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Original Research Article

Clinical evaluation of two different doses of Tramadol as an adjuvant to Hyperbaric bupivacaine 0.5% in subarachnoid block to prolong the duration of analgesia

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Abstract:

Background & Method: The aim of present study is to observe the effect of different doses of intrathecal tramadol as an adjuvant in subarachnoid block to prolong the duration of analgesia. All patients were evaluated thoroughly in preanesthetic checkup a day before surgery. During the preanesthetic evaluation a thorough general and systemic examination was done. The patients were examined clinically to note demographic data, baseline heart rate, blood pressure, respiratory rate, oxygen saturation of Hb. History of underlying medical illness, previous surgery, anaesthetic exposures and hospitalization was enquired.

Result: The mean onset time for sensory block in group A patients was observed as 4.62 ± 0.49 minutes and for group B patients it was 4.47 ± 0.51 minutes. We observed onset time for motor block in group A and B that was 5.85 ± 0.61 and 5.56 ± 0.61 minutes respectively. Duration of sensory and motor block in group A patients receiving Tramadol 25 mg was 173.32 ± 12.37 and 158.50 ± 10.71 minutes respectively whereas the duration of sensory and motor block for the patients in group B receiving Tramadol 40 mg was 182.03 ± 10.89 and 167.29 ± 11.09 minutes. The time for demand of dose of rescue analgesic by the patients in both groups was 244.68 ± 8.59 minutes and 306.53 ± 28.56 minutes, significantly higher in patients who received 40 mg tramadol.

Conclusion: The study was carried out in young healthy subjects of either sex belonging to ASA grade 1 and 2. A thorough pre-anaesthetic check-up was carried out. The procedure was explained and informed consent was taken.

Data on onset and offset of sensory and motor block, degree of muscle relaxation, postoperative pain free period were recorded. Vital parameters and incidence of drug related complications were also noted. Observations were tabulated and statistical tests were applied to find out the significance of observations. The observations recorded have been discussed to derive the conclusions.

Keywords: intrathecal, tramadol, subarachnoid & analgesia.

Study Designed: Observational Study.

1. INTRODUCTION

Modern medicine has many achievements to its credit and important being the relief of pain of surgery by WTG. Morton in 1885. Pain is common after most surgeries, but with varying severity[1]. It is only because of alleviation of pain of surgery that major surgical procedures became possible and allowed the surgeon to perform surgery more skilfully. About one third to half of all surgical patients experience significant postoperative pain.

Pain free surgery and postoperative period is perhaps the most gratifying experience an anaesthesiologist can provide to a patient. Proper postoperative pain management enhances smooth recovery and early discharge from hospital with greater patient satisfaction. Providing a patient adequate pain free period intraoperative and postoperatively has been a topic of continuous research and updates[2].

The term "Regional anaesthesia" first used by Harvey Cushing in 1901, refers to pain relief by injecting the cocaine paste near the nerve trunks. Local anaesthetics provide a reversible regional loss of sensation. They reduce pain, thereby facilitating surgical procedures. Delivery techniques have broadened the clinical applicability of local anaesthesia procedures[3].

The techniques include topical anaesthesia, infiltration anaesthesia, ring blocks and peripheral nerve blocks. Local anaesthetic procedures are safer and easier than general anaesthesia, so these can be used more often.

Leonard corning,[4] (1885) a neurophysiologist, while experimenting with spinal nerve of animals accidentally pierced dura mater and injected cocaine solution close to spinal cord that resulted in reversible paralysis of lower limbs associated with loss of sensations; and this unique observation made the history. Earlier other chemicals were used but resulted in permanent damage to nerves.

The Cocaine, Syncocaine and Nupercaine introduced as local anesthetic in early days were dropped from practice because of their addictive potential and the incidences of allergic reaction linked to these anesthetic solutions.

Lignocaine hydrochloride is one such local anesthetic synthesized and enjoyed worldwide acceptance for all types of local anaesthesia procedures that is infiltration block, blocks of nerve plexus, spinal and epidural block. Bupivacaine hydrochloride is aminoamide type of local anesthetic used in clinical anaesthesia. In 1963, Ekenstam found that wide acceptance in clinical anesthesiology because of longer duration of action than lignocaine. Both Lignocaine and bupivacaine are available in Indian market for clinical use[5&6].

2. MATERIAL & METHOD

Present study involves observations on 68 patients of ASA grade I and II between age 18-60 years, scheduled to undergo routine elective lower abdominal, perineal and lower limb surgeries, performed under subarachnoid block. R D Gardi Medical College, Ujjain, M.P. from December 2020-2021.

All patients were evaluated thoroughly in preanesthetic checkup a day before surgery. During the preanesthetic evaluation a thorough general and systemic examination was done.

The patients were examined clinically to note demographic data, baseline heart rate, blood pressure, respiratory rate, oxygen saturation of Hb. History of underlying medical illness, previous surgery, anaesthetic exposures and hospitalization was enquired.

Physical examination included general condition of the patient, examination of cardiovascular, respiratory, CNS and vertebral columns, airway assessment. Routine laboratory tests were done to rule out co-morbid condition associated that included complete

hemogram, blood counts, urine analysis, fasting and post meal glucose estimation and serum creatinine and whenever preoperative history suggested, coagulation profile, ECG and X-ray chest was done.
The protocol of present observational study was approved by the hospital ethics committee.

Inclusion criteria:

1) Informed consent from all patients.
2) Patients belonging to physical status ASA 1 and 2
3) Age – 18 to 60 years of age, both male and female
4) All patients scheduled for routine elective lower abdominal, perineal and lower limb surgeries to be performed under spinal anaesthesia.

Exclusion criteria:

1) Patient refusal for the procedure or uncooperative patients.
2) Patients belonging to American Society of Anaesthesiologists grade 3, 4 and 5.
3) Patients with systemic disease like respiratory, cardiac, hepatic, renal and neurological disorders, uncontrolled diabetes and hypertension
4) Patient with difficult airway.
5) Pregnant and lactating patients
6) Emergency surgery cases
7) Distortion of spinal anatomy
8) Superficial lumbar site infection
9) Patient with coagulopathy, dermatologic conditions, septicaemia or bacteraemia, shock or severe hypovolemia, a pre-existing disease involving the spinal cord, increased intracranial pressure.
10) Allergy to the study medications-Bupivacaine and Tramadol
11) Contraindication for spinal anaesthesia
12) Alcohol/drug abuse
13) Not fulfilling inclusion criteria.

In both the group of the patients SAB was given in sitting position in L3-L4 interspace. After injecting the drug, patients were made supine and a 10-degree head down tilt was given, a pillow was kept underneath the shoulder.

3. RESULTS

Table 1- Mean age of patients

Variable	Group(N=68)				P
	Group A (25 mg)		Group B (40 Mg)		
	Mean	SD	Mean	SD	
Age (Years)	40.29	13.54	41.50	12.08	0.700

The Mean age of the patients included in the study. The mean age of patients included in both groups was comparable, for group A it was 40.29 ± 13.54 years and group B it was 41.50 ± 12.08 years. The age of patients included in the study ranged from 18 to 60 years.

Table-2 Distribution of patients according to gender

Gender	Group(N=68)		Total
	Group A (25 mg)	Group B (40 Mg)	
Male	18	16	34
	52.9%	47.1%	50.0%
Female	16	18	34
	47.1%	52.9%	50.0%
Total	34	34	68
	100.0%	100.0%	100.0%
Chi-square= 0.235, p= 0.628			

The sex distribution of the patients included in the study in both groups. In group A; 18/34 were male and in group B; 16/34 were male patients.

Table-3 Mean Onset of Sensory and Motor Block

	Group(N=68)				p
	Group A (25 mg)		Group B (40 Mg)		
	Mean	SD	Mean	SD	
Onset time of sensory block(min)	4.62	0.49	4.47	0.51	0.231
Onset time of motor block(min)	5.85	0.61	5.56	0.61	0.051

The onset characteristics of subarachnoid block. The mean onset time for sensory block in group A patients was observed as 4.62 ± 0.49 minutes and for group B patients it was 4.47 ± 0.51 minutes. We observed onset time for motor block in group A and B that was 5.85 ± 0.61 and 5.56 ± 0.61 minutes respectively. Above observations clearly shows that the onset of both sensory and motor block occurred similarly in both patients receiving 25 mg and 40 mg tramadol with hyperbaric bupivacaine.

Table-4 Mean duration of sensory and motor block

	Group				p
	Group A (25 mg)		Group B (40 Mg)		
	Mean	SD	Mean	SD	
Duration of effective sensory block(min)	173.32	12.37	182.03	10.89	0.003

Duration of effective motor block(min)	158.50	10.71	167.29	11.09	0.001

Time of effective sensory and motor block in both groups. Duration of sensory and motor block in group A patients receiving Tramadol 25 mg was 173.32 ± 12.37 and 158.50 ± 10.71 minutes respectively whereas the duration of sensory and motor block for the patients in group B receiving Tramadol 40 mg was 182.03 ± 10.89 and 167.29 ± 11.09 minutes.

Table- 5 Mean duration of post-operative Analgesia

	Group				p
	Group A (25 mg)		Group B (40 Mg)		
	Mean	SD	Mean	SD	
Time of first rescue analgesic (min) (postoperative analgesia)	244.68	8.59	306.53	28.56	0.000

The duration of post-operative analgesia in both groups indicating that contemplated surgery could be finished without need of supplement anaesthesia as the minimum and maximum time for surgery were within the range of effective analgesia without movement of limb. The time for demand of dose of rescue analgesic by the patients in both groups was 244.68 ± 8.59 minutes and 306.53 ± 28.56 minutes, significantly higher in patients who received 40 mg tramadol. The statistical analysis has shown this finding to be highly significant (P= 0.000).

4. DISCUSSION

Age of the patients was between 18 to 60 years with a mean age of 40.89 years, the healthy young patients constituted the study group.

The mean weight was satisfactory in both study group of the patients.

There was equal distribution in gender, there were 34 male patients and 34 female patients however gender has got no significance in spinal anaesthesia and drugs used. It has got no relationship in subarachnoid block and drugs used in the present study.

In our study, the onset of sensory block was assessed by pin prick method at T10 level. The mean onset time was 4.62 minutes in patients of group A and 4.47 minutes in patients of group B. Statistically the value was insignificant ($p > 0.231$) and both groups were comparable[7].

Similar study demonstrated onset of sensory block assessed at T5-T6 level in group tramadol 10 mg + heavy bupivacaine 10 mg to be 5.9 ± 1.8 minutes which may be comparable to our study as we used 25 and 40 mg tramadol doses along with 15 mg heavy bupivacaine and assessment of onset done at level T10[8].

Study found mean onset time of sensory blockade prolonged (8.44 ± 2.35 minutes) with preservative free intrathecal Tramadol 50 mg combined with 0.5% hyperbaric bupivacaine 2.5 mg(0.5 ml) + normal saline 0.5 ml as compared to 6.53 ± 1.65 minutes with conventional dose of bupivacaine 10 mg(2 ml) in spinal anaesthesia for TURP procedures. This contradiction to our study can be attributed to the 10 mg increase in dose of tramadol used in this study, also the different highest dermatomal level T8, T6 assessed for mean onset of sensory blockade as we used T10 as standard level for onset assessment. However, for

different surgeries in our study, appropriate dermatomal level achieved which are necessary for smooth conduct of that surgery intraoperatively[9].

In our study, the mean onset time of motor block was assessed by bromage score 3. The onset time was 5.85 minutes in group A and 5.56 minutes in group B. Statistical analysis revealed that the value was insignificant ($p > 0.05$). This shows that Tramadol in different doses when added to bupivacaine gives similar onset of motor block.

Similar study demonstrated onset of motor block in group tramadol 10 mg + heavy bupivacaine 10 mg to be 5.3 ± 3.9 minutes which is comparable to our study as we used 25 and 40 mg tramadol dose. Here we can observe that there is no effect on onset time of motor block even with higher doses[10].

In our study, the duration of sensory block was greater (182.03 minutes) in group B, lesser in group A patients (173.32 minutes) where Tramadol 40 mg and 25 mg respectively was added to hyperbaric bupivacaine. This signifies that Tramadol prolongs the duration of sensory block but higher doses (40 mg) Tramadol are more promising in enhancing the duration of sensory block produced by hyperbaric bupivacaine in SAB. 25 mg intrathecal Tramadol act synergistically to potentiate bupivacaine induced sensory spinal block. The result of the study showed that the duration of subarachnoid block by intrathecal administration of 25 mg of Tramadol with 0.5% 3.5 ml of hyperbaric bupivacaine was significantly longer in duration (302.40 ± 12.00 minutes).

In our study, the duration of motor block as assessed by ability to move both lower limbs were also affected by addition of Tramadol in both doses to hyperbaric bupivacaine for spinal anaesthesia. The duration of motor block was greater (167.29 minutes) with group B when Tramadol 40 mg was added to bupivacaine as compared to 158.50 minutes with group A in which Tramadol 25 mg was added. Statistically the difference was highly significant ($p < 0.05$) among two groups.

Study demonstrated duration of motor block in group tramadol 10 mg + heavy bupivacaine 10 mg to be 126.1 ± 14.0 minutes which is comparable to our study as we used 25 and 40 mg tramadol dose.

Pain free period or duration of analgesia has been affected in both the study groups i.e., where Tramadol 40 mg and 25 mg was used as an adjuvant to hyperbaric bupivacaine for SAB. The mean duration of postoperative analgesia was 244.68 minutes in group A patients and 306.53 minutes in group B patients. Statistically the changes produced were highly significant ($p < 0.05$) between patients of group A and B. Time to first rescue analgesic requests (duration of analgesia) was longest in the group that had intrathecal Tramadol 40 mg combination with bupivacaine. This is in agreement with a study who also studied post-operative analgesic efficacy of intrathecal tramadol added to bupivacaine in spinal anaesthesia for lower limb orthopaedic surgery. They recorded duration of analgesia of 260 minutes, though with intrathecal tramadol 50mg. The slight difference here could be due to the difference in the dose of bupivacaine used in their study. They used bupivacaine 12.5mg while 15mg was used in this study. It has been reported that increasing doses of bupivacaine leads to increased duration of action [8] . The result is also in agreement with that of Afolayan and colleagues [9] who recorded time to first analgesic with intrathecal tramadol 25mg as 238.39±61.28 minutes in their comparison of intrathecal tramadol and intrathecal fentanyl for 122 pain control during bupivacaine subarachnoid block for open appendicectomy. This study showed that intrathecal Tramadol 25 mg was a safe replacement for intrathecal fentanyl 25 mcg in open appendicectomy patients.

5. CONCLUSION

The study was carried out in young healthy subjects of either sex belonging to ASA grade 1 and 2. A thorough pre-anaesthetic check-up was carried out. The procedure was explained and informed consent was taken.

Data on onset and offset of sensory and motor block, degree of muscle relaxation, postoperative pain free period were recorded. Vital parameters and incidence of drug related complications were also noted. Observations were tabulated and statistical tests were applied to find out the significance of observations. The observations recorded have been discussed to derive the conclusions.

Intrathecal tramadol extended post operative analgesia with minimal side effects, when combined with bupivacaine for spinal anaesthesia in patients who had undergone general, gynaecological and orthopaedic surgery. Intrathecal tramadol 40mg provided longer duration of analgesia than intrathecal tramadol 25 mg, with comparable side effect profile in the two doses.

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