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Research Article

A comparative study between epidural butorphanol with bupivacaine and bupivacaine alone for intra-operative and post-operative analgesia in lower limb orthopaedic surgeries

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ABSTRACT

Background: Addition of opioids to epidural local anaesthetic improves the onset and duration of analgesia. The present study was conducted to evaluate the safety and efficacy of addition of various doses of butorphanol to epidural bupivacaine.
Methods: After taking written informed consent, 100 American society of anesthesiologist (ASA) grade I and II patients of both gender and age between 20-50 years undergoing elective lower limb orthopedic surgery under epidural anaesthesia were recruited for the study. Epidural space was identified by standard technique and catheter was left in place. The patients were randomly divided into 4 groups: group-1- Bupivacaine 0.5% 16ml, group-II- bupivacaine 0.5% 16ml+1mg butorphanol, group-III- Bupivacaine 0.5% 16ml+2mg butorphanol, group-IV- bupivacaine 0.5% 16ml+4mg butorphanol. The final volume was made 18ml by addition of normal saline. hemodynamic parameters, various block characters like onset and duration of sensory block, quality of analgesia, quality of motor block, and side effects were noted. Data were compared using chi square test and ANOVA test with post-hoc analysis.
Results: The time to onset of sensory block was significantly lesser in patients receiving 2 and 4 mg butorphanol. The duration of analgesia was significantly prolonged in all the groups receiving butorphanol. There were no serious cardiorespiratory side effects. Incidence of sedation was higher in Group II and IV patients but there was no respiratory depression.
Conclusions: we conclude that butorphanol 2 mg and 4 mg can be used as safe and effective adjuvant to epidural bupivacaine in patients undergoing lower limb orthopedic surgeries.

Keywords: Epidural, Butorphanol, Bupivacaine

INTRODUCTION

Effective pain control is one of the biggest challenges in the post-operative period. Epidural analgesia is a commonly employed method of pain relief. Various adjuvants especially opioids are often added to local anaesthetic to increase the quality and duration of analgesia. Use of highly hydrophilic opioid leads to increased incidence of undesirable side effects like pruritus, nausea and vomiting, urinary retention and respiratory depression.[1,2] Butorphanol, a lipophilic opioid has weak μ agonist-antagonist activity but strong k activity.[3]

It is known to have strong analgesic activity without fear of respiratory depression. The aim of the present study was to evaluate the safety and efficacy of various doses of butorphanol as an adjuvant to epidural bupivacaine.

METHODS

After taking institute review board permission and written informed consent, 100 American society of anaesthesiologist (ASA) grade I and II patients of both gender and age between 20-50 years undergoing elective lower limb orthopaedic surgery were recruited for the study. Patients with spine deformity, neurologic disorder, cardiac disease, peripheral neuropathy, known contraindication to epidural placement, and emergency procedures were excluded. Written informed consent was obtained from all patients.

All patients were premedicated with tablet alprazolam (0.25mg) and ranitidine (150 mg) the night before surgery. The patients were familiarized with the 11 point visual analogue score (0- no pain, 10-worst imaginable pain) during the preoperative visit. In the operation theatre, intravenous line was secured and ECG, SpO_2, NIBP monitoring were attached. Baseline heart rate (HR), mean noninvasive arterial pressure (MAP), were noted.

All patients were randomly divided into 4 groups using computer generated randomisation chart. The serially labeled opaque envelopes containing the group allocation were opened immediately prior to study and study drugs were prepared by an anesthesia resident who did not participate in the process of anaesthesia and subsequent analysis.

The drugs given in each group were as follows. (Gr-I)-16cc of 0.5% bupivacaine, (Gr-II)-I6cc of 0.5% bupivacaine with1mg of butorphanol, Gr-III- I6cc of 0.5% bupivacaine with 2 mg of butorphanol, Gr IV- I6cc of 0.5% bupivacaine with 4 mg of butorphanol. The final volume of drug was made 18ml by addition of normal saline. All preoperative and intraoperative management were performed by the same anesthesiologist who was blinded to study drug and Intraoperative and post-operative data were noted by an investigator who was blinded to the patient group allocation.

Patients were positioned in right or left lateral position. Under strict aseptic conditions L2-3/ L3-4 epidural space was identified with a 18G tuohy needle with loss of resistance to air technique and epidural catheter was inserted and fixed in place. After excluding intrathecal placement with 3ml of 1.5% lignocaine, the bolus drug as described earlier were given as per group allocation. Onset of sensory block, maximum level of sensory block, quality of analgesia, duration of analgesia, quality of motor block, and duration of surgery were noted.

The onset of sensory blockade was defined as the time interval between completion of local anesthetic injection and loss of sensation at T12 level by pinprick method. The highest dermatomal level of sensory blockade was also noted. The quality of intraoperative analgesia was defined as grade-1- complete dense analgesia, grade-2-intravenous narcotics required to supplement analgesia, grade-3-GA cover required. Quality of motor blockade was defined using Bromage scale.

- Grade 0-Free movement of legs and feet with ability to raise extended leg
- Grade 1-Inability to raise extended leg and knee flexion is decreased but full flexion of feet and ankle present.
- Grade 2-Inability to raise legs or flexion of ankles and feet present
- Grade 3-Inability to raise leg, flex knee or ankle or move toes

Effectiveness of postoperative analgesia was measured using 11 point visual analogue scale (VAS). 0 meant no pain and 10 meant worst imaginable pain. VAS was assessed every hour till it was <4. In patients having VAS <4, rescue analgesia in the form of tramadol 50 mg in 10 ml of saline was administered through epidural catheter. The time from the administration of initial bolus drug till rescue analgesia was termed as duration of analgesia.

Heart rate (HR), mean arterial pressure (MAP), was measured at 5, 10, 15, 30, 60, 90 and 120 minutes after injection of study drug. Hypotension and hypertension were defined as 20% decrease or increase of MAP from baseline respectively. Hypotension was treated with fluid bolus of 200ml followed by ephedrine 5mg. Bradycardia was defined as HR less than 50 and tachycardia was defined as a 20% increase of HR from baseline. Bradycardia with hemodynamic instability was treated with atropine 0.6 mg. Patient having hypertension and/or tachycardia due to inadequate analgesia were given intravenous tramadol 50mg for 2 occassions. If analgesia was still inadequate, general anaesthesia was induced.

Side effects in the form of nausea and vomiting, sedation, pruritus and urinary retention and respiratory depression were assessed. Sedation was scored on a 4 point scale. 0-awake and alert. 1-drowsy, sleeping lightly, arouses to conversation. 2-sleeping soundly maintains oxygen saturation. 3-Deeply sedated and desaturates. Score ≥2 was considered a significant sedation. Urinary retention was defined as inability to void within 6 hours of epidural drug injection. These patients were catheterized. A respiratory rate of < 10 was defined as respiratory depression. Patients with respiratory depression were kept in intensive care unit managed as per intensive care protocol.

Statistical analysis

Data was analyzed using SPSS version 13. The sample size was calculated using power analysis. With an alpha error of 5% and power of 80%, a sample size of 21 in each group was required to detect a difference in analgesia duration of 30 minutes. Thus a sample size of 25 in each group was used to improve the validity of

study. Continuous variables were expressed as mean±SD and categorical variables as frequency of occurrence and percentage. The categorical data were compared by Chi square test. Continuous variables were analyzed using ANOVA with post hoc analysis. A p value <0.05 was considered significant for all the tests.

RESULTS

The study cohort included 25 patients in each group. The demographic details are given in Table 1. Demographic profile was comparable in all patients. The block characteristics are depicted in Table 2. The onset of sensory blockade was significantly faster in group III and IV as compared to group-I; however the onset of sensory block was not hastened in group-II.

Although more patients achieved a block level of T7-T8 in Group IV, the difference was not statistically significant. The quality of analgesia and motor block were comparable in all groups. The duration of analgesia were 178.6±21.21 minutes, 294.68±22.13 minutes, 361.52±17.59 minutes and 444.6±25.23 minutes in group I, II III and IV respectively. The duration of analgesia was significantly longer in group II, III, and IV as compared to group I (p- 0.02, p-0.0004, and p-0.001).

Table 1: Demographic parameters.

Parameter	Group-I Mean(SD)	Group-II Mean(SD)	Group-III Mean(SD)	Group-IV Mean(SD)	Significance
Age	34.4 (11.5)	33.8 (10.52)	34.68 (10.7)	34.08 (9.58)	NS
Sex(Male/Female)	22/3	23/2	23/2	22/3	NS
Height	161.26 (8.68)	163.96 (10.02)	161.2 (9.1)	162.3 (9.8)	NS
Weight	54.4 (5.49)	54.2 (6.35)	53.92 (5.25)	54.56 (6.1)	NS
Duration of surgery	94.30 (6.8)	91.6 (7.4)	98.4 (6.5)	95.04 (7.9)	NS

Table 2: Characteristic of block.

Parameter	Group-I	Group-II	Group-III	Group-IV
Onset of sensory block	14.64 (2.23)	14.24 (2.4)	11.24 (2.9)*	11.44 (3.2)*
Maximum height of block				
T7-T8	5 (20%)	5 (20%)	7 (28%)	8 (32%)
T9-T10	16 (64%)	17 (68%)	16 (64%)	15 (60%)
T11-T12	4 (16%)	3 (12%)	2 (8%)	2 (8%)
Quality of analgesia				
1	21 (84%)	23 (92)	25 (100%)	25 (100%)
2	4 (16%)	2 (8%)	0	0
3	0	0	0	0
Degree of motor blockade				
0	1	0	1	1
1	8	9	11	10
2	11	12	9	12
3	5	4	4	2
Duration of analgesia	178.6 (21.21)	294.68 (22.13)*	361.52 (17.59)*	444.6 (25.23)*

* denotes p<0.05 from group-I

Table 3: Side effects.

Side effects	Group I	Group-II	Group-III	Group-IV
Nausea and vomiting	2 (8%)	2 (8%)	1 (4%)	1 (4%)
Sedation	2 (8%)	3 (12%)	7 (28%)*	10 (40%)*
Pruritus	0	0	0	0
Urinary retention	4 (16%)	4 (16%)	6 (24%)	6 (24%)
Respiratory depression	0	0	0	0

*denotes p<0.05 from group I

The hemodynamic profile was comparable in all the groups at all time points. The side effect profile is tabulated in Table 3. Nausea and vomiting were seen in 2 (8%), 2 (8%), 1 (4%), and 1 (4%) patients in group I, II, III, IV respectively. The incidence of nausea and vomiting were not statistically different across the groups. Sedation score of ≥2 was observed in 2 (8%), 3 (12%), 7 (28%), and 10 (40%) patients respectively in group I, II, III, IV. Significantly more patients were sedated in group III and IV as compared to group I. None of the patient in the study group developed pruritus or had respiratory depression. The incidence of urinary retention was comparable in all groups.

DISCUSSION

The addition of opioids to local anesthetics is known to improve the quality and duration of analgesia. Butorphanol is a strong k-receptor agonist and a weak μ-receptor agonist-antagonist.[1] Epidural butorphanol is known to produce analgesia by action on spinal k receptors. In this study we chose to investigate the effect of addition of various doses butorphanol, on the intraoperative and postoperative analgesia in patients undergoing lower limb orthopedic surgeries.

The time to onset of sensory block was 14.64±2.23, 14.24±2.4, 11.24±2.9 and 11.44±3.2 minutes respectively. Our results demonstrated that addition of 2 and 4 mg of butorphanol significantly quickens the onset of sensory block. Kaur et al found onset of analgesia time to be 5.6 minutes in epidural butorphanol group however their definition of onset of sensory block was different from our study.[4] They defined it as loss of sensation to warmth or pin prick in any dermatome, whereas we defined it as loss of sensation at T12 level. This could be the explanation for early onset of analgesia in their study. Catherine et al have demonstrated reduction in onset of analgesia time to 6.9±3.6 minutes when butorphanol 2 mg was added to bupivacaine.[3]

This study was conducted in patients in labor. Spread of drug in epidural space and pharmacokinetics of drugs injected to epidural spread is likely to differ in parturients and non-parturient population like ours. This could explain the early onset of analgesia in their study. Aboud et al compared morphine 5mg with butorphanol 1, 2 and 4 mg for relief of post caesarean pain.[5] The time to pain relief was 0.37±0.03 hours. 0.38±0.04 hours and 0.36±0.04 hours respectively. Normal saline was used as a diluent in this study instead of bupivacaine. The delay in onset of analgesia could be because of omission of local anesthetic. The height of block was comparable in all the groups.

This result of ours corroborates with Kaur et al.[4] There was no difference in the quality of analgesia among the groups in our study which is in agreement with the study by Kaur et al.[4] The quality of motor blockade was comparable in all groups which states that epidural butorphanol does not increase the motor blockade. The duration of analgesia was also significantly increased in patients who were administered 1, 2 and 4 mg of butorphanol. The duration of analgesia in only bupivacaine group was 178.6±21.21 minutes while it was 294.68±22.13 minutes, 361±17.59 minutes and 444.6±25.23 minutes in group II, III and IV respectively. In a study by Aboud et al, mean duration of analgesia was 4.82 hours, 5.53 hours and 8.05 hours. in patients receiving 1, 2, 4 mg of epidural bupivacaine respectively which matches with the duration of analgesia in our study.[5] Gupta et al also found the duration of analgesia with 2 mg of butorphanol to be 5.35 hours.[6]

Opioids are well known for potential complications like sedation, respiratory depression, pruritus and urinary retention.[2] Hydrophilic opioids are more likely to produce these side effects as these drugs are carried by cerebrospinal fluid from lumbar region to the medullary region. Bromage suggested that lipid-soluble, highly protein bound narcotic analgesics might be less likely to exhibit this phenomenon.[1] Thus the complications are less likely to be encountered in butorphanol which is lipophilic in nature.

Eight percent patients in both group I and II, and 4% patients in group III and IV had nausea and/or vomiting. The incidence was comparable to that of Aboud et al. In our study the incidence of sedation was significantly higher in 2 mg and 4 mg group. Aboud et al found the incidence of sedation to be 72.4% and 67.5% respectively in butorphanol 2 mg and 4 mg group. Increased incidence of sedation was also observed by gambling et al in his study using 1, 2 and 3mg butorphanol. Sedation caused by butorphanol was not associated with desaturation in our patients. Thus it can be considered as a desirable effect in the perioperative period.

Pruritus has been observed in few patients receiving epidural butorphanol in previous studies. Palacious et al and Ackerman et al reported incidence of pruritus to be 1.4% and 6.7% respectively but none of the patients in our study developed this complication.[7,8] Bharati et al and Parikh et al also did not demonstrate pruritus in any of their patients.[9,10] Respiratory depression was not seen in any patient in the presence cohort. Aboud et al evaluated respiratory effect of butorphanol using ventilatory responses to hypercapnia. A decrease in central sensitivity to CO2 was observed as early as 1.5 hours. However the depression was lesser in butorphanol 2 and 4 mg groups as compared to morphine 5 mg.[5] Gambling et al reported no significant differences among groups in CO_2 challenge test data at any point during the study, but overall, a reduced sensitivity to CO_2 after opioid administration was observed across all groups receiving butorphanol.[11] Since neither CO_2 responses nor $PaCO_2$ was measured in our patients, we can neither support nor refute the above observation. Urinary retention was seen in 16% patients in group I and II and 24% patients in group III and IV. Aboud et al did not study the incidence

of urinary retention as all their patients were catheterized.[5] In our study patients were catheterized if they did not void in 6 hours.

CONCLUSION

Epidural butorphanol in 2 mg and 4 mg dose shortened the time to onset of sensory block and increased the duration of analgesia. There were no serious cardiorespiratory side effects. Although incidence of sedation was higher in 2 and 4 mg groups, there was no evidence of respiratory depression. Thus we conclude that butorphanol 2 mg and 4 mg can be used as safe and effective adjuvant to bupivacaine in patients undergoing lower limb orthopedic surgeries.

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