Original Article

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A Comparative Evaluation of Bupivacaine and Bupivacaine with Fentanyl in Lumbar Epidural Anaesthesia

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Abstract

Background: This study was carried out to assess the efficacy of epidural Fentanyl as intraoperative and postoperative analgesia when used along with bupivacaine epidurally. *Materials and Methods:* After taking the informed consent, 100 patients of ASA Grade 1 and 2 scheduled for elective lower abdominal or lower limb surgeries were randomly allocated into one of these two groups of 50 each. Group 1 patients received 15 ml of 0.5% bupivacaine by epidural route followed by 3 ml of boluses of bupivacaine after every 5 minutes if required till T10 level was achieved before start of surgery. Group 2 received 15 ml of bupivacaine with 1-2 µgm/kg of body weight fentanyl by epidural route followed by 3 ml of boluses of bupivacaine after every 5 minutes if required till T10 level was achieved before start of surgery. Both the groups were demographically similar and did not differ in term of pre-operative hemodynamics and mean duration of surgery. Patients were monitored for pain relief by VAS score and also hemodynamic and respiratory parameters were monitored both intraoperatively and for 3 hours in post-operative period. *Results:* The onset and maximum upper level of analgesia in Group 2 was statistically significant. The duration of analgesia in group 1 was less than group 2 and was found to be statistically significant. The mean of VAS in group 1 was 49.20±18.61 and in group 2 was 27.40±23.80 and this was found to be statistically significant. The sedation score was found to be statistically significant in group 2. *Conclusion:* Epidural fentanyl when added with epidural bupivacaine improves the quality, onset and duration of analgesia without causing any increase in intra-operative and post-operative complications.

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Introduction

Pain is one of the feared consequences of surgery, under treatment of which is very common [1]. Epidural anesthesia is a type of segmental neuraxial block that results in sympathetic, sensory and motor block [2]. Thus, intraoperative epidural anesthesia appears to provide better analgesia, improved diaphragmatic function and reduce frequency and severity of post-operative hypoxemia which are commonly seen with general anesthesia [3]. Surgical anesthesia requires dense sensory block and usually moderate to dense motor block [4]. The combination of opioids with local anesthesia provide excellent analgesia because it allows decreased requirement of drugs and lower incidence of side effects [5]. Initial studies were done on morphine [6] but failure to titrate effect, slower onset and higher incidence of side effects especially delayed respiratory depression were the main problems as compare to fentanyl which has rapid onset, short duration and analgesic efficacy of 75-125 times more than morphine [5]. Hence, we designed this study to compare the efficacy of epidurally administered 0.5% bupivacaine with fentanyl 2µgm/kg body weight versus bupivacaine 0.5% alone in patients undergoing lower abdominal surgery and lower limb orthopedic surgery.

Material and Methods

After institutional approval and informed consent 100 patients of ASA Grade I and II belonging to the age group 20-65 yrs. of either

sex scheduled for elective lower abdominal or lower limb surgeries were selected for the study. Patient with coagulation disorder or on anti-coagulation therapy, neurological disease, lumbosacral abnormalities, skin infection or sepsis, severe anemia, hypotension or hypertension and morbidly obese patients were excluded from study. The patients were randomly allocated into one of the following two groups using random number chart. Group 1 patients received 15 ml of 0.5% bupivacaine by epidural route. If required they were given boluses of 3 ml after every 5 min till T 10 level was achieved before start of surgery and group 2 patients received 15 ml of 0.5% bupivacaine with 1-2µgm/kg. of body weight fentanyl by epidural route. If required, they were given boluses of 3 ml of bupivacaine alone after every 5 min till T10 level was achieved before start of surgery.

All patients were given 0.5 mg alprax orally a night before surgery and 0.25 mg at 6 A.M. on day of surgery and were kept fasting for at least 6 hrs. prior to surgery. After shifting the patient on operation table BP, pulse rate, RR, HR, ECG, SpO_2 were monitored. An intravenous line was secured and patients preloaded with ringer lactate. Under strict aseptic conditions, epidural catheter 18G was inserted in lateral position by 16G Touhy needle through L2-3 interspace using loss of resistance technique. The epidural catheter was placed approximately 3 cm in the epidural space directed cephalad. Intravascular, or subarachnoid placement of catheter was excluded by giving test dose of 3cc of 2% lignocaine with 1: 200,000 lakh adrenaline. If the VAS score was more than 4, patient was given 3 ml of the respective drug. The duration of analgesia was defined as time between the first epidural drug and the requirement of first top up dose. Total number of top ups given intraoperatively were recorded. Also, onset and degree of motor block and intensity of sensory block and maximum upper level of sensory and motor block achieved was recorded. All the patients were monitored at every 10 minutes interval for first hour and 20 minutes interval for next two hours intraoperatively and postoperatively for first 3 hours for hemodynamic parameters like HR, SBP, DBP and SpO_2 and side effects like sedation, pruritis and nausea. The data was collected, tabulated and analyzed by applying unpaired T test to compare between group I and II and chi Square (X^2) test used for qualitative data comparison between groups.

Results

Both the groups were statistically comparable as regards to age, sex weight, preoperative hemodynamics of the patients including heart rate, systolic and diastolic blood pressure, and respiratory rate and also the duration of surgery (Table 1).

The mean time for onset of sensory block in group 1 and group 2 were 11.80 ± 2.10 and 8.28 ± 2.00 respectively which was found to be statistically significant (Table 3). The difference of onset of adequate analgesia (i.e. the time between the administration of the drug and the time to attain T10 level) between group I and group II was found to be statistically significant. The maximum upper level of sensory block of T5-T7 and T8-T10 were

Table 1:

Variable	Mean ± S.D.		T value/Chi-square (χ^2)	p value
	Group I	Group II		
Age (years)	50.02 ± 12.82	48.08 ± 13.23	0.741	0.461
Sex	M=17(34%) F=33 (66%)	M=27(54%) F=23(46%)	3.287	0.06
Weight (kg)	55.52 ± 8.69	57.68 ± 22.61	0.975	0.332

χ^2 value = non-significant (NS)
p value > 0.10 (NS)

Table 2:

Variable	Mean ± S.D.		T value/ χ^2	P value
	Group I	Group II		
Pulse rate (per min)	81.88±8.88	84.88±8.49	1.496	0.138
Systolic BP (mm Hg)	127.12±14.50	127.12±11.84	0.00	1.00
Diastolic BP (mm Hg)	83.14±9.62	82.64±8.71	0.272	0.786
Respiratory rate (per min)	20.06±2.53	21.46±2.31	2.889	0.005

p value > 0.10 (NS)

achieved by 8% and 92% in group 1 respectively and 26% and 74% in group 2 respectively and this difference was statistically significant (Table 4).

The mean time for onset of motor block in group I and II were 15.26 ± 3.19 and 11.16 ± 2.88 and the difference was found to be statistically significant (Table 5). Also, the difference of onset and level of the motor block achieved in both the groups was found to be statistically significant (Table 6). The mean time of analgesia request and duration of analgesia after 1st bolus dose between group I and group II was found to be statistically significant. The mean of number of total top up of epidural doses required in group I and II were found to be statistically significant. The mean of VAS in group I was 49.20 ± 18.61 and in group II was 27.40 ± 23.80 which was found to be statistically significant (Table 7).

Table 3:

Variables	Mean ± S.D.		T value/ $\chi 2$	P value
	Group I	Group II		
Duration of surgery (minutes)	132.2 ± 54.45	145.6 ± 52.38	1.254	0.213

p value >0.10 (NS)

Table 4:

Onset of analgesia (min)	Group I	Group II	T value	P value
Mean ± S.D.	11.80 ± 2.10	8.28 ± 2.00	8.583	0.00*

*p value <0.05 (Significant)

Table 5: Maximum Upper Level of Sensory Block (MULSB)

MULSB	Group I	Group II
T5-T7	4 (8%)	13 (26%)
T8-T10	46 (92%)	37 (74%)
Total	50	50
Mean ± S.D.	8.96 ± 1.29	8.08 ± 1.44

χ^2 value = 4.535 (significant)
p value <0.05 (significant)

Table 6:

Variable	Group I	Group II
Degree 1	27(54%)	48(96%)
Degree 2	23(46%)	2(4%)
Degree 3	50(100%)	50(100%)
Mean ± S.D.	1.46 ± 0.50	1.04 ± 0.20

χ^2 = 21.33 (significant)
p value< 0.05 (significant)

Table 7:

Onset of motor block (min)	Group I	Group II	T value	P value
Mean ± S.D.	15.26±3.19	11.16±2.88	6.748	0.00*

*p value <0.05(significant)

Table 8:

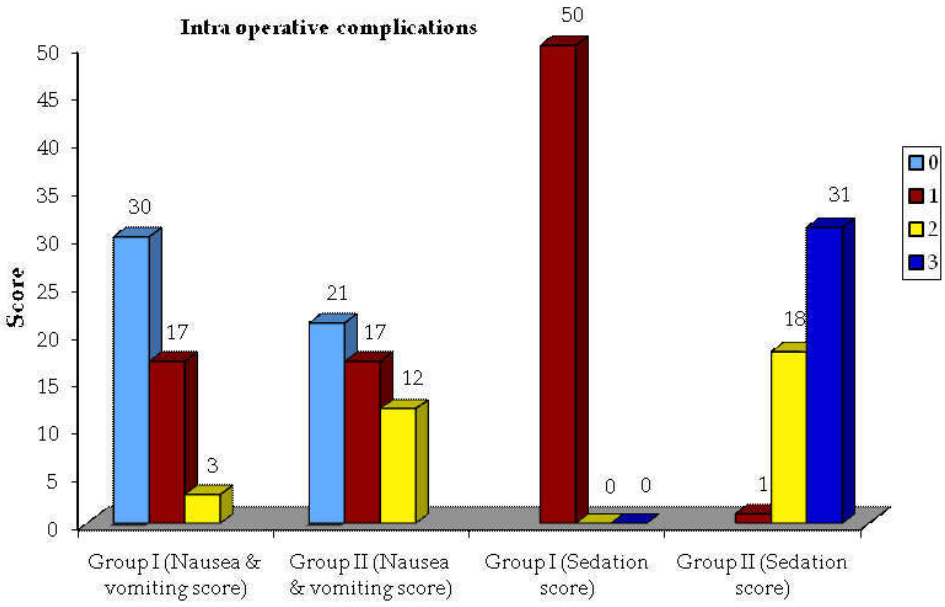
Level of Motor Block	Group I	Group II
T5-7	4 (8%)	13 (26%)
T8-10	46 (92%)	(37 (74%)
Total	50	50
Mean ± S.D.	8.96 ± 1.29	8.08 ± 1.44

χ^2 = 4.545 (significant)
p value <0.05 (significant)

Table 9:

Variable	Group I	Group II	T/Chi square value	P value
DOB (ml)	16.42 ± 1.92	15.94 ± 1.98	1.227	0.222
DOF (µgm)	0	111.2 ± 25.84		
TAR (min)				
<100	41(82%)	0		
>100	9(18%)	50(100%)		
Mean ± S.D.	76.46 ± 23.53	200.14 ± 54.58	66.14	0.0001*
DOA (min)				
<100	41(82%)	0		
>100	9(18%)	50(100%)		
Mean ± S.D.	76.46 ± 23.53	200.14 ± 54.58	66.14	0.0001*
TTU				
0	12(24%)	34(68%)		
≥1	38(76%)	16(32%)		
Mean ± S.D.	1.42 ± 1.24	0.48 ± 0.79	4.505	0.00*
VAS				
Mean ± S.D.	49.20 ± 18.61	27.40 ± 23.80	5.102	0.00*

*p value significant (p<0.05)



The fall in HR, SBP and DBP was found to be more in Group1 but it was not statistically significant. The incidence of sedation and nausea and vomiting was more in group II in comparison to group I and it was statistically significant. There was no incidence of pruritis seen in any of the groups. Post-operatively patients in both groups were found to be hemodynamically stable (Table 2).

Discussion

Effective analgesia in the peri-operative period makes the patient stress free, decreases morbidity and improves patient outcome [7]. The use of epidurally administered opioids in the relief of intra-operative and post-operative pain is now well established [8,9]. Studies in animals and humans have shown that pre-synaptic and post-synaptic receptors in the substantia gelatinosa of the dorsal horn of spinal cord is the major site of action of spinally administered opioids. In contrast, local anesthetics act by axonal membrane blockade, predominantly in spinal nerve roots [10]. However, the combination of epidural local anesthetic and opioids provide superior analgesia [12]. The exact relation between quality of analgesia and post-operative outcome is ill defined [11].

Previous studies have shown that traditional intramuscular injections of opioids are inferior to both patient controlled analgesia (PCA) with intravenous opioids [25] and epidural administration of opioid [13]. Whether epidural administration of opioids alone provides superior analgesia is controversial [13]. However, the combination of epidural local anesthetic and opioids provide superior analgesia [14]. The exact relation between quality of analgesia and post-operative outcome is ill defined [15].

In our study, we evaluated the role of fentanyl as an additive to bupivacaine in extradural analgesia intra-operatively with epidural bupivacaine as a control. We compared the quality of analgesia by VAS, the duration of analgesia, hemodynamic and respiratory parameters. Group II showed statistically significant increase in duration of analgesia after first bolus dose in comparison to group I. This was well supported by studies done by Torda et al. [16] and Ozalp et al. [17]. Also, the number of top up doses required were more in Group 1.

The onset of both sensory and motor block was rapid in bupivacaine- fentanyl group, which was statistically significant. Also, maximum upper level of block achieved in group II patients was more than in Group I patients. This observation was consistent with study of Gaffud et al. [18] who found that combination of bupivacaine 0.5% with 100 µg of fentanyl provide faster onset of action and superior and more effective analgesia.

In our study, heart rate changes were comparable in group I and II with no significant difference between the two groups which was well supported by studies conducted by George et al. [19] and Sjostrom et al. [20]. Statistically significant change between the groups in systolic blood pressure was observed during first 100 min of dose administered epidurally intra-operatively. Similarly change in diastolic BP was statistically significant during first 60 min after 20 min. of drug given epidurally between 2 groups. Gaffud et al. [21] in their study with 0.5% bupivacaine and fentanyl 10 µg epidurally versus 0.5% bupivacaine done observed hypotension in 30% of fentanyl group patients and 50% of bupivacaine alone group patients. Smedstad et al. [22] observed hypotension in 0% patients after initial epidural bolus dose in their study comparing 0.25% bupivacaine continuous infusion with intermittent boluses epidurally. Studies of George et al. [26] & Sjostrom et al. [27] using fentanyl and bupivacaine epidurally have shown similar blood pressure changes.

In our study, we found respiratory rate changes were, statistically, but not clinically significant intra-operatively. None of the patient in group I or II showed respiratory depression requiring naloxone in the 24 hrs post-operative period. Sjostrom et al. [27] in their study using 0.12% bupivacaine with fentanyl 2 µgm/ml versus bupivacaine 0.24% with fentanyl 4 µgm/ml during a 48 hrs study observed one case of respiratory depression in each group, but spontaneous respiration was attained by spontaneous awakening the patients. Scott et al. [15] in their study using epidural bupivacaine fentanyl infusion post-operatively in 1014 patients observed decrease in respiratory rate in 12 patients. No respiratory arrest was observed in these studies.

In our study, group II patients showed statistically significant sedation intra-operatively and post-operatively. Occurrence of sedation has also been reported by Salomaki et al. [23] and Badner et al. [24]. In our study, 40% in group II patients had nausea and vomiting. Similar incidences were reported by Salomaki et al. [23] and George et al [19]. None of the patients in group I and group II had pruritis.

The conclusions drawn from this study was that the quality of analgesia, onset of analgesia and maximum upper level of analgesia achieved by adding fentanyl to epidural bupivacaine is improved. Also, the analgesic duration is prolonged by addition of fentanyl to epidural bupivacaine with decrease in the number of top up doses of bupivacaine. The incidence of nausea, vomiting and sedation was increased by addition of fentanyl to epidural bupivacaine.

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