

A clinical study of comparison of intrathecal hyperbaric bupivacaine with nalbuphine and hyperbaric bupivacaine with pentazocine in lower abdominal surgeries

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Abstract

Background: To compare the clinical effects of Intrathecal 0.5% hyperbaric Bupivacaine and Nalbuphine and 0.5% hyperbaric Bupivacaine and Pentazocine in lower abdominal surgeries. **Materials and Methods:** 100 patients belonging to ASA physical status I and II of both sexes (each group 50 patients n=50) were randomly selected for the study. The time of onset of sensory and motor block, hemodynamic status, duration of analgesia and adverse effects if any 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:** The time of onset of sensory and motor block was significantly longer in group II than group I ($P < 0.05$). Haemodynamic changes did not differ in patients of 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 side effects were minimal in both the groups. **Conclusion:** Intrathecal administration of 0.8mg of Nalbuphine in combination with hyperbaric Bupivacaine 0.5% produces rapid onset of anaesthesia, longer duration of analgesia, with good sedation and minimal side effects. **Key words:** Bupivacaine, Nalbuphine, Pentazocine, intrathecal, lower limb and lower abdominal surgeries, duration of analgesia

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INTRODUCTION

Spinal anaesthesia is popular and commonly used worldwide. Spinal anaesthesia, is simple to perform and offers a rapid onset of action, reliable surgical analgesia and good muscle relaxation. These advantages are

sometimes offset by a relatively short duration of action and appearance of pain when it wears off. The popularity of spinal block is that, the block has well defined end points and anaesthesiologist can produce the blocks relatively with a single injection.¹ The versatility of spinal anaesthesia is afforded by a wide range of local anaesthetics and additives that allow control over the level, the time of onset and the duration of spinal anaesthesia. The distribution of local anaesthetic solutions within the subarachnoid space determines the extent of the neural blockade produced by spinal anaesthesia. Spinal anaesthesia with hyperbaric bupivacaine 0.5% is popular method for longer procedures due to its prolonged duration. But there is a need to intensify and increased duration of sensory blockade thus prolonging the duration of post operative analgesia². The addition of opioids has been suggested as a method to accomplish these goals.

Intrathecal administration of opioids can provide excellent pain relief after wide range of operative procedures. This study is designed to quantitatively examine the effects of adding Nalbuphine and Pentazocine to hyperbaric Bupivacaine hydrochloride spinal anesthesia, to evaluate the efficacy and to know the incidence of adverse effects and complications if any.

MATERIALS AND METHODS

Source of data: A randomized study was conducted on 100 patients undergoing elective operative procedures under spinal anaesthesia for lower abdominal and lower limb surgeries.

Inclusion Criteria: ASA physical status I and II. Patients of either sex. Patients aged between 18-60years.

Exclusion criteria: Patients coming for emergency surgery. Patients with severe respiratory, cardiovascular, renal and endocrine disorders. Patients allergic to the local anaesthetics. Patients with coagulation disorders. Patients with local sepsis.

Preanaesthetic Examination and Preparation: The study protocol was approved by Hospital Ethical committee and Ethical clearance was obtained from the institution for the study. Preanaesthetic check up was done one day prior to the surgery. All the Patients were visited and detailed pre anaesthetic examination including history,

clinical examination, systemic examination of cardiovascular, respiratory and central nervous system and examination of spine for deformity, infection was carried out. The procedure of spinal anaesthesia was explained to the patients and informed written consent was obtained. Routine investigations like complete haemogram, complete urine examination, blood sugar, electrocardiogram, chest X-ray, blood grouping, blood urea, serum creatine were done. Preparation of patients includes period of overnight fasting. Pre medication done with oral tablet *al.* prazolam 0.5mg and tablet ranitidine 150mg given at night and morning on the day of surgery.

Method: One hundred patients were randomly divided into two groups of fifty each.

Group I: Fifty patients received 3.2ml of injection 0.5%hyperbaric Bupivacaine with 0.8mg of Nalbuphine intrathecally.

Group II: Fifty patients received 3.2ml of hyperbaric Bupivacaine 0.5% with 3mg of Pentazocine intrathecally.

Preparation of operating room:

Boyle’s anesthesia machine was checked. Appropriate size endotracheal tubes, Working laryngoscope with medium and large size blades, stylet and working suction apparatus were kept ready before the procedure.

Emergency drug tray kept ready.

RESULTS

Table 1: Age distribution of patients studied

Age in years	Group I		Group II	
	No of pts	Percentage	No of pts	Percentage
20-30	13	26%	12	24%
31-40	21	42%	15	30%
41-50	9	18%	14	28%
51-60	7	14%	9	18%
Total	50	100%	50	100%

Statically not significant (p>0.05)

Table 2: SEX DISDTIBUTION

Sex	Group I		Group II	
	No of pts	Percentage	No of pts	Percentage
Male	24	48%	18	36%
Female	26	52%	32	64%
Total	50	100%	50	100%

Table 4 shows sex distribution of both groups. 100 patients of each sex had participated in this study group. Both have predominantly female patients 52% in group I and 64% in group II.

Table 3: Perioperative systolic blood pressure at different time intervals

Time in min	Group -I		P Value	Remarks
	Mean ±SD	Mean ±SD		
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 ± 10.48	111.39 ± 11.39	< 0.05	Significant
120	118.75 ± 13.37	120.93 ± 12.78	> 0.05	NS
150	124.00 ± 8.29	118.50 ± 11.15	> 0.05	NS

Mean systolic blood pressure at different time intervals in both groups. Inter group, intra operative BP and variation in BP was found to be statistically insignificant $p > 0.05$, except at 90 min time, intra operative BP was significant ($p < 0.05$).

Table 4: Perioperative diastolic blood pressure at different time intervals

Time in min	Group-I	Group-II	P Value	Remarks
	Mean ± SD	Mean ± SD		
0	79.98 ± 6.77	79.28 ± 8.30	>0.05	NS
10	69.84 ± 10.88	72.74 ± 11.37	> 0.05	NS
20	65.40 ± 8.95	68.42 ± 10.54	> 0.05	NS
30	65.54 ± 7.54	67.10 ± 10.09	> 0.05	NS
40	65.70 ± 9.70	67.36 ± 8.20	> 0.05	NS
50	65.76 ± 8.51	67.98 ± 8.57	> 0.05	NS
60	66.51 ± 7.80	69.21 ± 8.51	> 0.05	NS
90	66.69 ± 8.57	73.26 ± 9.01	< 0.01	Significant
120	70.00 ± 12.21	74.00 ± 9.83	> 0.05	NS
150	77.25 ± 10.94	73.83 ± 7.70	> 0.05	NS

Mean diastolic BP at different time intervals in both groups. Intra group intra operative BP found to be statistically insignificant ($p > 0.05$), except at 90 mins time interval intraoperative diastolic BP was significant ($p < 0.01$).

Table 5: Perioperative Heart rate of the patients at different time intervals

Time in min	Group-I	Group-II	P Value	Remarks
	Mean ± SD	Mean ± SD		
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	79.13 ± 11.86	74.20 ± 11.05	< 0.05	Significant
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

Table 8 shows mean HR per minute in both groups at different time intervals. Inter group, intra operative HR and the variation in HR was found to be statistically insignificant, $p > 0.05$ except at 50 minute time interval was significant ($p < 0.05$).

Table 6: Onset of sensory blockade (seconds) in either groups

Group-I	Group-II	P Value	Remarks
Mean ± SD	Mean ± SD		
184.86 ± 48.86	207.60 ± 43.22	< 0.05	significant

The difference between the groups was statistically significant.

Table 7: Onset of motor blockade (seconds) in either groups

Group-I	Group-II	P Value	Remarks
Mean ± SD	Mean ± SD		
280.94 ± 70.06	316.14 ± 57.38	< 0.05	significant

The difference between the groups was statistically significant ($p < 0.05$).

Table 8: Perioperative Sedation score at different time intervals

Time in min	Group-I	Group-II	P value	Remarks
	Mean ± SD	Mean ± SD		
0	1	1		
10	1.10 ± 0.30	1.02 ± 0.14	> 0.05	NS
20	1.73 ± 0.49	1.44 ± 0.50	< 0.001	Sig
30	2.08 ± 0.53	1.80 ± 0.40	< 0.001	Sig

40	2.10±0.51	1.84±0.37	<0.001	Sig
50	2.09±0.47	1.88±0.39	<0.05	Sig
60	1.88±0.46	1.76±0.48	>0.05	NS
90	1.39±0.55	1.48±0.51	>0.05	NS
120	1.25±0.45	1.57±0.51	>0.05	NS
150	1	1.17±0.41	>0.05	NS

The difference between the groups was statistically highly significant at 20, 30, 40 mins p<0.001 and significant at 50 min time intervals p<0.05.

Table 9: Duration of analgesia (in minutes) in either group

Group -I	Group -II	P Value	Remarks
Mean ± SD	Mean ±SD		
414.40 ±15.10	339.30 ± 51.06	< 0.001	Highly significant

The difference between the groups was statistically highly significant.

Table 10: Side Effects

Side Effect	Group -I	Percentage	Group -II	Percentage
Nausea and Vomiting	4	8%	4	8%
Pruritus	0	0	0	0
Urinary retention	1	2%	1	2%
Euphoria and dysphoria	0	0	0	0
Respiratory depression	0	0	0	0
Desaturation	0	0	0	0
Hypotension	17	34%	19	38%
Bradycardia	3	6%	0	0

- Hypotension was noted in 17(34%) of patients in group 1 and 19(38%) of patients in group 2.
- Bradycardia was noted in 3 (6%) of patients in group 1, no bradycardia was noted in group 2.
- Nausea and vomiting was observed in 4 patients of each group. 29 patients in group 1 and 28 patients in group 2 were catheterized; urinary retention was noted in 1 patient of each group of remaining uncatheterised patients. There was no clinical or statistical significance in the incidence of side effects in both groups.

DISCUSSION

Subarachnoid block is a commonly employed anaesthetic technique for lower abdominal and lower limb surgeries. Local anaesthetics commonly used for this purpose have various side effects and have less duration of analgesia. One disadvantage with spinal anaesthesia using local anaesthetics alone is that analgesia ends with regression of the block, which means that there is an early need of analgesia for post operative 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 post operative analgesia in patients undergoing major abdominal surgery, their efficacy after intrathecal administration have not been studied sufficiently. Hence we thought it would be appropriate to study the effects of intrathecally administered Nalbuphine and Pentazocine along with bupivacaine 0.5%.

Changes in perioperative cardiovascular parameters:

In the present study there was no significant fall in the BP and HR in both groups during the initial 30 minutes.

Culebras X *et al.*³ in 2000 evaluated the effects of different doses of intrathecal Nalbuphine with Bupivacaine 10mg and found no significant changes in hemodynamic status. Lin ML in 1992⁴ evaluated the effects of intrathecal Nalbuphine or Morphine with Tetracaine and found no significant changes in hemodynamic status. Cheun JK *et al.*⁵ in 1988 evaluated the effects of intrathecal Pentazocine 45mg and found to have hypotension in 6% of patients and bradycardia in one patient. Our study results were similar to above studies.

Changes in respiratory parameters: Respiratory depression is respiratory rate <9 breaths per minute, SpO₂<90%. None of the patients in the present study had respiratory depression. Culebras X *et al.*³ in 2000 observed that intrathecal Nalbuphine at different doses with Bupivacaine 10mg produced good analgesia without maternal or newborn respiratory depression. Rudra A *et al.*⁶ in 1991 studied the effect of 1/2ml of 5% heavy lignocaine with 1/2ml (15mg of pentazocine) intrathecally 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.

Changes in onset of sensory and motor blockade:

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 Pentazocine to local anaesthetics delays the 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 ($p < 0.05$). That is the addition of Pentazocine to local anaesthetics delays the onset of motor blockade. Cheun JK⁵ in 1988 showed that the onset of sensory blockade with Pentazocine intrathecally was 3.2 ± 0.9 minutes and motor block was 4.1 ± 1.9 minutes. Tiwari CS *et al.*⁷ in 1997 showed that the onset of sensory blockade with 1.5mg per kg of Pentazocine intrathecally was 5.35 ± 3.28 minutes and motor block was 3.16 ± 2.33 minutes.

Duration of analgesia: In the present study the 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 significantly longer period of analgesia with intrathecal Nalbuphine. This is a considerably longer duration of analgesia when compared to using local anaesthetics alone. Culebras X *et al.*³ in 2000, Yoon HJ *et al.*³⁹ in 2002 and Lin ML in 1992⁵⁰ found prolonged duration of post operative pain relief with intrathecal Nalbuphine with Bupivacaine. Kalia *et al.*⁸ in 1983, found duration of analgesia ranged from 4 to 24 hours with Pentazocine given epidurally. Tiwari CS *et al.*⁷ in 1997, found duration of post operative analgesia considerably prolonged when Pentazocine given intrathecally. Chawla R *et al.*⁹ in 1989 found that duration of post operative analgesia with intrathecal Pentazocine was dose related till 3mg.

Adverse effects: Culebras X *et al.*³ in 2000 and Yoon HJ *et al.*³⁹ in 2002, found no pruritus, PONV, euphoria, dysphoria with intrathecal Nalbuphine. Lin ML in 1992⁴ found less side effects with Nalbuphine than with Morphine. Cheun JK *et al.*⁵ in 1988 and Rudra A *et al.* in 1991 found no pruritus, respiratory depression, PONV, urinary retention with intrathecal Pentazocine. Chawla R *et al.*⁹ in 1989 found urinary retention in 2 patients, PONV in one patient and no respiratory depression with inthecal Pentazocine. Tiwari CS *et al.*⁷ in 1997 found hypotention in 11.6% of patients, bradycardia in 2 cases, PONV in (15%) 3 cases, urinary retention in 15% of patients. Swaraj *et al.*¹⁰ in 1988 found hypotention in 3 cases, PONV in one patient, urinary retention in one patient, and no respiratory depression, pruritus. As far as 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 in both the groups. Nausea and vomiting found in 4 patients in both groups. Urinary retention in 1 patient in each group in uncatheterised patients. Bradycardia occurred in 3 patients in group I and no bradycardia in group II patients. Hypotension occurred in 17 patients in group I and 19 patients in group II.

CONCLUSION

Intrathecal administration of 0.8mg of Nalbuphine in combination with hyperbaric Bupivacaine 0.5% produces rapid onset of anaesthesia, longer duration of analgesia, with good sedation and minimal side effects.

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