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A Comparative Study of Epidural, Bupivacaine with Butorphanol and Bupivacaine with Fentanyl In Lower Limb Surgeries

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Abstract:
Introduction*: Intrathecal anesthesia and epidural anesthesia (EA) are the most popular regional anesthesia techniques used for surgeries below umbilicus. EA is more versatile in providing anesthesia, analgesia and treatment of chronic disease syndromes. It provides better postoperative pain control and more rapid recovery from surgery. It also provides effective prolonged surgical anesthesia, prolonged postoperative analgesia, reduces the incidence of hemodynamic changes and reduces the incidence of PDPH as the dura is not pierced.*
Aims And Objectives: *To Compare with the efficacy of lumbar epidural block with 0.5% bupivacaine 10ml with Fentanyl 50µg and 0.5%bupivacaine 10ml with butorphanol 1mg in lower limb surgeries focusing on Onset and duration of analgesia, Cardio respiratory effects, Sedation, Adverse effects*
Summary: *The study was conducted to compare the effect in lower limb surgeries.*
100 patients belonging to ASA grade I&II were selected. Bupivacaine (0.5%)
10ml with fentanyl (50µg) was given in Group I, and Bupivacaine (0.5%)10ml with butorphanol (1mg) was given in Group II.
The patients studied across the group did not vary much with respect to age, sex or height. The onset of sensory blockade was delayed by about 20 seconds in groupII and the onset of motor blockade was delayed by about 20-25 seconds in group-II compared to group-I. Duration of sensory blockade in Group II is longer compared to group I , thus prolonging the duration of analgesia. Duration of motor blockade in group II is prolonged than in Group I .
The time of first request of analgesics by the patients in group-II is longer (360 minutes) compared to group-l (206 minutes) thus prolonging the duration of analgesia. Visual analogue scores were significantly lower in group-II compared to group-l thus reducing the requirement of supplemental postoperative analgesics. The adverse effects observed in the study were minimal.
Conclusion: *Addition of the opioids, i.e., Butorphanol and Fentanyl significantly quickens the onset and prolongs analgesia Onset is fast with Bupivacaine with Fentanyl combination compared with Bupivacaine with Butorphanol combination . Bupivacaine with Butorphanol provide more effective and longer duration of analgesia as compared with Bupivacaine with Fentanyl.*
Key Words: *Epidural Anaesthesia, 0.5%Bupivacaine,Butorphanol,Fentanyl*

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I. Introduction

Intrathecal anesthesia and epidural anesthesia (EA) are the most popular regional anesthesia techniques used for surgeries below umbilicus. EA is more versatile in providing anesthesia, analgesia and treatment of chronic disease syndromes. It provides better postoperative pain control and more rapid recovery from surgery. It also provides effective prolonged surgical anesthesia, prolonged postoperative analgesia, reduces the incidence of hemodynamic changes and reduces the incidence of PDPH as the dura is not pierced.

Among opioids, Morphine, Pethidine, Fentanyl, Sufentanyl, Buprenorphine and Butorphanol are most commonly used drugs epidurally. In the present study, Fentanyl and Butorphanol have been selected as an adjuvant to Bupivacaine for intraoperative / postoperative epidural analgesia.

A local anesthetic–opioid combination provides superior analgesia during perioperative period[1.] . This combination limits rapid regression of sensory blockade and possibly decreases the dose of local anesthetic administered. Analgesia provided by epidural opioids is superior to that with systemic opioids. Bupivacaine a local anesthetic is widely used drug in epidural anesthesia. Butorphanol is mu-receptor partial agonist and antagonist. It is effective in relieving moderate to severe pain. Fentanyl is a phenylpiperidine-derivative synthetic pure opioid agonist; which is also a very effective analgesic.

Hence the present study is designed to compare the effectiveness of fentanyl and butorphanol as adjuvants to plain bupivacaine through epidural route.

AIM :
A COMPARATIVE STUDY OF EPIDURAL BUPIVACAINE WITH BUTORPHANOL AND BUPIVACAINE WITH FENTANYL IN LOWER LIMB SURGERIES.

OBJECTIVES:
Compare with the efficacy of lumbar epidural block with 0.5% bupivacaine 10ml with Fentanyl 50µg and 0.5%bupivacaine 10ml with butorphanol 1mg in lower limb surgeries focusing on Onset and duration of analgesia, Cardio respiratory effects, Sedation, Adverse effects.

PATIENTS AND METHODS

Hundred adult patients of ASA grade I and II, of either sex, belonging to 18-70 years of age, posted for elective lower limb surgeries in orthopedics, were selected for this study. Patients were randomly divided into two groups of 50 each.
GROUP I (BF)- Bupivacaine (0.5%) 10ml with Fentanyl (50µg).
GROUP II(BB)- Bupivacaine (0.5%)10ml with Butorphanol (1mg)

EXCLUSION CRITERIA:
1. Consent not given
2. Patients with renal and / or hepatic disorders/ cardio-respiratory disorders
3. Any bleeding disorders or patient on anticoagulents
4. ASA grade 3 and 4
5. History of allergy to local anesthetics.
6. Spinal deformities
7. Emergency surgeries

POST OPERATIVE PERIOD:

After completion of the surgery, patient was shifted to recovery room and monitoring was continued. When patient recovered from motor blockade, they were shifted to postoperative ward.

In the postoperative period, when the patient first complained of pain, intensity of pain was assessed using VAS scale.

The intensity of pain and pain relief was assessed using VAS at 5, 10,15,30,60 minutes2hours, and thereafter 2 hourly for12 hours postoperatively. If it was 4 or more, rescue analgesia was given in form of Injection Diclofenac 75 mg intravenously slowly as per the ward protocol and the study would end at this stage.

STATISTICAL METHODS: Student t test (two tailed, independent) has been used to find the significance of duration of analgesia, onset of analgesia and VAS scores between two groups, Chi-square and Fisher Exact test has been used to find the significance incidence of side effects between two groups. Microsoft word and Excel have been used to generate graphs, tables etc**.**

II. Observation And Results

The present study was conducted in government general hospital , Guntur ,from june 2016 to December 2017 attached to guntur medical college, Guntur.
Group I(BF)- Bupivacaine (0.5%)10ml + Fentanyl (50µg) .
Group II(BB)- Bupivacaine (0.5%)10ml + Butorphanol (1mg), to study the efficacy based on onset of analgesia, duration of analgesia and adverse effects.

Table: Sex wise distribution

Sex	Group I(BF)		Group II(BB)			Total
	No.	%	No.	%	No.	%
Males	32	64.00%	32	64.00%	64	64.00%
Females	18	36.00%	18	36.00%	36	36.00%
Total	50	100.00%	50	100.00%	100	100.00%

In Group I(BF) and Group II(BB) male patients were 64% and female patients were 36%. The sex ratio in both groups is equal.

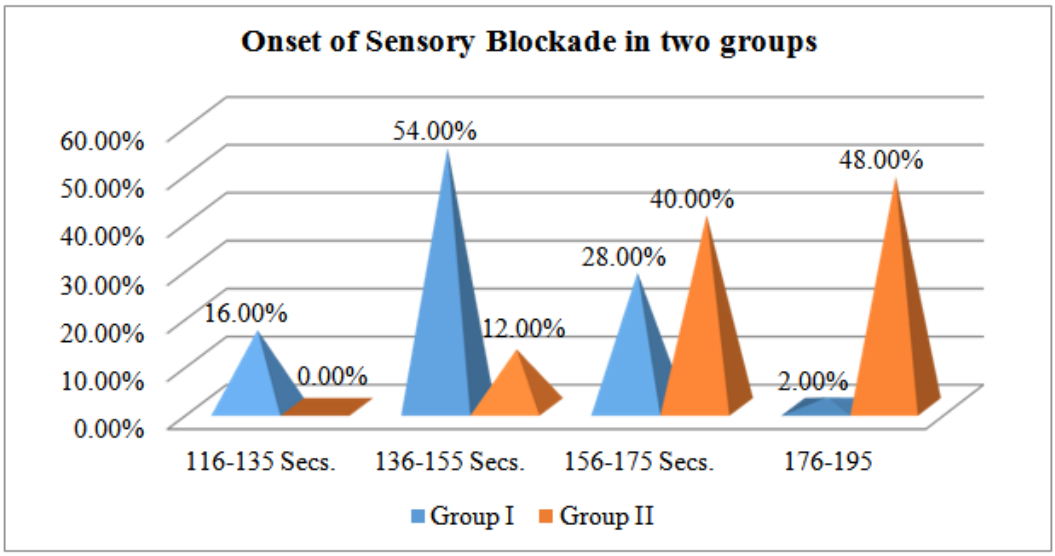
Table: Age wise distribution

Age (Yrs)	Group I(BF)		Group II(BB)		Total	
	No.	%	No.	%	No.	%
16-30	14	28.00%	18	36.00%	32	32.00%
31-45	16	32.00%	12	24.00%	28	28.00%
46-60	17	34.00%	16	32.00%	33	33.00%
61-75	3	6.00%	4	8.00%	7	7.00%
Total	50	100.00%	50	100.00%	100	100.00%
Mean +/- SD	**40.8 +/- 13.96**		**41.02 +/- 14.09**			
Unpaired ttest t-statistic			**0.078**			
P Value			**0.937**			
Inference			**Not Significant**			

The mean age of patient in Group I(BF) is 40.8± 13.96 and in group II(BB) is 41.02±14.09. Age incidence between two groups are comparable. Age distribution in both groups is comparable.

Table: Comparison of Onset of Sensory Blockade

On set of Sensory Blockade (Seconds)	Group I(BF)		Group II(BB)		Total	
	No.	%	No.	%	No.	%
116-135	8	16.00%	0	0.00%	8	8.00%
136-155	27	54.00%	6	12.00%	33	33.00%
156-175	14	28.00%	20	40.00%	34	34.00%
176-195	1	2.00%	24	48.00%	25	25.00%
Total	50	100.00%	50	100.00%	100	100.00%
Mean +/- SD	**149.08 +/- 12.312**		**171 +/- 11.082**			
Unpaired t-test t-statistic	**9.36**					
P Value				**< 0.0001**		
Inference				**Highly Significant**		

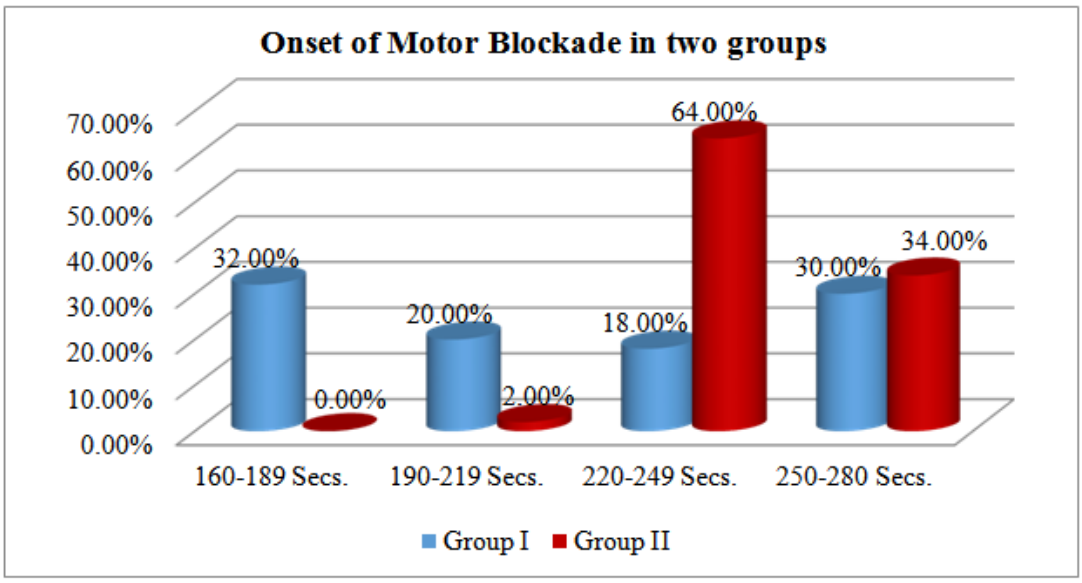


Onset of sensory blockade in group I(BF) patients in seconds 149.08±12.312 and in Group II(BB) patients is in seconds 171±11.082 which is statistically highly significant.(p<0.0001). Onset was delayed in Group II(BB).

Table: Comparison of Onset of Motor Blockade

Onset of Motor Blockade (Seconds)	Group I(BF)		Group II(BB)			Total
	No.	%	No.	%	No.	%
160-189	16	32.00%	0	0.00%	16	16.00%
190-219	10	20.00%	1	2.00%	11	11.00%
220-249	9	18.00%	32	64.00%	41	41.00%
250-280	15	30.00%	17	34.00%	32	32.00%
Total	50	100.00%	50	100.00%	100	100.00%
Mean +/- SD	**218.64 +/- 36.33**		**242 +/- 11.67**			
Unpaired ttest t-statistic			**4.33**			

P Value		**< 0.0001**		
Inference		**Highly Significant**		



Onset of motor blockade is 218.64±36.33 seconds in Group I(BF) and 242±11.67 seconds in group II(BB). Onset is delayed in group II(BB). The difference in groups is statistically highly significant. (p<0.0001).

Table: Comparison of Motor Blockade

Duration of Motor Blockade (Seconds)	**Group I(BF)**		**Group II(BB)**		**Total**	
	No.	**%**	**No.**	**%**	**No.**	**%**
130-149	43	86.00%	0	0.00%	43	43.00%
150-169	7	14.00%	37	74.00%	44	44.00%
170-189	0	0.00%	13	26.00%	13	13.00%
Total	50	100.00%	50	100.00%	100	100.00%
Mean +/- SD	**140.48 +/- 7.28**		**165.48 +/- 5.03**			
Unpaired t-test t-statistic			**19.98**			
P Value			**< 0.0001**			
Inference			**Highly Significant**			

Duration of Motor blockade in group I(BF) in minutes 140.48±7.28 and in group II(BB) in minutes 165.48±5.03 which is prolonged in group II. The difference between two groups is statistically highly significant. (p value <0.0001).

Table: Comparison of Duration of Sensory Blockade

Duration of Sensory Blockade (Seconds)	**Group I(BF)**		**Group II(BB)**		**Total**	
	No.	**%**	**No.**	**%**	**No.**	**%**
170-179	18	36.00%	14	28.00%	32	32.00%
180-190	32	64.00%	36	72.00%	68	68.00%
Total	50	100.00%	50	100.00%	100	100.00%
Mean +/- SD	**180.04 +/- 5.15**		**181.12 +/- 5.20**			
Unpaired t-test t-statistic	**1.04**					
P Value	**0.3**					
Inference	**Not Significant**					

Duration of sensory blockade in Group I(BF) in minutes 180.4±5.15 and in group II(BB) in minutes 181.12±5.20. The difference between the two groups is statistically not significant. (p<0.3)

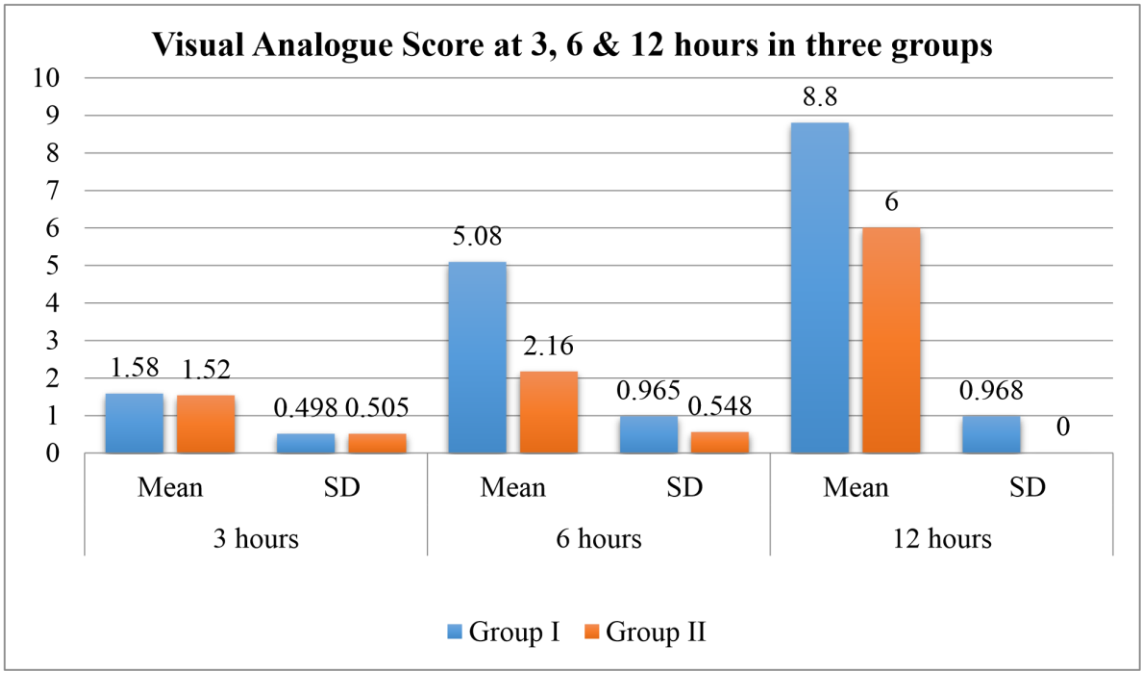
Table: Comparison of Post operative Analgesia

Duration of Post Operative Analgesia (Seconds)	Group I(BF)		Group II(BB)		Total	
	No.	%	No.	%	No.	%
191-220	49	98.00%	0	0.00%	49	49.00%
221-250	1	2.00%	0	0.00%	1	1.00%
341-370	0	0.00%	43	86.00%	43	43.00%
371-400	0	0.00%	7	14.00%	7	7.00%
Total	50	100.00%	50	100.00%	100	100.00%
Mean +/- SD	**206.96 +/- 8.31**		**361.3 +/- 8.25**			
Unpaired t-test t-statistic			**93.2**			
P Value			**< 0.0001**			
Inference			**Highly Significant**			

Duration of post operative .analgesia in group I(BF) is in seconds 206.96±8.31 and in group II(BB) is 361.3±8.25 which is prolonged in group II. The difference between two groups is statistically highly significant. (p value <0.0001)

Table: Comparison of Visual Analogue Score

Time (Hrs)	Visual Analogue Score		Unpaired t-test t-statistic	P-Value	Inference
	Group I(BF) (Mean +/- SD)	Group II(BB) (Mean +/- SD)			
3 Hrs	1.58 +/- 0.498	1.52 +/- 0.505	**0.598**	> 0.05	Not Significant
6 Hrs	5.08 +/- 0.965	2.16 +/- 0.548	**18.597**	< 0.0001	Highly Significant
12 Hrs	8.8 +/- 0.968	6 +/- 0	**20.434**	< 0.0001	Highly Significant



Visual analogue scores are low in Group II(BB) than in Group I(BF) at all time intervals. The difference is statistically highly significant. (p value <0.0001)

Table : Comparison of Mean Heart Rates at different time intervals

Mean HR (bpm)	Group I(BF) (n=50)		Group II(BB) (n=50)		Unpaired t-test t-statistic	P - Value	Inference
	Mean	SD	Mean	SD			
0 Mts.	82.16	6.31	80.8	6.67	1.04	> 0.05	Not Significant
5 Mts.	82.92	6.31	82.32	5.56	0.504	> 0.05	Not Significant
10 Mts.	83.64	5.48	82.72	5.82	0.813	> 0.05	Not Significant
20 Mts.	84.08	4.89	82.56	4.89	1.551	> 0.05	Not Significant
30 Mts.	82.8	6.35	81.9	4.97	0.789	> 0.05	Not Significant
45 Mts.	81.84	5.93	81.4	4.85	0.405	> 0.05	Not Significant
60 Mts.	83.36	6.62	81.04	5.19	1.949	> 0.05	Not Significant
120 Mts.	83.12	6.27	81.24	5.58	1.582	> 0.05	Not Significant

Change in heart rate at different time intervals in group I(BF) and Group I(BB)I is statistically not significant.

Table : Comparison of Mean systolic blood pressures at different time intervals

Mean Systolic Blood Pressure	Group I(BF) (n=50)		Group II(BB) (n=50)		Unpaired t-test t-statistic	P - Value	Inference
	Mean	SD	Mean	SD			
0 Mts.	126.4	9.13	124.92	9.3	0.802	> 0.05	Not Significant
5 Mts.	123.58	7.96	120.24	8.18	2.06	**< 0.05**	**Just Significant**
10 Mts.	114.96	9.13	115.44	8.29	0.275	> 0.05	Not Significant
20 Mts.	113.06	8.78	111.44	7.68	0.981	> 0.05	Not Significant
30 Mts.	119.22	6.76	114.56	8.18	3.103	**< 0.05**	**Significant**
45 Mts.	120.28	6.82	117.4	8.32	1.892	> 0.05	Not Significant
60 Mts.	120.28	7.79	119.8	7.09	0.322	> 0.05	Not Significant
120 Mts.	122.44	7.41	120.08	7.48	1.584	> 0.05	Not Significant

Change in mean systolic blood pressure at different time intervals in two groups is statistically not significant.

Discussion

In the present study, the onset of epidural analgesia in group BF (10ml of 0.5% Bupivacaine + 50u Fentanyl) was varied from 2- 4 minutes (mean 5.27 minutes) whereas in group BB (0.5% Bupivacaine+ 1mg Butorphanol) the onset was 4-8 minutes (mean 2.69, p <0.0001) which is statistically significant. The duration of analgesia in group BF lasted for 2-4 hours (mean 2.98) where as in group BB patients duration of analgesia lasted for 3-5 hours (mean 6.98 p<0.0001) which is also statistically significant.

Our findings were consistent with Modig and Paalzov.[2] Various studies using epidural butorphanol for post-operative analgesia have reported the duration of analgesia to be 4-6 h, 5 h and 5.35 h with 0.5 mg, 1 mg, 2 mg and respectively.[3,4,5] Malik et al. [6] have also reported in their study that butorphanol provides a longer duration of analgesia than fentanyl.

The Visual analog scores of patients in group BB at the time of recovery, were in the range of 7 to 9 with a mean of 7.84, whereas in Group BB patients the Visual Analog Scores at the time of recovery were in the range of 5 to 6 with a mean value of 5.44 (p<0.0001) .

The "p"value signifies that group BB patients are having higher intensity of block and pain relief which is reflected in the low Visual Analog Scores. The patients were continuously observed for respiratory depression with SpO_2 (< 90%) and RR (< 10). No case of respiratory depression was observed in Butorphanol group.

The results demonstrate that the addition of Fentanyl and Butorphanol to B quickens the onset . Administration of 10 ml of 0.5% plain Bupivacaine showed latency of 6-11 min (mean 7.28) consistent with the study by Moore *et al*[7]. Addition of 1 mg butorphanol to 20 ml 0.5% plain Bupivavaine reduced the latency of onset of analgesia to 5-9 min and the completion of analgesia occurred earlier (9-14 min; mean 11.80). Abboud *et al*.[8] studied epidural butorphanol for the relief of postoperative pain after caesarean section and reported the time of onset of pain relief with 1 mg butorphanol to be 15 min. Mok *et al*.[9] compared epidural butorphanol and morphine for the relief of post-operative pain and reported the onset of pain relief at 15 min with 4 mg butorphanol and peak pain relief at 30 min. the difference observed is probably due to the fact that the authors had used butorphanol dissolved in normal saline in the post-operative period, when the patient complained of moderate to severe pain and while in our study, 1 mg butorphanol was administered along with 20 ml 0.5% plain B before the start of surgery. The onset of analgesia was more rapid (4-8 min; mean 4.92) and was completed in 8-13 min (mean 10.80) with the addition of 100 µg fentanyl to 20 ml 0.5% plain Bupivacaine. Cousins and Mather[10] reported the time of onset of analgesia with epidural fentanyl 100 µg to be 4-10 min.

The pain scores as assessed on the VAS were low and remained low for a significant time in the post-operative period with the addition of fentanyl or butorphanol to Bupivacaine . The duration of analgesia was also significantly prolonged with the addition of opiods to Local Anesthetics. We observed duration of analgesia with 10 ml 0.5% B with 50µg Fentanyl to be 2- 4h (mean 4.76) in consistent with other studies that given by Modig and Paalzov et al.[2] (range 2.7-5 h; mean 4.3) and Paech *et al*.[11] (mean 5.2 h). The duration of analgesia was prolonged with the addition of 50 µg fentanyl (3-5h; mean 5.96) in the present study, consistent with that given by Cousins and Mather (5.7 h) and Paech *et al*.[11] (5.2 h). The duration of analgesia was longest with B with 1mg butorphanol combination (3-5 h; mean 7.64). Various studies using epidural butorphanol for post-operative analgesia have reported the duration of analgesia to be 4-6 h, 5 h and 5.35 h with 0.5 mg, 1 mg, 2 mg and respectively.[4,5] Malik *et al*.[6] have also reported in their study that butorphanol provides a longer duration of analgesia than fentanyl, similar to our study.

The duration of analgesia was prolonged with the addition of 50µg fentanyl (2-4 h; mean 5.96) in our study, consistent with that given by Cousins and Mather[10] (5.7 h) and Paech *et al*. [11] (5.2 h). The duration of analgesia was longest with B-butorphanol combination (3-5 h; mean 7.64). Various studies using epidural butorphanol for post-operative analgesia have reported the duration of analgesia to be 4-6 h, 5 h and 5.35 h with 0.5 mg, 1 mg, 2 mg and respectively.[3,5] Malik *et al*.[6] have also reported in their study that butorphanol provide longer duration of analgesia than fentanyl, similar to present study.

In the present study, both fentanyl and butorphanol along with bupivacaine, provided adequate anesthesia and analgesia; but significantly lesser analgesic requirement was observed in the group receiving epidural Butorphanol and Bupivacaine mixture compared to epidural Fentanyl and Bupivacaine mixture. The time for first request of analgesia with the use of epidural Butorphanol and Fentanyl, in conjunction with bupivacaine, in the present study was about 5 hours and 4 hours respectively from the time of epidural injection. Kim *et al*[12]. have reported the duration of analgesia of approximately 7 hours after the use of 4 mg bupivacaine with 25 µg fentanyl for TURP. Earlier studies report the duration of analgesia with intrathecal fentanyl ranging from one to four hours.[13] Singh V *et al*., have also reported that lesser number of patients receiving intrathecal butorphanol requested for rescue analgesia as compared to those receiving intrathecal fentanyl.[14] Studies comparing intravenous butorphanol and fentanyl have reported the equianalgesic doses as 1 µg/kg and 20 µg/kg for fentanyl and butorphanol, respectively.[15]

ADVERSE EFFECTS:

In the present study;

Sedation: It was the main side effect in Bupivacaine and Butorphanol group which constituted 45% compared to Bupivacaine and Fentanyl group (12%). Majority of the patients had mild sedation, patient sedated but arousable. This was statistically significant. Catherine O Hunt[72] in his study has reported a higher incidence of sedation with epidural Butorphanol and is a dose dependent side effect.

Pruritis: In our study none of the patients in group BB had pruritis and 4 patients (16%) in group BF had pruritis which was statistically significant (p0.05). No patients had respiratory depression or hypotension with Butorphanol in studies conducted by Catherine O Hunt et al[16] in 19897.

III. Summary

The study was conducted to compare the effect in lower limb surgeries.

100 patients belonging to ASA grade I&II were selected. Bupivacaine (0.5%)

10ml with fentanyl (50µg) was given in Group I, and Bupivacaine (0.5%)10ml with butorphanol (1mg) was given in Group II.

American Society of Anesthesiologists (ASA) classification 1 & II, aged between 18-70 years, posted for elective lower limb surgeries were randomly allocated for the study.

GROUPI(BF)- Bupivacaine (0.5%) 10ml with Fentanyl(50µg)

GROUPII(BB)- Bupivacaine (0.5%)10ml with butorphanol (1mg).

The patients studied across the group did not vary much with respect to age, sex or height.

The onset of sensory blockade was delayed by about 20 seconds in groupII and the onset of motor blockade was delayed by about 20-25 seconds in group-II compared to group-I.

Duration of sensory blockade in Group II is longer compared to group I , thus prolonging the duration of analgesia.

Duration of motor blockade in group II is prolonged than in Group I

The time of first request of analgesics by the patients in group-II is longer (360 minutes) compared to group-l (206 minutes) thus prolonging the duration of analgesia.

Visual analogue scores were significantly lower in group-II compared to group-l thus reducing the requirement of supplemental postoperative analgesics. The adverse effects observed in the study were minimal.

With the present study we can summarize that Bupivacaine (0.5%)10ml with Butorphanol 1mg, thereby bringing about better quality and longer duration of analgesia, better postoperative outcome with minimum side effects.

Advantages are:

1. Superior quality of analgesia.
2. Longer duration of analgesia.
3. Reduced post operative analgesic requirements.
4. Minimal side effects.

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