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### RESEARCH ARTICLE

#### A COMPARATIVE STUDY EFFECT OF INTRATHAECAL TRAMADOL (20MG) USE AS ADJUVANT WITH HYPERBARIC BUPIVACAINE (15MG) AND HYPERBARIC BUPIVACAINE FOR POSTOPERATIVE ANALGESIA IN INFRAUMBILICAL SURGERIES.

**Dr. Sunita Meena<sup>1</sup>, Dr. Rakesh Agarwal<sup>2</sup> and Dr. Ramesh Chandra Sunar<sup>3</sup>.**

1. Assistant Professor, Department of Anaesthesia, SMS Medical College, Jaipur Rajasthan India.
2. junior specialist, Department of Anaesthesia, SMS Medical College, Jaipur Rajasthan India.
3. Senior Professor, Department of Anaesthesia, SMS Medical College, Jaipur Rajasthan India.

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#### Abstract

**Background:** Various adjuvants have been used with local anaesthetic intrathecally for prolong postoperatively analgesia. Neuraxial opioids bind to intrathecal opioids receptors and produce analgesia. Tramadol is a centrally acting opioid, without common side effects of opioids. This prospective double blind randomized placebo controlled study aimed to evaluate duration of analgesia produced by intrathecal tramadol (20mg) used as adjuvant with bupivacaine 0.5% (15mg) in infraumbilical surgeries.

**Material and method:** In the study included total 56 patients either sex in age group 30-60 yrs, ASA 1&2 undergoing for infraumbilical surgeries randomly allocated in two groups. Group A (N=28) received 3 ml of hyperbaric bupivacaine 0.5% with 0.4ml of normal saline, Group B (N=28) received 3 ml of hyperbaric bupivacaine 0.5% with tramadol (20mg) 0.4ml injected intrathecally. The onset and duration of motor & sensory blockade, VAS, sedation score, intraop haemodynamic monitoring, side effects, duration of analgesia, demand of first rescue of analgesia, were also compared in both groups at predetermined intervals. **Results:** There was no significant difference in demographical data, haemodynamic parameters and any side effects. There was significant difference in, onset of sensory blockade mean  $\pm$  SD group A  $3.39 \pm 0.562$  min VS group B  $1.91 \pm 0.438$  min, onset of motor blockade mean  $\pm$  SD group A  $4.67 \pm 1.56$  vs group B  $2.4 \pm 0.512$ , duration of sensory blockade mean  $\pm$  SD group A  $138 \pm 27.30$  vs group B  $2.54 \pm 25.64$ , duration of motor blockade mean  $\pm$  SD group A  $118.78 \pm 23.44$  vs group B  $210.66 \pm 24.60$ , demand of first rescue of analgesia of mean  $\pm$  SD group A  $180 \pm 8.99$  min vs group B  $324.39 \pm 5.79$  min (p value  $< 0.001$ ). VAS score was significantly low in group B than group A.

**Conclusion:** we conclude that use of tramadol as adjuvant intrathecal with hyperbaric bupivacaine early the onset of sensory and motor blockade and prolonged of duration of analgesia by prolonging duration of requirement of first rescue of analgesia without increasing incidence of side effects in infraumbilical surgeries.

## Introduction:-

Spinal anesthesia is the most popular regional anesthesia technique for lower abdominal and limb surgeries. However, the local anesthetic drugs used for spinal anesthesia don't have the advantage of prolonged postoperative analgesia. It is a continuous challenge for the anesthesiologists as perioperative pain management is their domain.

Various types of medications can be used to overcome pain but opioids provide the most effective pain relief and are a standard of care<sup>(1)</sup>.

Intrathecal opioids administration has been demonstrated to provide effective postop analgesia after a variety of surgical procedures at the cost of increased risk of respiratory depression<sup>(2)</sup>. Tramadol, in contrast to a centrally acting opioid analgesic, has minimal respiratory depressant effect<sup>(3,4)</sup>, because it has 6000 fold less affinity for  $\mu$  receptors compared to morphine<sup>(5,6)</sup>. It also inhibits serotonin and norepinephrine reuptake in the spinal cord and has no reported neural toxicity<sup>(7)</sup>. Therefore, tramadol has the potential to provide effective postoperative analgesia, with no risk of respiratory depression after central neuraxial administration. However, pruritus, nausea, vomiting, urinary retention, activation of herpes labialis<sup>(8)</sup> and risk of unpredictable respiratory depression<sup>(9,10)</sup> have directed the clinicians to use a lower dose of tramadol that can be used intrathecally to produce effective and prolonged analgesia without such complications.

In view of this we planned this present study to effect of tramadol as adjuvant with bupivacaine intrathecally on postop duration of requirement of first rescue of analgesia in various infraumbilical surgeries.

## Material and method:-

This study was prospective randomized double blind placebo controlled study was conducted at SMS Medical college and attached hospital Jaipur. After taking approval by the ethical committee and obtaining a well informed written consent from patients, total 56 patients, ages of 30-60yrs, of either sex (ASA status grade 1&2) who were scheduled for infraumbilical surgeries like open appendectomy, inguinal hernia repair, hydrocele, TURP, abdominal hysterectomy, orchidectomy included in study. Patients who had history of local anaesthetic drug allergy, ASA grade 3&4, chronic opioid therapy opioid addict, patients on pain modifying drugs, contraindication of spinal anaesthesia were excluded from the study. Every patient was assessed properly in pre-anaesthetic clinic one day prior to surgery. All patients were instructed to NBM 8 hrs, premedicated with Tab Ranitidine 150 mg and Tab Alprazolam 0.5 mg orally the night before and also on the morning of surgery.

After arrival of patient in OT an I.V. line was secured with 18G or 20G canula and standard monitoring including NIBP cuff, ECG leads and pulse oximeter were monitored. Baseline parameters like NIBP, SPO<sub>2</sub>, pulse rate, respiratory rate were noted.

All selected patients were made familiar with VAS for grading of postoperative pain intensity. Patients were randomly divided into two groups of 28 each, using chit in box method in double blind manner. Group A (N=28) received 3 ml of hyperbaric bupivacaine 0.5% with 0.4ml of normal saline, Group B (N=28) received 3 ml of hyperbaric bupivacaine 0.5% with tramadol (20mg) 0.4ml injected intrathecally. Preloading was done with ringer lactate at a dose of 10 ml/kg B.W. within 30 minutes. The procedure of SAB was explained to the patients, after taking all aseptic precautions and proper draping. Lumbar interspace either L3-L4 was identified in sitting position & infiltrated with injection Xylocaine HCL 1%. Subarachnoid space was identified by using a 25 G Whit-care spinal needle and once free flow of CSF appeared.

Vital parameters like pulse, blood pressure, oxygen saturation, RR along with onset & duration of motor and sensory blockade, pain scores VAS 4 & sedation scores (Ramsey sedation score) 5 were checked every minute for first 5 min every 5 min for the next 15 min and every 10 min thereafter till end of procedure.

Duration of surgery was noted at end of surgery. Patient shifted to post anaesthesia care unit for continued vital monitoring without any prophylactic analgesic.

VAS score, sedation score, level of sensory & motor blockade were noted every 15 min for first 2 hrs, every 30 min next 4 hrs and thereafter at 2 hr interval for 24 hrs.

Duration of analgesia was considered as interval from time of intrathecal injection to the time of first rescue of analgesia demanded postoperatively or VAS score was more than 4. Injection Diclofenac 1.5 mg/kg I.M. was used as a rescue analgesia.

Adverse effects like headache, hypotension, bradycardia, respiratory depression, postop nausea, vomiting, pruritis, sedation urinary retention were noted & treated.

The patients were followed up postoperatively till recovered completely and sensory & motor block and analgesia.

Statistical analysis was performed by computer software SPSS, version 20 for windows statistical software package (SPSS inc., Chicago, IL, USA). Discrete variables were expressed as counts (%) and compared using the Chi-square tests. Continuous variables were expressed as mean  $\pm$  S.D. and compared using student's t-test. Probability was considered to be statistically significant if  $P < 0.05$ .

### Results:-

Total 56 patients were allocated randomly in two groups of 28 in each group. No statistically significant difference was found by applying unpaired T-test  $p > 0.05$  in demographic data.

**Table 1**

Parameters	Group A (28)	Group B (28)	P value
Age (years)	49.50 $\pm$ 7.326	52.07 $\pm$ 7.892	0.212(NS)
Sex ratio(M:F)	14:14	13:15	
Weight(kg)	56.79 $\pm$ 4.833	57.57 $\pm$ 4.509	0.535(NS)
Duration of surgery (min)	49.79 $\pm$ 5.065	49.11 $\pm$ 3.665	0.568(NS)
Height(cm)	153.96 $\pm$ 3.967	154.86 $\pm$ 4.20	0.426(NS)

Onset of sensory blockade in was comparable in both groups group A mean  $\pm$  SD 3.39 $\pm$ 0.562 min VS group B mean  $\pm$  SD 1.91 $\pm$ 0.438 min. Onset of motor blockade was comparable group A mean  $\pm$  SD 4.67 $\pm$  1.56 group B mean  $\pm$  SD 2.4 $\pm$ 0.512. Duration of sensory blockade was in group A mean  $\pm$  SD 138 $\pm$ 27.30 group B 2.54 $\pm$  25.64. Duration of motor blockade was in group A 118.78 $\pm$ 23.44 group B 210.66 $\pm$ 24.60. Demand of first rescue of analgesia of group A was 180 $\pm$  8.99 min, in group B it was 324.39 $\pm$ 5.79 min.

**Table 2:-**

	Group A (mean $\pm$ SD)	Group B (mean $\pm$ SD)	P value
Onset of sensory blockade(min)	3.39 $\pm$ 0.562	1.91 $\pm$ 0.438	<0.001
Onset of motor blockade(min)	4.67 $\pm$ 1.56	2.4 $\pm$ 0.572	<0.001
Duration of motor blockade(min)	118.78 $\pm$ 23.44	210.66 $\pm$ 24.60	<0.001
Duration of sensory blockade(min)	138 $\pm$ 27.30	2.54 $\pm$ 25.64	<0.001
Demand of first rescue of analgesia (min)	180 $\pm$ 8.99	324 $\pm$ 5.79s	<0.001

Changes in VAS score for pain were significant from 3.5 hrs onwards upto 5 hrs. Visual analog score were low in group B than group A. There was no significant difference between haemodynamic parameters (SBP, DBP, HR).

Side effects observed in group B were nausea, vomiting in 5 patients and urinary retention in 2 patients. Two patients group A had nausea and vomiting while one had urinary retention.

Side effects	Group A (B)	GroupB (B+T)
Nausea	2	5
vomiting	2	5
Urinary retention	1	2

### Discussion:-

Pain in the post-operative period is one of the major factors that impede recovery from anaesthesia and surgery. Subarachnoid block is a easy, early and effective method of regional anaesthesia for postoperative analgesia in lower abdominal and lower limb surgeries. Various adjuvants used with local anaesthetic intrathecally to prolonged analgesia like morphine, buprenorphine, fentanyl, sufentanil, ketamine, clonidine etc.

Tramadol is a centrally acting analgesic agent with a terminal elimination half life 5.5 hrs and provides clinical analgesia for 10 hrs after epidural administration<sup>(11,12)</sup>. Tramadol stimulates the  $\mu$  receptors and to a lesser extent the delta and kappa receptors. It also activates spinal inhibition of pain by decreasing the reuptake of norepinephrine and serotonin. Although tramadol is one fifth as potent as morphine as an analgesic, it causes less respiratory depression and pruritus. It was suggested by other studies that tramadol have local anaesthetic effects on peripheral nerves<sup>(7)</sup>.

The present study had demonstrated that intrathecal tramadol (20 mg) used as adjuvant with 0.5% hyperbaric bupivacaine (15 mg) prolonged the postoperative analgesia in infraumbilical surgeries without any significant side effect like nausea, vomiting, pruritus, respiratory depression.

In the present study there was no significant difference between groups in the pattern of decrease in systolic or diastolic blood pressure during this period. Alsheshmi et al (2003)<sup>(13)</sup> found that Intrathecal tramadol did not seem to influence the intraoperative hemodynamic profile.

Rakshith B Prasad et al 2015<sup>(14)</sup> studied effectiveness of addition of intrathecal tramadol (10 mg) with hyperbaric bupivacaine (10 mg) in prevention of shivering in caesarean section. They were found that tramadol along with bupivacaine intrathecally significant role in reducing anaesthesia induced shivering in parturients while prolonging both sensory and motor components of subarachnoid block. They were found Mean $\pm$ SD time for first postoperative analgesic request (min) in tramadol group (232.18 $\pm$ 80.55) and bupivacaine group (176.56 $\pm$ 47.39).

In our study Mean $\pm$ SD duration of requirement of first rescue analgesia in bupivacaine –tramadol group 324 $\pm$ 5.79 min than bupivacaine group 180 $\pm$ 8.99 min showed significant difference (p-value, 0.001), thus highlighting the fact that group B had prolonged postoperative analgesia. Use of tramadol as adjuvant with bupivacaine intrathecally prolonging duration of analgesia.

### Conclusion:-

In our study we found that tramadol (20mg) adjuvant with bupivacaine given intrathecal route significantly early onset and prolonging duration of sensory and motor blockade, provide effective postoperative analgesia and prolongs the duration for first rescue analgesia without any significant difference in side effects and haemodynamic parameter. Tramadol (20mg) with hyperbaric bupivacaine 0.5% (15mg) intrathecally good for intra and postoperative pain and discomfort peritoneal and intestinal manipulation in various infraumbilical surgeries.

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