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Epidural Anasthesia in Lower Limb Surgeries: A Comparison between Bupivacaine Alone and Bupivacaine with Tramadol

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ABSTRACT

Compare the epidural bupivacaine alone and bupivacaine with tramadol in lower limb surgeries. The patients were randomly divided into two groups with 50 patients in each group as under: Group I (Bupivacaine): These patients received 20ml of 0.5% Bupivacaine + 1 ml of normal saline total volume 21ml administered through epidural route. Group II (Bupivicaine Tramadol): These patients received 20ml of 0.5% Bupivacaine + 1 ml of Tramadol (50mg) total volume (21ml) administered through epidural route. The parameters studied were onset of action, quality of anaesthesia, degree of motor blockade, duration of analgesia, hemodynamic alterations, intraoperative and postoperative complications. Mean onset of action was comparable in both groups. Quality of surgical anaesthesia was excellent in both groups. All patients in group I (Bupivacaine) and group II (Bupivacaine Tramadol) reached Bromage grade I. Duration of analgesia was prolonged in group II (Bupivacaine – Tramadol) as compared to group I (Bupivacaine). Group II (Bupivacaine Tramadol) remained superior to group I (Bupivacaine) in respect of duration of analgesia. In group I Bupivacaine 1 (2%) patient developed hypotension and none of the patient had bradycardia. Two (4%) patients developed nausea. Two (4%) developed shivering. None of the patients had intraoperative vomiting. In group II (Bupivacaine Tramadol) 1 (2%) patient developed hypotension and none of the patient had bradycardia. 2(4%) patients developed nausea. None of the patient had intraoperative vomiting. None of the patients had shivering. None of the patient in any study group developed postoperative nausea, vomiting, postdural puncture headache or backache. Tramodol is a safe and effective adjuvant to epidural bupivacaine for prolongation of total duration of analgesia in lower limb surgeries.

Keywords: Bupivacaine, tramodol, epidural, lower limb surgeries.

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INTRODUCTION

Major orthopaedic procedures on hip and lower limbs are commonly performed in elderly patients. These patients may have associated medical ailments (Cote J et al 1985)[1] in the form of essential hypertension, coronary artery disease, cardiac dysrythmias, chronic obstructive pulmonary disease with decreased respiratory reserve and diabetes mellitus. Considering these problems, regional anaesthesia appears to be safe and beneficial in elderly patients (Tsui BC et al 2004)[2]. Among various regional anaesthesia techniques epidural anaesthesia has become increasingly widespread and popular in recent years because of its use in postoperative analgesia. Further side effects like hypotension, post dural puncture headache, bradycardia are very less. Local anesthetics are the drugs that cause neural blockade and thus inhibit transmission of impulse. Bupivacaine 0.25%, 0.5% solution was found to be excellent drug giving rapid onset and a profound degree of analgesia. Opioids produce analgesia by binding to opioid receptors in substantia gelatinosa of spinal cord whereas local anaesthetics provide analgesia by blocking pain transmission at nerve roots and dorsal root ganglion. Even if an extremely low concentration of local anaesthetic is added to an opiod, quality of analgesia may be superior. With the objective of attaining analgesia synergy between different analgesia drug combinations to produce pain relief of greater magnitude while decreasing the incidence and severity of side effects the present study was undertaken.

AIMS and OBJECTIVES

The present study was undertaken to compare two drugs viz 0.5% Bupivacaine alone and 0.5% Bupivacaine + Tramadol 50mg administered through epidural route in lower limb surgeries as regards their:

1. Onset of anaesthesia
2. Quality of surgical anaesthesia
3. Degree of motor blockade
4. Post operative analgesia for first 24 hrs.
5. Alterations in vital signs
6. Undesirable sequelae

The relevant findings obtained were evaluated statistically.

MATERIAL AND METHODS

After approval of Ethics Committee of the Institution, Govt. Medical College, Srinagar, J&K, India, the study population of either sex in the age range 30-60 years belonging to ASA I, scheduled for elective lower limb surgery were include in the study and were divided into two groups as under: **Group-I:** This group consisted of 50 patients who received 0.5% Bupivacaine (20ml) + (1ml) normal saline. **Group-II:** This group consisted of 50 patients

who received 0.5% Bupivacaine (20ml) + Tramadol 50mg (1ml). Total volume administered through epidural route was 21ml. Pre-anaesthetic evaluation was done at least 24 hours prior to surgery. All Patients belonging ASA-I and age range 30- 60 years were include in study except the Patients with following diseases who were excluded from the study: Bleeding disorders, Neurological orders, Emotional instability, Skin sepsis in the lumber region, Sever back deformities, Raised intracranial pressure, Fixed Cardiac output states like severe valvular stenosis, Grossly obese patients. All the patients were thoroughly explained about the anaesthetic procedure. An informed written consent was taken from all the patients. Tablet Alprazolam 0.25 – 0.5 mg oral night before surgery was given to all the patients. Intravenous line was established on the non-dominant hand using 16 gauge intravenous cannula. Preloading was done with reasonably warm Ringer Lactate 10-15 ml per Kg body weight administered over a period of 15-20 minutes before the block. The multichannel monitor was attached and baseline pulse rate, blood pressure, ECG, and SPO_2 were recorded. Under all aseptic precautions and proper position, the epidural block was performed at L_3 – L_4 space. In order to exclude both subarachnoid injection and intravascular injection a test dose was performed in both the groups by using 3ml of 2% lignocaine and 1:200000 epinephrine. Absence of tachycardia or motor blockade within 5 minutes ruled out intravascular and subarachnoid placement of the drug. The patient was then positioned on the orthopaedic table after the establishment of block. After the regional block vitals were monitored every 3 minutes for initial 15 minutes and every 5 minutes thereafter till the completion of surgery. The ECG was monitored continuously. Oxygen 3L/minute was administered through Hudson's mask. Bradycardia (heart rate less than 60 beats per minute) was treated with injection glycopyrrolate 0.2mg intravenously in diluted and divided doses. Hypotension (defined as 25% decrease in systolic blood pressure compared with preoperative control levels) was treated intravenous fluids and Vasopressor (ephedrine). The following parameters were studied in the intra-operative period:

01. **Onset of Action: -** Onset of action was taken as the same time from injection of anaesthetic solution to start of loss of sensation to pin prick.The level of sensory block was tested at one minute interval by pinprick. After 5 minutes it was tested at 5 minute intervals until the start of surgery.
02. Quality of Surgical Anaesthesia: Using a "Four-Grade Scale". This was graded as:-

    Excellent: No Supplementary Sedative or Analgesic required

    Good: Only Sedative required

    Fair: Both Sedative and Analgesic required

    Poor: General Anaesthesia and Tracheal Intubation required.

03. Degree of motor blockade or muscle relaxation assessed by **Bromage Scale as under:-**

Grade I:- Inability to move feet

Grade II:- Ability to move feet only.

Grade III:- Just ability to move knees.

Grade IV:- Full flexion of knees and feet.

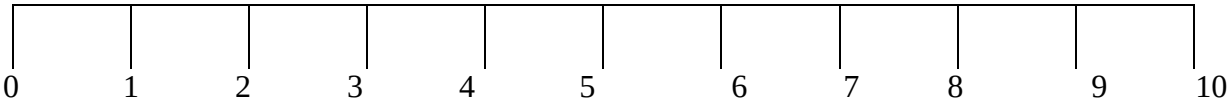
04. Alterations in Vital Signs.

05. Other Undesirable Sequelae like Nausea, Vomiting. and Any other Undesirable Complication like shivering, anaphylactoid reaction, respiratory distress.

Postoperative Period

The patients were observed for the first 24 hours for following observations:

1. Post operative analgesia: Post operative pain was assessed by visual analogue scale (VAS). VAS scale consists of 10cm line with 0 equal to no pain and 10cm worst possible pain. VAS score was noted hourly till 6 hours and then 6 hrly for 24 hrs and time noted to a score of 4 or demand for rescue analgesia. Duration of analgesia or pain free period in both groups was calculated from completion of epidural anaesthesia to the time of rescue analgesia administered or VAS score more than 4.



Visual analogue scale

Post operative analgesia was administered by injection diclofenac sodium (75mg) intramuscularly and total numbers of injections in 24 hrs were recorded

2. Backache (if any)
3. Nausea, vomiting
4. Headache (if any)

Statistical Analysis: The data was analyzed by applying parametric and non-parametric tests. The whole data was measured by mean, percentage and standard deviation. Intergroup variance and difference in proportions between two study groups was assessed by student's t-test, Mann-Whitney U test, Chi Square test. The intergroup variance was measured by students paired t-test and Wilocoxon sign rank test. The overall difference was measured by Friedmann test. A value of $p<0.05$ was considered significant.

RESULTS AND DISCUSSIONS

The present study comprised of 100 healthy adults of either sex, of ASA grade I who were scheduled for elective lower limb surgery. The patients were randomly divided into two groups: group I (Bupivacaine) and Group II (Bupivacaine Tramadol) of 50 patients each.

After appropriate preparation, the patients of group I (Bupivacaine) were given injection 0.5% Bupivacaine (20ml) + (1ml) normal saline total volume 21 ml administered through epidural route. The Group II (Bupivacaine Tramadol) were given inj. 0.5% Bupivacaine (20ml) + Tramadol 50mg (1ml) total volume (21ml) administered through epidural route.

Age and weight distribution

In present study, mean age in group I (Bupivacaine) was given 44.56 + 5.88 years and in group II (Bupivacaine Tramadol) mean age was 45.44 + 4.29 years. Mean weight in group I (Bupivacaine) was 65.56 + 4.17 kgs. Mean weight in group II (Bupivacaine Tramadol) was 64.86 + 3.56 Kg. Thus the two groups were comparable in age and weight distribution (table 1).

Table 1: Demographics characteristics of two groups

	Group I	Group II	P value
Age (years)	44.55±5.88	45.44±4.28	**0.395**
Weight (kg)	65.56±4.171	64.86±3.55	**0.369**
Sex (M/F)	33/17	34/16	**0.500**
Duration of surgery (min)	148.68±13.39	152.52±17.14	**0.101**
Data expressed as mean ± SD and numbers			

Surgical procedures performed on the patients

55% patients underwent Dynamic hip screw surgery, 12% patients underwent interlocking intramedullary nailing, 10% underwent open reduction internal fixation with K nail, 10% underwent Hemiarthoplasty, 31% underwent osteosynthesis, 2% underwent disarticulation and 1% underwent Girdle bone excision, total hip replacement, tendoachilles lengthening, removal of hardware and arthodesis, buttress plating, V. nail, dynamic compression screw and dynamic compression plating each.

Duration of surgery

In group I (Bupivacaine) minimum duration of surgery was 138 minutes and maximum duration of surgery 155 minutes. Mean duration of surgery 148.68 + 13.397 minutes.

In group II (Bupivacaine Tramadol) minimum duration of surgery was 145 minutes and maximum duration of surgery was 162 minutes. Mean duration of surgery was 152.52 + 17.143

Onset of Action

Mean onset of action in group I (Bupivacaine) was 11.59 + 0.740 minutes. In group II (Bupivacaine Tramadol) the mean onset of action was 11.41 + 0.703 minutes. Thus the two groups were comparable in the mean onset of action.(table 2)

Table 2: Block Characteristics of Two Groups

	Group I	Group II	P value
Onset of action (min)	11.59±0.74	11.41±0.70	**0.270**
Duration of analgesia (hrs)	5.430±0.235	6.83±0.75	**0.000**
Quality of anesthesia (n):-			
Excellent	50 (100%)	50 (100%)	1.000
Good	0%	0%	
Degree of motor blockade			
(Grade I/II) (n)	50/0	50/0	1.000

Data expressed as mean ±SD, numbers (n) and percentage (%)

Quality of surgical Anaesthesia

In the present study all the patients (n = 50) in group I (Bupivacaine) had excellent quality of anaesthesia i.e none of the patients required supplemental sedative or analgesia. Similarly all the patients (n =50) in group II (Bupivacaine Tramadol) experienced excellent quality of anesthesia (table 2). The present study correlates with those of Dunne et al (1991)[3] who used 0.5% Bupivacaine through epidural route and reported that it produced excellent intra operative analgesia, with less toxic effects than 0.75% Bupivacaine. None of the patients needed supplemental general anaesthesia.

Degree of Motor Blockade

In the present study all the patients (n=50) in group I (Bupivacaine) reached Bromage grade I i.e. inability to move feet. Similarly all the patients (n=50) in group II (Bupivacaine Tramadol) reached Bromage grade I i.e. inability to move feet. The present study correlates with those of Dunne et al (1991)[3] who used 0.5% Bupivacaine through epidural route and reported that all the patients reached Bromage grade I (table 2).

Total duration of Analgesia

The mean duration of analgesia (duration of pain free period from completion of epidural anaesthesia to the time of rescue analgesia or VAS score more than 4) in group I (Bupivacaine) was 5.43 + 0.24 hours and in group II (Bupivacaine Tramadol) mean duration of analgesia was 6.84+0.75 hours (table 2). These findings have been found consistent with the studies conducted by Modig et al (1981)[4], Subash P. N et al (1998)[5]. There was no appreciable difference in the pain score up to 1 hour post operatively among the two groups, but group – I showed higher pain scores at 2^{nd}, 3^{rd}, 4^{th} and 5^{th} hours post operatively by the Visual Analogue Scale (VAS) than group II (Bupivacaine Tramadol) ($p<0.05$) (Table 3 and 4).

Table 3: VAS

	Hour	I Bupivacaine	II Bupivacaine–Tramadol	p-value
Mean + standard deviation	2	1.16+0.37	0	0.0
	3	2.04+0.19	1.04+0.19	0.0
	4	3.02+0.24	2.04+0.19	0.0
	5	3.78+0.46	3.10+0.36422	0.0
	6	4.94+0.23	4.94+0.2399	1
	12	4.94+0.23	4.94+0.23	1
	18	4.98+0.24	4.98+0.24	1
	24	6.04+0.197	6.04+0.197	1

Table 4: VAS

Group	Hour	Mean	Standard deviation
II	0	0	0
Bupivacaine Tramadol	1	0	0
	2	0	0
	3	1.04	0.19795
	4	2.04	0.19795
	5	3.10	0.36422
	6	4.94	0.23990
	12	4.94	0.23990
	18	4.98	0.24661
	24	6.04	0.19795

In the 1970's, Tramadol was introduced by Grunenthal to the German market as weak opioid with an atypical clinical profile. Tramadol is a central analgesic with an intermediate potency and dual mode of action (Jean-Marie Besson et al 1994)[6]. In the present study, Group II (Bupivacaine Tramadol) received 0.5% Bupivacaine (20ml) with Tramadol 50mg (1ml). The total duration of analgesia was 6.84 + 0.75 hours. This was significantly longer than the group I (Bupivacaine). These values agree with various studies which show analgesic duration of 6 – 8 hours with Tramadol, Houmes et al (1992)[7], Delikan et al (1993)[8]. The pain scores were similar to the other group up to 1 hour post operatively. But group II (Bupivacaine Tramadol) had significantly better pain scores than group I (Bupivacaine) after 2^{nd}, 3^{rd}, 4^{th} & 5^{th} hours post operatively. Thus the addition of Tramadol to Bupivacaine had significantly improved duration of epidural analgesia than the other group. Similar findings have been made in a study conducted by Subash P. N. et al (1998)[5], in which 105 patients aged 20 – 70 years, undergoing surgeries that could come under lumbar epidural anaesthesia, were allocated randomly into three groups receiving Bupivacaine, pethidine and Tramadol and it was reported that addition of Tramadol to Bupivacaine when both drugs were given epidurally, increased the duration of quality of analgesia with Bupivacaine.

Hemodynamic changes (Figure 1and 2)

In the present study hypotension was taken as 25% decrease of systolic blood pressure compared with preoperative control levels. Pulse rate less than 60 beats per minute was considered as bradycardia.

In group I (Bupivacaine) 1(2%) patient developed hypotension while none of the patient developed bradycardia. In group II (Bupivacaine Tramadol) 1 (2%) patient developed hypotension while none of the patient developed bradycardia .

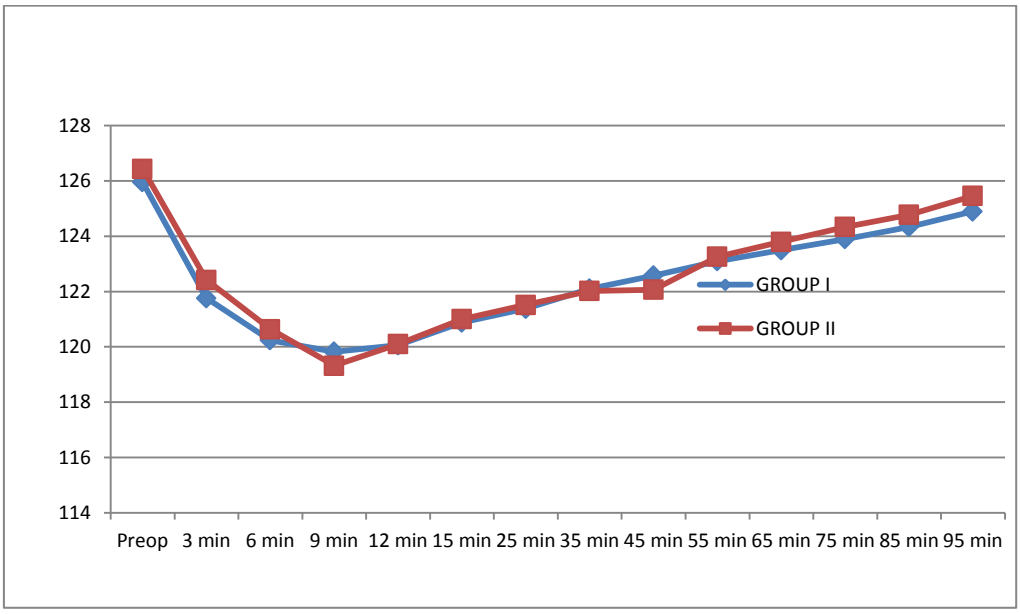


Figure 1: Mean heart rate at differnt time intervals in two groups

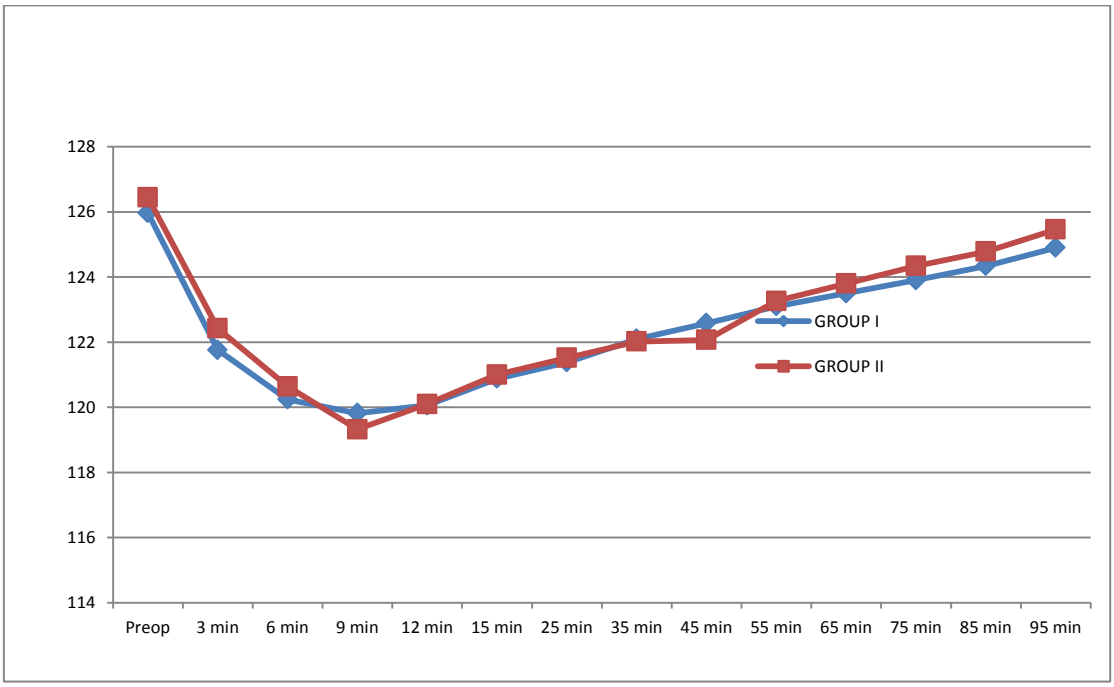


Figure 2: Mean systolic pressure at different time intervals in two groups

The attributable factor for insignificant hemodynamic changes is slower onset of epidural action. This is in accordance with the findings of Subash P. N. et al (1998)[5].

Intraoperative complications

Nausea and vomiting: In the present study 2(4%) patients in group I (Bupivacaine) developed nausea. In group II (Bupivacaine Tramadol) 2 (4%) patients had nausea. None of the patient in any group developed vomiting. This is thought to be an opioid related side effect is in accordance with finding of Vickers et al (1992)[9]. Complications like nausea, vomiting, respiratory depression have been seen with epidural administration of groups notably opioids. Houmes et al (1991)[7] higher incidence of adverse effects with Morphine as compared to Tramadol especially respiratory depression. Naguib et al (1991)[10] observed patients having nausea, vomiting, urinary retention after caudal Bupivacaine and Ketamine. Morphine is known to cause nausea, vomiting, respiratory depression when given epidurally, Modig et al (1981)[4]. In the present study in all the two groups respiratory depression, vomiting were not seen at all.

There was no respiratory depression seen in the Tramadol group as in accordance with studies of Vickers et al (1992)[9], houmes et al (1992)[7], Delikan et al (1993)[8], Baraka et al (1993)[11].

Postoperative complications:

Post Dural Puncture Headache (PDPH): In the present study none of the patients in any group developed post dural puncture headache. The possible reason for this may be: The blunt, curved tip helps push away the dura after passing through the ligmentum flavum instead of penetrating it.

CONCLUSION

Tramadol is a safe and effective adjuvant to epidural bupivacaine for prolongation of total duration of analgesia in lower limb surgeries. Tramadol can fill an important gap in the physicians armoury with regards to the treatment of acute and sub-acute postoperative pain, day care surgery and as a step 2 agent in WHO Ladder for treatment of cancer pain

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