Section: Anaesthesiology

Original Research Article

COMPARATIVE EVALUATION OF CLONIDINE VERSUS TRAMADOL AS ADJUVANT TO EPIDURAL ANAESTHESIA WITH 0.5% BUPIVACAINE FOR LOWER LIMB ORTHOPEDIC PROCEDURES

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Abstract

Background: Because of its high versatility & well-established use in lower limb orthopedic surgeries, epidural anaesthesia is the most commonly used regional anaesthetic technique. Epidural adjuvants enhance the quality and duration of surgical anaesthesia. Utilized as a polypharmacy method to relieve pain during & after surgery. Aim is to compare the onset and duration of sensory and motor blockade in clonidine and tramadol group with 0.5% bupivacaine and duration of postoperative sensory analgesia. **Materials and Methods:** 60 patients of both gender of ASA physical status I or II, scheduled for lower limb surgeries were randomly allocated equally into two groups-Group 1: Patients was given 14ml of 0.5% Bupivacaine with 1ml(50µg) clonidine. Group 2: Patients was given 14ml of 0.5% Bupivacaine with 1ml(50mg) tramadol. All patients were assessed for onset and duration of sensory and motor blockade and time to achieve highest cephalic dermatome level and duration of sensory analgesia with hemodynamic monitoring and adverse effects if, any. **Result:** Onset of sensory blockade at T10 was faster in patients of Group 1 than Group 2 which was comparable between the groups. Time to achieve highest cephalic dermatome level was earlier in Group 1 than Group 2 with comparable difference. Duration of motor blockade was earlier in patients of Group 1 than Group 2 respectively with statistically significant difference as $p<0.05$. Duration of sensory analgesia was enhanced in Group 2, delaying the need for rescue analgesia. The hemodynamics parameters were comparable among the study groups. In group 1, hypotension was observed only in 3 patients. **Conclusion:** Study validates the use of tramadol as epidural adjuvant for enhancing the sensory and motor blockade along with postoperative analgesia in patients undergoing lower limb orthopedic procedures.

INTRODUCTION

Epidural anesthesia is well established regional anesthetic technique. This technique is commonly employed for surgical procedures involving the lower abdomen, pelvis, and lower limbs. Epidural anesthesia is safe to provide surgical anesthesia and postoperative analgesia.[1]

Epidural anaesthesia attenuates the stress response to surgery due to sympathetic blockade,[2] Epidural block can be performed at any level of spine, as epidural space extends from foramen magnum to sacral hiatus. Out of all lumbar epidural block is simple and safe to perform.[3]

The addition of epidural adjuvants like opioids or α 2 adrenoreceptor agonist can further enhanced the effectiveness of local anaesthetics by intensifying the block and prolonging the duration of analgesia. They also decrease the dose requirement of local anesthetic thus prevents side effects associated with large doses.[4]

Opioid analgesics activate opioid receptors located on primary afferent neurons. This activation leads to the modulation of pain systems and the suppression of action potential transmission in ascending pain pathways. Tramadol, an opioid, has analgesic potency but lacks respiratory depressant effects. It achieves its anti-nociceptive effect by inhibiting the neuronal reuptake of norepinephrine and serotonin.[5]

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Clonidine, a centrally acting α2-adrenergic agonist, reduces sympathetic nervous system outflow of norepinephrine by inhibiting voltage-gated sodium channels. Consequently, it prevents action potential generation in dorsal horn cells, resulting in analgesia, sedation, and anxiolysis without affecting respiratory function.[6,7]

MATERIALS AND METHODS

This hospital based observational study was conducted at The Department of Anaesthesiology, Muzaffarnagar Medical College, Uttar Pradesh, after the approval of Institutional Ethical Committee and informed consents from the patients.

60 patients of either gender of ASA physical status I and II, aged 35 to 60 years posted for elective lower limb surgery under epidural anaesthesia were included in the study and randomly allocated into two groups of 30 each, Group 1-received 14 ml of 0.5% Bupivacaine with 1 ml(50µg) of Clonidine and Group 2- received 14 ml of 0.5% Bupivacaine with 1 ml(50mg) of Tramadol. All patients were subjected to pre-anaesthetic checkup and patients with history of any systemic diseases, having coagulopathy, any skin infection near the lumbar puncture site, history of opioid dependence and patient refusal to technique were excluded from this study.

Methodology

All patients were premedicated with tab alprazolam 0.25 mg and tab ranitidine 150 mg at bedtime the previous day. They were kept fasting for 8 hours prior to surgery. Patients were explained the procedure of epidural anaesthesia at the time of pre-anaesthetic evaluation. After shifting the patients to the operation theatre, routine monitoring of heart rate (HR), electrocardiogram (ECG), pulse oximetry (SpO2), and Non-invasive arterial blood pressure (NIBP) was commenced. An intravenous access was secured and pre-loading with Ringer Lactate at rate of 20ml/kg was done.

The epidural block was administered with strict aseptic precautions. The patient was positioned on the operating table with elbows resting on their thighs. The Epidural needle was inserted midway between the two lumbar spinous processes at L2-L3 or L3-L4 using a 18G Tuohy needle in sitting position, and epidural catheter was advanced, when the epidural space was located by loss of resistance. Following a negative aspiration for CSF or blood, a 3ml (2% Lidocaine with epinephrine 1:200,00) test dose was administered. Five minutes following the test dose, when there were no signs of hypotension and bradycardia, an epidural catheter was fixed at the patient's back, then anaesthetic drugs were given through a lumbar epidural catheter. The total volume of drug solution of 15 ml was given through a catheter. Vital parameters of heart rate, blood pressure, ECG and pulse oximetry were continuously monitored.

Assessment of Sensory and motor block characteristics

The sensory and motor block characteristics were assessed after the injection of the study drug solution at 2 minutes interval till surgical anaesthesia was achieved.

The segmental level of sensory block was assessed by Hollmen scale measured with pinprick test bilaterally along the mid-clavicular line by using a short beveled 26 G hypodermic needle. 0- Sharp pain
1-Dull pain(analgesia)
2- No pain(anaesthesia).

The motor block of the lower extremities was evaluated bilaterally by a Modified Bromage Scale:
0=Full movement and able to raise straight leg against resistance
1= unable to raise extended leg at the hip but able to flex knee
2=unable to flex the knee but able to move ankle joint
3=unable to move hip, knee or ankle (no motor activity)

The surgical anaesthesia was considered adequate when at least the T10 dermatome level was anesthetized. Postoperatively, the sensory and motor block levels were assessed at 30-minute intervals until the patient complained of pain. Pain was assessed using visual analogue scale (VAS) score where 0 represented no pain and 10 meant worst possible pain. If VAS >4, 1st rescue analgesia is given in the form of epidural top-up (8 ml of 0.125% bupivacaine).

Statistical Analysis: Data collected was tabulated in an excel sheet. The mean and standard deviations were used for statistical analysis. Difference between two groups were determined using student's t-test or chi-square test and the level of statistically significant was set at $p < 0.05$.

RESULTS

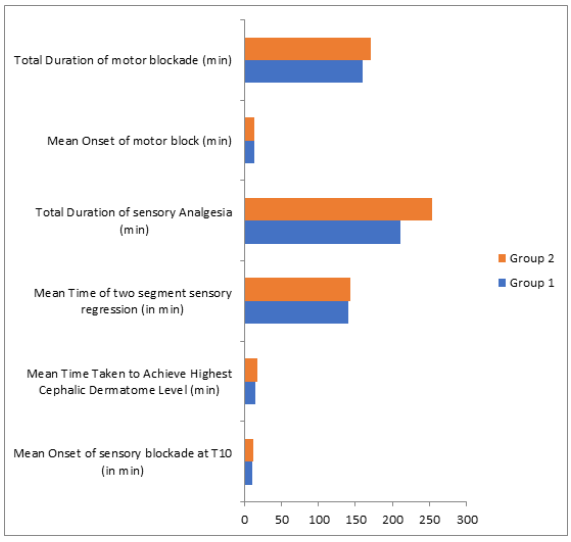

Figure 1: Comparison of epidural blockade characteristics

The mean time required for onset of sensory blockade at T10 in patients of Group 1 was 10.1 ± 2.3 minute and in patients of Group 2 was 11.57 ± 2.04. The

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onset of sensory blockade, time to achieve highest cephalic dermatome, time of two segment sensory regression and onset of motor blockade was faster in patients with epidural clonidine than patients with epidural tramadol, but with comparable difference. The mean duration of motor blockade was 156.25±23.41 minutes and 172.55±21.34 minutes in patients of Group 1 and Group 2 respectively with statistically difference between the groups as(p=0. 42). The mean duration of sensory analgesia in patients of Group 1, was 210.28 ± 24.19 minute and in patients of Group 2, was 253.18 ± 21.7 minute with statistically highly significant difference between the groups as(p=0.005). Side Effects Hypotension was observed in 3 (10%) patients of clonidine group, which was treated by increasing the infusion rate of crystalloid solutions only. No vasopressor medication was required. Rescue analgesia was not required in any patient till 4hours after giving epidural anesthesia. The patients of Group 1 required first rescue analgesic after 210.28 ± 24.19 min, while in patients of Group 2, analgesia lasted longer 253.18 ± 21.7 min when they required first rescue analgesia. Duration of sensory analgesia was maximum in patients of tramadol group.

Table 1: Comparison of epidural blockade characteristics.

Variables	Group 1		Group 2		p value
	Mean	SD	Mean	SD	
Mean Onset of sensory blockade at T10 (in min)	10.1	2.3	11.57	2.04	0.07
Mean Time Taken to Achieve Highest Cephalic Dermatome Level (min)	15.03	2.78	17.16	3.52	0.12
Mean Time of two segment sensory regression (in min)	140.78	14.17	142.6	16.3	0.71
Total Duration of sensory Analgesia (min)	210.28	24.19	253.18	21.7	0.005*
Mean Onset of motor block (min)	13.4	3.85	13.67	3.58	0.83
Total Duration of motor blockade (min)	156.25	23.41	172.55	21.34	0.042*

*: statistically significant

DISCUSSION

Epidural anaesthesia administered before surgical stimuli in lower limb procedures reduces the stress response by preventing central sensitization to pain. It offers sufficient surgical anaesthesia, muscular relaxation, and minimal central nervous system or cardiovascular toxicity. Additionally, epidural anaesthesia provides the added benefit of prolonged duration for postoperative pain management.[1] Different local anaesthetic can be used, but 0.5% bupivacaine is preferred. Adjuvants are used to improve surgical anaesthesia and postoperative analgesia of epidural blockade. Some studies have shown that opioid analgesics and α2-adrenergic agonists administered epidurally could relieve the visceral pain. Therefore, this study was conducted to compare outcomes of clonidine versus tramadol as an adjuvant to epidural anaesthesia with 0.5% bupivacaine for lower limb orthopedic procedures.[8]

In the present study, addition of clonidine and tramadol to epidural bupivacaine produce rapid onset and prolong the duration of sensory blockade. Though sensory blockade profile was significantly better in patients of tramadol groups, but mean onset of sensory block was faster in patients of clonidine group. Sutariya M et al concluded that onset of sensory blockade was faster in patients received clonidine but total duration of sensory blockade was longest in patients received tramadol.[9]

Kumkum Gupta et al in their study similarly reported that mean onset time and two dermatome sensory regressions was comparable but the mean duration of sensory analgesia was 216.08±46.18 mins in patients of Group I (clonidine) and 251.33 ± 58.5 mins in patients of Group II (tramadol) with statistically highly significant difference between the groups (P=0.000). Mean onset time and duration of motor blockade was comparable.[8]

Gupta S et al concluded that the mean onset time of sensory anaesthesia was significantly faster (493.8 ±31.66 seconds) in patients of clonidine group as compared to patients of control group (686.4 ±47.42 seconds).The results of their study was in agreement with present study.[10]

Noha Sayed Hussien and Tanmoy Ghatak et al also observed no difference in the quality of motor blocks between the groups. The result of their study was consistent with the present study.[11]

In this study, significantly lower VAS scores were observed in patients receving epidural tramadol, indicating good postoperative analgesic effect. Mahesh Sutariya et al in their study concluded that total duration of analgesia was longest in Group B, followed by Group C based upon Visual Analogue Scale. Both tramadol (Group B) and clonidine (Group C) prolong duration of analgesia and decrease the requirement of post-operative analgesic doses and amongst them tramadol (Group B) is superior.[9]

Epidural clonidine has been reported to result in intra operative hypotension. In this study, hypotension was observed in 3 patients of clonidine group which was treated by increasing the rate of crystalloid solution infusion only. No vasopressor medication was required to manage the hypotension.

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CONCLUSION

Based on our study findings, it is evident that both epidural adjuvants i.e. clonidine and tramadol could provide effective anaesthesia and analgesia but tramadol 50 mg with 0.5% bupivacaine augments the sensory and motor blockade along with postoperative analgesia. Therefore, tramadol is recommended over clonidine when prolongation of anaesthesia is desired. In this study, both groups showed no significant differences in hemodynamic parameters, and adverse effects were not observed. However, there is potential for further investigation to optimize the concentration and volume of the local anaesthetic agent, which could improve overall outcomes in this approach.

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