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# **Original Research Article**

# Onset and duration of epidural analgesia with bupivacaine and bupivacaine plus fentanyl: a comparative study

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#### **ABSTRACT**

**Background:** Bupivacaine has got the more cardiac toxicity due to high degree of protein binding. There have been many attempts for improving the duration and onset of epidural block. Fentanyl when administered epidurally was found to reduce the requirement of doses by double in some cases. The objective of the study was to compare the efficacy of bupivacaine plus fentanyl in terms of onset and duration of epidural analgesia.

**Methods:** A clinical study was undertaken to evaluate the onset and duration of analgesia with bupivacaine and mixture of bupivacaine plus fentanyl when given epidurally for patients undergoing lower limb orthopedic surgeries. The study was undertaken in 50 patients who were divided into two groups of 25 each. The patients were undergoing surgery in orthopedic theatre at S. V. S. Medical College and Hospital. Patients studied comprised of both the sexes between the 18-55 years of age.

**Results:** It is seen that the onset of analgesia was equal in both the groups 72% of patients in group II had excellent quality of intra operative analgesia compared to only 36% of patients in group I. This difference was found to be statistically significant (p<0.05). It was seen that none of the patients had analgesia of less than 1 hour 30 minutes. The two-segment regression time was uniformly distributed amongst the two groups. It was found that the incidence of intra operative complications like bradycardia, hypotension, nausea/vomiting were almost equal in both the groups. It was found that the duration of post-operative analgesia in patients of two groups was almost equal.

**Conclusions:** Addition of fentanyl to bupivacaine was found to increase the quality of intra operative analgesia. Otherwise there was no added advantage over bupivacaine alone.

**Keywords:** Analgesia, Bupivacaine, Complications, Fentanyl

## INTRODUCTION

For epidural anesthesia, local anesthetics are commonly used. Hence, we should know the pharmacology of the local anesthetics. Certain factors should be considered before an anesthetist wants to give the epidural analgesia. These factors are duration, location, whether he wants to give the motor block or sensory block, he should also know the potency and duration of the local anesthetic to be used. On the basis of length of action required, he can select the local anesthetic agent to be used. Chloroprocaine is the shortest acting local anesthetic

available. It is useful in short duration surgeries. It eliminates the need of keeping the patient for long durations after surgery. Another agent of choice for little more longer surgical procedures is lidocaine. It is an intermediate acting local anesthetic. Mepivacaine is another agent which has a longer duration of action but having onset profile similar to lidocaine. If we add epinephrine, then their length of action can be prolonged. But epinephrine can lead to hypotension.<sup>1</sup>

Bupivacaine or ropivacaine are commonly used a long acting local anesthetic for epidural analgesia. Their doses

may vary. It produces motor as well as sensory block. Ropivacaine is an analog of mepivacaine. It has a shorter duration of motor block and also a lower toxicity as compared to bupivacaine.<sup>2</sup>

Bupivacaine has got the more cardiac toxicity due to high degree of protein binding. There have been many attempts for improving the duration and onset of epidural block. There were attempts of addition of sodium bicarbonate in different concentrations, epinephrine, phenyl epinephrine etc. However ultimately it was clear that opioids can augment the effects of these local anesthetics for use in epidural space. Fentanyl when administered epidurally was found to reduce the requirement of doses by double in some cases.<sup>3</sup>

Even though opioids were found to be effective, they do have their own side effects. Itching, vomiting, nausea, hypotension and urinary retention are some of them. Alpha adrenergic agonists like clonidine can also be used instead of opioids. When clonidine is added to opioids, it gives an additive effect. This necessitates the lower doses of narcotics. When given in the mid or upper thoracic regions, epidurally administered clonidine causes an even greater decrease in blood pressure. 6

Clonidine has vagomimetic effects in addition to neither inhibiting nor epinephrine release. Additional side effects such as sedation and dry mouth are possible, but seem to be dose related. Even more esoteric compounds such as neostigmine, ketamine, ketorolac, midazolam, and dexamethasone are being studied with hopes to develop additional tools to supplement or even replace the neuraxial analgesia and anesthesia of local anesthetics. While this discussion focuses on epidural use of these agents, their clinical use may have far greater application. Current studies are not only investigating these agents in the acute pain setting, but are also for use in various chronic pain disorders. <sup>1</sup>

Hence present study was undertaken to study the efficacy of bupivacaine plus fentanyl in terms of onset and duration of epidural analgesia.

#### **METHODS**

A total of 50 skulls (27 male and 23 female) available in a clinical study was undertaken to evaluate the onset and duration of analgesia with bupivacaine and mixture of bupivacaine plus fentanyl when given epidurally for patients undergoing lower limb orthopedic surgeries. The study was undertaken in 50 patients who were divided into two groups of 25 each. The patients were undergoing surgery in orthopedic theatre at S. V. S. Medical College and Hospital. Patients studied comprised of both the sexes between the 18-55 years of age.

Detailed history and a complete clinical examination were done, so as to exclude patients with any systemic diseases like diabetes mellitus, hypertension, neurological diseases and bleeding diathesis. Selected patients were graded according to American Society of Anesthesiologists classification as Grade I or Grade II.

Routine investigations like complete urine examination, complete blood picture, blood sugar and blood urea, serum electrolytes, bleeding time, clotting time, ECG and chest x-ray in elderly patients whenever indicated was undertaken to rule out the presence of any systemic illness.

The 50 patients studied were divided into two groups. 25 patients in Group I (control) who received 20 ml of 0.5% Bupivacaine plus 2 ml of 0.9% Normal Saline. Another 25 patients were in Group II who received 20 ml Bupivacaine 0.5% plus 100 mcg of fentanyl citrate 2 ml.

Prior to scheduled operation a written and informed consent was taken according to hospital ethical committee. Irrespective of the group studied, patients were explained about the procedure of the epidural analgesia i.e. about the position and the technique which was going to be performed, effects of the procedure and the parameters to be studied to gain confidence and cooperation of the patients.

All the emergency drugs like atropine, mephenteramine, adrenaline, endotracheal tubes and working laryngoscope were kept ready. Prior to that Boyle's anesthetic apparatus was checked and kept ready.

On the day of surgery, per-operatively, pulse rate, blood pressure and respiratory rate were recorded in addition to height and weight. Patients were explained the complete procedure of epidural analgesia and surgery and they were assessed.

An intravenous line was secured in the forearm before the procedure was commenced and patients were preloaded with 1000 ml of Ringer's lactage. And no other premedication was given. The patient was kept in sitting or lateral position and suitable flexion was given by asking the patient to bend his/her head and raise their knees towards the chin.

#### Statistical analysis

The data was entered in the Microsoft Excel sheet and analyzed using proportions. Chi square test was applied whenever necessary. P value of less than 0.05 was considered as significant.

#### **RESULTS**

Table 1 shows comparison of onset of analgesia in the two groups. It is seen that the onset of analgesia was equal at 56% in both the groups when it was given at T 8 level. In case of T 6 level it was more in group II compared to group I, but the margin of difference was only 4%. While analgesia at T 10 level was more in

group I compared to group II but again the margin of difference was only 4%.

Table 1: Comparison of onset of analgesia in the two groups.

Dermatome	Group I		Group II		
level	No.	%	No.	%	
T 6	09	36	10	40	
T 8	14	56	14	56	
T 10	02	08	01	04	

Table 2: Comparison of quality of intra operative analysis in the two groups.

Quality of intra	Group I		Group II		Chi
operative analgesia	No.	<b>%</b>	No.	%	square (p value)
Excellent	09	36	18	72	
Satisfactory	11	44	06	24	5.153
Unsatisfactory	05	20	01	04	(0.005734)
Inadequate	00	00	00	00	

Table 2 shows comparison of quality of intra operative analgesia in the two groups. 72% of patients in group II had excellent quality of intra operative analgesia compared to only 36% of patients in group I. This difference was found to be statistically significant (p<0.05). No patient in both the groups had inadequate analgesia during surgery. Group I patients had more proportion of unsatisfactory analgesia during surgery i.e. 20% compared to only 5% in group II.

Table 3: Duration of analgesia (two segment regression).

Time	Group	Group I		Group II		
(min)	No.	<b>%</b>	No.	<b>%</b>		
110-119	03	12	00	00		
120-129	03	12	02	08		
130-139	08	32	11	44		
140-149	04	16	08	32		
150-159	07	28	04	16		

Table 3 shows duration of analgesia (two segment regression). It was seen that none of the patients had analgesia of less than 1 hour 30 minutes. The calculated value (1.76) is much less than the tabulated value (9.49) and is highly significant. Thus, we accept the null hypothesis (p>0.05). Hence, we conclude that the two-segment regression time was uniformly distributed amongst the two groups.

Table 4 shows comparison of intra operative complications in the two groups. It was found that the incidence of intra operative complications like bradycardia, hypotension, nausea/vomiting were almost equal in both the groups. Only itching was found to be

36% in group II patients compared to nil in group I patients.

Table 4: Comparison of intra operative complications in the two groups.

Intra operative	Grou	рI	Grou	Group II	
complications	No.	%	No.	%	
Bradycardia	02	08	02	08	
Hypotension	03	12	02	08	
Nausea/vomiting	02	08	03	12	
Itching	00	00	09	36	

Table 5: Comparison of duration of post-operative analysis in the two groups.

Time	Group	Group I		Group II		
(min)	No.	%	No.	<b>%</b>		
180-199	00	00	00	00		
200-219	03	12	00	00		
220-239	05	20	05	20		
240-259	08	32	10	40		
260-279	06	24	06	24		
280-299	03	12	04	16		

Table 5 shows comparison of duration of post-operative analgesia in the two groups. It was found that the duration of post-operative analgesia in patients of two groups was almost equal. There was no statistically significant difference found in two groups.

## **DISCUSSION**

It is seen that the onset of analgesia was equal at 56% in both the groups when it was given at T 8 level. In case of T 6 level it was more in group II compared to group I, but the margin of difference was only 4%. While analgesia at T 10 level was more in group I compared to group II but again the margin of difference was only 4%. 72% of patients in group II had excellent quality of intra operative analgesia compared to only 36% of patients in group I. This difference was found to be statistically significant (p<0.05). No patient in both the groups had inadequate analgesia during surgery. Group I patients had more proportion of unsatisfactory analgesia during surgery i.e. 20% compared to only 5% in group II. It was seen that none of the patients had analgesia of less than 1 hour 30 minutes. The calculated value (1.76) is much less than the tabulated value (9.49) and is highly significant. Thus, we accept the null hypothesis (p>0.05). Hence, we conclude that the two-segment regression time was uniformly distributed amongst the two groups. It was found that the incidence of intra operative complications like bradycardia, hypotension, nausea/vomiting were almost equal in both the groups. Only itching was found to be 36% in group II patients compared to nil in group I patients. It was found that the duration of post-operative analgesia in patients of two groups was almost equal. There was no statistically significant difference found in two groups.

Harukuni et al conducted a study to compare the effect of epidural fentanyl (EP-F), epidural lidocaine (EP-L), and intravenous fentanyl (IV-F) on hemodynamic and hormonal responses to surgery and postoperative analgesic requirement in 30 patients undergoing gastrectomy during isoflurane anesthesia.<sup>3</sup> The total number of analgesic administrations within the first 48 h postoperatively was compared. Group EP-L developed more frequent episodes of hypotension. Group IV-F required higher isoflurane concentrations and the plasma epinephrine levels increased more than in Groups EP-F and EP-L. In groups EP-L and IV-F, the plasma antidiuretic hormone (ADH) level increased more than in group EP-F. In groups EP-F and IV-F, the plasma cortisol and adrenocorticotropic hormone (ACTH) levels increased more than in group EP-L. The use of postoperative analgesics was significantly less in group EP-F. In conclusion, in group EP-F, attenuated hormonal responses to surgery were accompanied with less hypotension and postoperative analgesic requirements were reduced.

Guo et al found that analgesia with ropivacaine in combination with fentanyl at 0.1%:0.0002% ratio for labor pain relief is associated with lower incidence of motor blocks in comparison with analgesia with bupivacaine and fentanyl at similar ratio (0.1%: 0.0002%).<sup>7</sup>

Asik et al concluded that epidural bupivacaine 0.2% and ropivacaine 0.2% combined with fentanyl produced equivalent analgesia for pain relief during labor and delivery. It is concluded that ropivacaine 0.2% combined with fentanyl 2 microg mL (-1) provided effective analgesia with significantly less motor block and need for an instrumental delivery than a bupivacaine/fentanyl combination at the same concentrations during labor and delivery.

Bolukbasi et al found that there were no differences in pain scores, total dose of local anesthetics used, sensory or motor blockade, labor duration, mode of delivery, side effects, patient satisfaction, or neonatal outcome between the two local anesthetics at these dosages, but at the end of the second stage and delivery, adequate analgesia quality could not be ensured. They concluded that there was no major advantage of continuous epidural infusion of ropivacaine 0.0625% plus fentanyl 2 microg/mL over bupivacaine 0.0625% plus fentanyl 2 microg/mL for labor analgesia. We believe that different methods or dosages may be tried in order to improve comfort at the second stage of labor and the delivery.

Sanchez-Conde et al found that the demographic and delivery characteristics were similar in both groups. <sup>10</sup> We found no statistically significant differences between the two groups for level of motor blockade, which was nil for 29 patients (96.66%) in group R and 28 patients (93.33%) in group B. No differences in degree of pain or level of sensory block (T 8 - T 10 in both groups) were observed.

The total doses of local anesthetic used were similar at 23.7±11.6 mg in group R and 16.5±7.3 mg in group B (non-significant difference). Nor did we find differences in manner of delivery, neonatal Apgar scores, degree of maternal satisfaction or side effects.

#### CONCLUSION

The onset of analgesia was equal in both the groups i.e. 15 minutes in 56% of patients. The duration of analgesia as deduced by two segment regressions was also equal in the two groups i.e. 32% in bupivacaine group and 44% in bupivacaine plus fentanyl group. The quality of analgesia was excellent in fentanyl group i.e. 72% were showing excellent analgesia when compared to bupivacaine group. Maximum level of sensory blockade was equal in two groups.

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