Section: Anesthesia

Original Research Article

COMPARATIVE EVALUATION OF TWO DIFFERENT DOSES OF INTRATHECAL NALBUPHINE VERSUS FENTANYL IN SPINAL ANESTHESIA BLOCK FOR LOWER ABDOMINAL SURGERIES

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Abstract

Background: The aims and objective are to compare the effectiveness of two non identical doses of nalbuphine (0.5 and 1 mg) in contrast to fentanyl (25µg) as appurtenant to 0.5% hyperbaric Bupivacaine in terms of, Time to reach complete sensory level (T10). Duration of motor block. Duration of analgesia. 2. To asses the safety of two different doses of nalbuphine (0.5 and 1 mg) versus fentanyl (25 µg) as adjuvant to 0.5% hyperbaric Bupivacaine in terms of, A. Hemodynamic parameters. B. Complications/ side effects. **Materials and Methods:** It is an anticipated double blind randomized control work. Group F receives 12.5 mg (2.5 ml of 0.5% hyperbaric Bupivacaine) +25 ug Fentanyl (0.5 ml). Group NL receive 12.5 mg (2.5 ml of 0.5% hyperbaric Bupivacaine) + 0.5 mg Nalbuphine (0.5 ml). Group NH receive 12.5 mg (2.5 ml of 0.5% hyperbaric Bupivacaine) + 1 mg Nalbuphine (0.5 ml). **Result:** Demographic particulors and surgical properties were equivalent in both the groups. The time to reach complete sensory level were outstandingly shorter in NL than F and NH group ($P < 0.001$). Duration of motor block was significantly longer ($P < 0.001$) in NL group. The duration of analgesia was significantly longer in NL group than F and NH group ($P < 0.001$). Hemodynamic parameters like HR, SBP, DBP were lower in group NL. **Conclusion:** Nalbuphine in 0.5 mg added as an adjuvant to Bupivacaine intrathecally was safe and superior when compared with that of Bupivacaine with Fentanyl and 1 mg of Nalbuphine.

INTRODUCTION

There are many adjuvants have been used along with Bupivacaine in spinal anesthesia1. Spinal anaesthesia is the most common type of anaesthesia preferred for surgeries below umbilicus procedure. Bupivacaine is the most common drug used for the spinal anaesthesia. As the duration of action of bupivacaine is less concern for adjuvants started. Many drugs have been used as additive to bupivacaine in spinal anaesthesia but some have advantages some have disadvantages. opioid are the most common additive used for spinal anaesthesia. As they provide good post op analgesia but side effects like nausea, vomiting, pruritis, respiratory depression are more common. To overcome this many other additives has been tried. As many study shown Good analgesia can reduce deleterious effects, like earlier mobilization, fewer pulmonary and cardiac complications, reduced risk of deep vein thrombosis, fast recovery.[1] Many adjuvants have been used and most commonly Fentanyl which is an Opioid shown good result compared to other adjuvants, still Fentanyl has some drawbacks like less motor effect, itching, post op nausea vomiting, respiratory depression. Though many side effects are benign but some like over sedation, respiratory depression are more dangerous and can be life threatening.[2]

Nalbuphine which also an Opioid (varied Opioid agonist antagonist).[3]

It has been proved any Opioid when added to Bupivacaine it increases the efficacy of local anaesthetics and removes some of the not desiring side effects. Nalbuphine is a kappa Opioid receptor agonist and a partial mu opiod antagonist. Analgesic properties are mediated through agonist activity at the kappa Opioid receptor. Because of this unique mixed agonist antagonist Opioid receptor activity of Nalbuphine, it provides analgesia with less nausea, pruritis, and respiratory depression.[4-8]

Adding Nalbuphine enhances features like analgesia, both intra operatively and post operatively. It decreases side effects like pruritis,

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nausea, vomiting. One of the main side effects of Opioid is respiratory depression but adding Nalbuphine in smaller doses shown less respiratory depression.[9-12]

Aims and Objectives of Study

To compare the effectiveness of two non identical doses of Nalbuphine 0.5mg and 1 mg in contrast to Fentanyl 25 mg as an appurtenant to 0.5% hyperbaric Bupivacaine in terms of,

- Time to reach complete sensory level (T10).
- Duration of motor block.
- Duration of analgesia.

To asses the safety of two non identical doses of Nalbuphine versus Fentanyl as an appurtenant to 0.5% hyperbaric Bupivacaine in terms of,

- Hemodynamic parameters
- Complication/side effects.

MATERIALS AND METHODS

Our study presented before ethical committee and taken approval. Informed consent taken from the patient. 40 patients of ASA physical status 1 and 2 of both gender planned for lower abdominal surgeries were enrolled for this prospective, randomised comparative control study.

Inclusion Criteria

- Patient who have given written informed consent.
- Age 18-60 years.
- ASA grade 1 and 2 patients.
- Elective various lower limb and lower abdominal surgeries where the duration of surgeries is about 1 and half to 2 hours.

Exclusion Criteria

- Patient refusal.
- ASA grade 3 and 4.
- Any bleeding disorders (pt on anti coagulants).
- Pt allergic to local anaesthetics.
- Pt with heart block and liver diseases.

Patients Divided into 3 Groups as Following

1. Group F receives 12.5 mg (2.5 ml of 0.5% hyperbaric Bupivacaine) +25 ug Fentanyl (0.5 ml).
2. Group NL receive 12.5 mg (2.5 ml of 0.5% hyperbaric Bupivacaine) + 0.5 mg Nalbuphine (0.5 ml)
3. Group NH receive 12.5 mg (2.5 ml of 0.5% hyperbaric Bupivacaine) + 1 mg Nalbuphine (0.5 ml)

Patient vitals like pulse rate, blood pressure, Spo2 were monitored in the pre op area and shifted to OT. On the table monitors attached. Patient in sitting position, under all aseptic precaution lumbar puncture done, after confirming free back flow of CSF the drug prepared by independent anaesthesiologist (who is not a part of study) injected. Vitals like PR, BP, Sp02 monitored immediately after giving anaesthesia and vitals monitored every 10 min till 30 minutes, then every 30 minutes until 120 minutes and at 4 hours thereafter for 24 hours.

Sensory motor level assessed and necessary recordings were done. Side effects like nausea, vomiting, shivering, Spo2, level of sedation, hypotention, bradycardia recorded. Pin prick sensation used for sensory testing with 23G needle. Surgery started after achieving T8 level of sensory blockade. Modified Bromage scale used for motor block assessment. Verbal rating scale(VAS) used for pain assessment. Pain assessed every 30 minutes for 2 hours and then every 2 hours till the patient complains of pain. Sedation of patient assesd by Ramsay sedation scale every 30 min after for 24 hours then every 2 hours till 24 hour. Time from spinal injection to the first requirement for rescue analgesic is considered as duration of analgesia. Intramuscular Diclofenac 75 mg used as rescue analgesia.

Statistical evaluation of data or parameters will be done as follows, For categorical data – Chi- square test or Fischer's exact probability test. For nominal data –ANOVA test.

RESULTS

The three groups were similar regarding age, gender, weight, type of surgery, and duration of surgery. There was no significant difference in all three groups. ($p>0.05$).

The mean time to reach sensory block was found to be 6.9 ± 0.3 seconds in group F, 9.5± 0.7 in Group NL while 9.5 ±0.4 minutes in group NH. The difference in mean time to reach sensory block was statistically significant ($P<0.001$).

The mean duration of motor block was found to be 197.1 ±6.2 minutes in group F, 257.1 ± 15.6 minutes in Group NL, while 243.1 ±14.5 minutes in group NH. The difference in mean duration of motor block was statistically significant ($P <0.001$).

The mean duration of analgesia was found to be 274.3 ± 6.5 minutes in group F, 410.4± 32.7 in Group NL, while 314.6 ± 32.2 minutes in group NH. The difference in mean total duration of analgesia was statistically significant ($P <0.001$).

The mean intraoperative heart rates, systolic blood pressure, diastolic blood pressure, mean arterial pressure, of patients from Group NL was more stable as compared to Group F and Group NH at different time intervals with no statistical significance ($P>0.05$).

The mean post-operative VAS score of patients from Group F, Group NL was more as compared to Group NH at different time intervals with statistical significance ($P<0.001$).

Incidence of side effects and complications was 5%, 7.5%, 35% respectively in Group F, Group NL, and Group NH. Shivering was the major side effect in group NH (23%).

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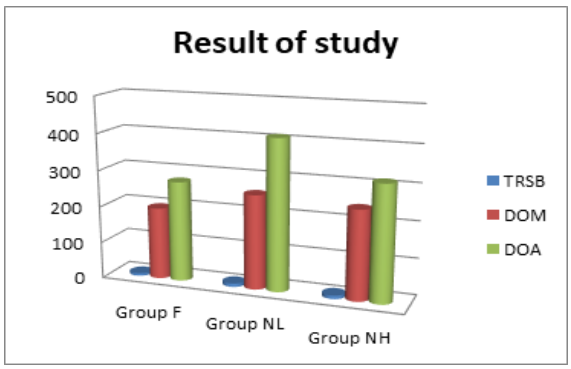

Figure 1: Comparison of TRSB, DOM, and (in min) in Group F, Group NL and Group NH.

Table 1: Comparison of TRSB, DOM, and DOA (in min) in Group F, Group NL and Group NH.

GROUP	NO OF PT	TRSB	DOM	DOA	P VALUE
Group F	40	6.9	197.1	274.3	<0.001
Group NL	40	9.5	257.1	410.4	<0.001
Group NH	40	9.5	243.1	314.6	<0.001

DISCUSSION

The present study was conducted to see the analgesic effectiveness of non identical doses of Nalbuphine along with 0.5% Bupivacaine and Fentanyl with Bupivacaine in lower abdominal surgeries.[13-15]

There are two types Opioid receptors μ and kappa. Nalbuphine called as mixed agonist and antagonist as it binds to both receptors. But its action different when it was used in different doses.[16]

When given intrthecally with Bupivacaine it binds to kappa receptors in the brain and spinal chord and act on nociception, which produces analgesia and sedation without μ receptor effect. From our study it has been noted that adding Nalbuphine to Bupivacaine prolonged the post op analgesia with minimal side effects which helped the patient for early post op recovery.[17,18]

Demograophic characteristics: The mean age in group F was 43.9 years, Group NL 44.9 and group NH was 46.5 years. The difference was insignificant in age distribution. (p>0.05).

There was no gender difference when three groups were compared statistically (p>0.05).

Mean weight are 72.7 ±9.3, 70 ± 8.3, and 69.9 ± 7.6 in group F Group NL and Group NH respectively. There was no significant difference in weight distribution amongst the three groups (p>0.05).

From the above data it was evident that demography (age, sex, weight, ASA grading) was comparable in all three groups.

Surgical characteristics

Time to reach sensory block: In our study, the mean time to reach sensory block was found to be 6.9 ± 0.3 seconds in group F, 9.5± 0.7 in Group NL while 9.5 ±0.4 minutes in group NH. The difference in mean time to reach sensory block was statistically significant (p<0.001). Earlier onset of sensory block in group F was due to the high lipophilic nature of Fentanyl.

Duration of motor block: The mean duration of motor block was found to be 197.1 ±6.2 minutes in group F, 257.1 ± 15.6 minutes in Group NL, while 243.1 ±14.5 minutes in group NH. The difference in mean duration of motor block was statistically significant. (p<0.001)

Duration of analgesia: The duration of analgesia was defined as time from intrathecal administration to requirement of rescue analgesia.

In our study the mean duration of analgesia was found to be 274.3 ± 6.5 minutes in group F, 410.4± 32.7 in Group NL, while 314.6 ± 32.2 minutes in group NH. The difference in mean total duration of analgesia was statistically significant. (p<0.001).

In a study done by Ravikiran et al,[8] Comparison among intrathecal Fentanyl and Nalbuphine in combination with Bupivacaine observed that time to reach sensory block Group B (Bupivacaine + normal saline) was 3.78 ±1.31 min and Group N (Bupivacaine+ Nalbuphine) was 9 ± 4.3 min(P < 0.05). There was significant difference (p-value < 0.001) between mean onset and complete sensory block in group N (Nalbuphine with Bupivacaine) and group B (Bupivacaine alone). The mean onset and complete motor block in group N and group B also showed statistical significance (p-value<0.05).

In a study done by Pallavi Ahluwalia et al,[9] (A Prospective Randomized Double-Blind Study to Evaluate the Effects of Intrathecal Nalbuphine in Patients of Lower Abdominal Surgeries under Spinal Anaesthesia) mean time to reach sensory block in patient receiving Nalbuphine (0.8mg)+3ml Bupivacaine was 8.43 ±0.57 min and in patient receiving 3ml 0.5% Bupivacaine was 3.03 ±1.03. Duration of motor blockade (Group B; 178.67 ± 28.34 min and Group N; 256.41 ± 33. 41 min) (P<0.05). Duration of analgesia in Group B (201.31 ± 34.31 min) and Group N (298.43 ± 30.92 min) was statistically significant among groups (P < 0.05). Similar findings seen in our study also.

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Akhilesh Kumar et al,[10] (2013) studied "Intrathecal Bupivacaine in Comparison With a Combination of Nalbuphine and Bupivacaine for Subarachnoid Block: A Randomized Prospective Double-Blind Clinical Study." The aim of the randomized, prospective double blind study to evaluate the effects of 2 different doses of intrathecal Nalbuphine (a synthetic Opioid agonist– antagonist) on the onset, duration of action, side effects, and complication produced by intrathecal hyperbaric 0.5% Bupivacaine in lower abdominal, shows that there was no significant dose related difference related to onset of sensory block and time to reach sensory block .They also demonstrated that duration of motor blockade were not affected.

Jyothi B, Shruthi Gowda, Safiya I Shaikh,[11] (2016) (A comparison of analgesic effect of different doses of intrathecal nalbuphine hydrochloride with bupivacaine and bupivacaine alone for lower abdominal and orthopaedic surgeries) evaluated the onset of sensory block, hemodynamic changes, duration and quality of analgesia, and adverse effects of different doses of nalbuphine with bupivacaine for spinal anesthesia. Randomized double blind study done on 100 patients undergoing lower abdominal and lower limb orthopaedic surgeries under subarachnoid block. Patients were randomly allocated to four groups receiving either intrathecal 15 mg of bupivacaine + 0.5 mL normal saline alone or 15 mg of bupivacaine with either of nalbuphine 0.8, 1.6, and 2.5 mg + 0.5 mL normal saline. the mean visual analogue scale score in group A is 4.08 •} 0.5 and in groups B, C, and D are 3.4 •} 0.4, 3.5 •} 0.5, and 3.5 •} 0.5, respectively. the duration of analgesia in group A is 190.4 •} 20.0 and in groups B, C, and D were 322.4 •} 31.1, 319 •} 39.8 and 317.8 •} 47.5. The quality of analgesia was good in 72%-76% and excellent in 16%- 28% in groups B, C, and D and poor 28% to satisfactory 72% in group A. Addition of 0.8 mg of nalbuphine to 0.5% bupivacaine for subarachnoid block provides excellent analgesia with longer duration of action compared with 1.6 and 2.4 mg of nalbuphine.

CONCLUSION

The conclusion of our study was that adding Nalbuphine to 0.5% hyperbaric Bupivacaine in small dose for spinal anaesthesia gives excellent post op analgesia with increased duration of motor block and less side effects in both intra op and post op period.

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