operative analgesia was calculated on basis of VAS scores. We noted in less post-operative VAS scores at 3,4,6,12,18 and 24 hours in group N and difference was statistically significant.

**Table 2:** Mean VAS scores at rest

Time (hrs.) since post-op	Group N (Mean ± SD)	Group F (Mean ± SD)	P value
1	3.22 ± 1.51	3.00 ± 1.63	0.348
2	3.62 ± 1.32	3.16 ± 1.22	0.079
3	3.03 ± 1.62	2.39 ± 1.01	0.049
4	3.17 ± 0.94	2.57 ± 1.12	0.040
6	2.99 ± 0.98	2.14 ± 0.67	0.038
12	2.83 ± 0.88	2.14 ± 0.67	0.038
24	2.54 ± 1.01	2.18 ± 1.08	0.065

## DISCUSSION

The duration of action of bupivacaine in spinal anaesthesia can be prolonged by using adjuvants such as midazolam, opioids, neostigmine, dexmedetomidine and clonidine. Various additives has been used with local anesthetics and evaluated in quest for an ideal adjuvant which can enhance the quality of analgesia and prolong the duration of spinal anesthesia with minimal side effects.<sup>6</sup> In the study done by Thote *et al.* in patients undergoing lower abdominal surgeries using 25 µg of fentanyl and 0.5 mg of nalbuphine with 12.5 mg of 0.5% bupivacaine observed longer duration of analgesia with nalbuphine group when compared to fentanyl group. The study also showed the greater intensity of analgesia with nalbuphine group. Similar findings were noted in present study.<sup>7</sup> In study Koppal R *et al.*,<sup>8</sup> among 90 patients undergoing infra umbilical surgeries were selected divided into two groups of 45 each as Group A (intrathecal fentanyl with Levobupivacaine) and group B (intrathecal nalbuphine with levobupivacaine). The duration of first rescue analgesia required prolonged in group B (430.3±11.13min) compared to group A is 285.97±8.8 min (p value of 0.001). Both the groups were equally efficacious with good intraoperative conditions with haemodynamic stability however group B improves the quality of intraoperative and postoperative analgesia with minimal side effects. Sharma DN *et al.*,<sup>9</sup> studied patients scheduled for elective lower limb orthopedic surgery under subarachnoid block. Duration of sensory blockade was significantly prolonged (112.6 ± 8.3 min) in nalbuphine group than in fentanyl group (103.7 ± 7.5

min) and duration of motor block was significantly extended in patients of nalbuphine group (155.7 ± 16.8 min) than fentanyl group (133.1 ± 12.4 min). The duration of effective analgesia was significantly more in nalbuphine group than in fentanyl group. Nalbuphine (1 mg) as intrathecal adjuvants to 0.5% hyperbaric bupivacaine increases the duration of sensory block, motor block and the effective analgesia time more efficiently than fentanyl. In study by Gurunath BB,<sup>10</sup> 124 patients were divided into Group N (bupivacaine with nalbuphine) and Group C (bupivacaine with fentanyl). Duration of onset of sensory blockade was 3.9 ± 0.35 min in Group C and 3.1 ± 0.18 min in Group F. Two-segment sensory regression time was prolonged in Group C (193.16 ± 39.55) compared to Group F (167.41 ± 30.17 min). Intrathecal nalbuphine at a dose of 300 µg in 3 ml 0.5% heavy bupivacaine in patients undergoing elective lower abdominal surgeries showed delay in onset time for sensory blockade and produced prolonged postoperative analgesia, prolonged sensory blockade, and minimal bradycardia which could be easily managed. Bindra TK *et al.*,<sup>11</sup> noted that both intrathecal nalbuphine 0.8 mg and fentanyl 20 µg are effective adjuvants to 0.5% hyperbaric bupivacaine in subarachnoid block. However, intrathecal nalbuphine (259.20 ± 23.23 min) prolongs postoperative analgesia maximally and may be used as an alternative to intrathecal fentanyl (232.70 ± 13.15 min) in cesarean section. Sharma A *et al.*,<sup>12</sup> noted different findings from present study. Patients who received intrathecal nalbuphine (group N) had a significantly delayed onset of sensory and motor block as compared to patients who received fentanyl (group F). Duration of spinal analgesia

was comparable in group N ( $323.18 \pm 57.39$  minutes) and group F ( $287.05 \pm 78.87$  minutes) and difference was not significant. Intrathecal nalbuphine in a dose of 1 mg is an equally useful alternative to fentanyl in a dose 25  $\mu$ g when used as an intrathecal adjuvant to bupivacaine for lower limb surgeries. In study by Prabhakaraiah UN *et al.*,<sup>13</sup> postoperative visual analog scale score was  $4.8 \pm 1.12$  in Group BN, and in Group BF, it was  $3.86 \pm 1.04$  which was statistically highly significant ( $P = 0.0007$ ). The number of patients demanding rescue analgesia in early postoperative period was 18 (60.0%) in Group BN and 7 (23.33%) in Group BF which was statistically significant ( $P = 0.004$ ). Fentanyl was more efficient than nalbuphine in providing early postoperative analgesia when used as an adjuvant to hyperbaric bupivacaine. Our findings are contrary to above study findings. Both fentanyl and nalbuphine are opioid analgesics. Fentanyl is an opioid agonist and acts on  $\mu$ -opioid receptors.<sup>14</sup> Nalbuphine is a synthetic opioid analgesic with agonist-antagonist activity and acts as antagonist at  $\mu$ -receptors and agonist at  $\kappa$ -receptors to provide reasonably potent analgesia. Nalbuphine, when used as adjuvant to hyperbaric bupivacaine, has improved the quality of perioperative analgesia with fewer side effects.<sup>15</sup> Nalbuphine has been used intrathecally by various investigators to enhance the postoperative analgesia and they did not document any reports of neurotoxicity.<sup>16,17</sup>

## CONCLUSION

In present study, nalbuphine as an adjuvant to hyperbaric bupivacaine 0.5% for spinal anaesthesia provides excellent post-operative analgesia with a longer duration of effective analgesia in comparison to intrathecal hyperbaric bupivacaine plus 0.4 ml fentanyl.

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