Original Research Article

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A Comparative Study of Efficacy of Intrathecal Fentanyl and Nalbuphine as an Adjuvant to Bupivacaine 0.5% Heavy for Lower Limb and Lower Abdominal Surgeries

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Abstract

Introduction: Opioids have been extensively used as an adjuvant because of excellent results in neuraxial blocks. Fentanyl is widely used but is found to have higher incidence of pruritus for which Nalbuphine was considered as an adjuvant.

Aim: To compare the efficacy of Fentanyl and Nalbuphine as an adjuvant to bupivacaine 0.5% heavy.

Methods and Material: Randomised control trial was carried out on 60 patients between 18-60 years of age and ASA grade I and II with groups having 30 patients each: GROUP A - Bupivacaine (2.5 ml) + Fentanyl 25µg (0.5 ml), GROUP B - Bupivacaine (2.5 ml) + Nalbuphine 400ug (0.5 ml). The observation and results were compared and statistical analysis was done. Statistical analysis was performed by the SPSS program for Windows. For comparing the two main groups Paired t test was applied. In this study p value < 0.05 is considered as statistically significant.

Results: Onset of sensory block was significantly rapid with nalbuphine (2.05±0.887 mins) as compared to fentanyl group (4.67±0.816mins) ($p<0.001$). The duration of analgesia was statistically prolonged with fentanyl (244.27±5.457mins), compared with the nalbuphine (243.25±8.091 mins). ($p< 0.05$) but it was clinically not significant.

Conclusion: 400 mcg intrathecal nalbuphine is superior to 25mcg intrathecal fentanyl regarding the duration of analgesia and reduced the analgesic requirement in the early postoperative period.

Keywords: Analgesia; Anesthesia; Bupivacaine; Nalbuphine; Fentanyl; Spinal.

Introduction

Spinal anesthesia, defined as regional anesthesia obtained by blocking nerves in the subarachnoid space, was introduced in clinical practice by Karl August Bier in 1898 [1].

Spinal anesthesia using local anesthetics like cocaine, procaine, lignocaine, bupivacaine, ropivacaine is one of the most popular techniques for both elective and emergency surgical procedures.

Adding adjuvant drugs to intrathecal local anesthetics improve or prolong analgesia, decrease the adverse effects associated with high doses of single local anesthetic, increase speed of onset of neural blockade(reduce latency) and increases analgesic gap [2,3].

A number of adjuvants have been used along with local anesthetics which include Opioids (Morphine, Fentanyl, Nalbuphine, Nalbuphine, Pentazocine, etc.), Alpha-2 Agonists(clonidine, dexmedetomidine) GABA Agonists (Midazolam), NMDA Receptor Antagonists (Ketamine), Neostigmine, NSAIDS, Neuromuscular Blocking Drugs, Dextrans, Adenosine [3,4].

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Opioids have been extensively used as an adjuvant because of excellent results in neuraxial blocks. Fentanyl is widely used and has become standard adjuvant drug via intrathecal and extrathecal approaches for various lower surgeries for postoperative pain relief [5].

But Fentanyl was found to have higher incidence of pruritus for which Nalbuphine was considered as an adjuvant.

In the present study we intend to compare the effects of fentanyl a pure agonist opioid agent with Nalbuphine an agonist antagonist opioid agent when used intrathecally in patients undergoing lower limb surgery.

Aim and Objectives

Aim

- To compare the efficacy of Fentanyl and Nalbuphine as an adjuvant to bupivacaine 0.5% heavy for lower limb and lower abdominal surgeries.

Objectives

To study and compare Fentanyl and Nalbuphine as an adjuvant to bupivacaine 0.5% heavy with respect to:

1. Onset and duration of sensory block.
2. Onset and duration of motor block.
3. Duration of post-operative analgesia
4. Adverse effects – hypotension, bradycardia, nausea vomiting, respiratory depression, shivering and pruritus.

Material and Methods

Study Design

Randomised Control Trial On "A Comparative Study of Efficacy of Intrathecal Fentanyl and Nalbuphine as an Adjuvant to Bupivacaine 0.5% Heavy for Lower Limb and Lower Abdominal Surgeries" was carried out on 60 patients between 18-60 years of age and ASA grade I and II physical status.

Inclusion Criteria

1. ASA grade I and II of either sex
2. Age between 18 to 60 years
3. Patient with written valid consent
4. Patient undergoing elective lower limb surgery.

Exclusion Criteria

1. Patient refusal
2. Allergy to any anesthetic drug
3. Infection at the site of injection
4. Patient on anticoagulants or bleeding disorder
5. ASA III and IV
6. Patients on tranquilizers, hypnotics, sedatives, and other psychotropic drugs.
7. Duration of surgery > 2 hours

Sample Size Estimation

30 per group making total of 60

Methodology

Pre anesthetic check-up was done on the previous day and on morning of surgery. Routine and specific investigations were noted.

Patients were randomly allocated into 2 groups each having 30 patients.

Group A: Intrathecal bupivacaine 0.5% heavy (2.5 ml) + Fentanyl 25μg (0.5 ml)

Group B: Intrathecal bupivacaine 0.5% heavy (2.5 ml) + Nalbuphine 25ug (0.5 ml)

All the patients were kept fasting overnight prior to the scheduled day of operation. Sedatives and hypnotics, inclusive of Opioids were avoided in pre medication as well as intra operatively. Patients received Inj. Ranitidine 50mg IV as premedication after entering the operation theatre. All standard monitors (ECG, NIBP, SpO2) were applied. Baseline BP, PR, RR were recorded. All patients were preloaded through 18 G cannula with 10 ml/kg of RL solution over 15-20 min. Under all aseptic precautions, lumbar puncture was performed in the L_{3-4} Intervertebral space using 25 G Quincke's spinal needle in sitting position. The patient received either one of the drug solution. Patient were turned supine and position of table was kept horizontal. Recording of HR, SBP, DBP, MAP, SpO2 and RR was done every 3 mins for 15 min, every 5 mins for 30 mins, and every 15 mins till 3 hours. In the intra operative period, crystalloid solutions (Ringer Lactate) 4ml/kg/hr was infused. The onset of sensory block was tested by pin-prick method using a 24G hypodermic needle every 2 minutes until the level had stabilized for 4 consecutive tests. Motor block was assessed by modified Bromage

scale. VAS was noted when the patient first complains of pain. VAS > 3 was treated with inj. Diclofenac 75mg IV.

The following parameters were noted:

1. Time to onset of sensory block (i.e. time from intrathecal injection of drug to complete loss of sensation to pin prick at T10).
2. Time taken to achieve the highest level of sensory block (time from intrathecal injection to highest level of sensory block).
3. The time for two dermatomal segments regression of sensory level.
4. Time taken to achieve complete motor block by Modified Bromage Score (time from intrathecal injection to achievement of Bromage 3).
5. Duration of motor block was noted (time from Bromage 3 to Bromage 2).

Modified Bromage Scale (for grading of motor block)

1. Grade 0 - No motor block
2. Grade 1 - inability to raise extended leg, able to move knees and feet
3. Grade 2 - inability to raise extended leg and move knees, able to move feet
4. Grade 3 – complete motor block of lower limbs.

6. Duration of analgesia (time from onset of sensory block to first complaint of pain by patient).
7. Peri-operative pain was assessed using 10 point Visual Analogue Scoring method (0-no pain, 10-worst pain)

   Pain score '0' to '3' - Mild pain, Pain score '3' to '7' - Moderate pain, Pain score > 7 - Severe pain
8. Adverse effects

A. If Hypotension occurred (MAP fall below 20% of base line) – was treated as follows in that order, till blood pressure normalized.

- Bolus of 100 – 200 ml of crystalloid solution
- Sympathomimetics

Inj. Mephenteramine IV 6mg to begin with and repeated if necessary, not to exceed the maximum of 30mg.

Inj.dopamine 3-10 mcg / kg / min I.V. infusion if no response to mephenteramine.

- Colloid/Blood transfusion in case hypovolemia ensued due to bleeding.

B. If Bradycardia(HR<50) was encountered,

- Inj. Atropine 0.5mg IV was given

C. If Respiratory depression RR<10/min.

- Oxygenation and IPPV if required.

D. If Nausea and vomiting

- Inj. Ondansetron 4 mg i.v.

E. Shivering

- Use of patient warming system-baer hugger.

F. Pruritus

- Inj hydrocortisone 100mg iv.

Results

The observation and results of the study were compared and statistical analysis was done. Data was managed in an excel spreadsheet. Statistical analysis was performed by the SPSS program for Windows, version 17.0. Continuous variables are presented as mean±SD, and categorical variables are presented as absolute numbers and percentage. For

Table 1: Comparison of age, height, weight and sex in study groups

	Group F	Group N	P Value
Age in years	35.10 ± 12.17	33.53 ± 11.39	0.880
Height in cm	162 ± 4.63	163.23 ± 4.23	0.357
Weight in Kg	65.93 ± 4.97	64.43 ± 6.66	0.239
Sex			
F	4 (13.3%)	8 (26.7%)	0.186
M	26 (86.7%)	22 (73.3%)	

Table 2: Comparison of ASA physical status in study groups

ASA	Group F Frequency (%)	Group N Frequency (%)	P Value
I	19 (63.3%)	16 (53.3%)	0.659
II	11 (36.7%)	14 (46.7%)	
Total	30 (100%)	30 (100%)	

comparing the two main groups Paired t test was applied.

In this study p value < 0.05 have been considered as statically significant.

Data is presented as Mean ± SD

The two groups were comparable with regards to age, height, weight. There were no difference in the demographical profile i.e. age, sex, height, weight and ASA grade between two groups and the two groups were comparable and statistically not significant.

On intra group comparision after SAB, there was no statistically difference in the intraoperative PR, SBP, DBP, RR and SpO_2 between the groups.

Onset of sensory was earlier in Nalbuphine group with a p- value of less than 0.001 and the result was statistically significant.

The onset of motor block was comparable in both the groups.

Duration of sensory and motor block were comparable in both groups

Table 3: Comparison of preoperative vitals in study groups

	Group F Mean ± SD	Group N Mean ± SD	P Value
SBP	125.6 ± 12.76	124.07 ± 10.73	0.366
DBP	78.33 ± 8.17	75.63 ± 7.78	0.446
PR(bpm)	79.43 ± 9.94	80.83 ± 10.76	0.812
SPO2	100.00 ± 0.00	100.00 ± 0.00	–
RR(cpm)	14.23 ± 1.72	14.23 ± 1.72	0.539

Table 4: Onset of Sensory and Motor Blocks

	Group F	Group N	P-value
Time of onset of sensory block (T10)	4.67±0.816	2.05±0.887	<0.001
Time to highest sensory	4.6±0.91	4.55±1.276	0.18
Time to motor bromage 3	4.8±1.146	4.85±1.089	0.985

Table 5: Duration of Sensory and Motor blocks

	Group F	Group N	P value
Duration of motor block	148.33±7.108	148.6±7.308	0.854
Time of 2 dermatomal regression	145.07±5.788	144.85±5.204	0.52

Table 6: Duration of Analgesia

	Group F	Group N	P value
Duration of analgesia (VAS>3)	244.27±5.457	243.25±8.091	0.047

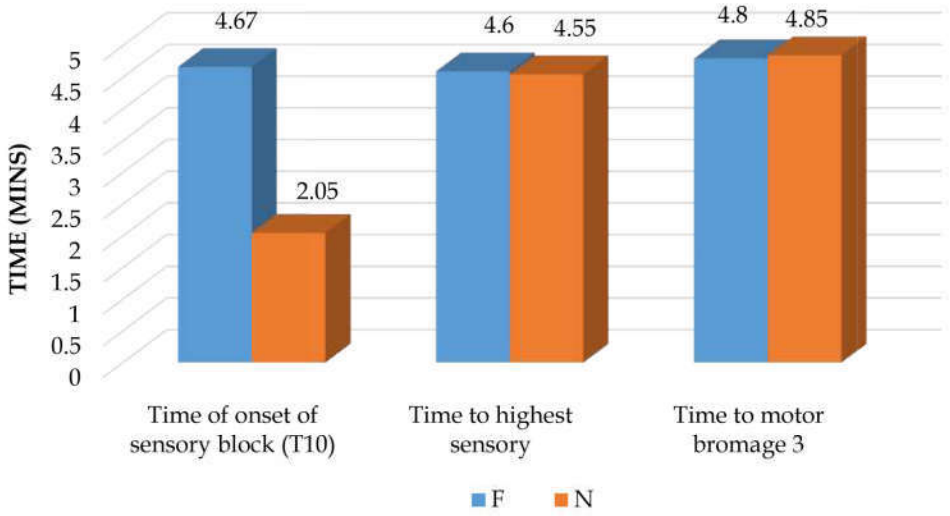

Fig. 1: Onset of Sensory and Motor Blocks

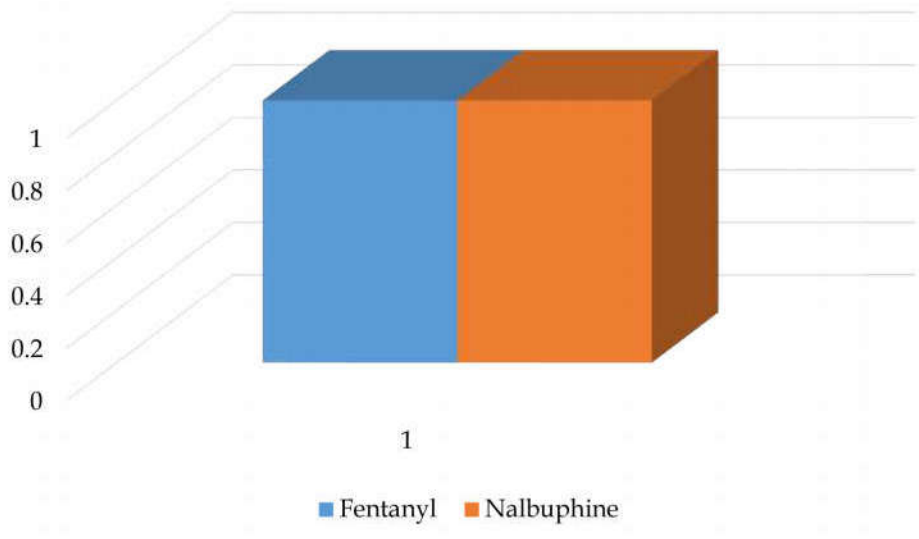

Fig. 2: Duration of Sensory and Motor blocks

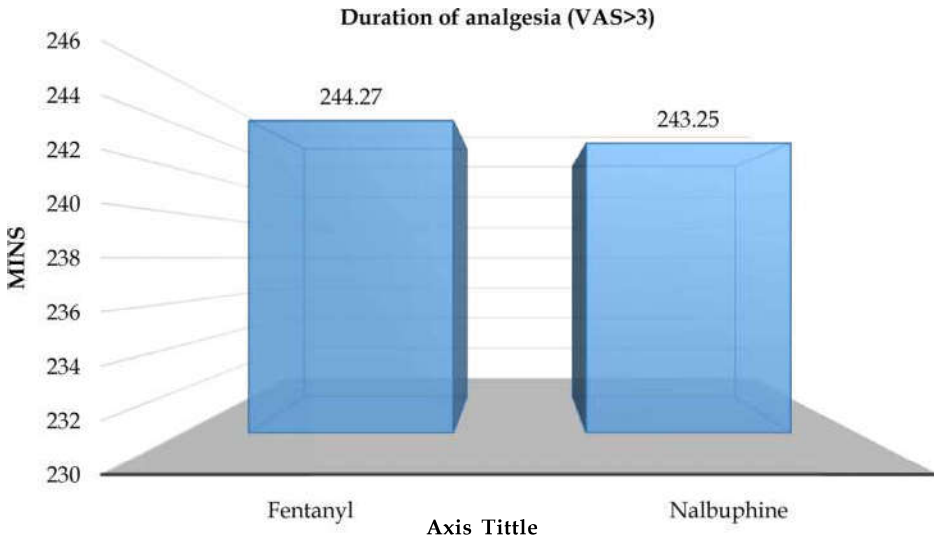

Fig. 3: Duration of Analgesia

The duration of analgesia was more for fentanyl but it was statistically not significant.

Discussion

Regional anaesthesia as an alternative to general anaesthesia or to supplement general anaesthesia has become a popular procedure in clinical anaesthesiology. The development of different local anaesthetics and various techniques in regional anaesthesia have been boosted by the growing interest in regional anaesthesia due to its effective pain relief without compromising the patient's consciousness and improved patient comfort. Furthermore, it has been influenced by the implementation of perioperative anaesthesia standards and the increasing awareness among healthcare professionals that postoperative analgesia plays an important part in the convalescence of patients

In this study we have used Bupivacaine along with nalbuphine or fentanyl for postoperative pain relief. Here we have compared analgesia and side effects of nalbuphine (400mcg in 0.5 ml) and fentanyl (25 mcg in 0.5 ml) with bupivacaine when administered by intrathecal route.

In our study, the onset of sensory block was delayed in Group F (4.67±0.816 mins) when compared to Group N (2.05±0.887 mins) by about 2.5 mins. It was both statistically and clinically significant.

The onset of complete motor block was comparable in fentanyl than Nalbuphine group.

The duration of sensory block and the duration of analgesia were comparable in nalbuphine and fentanyl group with no statistically significant difference.

Also in the present study, no statistically significant difference was found between both groups as regards the duration of motor block, hemodynamics and oxygen saturation. Neither bradycardia nor oxygen desaturation was recorded.

Hala Mostafa Gomaa et. al. [6], in their study compared intrathecal Nalbuphine 800mcg with fentanyl 25 mcg after cesarean section, concluded that- The onset of complete motor block was significantly more rapid in fentanyl group than in nalbuphine group. The duration of post-operative analgesia was more prolonged in nalbuphine group but the difference was insignificant. No significant difference was found between both groups as regards the duration of sensory block, motor block, duration of analgesia.

Culebras et. al. [7] compared intrathecal morphine (0.2 mg) added to hyperbaric bupivacaine with different doses of intrathecal nalbuphine (0.2 mg), (0.8 mg) and (1.6 mg) and their study concluded that intrathecal nalbuphine 0.8 mg provides good intra-operative and early post-operative analgesia without side effects (no PONV or pruritus).

Mukherjee et. al. [8] had studied 100 patients undergoing lower limb orthopedic surgery using subarachnoid block. They used different doses of nalbuphine intrathecally (200, 400 and 800) mcg added to 0.5% hyperbaric bupivacaine. They concluded that the duration of sensory block and the duration of effective analgesia were prolonged with the doses 400 mcg and 800 mcg but the side effects were higher with the dose 800 mcg.

Fournier et. al. [9] compared between intrathecal nalbuphine 400 mcg and intrathecal morphine 160 mcg in old patients undergoing total hip replacement using continuous spinal anesthesia. They concluded that intrathecal nalbuphine produces faster onset of pain relief but the duration of analgesia is shorter than intrathecal morphine.

Tiwari et. al. [10] had compared intrathecal nalbuphine 200 mcg and 400 mcg added to hyperbaric bupivacaine with bupivacaine alone. They concluded that the duration of sensory block and duration of analgesia was maximally prolonged with nalbuphine 400 mcg without complications.

Conclusion

Both fentanyl and nalbuphine in a dose of 25mcg and 400mcg were comparable in all aspects of intrathecal block except for onset of sensory block which was significantly faster in Nalbuphine group.

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