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EFFECT OF INTRATHECAL TRAMADOL ON SUBARACHNOID BLOCK BY 0.5% BUPIVACAINE

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ABSTRACT Drugs when given intravenously in adequate doses for pain relief produce reliable pharmacokinetic curves. But this route produces unwanted effects, as large quantities of drugs are needed for adequate analgesia. In present study, effect of intrathecal tramadol on subarachnoid block produced by 0.5% bupivacaine was conducted at Mayo hospital, Nagpur. Visual analog scale score was statistically highly significant in Group A till 6 hours as compared to Group B. After this period, patients in Group A demanded rescue analgesic. Visual analog scale score was comparatively less in Group B at all the stages of observation over 24 hours as shown by the p value. Result of the study, it is concluded that 25 mg of tramadol can be used intrathecally along with 0.5% bupivacaine to prevent the postoperative pain for 6-8 hours duration; it has no effect on the quality of spinal subarachnoid block produced by 0.5% bupivacaine.

KEYWORDS : Bupivacaine, Tramadol, opioid analgesia, spinal anesthesia.

INTRODUCTION

One of the primary aims of anaesthesia is to render the patient pain free during surgery, but pain during post operative period is equally important issue. Unrelieved post-operative pain results in patient discomfort, long hospital stay, poor patient outcome and greater use of health care resources. Expressions of gratitude from the patients, free from pain, can contribute to feelings of self-esteem and job satisfaction.

Drugs when given intravenously in adequate doses for effective pain relief produce reliable pharmacokinetic curves. But this route produces unwanted side effects, as large quantities of drugs are needed for adequate analgesia.

Opioids administered by both these routes can produce ill effects like nausea, vomiting, itching and severe respiratory depression. Respiratory depression of life threatening severity has been reported with intravenous route and concern for this risk has limited the widespread use of continuous opioid infusions for perioperative pain. So there was a need for some new routes for administration of these drugs and also some new drugs, which retain the analgesic potency of these opioids without many side effects. Therefore in order to maximize postoperative analgesia, a number of agents have been added to spinal anesthetics.

The unique feature of spinal opioid analgesia is the lack of sensory, sympathetic or motor block. It also provides prolonged analgesia at doses that are far less than usual intramuscular or intravenous doses.

In 1988, Chrubusic demonstrated the efficacy of Tramadol, which acts as opioid receptor agonist and serotonin and non-adrenaline reuptake inhibiter at central and spinal level, to be an effective analgesic with no significant adverse effects (1).

So, we decided to evaluate effects of intrathecal tramadol hydrochloride on spinal anaesthesia produced by bupivacaine, a widely used spinal local anesthetic in patients undergoing elective infra-umbilical general or orthopedic operative procedures of lower limb and hip.

MATERIAL AND METHODS

The present study "Effect of intrathecal tramadol on subarchnoid block produced by 0.5% bupivacaine was conducted at Mayo Hospital, Nagpur, after approval from ethics committee. The aim of the study was to evaluate the effect of intrathecal tramadol on spinal subarachnoid block produced by 0.5 % bupivacaine. For this purpose a clinical study was undertaken and following effects were studied.

1. Onset of sensory block
2. Ascent of sensory blockade
3. Duration of sensory blockade
4. Onset of motor blockade and grades of motor blockade using Bromage criteria.
5. Duration of motor blockade
6. Duration of postoperative analgesia as assessed by visual analog scale.

This was a hospital based randomized control trial consisting of 150 patients of either sex, aged 20-60 years belonging to ASA physical status I or II, posted for various type of elective general, orthopedic or gynecological infra umbilical, surgical procedures.

All patients underwent through clinical checkup prior to surgery and subjected to necessary investigations, such as estimation of hemoglobin percentage and routine urine examination. Blood urea, fasting and post meal – blood sugar, electrocardiogram, chest X-ray were done for the elderly patients and as and when required in young patients also. Similarly hematological investigations were advised if there was relevant history.

Patients with history of psychological and neurological problems, chronic headache, allergic response to local anesthetics and local infections at lumbar puncture site were excluded. Study was conducted in two equal groups, each containing 75 patients. Group A, patients acted as study group and received 25mg tramadol hydrochloride (0.5 ml), preservative free along with 2.5 ml of 0.5% bupivacaine for spinal subarachnoid block. Group B, patients acted as control and received 0.5%, bupivacaine, 2.5 ml for spinal subarachnoid block.

Pre-operatively in the operation theatre, all the patients were given tablet diazepam 5mg orally 1 to $1^{1/2}$ hour, prior to procedure with a sip of water. Later on an intravenous line was secured and all the patients were circulatory preloaded with 400-500 ml of Ringer lactate solution before giving the block.

On the operation table, patient's baseline pulse rate and blood pressure were noted.

Lumber puncture was done in patients with a spinal needle 22 gauge in lateral position or if required in the sitting position, under all aseptic precautions.

After obtaining a free flow of cerebrospinal fluid, freshly prepared preservative free test drugs or control drug were injected intrathecally, as decided earlier.

The patients were turned immediately to supine position. Slight head

up position of 15 degree was maintained.

The onset of sensory block, highest level of sensory blockade and the time required to achieve the level was noted. All the observations were assessed by pin prick at every minute interval upto 10 minutes after administration of block.

Motor block was assessed using the Bromage Scale, according to which 0-no impairment of legs or feet; 1- barely able to flex the knees, no impairment of movement of the feet; 2- unable to move knees or feet. Intra-operatively patient's pulse rate and blood pressure were monitored every minute till 5 minutes, and thereafter every 5 minutes till 30 minutes and at regular intervals thereafter (2).

Assessment of the degree of the postoperative pain relief was carried out by subjective visual analog scale using a 10cm long line. Zero end of this line was marked "no pain at all", while the other end denoted "the worst possible pain." The patient pointed out on the scale, the intensity of the pain as-

0- Absolutely no pain
1- Negligible pain
2- Very very minimal pain
3- Very minimal pain
4- Minimal pain
5- Pain requiring relief
6- Pain with little distress
7- Severe pain
8- Very severe pain
9- Very very severe pain
10- Worst possible pain

RESULTS

The table showing number of patients with different grades of motor blockade as assessed by Bromage scale with passage of time in both groups.

Table no.1: Showing number of patients with different grades of motor blockade as assessed by Bromage scale with passage of time in both groups.

Time range in minutes	Group A (n = 7.5)		Group B (n = 75)	
	Bromage grades			
<5-6	8		10	
>6-8	66	1	63	
>8-10	1	1	2	2
>10-12	0	46	0	51
> 12-14		26		19
>14-16		1		1
> 16-18		0		2
Total	75	75	75	75
Mean ± SD	7.26 +.0.7	12.12 ± 1.02	7.22 + 0.81	12.17± 1.32

Bromage Grade I indicates onset of motor blockade, while Grade II indicates complete motor blockade. In Group A & B the mean time for the onset of motor blockade, the mean time for complete motor blockade were almost equal. Thus by addition of intrathecal tramadol to intrathecal bupivacaine in Group A there was no change in onset & completion of motor blockade.

Table no.2: Showing mean visual analog scale scores in two groups at various time intervals

TIME FROM ONSET OF BLOCK IN HOURS	VISUAL ANALOG SCORE MEAN ±SD		P VALUE
	GROUP A	GROUP B	
1	0	0	--
2	0	0	--
4	0.65 ± 0.68	5.25 ±0.46	< 0.001
6	0.76 ± 0.69	4.46 ± 0.84	< 0.001
12	5.06 ± 0.25	5.05 ±0.86	> 0.05
24	2.88 ±0.83	4.84 ± 1.16	> 0.01

The visual analog scale score was statistically highly significant in Group A till 6 hours as compared to Group B. After this period, patients in Group A demanded rescue analgesic. The visual analog scale score was comparatively less in Group B than in Group A at all the stages of observation over 24 hours as shown by the p value (highly significant).

Table no.3: Showing distribution of time for need of first analgesic

Time For Analgesic From The Onset Of Block In Hours	Group A n(%)	Group B n(%)
0-2	0	0
>2-4	0	75(100%)
>4-6	0	0
>6-8	12 (16%)	0
>8-10	21(28%)	0
>10-12	42(56%)	0
TOTAL	75	75

In Group A, all the 75 patients demanded rescue analgesic between 6 to 12 hours after onset of sensory block, while in Group B all the patients demanded rescue analgesic between 2-4 hours. The difference was statistically highly significant.

DISCUSSION

The present study was carried out to clinically evaluate the effect of intrathecal tramadol on subarachnoid block produced by 0.5% hyperbaric bupivacaine. The study included 150 patients belonging to ASA physical status I & II. Patients were randomly allocated to two groups of 75 each to receive the intrathecal injection of drugs as decided.

Both the groups were demographically comparable in characteristics like age and sex. Both the groups were also comparable for the type of surgery they underwent and duration of surgery.

The mean time for the onset of sensory blockade in Group A was 6.29 ± 0.71 minutes and in group B was 6.36 ± 0.74 minutes.

In group A, as assessed by the Bromage scale, the mean time for the onset of motor blockade was 7.26 ± 0.7 minutes. While in group B, it was 7.22 + 0.81 minutes. The mean time for obtaining complete motor blockade was 12.12 ± 1.02 minutes in group A, where as it was 12.17 ± 1.32 minutes in group B. The muscle relaxation as graded by Bromage scale was excellent in all the patients from both the groups.

The mean time for the onset of sensory blockade in the two groups was statistically not significant with p value > 0.05. Thus addition of 25 mg tramadol to intrathecal bupivacaine had no effect on onset of sensory blockade. Similar observations have been made by Brijesh Jain and V.K. Saraswat (2001), who used intrathecal tramadol in a dose of 25 mg. The mean time for onset of sensory blockade was 6.11 ± 0.99 minutes (3). H.H. Rawal et al studied effect of epidural tramadol. Within 10-20 minutes the VAS diminished markedly with epidural tramadol (4). P. Yazbeck et al compared epidural tramadol-bupivacaine combination verses fentanyl-bupivacaine combination. They achieved satisfactory analgesia within 15 minutes using both (5). Postoperatively patients were monitored for 24 hours. Time for the need of first analgesia and total number of analgesics supplementation in 24 hours were noted. Patient's pain was assessed with the help of visual analog scale at 1,2,4,6,12 and 24 hours from the onset of block and recorded in the proforma. The analgesic was given when the visual analog scale score was 5 or more. Intramuscular injection of diclofenac sodium 75 mg was used as analgesic. The visual analog scale score was comparatively less in Group A than in Group B at all the stages of observation over 24 hours, except at 12 hours, where the difference in the two groups was statistically not significant.

In our study the mean visual analog scale score at 1 and 2 hours in both the groups was zero. So, there was good analgesia in both the groups at the end of two hours.

At 4 hours in Group A, mean visual analog scale score was 0.65 + 0.68, while in Group B, it was 5.25 + 0.46 ($p < 0.001$). The difference was statistically highly significant. Between 2-4 hours all the patients in Group B demanded rescue analgesic.

At 6 hours the mean visual analog scale score was 0.76 ± 0.69 in Group A, while it was 4.46 ± 0.84 in Group B ($p < 0.001$). Again there was statistically significant difference between the visual analog scale score of the two groups at 6 hours. Almost all the patients in Group A were having good analgesia at the end of 6 hours.

At 12 hours, in Group A, the mean visual analog scale score was 5.06 ± 0.25, while in Group B it was 5.05 + 0.86 with $p > 0.05$. The difference was statistically insignificant at this stage.

In Group A during 6 to 12 hours almost all the patients requested rescue analgesic.

At 24 hours, in Group A, the mean visual analog scale score was 2.88 ± 0.83, while in Group B it was 4.84 + 1.16 ($p<0.001$). The difference was statistically highly significant at the end of 24 hours.

The visual analog score in Group A was less than in Group B during 24 hours. It can be suggested from our study that addition of 25 mg tramadol intrathecally to bupivacaine for spinal subarachnoid block improved post operative analgesia when compared to spinal bupivacaine alone.

Thus results are consistent with those published by Brijesh Jain and V.K. Saraswat on intrathecal tramadol, P. Yazbeck et al, A.E. Delilkan and associate (6), Anis Baraka et al (7), all on epidural tramadol.

In Group A, the minimum time for the need of first analgesic was 380 minutes and the maximum time was 730 minutes from the onset of block with the mean of 605.2 ± 87.03 minutes. In Group B, the minimum time for the need of first analgesic was 145 minutes and the maximum time was 190 minutes from the onset of block with the mean of 160.74 ± 4.65 minutes. Thus in Group B all the 75 patients requested for analgesic within 200 minutes from the onset of block.

In Group A, none of the patients requested for analgesic till 6 hours from the onset of block. Out of 75, 33(44%) patients had analgesic supplementation within 6 to 10 hours and 42 (56%) patients had analgesic within 10 to 12 hours from the onset of block.

The difference between the two groups for the time for first analgesic supplementation was statistically highly significant ($p<0.001$) suggesting that analgesic effect of intrathecal bupivacaine is prolonged by addition of 25 mg tramadol.

Brijesh Jain and V.K. Saraswat studied addition of 25 mg of intrathecal tramadol to spinal lignocaine and bupivacaine. They found that the duration of analgesia, as evaluated from the time of spinal anaesthesia to the time patient had discomforting pain, was 9.13 ± 2.52 hours with lignocaine and 10.16 ± 3.19 hours with bupivacaine.

Similarly A.K. Pan (8) found that addition of 50 mg epidural tramadol to lignocaine with adrenaline prolonged the time for next analgesic request. In Tramadol- lignocaine with adrenaline Group, mean time for next post operative analgesia was 10.39 ± 0.47 hours, while in lignocaine with adrenaline group it was 2.46 ± 0.60 hours, in their study.

H.H. Rawal (4), used 100 mg, tramadol epidurally for post operative analgesia, found that after this dose the mean time for the demand of next dose was 10.98 ±3.12 hours.

CONCLUSION

From the result of the study, it is concluded that 25 mg of tramadol can be used intrathecally along with 0.5% bupivacaine to prevent the postoperative pain for 6-8 hours duration; it has no effect on the quality of spinal sub arachnoid block produced by 0.5% bupivacaine.

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