

A Study To Compare The Effects Of Low Dose Intrathecal Fentanyl And Low Dose Intrathecal Tramadol Combined With 0.5% Bupivacaine (Heavy) In Patients Undergoing Lower Limb Surgeries

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Abstract

Introduction: Intrathecal opioids are used as adjuvants in spinal anaesthesia to increase the duration and quality of anaesthesia. The present study was designed to quantitatively examine the safety and efficacy of fentanyl and tramadol to hyperbaric bupivacaine for spinal anaesthesia in lower limb surgeries

Materials and Methods: Sixty patients undergoing elective lower limb surgeries under spinal anaesthesia at our hospital were chosen for the study during the period January 2015 and September 2016. Patients were randomly allocated into two groups of 30 each. Both groups compared for sensory and motor blockade characteristics. Statistical analysis was performed using statistical package for social sciences (SPSS) for Windows version 16.0 software, Chicago, SPSS Inc.

Results: Demographic parameters like age, sex, and ratio of ASA were comparable between the study groups. The mean time to reach T10 sensory block level in group F and group T were 3.14 ± 0.69 and 3.16 ± 0.65 respectively, the time to reach peak sensory block level were 9.14 ± 1.22 min and 8.94 ± 0.87 min in group F and group T, time for two segment regression of sensory level in group F and group T were 98.13 ± 8.01 min and 100.76 ± 8.601 min ($p=0.9084, 0.4677, 0.2253$ respectively). The time of onset of Bromage 3 motor block were 9.33 ± 1.13 min and 9.45 ± 1.19 min in group F and group T and time to regression to Bromage 0 motor block in group F and group T were 237.46 ± 8.20 min and 235.33 ± 12.98 min ($p=0.69, 0.45$ respectively). The mean duration of analgesia in group F was 423.26 ± 12.83 and the mean duration of analgesia in group T was 351.7 ± 20.78 which was statistically significant ($p < 0.0001$).

Conclusion: The present study showed that the sensory blockade and motor blockade characteristics were similar with fentanyl and tramadol when added to hyperbaric bupivacaine but the duration of analgesia was significantly higher with lower visual analogue scale scores in fentanyl group compared to tramadol group.

KeyWords: Spinal Anaesthesia, bupivacaine, tramadol, fentanyl

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I. Introduction

Regional anaesthesia is the preferred technique for most of the lower abdominal and lower limb surgeries. Though the technique of spinal anaesthesia is simple to perform and onset of anaesthesia is rapid, the advantages of spinal anaesthesia are offset by its relatively short duration of action with uncomfortable postoperative period when its action wears off. Use of adjuvants had prolonged the duration of analgesia of which intrathecal opioids are most popular[1]. Morphine, fentanyl and tramadol are the common opioids used as adjuvants to spinal anaesthesia. The present study was designed to quantitatively examine the safety and efficacy of adding fentanyl and tramadol to hyperbaric bupivacaine for spinal anaesthesia in lower limb surgeries

II. Materials And Methods

Sixty patients undergoing elective lower limb surgeries under spinal anaesthesia at our hospital were chosen for the study during the period January 2015 and September 2016.

Study protocol was approved by the hospital ethical committee and ethical clearance was obtained from the institution for the study.

2.1 Inclusion Criteria:

1. ASA physical status I and II
2. Patients of either sex
3. Patients aged between 18 and 65 years

2.2 Exclusion Criteria:

1. Emergency surgery
2. ASA physical status III and IV
3. Pregnant and lactating mothers
4. Patients with history of hypersensitivity to local anesthetic drugs
5. Patients on chronic opioid therapy and opioid addicts
6. Patients with deformities of spine
7. Contraindications to spinal anaesthesia- patient refusal and bleeding disorders

Patients were randomly allocated into two groups of 30 each.

Group F received 3 ml of 0.5% hyperbaric bupivacaine + 25 µg fentanyl (volume 0.5 ml)

Group T received 3 ml of 0.5% hyperbaric bupivacaine + 25 mg of tramadol (volume 0.5 ml)

Pulse rate, noninvasive blood pressure, respiratory rate, SpO₂ were recorded every 5 minutes for the first 30 minutes, and every 15 minutes till the end of surgery.

The level of sensory block was determined in the midclavicular line bilaterally, by pin-prick sensation using 20 gauge hypodermic needle every 2 min, till the level had stabilized for four consecutive tests. The time taken to attain T10 sensory block level, the peak sensory block level and the time taken to attain it from the time of the intrathecal injection, time for two segment regression of sensory level were recorded.

Motor blockade was assessed with modified Bromage scale[2]. The time interval between injection of drug into subarachnoid space, to the patient's inability to move the straight extended leg (Bromage 3) was taken as onset time. The duration of motor block was taken from time of injection to complete regression of motor block (Bromage 0)

The quality of anaesthesia was assessed as excellent, good, fair or poor during the operation and pain was assessed using visual analogue scale[3]

2.3 Statistical Methods:

Statistical analysis was performed using statistical package for social sciences (SPSS) for Windows version 16.0 software, Chicago, SPSS Inc. Student t test was used to analyze age, weight, height, systolic and blood pressure, heart rates, time to T10 sensory block level, time to reach peak sensory block level, time for two segment regression of sensory block, time to onset of bromage 3 and regression to bromage 0 and duration of analgesia. Chi square test was used to analyze sex, ASA, quality of analgesia, peak sensory block level attained and side effects

III. Results

Sixty adult patients of ASA physical status I and II in the age group 18 to 64 years of either sex posted for elective surgeries under spinal anesthesia were selected for study. Patients were randomly allocated into two groups of 30 each. The mean age in group F was 47.22±10.49 and mean age in group T was 45.78±9.08 which was comparable among two groups (p= 0.4062). Sixteen (59.34%) and 15(50%) patients were males in group F and group T respectively. Fourteen (46.66%) and 15(50%) patients were females in group F and group T respectively. There was no significant difference between two groups in sex distribution ($\chi^2=0.0667$, p=0.796).

Fifteen (50%) and 15(50%) patients were ASA I and II respectively in group F. Seventeen (56.67%) and 13(43.33%) patients were ASA I and II respectively in group T. There was no statistically significant difference between group F and group T in the distribution of ASA physical status ($\chi^2=0.2679$, p=0.6047). Preoperative, intraoperative systolic, diastolic blood pressures and heart rate were analysed and there was no statistically significant difference between group F and group T at different time intervals at which they were measured

3.1 Sensory Blockade

The characteristics of sensory blockade of two groups were tabulated in Table 1. The peak sensory block level attained in both groups was T4-T8. The mean time to reach T10 sensory block level in group F and group T were 3.14±0.69 and 3.16±0.65 respectively, which was statistically insignificant (p=0.9084). The mean time to reach peak sensory block level were 9.14±1.22 min and 8.94±0.87 min in group F and group T respectively which was statistically insignificant (p=0.4677). The mean time for two segment regression of sensory block level in group F and group T were 98.13±8.01 min and 100.76±8.601 min respectively which was statistically insignificant (p=0.2253). The peak sensory block level attained was shown in the table 2.

Table 1: Characteristics of sensory blockade of two groups

Parameter	Group F(n=30)	Group T(n=30)	p Value
Time to reach T10 sensory block level(min)	3.14±0.69	3.169±0.65	0.9084
Peak sensory block level attained (range)	T4- T8	T4-T8	
Time to reach peak sensory block level (min)	9.14±1.22	8.94±0.87	0.4677
Time for two segment regression of sensory level (min)	98.13±8.01	100.76±8.601	0.2253

Table 2: Comparison of peak sensory block level of two groups

Peak Sensory Block Level	Group F(n=30)	Group T(n=30)
T8	06(20%)	09(30%)
T7	05(16.6%)	04(13.3%)
T6	07(23.4%)	04(13.3%)
T5	02(6.7%)	05(16.7%)
T4	10(33.3%)	08(26.7%)

Motor Blockade:

The characteristics of motor blockade were tabulated in Table 11. The time of onset of Bromage 3 motor block were 9.33±1.13min and 9.45±1.19 min in group F and group T respectively which was statistically insignificant (p=0.6902). Time to regression to Bromage 0 motor block in group F and group T were 237.46±8.20 min and 235.33±12.98 min respectively which was statistically insignificant (p=0.4504).

Table 3: Characteristics of motor blockade of two groups

	Group F(n=30)	Group T(n=30)	P Value
Time of Onset of Bromage 3 motor block (min)	9.33±1.13	9.45±1.19	0.6902
Time to regression to Bromage 0 (min)	237.46±8.20	235.33±12.98	0.4504

3.3 Quality of Anaesthesia:

The quality of anaesthesia among two groups was tabulated in Table 4.

Table 4: Comparison of quality of anaesthesia of two groups

	Group F(n=30)	Group T(n=30)
Excellent	29(96.6%)	28(93.3%)
Good	01(3.4%)	02(6.7%)
Fair	0	0
Poor	0	0

3.4 Visual Analogue Scale scores and Duration of Analgesia:

The visual analogue scale scores recorded at 180,240,300 and 360 in group F were 1.06±0.44, 1.56±0.49, 2.43±0.49, 3.3±0.69 compared to 1.4±0.48, 2.33±0.59, 3.46±0.49, 4.00±0.00 which was statistically significant(p=0.0059, <0.0001, <0.0001, <0.0001 respectively). the mean duration of analgesia in group F was 423.26±12.83 and the mean duration of analgesia in group T was 351.7±20.78 which was statistically significant (p=<0.0001).

3.5 Side Effects:

The side effects between the two groups were comparable. Nausea was seen n 3.3% and 6.7% patients in group F and group T respectively. None of the patients had vomiting. Pruritis was seen in 10% patients in group F and none of the patients had pruritis in group T. There was no respiratory depression, urinary retention and sedation among two groups. Bradycardia was seen in 10% and 6.7% of patients in group F and group T patients respectively. Hypotension was seen in 10% and 13.3% patients in group T and group F patients respectively. There was no significant difference between the two groups ($\chi^2=3.4971$, p=0.3211).

IV. Discussion

Spinal anaesthesia is a popular anaesthetic technique for surgeries on abdomen and lower limbs. Though subarachnoid block provides effective analgesia in the initial postoperative period, the effects are short lasting. Hence, additional analgesics are needed to lengthen the duration of analgesia.

The use of potent opioid analgesics systemically has been associated with respiratory depression, nausea, vomiting, pruritis and urinary retention. Hence attempts were made to increase the duration of analgesia produced by spinal anaesthetic blockade by the addition of various adjuvants like opioids, clonidine, dexmedetomidine, ketamine, neostigmine, midazolam etc., The present study was a single center prospective randomized study. The patients were divided into 2 groups of 30 patients each. We have sought to compare the onset, duration and analgesic effect of intrathecal fentanyl-bupivacaine with that of tramadol-bupivacaine. Group F received 3 ml of 0.5% hyperbaric bupivacaine + 25 µg fentanyl (volume 0.5 ml) and Group T received 3 ml of 0.5% hyperbaric bupivacaine + 25 mg of tramadol (volume 0.5 ml). Mixing of these drugs didn't show any physical changes like precipitation, turbidity and changes in colour.

In the present study demographic parameters like age, sex, and ratio of ASA were comparable between the study groups. The duration of surgery and types of surgery in both groups were also comparable. There were no significant hemodynamic alterations between two groups. Harbhej Singh et al[4], S Goel et al[5], Arora N et al[6], B N Biswas et al[7] in their studies found no significant hemodynamic alterations with addition of fentanyl to bupivacaine. Alsheshmi JA et al[8] in 2003 found that intrathecal tramadol didn't seem to influence the intraoperative hemodynamic profile. Parthasarathy et al[9], S Chakraborty et al[10] also found no significant hemodynamic alterations with intrathecal tramadol in their studies. The findings in the present study were consistent with these studies.

In the present study the mean time to reach T10 sensory block level, the time to reach peak sensory block and the mean time for two segment regression of sensory block were insignificant between both the groups. These results were comparable with the study done by Routray et al[11] and discordant with a study by Naina P Dalvi et al [12]. The mean time of onset of Bromage 3 motor block was statistically insignificant between both the groups. These results were comparable to the study done by Routray et al [11] and Naina P Dalvi et al[12]. Time to regression to Bromage 0 motor block was statistically insignificant. These results were comparable to the study done by Routray et al[11] and Singh DA[13] but the results were discordant with the study by Naina P Dalvi et al[12].

Duration of analgesia was assessed as the time taken from intrathecal injection till the time of first request of rescue analgesic by the patient. The duration of analgesia was significantly prolonged in group F (423.26 ± 12.83 min) compared to group T (351.7 ± 20.78 min). Similar results were seen in the studies by Naina P Dalvi et al[12], Afolayan et al[14] and Singh DA[13].

In the study by Routray et al[11], no significant difference in duration of analgesia was found between intrathecal fentanyl 25µg and tramadol 25mg. Subedi et al demonstrated that for caesarean section under subarachnoid block with hyperbaric bupivacaine, intrathecal tramadol 10mg produces a longer duration of pain relief with a lower incidence of shivering compared to intrathecal fentanyl. Varrassi et al[15] in 1992, Dahlgren et al[16] in 1997, Goel et al[5], Roussel et al[17] in 1999, Harbhej Singh et al[4] in 1995, B N Biswas et al[7] in 2002 in their retrospective studies concluded that intrathecal fentanyl increased the mean duration of analgesia in their patients. Parthasarathy et al [9], S Chakraborty et al[10], Akil Hussian et al[18] in their respective studies demonstrated that intrathecal tramadol added to bupivacaine increases the mean duration of analgesia when compared to bupivacaine alone. Patients in both groups have minimal side effects. Bruce Ben David et al[19] and Dahlgren et al[16] have found significant pruritis with the use of intrathecal opioids

V. Conclusion

It is concluded from our study that the peak sensory block level attained, the time to reach T10 sensory block level, time to reach peak sensory block level and time for two segment regression of sensory level were similar between fentanyl and tramadol when added to bupivacaine and there was no statistically significant difference between fentanyl group and tramadol group in time of onset of bromage 3 motor block and time to regression to bromage 0. Significantly lower Visual analogue scores and higher duration of analgesia in fentanyl group compared to tramadol shows that fentanyl is a better alternative as adjuvant when longer durations of analgesia is needed which also obviates the need of excess doses of rescue analgesics. There was no significant difference in the side effects observed between two groups.

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