

A Comparative Study of the Effects of Intrathecal Tramadol and Intrathecal Fentanyl as Adjuvants with 0.5% Bupivacaine Heavy in Lower Limb Surgery.

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ABSTRACT

Background: The aim of this study is to compare the effects of tramadol and Fentanyl as intrathecal adjuvant to hyperbaric Bupivacaine in lower limb surgeries under spinal anaesthesia. **Methods:** 100 patients of ASA status I and II posted for lower limb surgery were randomly divided into two groups. Group T was administered Hyperbaric Bupivacaine 15 mg + tramadol 25 mg, group F was administered Hyperbaric Bupivacaine 15 mg + Fentanyl 25 µg. Hemodynamic parameters, duration and quality of sensory and motor block and any side effects were assessed. **Results:** Intrathecal tramadol and intrathecal fentanyl acted synergistically to potentiate bupivacaine induced sensory spinal block. Excellent surgical anaesthesia and an extended analgesia were observed in the post-operative period with minimum side effects in both groups. **Conclusion:** Addition of either intrathecal tramadol or fentanyl to bupivacaine produced comparable hemodynamic changes, post-operative analgesia and sensory blockade.

Keywords: Intrathecal, tramadol, Fentanyl, bupivacaine.

INTRODUCTION

The spinal subarachnoid block is one of the most versatile regional anaesthesia techniques available today. Spinal anaesthesia is advantageous in that it uses a small dose of the local anaesthetic, is simple to perform and offers a rapid onset of action, reliable surgical analgesia and good muscle relaxation.^[1,2] The aim of intrathecal local anaesthetic is to provide adequate sensory and motor block necessary for all infra umbilical surgeries. These advantages are sometimes offset by the relatively short duration of action and complaints of post-operative pain when it wears off. If we can provide post-operative analgesia in a simple and inexpensive manner, it may go a long way in alleviation of pain and suffering.

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Spinal anaesthesia with hyperbaric Bupivacaine Hydrochloride is popular for longer procedures due to its prolonged duration. 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 postoperative analgesia. The addition of opioids has been suggested as a method to accomplish these goals. Tamadol is a lipophilic, moderately potent, partial opioid agonist with central alpha-1 agonist activity.^[3,4] It has got the advantage of prolonging the intensity of intra and postoperative

analgesia when combined with intrathecal Hyperbaric Bupivacaine.

Various adjuvants have been added to Bupivacaine hydrochloride to shorten the onset of block and prolong the duration of the block. Fentanyl Citrate a lipophilic opioid agonist is used as an adjuvant, which prolongs the duration of spinal block.

This study was designed to examine the effects of adding fentanyl and tramadol to Hyperbaric Bupivacaine Hydrochloride in spinal anaesthesia on duration and recovery of sensory and motor blockade.

MATERIALS AND METHODS

This study was conducted in the Department of Anaesthesiology in cooperation with the Department of Orthopaedic and Department of Plastic Surgery, S.C.B Medical College & Hospital, Cuttack over a period of 24 months from November 2012 to October 2014. After obtaining approval from the Ethical Clearance Committee of the hospital, 100 patients belonging to "American Society of Anaesthesiology" (ASA) GRADE I & II Physical Status aged between 18 to 75 years, scheduled for elective lower limb surgeries under spinal anaesthesia were included in the study. The selection of patients was carried out randomly, depending on the lists of operations submitted by the surgical team on the previous day. A written informed consent was obtained from all these patients. Exclusion criteria were contraindications for Sub-arachnoid block and emergency surgery, hypersensitivity to any of the drugs, patient refusal, bleeding diathesis. Routine investigations were

carried out before taking up the patient for surgery. All patients were kept nil per orally from midnight. All patients were instructed about the visual analogue scale for pain. 0- no pain and 10- worst pain ever. All patients were given injection ondansetron 4mg I.V prior to spinal anaesthesia. After shifting the patients to the operation theatre, intravenous access was secured with 18gauge cannula. All patients are preloaded with 15 ml/kg Ringer's lactate 15 mins before surgery. Under strict aseptic precautions spinal anaesthesia was performed using 25 gauge disposable Quinke type of spinal needle at L2 – L3 spinal intervertebral space by midline approach in sitting position.

Patients were monitored continuously using electrocardiograph, NIBP and pulse oximetry. In supine position before the spinal injection baseline arterial blood pressure and heart rate were recorded.

Patients were randomly allocated into two following groups

Group T: spinal anaesthesia with addition of 25 mg tramadol to 3ml of 0.5% Bupivacaine hydrochloride (hyperbaric).

Group F: spinal anaesthesia with addition of 25 µg fentanyl to 3ml of 0.5% Bupivacaine hydrochloride (hyperbaric)

After spinal anaesthesia all the patients were turned supine, pulse rate and blood pressure were recorded immediately and at 5, 10, 15, 30, 60,120, 180 minutes.

Level of sensory blockade was checked with a 23G hypodermic needle and level of motor blockade were assessed by using the Bromage scale immediately after spinal anaesthesia and at 5, 10, 15, 30, 60, 120, 180 minutes.

Bromage scale 0-full flexion of kneed and feet; 1 – just able to flex knees, full flexion of feet; 2-unable to flex knees, but some flexion of feet possible, 3- unable to move legs or feet. Time for two-segment regression of sensory level in minutes was also noted down.

The side effects like nausea, vomiting, pruritis, shivering, desaturation or hypoxaemia (SpO₂ <90%), respiratory depression (RR < 10), hypotension, sedation, urinary retention due to intrathecal administration of fentanyl were noted down during the perioperative period. Hypotension was defined as a decrease in systolic blood pressure more than 30% of the base line and was treated with Inj. Ephedrine 6 mg increments. IV. Inj. Atropine was given when heart rate decreases > 20% of baseline or become < 50/min. The retention of urine was noted in the non – catheterised patients.

The duration of postoperative analgesia was calculated from the time when the block was given. The patients were followed up to 24 hours after surgery. They were asked to point out the intensity

of their pain on the linear visual pain scale. VAS score along with heart rate and blood pressure was recorded in the recovery room (3 hours after spinal anaesthesia), evening of surgery (6 hours after spinal anaesthesia) and on the first post-operative day (24 hours after spinal anaesthesia). Patients were explained about “Visual analogue scale” (VAS) which is a 10 cm scale.

0. Indicating no pain
1. Probably no pain
2. Mild discomfort
3. Mild Pain
4. Mild to moderate pain
5. Moderate pain
6. Increased moderate pain
7. Moderate to severe pain
8. Severe pain
9. Severe to excruciating pain
10. Mad with pain

During the post-operative period the injections of analgesics or opioids were avoided until demanded by the patients due to pain. The time at which first rescue analgesia (iv paracetamol) given was noted down. This point corresponded to poor analgesia on the scale. Pain assessment was conducted by a single observer. The time taken for complete motor and sensory recovery was noted.

The duration of motor blockade was taken from the time of injection of the drug to the time when the patient was able to move his ankle. The duration of sensory blockade was taken from the time of injection of the drug to the time when the patient was able to appreciate pain in the S1 dermatome (i.e. the heel).

Data was collected and the results were subjected to statistical analysis before making conclusions and results. Statistical analyses were performed using SPSS (Statistical Package for Social Sciences) Quantitative variables were expressed as mean + SD (standard deviation), while qualitative variables were expressed as a percentage. All the parametric data were analysed by Student's t test and nonparametric data by Chi-square test, and the result was considered to be significant if P <0.05.

RESULTS

There was no statistical significant difference among the two groups regarding demographic profile like age, sex, height, weight and duration of surgery.

There was neither any significant difference in heart rate over time in both groups nor there was any significant difference between Groups in the pattern of decrease in heart rate [Table 1].

Table 1: Shows mean heart rate and standard deviation at different intervals.

Minutes	Group T Mean (Sd)	Group F Mean (Sd)	P value
Base Line 0	82.0 (10.6)	80.3 (11.4)	P=0.68
5	78.5 (11.6)	76.0 (9.8)	P=0.68
10	73.7 (11.3)	73.8 (10.7)	P=0.68
15	71.5 (11.4)	71.0 (10.5)	P=0.68
30	71.1 (10.9)	69.7 (12.7)	P=0.68
60	71.6 (10.0)	67.3 (12.7)	P=0.19
120	70.4 (10.5)	70.8 (11.4)	P=0.95

Table 2: Shows mean systolic blood pressure at different intervals

Base line 0	Group T	Group F	P value
Base line 0	124.6 (11.2)	128.9 (14.5)	P=0.16
5	116.8 (13.2)	121.1 (14.5)	P=0.16
10	110.5 (16.8)	115.9 (16.8)	P=0.16
15	111.2 (12.2)	115.4 (12.5)	P=0.16
30	109.7 (14.7)	115.5 (13.4)	P=0.16
60	113.0 (11.9)	114.8 (12.0)	P=0.62
120	112.1 (12.6)	120.1 (11.1)	P=0.10

There was neither any significant difference in systolic blood pressure over time in both groups nor there was any significant difference between

Groups in the pattern of decrease in systolic blood pressure [Table 2].

Table 3: Shows diastolic blood pressure at different intervals

Base line 0	Group T	Group F	P value
Base line 0	79.6 (10.2)	79.1 (7.9)	P=0.33
5	75.1 (9.6)	74.8 (9.4)	P=0.33
10	72.0 (11.3)	68.6 (9.7)	P=0.33
15	72.4 (9.3)	69.2 (10.1)	P=0.33
30	72.4 (8.3)	68.0 (12.1)	P=0.33
60	71.2 (7.6)	71.7 (9.5)	P=0.83
120	70.8 (8.0)	68.1 (13.6)	P=0.54

There was neither any significant difference in diastolic blood pressure over time in both groups, nor there was any significant difference between

Groups in the pattern of decrease in diastolic blood pressure [Table 3].

Table 4: Shows visual analogue scale at immediate post op, 6 hrs and 24 hrs.

Visual analogue scale	Group T Mean (Sd)	Group F Mean (Sd)
0	0	0.1 (0.4)
6	0.6 (1.4)	0.6 (0.7)
24	2.7 (1.5)	1.7 (1.2)

Visual analogue scale 6 hours, post operatively was significantly more likely to be in Group T as compared to Group F. Visual analog scale 24 hours

post operatively in group T was significantly more likely to be than in Group F [Table 4].

Table 5: Characteristics of spinal block

Variables	Group F in min (Mean ±Sd)	Group T in min (Mean ±Sd)	Significance
Time of onset of sensory block	8.2±1.6	8.0±1.5	0.235
Time of onset of motor block	9.5±2.3	9.3±2.7	0.124
Time taken to reach highest level of sensory block	10.4±4.01	9.33±3.50	0.346
Time to 2 segment regression of sensory level	93.2±23.9	95.4 ±19.3	P=0.72
Time of first request for Analgesia	562.0 ±152.1	551.2±115.0	P=0.78
Shows total Analgesic requirement	106.8 ±34.7	99.2±24.1	P=0.37
Time to full motor recovery	228.8±27.4	227.8±27.2	P=0.90

Table 6: Side Effects

Variables	Group T	Group F
Nausea	Nil	Nil
Vomiting	Nil	Nil
Pruritis	2	2
Shivering	Nil	0
Desaturation or hypoxaemia (SpO2 < 90%)	Nil	Nil
Sedation	Nil	Nil
Urinary retention	Nil	Nil

There was no statistically significant difference regarding the characteristics of spinal block and side effects among two groups [Table 5,6].

DISCUSSION

In recent years, the use of intrathecal narcotics has become widespread, albeit at the cost of an increased risk for respiratory depression. Tramadol, in contrast, is a centrally acting analgesic that has minimal respiratory depressant effects, by virtue of its 6000 fold decreased affinity for μ receptors compared to morphine^[5]. Fentanyl has a rapid onset and shorter duration of action following intrathecal administrations. It prolongs the duration of the bupivacaine induced sensory blockade. This suggests a potential synergism between fentanyl and bupivacaine as reported in an animal study by Wang et al^[6]. Gielen MJM et al^[7] in 1993 reported that fentanyl is one of the safest opioids. Akanmu N.O et al^[8] (2013) also reported that in adding 25 mcg Fentanyl to 10 mg of 0.5% hyperbaric Bupivacaine intrathecally for lower limb surgeries significantly prolonged the duration of complete analgesia and reduced the need for postoperative analgesia without an increase in severe side effects. Alsheshmi J.A et al^[9] in found that intrathecal tramadol did not seem to influence the intra operative hemodynamic profile. Same findings also with the study conducted by Mostafa G.M. et al^[10]. None of the patients in our study experienced respiratory depression. Baraka A et al^[11] found that mean PaO2 values did not change in the epidurally administered tramadol group. Scott et al^[12] studied different dosages from 0 to 50 mcg of fentanyl and observed that not a single patient had respiratory depression.

The mean duration of analgesia in the fentanyl group was 562.0 minutes and in group T was 551 minutes. The two groups did not differ significantly with regard to the mean duration of analgesia or with regard to the total dose of analgesics required in 24 hours. Brijesh Jain et al^[13] found that intrathecal tramadol 25 mg added to bupivacaine provided a mean duration of post-operative pain relief of about eight hours, which is similar to our finding. Same findings also observed by Mostafa G. M. et al^[10]. Prosser D.P. et al^[14], Dellikan A E et al^[15]

We found that the time for two-segment regression of sensory level did not differ significantly in both groups. An average of 90 min was the time taken for two segment regression of sensory level in both groups. Other studies showed lesser time for two segment regression when a local anaesthetic alone was used. As far as side effects of intrathecal opioids were concerned patients in both groups had minimal side effects. Only two patients in both groups had pruritis. Kumar B, et al^[16] have found significant priority with the use of intrathecal opioids. The prophylactic use of ondansetron in both groups would explain the incidence of minimal pruritis and nausea in our study.

CONCLUSION

Addition of either intrathecal tramadol or fentanyl to bupivacaine produced comparable hemodynamic changes, post-operative analgesia, sensory blockade without prolonging motor blockade. Addition of both opioids produced minimal intraoperative and postoperative side effects.

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