Original Research Article

Intrathecal nalbuphine versus intrathecal pentazocine as adjuvant to 0.5% hyperbaric bupivacaine for infraumbilical surgeries under subarachnoid block: A comparative evaluation

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Abstract

Background: Subarachnoid block possesses many benefits with the disadvantage of limited duration of anesthesia. Intraspinal opioids have been used to increase the duration of action of local anesthetic drugs. Our study was aimed to compare the clinical efficiency of intrathecal nalbuphine with pentazocine as adjuvant to 0.5% hyperbaric bupivacaine for infraumbilical surgeries. **Materials And Methods:** Total 100 patients belonging to ASA physical status I and II of both sexes (50 patients in each group) were selected randomly for this study. Onset of sensory and motor block, hemodynamic variables, duration of analgesia, visual analogue score and adverse effects were compared in both the groups. Group I patients received 3.2ml of 0.5% hyperbaric bupivacaine and nalbuphine 0.8mg intrathecally. Group II patients received 3.2ml of 0.5% hyperbaric bupivacaine and pentazocine 3mg intrathecally. **Results:** Onset of sensory and motor block was significantly longer in group II than group I ($p< 0.05$). Haemodynamic variables did not show any difference in either group ($p >0.05$). The duration of analgesia in group I was 414.40 ± 15.10 minutes and in group II was 339.30 ± 51.06 minutes which was statistically significant ($p<0.001$). The VAS scores were significantly less in group I at 6, 12 and 24 hrs ($p<0.001$) compared to group- II. The adverse effects were minimal in both the groups. **Conclusion:** Intrathecal administration of 0.8 mg nalbuphine in combination with 3.2 ml of 0.5% hyperbaric bupivacaine produces rapid onset of anesthesia, longer duration of analgesia, with good sedation and minimal side effects, thus reducing postoperative analgesic requirement.

Keywords: Bupivacaine, nalbuphine, pentazocine, intrathecal, infraumbilical surgeries, duration of analgesia.

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INTRODUCTION

Spinal anesthesia offers significant benefits over general anaesthesia, such as diminished stress response to surgery with postoperative analgesia. As spinal anesthesia provided postoperative analgesia for a short time, many intrathecal adjuvants to local anesthetics have been added to augment the clinical efficiency and duration of analgesia. Among various adjuvants, intrathecal opioids have provided an effective prolongation of postoperative analgesia for infraumbilical surgical procedures. Both nalbuphine and pentazocine are opioid analgesics. Nalbuphine, a synthetic opioid analgesic with agonist-antagonist activity acts as an antagonist at μ - receptors and agonist at kappa receptors to provide potent analgesia.

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Pentazocine is a synthetic agonist-antagonist opioid analgesic. It acts as a weak antagonist or a partial agonist at μ - opioid receptors. Analgesia is produced mainly through interaction with kappa (k1) receptor at substantia gelatinosa of dorsal horn of spinal cord. This randomized double-blind study was designed to quantitatively assess the effects of adding nalbuphine or pentazocine to 0.5% hyperbaric bupivacaine for spinal anesthesia to evaluate the efficacy, to know the duration of analgesia and to know the incidence of adverse effects and complications if any.

AIMS AND OBJECTIVES

The objective of the study is to compare the effects of intrathecal nalbuphine and pentazocine as adjuvants to hyperbaric bupivacaine in regard to analgesic efficacy, duration of postoperative analgesia and the incidence of adverse effects if any.

MATERIALS AND METHODS

After getting approval of the Institutional Ethics Committee and written informed consent ,this prospective randomized double-blinded study has been conducted at the Department of Anesthesiology and CriticaI Care, Santhiram Medical College and General Hospital .The study was conducted on 100 adult patients of American Society of Anesthesiology (ASA) physical status I and II of both sexes aged between 18-60 years , scheduled for elective operative procedures under spinal anesthesia for infraumbilical surgeries. After complete pre-anesthetic assessment and investigations, patients with a history of significant cardiovascular, pulmonary, hepatic, renal, neurologic, metabolic disease were excluded from the study. Patients who were obese, having coagulation or bleeding abnormalities, severe spinal deformity, allergy to local anesthetics and any contraindication to spinal anesthesia had been excluded from the study. The selected patients were randomized into two groups of 50 patients each by computer generated random number table. Patients of group I received 3.2 ml of 0.5 % hyperbaric bupivacaine with 0.8 mg of nalbuphine intrathecally. Total volume of the administered drug is 4 ml. (3.2 ml bupivacaine + 0.8 ml of nalbuphine) Patients of group II received 3.2 ml of 0.5 % hyperbaric bupivacaine with 3 mg of pentazocine intrathecally. The volume of the drug to be administered totally is 4 ml (3.2 ml of bupivacaine + 0.8 ml of pentazocine). All selected patients remained fasting on the night before surgery and premedication was given with tablet diazepam 10 mg and tablet pantaprozole 40 mg. Before giving anesthesia, patients were explained about the methods of sensory and motor blockade assessments. All patients were explained regarding the visual analogue scoring system. The VAS has a 10 cm horizontal paper strip with two endpoints: 0 = no pain and 10 = worst possible pain. After arrival to operation theatre, standard monitoring for heart rate (HR), non-invasive blood pressure (NIBP), electrocardiogram (ECG) and pulse oxymetry (Spo2) was commenced and recorded at 5-minute intervals throughout the surgery. A peripheral intravenous (IV) access with 18 G IV cannula was secured and lactated ringer's solution was preloaded at 10 ml/kg to replace the fluid deficit. Under strict aseptic precautions, all patients received SAB with the patient in the lateral decubitus position using a 25 gauge Quincke needle at L3-L4 or L4-L5 interspaces. The study drug was administered intrathecally as per group allocation and the patient was placed in the supine position immediately after injection. After the spinal block, intraoperatively, the following parameters were observed and recorded. 1. HR, RR, SpO2 and NIBP were recorded immediately and at 10, 20, 30, 40, 50, 60, 90, 120, 150 mins. 2. Level of sensory block will be assessed by pin prick and motor block by Bromage scale. Surgery will be allowed to start as soon as the sensory block reaches the required level of anesthesia for concerned surgery. 3. The side effects like nausea, vomiting, pruritus, hypoxaemia, respiratory depression, sedation, hypotension, bradycardia was observed and recorded in the intraoperative period. Onset of sensory blockade was taken from time of injection of the drug into the subarachnoid space to loss of pin prick sensation. The time to achieve maximum sensory blockade was noted from time of injection of drug to loss of pinprick sensation at highest dermatomal level. The time interval between injection of the drug into subarachnoid space, to the patient's inability to lift the straight extended leg was taken as onset time of motor blockade. The time to achieve maximum motor block was noted from the time of injection of the drug to gain maximum degree of motor block.

Bromage Scale: 0. Full flexion of knees and feet. 1. Inability to raise the extended leg. 2. Inability to flex knee, but some flexion of feet possible. 3. Unable to flex the ankle (complete motor block). The duration of pain relief was calculated from the intrathecal injection of drug to first analgesic demand i.e. VAS more than 3. The patients were followed up for 24hrs after surgery. VAS score along with HR, BP, and SP02 were recorded in the recovery room, immediately after surgery, and then 6, 12, 24 hr in the postoperative ward. During the post operative period, the injections of analgesic or opioids were avoided until VAS>3. Side effects like nausea, vomiting, pruritus, respiratory depression, urinary retention, hypotension, bradycardia, euphoria, dysphoria, pupillary changes, and altered sensorium, if any were observed and recorded in both intraoperative and postoperative periods.

Hypotension was managed by increasing the rate of infusion of crystalloids and by incremental doses of IV

mephentermine 6mg if required. Bradycardia was managed with 0.6 mg atropine intravenously. Intraoperative nausea and vomiting was treated with ondansetron (4mg).

Sedation score was assessed by a Categorical scale which was used by Mostafa *et al.* [1] and graded as:

1. awake and alert
2. awake but drowsy , responding to verbal stimulus
3. drowsy but arousable, responding to physical stimulus and
4. unarousable, not responding to physical stimulus

After the procedure the patients have been transferred to the recovery room for further monitoring.

STATISTICAL ANALYSIS

Descriptive statistical analysis is carried out in the present study. Results on continuous measurements are presented as Mean SD (Min-Max). Significance is assessed at 5 % level of significance. Student 't' test (two tailed, independent) has been used to assess the significance of study parameters on a continuous scale between two groups. $p < 0.05$ was considered to be statistically significant and $p< 0.01$ was considered statistically highly significant.

RESULTS

Patients of both groups were compared statistically regarding mean age, gender, weight and duration of surgery.

TABLE 1: DEMOGRAPHIC PROFILE OF PATIENTS (n=100)

Parameters	Group – I	Group – II
Age (years)	38.24 ± 10.55	39.94 ± 11.80 (p>0.05)
Gender (M:F)	24 : 26	18 : 32
Weight (kg)	54.74 ± 11.22	55.12 ±12.57 (p>0.05)
Duration of surgery	109.38 ±23.32	108.80 ±25.22 (p>0.05)

The onset of sensory blockade in patients of group-I was 184.86 ± 48.86 seconds and 207.60 ±43.22 seconds in patients of group-II which was statistically significant (p-value < 0.05) The onset of motor blockade in patients of group-I was 280.94 ± 70.06 seconds and in patients of group-II was 316.14± 57.38 which was statistically significant (p-value <0.05). When the degree of motor blockade was compared between two groups, it was found statistically insignificant (p-value >0.05) as complete motor blockade was observed in all patients in both the groups. The total duration of analgesia was 414.40 ± 15.10 minutes in patients of group-I and 339.30 ± 51.06 minutes in patients of group-II which was statistically highly significant (p-value <0.001).

TABLE 2: SENSORY AND MOTOR BLOCKADE PROFILE

	Group-I	Group-II	P value
1.Onset of sensory block(sec)	184.86 ±48.86	207.60 ±43.22	< 0.05
2.Onset of motor block (sec)	280.94 ±70.06	316.14 ±57.38	< 0.05
3.Degree of motor block Grade-3	50 (100 %)	50 (100%)	> 0.05 (NS)
4.Duration of analgesia (min)	414.40 ±15.10	339.30 ± 51.06	< 0.001 (HS)

NS – NOT SIGNIFICANT ; HS – HIGHLY SIGNIFICANT

There is significant reduction in the visual analogue score of the patients in group-I in comparison with higher VAS in patients of group-II recorded at 6, 12 , 24 hrs after completion of surgery.

TABLE 3: VISUAL ANALOGUE SCORES

Time in hours	Group-I	Group-II	P value
6	1.20 ±1.48	2.10 ± 1.39	<0.001 (HS)
12	3.54 ±1.07	4.52 ± 1.16	< 0.001 (HS)
24	4.96 ± 1.01	5.60 ± 0.61	< 0.001 (HS)

The hemodynamic parameters of Systolic blood pressure (SBP), Diastolic blood pressure (DBP), and Heart rate (HR) were comparable and there was no statistically significant difference in SBP, DBP and HR during intra and postoperative periods between both groups (p > 0.05).

TABLE 4: CHANGES IN SYSTOLIC BLOOD PRESSURE (mm Hg)

Time in min	Group - I	Group – II	P-value	Remarks
0	128.14 ± 9.19	126.88 ± 9.87	> 0.05	NS

10	115 ± 14.13	118.70 ±14.53	>0.05	NS
20	127.62 ± 13.25	113.58 ± 12.86	>0.05	NS
30	109.56 ± 11.42	111.52 ± 12.70	>0.05	NS
40	110.80 ± 12.14	110.52 ± 10.91	>0.05	NS
50	109.91 ± 11.70	110.39 ± 11.95	>0.05	NS
60	110.04 ± 9.99	111.62 ± 9.58	>0.05	NS
90	110.56 ± 9.98	111.39 ± 9.52	>0.05	NS
120	118.75 ± 13.37	120.93 ±12.78	>0.05	NS
150	124.00 ± 8.29	118.50 ± 11.15	>0.05	NS
Post-op HR	115.28 ± 6.55	117.56 ± 6.85	> 0.05	NS

TABLE 5: CHANGES IN HEART RATE (beats/min)

Time in min	Group - I	Group – II	P-value	Remarks
0	86.44±12.98	85.98 ± 14.59	> 0.05	NS
10	84.16 ± 14.10	84.40 ± 14.70	>0.05	NS
20	80.44 ± 14.43	80.78 ± 15.35	>0.05	NS
30	78.74 ± 12.51	88.90 ± 14.91	>0.05	NS
40	78.74 ± 10.97	74.96 ± 12.09	>0.05	NS
50	78.56 ± 10.02	76.92 ± 11.05	>0.05	NS
60	77.40 ± 9.53	73.81 ± 11.45	>0.05	NS
90	77.06 ± 12.43	75.28 ± 12.51	>0.05	NS
120	79.25 ± 12.63	74.36 ± 10.09	>0.05	NS
150	80.50 ± 11.70	74.67 ± 14.29	>0.05	NS
Post-op HR	75.12 ± 4.28	76.16 ± 6.29	> 0.05	NS

The mean sedation scores at different time intervals were comparable between two groups, and it was found statistically highly significant at 20, 30, 40 minutes ($p < 0.001$) and significant at 50 minutes time interval ($p < 0.05$).

Patients in both the groups had minimal side effects. No pruritus , euphoria, dysphoria , respiratory depression and desaturation were observed in both groups. Nausea and vomiting was found in 1 patient in each group. Urinary retention occurred in 1 patient in each group. Bradycardia occurred in 1 patient in group I and no bradycardia in group II patients. Hypotension occurred in 1 patient in group I and 2 patients in group II .There was no clinical or statistical significance in the incidence of side effects in both groups.

DISCUSSION

Subarachnoid block is a commonly employed anesthetic technique for lower abdominal and lower limb surgeries. Local anesthetics used for this purpose have various side effects and have less duration of analgesia. One disadvantage with spinal anesthesia using local anesthetics alone is that analgesia ends with the regression of the block, which means that there is an early need of analgesia for postoperative pain. In recent years, the use of intrathecal opioids has become widespread, albeit at the cost of an increased risk for respiratory depression. Nalbuphine and pentazocine as they have agonist and antagonist actions, have minimal respiratory depressant effects, while providing analgesic effects by agonist actions. Although epidural nalbuphine and pentazocine have been demonstrated to provide adequate postoperative analgesia in patients undergoing major abdominal surgery, their efficacy after intrathecal administration have not been studied sufficiently. So we thought it would be apt to study the effects of intrathecally administered nalbuphine and pentazocine along with 0.5% bupivacaine. In the present study onset of sensory blockade in group I was 184.86±48.46 seconds compared to 207.60±43.22 seconds in group II, which was statistically significant ($p< 0.05$). It shows that addition of nalbuphine to local anesthetics results in early onset of analgesia than addition of pentazocine. Fournier R *et al.* [2] in 1998 conducted a study in 24 patients in whom 400 µg nalbuphine in 4ml sodium chloride 0.9% were administered. They concluded that administration of intrathecal nalbuphine results in significantly faster onset of analgesia. The onset of motor blockade in group-I was 280.94±70.06 seconds compared to 316.14±57.38 seconds in group- II, which was also statistically significant ($p< 0.05$). Hence the addition of

nalbuphine produces motor blockade earlier than with the addition of pentazocine. However, all patients in either group attained complete motor blockade. There is significant reduction in the visual analogue score of patients in group-I in comparison with higher VAS in group-II patients recorded at 6 , 12 , 24 hrs after completion of surgery. Duration of analgesia in group - I was 414.40±15.10 minutes compared to 339.30±51.06 minutes in group II which was statistically highly significant ($p< 0.001$). This shows that there was prolonged analgesia with intrathecal nalbuphine than with intrathecal pentazocine. The results of the present study correlates well with other studies. Prasanna Vadhanan, Kiruthika Balakrishnan [3] in 2017 conducted a study to compare 0.8 mg and 1.6 mg of nalbuphine as additive to bupivacaine intrathecally and concluded 0.8 mg of nalbuphine as optimal dose for postoperative analgesia. Tiwari AK, Tomar G S and Agarwal J [4] in 2013 conducted a randomized prospective double-blind study to compare the effects of intrathecal bupivacaine with a combination of nalbuphine and bupivacaine for subarachnoid block. They concluded that Nalbuphine hydrochloride significantly prolongs the duration of sensory blockade and postoperative analgesia when introduced intrathecally along with hyperbaric bupivacaine. Gomaa HM *et al.* [5] conducted a comparative study to observe postoperative analgesia with intrathecal nalbuphine plus bupivacaine and intrathecal fentanyl plus bupivacaine after caesarean section. They observed that duration of postoperative analgesia was more prolonged in nalbuphine group. Their studies are in accordance with the findings of our study. There was no significant fall in BP and HR in both groups. Mean systolic blood pressure at different time intervals in both groups, both intraoperatively and postoperatively was found to be statistically insignificant. Lin ML [6] in 1992 evaluated the effects of intrathecal nalbuphine or morphine with tetracaine and found no significant changes in hemodynamic status. Chawla R *et al.* [7] in 1989 evaluated the effects of different doses of intrathecal pentazocine with bupivacaine 1% and found no significant changes in hemodynamic status. Our study results were similar to the above studies. Respiratory depression is respiratory rate <9 breaths per min, SPO2<90%. No patient in our study had respiratory depression. Rudra A *et al.* [8] in 1991 studied the effect of 1/2ml of 5% heavy lignocaine with 0.5 ml (15mg of pentazocine) intrathecally and found no respiratory depression. Swaraj *et al.* [9] in 1988 studied the effects of intrathecal pentazocine 5mg with lignocaine 5% 1.4-1.8ml and found no respiratory depression. The above observations were similar to our study results. We conclude that intrathecal nalbuphine 0.8mg and pentazocine 3mg is safe to use without causing respiratory depression. As far as the side effects of intrathecal opioids were concerned in our study, patients in both groups had minimal side effects. No pruritus, respiratory depression, euphoria, dysphoria, desaturation were observed in both groups. Nausea and vomiting found in 1 patient in each group. Urinary retention in 1 patient in each group. Bradycardia occurred in 1 patient in group I and no bradycardia in group II patients. Hypotension occurred in 1 patient in group I and 2 patients in group II. Yoon HJ *et al.* [10] in 2002 conducted a comparative study to find adverse effects of intrathecal nalbuphine 1mg and morphine 0.1mg for pain relief during a caesarean section. The incidence of pruritus was lower in the nalbuphine group. Parker *et al.*[11] in 1997 studied the effects of adding nalbuphine(NB) an opioid agonist-antagonist to hydromorphone(HM) for patient controlled epidural analgesia(PCEA). They concluded that combination of HM 0.075mg/ml and NB 0.04mg/ml resulted in decreased nausea and a decreased incidence of urinary retention compared with HM alone, without increasing the opioid analgesic requirement. All these studies are in accordance with the findings of our study.

CONCLUSION

From the present study it is concluded that intrathecal administration of 0.8 mg nalbuphine in combination with 3.2 ml of 0.5 % hyperbaric bupivacaine produces rapid onset of anesthesia, longer duration of analgesia, thus reducing postoperative analgesic requirement with good sedation and minimal side effects when compared to 0.5% hyperbaric bupivacaine with pentazocine 3mg in infraumbilical surgeries.

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