



COMPARISON OF EFFICACY OF EPIDURALLY ADMINISTERED BUTORPHANOL AND TRAMADOL IN PROVIDING POSTOPERATIVE PAIN RELIEF IN ELECTIVE LOWER LIMB SURGERIES - AN OBSERVATIONAL STUDY

Anaesthesiology

Dr. Asmita Desai*	Junior Resident-3, Department of Anaesthesiology, Government Medical College and Hospital, Miraj*Corresponding Author
Dr. Ujjwala Khairmode	Associate professor, Department of Anaesthesiology, Government Medical College and Hospital, Miraj
Dr. Raviraj Shivajirao Pol	Assistant professor, Department of Anaesthesiology, Government Medical College and Hospital, Miraj

ABSTRACT

BACKGROUND: Using local anaesthetic agent as epidural analgesia is simple, effective and economical way of providing postoperative analgesia. Local anaesthetics used epidurally provide good pain relief in the perioperative period. The present study was conducted to assess the safety and efficacy of post-operative analgesia with epidural butorphanol and epidural tramadol and their efficacy been compared. **MATERIAL:** All adult patients eligible by the mentioned inclusion criteria were considered as sample, and were observed and analyzed for a duration-based study. Present study includes total 78 patients, which were further divided in two equal groups. Group A (39 Patients) received 15ml of 0.5% Bupivacaine with 1 mg of butorphanol (Total volume 16 ml) Group B (39 Patients) received 15ml of 0.5% Bupivacaine with 50 mg of tramadol (Total volume 16 ml). **RESULTS:** In present study there was no statistically significant difference in both in both group with respect to demographically such as age, gender, height, weight and ASA grade. In this study it was found that VAS score increased at 5 hours in butorphanol group whereas in tramadol group increased at 6 hours and there was statistically significant difference in VAS score from 4 hours to 8 hours postoperatively. There was no statistically significant difference seen between two groups in mean reductions of heart rate. In this study there was no statistically significant difference between two groups in mean systolic and mean diastolic blood pressure from baseline till 120 mins. The mean time of onset of sensory block in the study was 12.79 ± 1.43 min in Group A and 13.87 ± 1.43 min in Group - B. **CONCLUSION:** It can be concluded from this study that epidural bupivacaine with butorphanol provides a rapid but shorter duration of analgesia when compared to epidural bupivacaine with tramadol. Epidural bupivacaine with butorphanol had lesser side effects like nausea, vomiting, pruritus than bupivacaine with tramadol group.

KEYWORDS

Butorphanol, Tramadol, Elective Lower limb, Postoperative Pain, Epidural Anaesthesia

INTRODUCTION

International association for study of pain has defined pain as an unpleasant sensory and emotional experience associated with actual or potential tissue damage or defined in terms of such damage.

In major surgery cases, postoperative analgesia is the most important aspect of anaesthesia. Postoperative pain may raise various psychological and physiological phenomenon, therefore effective pain control is important for early mobilization and postoperative discharge.^{1,2}

Epidural anaesthesia and analgesia remain superior route for thoraco-abdominal and lower limb surgeries since it preserves the pulmonary function and provides early mobilization with lesser risk of deep vein thrombosis.³

Using local anaesthetic agent as epidural analgesia is simple, effective and economical way of providing postoperative analgesia. Local anaesthetics used epidurally provide good pain relief in the perioperative period.^{4,5}

Opioids have been added due to short duration of action of local anaesthetics so that even small doses can provide more duration of analgesia with lesser side effects. Addition of opioids to local anaesthetics, reduces frequent supplementation of drugs. Pethidine and Morphine remain the standard opioids which are used for postoperative pain. However they are related with delayed respiratory depression and abuse potential.^{5,6}

With discovery of newer opioids like butorphanol tartrate, tramadol hydrochloride and fentanyl citrate, a new era in pain relief has commenced. Butorphanol tartrate, a synthetic opioid derivative is a mixed agonist and antagonist non-narcotic opioid analgesic where as tramadol hydrochloride is a synthetic 4-phenyl-piperidine analog of codeine and has dual mechanism of action. The advantage with these newer drugs is that their potency is comparable to that of morphine, produce lesser respiratory depression, easily available, larger margin of safety and lesser incidence of nausea, vomiting, urinary retention, pruritus compared to morphine.⁷ Hence, the present study was conducted

to assess the safety and efficacy of post-operative analgesia with epidural butorphanol and epidural tramadol and their efficacy been compared.

MATERIAL AND METHODS

An Observational study was conducted in Department of Anaesthesiology, Tertiary Care Government Teaching Hospital. During March 2021 to August 2022. All adult patients eligible by the mentioned inclusion criteria were considered as sample, and were observed and analyzed for a duration-based study. Present study includes total 78 patients, which were further divided in two equal groups. Group A (39 Patients) received 15ml of 0.5% Bupivacaine with 1 mg of butorphanol (Total volume 16 ml) Group B (39 Patients) received 15ml of 0.5% Bupivacaine with 50 mg of tramadol (Total volume 16 ml)

INCLUSION CRITERIA:

1. Patients undergoing elective lower limb orthopaedic surgeries
2. Patients willing to participate and giving written informed consent.
3. ASA Grade - I and II
4. Patients in age group between 18 to 60 years of either sex

EXCLUSION CRITERIA:

1. Not willing to participate or not giving written informed consent.
2. Skin infection near injection site.
3. Coagulopathy.
4. Patients with history of drug allergy.
5. Patients requiring on table supplementation with general anaesthesia.

DETAILED PROCEDURE OF STUDY CONDUCT

After obtaining approval from institutional ethics committee, patients were fully explained about the study procedure. Then written informed consent was obtained from patients. A detailed history and pre anaesthetic evaluation were done on the previous day of the surgery. Routine investigations like hemoglobin, blood grouping, serum electrolytes, blood sugar were measured. Patient were kept nil oral for 6 hours before surgery.

All patients were monitored with electrocardiography, pulse oximetry

and blood pressure, baseline heart rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial blood pressure (MAP) and oxygen saturation (SPO2) were recorded. A peripheral intravenous line was secured with 18G intravenous cannula and ringer lactate solution was started as maintenance fluid.

Premedication

Inj.Ondansetron (0.1mg/kg) IV was given.

PROCEDURE:

Under strict aseptic precaution with patient in sitting position, painting draping done, L1-L2 or L2-L3 interspace was identified, after injecting local anaesthetic solution, epidural space was identified using 18G Tuohy's needle by loss of resistance technique and hanging drop technique. 18G Epidural catheter was inserted 3-4cm inside epidural space and aspiration was done to rule out any subarachnoid or intravascular placement of the catheter. Test dose of 3ml of 2% lidocaine with adrenaline 1:2,00,000 was given, 5 min after the test dose in absence of any adverse effects catheter fixation was done. Duration of surgeries chosen for the study was of 90-120 minutes. **Group A** received 15ml of 0.5% Bupivacaine with 1 mg of butorphanol (Total volume 16 ml) **Group B** received 15ml of 0.5% Bupivacaine with 50 mg of tramadol (Total volume 16 ml) No other intravenous opioids or analgesics were administered during surgery.

Assessment of sensory and motor blockade were done at the end of each minute with patient in supine position after completion of the injection of study drug, Hemodynamic parameters like pulse rate, blood pressure, saturation and ECG changes were noted at an interval of 5 min, at intervals for every 5 min for first 30 min and every 30 min throughout the intra-operative period.

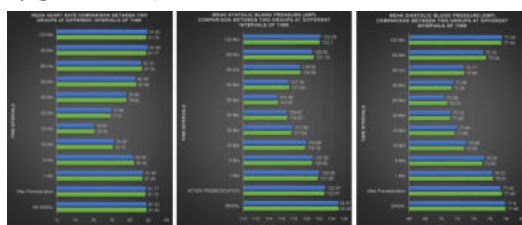
Sensory blockade was assessed by pin prick method using a short beveled 24-gauge needle. The sensory block was evaluated by using a modified Hollmen scale. Sensory block was assessed at each minute till a complete sensory block (Hollmen scale = 4) was achieved and then every hour till Hollmen scale 1 was achieved Post operative monitoring was done upto 24 hours and duration of post operative analgesia was done, requirement of rescue analgesia was noted. The side effects due to opioids like nausea, vomiting, pruritus, urinary retention was noted down.

Statistical analysis was performed by using SPSS. Using this software range, frequencies, percentages, means, standard deviations, chi square and 'p' values was calculated. Chi-square test to be used to test the significance of difference between quantitative variables and. A 'p' value less than 0.05 is taken to denote significant relationship.

RESULTS

Present study was conducted in department of anesthesiology in tertiary care center on 78 patients undergone elective lower orthopedic lower limb surgery which was divided in two grouped randomly into either butorphanol with Bupivacaine (A) group and tramadol with bupivacaine (B) group which include 39 patients each group.

In this study, Majority of patients belong to age group 31-40 years with mean age in Group A was 35.87±8.88 years and Group B was 38.48±10.19 years. There was no statistically significant difference in age distribution among both the groups in present study (p-value>0.05). In Group A out of 39 patients 25(64.10%) were males and 14(35.90%) were females. In Group B out of 39 patients 28(71.79%) were males and 11(28.21%) were females. There was no significant difference in Gender distribution between two groups. (p-value>0.05) Mean weight in Group A was 64.61±7.75 kg and in Group B it was 67.15±7.02kg. Mean height in Group A was 161±26 cm and in Group B it was 162±9.89 cm. Both the weight and height showed no statistically significant difference among both the groups in present study (p-value>0.05).



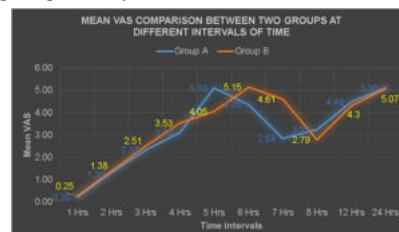
There was no statistically significant difference seen between two groups in mean reductions of heart rate. In this study there was no statistically significant difference between two groups in mean systolic and mean diastolic blood pressure from baseline till 120 mins. The mean time of onset of sensory block in the study was 12.79±1.43 min in Group A and 13.87±1.43 min in Group – B.

The Mean time to sensory regression at S1(min) in our study was 245±12.88 min in group A, while it was 269.38±6.86 min in group B, which was statistically significant.

Mean time taken for onset of motor block was 22.35±1.45 min in Group A and in Group B was 22.56±1.84 min. There was no statistically significant difference in mean time taken for onset of motor block between two groups. The mean time of duration of motor block in group A was 204.95±9.23 min and the mean time of duration of motor block in group B was 208±8.05 min which was statistically insignificant in both the groups.

	Group A (Bupivacaine with butorphanol)	Group B (Bupivacaine with tramadol)	P Value
	Mean ± SD	Mean ± SD	
Mean Onset of Sensory Blockade	12.79±1.43 min	13.87±1.43 min	0.719
Mean Duration of Sensory Blockade	245±12.88 min	269.38±6.86 min	0.003*
Mean onset of Motor Blockade	22.35±1.45 min	22.56±1.84 min	0.123
Mean Duration of Motor Blockade	204.95±9.23 min	208±8.05 min	0.262
Mean duration of analgesia	342 min	402 min	0.001*

In this study it was found that VAS score increased at 5 hours in butorphanol group whereas in tramadol group increased at 6 hours and there was statistically significant difference in VAS score from 4 hours to 8 hours postoperatively.



In Group A, 4(10.26%) had Nausea and vomiting and in group B 10(25.64%) patients had nausea and vomiting, this was statistically significant. In the study no patients in group A and 1(2.56%) of group B patients had pruritus. That was statistically insignificant.

DISCUSSION

Effective postoperative pain control is an important component of postoperative recovery and a prime concern for anaesthesiologists. The goal of modern postoperative pain management is to minimize suffering and enhance recovery and rehabilitation through blunting mal-adaptive reflexes.⁸ Epidural route is being used extensively for post operative pain control. The advantages of epidural route include the use of lower doses, longer duration of effects and lower incidence of side effects.⁹

Epidural anaesthesia is superior to spinal as the desired block levels can be achieved without significant Hemodynamic disturbances and top-up doses of anaesthetics & analgesics can be given. In modern anaesthesia practice Epidural anaesthesia is widely used especially in patients undergoing surgical procedures involving lower parts of the body. To fulfil this demand, there is a need for local anaesthetic with desirable properties like longer duration of sensory blockade and shorter duration of motor blockade.¹⁰

Traditionally epidural bupivacaine was used for post-operative analgesia. The epidural bupivacaine 0.5% causes motor, sensory and sympathetic blockade, 0.25% causes sensory and autonomic blockade and 0.125% causes autonomic blockade only.

Epidural and intrathecal opioids are today being used for intraoperative and postoperative analgesia.

This study was done to evaluate the sensory and motor blocking properties, quality and duration of analgesia and side effects if any of both butorphanol and tramadol.

After informed consent 78 patients of ASA class I and II, posted for various elective lower limb orthopedic surgeries were grouped randomly into either butorphanol with Bupivacaine (A) group or tramadol with bupivacaine (B) group.

Epidural space was identified with loss of resistance technique to air. Epidural catheter was inserted and secured 3-4cms inside epidural space and 3 ml of lignocaine 2% with adrenaline test dose given, patients were observed for 3mins for any intravascular or intrathecal placement of catheter. Later 15 ml of the study drug was injected and various parameters were studied.

In present study there was no statistically significant difference in both in both group with respect to demographically such as age, gender, height, weight and ASA grade.

A study conducted by Deo et al, found that mean base line HR (bpm) of epidural butorphanol was 82.8 ± 11.2 bpm and that of epidural tramadol was 85.7 ± 9.9 bpm which is close to our study.¹¹ Khot B et al also observed that among postoperative parameters pulse rate decreased significantly ($p < 0.05$) when compared with the time intervals during 0 hours and 24hour period in both the groups, however on intergroup comparison the difference was not found statistically significant ($p > 0.05$).¹² The results are similar to our study.

A study conducted by, Khot B et al., observed that among postoperative parameters mean systolic and diastolic blood pressure decreased significantly ($p < 0.05$) when compared with the time intervals during 0 hours and 24hour period in both the groups, however on intergroup comparison the difference was not found statistically significant ($p > 0.05$).¹² Another study conducted by Chattopadhyay S et al., to compare the efficacy of low-dose butorphanol as additive to epidural bupivacaine and epidural bupivacaine alone for perioperative analgesia. During study they found that in bupivacaine with butorphanol group the mean SBP at base line was 124.33 ± 7.18 mmHg which was reduced to 107.47 ± 5.70 mmHg at 60 min and gradually increased to 122.67 ± 3.50 at 240 min. and the mean DBP at base line was 77.73 ± 5.75 mmHg which was reduced to 65.67 ± 4.33 mmHg at 60 min and gradually increased to 77.475 ± 0.6 at 240 min.² Similar results were observed in present study.

Chattopadhyay S et al found that onset of sensory blockade in the bupivacaine and butorphanol group was 14.27 ± 2.26 min.¹³ However they did not compare tramadol with butorphanol group. Another study conducted by Kar P. compared epidural bupivacaine with butorphanol with bupivacaine alone for intra-operative and post operative analgesia in lower limb orthopaedic surgeries. They found that the mean duration of onset of sensory blockade was 11.24 ± 2.9 min in Bupivacaine 0.5% with 2mg butorphanol group.¹³ Similar results were observed in present study.

A study conducted by Chattopadhyay S et al study showed duration of sensory blockade of bupivacaine with butorphanol group to be 229.67 ± 19.78 min.¹⁸ However they did not compare tramadol with butorphanol group. another study conducted by Bhadla S et al., found that with Inj. Bupivacaine 0.5% and Inj. Tramadol 50 mg (20 ml), the mean duration of sensory blockade was 3.96 ± 1.18 hrs.¹⁵ Similar results were observed in present study.

Chattopadhyay S et al study showed onset of motor blockade in bupivacaine with butorphanol group to be 22.33 ± 2.22 min.¹⁴ The results are close to our study however they did not compare tramadol with butorphanol group.

Chattopadhyay S et al study showed duration of motor blockade with bupivacaine and butorphanol to be 203.20 ± 14.75 min.²⁸ The results are similar to our study. However, they did not compare tramadol with butorphanol group. In a study conducted by Bhadla S et al.,¹⁵ compared epidural tramadol with intrathecal tramadol for post operative analgesia they found the time required to recover from motor block in epidurally administered tramadol group was 3.32 ± 1.01 hr and their

results are similar to the present study. SpO₂ and ECG were within normal limits throughout the intraoperative period.

A study conducted by, Revar B et al. found that the VAS Score increased at 6 hours in butorphanol group whereas increased at 8 hours in tramadol group. VAS scores were significantly lower in butorphanol group than in tramadol group at many occasions.¹⁶ Their results are similar to the present study.

A study conducted by Deo et al, they found that the mean duration of analgesia in butorphanol group was 317.1 ± 99.1 min and in tramadol group was 438.8 ± 136.6 . there was statistically significant difference among both the groups.¹¹ Chattopadhyay S et al conducted a comparative study on epidural bupivacaine and epidural bupivacaine with low-dose butorphanol for perioperative analgesia in patients undergoing elective gynaecological surgeries during study they found that duration of analgesia in bupivacaine with butorphanol group was 347.20 ± 18.73 . The result of present study is in accordance to this study.¹³

A study conducted by Revar B et al., they found that Nausea was observed seen in 2(6%) patients in Group A and in 6(18%) patients in Group B and Vomiting was found in 1(3%) patient in Group A and in 3(10%) patients in Group B which was statistically significant. 2(6%) out of 30 patients in Group B also had pruritus. No other complication was observed in either group.¹⁶ The result of present study is in accordance to this study.

CONCLUSION

It can be concluded from this study that epidural bupivacaine with butorphanol provides a rapid but shorter duration of analgesia when compared to epidural bupivacaine with tramadol. Epidural bupivacaine with butorphanol had lesser side effects like nausea, vomiting, pruritus than bupivacaine with tramadol group.

From our study it appears that both epidural bupivacaine with butorphanol and epidural bupivacaine with tramadol have equal efficacy except duration of analgesia which is prolonged with tramadol group were as lesser side-effects with butorphanol group.

REFERENCES

- Dhimar AA, Patel MG, Swadia VN, Desai DJ. Epidural butorphanol: comparison of two different doses for lower limb orthopedic surgery. *J Anaesth clin pharmacol* 2006;22(1):47-52.
- Jayr C, Thomas H, Rey A, Farhat F, Lasser P, Bourgain JL. Post operative complications of epidural analgesia using bupivacaine and opioids versus parental opioids. *Anesthesiology* 1993;78:666-76.
- Reiz S, Westberg M. side effects of epidural morphine. *lancet*. 1980;2:203-4.
- Abboud TK, Moore M, Zhu J, Murakawa K, Minehart M, Longhitano M, et al. Epidural butorphanol or morphine for the relief of post-caesarean section pain: ventilatory responses to carbon dioxide. *Anesth Analg*. 1987;66:887-93.
- Gupta R, Kaur S, Singh S, Aujla KS. A comparison of epidural butorphanol and tramadol for postoperative analgesia using CSEA technique. *J Anaesthesiol clin pharmacol* 2011;27:35-8.
- Pokharel K, Rahman TR, Singh SN, Bhattarai B, Basnet N, Khaniya S. The efficacy and safety of low dose epidural butorphanol on postoperative analgesia following cesarean delivery. *JNMA J Nepal Med Assoc* 2008;47:5761.
- Venkatraman R, Sandhiya R. Evaluation of efficacy of epidural butorphanol tartrate for postoperative analgesia in surgical practice. *Ann Surg* 2003;238:663-73.
- Grass JA, Sakima NT, Schmidt R, Michitsch R, Zuckerman RL, Harris AP. A randomized double blind dose response comparison of epidural fentanyl versus sufentanil analgesia after Caesarean Section. *Anesth Analg* 1997;85:365-71.
- Raj PP. Conduction block. In: Text book of regional anaesthesia. Newyork: Churchill Livingstone; 2002. p. 292-95.
- Wheatley RG, Schug SA, Watson D. Combination of local anaesthetic and an opioid combination. *Br J Anaesth*. 2001;87:47.
- Deo GP, Shrestha SK, Shrestha IN. Epidural butorphanol for post operative analgesia in lower limb surgeries: A comparative study with epidural tramadol. *Journal of Chitwan Medical College*. 2016;6(3):26-32.
- Gaikwad B D, Khot B H. comparative study of epidural butorphanol and epidural tramadol for post operative analgesia. *International Journal of Medical Science and Diagnosis Research (IJMSDR)*, 2019;3(2):13-17.
- Kar P. A comparative study between epidural butorphanol with bupivacaine and bupivacaine alone for intra-operative and postoperative analgesia in lower limb orthopaedic surgeries. *Int J Res Med Sci* 2016;4:4251-5.
- Chattopadhyay S, Sarkar S, Mandal M, Chakrabarti S. A comparative study of epidural bupivacaine and epidural bupivacaine with low-dose butorphanol for perioperative analgesia in patients undergoing elective gynaecological surgeries. *J Evolution Med Dent Sci*. 2017 Mar 23;6(24):1985-91.
- Bhadla S, Chandnani A, P. Kumar. A Comparative Study of Intrathecal versus Epidural Tramadol for Post Operative Analgesia. *Indian J Anesth Analg*. 2019;6(3):1024-1029.
- Revar B, Patel V, Patel B, Padavi S. A comparison of epidural butorphanol tartrate and tramadol hydrochloride for postoperative analgesia using CSEA technique. *Int J Res Med*. 2015;4(1):1-6.