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Original Article

Hemodynamic and Sedative Effects of Intrathecal Tramadol with Bupivacaine and Bupivacaine Alone in Patients Undergoing Elective Lower Abdominal Surgery: A Comparative Study

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Abstract

Background: Effective pain control is essential for optimum care of patients in the post-operative period. Epidural and intrathecal administration of drugs have been used increasingly for relief of post-operative pain. Intrathecal adjuvants apart from producing postoperative analgesia cause respiratory depression and haemodynamic instability like morphine, clonidine, dexmedetomidine etc. The purpose of this study is to compare the hemodynamic changes and level of sedation following intrathecal administration of tramadol with bupivacaine and bupivacaine alone in patients undergoing lower abdominal surgical procedures.

Materials and Methods: 60 ASA I and II patients were randomly assigned to two groups. Group B (*n* = 30) received 3 ml of 0.5% hyperbaric bupivacaine with 0.5 ml of normal saline and Group BT (*n* = 30) received 3 ml of hyperbaric bupivacaine with 0.5 ml (25 mg) of preservative free tramadol by intrathecal route at L3-L4 intervertebral space. Patient's vital parameters, sedation scores and side effects were recorded every 2 min for the first 20 min and then every 10 min for the rest of surgical procedure.

Results: The vital parameters such as heart rate, blood pressure, oxygen saturation, and respiratory rate were comparable and were within normal limits in both the groups. Sedation score in both the groups was well comparable.

Conclusion: Tramadol (25 mg) with hyperbaric bupivacaine intrathecally provides a better post-operative analgesia with preserved hemodynamic stability and minimal sedation.

Key words: Bupivacaine, Intrathecal adjuvants, Sedation, Spinal anesthesia, Tramadol, Vital parameters

INTRODUCTION

The provision of effective anesthesia during the procedure and post-operative analgesia is still evolving and getting fine-tuned in the specialty of anesthesia. One of the primary aims of anesthesia is to provide analgesia during the surgical procedure.

Anesthesiologists are the leaders in the development of acute post-operative pain services and application of evidence-based practice to acute post-operative pain and creation of innovative approaches to acute pain management. If we can provide post-operative analgesia in a simple and inexpensive manner, it may go long way in alleviation of pain and suffering. In order to do these, a number of adjuvants have been added to spinal anaesthetics. During the past two decades epidural and intrathecal administration of drugs have been used increasingly for relief of post-operative pain. Various drugs have been studied including morphine, pethidine, ketamine, tramadol, clonidine, neostigmine, dexmedetomidine, and midazolam.

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Although various drugs used as adjuvants in spinal anesthesia provide good post-operative analgesia they are also associated with various side effects such as respiratory depression,[1] sedation, hypotension, bradycardia, nausea, and vomiting. Tramadol in contrast to a centrally acting

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opioid analgesic has minimal respiratory depressant effect,[2,3] because it has 6000-fold less affinity for μ receptors compared to morphine.[4,5] It also inhibits serotonin and norepinephrine reuptake in the spinal cord and has no reported neural toxicity.[6] Therefore, tramadol has the potential to provide effective post-operative analgesia with no risk of respiratory depression after central neuraxial administration. Hence, we thought it would be appropriate to study the hemodynamic and sedative effects of intrathecally administered tramadol and compare it with intrathecally administered hyperbaric bupivacaine in patients posted for lower abdominal surgical procedures.

MATERIALS AND METHODS

This prospective randomized control study was done after obtaining institutional ethical committee approval and written informed consent. 60 patients of physical status ASA I and II aged between 18 and 50 years of both the sexes posted for elective lower abdominal surgical procedures from various specialties under subarachnoid block were included in this study. This study was carried out at Kempegowda Institute of Medical Sciences and Hospital, Bangalore during the period of 2004-2005. Patients with spinal deformity, history of allergy to the drugs used and having contraindications to regional anesthesia were excluded from the study.

Patients were randomly divided into two groups (B and BT) of 30 each. Group B received 3 ml of 0.5% bupivacaine heavy with 0.5 ml of 0.9% normal saline intrathecally and Group BT received 3 ml of 0.5% bupivacaine heavy with preservative free tramadol 0.5 ml that is 25 mg intrathecally. In the operating room, after securing intravenous access with appropriate sized cannula, intravenous fluid started. Pulse rate, blood pressure (BP), respiratory rate (RR), oxygen saturation (SPO_2), and electrocardiogram monitoring were applied and recorded before the induction of spinal anesthesia and thereafter during the procedure. Spinal anesthesia was carried out in sitting position, with 26 G Quincke's needle at L_{3-4} interspace by a standard technique. After free flow of cerebrospinal fluid, 3.0 ml of hyperbaric bupivacaine 0.5% with 0.5 ml of 0.9% normal saline was deposited slowly in patients of Group B. In patients of Group BT 3.0 ml of 0.5% hyperbaric bupivacaine with 0.5 ml (25 mg) of preservative free tramadol was deposited. After the drug was deposited, the patients were made to lie down in supine position immediately. Pulse rate, BP were recorded immediately and at 5, 10, 15, 30, 60, 120, 180 min. Side effects of intrathecal administration of tramadol such as nausea, vomiting, hypoxemia, hypotension, bradycardia, and sedation were noted down during the intra-operative and post-operative period. The patients were followed up for 24 h after surgery.

Hypotension (defined as decrease in systolic BP more than 20% of the base line value or <90 mm of Hg) after spinal injection was treated by increasing the rate of intravenous fluid administration and/or 5-10 mg of intravenous administration of bolus dose of ephedrine hydrochloride as and when required. Bradycardia (heart rate <60 bpm) was treated with intravenous atropine 0.2 mg as and when needed. Respiratory depression defined as RR <8/min and or SpO_2 <85%. This was planned to be managed with bag and mask ventilation or intubation and invasive positive-pressure ventilation if necessary.

The degree of sedation was assessed by "Ramsay sedation scale."

Ramsay Sedation Scale

1. Patient is anxious and agitated or restless, or both
2. Patient is cooperative, oriented, and tranquil
3. Patient responds to commands only
4. Patient exhibits brisk response to light glabellar tap or loud auditory stimulus
5. Patient exhibits a sluggish response to light glabellar tap or loud auditory stimulus
6. Patient exhibits no response.

Statistical Analysis

All the parametric data were analyzed using Student's *t*-test and nonparametric data by Chi-square test, statistical software SPSS 11.0, and Systat 8.0 were used for the analysis of the data and the result was considered to be statistically significant only if $P < 0.05$.

RESULTS

Both the groups were comparable with respect to age, sex, height, and weight distribution (Table 1), ASA grade and duration of the surgery (Table 2).

Table 1: Basic characteristics of the study

Basic characteristics	Group B	Group BT
Number of patients	30	30
Age in years (Mean±SD)	36.53±8.83	36.63±7.89
Height in cm (Mean±SD)	158.60±9.98	157.73±8.17
Weight in kg (Mean±SD)	57.47±8.66	55.73±5.54
Sex *N* (%)		
Male	15 (50.0)	16 (53.3)
Female	15 (50.0)	14 (46.7)

SD: Standard deviation, Group B: Bupivacaine, Group BT: Bupivacaine-tramadol

The mean SpO_2 of both the groups are shown in Figure 1, the values between both the groups are well comparable. The mean pulse rate and RR of both the groups are shown in Table 3. The pulse rate and RR between both the groups at 5, 10, 15, 20, 25, 30, 60, 120, and 180 min were comparable with no statistical differences. Table 4 shows mean systolic and diastolic BP values at different intervals in both the groups, which were comparable.

DISCUSSION

A revolution in the management of acute post-operative pain has occurred during the past two decades. Anesthesiologists with their knowledge of and familiarity with pharmacology, various regional techniques and the neurobiology of nociception are continually in the forefront of clinical and research advances in acute post-operative pain management.

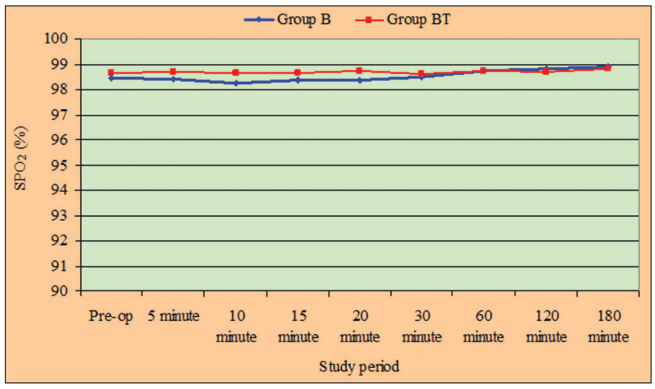

Figure 1: Comparison of oxygen saturation between two groups

Spinal anesthesia with bupivacaine hydrochloride is popular for longer procedures due to its prolonged duration of action, but there is a need to intensify and increase duration of sensory blockade without increasing the intensity and duration of motor blockade and thus prolong the duration of post-operative analgesia. The addition of opioids has been suggested as a method to accomplish these goals. Several drugs have been added as adjuvants to bupivacaine for intrathecal anesthesia namely opioids, midazolam, clonidine, dexmedetomidine, but they are also associated with side effects like respiratory depression, pruritus, hypotension, bradycardia, sedation, nausea and vomiting. Therefore, our study was performed to demonstrate that intrathecal administration of 25 mg of tramadol when used with 0.5% bupivacaine for prolongation of post-operative analgesia produces less hemodynamic instability with minimal sedation.

The result of the study showed that there was no significant difference between groups in the pattern of decrease in systolic or diastolic BP, RR, heart rate, and SPO_2.

Table 2: Comparison of duration of surgery and ASA grade between two groups

Basic characteristics	Group B	Group BT	Remarks
ASA grade (%)	I - 26 (86.7) II - 4 (13.3)	I - 25 (83.3) II - 5 (16.7)	ASA grade is statistically similar between two groups with *P*=0.718
Duration of surgery (Mean±SD)	93.50±39.53	96.00±43.52	Duration of surgery is statistically similar between two groups with *P*=0.817

SD: Standard deviation, Group B: Bupivacaine, Group BT: Bupivacaine-tramadol

Table 3: Comparison of pulse rate (beats/min) and RR between two groups

Study period (minutes)	Pulse rate (beats/min)		*P* value	RR		*P* value
	Group B	Group BT		Group B	Group BT	
Pre-operative	77.53±7.57 (64-88)	79.13±7.73 (68-92)	0.421	13.10±0.66 (12-14)	12.97±0.81 (12-14)	0.487
5	79.13±7.12 (66-90)	77.20±8.98 (62-90)	0.359	12.50±0.63 (12-14)	12.57±0.68 (11-14)	0.695
10	79.60±8.50 (64-99)	76.67±9.40 (60-96)	0.210	12.47±0.57 (12-14)	12.20±0.41 (12-13)	0.042*
15	79.87±8.37 (60-92)	76.13±9.74 (62-94)	0.117	12.67±0.76 (12-15)	12.33±0.48 (12-13)	0.046*
20	78.97±8.33 (62-92)	76.67±10.93 (60-98)	0.383	12.77±0.68 (12-14)	12.73±0.45 (12-13)	0.823
30	81.07±7.71 (60-99)	77.67±10.93 (62-96)	0.160	12.67±0.61 (12-14)	12.23±0.50 (12-14)	0.004**
60	80.33±6.62 (64-90)	77.93±8.76 (64-94)	0.236	12.93±0.73 (12-15)	12.27±0.50 (11-14)	0.001**
120	80.67±6.09 (68-90)	79.07±9.09 (64-96)	0.426	12.87±0.82 (12-15)	12.60±0.56 (12-14)	0.147
180	81.40±6.24 (64-90)	80.27±9.23 (64-94)	0.580	13.23±0.73 (12-15)	12.70±0.47 (12-13)	0.001**

Results are presented in Mean±SD (Min-Max). *,**: *P*<0.05 , RR: Respiratory rate, SD: Standard deviation, Group B: Bupivacaine, Group BT: Bupivacaine-tramadol

Table 4: Comparison of systolic and diastolic BP between two groups

Study period (minutes)	Systolic BP (mmHg)		*P* value	Diastolic BP (mmHg)		*P* value
	Group B	Group BT		Group B	Group BT	
Pre-operative	120.00±6.95 (110-130)	123.20±7.91 (108-138)	0.103	76.03±6.29 (60-90)	78.13±5.48 (64-86)	0.173
5	110.80±6.80 (100-122)	113.13±8.15 (100-130)	0.233	71.13±7.18 (56-80)	75.07±5.79 (60-82)	0.023*
10	108.80±4.29 (100-120)	111.13±7.42 (100-126)	0.141	70.37±6.64 (58-82)	73.80±6.42 (58-82)	0.046*
15	109.07±4.72 (100-120)	111.87±7.57 (100-126)	0.091	70.40±7.13 (56-82)	72.93±5.65 (60-82)	0.133
20	110.67±5.23 (102-124)	113.33±7.43 (100-130)	0.114	71.22±6.74 (54-84)	73.80±5.10 (62-82)	0.166
30	110.80±4.63 (102-124)	115.60±8.64 (102-132)	0.009**	71.67±6.01 (58-82)	74.93±4.98 (68-84)	0.026*
60	112.67±5.71 (104-126)	117.93±8.14 (104-134)	0.005**	73.20±6.05 (60-82)	76.27±4.89 (64-84)	0.035*
120	114.40±5.79 (106-130)	120.80±7.16 (104-130)	<0.001**	74.33±5.85 (60-80)	77.07±5.14 (64-84)	0.059*
180	116.27±6.19 (108-130)	122.27±6.88 (110-134)	0.001**	75.40±5.64 (60-82)	76.67±4.65 (66-84)	0.346

Results are presented in Mean±SD (Min-Max). *,**: *P*<0.05 , SD: Standard deviation, Group B: Bupivacaine, Group BT: Bupivacaine-tramadol, BP: Blood pressure

Wang *et al.*[7] in their experimental work found that the decrease in sympathetic efferent activity after spinal anesthesia is related to bupivacaine and not to the intrathecal opioid which was added.

Alhashemi and Kaki[8] in 2003 found that Intrathecal tramadol did not seem to influence the intraoperative hemodynamic profile.

In our study, none of the patients experienced respiratory depression. Baraka *et al.*[9] in 1993 found that mean PaO_2 values did not change in the epidurally administered tramadol group. Similar findings were also observed by Yaddanapudi *et al.*[10] in 2000 with epidurally administered tramadol.

CONCLUSION

It can be inferred that tramadol 25 mg (preservative free) in combination with bupivacaine 0.5% heavy can be safely administered intrathecally for better post-operative analgesia in lower abdominal surgical procedures without producing hemodynamic instability and minimal sedation.

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