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Comparative Study of Efficacay of Intrathecal Fentanyl and Intrathecal Tramadol Added as Adjuvant to 0.5% Hyperbaric Bupivacaine in Patients Undergoing Surgeries Under Spinal Anaesthesia.

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ABSTRACT

Background: In view of the safety and limited duration of spinal anaesthesia, many adjuvants have been used to increase the duration of analgesia as well as quality of block. Aim: The study was undertaken to compare tramadol with the commonly used injection fentanyl when used as adjuvant to intrathecal bupivacaine on the spinal anaesthesia block characteristics. Design: Prospective, randomized, double blind study. **Methods:** 60 ASA grade I and II patients, undergoing infraumbilical and lower limb surgeries were randomly divided into two groups. All patients received 3 ml of 0.5% hyperbaric bupivacaine along with either 0.4ml (20mg) tramadol (group BT) or 0.4ml (20µg) fentanyl (group BF) intrathecally. The two groups had comparable results with respect to maximum sensory level achieved and the onset of sensory block. **Results:** The duration of block was 161.33±18.43 in group BT, while it was 267.8±556.7 in group BF (p=0.001). The duration of motor block was also prolonged (group BT: 155.83±13.96 versus group BF: 264.67±52.57; p=0.001). The side effects were comparable in both the groups. **Conclusion:** There was greater prolongation of both sensory and motor block when fentanyl was used as adjuvant intrathecally as compared to tramadol.

Keywords: Intrathecal fentanyl, intrathecal tramadol, spinal anaesthesia.

INTRODUCTION

Spinal Anaesthesia or intrathecal anaesthesia is the first choice for infraumbilical and lower limb surgeries. In-order to further increase the duration of spinal local anaesthetics, as well as to increase its safety profile, various adjuvants has been used. Since the isolation of opioids in the spinal cord in 1976, intrathecal administration of opioids in patients undergoing surgery has gained wide popularity.[1]

Tramadol, a centrally acting analgesic drug is used mainly for treatment of moderate-to-severe pain. Tramadol is not a single-mechanism analgesic. In addition to µ-opioid agonist effect, it affects modulatory effects on central monoaminergic pathways, inhibiting neuronal uptake of noradrenaline and serotonin.[2]

Fentanyl is a lipophilic opioid with rapid onset of action following intrathecal administration. It is commonly used as adjuvant to local anaesthetics to improve the quality of blockade and also to prolong the duration of postoperative analgesia during spinal or other regional anaesthesia.[3,4]

However, there is not enough evidence for intrathecal tramadol to draw meaningful conclusion on its ability to enhance the sensory and motor components of spinal anaesthesia. The effective dose range for intrathecal tramadol for postoperative analgesia is still confusing till date.[5] Hence we conducted the randomized study to compare the effects of tramadol with commonly used fentanyl when added as adjuvant to subarachnoid hyperbaric bupivacaine.

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MATERIALS AND METHODS

After obtaining ethical clearance and informed consent from the patients, the 60 American Society of Anesthesiologist Grade I and II patients scheduled for infraumbilical and lower-limb surgeries were selected for the study. The exclusion criteria comprised uncooperative patient, patients undergoing emergency surgeries, patients with signs of endocrine, renal, hepatic or immunological diseases, alcoholic and pregnant patients. Patients

were randomly divided into two groups of 30 patients each, with randomization done using opaque sealed envelopes. Group BT included patients receiving 0.4ml (20mg) tramadol with 3ml of 0.5% hyperbaric bupivacaine. Group BF included patients receiving 0.4ml (20µg) fentanyl with 3ml of 0.5% hyperbaric bupivacaine. The random assignments were done outside the study place and delivered in opaque, sealed, sequentially numbered envelopes.

The patients scheduled for surgery were given 0.25mg tablet alprazolam. On the day of surgery, after confirming the Pre -Anaesthetic Clearence, patients were taken to Operation Theater, where intravenous infusion of injection ringer lactate was started and baseline parameters, which included non-invasive blood pressure, electrocardiogram and Sp02, attached.

Under all aseptic precaution, spinal puncture was done with 25 gauze Quincke needle in sitting position at L3-4/ L4-5 intervertebral space. Once the free flow of CSF was documented, the study drug was administered into the subarachnoid space. The study drug was prepared by an anaesthesiologist according to the group allocation and who was no further involved in the course of study. The drug was administered by an anesthesiologist who did not know the nature of study drug and who was also in-charge of the case. Patients were also not aware of the nature of the drug administered to them. The surgery was allowed to commence once the good quality block was determined.

Sensory bock characteristics were studied with respect to onset time (time taken from deposition of study drug till the patient does not feel the pin-prick at L1), maximum level of block (defined as time taken from deposition of study drug to the maximum sensory blockade attained), time taken to reach maximum level of block, and duration of analgesia (time when patient first complains of pain or visual analogue scale ≥3). Motor block was graded on modified bromage scale. Duration of motor block was defined as time taken from the onset of motor block to the time when the patients were able to perform limb movement. Haemodynamic and respiratory parameters were studied, as were the side effects.

Data was recorded as mean± standard deviation or as numbers (percentage). It was analyzed using SPSS version 11. Continuous data was analyzed using student's t-test while categorical data was analyzed using chi-square test. The level of statistical significance was taken as $p \leq 0.05$.

RESULTS

The study compared intrathecal tramadol (group BT) with intrathecal fentanyl (group BF) used as adjuvant with 0.5% hyperbaric bupivacaine in patients undergoing infraumbilical surgeries. Total of 60 patients were selected and divided randomly into these two groups, with 30 patients in each group.

The demographic profile of patients was comparable in both the groups [Table 1]. The patients of both the groups were comparable with respect to age, weight, gender and types of surgeries.

Table 1: Demographic profile of patients in two groups. (Values as Mean±SD or numbers)

	Group BT	Group BF
Age	38±11.02	35.60±9.29
Weight	66.63±9.22	65.47±8.13
Gender (male:female)	14:16	13:17
Types of Surgeries		
Gynaecological	15	14
Appendicectomy	5	3
Hernia	4	5
Anal	1	0
Orthopaedics	4	6
Uretheral	1	2

Maximum sensory block level was T4 in both the groups. (53.4% in group BT and 46.7% I group BF; P =0.2). Similarly, the grade of maximum motor block was also similar in both the groups.

The motor and sensory characteristics of spinal anaesthesia with tramadol and fentanyl when used as adjuvant are given in [Table 2]. Intrathecal fentanyl (group BF) caused a greater increase in duration of postoperative analgesia as compared to intrathecal tramadol. Also the duration of motor block was prolonged in group BF. However the common side effects were comparable in both the groups.

Table 2: Spinal block characteristics in two groups. (Values as Mean±SD or numbers)

	Group BT	Group BF	P value
Onset of sensory block	4.33±1.63	3.63±1.73	0.08
Time to achieve maximum sensory block	12.67±3.58	12.23±2.74	0.6
Rescue analgesia	161.33±18.43	267.8±556.7	0.001
Motor block regression	155.83±13.96	264.67±52.57	0.001
Grade of motor bock	3.73±0.45	3.90±0.31	0.96
Side effects (number of patients)			
Nausea-vomiting	9	10	
Shivering	11	10	
Respiratory depression	0	0	NS

DISCUSSION

Tramadol is synthetic 4-phenyl-piperidine analogue of codeine and acts as analgesic via an affinity with u receptors, by alpha-2 adrenoreceptor agonistic and serotoninergic effects and by inhibiting the reuptake of noradrenaline and 5-hydroxytryptamine. It may also directly act on spinal receptors, in a manner

similar to opioids. There are limited studies with variable results when tramadol is used with bupivacaine intrathecally.[5,6]

Our results are similar to those attained by Afolayan et al, who demonstrated the similar maximum sensory levels of T4 in both the groups.[7]

With fentanyl the prolongation of postoperative analgesia was 2hrs.[1] The incidence of nausea was 6.1% with fentanyl. Data for vomiting was not much relevant.[1] Our study too demonstrated similar findings.

In contrast, study by Subedi et al showed a significant increased duration of analgesia and postoperative shivering in tramadol group. They had used 10mg of bupivacaine with either 10mg tramadol or 10µg fentanyl in patients undergoing lower segment cesarean section.[8]

Chakraborti demonstrated postoperative analgesia for 300min with tramadol.[5] However they had used only patients with gynecological surgeries. Our study showed significantly less duration of analgesia as compares to fentanyl. Our results are in accordance with Alhesami et al who also found lack of analgesic efficacy of tramadol. The reason for this could be that tramadol has decreased affinity for µ-receptors, which are the site of action of spinally administered opioid receptors. Thus, it is conceivable that analgesic efficacy of tramadol could decrease after intrathecal administration. Also lipophilic properties of tramadol resulted in rapid diffusion of drug out of subarachnoid space.[9] Thirdly tramadol has been shown to have anti-analgesic effects when administered epidurally.[9,10]

In accordance with our study, Dandona et al have shown the duration of both sensory and motor block to be significantly more in fentanyl group as compared to tramadol group. The incidence of shivering and nausea-vomiting were also same as in our study.[11]

Study by Sadegh A et al, showed 10 % incidence of shivering as compared to 25% in our study in fentanyl group.[12] They had used it in elective cesarean section. The dose of bupivacaine in our study was higher than they had used. This would have resulted in more intense and higher blocks, with resultant greater shivering in our study group.

CONCLUSION

There was greater prolongation of both sensory and motor block when fentanyl was used as adjuvant intrathecally as compared to tramadol.

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