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Original Research Article

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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Conflict of interest: Nil

Abstract:

Background: Spinal anaesthesia with hyperbaric Bupivacaine hydrochloride is popular for longer procedures due to its prolonged duration. With the addition of opioids, we can intensify and increase the duration of sensory blockade without increasing the intensity and duration of motor blockade, thus prolonging the duration of postoperative analgesia. This study aimed to compare the onset, duration, and recovery of sensory and motor blockade, perioperative hemodynamic parameters, level of sedation, and time to first rescue analgesia, side effects, and complications in the perioperative period.

Material and Methods: In this comparative, observational, and prospective study, a total of 60 patients were enrolled undergoing lower limb surgery under spinal anaesthesia, divided into two groups. Group-F received 0.5% bupivacaine heavy 3 ml (15 mg) + fentanyl 0.5 ml (25 µg) intrathecally, and Group-T received 0.5% bupivacaine heavy 3 ml (15 mg) + tramadol 0.5 ml (25 mg) intrathecally. Both groups were observed for characteristics of motor and sensory blockade, hemodynamic parameters, and perioperative complications. Patients were monitored for a Ramsay score for sedation, a VAS score for pain, and the time required for post-operative analgesia.

Result: The time to onset of sensory block at T10 level was statistically not significant between the two groups, while the time for regression of sensory blockade to the S2 dermatome was prolonged in group F as compared to group T. The mean time to achieve motor block was statistically not significant, while the time for regression of motor block from grade 3 to 0 was prolonged in group F as compared to group T. There was no significant difference in hemodynamic parameters between the two groups. The time required for first-rescue analgesia was longer in group F than in group T.

Conclusion: Intrathecal 0.5% hyperbaric bupivacaine with 25 µg fentanyl significantly prolonged both sensory and motor block as well as time for the 1st rescue analgesic when compared with 25 mg tramadol as adjuvant. Fentanyl also produces perioperative sedation.

Keywords: Lower limb surgery, spinal anaesthesia, Bupivacaine heavy, Fentanyl, Tramadol.

Introduction

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 the 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. This study aimed to compare the onset, duration, and recovery of sensory and motor blockade, perioperative hemodynamic parameters, level of sedation, and time to first rescue analgesia, side effects, and complications in the perioperative period in

patients undergoing lower limb surgery under spinal anaesthesia with 0.5% hyperbaric bupivacaine with fentanyl or tramadol as adjuvant. Fentanyl acts as a μ (mu) receptor agonist at the supraspinal site, leading to analgesia that is greater than that of morphine, pethidine, and alfentanyl. Its action on κ (Kappa) and δ (Delta) receptors leads to spinal analgesia. Action on the κ (Kappa) receptor also causes sedation. Tramadol is a synthetic 4-phenyl-piperidine analogue of codeine with mixed μ opioid and non-opioid activity. It also has peripheral local anaesthetic properties, and in addition to that, when compared to other opioids, it has less respiratory depressant effect. It has the advantage of prolonging the intensity of intra and postoperative analgesia when combined with intrathecal hyperbaric bupivacaine.

In this study, we have compared intrathecal tramadol with bupivacaine and fentanyl with bupivacaine in lower limb surgeries. We have observed the onset and duration of sensory and motor blockade, hemodynamic parameters, the duration of analgesia, and complications in both groups.

Materials and Methods

This was a comparative, observational, and prospective study. In this study, 60 patients scheduled for lower limb surgery were selected. Patients aged between 18 and 60 years with ASA grades I and II undergoing lower limb surgery under spinal anaesthesia were included in the study. The study excluded patients with age groups <18 years and >60 years; an ASA grade of III or above; pregnant females; patients with known hypersensitivity to bupivacaine, tramadol, or fentanyl; patients with hepatic or renal dysfunction; patients with coagulation disorder; patients with a current history of psychiatric illness; patients on beta blocker drugs; or any other contraindication to spinal anaesthesia. Patients were divided into two groups.

Group-F: 0.5% bupivacaine heavy 3 ml (15 mg) + fentanyl 0.5 ml (25 μg)

Group-T: 0.5% bupivacaine heavy 3 ml (15 mg) + tramadol 0.5 ml (25 mg)

Every patient had a pre-anaesthetic check-up, as per the institutional protocol. The nature and consequences of the study and the visual analogue scale for evaluating pain intensity were explained to them. Written and informed consent was obtained from all the patients. All patients were kept nil per oral for 8 hours. Venous access was secured using an 18 or 20-gauge intravenous cannula in the dorsum of the non-dominant hand. Patients were preloaded with 8–10 ml/kg of Ringer's lactate solution. Basal parameters such as heart rate, blood pressure, and oxygen saturation were noted using a pulse oximeter, a non-invasive blood pressure cuff, and an electrocardiography monitor (lead II and V5). Under all aseptic and antiseptic precautions, spinal anaesthesia was performed in the sitting/left lateral position at L2-L3 or L3-L4 intervertebral space with a 23 G Quincke's spinal needle. One of the selected drugs was injected slowly after a clear and free flow of CSF. Time and vitals at that time were noted. Pulse rate, mean arterial pressure, and SpO2 were recorded every 5 minutes initially for half an hour and then every hour interval till the end of surgery. During the course of anaesthesia, onset of sensory blockade (noted as loss of pinprick sensation at T10 level from time of subarachnoid injection), level of highest sensory dermatome, and time for regression of sensory blockade to S2 dermatome were noted.

Motor block was assessed with the Modified Bromage Scale as follows: 0: no motor block. 1: Inability to raise an extended leg; able to move knees and feet. 2: Inability to raise an extended leg and move the knee; able to move feet. 3: Complete motor block of limb. [1]

The onset of motor block was noted, and it's defined as the time from grade 0 to reach grade 3 on the Modified Bromage scale. The time to regression of motor blockade from grade 3 to grade 0 was noted. Patients were observed for hypotension, bradycardia, nausea and vomiting, respiratory depression, sedation, pruritus, shivering, and post-dural puncture headache (PDPH). The duration of the surgery was noted, and the level of motor and sensory block was noted. The time till the first dose of rescue analgesic was noted. Injection Diclofenac sodium 75 mg I.V. was given as a rescue analgesic when the VAS score was ≥4. Patient hemodynamic parameters were recorded every hour till 6 hours post-operatively.

The visual analogue scale (VAS), which ranges from no pain (0) to the worst pain (10), was used to measure the degree of pain relief. [2] Ramsay's sedation score was used to assess sedation postoperatively as follows: 1 = awake; agitated, restless, or both. 2 = awake; cooperative, oriented, and tranquil. 3 = awake but responds to commands only. 4 = asleep; brisk response to a light glabellar tap or loud auditory stimulus. 5 = asleep; sluggish response to a light glabellar tap or loud auditory stimulus. 6 = asleep; no response to a light glabellar tap or loud auditory stimulus. [3] Statistical analysis was performed on the collected data using the Chi-square and paired and unpaired student t-tests. The p-value <0.05 was taken as significant for all statistical comparisons.

Results

Table 1 shows that the demographic data of all the patients were comparable in both groups (p value >0.05).

Table 1: Demographic characteristics of patients

	Group F	Group T	p value	Significance
No. Of patients	30	30		
Age (Years)	40.17 ± 12.04	39.10 ± 11.98	0.732	NS
Weight (kg)	59.87 ± 7.60	61.83 ± 7.54	0.318	NS
Height (cm)	162.07 ± 7.54	162.43 ± 6.38	0.840	NS
Sex (M:F)	17:13	18:12		
ASA Grade I	18	19		
Grade II	12	11		

Table 2 shows that the time to onset of sensory block at T10 level was 6.25 min in group F and 6.13 min in group T, which was statistically not significant (p = 0.585). The duration of regression to the S2 dermatome was 339.00 min in group F patients and 298.17 min in group T patients, which was statistically significant (p<0.0001). Therefore, the time for regression of sensory blockade to the S2 dermatome was prolonged in group F as compared to group T.

Table 2: Characteristics of sensory block (Mean ± SD)

	Group F	Group T	p value	Significance
Time for onset of sensory block at level T [10] (Mean ± SD) (Min)	6.25 ±0.89	6.13 ± 0.75	0.585	NS
Time for regression of sensory blockade to S2 dermatome (Mean ± SD) (Min)	339.00±18.91	298.17±15.56	<0.0001	HS

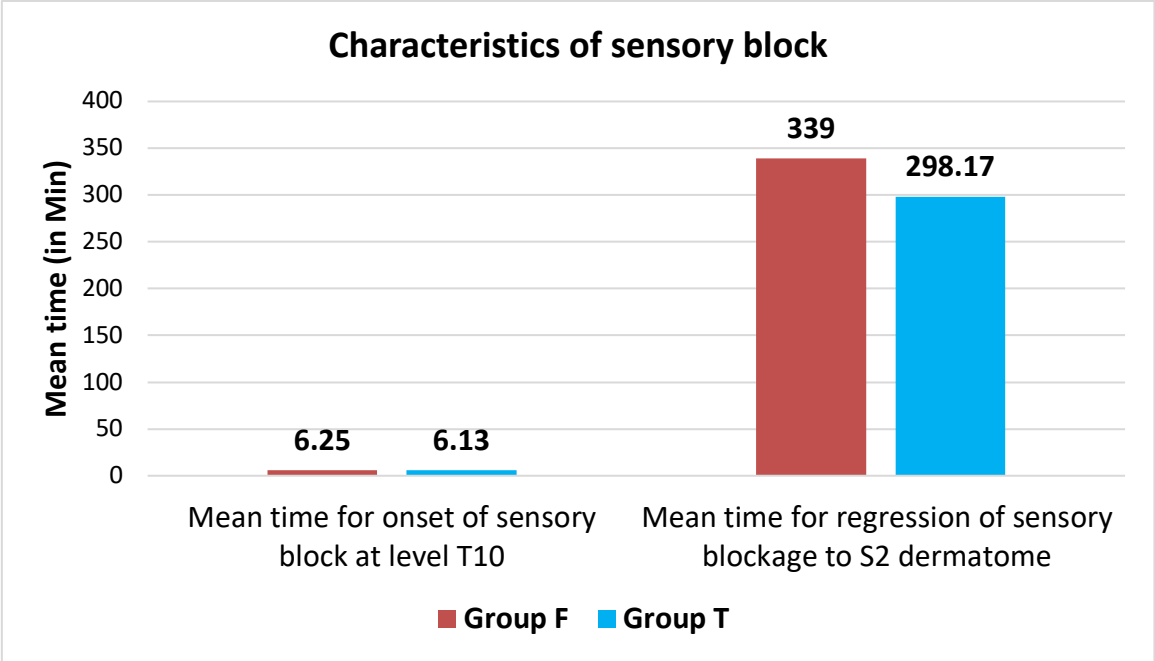

Figure 1: Characteristics of sensory block

Table 3 shows that the mean time to achieve motor block of grade 3 was 8.03 min in group F and 8.12 min in group T, which was statistically not significant (p = 0.691). Time taken to regression of motor block from grade 3 to 0 was 274.67 min in group F and 237.00 min in group T, which was statistically significant (p value <0.0001). Therefore, the time for regression of motor block from grade 3 to 0 was prolonged in group F as compared to group T.

Table 3: Characteristics of motor blockade (Mean ± SD)

	Group F	Group T	p value	Significance
Onset time to achieve motor block of grade 3(Mean ± SD) (Min)	8.03 ± 0.85	8.12 ± 0.76	0.691	NS
Time to regression of motor block from grade 3 to 0 (Mean ± SD) (Min)	274.67±13.77	237.00±38.79	<0.0001	HS

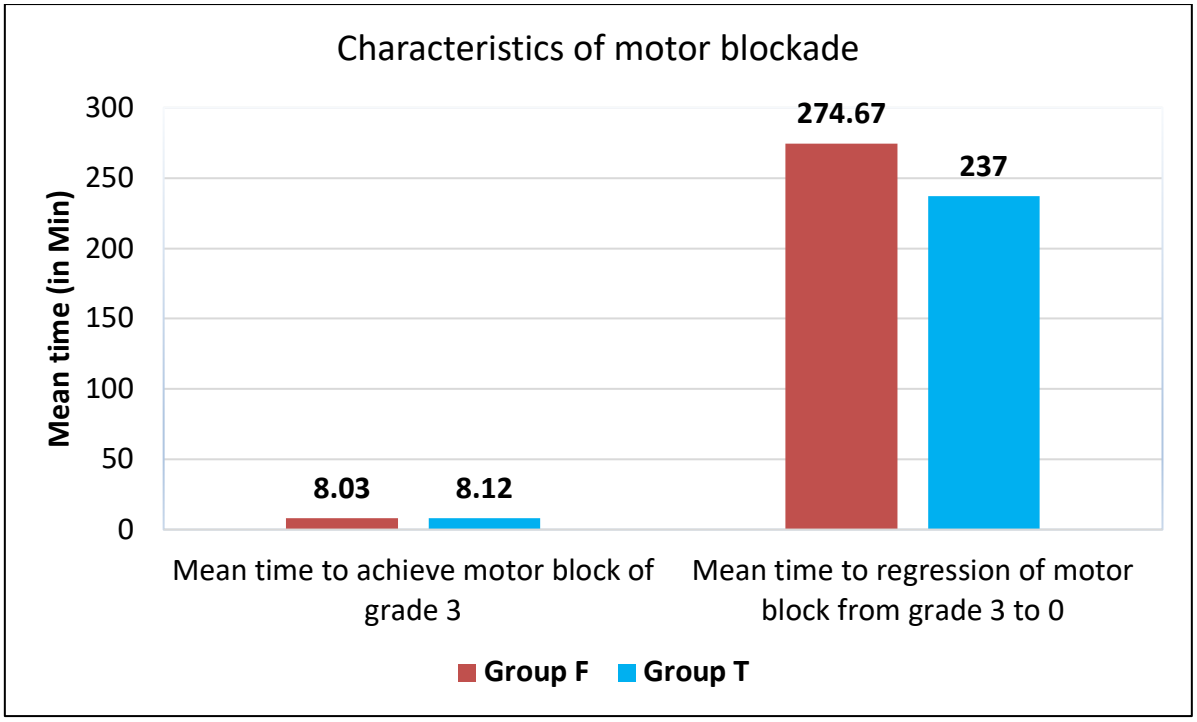

Figure 2: Characteristics of motor blockade

Table 4 compares the perioperative mean pulse rate in both groups. There was no statistically significant difference in mean pulse rate between group F and group T at different time intervals from 0 min to 6 hrs (p value > 0.05).

Table 4: Changes in mean pulse rate at different time intervals in both groups.

Time	Group F	Group T	p value	Significance
	Mean ± SD	Mean ± SD		
0 min	82.70 ± 4.31	83.03 ± 4.17	0.762	NS
5 min	80.20 ± 4.21	79.87 ± 4.83	0.776	NS
10 min	77.57 ± 4.60	77.37 ± 4.61	0.867	NS
15 min	74.80 ± 4.06	74.47 ± 5.02	0.778	NS
20 min	74.03 ± 4.21	73.73 ± 4.86	0.799	NS
25 min	72.00 ± 4.50	71.73 ± 5.22	0.833	NS
30 min	70.03 ± 4.60	70.10 ± 4.90	0.957	NS
1 hr	66.70 ± 4.06	66.83 ± 4.15	0.900	NS
2 hr	69.07 ± 3.71	70.00 ± 3.73	0.312	NS
3 hr	73.57 ± 3.66	74.37 ± 3.23	0.374	NS
4 hr	78.67 ± 3.84	79.53 ± 3.40	0.358	NS
5 hr	82.73 ± 2.90	83.77 ± 3.07	0.185	NS
6 hr	83.97 ± 3.72	84.87 ± 2.40	0.270	NS

Table 5 compares the perioperative mean arterial blood pressure in both groups. There was no statistically significant difference in mean arterial blood pressure between group F and group T at different time intervals from 0 min to 6 hrs (p value > 0.05).

Table 5: changes in mean arterial blood pressure at different time intervals in both groups (Mean ± SD)

Time	Group F	Group T	p value	Significance
	Mean ± SD	Mean ± SD		
0 min	96.66 ± 3.69	96.83 ± 3.83	0.849	NS
5 min	94.71 ± 3.08	94.69 ± 3.75	0.980	NS
10 min	91.68 ± 3.01	91.74 ± 3.77	0.940	NS
15 min	89.01 ± 3.08	88.93 ± 3.92	0.932	NS
20 min	84.79 ± 3.35	84.80 ± 3.14	0.989	NS
25 min	82.91 ± 3.72	83.22 ± 2.89	0.719	NS
30 min	80.76 ± 3.26	81.26 ± 4.54	0.626	NS

1 hr	81.33 ± 2.86	81.87 ± 2.70	0.460	NS
2 hr	86.13 ± 3.05	86.66 ± 2.96	0.504	NS
3 hr	90.20 ± 3.11	90.83 ± 3.37	0.453	NS
4 hr	93.26 ± 1.95	93.93 ± 2.62	0.261	NS
5 hr	95.27 ± 2.28	95.72 ± 2.25	0.450	NS
6 hr	96.68 ± 2.56	96.88 ± 2.13	0.743	NS

Table 6 compares the intra-operative and post-operative complications of both groups. For intra-operative complications, nausea/vomiting (10%), hypotension (10%), bradycardia (3.33%), pruritis (10%), and shivering (6.67%) were seen in group F, while nausea/vomiting (13.33%), hypotension (13.33%), and bradycardia (10%) were seen in group T. Two (6.67%) patients were presented with pruritis as a post-operative complication in group F, while none of the patients presented with post-operative complications in group T.

Table 6: Complication

Complication	**No of patients**			
	Group F		**Group T**	
	Intra-Op	Post-Op	Intra-Op	Post-Op
Nausea/Vomiting	3 (10%)	0	4 (13.33%)	0
Hypotension	3 (10%)	0	4 (13.33%)	0
Bradycardia	1 (3.33%)	0	3 (10%)	0
Respiratory depression	0	0	0	0
Pruritis	3 (10%)	2 (6.67%)	0	0
Shivering	2 (6.67%)	0	0	0

Table 7 compares the sedation scores in both groups. In group F, 63.33% patients were awake but responded only to verbal commands, while 36.67% patients were asleep with a brisk response to commands. In group T, 76.67% patients were cooperative and oriented, while 23.33% patients were awake but responded only to verbal commands.

Table 7: Sedation Score Measured by Ramsay Sedation Score (RSS)

Sedation Score	**Group F**	**Group T**
1	0	0
2	0	23 (76.67%)
3	19 (63.33%)	7 (23.33%)
4	11 (36.67%)	0
5	0	0
6	0	0
Total No. Of Patients	**30**	**30**

Table 8 compares time to first-rescue analgesia in both groups. The mean time to first rescue analgesia in group F was 474.50 min, while in group T it was 360.83 min, which was statistically significant ($p < 0.0001$). The time required for first rescue analgesia was prolonged in group F than in group T.

Table 8: Time to first rescue analgesia

Time (Min)	**No Of Patients**	
	Group F	**Group T**
301-350	0	12
351-400	2	18
401-450	7	0
451-500	12	0
501-550	9	0
Minimum Time	385 Min	305 Min
Maximum Time	530 Min	395 Min
Mean Time ± SD	474.50 ± 37.54 Min	360.83 ± 25.90 Min

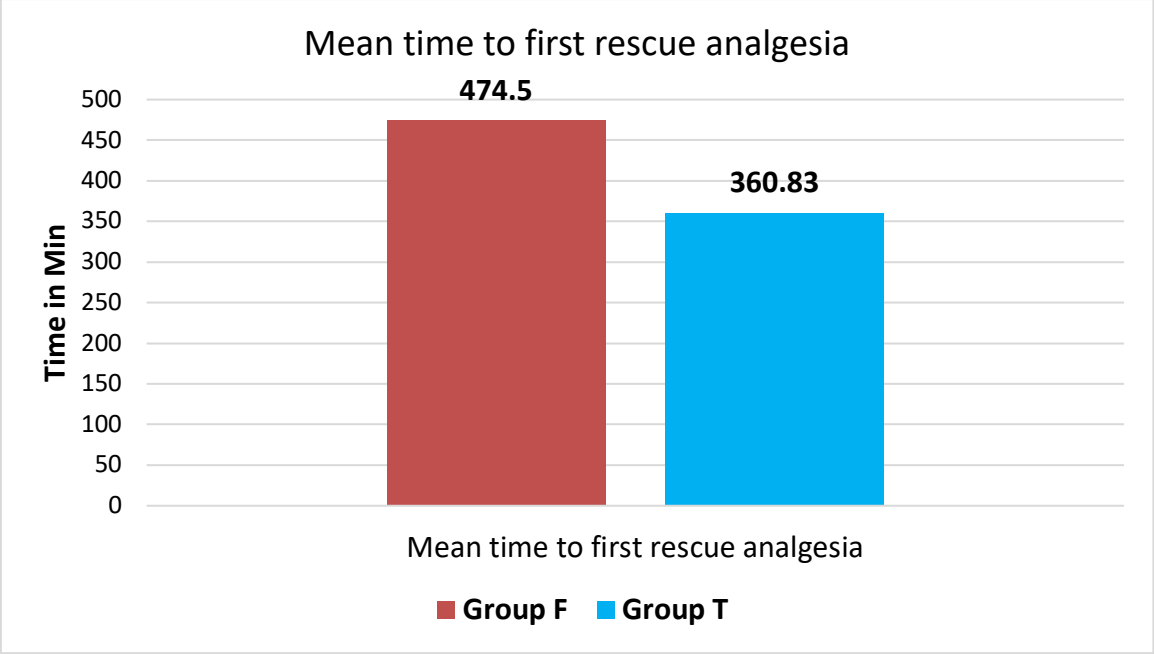

Figure 3: Mean time to first rescue analgesia

Discussion

Kalyan Chakravarthy et al 2019 studied to compare the effects of low-dose intrathecal fentanyl and low-dose intrathecal tramadol combined with 0.5% bupivacaine (heavy) in patients undergoing orthopaedic surgeries. Both intrathecal tramadol and fentanyl act synergistically to potentiate bupivacaine induced sensory spinal block. Excellent surgical anaesthesia and extended analgesia were observed in the post-operative period with minimal side effects among both groups. [9]

Reuben et al 1994 studied various doses of intrathecal fentanyl (0, 5, 10, 20, 40, and 50 µg) and concluded that patients in the 40 and 50 µg groups had excellent analgesia. No patient experienced respiratory depression, hypoxemia, or any hemodynamic alterations (20% change greater or less than baseline heart rate or blood pressure). In the 50 µg group, 5 of 10 patients complained of pruritus. [10]

Singh et al 1995 concluded that fentanyl 25 µg with bupivacaine (13.5 mg) intrathecally did not enhance the onset of sensory or motor block. It prolonged the duration of bupivacaine induced sensory block and reduced the analgesic requirement during the early post-operative period. [11]

Akanmu et al 2013 studied the effect of 25 µg of fentanyl with hyperbaric bupivacaine (10 mg) intrathecally and concluded that it significantly prolonged the duration of complete analgesia as well as effective analgesia, thereby reducing the need for early postoperative analgesics without increase in severe adverse effects. [12] Bhasker PAV et al 2022 studied to compare the effects of low dose intrathecal fentanyl and low dose intrathecal tramadol combined with 0.5% bupivacaine heavy in patients undergoing orthopaedic surgeries.

The addition of either intrathecal tramadol or fentanyl to bupivacaine produced comparable hemodynamic changes, post-operative analgesia, and sensory blockade without prolonging motor recovery.

The addition of both opioids produced minimal intraoperative and postoperative side effects. [13]

Conclusion

We concluded in our study that intrathecal 0.5% hyperbaric bupivacaine with 25 µg fentanyl significantly prolonged both sensory and motor block as well as time for the 1st rescue analgesic when compared with 25 mg tramadol as adjuvant. Fentanyl also produces perioperative sedation.

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