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Original Article

Comparison of Epidural Fentanyl and Buprenorphine as Adjuvants to Bupivacaine in Lower Abdominal Surgeries: A Randomized Clinical Study

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Abstract
Background: *Epidural neuraxial opioids when added to local anaesthetics improves the onset and duration of analgesia. The present study was conducted to evaluate the safety and efficacy of epidural buprenorphine and fentanyl as adjuvants to epidural bupivacaine.*
Methods: *After taking written informed consent, 75 American society of anesthesiologist (ASA) grade I and II patients between 20-50 years undergoing elective lower abdominal surgery under epidural anaesthesia were enrolled for the study. The patients were randomly divided into 3 groups: group-B-(Received Bupivacaine 0.5% 20ml epidurally), group-BB-(Received Bupivacaine 0.5% 20ml+0.3mg buprenorphine epidurally), group-BF-(received Bupivacaine 0.5% 20ml+100µg fentanyl). Hemodynamic parameters and block characters like onset and duration of sensory analgesia, quality of analgesia, quality of motor block, and all side effects were noted. Statistical analysis was performed.*
Results: *The time to onset of sensory block was significantly lower in the epidural fentanyl group. The duration of analgesia was significantly prolonged with both adjuvants ,more so with epidural buprenorphine. Incidence of side effects like sedation, nausea vomiting and urinary retention was higher in the epidural buprenorphine group. No patients had cardiovascular or respiratory depression.*
Conclusions: *Fentanyl and buprenorphine are safe and effective adjuvants to epidural bupivacaine, in patients undergoing lower abdominal surgeries with fentanyl being a better choice over buprenorphine in view of its faster onset of action,good quality analgesia and fewer side effects.*
Keywords: *Epidural, Buprenorphine, Fentanyl, Bupivacaine.*

INTRODUCTION

Narcotic analgesics when used as adjuncts to epidural local anesthetics hasten the onset, prolong the duration of analgesia and also improve the quality of the block obtained. They also have profound dose sparing effects on the local anesthetics [(1)].

Epidural morphine, the earliest opioid used has been associated with numerous undesirable side effects as respiratory depression, pruritus, nausea, vomiting, and urinary retention [(2)]. In view of these side effects, there has been a constant search for newer and safer drugs. Buprenorphine is a semi-synthetic opioid with strong agonistic activity at the μ-receptor and antagonistic properties at the κ-receptor [(3)]. Being more potent than Morphine, it has strong analgesic and sedative properties [(3)]. Buprenorphine has been a popular choice for post-operative analgesia. Fentanyl, a phenyl piperidine derivative, is a highly lipophilic opioid with a primary μ-receptor agonistic activity [(4)]. It has a rapid onset and short duration of action. Previous studies have compared the two narcotics for post-operative epidural analgesia [(5)]. There is a plethora of studies comparing Buprenorphine and fentanyl for postoperative analgesia. However there is a relative paucity of literature on the use of these drugs as adjuncts for intraoperative epidural anesthesia. The current study was undertaken to compare the safety and efficacy of epidural buprenorphine with epidural fentanyl for lower abdominal surgeries.

MATERIALS AND METHODS

After obtaining the Institute's Ethical Committee approval, 75 American Society of Anesthesio-logist (ASA) grade I or II patients of both gender in the age group of 20-60 years, undergoing lower abdominal and lower limb surgery under epidural anesthesia were recruited for the study [(6)]. Written informed consent was obtained from all the patients. Exclusion criteria included patient's refusal, coagulopathy, spine deformity, sepsis, significant cardiorespiratory and neurological disease. Patients were familiarized with visual analgesia scale (VAS) scoring pre-operatively and taught to grade their pain on the scale [(7)]. All patients were premedicated with tablet alprazolam (0.25mg) and ranitidine (150 mg) the night before surgery. The patients were familiarized with the 11 pointvisual analogue score (0- no pain, 10- worst imaginable pain) during the preoperative visit. In the operation theatre, intravenous line was secured and standard monitoring with ECG, heart rate (HR), pulse oximetry (SpO2), and noninvasive arterial pressure was commenced. Under proper aseptic precautions epidural space was located at L_{2-3} /L3-4 intervertebral space using 18G Tuohy's needle with the loss of resistance to air or saline technique. Epidural catheter was threaded 4-5 cms within the epidural space and secured. Patients were randomly divided into 3 groups of 25 each using computer generated randomisation chart. The study drugs were prepared by an anaesthetist who was not involved in both the process of anaesthesia or subsequent analysis and intraoperative and postoperative data were noted by an investigator who was blinded to the patient group allocation.

GROUP B: 20 ml 0.5% bupivacaine

GROUP BB: 20ml 0.5% bupivacaine + 0.3mgs buprenorphine

GROUP BF: 20 ml 0.5% bupivacaine + 100 μg fentanyl.

Heart rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP), SpO_2 were noted at 5, 10, 15, 20mins after epidural drug administration and then every 10 min till the end of surgery. Hypotension and hypertension were defined as 20% decrease or increase of MAP from baseline respectively. Hypotension was treated with fluidbolus 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. The various block characteristics studied included: Onset of sensory block (defined as the time

interval between completion of local anesthetic injection and loss of sensation to cold or pinprick at any dermatome), maximum dermatomal level of sensory block, quality of analgesia, duration of analgesia (the time from the onset of analgesia up to the time when the VAS reached 5),onset and quality ofmotor block, and duration of surgery were noted. The quality of intraoperative analgesia was defined as grade-1: no complaint of pain during the procedure, Grade 2: slight pain or discomfort eg: during traction on viscera/ peritoneum, grade 3: pain requiring rescue analgesic intervention. 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

Postoperatively pain was assessed by the VAS scale every 1 hour till 6 h and then every 2 h till 24 h. Hemodynamic parameters were recorded at the same time. In patients having VAS <5, rescue analgesia in the form of tramadol 50 mg in 10 ml of saline was administered through epidural catheter. Side effects such as nausea and vomiting, pruritus, sedation, urinary retention and respire-tory depression were assessed and appropriately treated. 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 desatu rates. Score ≥2 was considered as significant sedation. Urinary retention was defined as inability to void within 6 hours of epidural drug injection. A respiratory rate of < 10 was defined as respiratory depression. Patients with respiratory depression were shifted to the intensive care unit managed as per intensive care protocol.

Statistical Analysis

Statistical analysis was performed using the Statistical Package for the Social Sciences (16^{th} version SPSS Inc., 233 South Wacker Drive, 11^{th} Floor, Chicago, IL). Taking an alpha error of 5% and to yield a power of 80%, the minimum sample size required to conduct the study would be 21/group. To enable better validity, 25 patients were included in each group. 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. P value significance was: P > 0.05 - Not significant, P< 0.05 – Significant,P< 0.001 - Highly significant

RESULTS

Demographic variables were comparable between the three study groups (Table 1). There were no statistically significant differences in the hemodynamic parameters in the 3 groups throughout the study period. The block characteristics of all the 3 groups are mentioned in Table-2. The side effects are tabulated in Table-3.

Table 1: demographic variables

Variable	Group B Mean(SD)	Group BB Mean(SD)	Group BF Mean(SD)	pvalue
Age	38.9(11.2)	38.1(10.8)	37.9(11.0)	0.754
Sex (male/female)	20/5	21/4	19/6	0.651
Height	157.8(10.6)	158(10.9)	158.2(11.1)	0.762
Weight	63(9.4)	64.6(8.8)	62.7(9.2)	0.523
Duration of surgery	90.8(6.6)	94.4(6.9)	92.8(6.8)	0.653

Table 2: Block characteristics- *Denotes significant difference from group-B

Variable	Group B Mean(SD)	Group BB Mean(SD)	Group BF Mean(SD)
Onset of sensory block	14.5(4.2)	13.2(3.9)	9.53(2.88) *
Quality of analgesia 12 3	20 3 2	23 2 0	24 1 0
Height of Sensory Block T6-T8 T9-T11 T11-T12	 5 15 5	 6 17 2	 6 14 5
Degree of Motor Block 0 1 2 3	 2 7 10 6	 1 6 11 7	 1 6 10 8
Duration of analgesia	218(19.8)	586(26.1) *	311(21.5) *

Table 3 : Side Effects

Variables	Group B	Group BB	Group BF
Nausea/vomiting	3	7	4
sedation	0	5	2
pruritus	0	0	1
headache	0	3	1
Urinary retention	0	0	2

DISCUSSION

In our study we found that the addition of both fentanyl and buprenorphine to Bupivacaine hastens the onset of analgesia. We found a statistically significant difference in the mean time of onset of analgesia between 9.5 mins in the fentanyl group as compared to 13.2 mins with buprenorphine. Stephen Naulty and Blanco J et al have reported similar findings in their studies. [8,9]

In the present study the mean duration of analgesia in fentanyl group was 311 minutes and 586 minutes in buprenorphine group. The duration of analgesia of buprenorphine was longer than that of fentanyl group and only Bupivacaine group(p 0.000). Stephen Naulty et al [8], using 100 microgram of epidural fentanyl for LSCS, have reported a mean duration of analgesia of 1.5 hours. Alfred Lomessay et al using 200 microgram of epidural fentanyl for abdominal surgery reported a mean duration of analgesia of 2 hours.[10] Wolff et al. in their study showed that the duration of analgesia was 620 min with epidural buprenorphine (0.3 mg) for postoperative pain relief after major orthopedic surgery which was consistent with our study [11]. Agarwal et al. showed that epidural bupivacaine (0.125%) and buprenorphine (0.075 mg) produced significantly longer duration (690 ± 35 min) of postoperative analgesia in lower segment caesarean segment patients [12]. The quality of the sensory block was significantly improved with the addition of both the opioids to Bupivacaine. None of the patients required any supplemental analgesic during the surgery.

In our study respiratory depression was not seen in any patient who received epidural fentanyl or buprenorphine. This correlates with study findings of Lanz and Cahil et al [13,14]. Harcus et al reported that respiratory depression to bea problem with epidural buprenorphine[15]. Nausea and vomiting

have been reported in various studies with varying frequency. Grass et al and Blanco et al [16,9] reported that nausea and vomiting was uncommon with epidural fentanyl .In our study 4 patients had nausea and vomiting in fentanyl group where as 7 patients had vomiting after epidural buprenorphine. In the present study only 1 patient complained of pruritis in fentanyl group, whereas this was not seen in any patients receiving buprenorphine. Drowsiness with fentanyl has been reported in many studies. We found 2 patients in fentanly group who experienced sedation, In comparison to 5 patients in buprenorphine group. Headache was not seen in the epidural fentanyl group, this findings correlates with that of the previous workers like Stephen Naulty et al and Alfred Lomessy et al [8,17]. Three patients in the buprenorphine group complained of headache. Lanz et al also reported a similar incidence of headache in their study.[13] Urinary retention was not seen in any patient with the use of epidural fentanyl. This finding corroborates with that of Blanco et al [9]. Kamal et al and Lanz et al have found urinary retention to be a problem with epidural buprenorphine [18,13]. In our study 6 patients complained of urinary retention out of which 3 needed catheterization.

CONCLUSION

A single bolus dose of neuraxial opioids like buprenorphine and fentanyl significantly hastens the onset of analgesia and provide denser and longer duration of analgesia as compared with Bupivacaine alone without any cardiorespiratory complications. Though buprenorphine provides a longer duration of post operative analgesia, it is associated with more side effects. Hence, we conclude Fentanyl to be a better choice over buprenorphine in view of its faster onset of action, good quality analgesia and fewer side effects.

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Declaration of Interest- none to declare

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