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Research Article

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Evaluation of Postoperative Analgesic Effects of Intrathecal Tramadol with Bupivacaine and Bupivacaine Alone in Patients Undergoing Lower Abdominal Surgery: A Comparative Study

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ABSTRACT

Effective pain control is essential for optimum care of patients in the postoperative period. Epidural and intrathecal administration of drugs have been used increasingly for relief of postoperative pain. Tramadol is a centrally acting analgesic that has minimal respiratory depressant effects compared to other opioids like morphine. This study was conducted to evaluate safety and efficacy of the intrathecal tramadol and to determine the postoperative analgesia. Sixty ASA I and II patients were randomly assigned to two groups. Group B (n=30) received 3ml of 0.5% heavy bupivacaine with 0.5ml of normal saline and group BT (n=30) received 3ml of heavy bupivacaine with 0.5ml(25mg) of preservative free tramadol by intrathecal route at L3-L4 intervertebral space. Patient's vital parameters, level of sensory block and sedation score were recorded every two minutes for the first 20 minutes and then every ten minutes for the rest of surgical procedure. Assessment of pain was done using visual analogue scale (VAS= 0-100mm). Duration of analgesia was estimated from the time of completion of spinal injection to administration of rescue analgesic. In group BT patients the VAS score was significantly lower as compared to group B patients. The mean duration of analgesia was 393.33±123.21 minutes in group BT, whereas in group B it was 167.47±12.46 minutes, which was found to be statistically significant. We hereby conclude that 25mg tramadol with hyperbaric bupivacaine intrathecally provides a better postoperative analgesia in lower abdominal surgeries.

Keywords: Intrathecal opioids; Tramadol; Bupivacaine; Postoperative analgesia; Lower abdominal surgeries

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INTRODUCTION

Anaesthesiologist plays a major role in post-operative pain management. Spinal anaesthesia with 0.5% hyperbaric bupivacaine is routinely administered for lower abdominal and major gynaecological surgeries. To increase the duration of analgesia produced by local anaesthetics a number of adjuvants have been added through the central neuraxial route. Intralthecal opioid administration has been demonstrated to provide effective post-operative analgesia after variety of surgical procedures, at the cost of increased risk of respiratory depression [1].

Tramadol, in contrast to a central acting 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. however pruritus, nausea, vomiting, urinary retention, unpredictable respiratory depression [7,8] has directed the clinicians to use a lower dose of tramadol, the present study was undertaken to assess the effects of intrathecally administered tramadol with bupivacaine on the duration of post operative analgesia as well as its safety and efficacy in patients undergoing lower abdominal surgeries.

EXPERIMENTAL SECTION

This prospective randomized control study was done after obtaining institutional ethical committee approval and written informed consent. Sixty 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 specialities under subarachnoid block were included in this study. Patients with spinal deformity, history of allergy to the drugs used and having contraindications to regional anaesthesia 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 0.5ml of 0.9% normal saline intrathecally and Group BT received 3ml of 0.5% bupivacaine heavy with preservative free tramadol 0.5ml that is 25 mg intrathecally.

All the patients received oral diazepam 10 mg at night preoperatively. Visual analogue scale (VAS), consisting of 100 mm line with '0' = no pain and 100= worst possible pain, was explained to all the patients preoperatively. In the operating room, after securing intravenous access with appropriate sized cannula, intravenous fluid started. Pulse rate, blood pressure, respiratory rate, oxygen saturation and ECG monitoring were applied and recorded before the induction of spinal anaesthesia and thereafter during the procedure. Spinal anaesthesia was carried out in sitting position, with 26G Quincke`s needle at L_{3-4} interspace by a standard technique. After free flow of CSF, 3.0ml of hyperbaric bupivacaine 0.5% with 0.5ml of 0.9% normal saline was deposited slowly in patients of group B. In patients of group BT 3.0ml of 0.5% hyperbaric bupivacaine with 0.5ml (25mg) of preservative free tramadol was deposited. After the drug was deposited, the patients were made to lie down in supine position immediately. Pulse rate, blood pressure were recorded immediately and at 5, 10, 15, 30, 60, 120, 180 minutes. Level of sensory blockade was assessed by using the 23G hypodermic needle immediately after spinal anaesthesia. Side effects of intrathecal administration of tramadol like nausea, vomiting, hypoxemia, hypotension and sedation were noted down during the intra-operative and postoperative period. (Figure 1)

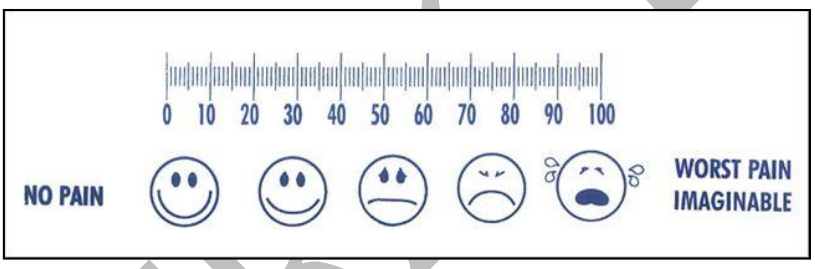

Figure 1: Visual Analogue scale

The duration of analgesia in groups B and BT was obtained from the completion of spinal anaesthesia to the time of rescue analgesic administered on demand or when the VAS score was ≥ 40mm. The patients were followed up for 24 hours after surgery. They were asked to point out the intensity of their pain on the linear visual analogue scale along with heart rate and blood pressures were recorded in the recovery room. The time at which supplementation given was noted down along with drug and dosage. This point corresponded to poor analgesia on the scale. Total dose of analgesics administered to the patients in 24 hours was noted. Sedation score (awake=0, sleeping comfortable and easily arousable=1, deep sleep but arousable=2, deep sleep but not arousable=3) was noted every 2 minutes for 20 minutes, then every 10 minutes till the end of surgery. Hypotension (defined as decrease in systolic blood pressure more than 20% of the baseline value or less than 90mm of Hg) after spinal injection was treated by increasing the rate of intravenous fluid administration and / or 5-10mg of intravenous administration of bolus dose of ephedrine hydrochloride as and when required. Bradycardia (Heart rate < 60 beats per minute) was treated with intravenous atropine 0.2mg as and when needed.

All the parametric data were analysed 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-value <0.05.

RESULTS

The two groups, group B and group BT were comparable with respect to age, sex, height and weight distribution, ASA physical status and duration of the surgery (Table 1). The duration of analgesia or pain free period in group B was 167.47 minutes (with standard deviation of 12.46) and in group BT it was 393.33 minutes (with standard deviation of 123.21) as shown in table 2.

In our study the total analgesic dose in group B was 202.50mg with standard deviation of 34.95 and in group BT it was 105mg with standard deviation of 37.37, p value is < 0.001, which is highly significant. No clinically significant changes were observed in the heart rate, blood pressure, respiratory rate and sedation score in each of the two groups intraoperative and postoperatively. A higher VAS score (≥ 40 mm) was observed in group B, whereas group BT patients showed significantly lower VAS score (≤ 40 mm) more than 6 hours after the intrathecal injection

None of the patients had any postoperative complications like pruritus, vomiting, respiratory depression and lower limb weakness. (Figures 2-4)

Table 1: Demographic profile of the study

Basic characteristics		Group B (n=30)	Group BT (n=30)	p Value
Age (in years, Mean ± SD)		36.53±8.83	36.63±7.89	p=0.963
Height (in cm, Mean ± SD)		158.60±9.98	157.73±8.17	p=0.714
Weight (in kg, Mean ± SD)		57.47±8.66	55.73±5.54	p=0.360
Sex	Male	15 (50.0%)	16 (53.3%)	p=0.796
	Female	15 (50.0%)	14 (46.7%)	
ASA grade		I-26 (86.7%)	I-25 (83.3%)	p=0.718
		II-4 (13.3%)	II-5 (16.7%)	
Duration of surgery (in minutes, Mean ± SD)		93.50±39.53	96.00±43.52	p=0.817

Table 2: Comparison of Study parameters (Analgesia parameters) between two groups

Study parameters	Group B	Group BT	p value
Duration of Analgesia (minutes)	167.47±12.46	393.33±123.21	<0.001**
	(144-188)	(220-720)	
Analgesic Time (Inj. Diclofenac sodium 75 mg IM) (in minutes)	180.50±13.64	404.57±121.48	<0.001**
	(158-210)	(230-730)	
Total rescue analgesic dose (in mg)	202.50±34.95	105.00±37.37	<0.001**
	(150-225)	(75-150)	

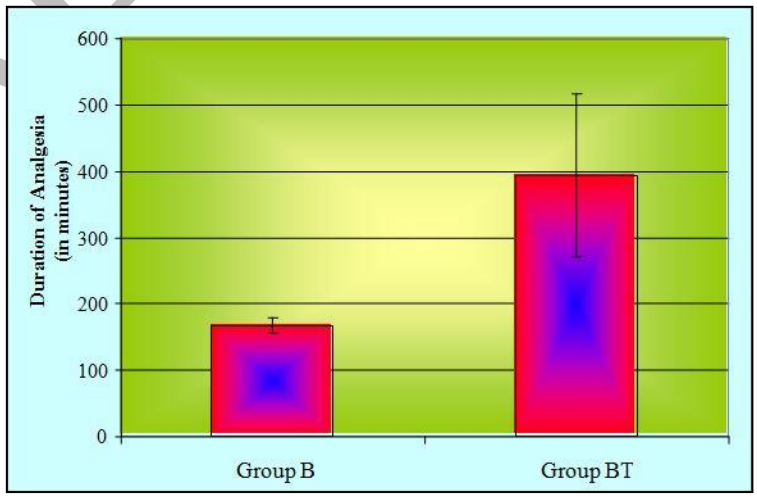

Figure 2: Duration of Analgesia (minutes)

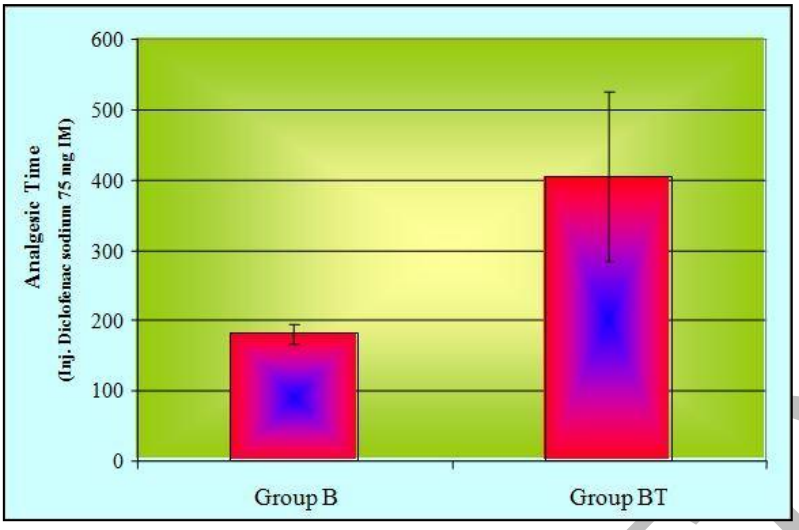

Figure 3: Analgesic Time (Inj. Diclofenac sodium 75 mg IM)

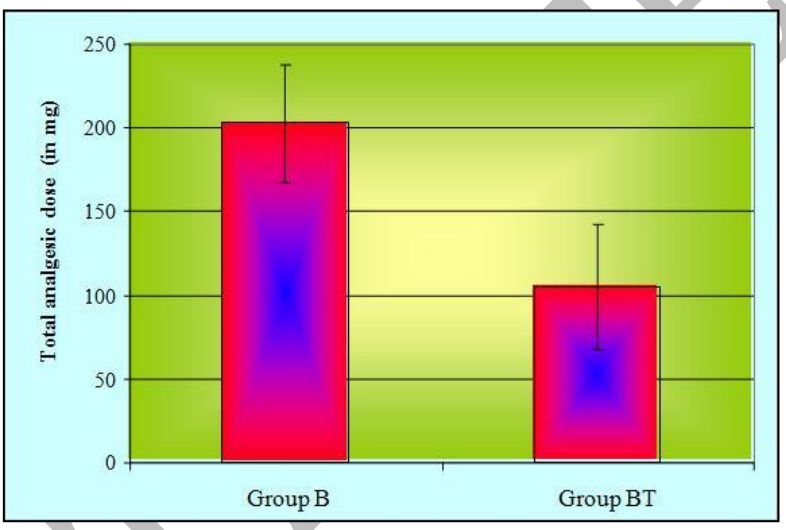

Figure 4: Total analgesic dose (in mg)

DISCUSSION AND CONCLUSION

Effective pain control is essential for optimum care of patients in the postoperative period. If a method of analgesia is to be successful and available to large number of patients, it must be suitable for use in a general surgical ward and should require only simple routine nurse monitoring.

In recent year's epidural and intrathecal narcotic therapies have been used increasingly for the postoperative pain relief. The present clinical study is a randomized prospective study in 60 patients belonging to the age group of 18-50 years of both the sexes and of ASA grade I and II who were scheduled to undergo selective lower abdominal surgical procedures from various specialities. The patients of group B received 3 ml of 0.5% bupivacaine heavy with 0.5 ml of 0.9% normal saline intrathecally and patients of group BT received 3 ml of 0.5% bupivacaine heavy with tramadol (preservative free) 0.5ml, i.e., 25 mg intrathecally.

In the present study there was no significant difference between groups in the pattern of decrease in systolic or diastolic blood pressure during this period. Alsheshmi et al found that Intrathecal tramadol did not seem to influence the intraoperative hemodynamic profile [9].

The mean duration of analgesia in the group B was 167.47 ± 12.46 minutes and in group BT it was 393.33±123.21 minutes. So there is considerably a longer duration of analgesia in group BT compared to group Brijesh Jain et al in 2000 found that intrathecal tramadol 25 mg added to bupivacaine provided a mean duration of postoperative pain relief of about eight hours, which is similar to our finding [10].

The effectiveness of postoperative pain relief based on VAS in group BT was higher than group B especially after 3 hours, which is statistically significant. The addition of tramadol has improved the effectiveness of postoperative pain relief.

In 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 postoperative analgesia in lower abdominal surgical procedures

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