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A Comparative Study of Intrathecal versus Epidural Tramadol for Post Operative Analgesia

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Abstract

Back ground: Pain is an integral part of all surgery and is the biggest cause of apprehension amongst patients. This apprehensive behavior creates a feeling of dissatisfaction with the pain relief methods used conventionally. Easy availability, ease administration and economical makes a method of analgesia successful (Lehmann et al.). Inj. Tramadol is a synthetic agonist opioid analgesic without any preference for any particular type of opioid receptor. Its presence in the central neuraxial system mediates the nociceptive action when given either intra thecally or epidurally. *Aim:* The present study was designated to compare postoperative analgesic efficacy and safety of epidural tramadol vs. intrathecal tramadol along with its physiological side effects. *Study Design:* Prospective, randomized-controlled, blinded trial. *Methodology:* 60 patients of either sex, ASA status I or II and posted for abdominal surgeries, gynecological surgeries, orthopedic surgeries were studied in two groups to receive either Inj. Tramadol intra thecally (Group II) along with spinal anesthesia or Epidurally (Group I) along with single shot epidural anesthesia. Duration and quality of analgesia (visual analog scale [VAS] scores), hemodynamic parameters, and adverse event were recorded and statistically analyzed using Chi square test and a p value of <0.05 was considered significant. *Results:* Mean duration of analgesia after epidural bolus of opioid tramadol was 9.86 ± 2.19 hours as compared to intrathecal tramadol which was significantly higher 14.23 ± 1.76. VAS score was always lower in Group I in comparison to other group during the study at various intervals. Hemodynamic parameter remained stable in both the groups. *Conclusion:* We conclude that tramadol 0.5 mg/kg with bupivacaine 0.5% intrathecally provides more effective and longer-duration analgesia than tramadol 1 mg/kg with bupivacaine 0.05% when given epidurally.

Keywords: Epidural analgesia; Postoperative pain; Tramadol.

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Introduction

"For all pleasure mankind can get in not in happiness but from relief of pain." – *John Droden*

A patient posted for surgery is most apprehensive about the pain. They differ in their pain thresholds. It seems that most of the patients are dissatisfied with the techniques used for pain relief. The adequate treatment of pain has been an important yard stick for the quality care the hospital provides. Effective pain control is essential for optimum care

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of patient in the post operative period. If a method of analgesia is to be successful and available to a large number of patients it must be suitable for use even in a general ward and with ease of administration. (Lehmann et al., 1990) [5]. Tramadol a synthetic opioid, without the much dreaded side effects of Opioids, has recently found a place in the management of pain relief post operatively without the fear of respiratory depression. If used intrathecally its antinociceptive effect is known to be transmitted through opioid receptors present at the level of spinal cord. (Bernatzky et al. 1986) [2]. With this back ground we carried out this study (done in 1998) to study the effectiveness of opioids (Tramadol) when given intrathecally as compared to single shot epidural injection for providing pain relief in the post operative period along with the observation for its side effects if any.

Material and Methods

This prospective randomized study was conducted after approval from institutional ethical committee and written informed consent of the patients. For the study 60 patients posted for elective genitourinary and lower limb surgeries of ASA grade I & II, aged 20-55 years of either sex were selected. They were divided in two groups randomly to receive either.

Group I Epidural Tramadol: Inj. Bupivacaine 0.5% 20 ml with Inj. Tramadol 50 mg.

Group II Intra thecal Tramadol: Inj. Bupivacaine 0.5% heavy 3 ml with Inj. Tramadol 25 mg.

After proper pre anesthetic checkup including the vital parameters, investigations, written informed consent patients were premedicated with Inj. Glycopyrrolate 0.2 mg, Inj. Midazolam 1 mg, Inj. Ondansetron 4 mg patients were randomly selected to receive either spinal or epidural anesthesia. No Analgesics were given pre or per operatively. Patients with failed block in whom general anesthesia was to be supplemented were excluded from the study. The Anesthesia procedure was performed under strict aseptic and antiseptic precautions either with 18 G Toughy needle (Group I) or 23 G spinal needle (Group II). Patients were observed for any change in the vital parameters per operatively and post operatively till 24 hours. For post operative pai assessment, Visual Analogue Scale (VAS 1-10) was used. Rescue analgesic of Inj. Diclofenac 75 mg was given when VAS was > 5. Any untoward event or complications were recorded.

Results

The two groups were comparable in age, weight, sex, duration of surgery as showed in table 1. Table 2 shows the level of sensory block received after either of the procedure and table 3 shows the types of procedure selected in either group. Table 4 shows the mean duration of surgery in both the groups. All the observations were clinically and statistically comparable with no much significant change.

Per operative monitoring of Pulse, Blood pressure, SpO_2, respiration was done for both the groups. Graph 1 and Graph 2 show the changes in the mean pulse rate and mean arterial blood pressure in both the groups. The changes in the mean pulse rate were not much significant as compared with the pre operative value and also when compared statistically between both the groups. Even the mean Arterial pressure (MAP) did not show much change per operatively except at end of 2 hours in Group I which might be due to

Table 1: Demographic Variables

Parameters	Group I (n=30)	Group II (n=30)	p value
Mean Age (years)	37.43 ± 13.46	38.56 ± 14.1	0.946
Sex Ratio (M:F)	20:10	09:21	
Weight (kg)	56.93 ± 17.22	51.33 ± 8.78	0.562
ASA grading (I/II)	14:16	14:16	1

Values are Mean ± SD or numbers

Table 2: Sensory Block Level

Level	Group I (n=30)	Group II (n=30)
T12	02	02
T1	13	11
T8	15	16
T6	00	01
Total	30	30

pain in patient. The block level was not very high in either of the group and we did not observe any respiratory depression either due to technical snag or even the study drug used.

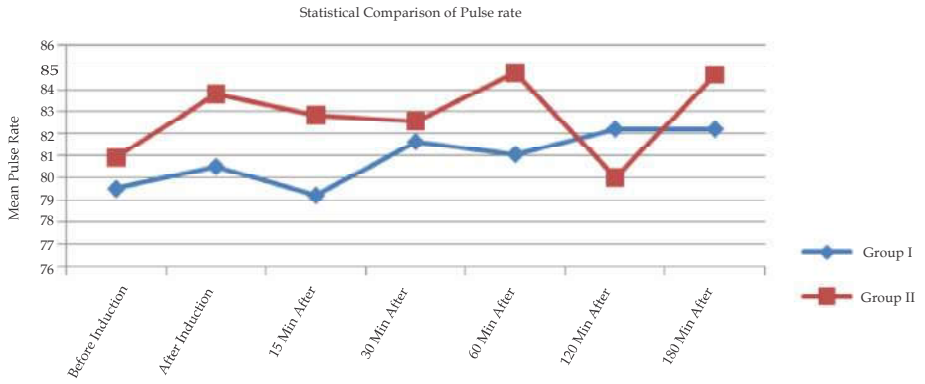
Post operative analgesia was noted for its duration and intensity using VAS. It was observed that 10 patients in group I had pain free period for 9 hours post surgery whereas it was 24 in Group II who were pain free even till 10-14 hours. 20 patients in Group I had pain free period of up to 14 hours and in Group II, 6 patients had pain free period up to 16 hours of surgery (Table 5). The need of rescue analgesia was more in Group I than in Group II. The mean VAS was 3.8 in group I and 3 in group II at the end of 12 hours which was still around 3.2 at the end of 24 hours in group I which was around 5.5 in group II (Table 6).

The duration of recovery from the anesthetic effect in both the group i.e., the recovery from sensory block and motor block (Modified Bromage Scale) were observed (Table 8 and Table 7 respectively).

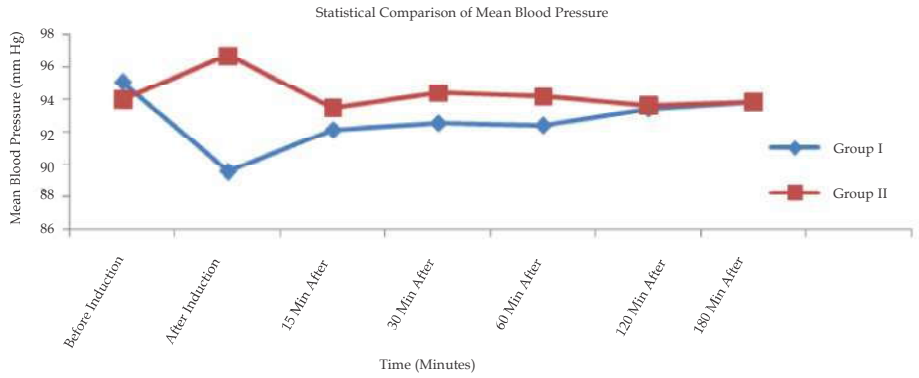
Anticipated complications like hypotension, bradycardia, nausea, vomiting, itching, urinary retention and drowsiness were not seen in any patients in either group except for two patients who had backache 24 hours of procedure in Group I.

Table 3: Types of Surgery

No.	Surgery	Group I	Group II
1	Abdominal Hysterectomy	6	5
	Inguinal Hernioplasty	10	12
3	Vaginal Hysterectomy	5	2
4	Haemorrhoidectomy	3	3
5	DHS for # hip	6	8



Graph 1:



Graph 2:

Table 4: Showing the Mean Duration of Surgery

Duration of Surgery In Minutes	Group I	Group II
30-40	01	00
41-50	00	02
51-70	05	06
71-90	10	10
91-100	11	12
101-140	03	00
Mean ± SD	76.36 ± 26.62	74.52 ± 23.53

Table 5: Showing the Mean Duration of Analgesia in Both Groups

Duration (Hours)	Number of Patients	
	Group I	Group II
5-9	11	00
10-14	19	24
15-16	00	06
20-25	00	00
MEAN ± SD	9.86 ± 2.19	14.23 ± 1.76
p value	<0.01 = Highly significant	

Table 6: Showing Comparison of Pain Score (VAS) at Different Intervals

Duration (Hrs)	Visual Analogue Scale		T Value	p Value	Inference
	Group I	Group II			
1	0.5 ± 0.67	0.1 ± 0.33	0.34	>0.05	NS
2	1.1 ± 0.83	± 0.44	0.23	>0.05	NS
4	1.7 ± 1.05	1.5 ± 0.5	0.95	>0.05	NS
8	3.9 ± 0.92	2.2 ± 0.55	8.71	>0.01	HS
12	5.1 ± 0.56	4.1 ± 0.58	6.8	>0.01	HS
24	5.5 ± 0.49	4.6 ± 0.47	7.5	>0.01	HS

Table 7: Showing Time to Recover from Motor Block (Bromage Scale)

Time (Hours)	Group I	Group II
2-4	20	08
4-6	10	19
6-8	00	03
8-10	00	00
Mean ± SD	3.32 ± 1.01	4.15 ± 0.98

Table 8: Showing Time to Recover from Sensory Block by Pin Prick Method Below T 12 Levels

Time (Hours)	Group I	Group II
2-4	20	12
4-6	09	18
6-8	01	00
8-10	00	00
MEAN ± SD	3.96 ± 1.18	4.36 ± 1.25

Table 9: Showing Post Operative Complications

Complications	Group I	Group II
Nausea	02	00
Vomiting	00	00
Hypotension	00	00
Bradycardia	00	00
Urinary retention	00	00
Drowsiness	00	00
Itching	00	00
Backache	02	00

Discussion

Post operative pain is a self limiting phenomenon and most severe during first day following surgery. Various factors are attributed as the cause of post operative pain like type of surgery and its incision, subjective threshold of the patients, surgical complications, anesthetic management and quality of post operative care. Narcotics have established their role for the relief of post operative pain where it is used either orally, systemically, as infusions or dermally. Use of opioids in central neuraxial block was first done in 1979 after the discovery of opiates receptor in spinal cord. Whether given intra thecally or epidurally the effect of opioids is caused after crossing the meningeal layers and covering the whole cord through CSF where it causes its action by acting on opioid receptors [1]. The known side effects of opioids also occur after administration by spinal or epidural route as they get absorbed in the systemic circulation.

Tramadol a synthetic opioid when used in central neuraxial blockade causes its effect by acting on spinal as well as supra spinal opioid receptors in the CNS (Karl et al., 1976). The anti nociceptive action is mediated by its acting on μ receptors (Shank et al., 1992) [8]. Moreover it was also observed that the effect of Tramadol was not antagonized by Naloxone totally suggesting its non opioid mechanism of its anti nociceptive property (shown by inhibition of non amine uptake).

In this present study done in 1998 where Tramadol was administered through either epidural or intrathecal route for relief of post operative pain in patients under going various types of surgeries as shown in table 3. Monitoring of patients for pulse, blood pressure, SpO_2, respiration and comparing at various intervals showed that vitally patient stayed stable all through out the surgery when compared to pre operative values as well as between two groups. A good pre loading and not allowing the sensory effect to rise high above causing sympathetic block can be the reason for this stability (Graph 1 and Graph 2).

There was no respiratory depression in either group either due to high level of sensory block or the study drug. This implies that Tramadol 25 mg intra thecally or 50 mg epidurally is safe enough to have any adverse effect on respiration or cardio vascular system.

Our main concern of postoperative analgesia was observed by Visual Analogue Scale (VAS) and it revealed that patients receiving tramadol through epidural route experience pain earlier (10 patients had pain free period of around 9 hours, 20 patients had pain relief up to 15 hours) as compared to intra thecal route (24 patients had pain free period up to 14 hours, rest 6 had pain relief up to 16 hours). Rudra A et al. [7] observed that when tramadol used alone in epidural route produces analgesia for up to 10 hours post operatively when compared to local anesthetic alone which advocates the use of opioids in central neuraxial block for pain relief. Because of shorter duration of analgesia in Group I as compared to Group II, the use of rescue analgesia was early and evens more in Group I suggesting good quality of analgesia with intra thecal route Table 5 and Table 6.

Few patients do develop nausea and vomiting when Tramadol is used systemically. After its use in central neuraxial block, the rate of complications was found to be quite less in our study (Table 9).

Conclusion

Intrathecally administered tramadol 25 mg has longer duration of post operative analgesia than the epidurally administered tramadol 50 mg with substantial patient safety as there was no respiratory depression and minimal incidence of the anticipated complications like nausea, vomiting, allergic reaction, and hypotension. With advent of newer receptor specific opioids there is a scope for further evaluation of this route of administration of opioids for post operative pain relief.

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