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A COMPARATIVE STUDY OF EPIDURAL BUTORPHANOL AND EPIDURAL FENTANYL AS ADJUVANTS TO BUPIVACAINE IN LOWER ABDOMINAL SURGERIES

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ABSTRACT **AIM**: To compare the efficacy of butorphanol and fentanyl added as adjuvants to bupivacaine in epidural anaesthesia for elective lower abdominal surgeries.

MATERIALS & METHODS: 60 patients of either sex, aged between 20-60 years of ASA grade I & II admitted for elective surgeries in a tertiary care hospital. All cases were given epidural anaesthesia using 0.5% bupivacaine with butorphanol 1mg (total volume of 20ml) or 0.5% bupivacaine with fentanyl 100µg(total volume of 20ml) depending on study group BB or BF. In the perioperative period the following parameters were observed,1) Vital parameters-heart rate, SpO2,blood pressure and respiratory rate,2)Onset and completion of analgesia, 3)Quality of analgesia, 4)Duration of analgesia, 5)Sedation score 6)Side effects. In the postoperative period, intensity of pain was assessed using Linear Visual analog scale.

RESULTS: The statistical study showed no significant difference in the mean arterial blood pressure, mean pulse rate, SPO2 & mean respiratory rate between the 2 groups. **Onset the completion of analgesia** The mean onset of analgesia was 5-9mins vs (5-10mins; mean 5.95 mins) in both the BB &BF groups. Completion of analgesia occurred earlier in BB group (9-14 min, mean 10.10 mins) & In BF group (9-15mins; mean 10.96 mins). But there was no statistically significant difference between the two groups. **Duration of analgesia:** The duration of analgesia was longer in butorphanol group which ranged from 5 to 8hours & in fentanyl group it was 3 to 7 hours with a mean of 5.8 hours. This was clinically and statistically significant ($p<0.001$). **Quality of analgesia:** The quality of analgesia was good in both BB and BF group. There was no statistical significance between both the groups. **Sedation score:** The mean value of subjective sedation score was 1.00± 0.06 in group BF and 3.0±0.64in group BB. This was statistical significance ($p<0.001$). There was no statistically significant difference between the two groups in the incidence of side effects.

CONCLUSION; Epidural butorphanol provides a longer duration of good quality of analgesia with fewer side effects, when compared to epidural fentanyl.

KEYWORDS : Epidural anaesthesia, Butorphanol, Fentanyl ,Lower abdominal surgery.

INTRODUCTION

Epidural anaesthesia /analgesia is one of the best accepted and most commonly employed technique in modern anesthesiology for lower abdominal, pelvic , perineal ,thoracic and lower limb surgeries. It provides surgical anaesthesia as well as postoperative analgesia. Epidural anaesthesia provides good operative conditions with good sensory and motor blockade, contracted bowels retaining adequate spontaneous respiration, hemodynamic stability and facilities for postoperative analgesia.

MATERIALS AND METHODS

This study is a comparative and prospective study conducted in a tertiary care hospital. After obtaining clearance from institutional ethical committee and informed consent, a total of 60 patients of either sex aged between 20-60years belonging to ASA physical status I & II scheduled for elective lower abdominal surgeries were randomly selected.

INCLUSION CRITERIA

1, Patients aged between 20-60yrs
2, Weight between 40-70kgs
3, Both sex
4, ASA grade I & II
5, Patients undergoing elective lower abdominal surgeries

EXCLUSION CRITERIA

1, Pregnant women
3, Patients with h/o systemic illness.
4, Patients with h/o convulsions, neurological deficits
5, Spinal deformities and psychiatric diseases
6, ASA grade III & IV
7, Coagulopathies and patients with infection at the puncture site.

METHODOLOGY

60 patients posted for elective lower abdominal surgeries were randomly selected for the study. Routine preoperative investigations were done. All the patients were educated about the the verbal numerical pain scale for assessment of pain.
Grading of postoperative pain was done using Visual analog scale(VAS).

On the day of surgery patients were shifted to the operating room , and multiparameter monitors were connected. The base line heart rate, SpO_2 and blood pressure (Systolic, diastolic and MAP) were recorded. An 18 G iv cannula was inserted and patients were preloaded with 10ml/kg of ringer lactate over 15-30minutes prior to epidural block.

Patients were positioned in right lateral decubitus posture. Observing sterile precautions, L3-L4 space was identified. Skin was infiltrated with local anesthetic inj. 1% lignocaine 2 ml. Epidural space was identified with an 18GTuohys needle, by using loss of resistance to air technique and a 19G epidural catheter was inserted about 5cms into the epidural space and secured in place.

A test dose 3ml of 1.5% lignocaine with adrenaline (1:2,00,000) was given to rule out intravascular or intrathecal placement of the catheter. Five minutes after test dose, confirming the absence of intrathecal or intravascular placement,20ml of study drug was injected through epidural catheter depending on the study group.

Patients were divided into two groups:

Group BB 30 patients	Bupivacaine with butorphanol group 0.5% bupivacaine (18ml) with 1ml of 1mg butorphanol (preservative free) with 1ml of sterile normal saline to make a total of 20ml
Group BF 30 patients	Bupivacaine with fentanyl group 0.5% bupivacaine 18ml with 2ml (100mcg) of fentanyl (preservative free)

All patients were given oxygen at 5L/min through face mask.
No intravenous analgesics or sedation were administered during the surgery.

The time of injection of study drug was noted at "o" time. The drug was injected approximately at the rate of 1ml/second and the height of sensory blockade was determined by eliciting pin prick test

In the perioperative period the following parameters were studied.

1. vital parameters such as HR, BP, SPO_2, RR were continuously monitored every 5 mins for the first 15mins and then onwards every 15minus throughout the period and every ½ an hour in the postoperative period for 2hours. Intraoperative hypotension if any was treated with iv fluids, O2 supplementation and titrated doses of ephedrine 3-6mg or mephentermine3-6mg iv. Bradycardia if any was treated with Inj. Atropine.
2. Onset analgesia is the time taken from injection of local anesthetic solution upto loss of pin prick sensation in any dermatome.
3. Completion of analgesia is the time taken from the initial onset of analgesia upto the time when analgesia attained its maximum dermatome level, with no further rise for 5mins.
4. Quality of analgesia was graded as follows:

- Good –No complaint of pain or discomfort during the procedure
- Fair – pain or discomfort felt only during specific stages of procedure, like traction on viscera/peritoneum.
- Poor –pain during surgery and needed top up with epidural local anaesthetic solution.

5. Duration of analgesia is the time taken from the onset of analgesia upto the time when VAS reached a score of 5.
6. sedation score was assessed using subjective sedation score:

0 awake, conscious, no sedation to slightly restless
1 calm and composed
2 awakens on verbal commands
3 awakens on gentle tactile stimulation
4 awakens only on vigorous
5 unarousable

POST OPERATIVE OBSERVATIONS:
The following parameters were observed in the operative period:

1. **Pain score –VISUAL ANALOGUE SCALE**, every hour till 8 hrs.
2. **Vitals** were recorded at the same time intervals as the pain score.

When the vas score reached 5, rescue analgesia was given through the epidural catheter and the study in the patient ceased. Side effects like nausea, vomiting, urinary retention, headache, pruritus and respiratory depression if any were noted and treated accordingly.

OBSERVATION AND RESULTS
The data collected was subjected to statistical analysis using statistical package for social sciences. Chi – square test and the students ' t' test was used to test the significance of difference between the two groups. A 'p' value < 0.05 was taken to denote a significance.

COMPARISON OF AGE
Both the groups were comparable with respect to demographic profiles like age, sex, weight. The mean age is 41.37 years in BB group and 41.63 years in BF group. There is no statistical difference in the age comparison between the two groups.

SEX DISTRIBUTION
90% of patients in BB group are males, 92% in BF group are males. 10 % in BB group are females and 8 % in BF group are females. There is no statistical difference in sex comparison between the two groups.

COMPARISON OF HEART RATE
There is statistically no significant difference in mean heart rate from 5 minutes to 120 minutes between the groups BB and BF. Mean heart in BB group was 75.60/ min and BF group was 74.67/ min.

CHANGES IN MEAN ARTERIAL BLOOD PRESSURE
There is statistically no significant difference in the mean arterial pressure from 5 minutes between BB group and BF group. The mean arterial blood pressure in BB group is 83.4 mmHg±1.26 (SD) and in BF Group is 81.3 mmHg±1.05 (SD).

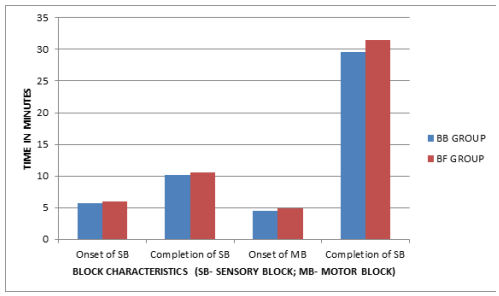
COMPARISON OF MEAN RESPIRATORY RATE/ MINUTE
There is statistically no significant difference in the mean respiratory rate from 5 mins to 120 mins between BB group and BF group. The mean respiratory rate in BB group is 12.6 and in BF group is 12.9.

COMPARISON OF MEAN SPO_2 IN BB AND BF GROUPS
There is no statistical significance in mean Spo_2 from 5 minutes

TABLE 1 : TIME OF ONSET AND COMPLETION OF SENSORY BLOCK IN GROUP BB & BF

PARAMETERS	GROUP BB		GROU BF		STATISTICAL INFERENCE
	MEAN IN MINUTES	S. D	MEAN IN MINUTES	S. D	
Onset of sensory block	5.73	1.48	5.96	1.67	0.871> 0.05 Not Significant
Completion of sensory block	10.10	1.26	10.53	0.89	0.132>0.05 Not Significant
Onset of motor block	4.45	0.30	4.88	0.30	0.310> 0.05 Not Significant
Completion of motor block	29.58	1.04	31.45	0.91	0.218>0.05 Not Significant

GRAPH 1: BLOCK CHARACTERISTICS

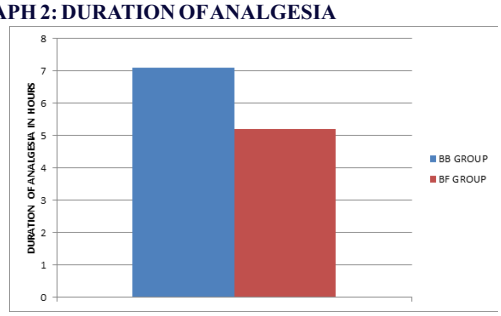


There is no significant statistical difference in the time of onset of sensory and motor block, completion of sensory and motor block in between group BB and group BF. Mean onset time of sensory block, completion of sensory block, onset of motor block and completion of motor block in group BB is 5.73 minutes, 10.1 minutes, 4.45 minutes and 29.58 mins, respectively. In BF group, mean time of onset of sensory, completion of sensory block, onset of motor block and completion of motor block are 5.96 mins, 10.53 mins, 4.88 mins and 31.45 mins respectively.

TABLE 2: COMPARISON OF DURATION OF ANALGESIA

PARAMETER	GROUP BB		GROUP BF		STATISTICAL INFERENCE
	MEAN HOURS	±S.D.	MEAN HOURS	±S.D.	
DURATION OF ANALGESIA	7.1	1.008	5.2	1.080	**0.001< 0.05 SIGNIFICANT**

GRAPH 2: DURATION OF ANALGESIA



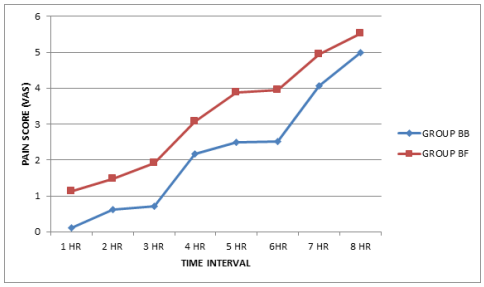
There is statistically significant difference in the duration of analgesia between group BB and group BF. The duration of analgesia was longest with butorphanol group (5-9 hours; mean – 7.1 hours), whereas in group BF was 3-9 hours, mean 5.2 hours.

TABLE 3: THE MEAN POST – OPERATIVE PAIN SCORES (VAS) AT DIFFERENT TIME INTERVALS IN GROUP BB & GROUP BF

TIME INTERVAL	GROUP BB		GROUP BF		STATISTICAL SIGNIFICANCE
	MEAN	±S.D.	MEAN	±S.D.	
1 HR	0.12	0.71	1.12	0.45	0.000 < 0.05 S
2 HR	0.61	0.61	1.48	0.91	0.008 < 0.05 S
3 HR	0.72	0.60	1.91	0.56	0.021 < 0.05 S

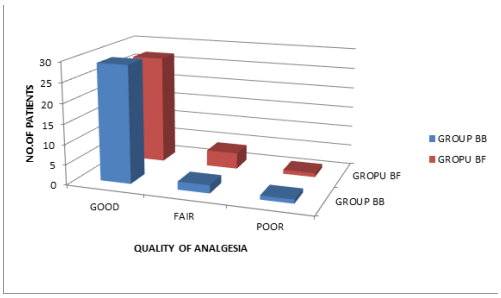
4 HR	2.18	0.87	3.06	1.70	0.001 < 0.05 S
5 HR	2.50	1.17	3.88	0.96	0.003 < 0.05 S
6 HR	2.51	1.07	3.96	0.91	0.012 < 0.05 S
7 HR	4.06	0.61	4.94	0.56	0.001 < 0.05 S
8 HR	5.00	0.08	5.51	0.54	0.44 < 0.05 NS

GRAPH 3: PAIN SCORES (VAS) IN GROUP BB & BF



As shown in graph 9, the pain scores as assessed on VAS were low and remained low for a significant time in the postoperative period in group BB when compared to group BF.

GRAPH 4: QUALITY OF ANALGES'



Majority of the patients in both group BB and Group BF had good quality of analgesia. None of the patients required top up doses of local anesthetics intra operatively.

TABLE 4: SEDATION CHARACTERISTICS

TIMES IN MINUTES	SUBJECTIVE SEDATION SCORE (% OF CASES)												STATISTICAL INFERENCE
	GROUP BB						GROUP BF						
	0	1	2	3	4	5	0	1	2	3	4	5	
30		100					85	15					0.001<0.05 S
60			100					100					0.001<0.05 S
90			100					80	20				0.000<0.05 S
120			75	25			12	32	56				0.003<0.05 S

In group BB, 100% patient had sedation score of 1 at 30 minutes, where as in group BF 85% patients had a sedation score of 0 at 30 minutes. At 60,90 and 120 minutes majority of the patients in group BB had a sedation score of 2 and 3, whereas in group BF the sedation score was 1 and 2.

COMPARISON OF SIDE EFFECTS BETWEEN GROUPS BB & BF:

In group BB, 3.33% of patients had nausea/ vomiting compared to 13.33% of patients in BF group, whereas 3.33% of patients had pruritus in BB compared to 16.66% of patients in BF group. This was not statistically significant ($p > 0.05$). none of the patients in both the groups were reported to have respiratory depression

DISCUSSION

Opioids are being extensively used as adjuvants to local anesthetics to improve the quality of the block and to produce dose-sparing effect. Butorphanol a mixed opioid, with an agonist and antagonist action at μ receptor and an agonist action at kappa receptor, is found to produce potent analgesia with fewer side effects and very low abuse potential. It is highly lipid soluble and has greater affinity to opioid receptors, which contributes to its greater potency and efficacy.

Fentanyl, being a synthetic opioid receptor agonist, is found to produce analgesia by binding to supra – spinal opioid receptors when administered into the epidural space. It is better retained in the epidural space because of its high lipid solubility. Epidural administration of fentanyl is associated with reduced respiratory depression and lesser incidence of side effects like nausea, vomiting and pruritus.

The present study is prospective, randomized, comparative study to compare the efficacy of butorphanol and fentanyl added as adjuvants to bupivacaine in epidural anaesthesia in lower abdominal surgeries with respect to intra operative hemodynamic stability and postoperative analgesia.

INTRA OP HEMODYNAMICS:

In our study, the majority of patients were hemodynamically stable intra operatively. Comparison of heart rate and MAP within the groups was done using paired 't' test whereas comparison of heart rate and MAP in between the two groups was done using unpaired 't' test.

The mean arterial BP in group BB was 83.4 mmHg ± 1.26 (S.D) mm Hg and in group BF was 81.3mmHg± 1.05 (S.D) mm Hg. The mean reduction in MAP was statistically insignificant between both the groups.

The mean pulse rate in group BB was 75.6±1.35 (S.D.)/ min and in group BF was 74.67 ± 0.92 (S.D.)/ min. the statistical analysis showed that there was no significant difference between the two groups.

The mean respiratory rate in group BB was 12.6± 1.32 (S.D.) per mins and in group BF was 12.9 ± 0.98 (S.D.) per min. the statistical study showed to significant difference in the mean respiratory rate between the 2 groups.

Oxygen saturation (SpO_2) maintained between 98-97% in both the groups. None of the patients in both the groups showed desaturation (SpO_2 < 95%). and RR of 14 (±3) to 16 (±4)/ min varied negligibly from basal recordings.

Premila Malik, Chhavi Manchanda, Naveen Malhotra et al., in 2006 conducted a study to assess and compare the safety and efficacy of postoperative analgesia with epidural butorphanol 2 mg and fentanyl 50 μg. Their study showed that there was no significant changes in pulse rate, systolic and diastolic BP, RR and SpO_2 in the 2 groups at different time intervals throughout the 24 hours study period ($p > 0.05$).

SEDATION SCORES:

Catherine O Hunt in her study has reported a higher incidence of sedation with epidural butorphanol and is a dose dependent side effect. In our study sedation scores were higher with butorphanol group as compared with fentanyl group. Mean value of subjective sedation score was 1.00 ± 0.06 in group BF and 3.0 ± 0.64 in group BB. Majority of the patients had mild sedation. The patients were awake but drowsy. This was statistically significant ($p < 0.001$).

JS Naulty in his study noted that sedation was significant, but was of mild type (arousable with verbal response). 72% of patients on epidural butorphanol 2mg had clinically significant sedation in a study by **Therese K et al.,**

Rutter DV et al., in 1981 reported that fentanyl 100 μg for postoperative pain relief produced increase in sedation.

ONSET AND COMPLETION OF SENSORY BLOCK:

Addition of 1 mg butorphanol to 20 ml 0.5% bupivacaine reduced the latency of onset of analgesia to 5-9 mins and completion of analgesia occurred earlier (9-14 mins, mean 10.10 mins). In BF group also the onset of analgesia was rapid (5-10 mins; mean 5.95 mins) and completion of analgesia occurred in (9-15 mins; mean 10.96 mins).

Maurice Lippmann in 1988 has reported in his study that epidural butorphanol 4 mg used for postoperative analgesia in non – obstetric abdominal surgeries has produced analgesia within 15 minutes. **Abboud et al.,** in 1986 studied the efficacy of epidural butorphanol for postoperative pain relief and reported the onset of analgesia with 1 mg butorphanol was 15 mins. **Cousins and Mather et al.,** in 1984 reported the time of onset of analgesia with epidural fentanyl 100 μg to be 5-10 mins. This is in concordance with our study.

QUALITY OF ANALGESIA:

In our study majority of the patients in both group BB and group BF reported good quality of analgesia.

Lytle SA et al., in 1991 did a retrospective analysis with fentanyl (50 µg) and showed that epidural fentanyl provides good to excellent pain relief. **Sugimoto M et al.,** in 1997 compared the degree of analgesia using different doses of epidural fentanyl and found that epidural fentanyl 25µg provided superior analgesia than 12.5 µg. **Hwang KB, Chung CJ, Lee et al.,** 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.

POST OPERATIVE PAIN SCORES:

The range of postoperative pain scores in group BB at 1,2,3,4,5,6,7 hours were between 0-5, where as in BF group for the same time interval was between 3-6. There was a statistically significant difference in pain score in between both the groups.

DURATION OF ANALGESIA:

The mean duration of analgesia with the group BF was 5.2 hours, where as in Group BB was 7.1 hours. Our study was consistent with those observed by **Cousins and Marther et al.,** 1984 and **Peach et al.,** in 1990, who observed the mean duration of analgesia with epidural fentanyl was 5.7 hours and 5.2 hours respectively. **Malik et al.,** in 2006 studied the duration of analgesia with epidural butorphanol with varying doses and observed that epidural butorphanol produced a significantly longer duration of analgesia when compared to fentanyl

SIDE EFFECTS;

Narcotics are well known for their potential side effects such as pruritus, nausea, vomiting urinary retention and respiratory depression. Delayed respiratory depression is one of the most troublesome of these side effects

1, Pruritus:

In our study 3.33% of patients in butorphanol group had pruritus and whereas 16.66%of patients in fentanyl group had pruritic which was statistically insignificant **(p > 0.05).**

In a study by **Ackermann et al.,** in 1989, 7% of patients reported pruritus with 2mg of epidural butorphanol and in a study by **Palacios et al** in 1991, 1.4% of patients reported pruritus with 2mg of butorphanol.

2, Nausea and vomiting:

In our study 3.3% of patients in butorphanol group had nausea whereas in fentanyl group 13.33% of patients had nausea which was insignificant statistically **(p>0.05).**

No patients on epidural butorphanol and nausea or vomiting in separate studies conducted by **JS Naulty et al., and Catherine O Hunt et al.,.** in a study by **Lytle SA et al.,** in 1991, nausea was reported in 25.5% of cases.

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

3, **Respiratory depression**: In our current study, none of the patients in butorphanol group or fentanyl group reported respiratory depression which was consistent with the following studies.

No patients had respiratory depression with butorphanol in studies conducted by **Maurice Lippmann et al.,** in 1988, **Catherine O Hunt et al.,** in 1989, **Naulty et al.,** in 1989

CONCLUSION

It can be concluded from the above study that epidural butorphanol provides a longer duration of good quality of analgesia with fewer side effects like sedation which are statistically significant when compared to epidural fentanyl.

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