Original Article

Postoperative Analgesic Efficacy of Intrathecal Fentanyl Compared to Nalbuphine with Bupivacaine in Spinal Anesthesia for Lower Abdominal Surgeries

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Abstract

Context: Subarachnoid block or spinal anesthesia is a commonly used technique for lower abdominal and lower limb surgeries. Bupivacaine is the commonly used cost-effective drug which gives satisfactory analgesia for 90–120 min. Additives such as opioids and α2 agonists extend the analgesia in the postoperative period. In this study, we compared the effects of nalbuphine with fentanyl. **Aims:** The aim of this study is to compare the effects of intrathecal nalbuphine and fentanyl as adjuvants to hyperbaric bupivacaine in regard to time of onset of sensory blockade, duration of sensory blockade, two-segment sensory regression time, duration of effective postoperative analgesia, and incidence of side effects. **Settings and Design:** This was a prospective, randomized double-blind study. **Subjects and Methods:** After ethical committee permission and patient consent, 124 patients aged 18–55 years with American Society of Anesthesiologists physical status I and II were randomly divided into two groups – Group N: hyperbaric bupivacaine with nalbuphine (300 μγ); Group C: hyperbaric bupivacaine with fentanyl (25 μγ). **Results:** 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). **Conclusions:** 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.

Keywords: Bupivacaine, fentanyl, nalbuphine, spinal anesthesia

Introduction

Subarachnoid blockade is a commonly used technique for lower abdominal and lower limb surgeries. It is easier to perform by injecting anesthetic drug into the subarachnoid space and with rapid onset of anesthesia, which provides analgesia both intra- and post-operatively.

Nalbuphine hydrochloride is primarily a kappa agonist/partial mu antagonist analgesic. The mu agonist, fentanyl, exerts its action by opening K+ channels and reducing Ca++ influx, resulting in inhibition of transmitter release.

The chemical name of bupivacaineis l-*n*-butyl-DL-piperidine-2-carboxylic acid-2,6 dimethylanilide hydrochloride.[1-4] Bupivacaine hydrochloride is an amide type of local anesthetic drug, which was synthesized by Ekenstam in 1957 and used clinically in 1963. Bupivacaine acts mainly by blockade of voltage-gated Na+ channels in the axonal membrane and possibly has a further effect on presynaptic inhibition of calcium channels.

The use of adjuvants such as nalbuphine with bupivacaine has shown to reduce its dose requirements in spinal anesthesia with reduced incidence of side effects and reduced dose of analgesia.

Intrathecal nalbuphine and fentanyl were studied with higher dose of nalbuphine (0.8 μg). Our study intended to compare lower dose of nalbuphine to know the efficacy and incidence of side effects.[5]

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Objectives

The objective is to study the onset and duration of sensory blockade; time to two-segment regression; and hemodynamic changes.

Subjects and Methods

Ethical committee permission and patient consent were obtained. It was a prospective randomized study.

Inclusion criteria were patients belonging to American Society of Anesthesiologists Grade I and II; aged 18–55 years; weight >45 kg <100 kg; height >150 cm.

Exclusion criteria were patients suffering from cardiac arrhythmias, heart blocks, and bradycardia; patients with known allergy to test drug; patients with gross spinal abnormality, localized skin sepsis, hemorrhagic diathesis, neurological involvement/diseases; patients with head injury, raised intracranial pressure; and patients who are hemodynamically unstable.

After obtaining informed consent, 124 patients were randomly divided into two groups of 62 each. Randomization was done by a computer-generated table.

- Group N: Hyperbaric bupivacaine with nalbuphine (300 μg)
- Group C: Hyperbaric bupivacaine with fentanyl (25 μg).

Patients were examined a day before surgery. They were kept fasting overnight after 10:00 pm and received tablet ranitidine 150 mg and tablet alprazolam 0.5 mg orally as premedication during the night before surgery and at 6:00 am with sip of water in the morning on the day of surgery. Patients were preloaded with 5 ml/kg Ringer lactate solution after securing intravenous (IV) access with 18G cannula. After the patient was shifted to the operation theater, pulse rate, blood pressure, electrocardiography, and oxygen saturation (SpO_2) were monitored.

Under all aseptic precautions after putting the patient in left lateral position, using 25-guage Quincke spinal needle, spinal block was performed at lumbar third and fourth interspace through a midline approach and the patient was put to supine position. Patients in Group C received 3 ml of 0.5% hyperbaric bupivacaine with 25 μg of fentanyl. Patients in Group N received 3 ml of hyperbaric 0.5% bupivacaine with 300 μg of nalbuphine. Total volume made up to 3.5 ml with distilled water. The time of intrathecal injection is considered as 0.

The parameters observed were pulse rate, systolic blood pressure, diastolic blood pressure, and mean arterial pressure. SpO_2 and respiratory rate were recorded every 2 min for 10 min and then every 10 min throughout the intraoperative period and at the end of surgery.

Time of onset of sensory blockade, the height of sensory blockade, motor blockade as per Bromage scale, total duration of sensory blockade and motor blockade, quality of analgesia (visual analogue score), two-segment sensory regression time, time to first rescue analgesic, and number of rescue analgesics in 24 h were also monitored.

The vital signs were recorded at time 0, 2, 5 min, then every 10 min for first hour and half-hourly until the end of surgery.

Statistical analysis

The collected data were coded and entered into an excel format. The quantitative data were presented using mean and standard deviation and confidence intervals and the qualitative data by proportions. Independent *t*-test was used to compare the significance of difference in means and Chi-square test for proportions. $P \leq 0.05$ was considered as statistically significant.

Sample size

The sample size was estimated based on the outcome variable duration of grade 4 motor block in a study by Thote *et al*.[6]

It was found that the average variance for duration of grade 4 motor block is found to be 8.3 min with a mean difference of 4.2 min. To detect a difference of 4.2 min in grade 4 motor block with 80% power with 95% confidence interval, the required sample size is 62 per treatment group.

Statistical evaluation of data or parameters was done as follows:

$$n = \frac{2\sigma^2 (Z_\alpha + Z_{1-\beta})^2}{d^2}$$

Sample size

Z_α =95% confidence level = 1.96

$Z_{1-\beta}$ = power at 80% =0.84

σ^2 = average variance = 8.3

Results

Significant difference were observed in heart rate (HR) between the two groups at 6, 9, and 12 min.

Lower HR was observed in nalbuphine group than fentanyl group during the above-said durations as shown in Figure 1.

A significant difference was observed in mean arterial blood pressure (MAP) between two groups at 6, 9, 12, 18, and 20 min.

Lower MAP was observed in fentanyl group than nalbuphine group during the above-said durations, as shown in Figure 2.

There is a significant difference in the onset of sensory blockade in both groups – nalbuphine group (Group N) showed delayed onset of sensory blockade (3.9 ± 0.35) min compared to fentanyl group (Group C) (3.1 ± 0.18 min), as shown in Figure 3.

The duration for two-segment regression in nalbuphine group was 193.16 ± 39.55 min which was significantly prolonged as compared to fentanyl group which was 167.41 ± 30.17 min, as shown in Figure 3.

Rescue analgesia was given at 268.33 ± 44.44 min in nalbuphine group which was significantly prolonged as

compared to fentanyl group in which rescue analgesia was given at 220.91 ± 24.36 min, as shown in Figure 3.

Based on the side effects between the groups, in Group N, there were 12.90% of bradycardia cases and there was no incidence of hypotension, whereas in Group C, there were 16.12% of hypotension cases and there was no incidence of bradycardia, as shown in Figure 4.

Discussion

Spinal anesthesia gives good analgesia, reduces the blood loss and the incidence of deep-venous thrombosis and pulmonary embolism, and avoids the adverse effects of general anesthesia. The local anesthetics commonly used for intrathecal anesthesia are lignocaine and bupivacaine in India. Bupivacaine 0.5% heavy intrathecal injection provides analgesia for about 2–2.5 h. Other ways of increasing the duration of analgesia are continuous epidural analgesia, which is difficult technically and not cost-effective.

Hence, adding intrathecal additives to the local anesthetics prolongs postoperative analgesia and increases the duration of anesthesia. As this is simple and less cumbersome, it has gained a wide acceptance.

In our study, we hypothesized that nalbuphine may provide a better pain relief after lower abdominal and lower limb surgeries under spinal anesthesia compared to fentanyl.

Bisht and Rashmi have done a comparison of intrathecal fentanyl and nalbuphine: a prospective randomized controlled study in patients undergoing total abdominal hysterectomy – Group FB: 15 mg of 0.5% bupivacaine (3 ml) plus 25 mcg of fentanyl and Group NB: 15 mg of 0.5% bupivacaine (3 ml) plus 1 mg nalbuphine (0.5 ml).

Onset of sensory blockade in Group NB was 4.20 ± 0.52 and in Group FB it was 3.09 ± 0.47. The onset of sensory block was faster in Group FB than in Group NB, which was statistically significant.[7]

Gupta *et al*. studied intrathecal nalbuphine versus intrathecal fentanyl as an additive with bupivacaine for orthopedic surgery of lower limbs in 2016. They concluded that duration of rescue analgesia was prolonged by 39.9 ± 7.75 min when 2 mg of nalbuphine +17.5 mg of hyperbaric bupivacaine was given intrathecally as compared to 25 µg of fentanyl +17.5 mg of hyperbaric bupivacaine intrathecally. This prolonged duration of rescue analgesia was statistically significant.[8]

Naaz *et al*. did a comparative study on analgesic efficacy of intrathecal nalbuphine (Group NL: 0.8 mg and Group NH: 1.6 mg) and fentanyl (Group F: 25 µg) as an adjuvant with 12.5 mg of 0.5% bupivacaine in lower limb orthopedic surgery in 2017 and concluded that time of two-segment sensory regression was comparable between Groups NL (91.6 ± 31.12 min) and NH (73.5 ± 17.95 min) and was significantly less ($P = 0.03$) when compared with Group F (108 ± 32.03 min).[9]

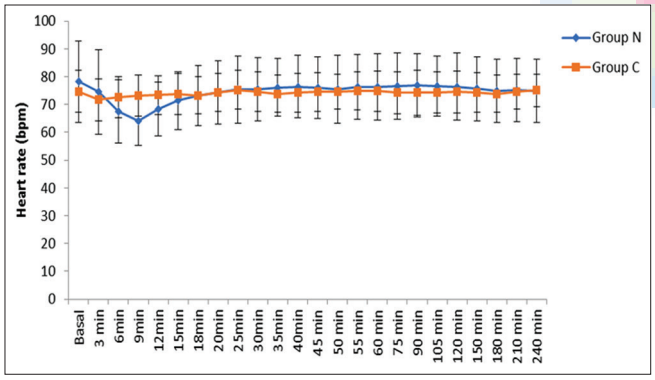

Figure 1: Line diagram showing heart rate variation

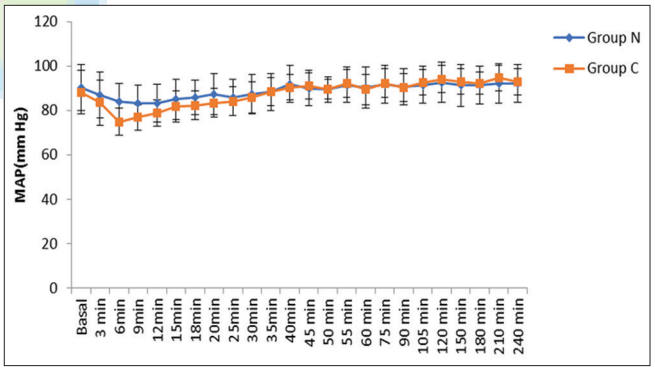

Figure 2: Line diagram showing mean arterial blood pressure variation between two groups

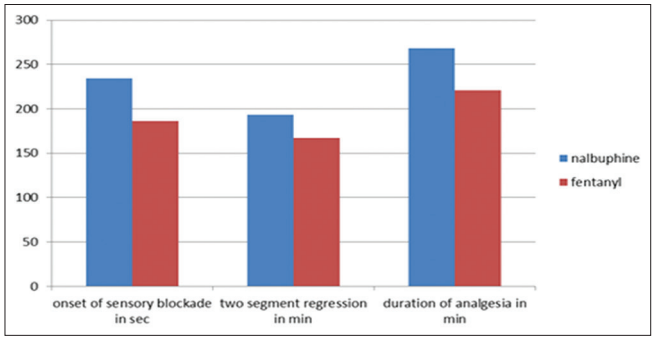

Figure 3: Bar diagram showing onset of sensory blockade, time of two-segment regression, and duration of analgesia in both the groups

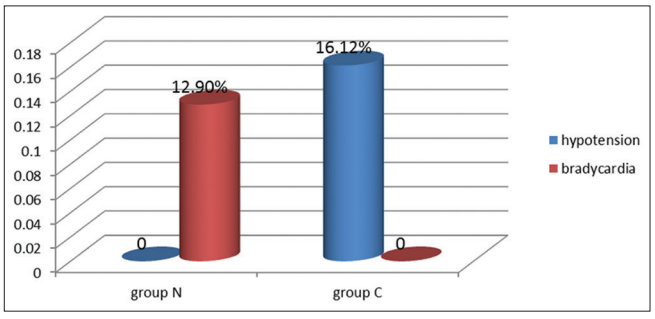

Figure 4: Bar diagram showing side effects between the two groups

Ben-David *et al*. did a study in 2000 and concluded that a small dose of 4 mg bupivacaine along with 20 mg fentanyl gives spinal anesthesia for repair of hip fracture in elderly.[10] The minidose combination resulted in a dramatically low hypotension as compared to 10 mg.

Singh *et al*. did a comparative study and concluded that the addition of nalbuphine to intrathecal bupivacaine has prolonged the duration of sensory block and postoperative analgesia and requirement of analgesics in the postoperative period is also decreased without increasing the side effects or complications. Addition of fentanyl has the same effect but lesser than nalbuphine.[12]

Khan and Hameedullah found that fentanyl had better hemodynamic stability and better analgesia than nalbuphine when used in total IV anesthesia with propofol in laparoscopic cholecystectomy cases. In their study, the recovery profile with both drugs was similar. Lesser number of patients required analgesia in the recovery in the nalbuphine group.[11]

Gomaa *et al*. compared two groups. One group received intrathecal nalbuphine 0.8 mg with bupivacaine and the other group received 25 µg of fentanyl with bupivacaine intrathecally in cesarean section, and they studied postoperative analgesic efficacy and concluded that intrathecal nalbuphine 0.8 mg and intrathecal fentanyl 25 µg combined with 10 mg bupivacaine both result in good intraoperative and early postoperative analgesia in cesarean section.[5] Comparing to our study, lesser dose of nalbuphine was used with good postoperative analgesia with reduced side effects.

In our study, significant difference was observed in HR between the two groups 6, 9, and 12 min.

Lower HR was observed in nalbuphine group than fentanyl group during the above-said durations. There was bradycardia in 8 (12.90%) patients in Group N and was treated with injection atropine 0.02 mg/kg.

In our study, there was bradycardia in 12.9% of cases in nalbuphine group and 16.12% of patients had hypotension in fentanyl group.

Strength and limitation of our study

Strengths of our study are that drugs used are cost-effective and low dose of nalbuphine used had good postoperative analgesia with less side effects.

Limitation was that nalbuphine could have been used in lesser doses to avoid bradycardia in few patients who needed treatment. Nalbuphine as an opioid could have been compared with any other group.

Conclusions

From the present study, it can be concluded that intrathecal nalbuphine in the dose of 300 mcg 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.

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Conflicts of interest

There are no conflicts of interest.

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