

## ORIGINAL ARTICLE

### A COMPARATIVE STUDY OF EPIDURAL BUTORPHANOL AND EPIDURAL FENTANYL FOR THE RELIEF OF POST-OPERATIVE PAIN IN LOWER ABDOMINAL AND LOWER LIMB SURGERIES

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**ABSTRACT: BACKGROUND:** Epidural anaesthesia is used extensively for both intra-operative and post-operative analgesia. This prospective randomized study was conducted using opioids epidurally for post-operative analgesia. Fentanyl is a pure opioid agonist. Butorphanol tartarate which is an agonist antagonist opioid is considered safer than pure opioid agonist. Hence, we compared epidural 4mg butorphanol and epidural 100 µg fentanyl for the relief of post-operative pain. **AIMS AND OBJECTIVES:** To compare the onset, duration, quality of analgesia, hemodynamic effects and side effects between the 2 study drugs. **MATERIALS AND METHODS:** 60 patients of either sex posted for elective lower abdominal and lower limb surgeries were randomly divided into 2 groups of 30 each. Group A received butorphanol 4mg epidurally. Group B received fentanyl 100 µg epidurally. All surgeries were done under lumbar epidural anaesthesia with catheter in situ. Post-operatively when patients complained of pain, intensity of pain was assessed using visual analogue scale [VAS]. When the VAS score was > 5, Group A received butorphanol 4mg diluted to 10 ml with NS or Group B received 100 µg fentanyl epidurally diluted to 10 ml with NS. Onset, duration, quality of analgesia, hemodynamic effects and incidence of side effects were compared between the two groups and treated accordingly. **RESULTS:** Demographic profile was comparable in both groups. Mean time of onset of analgesia was rapid ( $3.22 \pm 0.9$  (S.D) min) in group B compared to group A ( $6.38 \pm 1.26$  (S.D) min). Duration of analgesia was longer in group A ( $344.00 \pm 63.39$  min) compared to group B ( $227 \pm 38.12$  min). Quality of analgesia was better with group A compared to group B. There was no significant difference in hemodynamic parameters in both groups. Sedation was the main side effect in group A. Incidence of pruritis, vomiting, hypotension and respiratory depression was more in group B. **CONCLUSION:** Epidural Butorphanol though has a delayed onset of analgesia has a longer duration and better quality of analgesia than fentanyl with paucity of clinically significant side effects with both groups.

**KEYWORDS:** Epidural, Catheter technique, Butorphanol, Fentanyl, Post-operative pain.

**INTRODUCTION:** Pain after surgery is inevitable. Untreated acute pain has the potential to produce acute hemodynamic, neurohumoral changes, neuronal remodeling and long lasting psychological and emotional distress.<sup>1</sup>

Hence, relieving pain is one of the fundamental responsibilities of anesthesiologists and is frequently a primary goal for which patients are seeking care.

The epidural route is more popular for postoperative pain management as the technique can be used alone or in combination with general anesthesia.<sup>2</sup> Epidural technique has been found to provide better pain relief than systemic opioids and also decreased incidence of post-operative complications.<sup>3</sup>

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Among opioids morphine, pethidine, fentanyl, sufentanyl, buprenorphine and butorphanol are the most commonly used drugs epidurally.

Fentanyl citrate, a mu opiate receptor agonist has analgesic potency greater than morphine and pethidine.<sup>4</sup> Butorphanol tartarate is a synthetically derived agonist-antagonist opioid analgesic. It is a strong agonist on kappa receptor and either antagonist or partial agonist on mu receptor.<sup>5,6,7</sup> It is considered safer than a pure opioid agonist. Hence we compared butorphanol 4 mg and 100 µg fentanyl given epidurally for the relief of post-operative pain.

**METHODOLOGY:** After approval from the Institutional Ethical committee, this prospective randomized study was conducted on sixty adult patients of ASA grade I and II, of either sex, belonging to 18-60 years of age, posted for elective lower abdominal and lower limb surgeries. Patients were randomly divided into two groups of 30 each.

Group A – Butorphanol group and

Group B – Fentanyl group.

**INCLUSION CRITERIA:**

1. Age group: 18-60 years of either sex.
2. ASA grade I and II.

**EXCLUSION CRITERIA:**

1. Patients with cardio-respiratory disorders.
2. Patients with renal and / or hepatic disorders.
3. Contraindications for epidural anaesthesia.
4. Patients physically dependent on narcotics.
5. Patients with history of drug allergy.
6. Head injury cases.
7. Patients in whom epidural anaesthesia was not adequate and supplemented with other types of anaesthesia.

A detailed pre-anesthetic evaluation was done. Patients were explained about epidural technique with catheter in situ and also educated about usage of linear visual analogue scale [VAS]. A detailed written informed consent was obtained. All patients were premedicated with Tablet Alprazolam 0.5mg given night prior to the surgery. On table, basal vital parameters (pulse rate, Non-invasive blood pressure, Pulse oximetry, ECG) were recorded. Patient was placed in sitting or lateral position. Under aseptic precautions, epidural space was identified by Loss of resistance technique using 18 Gauge Touhy needle at L2-L3 or L3-L4 interspace. Epidural catheter was introduced cephalad so that 2-3 cms was in epidural space.

Intravascular and intrathecal placement of the catheter was ruled out using 3ml of 2% lignocaine with adrenaline 1: 2,00,000. Epidural anaesthesia was activated using 16-18 ml bolus dose of 0.5% Bupivacaine. Subsequent top up doses were given according to requirement. Intra-operatively pulse rate, Non-invasive blood pressure, SPO2 and respiratory rate were recorded at 3 minutes interval for the first half an hour then five minutes interval for the next half an hour, thereafter every 15 minutes till the end of the surgery.

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In the post-operative period, when the patient first complained of pain, intensity of pain was assessed using VAS scale. When the VAS score was >5, study drug was given through epidural catheter as:

**Group A** – received butorphanol 4mg diluted to 10ml in normal saline and.

**Group B** – received fentanyl 100µg diluted to 10 ml in normal saline.

The intensity of pain and pain relief was assessed using VAS at 5, 10,15,30,60 minutes and thereafter hourly for 8 hours and then at 4 hours interval for 24 hours post-operatively. As and when the patient complains of further pain during the period of observation, intensity of pain was assessed again using VAS to know the effect of the study drug given earlier. If it was > 5, IM injection as per the ward protocol was given and the study ended at this stage.

**FOLLOWING OBSERVATIONS WERE RECORDED:** Onset of analgesia: is the time interval from administration of the study drug (VAS score of >5) till VAS score came down to < 5.

**DURATION OF ANALGESIA:** is the time interval between onset of analgesia (VAS score < 5), till patient complaints of pain (VAS score >5) when rescue medication was given.

**QUALITY OF ANALGESIA:** was assessed during the duration of analgesia using below classification.

Quality of analgesia	Pain score	VAS Score
No pain relief	0	10
Poor pain relief	1	7-9
Fair pain relief	2	5-7
Good pain relief	3	2-5
Excellent pain relief	4	0-2

**HEMODYNAMIC PARAMETERS:** Pulse rate, Blood pressure and Respiratory rate were observed after giving study drugs at 0,5,10,15,30,60 and 120 minutes post-operatively.

**STATISTICAL METHODS<sup>8,9</sup>:** The Statistical software namely SPSS 15.0, Stata 8.0, Med Calc 9.0.1 and Systat 11.0 were used for the analysis of the data and Microsoft word and Excel have been used to generate graphs, tables etc. P < 0.05 was considered statistically significant.

**RESULTS:** In this Study, the demographic data between the two study groups were comparable. (Table 1). Mean onset of analgesia was rapid ( $3.22 \pm 0.93$ (S.D) minutes) in fentanyl group when compared to butorphanol group ( $6.38 \pm 1.26$ (S.D) minutes). This was clinically and statistically significant ( $p < 0.001$ ) (Table 2). Duration of analgesia was longer in butorphanol group which ranged from 200- 500 minutes with a mean of  $344.00 \pm 63.69$  minutes compared to fentanyl group which ranged from 135- 300 minutes with a mean of  $227 \pm 38.12$  minutes. This was clinically and statistically significant ( $p < 0.001$ ) (Table 3).

There was no significant difference in heart rate, blood pressure and respiratory rate post-operatively between the two study groups. Results represented as: Heart rate (Table 4) (Figure 1), Blood pressure (table 5, table 6)(Figure 2, figure 3). Respiratory rate (Table 7) (Figure 4). Quality of analgesia was better with butorphanol group which was clinically and statistically significant (p

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<0.01). (Table 8) In group A, 25 patients (83.3%) had good pain relief (VAS 2-5) whereas in Group B, 14 Patient (46.7%) had good pain relief (VAS 2-5).

Sedation was the main side effect in butorphanol group, which was assessed using sedation score. Incidence of nausea was more in butorphanol group. Frequency of pruritis, vomiting, hypotension and respiratory depression was more in fentanyl group. (Table 9) (Figure 5).

In Group A- Butorphanol 4mg was used as the study drug and in Group B- Fentanyl 100µg was used as the study drug for the relief of post-operative pain.

PARAMETERS	Group A (n=30) Mean+ SD		Group B (N=30) Mean + SD		P VALUE
	AGE (YEARS)	40.80+ 11.93		38.80+ 11.41	
GENDER	MALE -15	FEMALE -15	MALE -15	FEMALE -15	1.000

**Table 1: Demographic characteristics**

### Group A: Butorphanol 4mg.

### Group B: Fentanyl 100µg.

Onset of analgesia (min)	Group A (n=30)	Group B (n=30)
2-4	0	25(83.3%)
4-6	15 (50.0%)	5(16.7%)
6-8	13(43.3%)	0
>8	2(6.7%)	0
Mean ±SD	6.38±1.26	3.22±0.93
Significance	Onset of analgesia in minutes is significantly late in Group B with t=11.07; P<0.001**	

**Table 2: Comparison of Onset of analgesia between the two study groups**

p<.001 This was statistically significant.

### Group A: Butorphanol 4mg

### Group B: Fentanyl 100µg

Duration of analgesia (min)	Group A (n=30)	Group B (n=30)
135 - 200	0	7(23.3%)
201-300	9(30.0%)	23(76.7%)
301-400	16(53.3%)	0
401-500	5(16.7%)	0
Mean ± SD	344.00 ± 63.69	227.17 ± 38.12
Significance	Duration of analgesia in minutes is significantly less in Group B with t=8.620; P<0.001**	

**Table 3: Comparison of Duration of analgesia between two study groups**

p<.001 This was statistically significant.

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### Group A: Butorphanol 4mg

### Group B: Fentanyl 100µg.

HR (bpm)	0 min	5 min	10 min	15 min	30 min	60 min	120 min
Group A	80.97 ±10.88	79.03 ±10.28	77.60 ±10.10	78.20 ±9.09	79.93 ±9.31	80.30 ±10.01	82.20 ±9.32
Group B	81.03 ±9.87	79.37 ±11.07	76.87 ±10.13	76.57 ±9.01	78.80 ±8.49	81.67 ±9.34	83.90 ±8.57
P value	0.980	0.904	0.780	0.487	0.624	0.587	0.465

Table 4: Comparison of Heart rate between the two study groups

Results are presented in Mean ± SD.

Statistically there was no significant difference in the heart rate between the two groups with  $p > 0.05$ .

### Group A: Butorphanol 4mg

### Group B: Fentanyl 100µg.

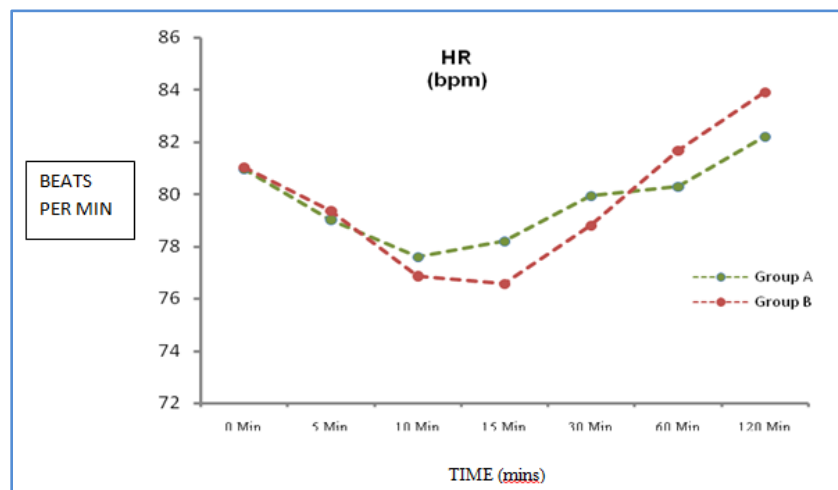


Fig. 1: Comparison of Heart rate between the two study groups

$p > 0.05$ : Statistically, there was no significant difference in the two study groups.

### Group A: Butorphanol 4mg

### Group B: Fentanyl 100µg.

SBP (mm Hg)	0 min	5 min	10 min	15 min	30 min	60 min	120 min
Group A	120.26 ±10.69	116.63 ±10.57	108.33 ±10.37	106.67 ±10.40	111.73 ±9.98	116.23 ±11.03	119.77 ±10.93
Group B	122.43 ±10.59	110.17 ±12.94	107.23 ±12.23	105.53 ±12.48	111.10 ±12.39	117.20 ±10.04	120.73 ±9.27
P value	0.434	0.038*	0.709	0.704	0.828	0.724	0.713

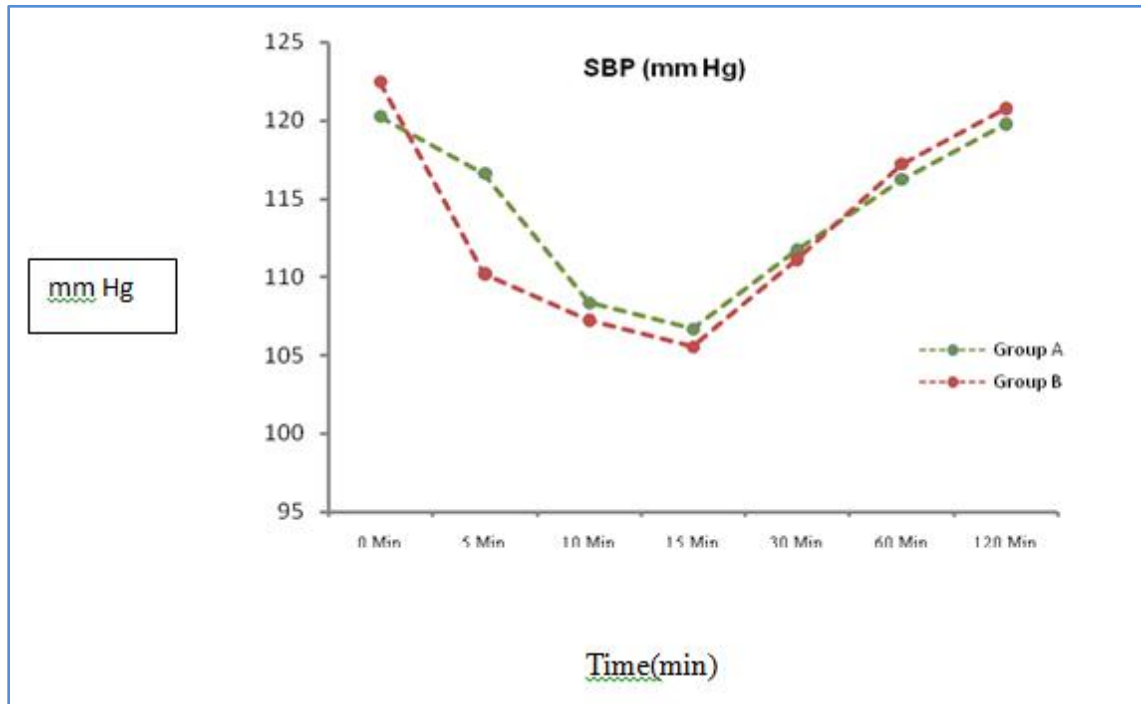
Table 5: Comparison of Systolic BP between the two study groups.

Results are presented in Mean ± SD

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**Group A: Butorphanol 4mg**

**Group B: Fentanyl 100µg.**



**Fig. 2: Comparison of Systolic Blood Pressure (mmHg) between two study groups**

**Group A: Butorphanol 4mg**

**Group B: Fentanyl 100µg.**

DBP (mm Hg)	0 min	5 min	10 min	15 min	30 min	60 min	120 min
Group A	73.57 ±7.46	71.87 ±8.05	66.13 ±6.97	65.17 ±7.45	68.93 ±8.35	71.50 ±6.97	73.43 ±7.47
Group B	75.93 ±7.61	68.07 ±8.42	66.57 ±8.29	65.80 ±7.58	71.23 ±7.58	74.23 ±7.66	75.53 ±7.54
P value	0.229	0.079	0.827	0.751	0.283	0.151	0.287

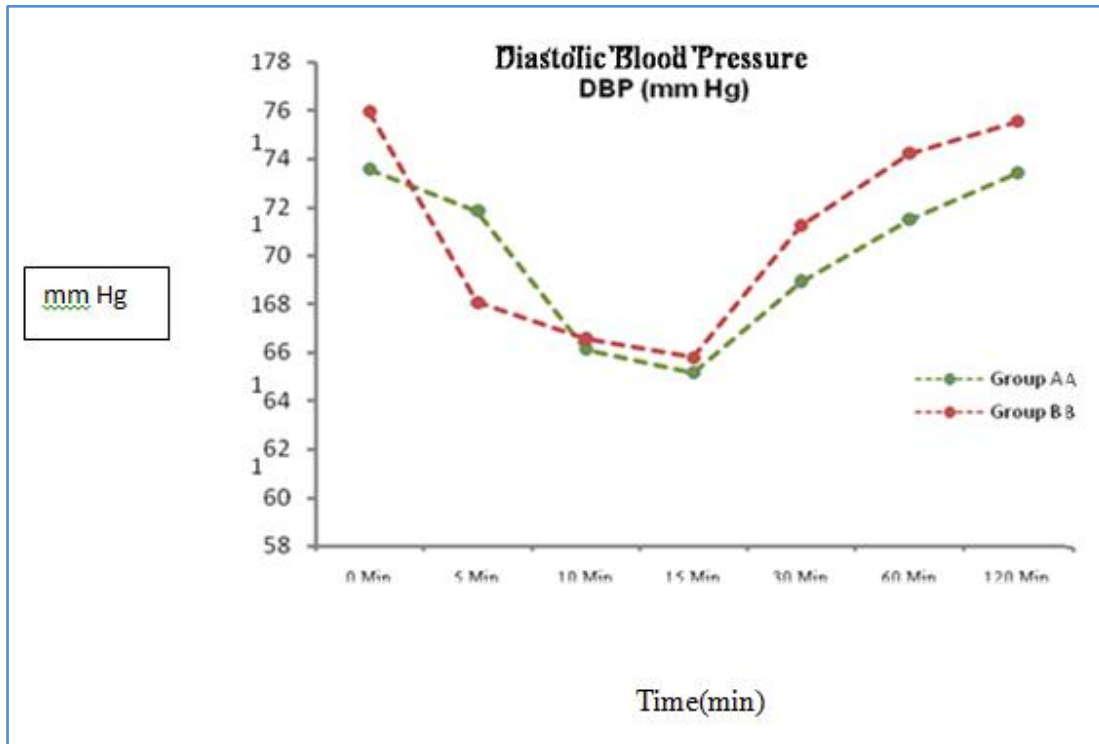
**Table 6: Comparison of Diastolic BP between the two study groups.**

Results are presented in Mean ± SD

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**Group A: Butorphanol 4mg**

**Group B: Fentanyl 100µg.**



**Fig. 3: Comparison of Diastolic Blood Pressure (mmHg) between the two study groups**

**Group A: Butorphanol 4mg**

**Group B: Fentanyl 100µg.**

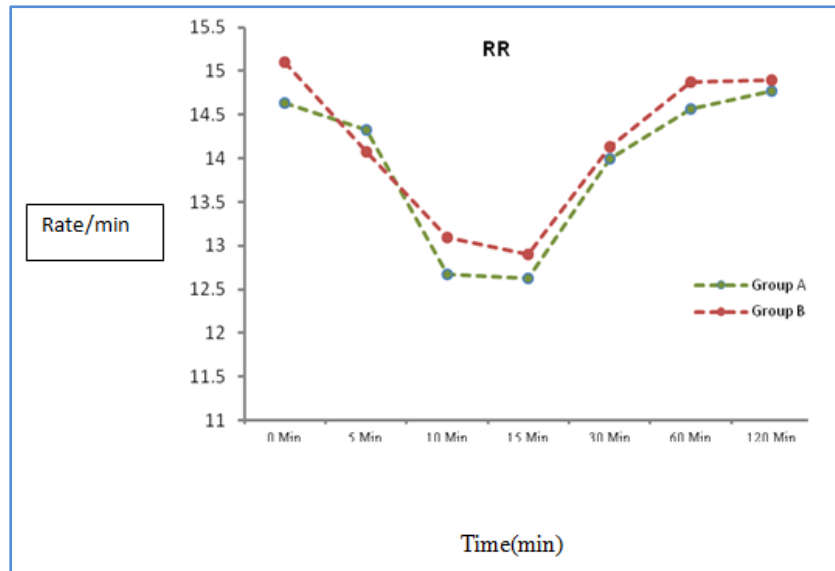
$p > 0.05$ . Statistically there was no significant difference in NIBP between the two groups.

RR (/ min)	0 min	5 min	10 min	15 min	30 min	60 min	120 min
Group A	14.63 ±1.19	14.33 ±1.42	12.67 ±1.37	12.63 ±1.43	14.00 ±1.08	14.57 ±0.94	14.77 ±0.82
Group B	15.10 ±1.58	14.07 ±1.98	13.10 ±1.52	12.90 ±1.45	14.13 ±1.53	14.87 ±1.48	14.90 ±1.60
P value	0.202	0.552	0.251	0.475	0.698	0.352	0.687

**Table 7: Comparison of Respiratory Rate between the two study groups**

Results are presented in Mean  $\pm$  SD.

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**Fig. 4: Comparison of Respiratory Rate between the two study groups**

$p > 0.05$ . Statistically there was no significant difference in Respiratory rate between the two groups.

Quality of analgesia	Group A (n=30)	Group B (n=30)	P value
No relief	-	-	-
Poor pain relief	1 (3.3%)	5 (16.7%)	0.195
Fair pain relief	2 (6.7%)	11 (36.7%)	0.005
Good pain relief	25 (83.3%)	14 (46.7%)	0.003
Excellent pain relief	2 (6.7%)	0	0.492
Mean $\pm$ SD	2.73 $\pm$ 0.64	2.47 $\pm$ 0.73	-

**Table 8: Comparison of Quality of analgesia between the two study groups**

$p < 0.01$ , this was statistically significant.

**Group A: Butorphanol 4mg**

**Group B: Fentanyl 100 $\mu$ g**

S.NO	Side effects	Group A (n=30)	Group B (n=30)	P value
1	Sedation	19 (63.3%)	0	<0.001**
2	Pruritis	1 (3.3%)	4 (13.3%)	0.353
3	Nausea	4 (13.3%)	2 (6.7%)	0.671
4	Vomiting	2 (6.7%)	10 (33.3%)	0.010
5	Respiratory depression	0	2 (6.7%)	0.492
6	Hypotension	0	2 (6.7%)	0.492

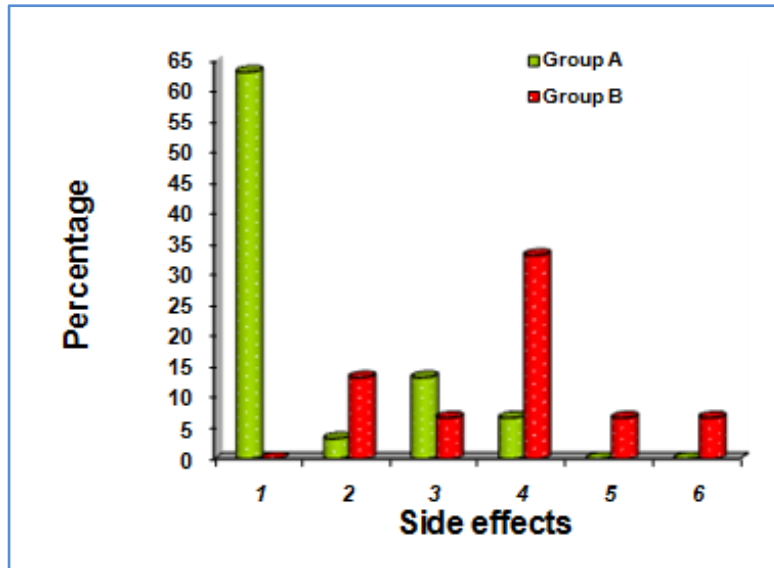
**Table 9: Comparison of Side effects between two groups**



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Group A: Butorphanol 4mg

Group B: Fentanyl 100µg



**Fig. 5: Comparison of Side effects between two groups**

Group A: Butorphanol 4mg

Group B: Fentanyl 100µg

**DISCUSSION:** The effective relief of pain to patients undergoing surgery is essential and is of paramount importance both on humanitarian grounds and also in reducing postoperative morbidity, hence should be done by the treating anesthesiologist.

The use of epidural opioids had become an increasingly popular technique for the management of acute postoperative pain in recent times. Recent studies would indicate that it is possible to achieve better analgesia with lower doses of opioid medication when these drugs are administered in extradural space as compared to intramuscular or intravenous routes of administration. However, there are disadvantages associated with narcotics as they are not always simple to use and may be associated with some unpleasant adverse effects, like nausea and vomiting (PONV), pruritis, respiratory depression and urinary retention.

Stimulation of spinal opiate receptors ( $\kappa$ ,  $\kappa$ ) can also produce spinal analgesia but with fewer side effects. Therefore, a drug such as butorphanol, a mixed narcotic agonist/antagonist, first introduced in 1978 acts as a  $\mu$  ( $\mu$ )agonist/antagonist and  $\kappa$  agonist, also produces analgesia, associated with fewer side effects and also low abuse potential. Its high lipid solubility and high affinity for opioid receptors are additional factors that contribute to paucity of side effects with its use.

Fentanyl was chosen for the study for advantages like no neurolytic preservatives, highly lipophilic, so better retained within the epidural space, short half-life, so less circulating blood levels resulting from absorption and finally because it is stable in salt solutions for more than 72 hours.

The present study is a prospective randomized controlled clinical comparative study done to assess the efficacy and safety of epidural butorphanol and fentanyl for the management of post-operative pain.

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Maurice Lippmann<sup>10</sup> in 1988 has reported in his study that epidural butorphanol 4mg used for postoperative analgesia in non- obstetric abdominal surgeries has produced analgesia within 15 minutes.

Rutter DV<sup>11</sup> et al., in 1981 reported that 100µg of epidural fentanyl for postoperative pain relief had a rapid onset of action i.e. almost 50% reduction in mean pain within 5 minutes.

Naulty JS<sup>12</sup> et al., in 1985 used different doses of epidural fentanyl in parturients following caesarean delivery. They concluded that fentanyl 100µg produced pain scores of 0 in 3-6 minutes.

In this study, the mean onset of analgesia in group A, butorphanol was 6.38±1.26 (S.D) minutes and in group B fentanyl was 3.22 ±0.93 (S.D) minutes. Statistical analysis showed that the onset of analgesia was faster in fentanyl group compared to butorphanol group. (p<0.0001).

In our study, duration of analgesia in group A (butorphanol group) ranged from 200-500 minutes(3.5 – 8.5 hrs) with a mean ±S.D of 344.00± 63.69 min and in group B (fentanyl group) ranged from 135- 300 minutes(2- 5 hours) with a mean± S.D of 227.17±38.12 min. The statistical analysis showed that duration of analgesia in group A was significantly longer when compared to group B (t=8.620; p<0.001).

Therese K et al<sup>13</sup>., in 1987 conducted a study on parturients who underwent caesarean delivery with epidural anaesthesia using different doses of butorphanol and concluded that butorphanol 4mg produces 6-8 hrs of analgesia and in 17 patients of the 30 patients analgesia lasted for upto 6- 24 hrs.

Maurice Lippmann<sup>10</sup> in 1988 reported in his study conducted for pain relief in non-obstetric patients after abdominal surgery using epidural butorphanol 4mg that duration of analgesia with epidural butorphanol 4mg was 5.6 hrs.

Rutter DV<sup>11</sup> et al., in 1981 reported that 100µg of epidural fentanyl for postoperative pain relief has a relatively shorter duration of action i.e. by 3<sup>rd</sup> hour almost 50% of patients complained of increase in pain.

In our study, quality of analgesia was assessed using VAS Score (and pain score). Accordingly, butorphanol provided fairly better quality of analgesia than fentanyl which was statistically significant (p< 0.01).

Lytle SA<sup>14</sup> et al., in 1991 did a retrospective analysis with fentanyl (50µg) and showed that epidural fentanyl provides good to excellent pain relief.

Hwang KB, Chung CJ, Lee et al<sup>15</sup>., in 2004 compared analgesic efficacy of epidural butorphanol and epidural fentanyl and concluded that there was no significant difference in the quality of analgesia between the two groups.

In our study heart rate, blood pressure and respiratory rate remained stable throughout the observatory period. 2 patients in fentanyl group had hypotension (fall in systolic BP <20% of basal reading) and respiratory depression (RR<10/min) which was not statistically significant (p> 0.05).

Gough<sup>16</sup> et al., in 1988 used epidural fentanyl 1.5µg/ kg body weight in 10ml of sterile solution and concluded that the range of mean(S.D) of cardio- respiratory variables like heart rate 84(2)- 95(18) beats/ min, systolic BP of 121(19)- 133(14) mm of Hg, diastolic BP of 70(10)- 76(10) mm of Hg and RR- 21(3)- 23(4) / min varied negligibly from basal recordings.

Premila Malik, Chhavi Manchanda, Naveen malhotra<sup>17</sup> in 2006 conducted a study to assess and compare the safety and efficacy of postoperative analgesia with epidural butorphanol 2mg and fentanyl 50µg. Their study showed that there was no significant changes in pulse rate, systolic and

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diastolic BP, RR and SpO<sub>2</sub> in the 2 groups at different time intervals throughout the 24 hours study period ( $p > 0.05$ ).

Sedation was the main side effect in butorphanol group which constituted 63.3% and none of the patients in fentanyl group had sedation. Majority of the patients had mild sedation, patient awake but drowsy. This was statistically significant ( $p < 0.001$ ).

Catherine O Hunt<sup>18</sup> in his study has reported a higher incidence of sedation with epidural butorphanol and is a dose dependent side effect.

72% of patients on epidural butorphanol 2mg had clinically significant sedation in a study by Therese K<sup>13</sup> et al.

In our study 3.3% of patients in butorphanol group had pruritis and 13.3% of patients in fentanyl group had pruritis which was statistically not significant ( $p > 0.05$ ).

In a study by Ackermann et al<sup>19</sup>, in 1989, 7% of patients reported pruritis with 2mg of epidural butorphanol.

In a study by Lytle SA<sup>14</sup> et al., in 1991 using fentanyl 50µg reported that 4% of patients had pruritis.

In our study 13.3% of patients in butorphanol group had nausea whereas in fentanyl group only 6.7% of patients had nausea which was not significant statistically ( $p > 0.05$ ).

Vomiting was reported in 6.7% of cases in butorphanol group and 33.3% of cases in fentanyl group which was significant statistically ( $p = 0.010$ ).

In a study by Lytle SA et al<sup>14</sup>, in 1991, nausea was reported in 25.5% of cases.

Premila Malik, Chhavi Manchanda, Naveen Malhotra<sup>17</sup> in 2006 compared the efficacy of epidural butorphanol 2mg and fentanyl 50µg found that the incidence of nausea and vomiting was higher in fentanyl group.

In our study, 6.7% of patients in fentanyl group had respiratory depression and in none of the patients in butorphanol group which was not significant ( $p > 0.05$ ).

No patients had respiratory depression with butorphanol in studies conducted by Maurice Lippmann<sup>10</sup> et al., in 1988.

Negre I et al<sup>20</sup>, in 1987 observed the effect of 200µg of fentanyl on ventilatory response to carbon dioxide and concluded that fentanyl induces a non-systemic ventilatory response that may be due to rostral spread of the drug.

It can be concluded from our study that epidural butorphanol though has a delayed onset of analgesia in comparison to fentanyl, provides longer duration of analgesia, better quality of analgesia with fewer side effects like sedation which were statistically significant when compared to epidural fentanyl.

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## ORIGINAL ARTICLE

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