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Dr. Jitta Sudershan Reddy
Associate Professor, Department of Anaesthesiology, Prathima Medical College, Karimnagar, Telangana, India

Corresponding Author:
Dr. Jitta Sudershan Reddy
Associate Professor, Department of Anaesthesiology, Prathima Medical College, Karimnagar, Telangana, India

A study on compare the efficacy of epidural, bupivacaine with buprenorphine and bupivacaine with fentanyl in lower limb surgeries

Dr. Jitta Sudershan Reddy

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Abstract
Background and Objectives: Pain is a complex subjective experience which has proved difficult to measure in reproducible way. It is found that operative pain is more severe after surgery and thereafter gradually diminishes over next 24 hours. Providing effective analgesia for patients undergoing major surgery is a daily challenge for most anaesthetists.
Methods: 60 patients in the age group 20-60 years belonging to ASA I-II posted for elective lower limb surgeries were studied. The patients were divided in to two groups of 30 each.
Group A- 0.5% Bupivacaine 15ml (75mg) with 0.5ml (150 ug) Buprenorphine (preservative free)
Group B- 0.5% Bupivacaine 15ml (75mg) with 1ml (50ug) Fentanyl (preservative free)
Intraoperatively, sensory and motor blockade, quality and duration of Postoperative analgesia, hemodynamic and respiratory parameters, side effects like nausea, vomiting, respiratory depression, urinary retention, pruritus were studied. Patients were monitored for 48 hours postoperatively to look for any delayed complications.
Results: Addition of 50 mcg fentanyl to 0.5 % bupivacaine (group B) resulted in faster onset of sensory and motor blockade which was statistically insignificant compared to 150mcg buprenorphine with 0.5% bupivacaine (group A). Duration of analgesia was significantly longer in Group A with mean duration of 766.6 minutes as compared to 471 min in Group B. Both the groups provided a good hemodynamic stability. There was no significant respiratory depression in both the groups. The incidence of Nausea and vomiting was more in group A (40 %) compared to group B (10 %) and mild pruritus which did not require any treatment was more in group B (10%) compared to none in group A.
Conclusion: In this comparative study an effort was made to study the peri operative analgesic efficacy of Inj. Buprenorphine and Inj. Fentanyl with 0.5 % Bupivacaine epidurally for lower limb surgeries. There were no significant hemodynamic and respiratory side effects in either of the groups. Both buprenorphine and fentanyl along with bupivacaine 0.5% can be given epidurally as a single shot injection for perioperative analgesia obviating the need for epidural catheter.

Keywords: Buprenorphine, Fentanyl, Bupivacaine, Lower Limb, Surgery

Introduction
The word pain is derived from the Greek term poine (―penalty‖) [1]. Pain is not just a sensory modality but is an experience. The international Association for the study of pain defines pain as ―an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage‖.
Intrathecal anaesthesia and epidural anaesthesia (EA) are the most popular regional anaesthesia techniques used for lower limb orthopaedic surgeries. Intrathecal anaesthesia also called as spinal anaesthesia has few limitations like, short duration of anaesthesia, extension of anaesthesia can be done for prolonged surgeries but chances of life threatening complications are more, shorter duration of post-operative analgesia and troublesome complication of postdural puncture headache (PDPH) [2].
EA is becoming one of the most useful and versatile procedures in modern anesthesiology. It is unique in that it can be placed at virtually any level of the spine, allowing more flexibility in its application to clinical practice. It is more versatile than spinal anesthesia, giving the clinician the opportunity to provide anesthesia and analgesia, as well as treatment of chronic disease syndromes.
The present study is designed to compare between epidural, Bupivacaine with Buprenorphine and Bupivacaine with Fentanyl in Lower Limb Surgeries.

Following points will be considered for the comparison:

1. Onset of action.
2. Sensory analgesia.
3. Degree of motor blockade.
4. Duration of sensory analgesia.
5. Hemodynamic and respiratory changes.
6. Adverse Effects, if any.

Materials & Methods

This study is a prospective study conducted at Pratima Medical College and Hospital, Karim Nagar. After Ethical committee clearance and informed consent, a total of 60 patients of either sex aged between 20-60 years belonging to ASA Grade I & II scheduled for elective lower limb surgeries were randomly selected.

Inclusion Criteria

- Patients aged between 20-60 years.
- Patients of either sex.
- Patients with ASA Grade I & II.
- All Patients selected for elective lower limb surgeries.

Exclusion Criteria

- Pregnant women.
- Patients with H/o Cardio-Respiratory disorders
- Patients with Hepatic and Renal diseases.
- Patients with H/o convulsions & neurological deficits.
- Patients with Spinal deformities & Psychiatric diseases.
- Patients with ASA Grade III & above.
- Patients with contra-indications for epidural anaesthesia.

Methodology

60 Patients posted for elective lower limb surgeries were randomly selected for the study. All patients undergone thorough pre-anaesthetic evaluation a day before surgery and explained in detail regarding the anaesthetic procedure. Routine investigations were done. Drugs used were explained to the patients and also educated about Verbal numerical scale for assessment of pain.

Grading of Post-Operative Pain is Done Using Vns (Verbal Numerical Scale):

The patient will be asked to quantify their pain by using VNS pain scores with 0 corresponding to no pain and 10 to the worst imaginable pain.

0 1 2	3 4	5 6 7	8 9 10
No pain to slight pain. Excellent analgesia.	Mild pain Good analgesia	Moderate pain FAIR analgesia	Severe pain POOR analgesia

For the purpose of assessing the pain

- 0 - 2.5 taken as no pain
- 2.5-5 taken as mild pain
- 5 - 7.5 taken as moderate pain
- 7.5 - 10 taken as severe pain.

Written informed consent was obtained. All patients received Tab. Alprozolam 0.25 mg orally on the previous night of surgery as pre-medication. Patients were advised nil orally for a period of 6 hours prior to surgery.

A test dose of 3ml of 2% lignocaine with adrenaline (1:2,00,000) was given to rule out intravascular or intrathecal placement. 5 minutes after test dose, in the absence of any adverse sequelae, 16ml of study drug was injected depending on patient study group through epidural catheter and patient were made to lie supine. After adequate blockade (T_{10}) patient was repositioned based on surgical requirements.

Patients were divided into two groups

Group A	Buprenorphine with Bupivacaine group - 0.5% Bupivacaine 15ml (75mg) with 0.5ml (150 ug) Buprenorphine (preservative free) with 0.5ml sterile normal saline made to a total of 16ml.
Group B	Fentanyl With Bupivacaine group - 0.5% Bupivacaine 15ml (75mg) with 1ml (50ug) Fentanyl (preservative free).

Results

A total of 60 patients of either sex randomly selected for the study. Statistical data was analysed using SPSS package.

Demographic Data Analysis

Table 1: Group-A: 0.5% bupivacaine with 150mcg of buprenorphine

No. of patients	Age (in yrs)	Weight (kgs)	No. of male patients	No. of female patients
30	22-58	46-72	19	11
Mean	43.77	57.90	63.3	36.7

Table 2: Group B: 0.5% bupivacaine with 50mcg of fentanyl

No. of patients	Age (in yrs)	Weight (kgs)	No. of male patients	No. of female patients
30	26-59	45-74	23	7
Mean	39.43	56.56	76.6	23.3

Table 3: Age Distribution

AGE	Group A	Group B
21-30	3	5
31-40	6	13
41-50	14	9
51-60	7	3

Table 4: Sex Distribution

GENDER	Group A	Group B
Male	19	23
Female	11	7

Table 5: Weight Distribution

Groups	Weight in Kgs
Group A	57.9
Group B	56.56

Table 6: Onset of Analgesia

Onset of Analgesia						Significance
Dermatome Level	GROUP A (in min)	SD	Group B (in min)	SD	t	
T12	7.56	3.11	6.66	2.44	1.246	
T10	11.06	3.08	10.20	2.80	1.138	P>O.O5 (NOT SIGNIFICANT)
T8	15.51	3.14	13.88	3.20	1.940	
T6	18.54	2.76	17.00	3.19	1.101	

SD: Standard Deviation - It is observed that onset of analgesia in Group- A (0.5% bupivacaine + 150mcg buprenorphine) was 7.56 min. When compared to Group-B (0.5% bupivacaine + 50 mcg fentanyl) which was 6.6 min, which is statistically insignificant (P<0.05). It shows that there was no difference in the onset of action.

Table 7: Bromage Scale

Mean Duration of Analgesia						
Dermatome Level	Group A (in min)	SD	Group B (in min)	SD	t	Significance
0	6.1	2.6	6.66	2.02		
1	10.3	2.84	10.13	2.35		
2	13.83	2.78	14.46	3.08		
3	18.9	3.55	18.63	3.25	0.204	P> 0.05 NS

The onset of motor blockade, degree and time required to achieve complete blockade were recorded. The degree of motor blockade was graded according to modified Bromage scale.

The mean time to achieve complete motor blockade was 18.9 min in group A and 18.63 in group B which was statically insignificant in both the groups.

Table 8: Mean Pulse Rate of Group A at Different Time Intervals

Time Intervals	Pulse Rate	
	MEAN	SD
Base line	81.2333	8.98
05 min	82.9333	8.54
10 min	83.2667	7.81
15 min	80.6	7.10
30 min	78.9	7.07
45 min	77.1333	7.55
60 min	78.9667	5.01
75 min	78.9667	5.13
90 min	81.2	4.51
105 min	80.5333	3.91
120 min	79.9	4.14
135 min	79.5	4.65
150 min	78.2333	5.51
165 min	77.9667	5.03
180 min	77.5333	4.82

Table 9: Mean Pulse Rate of Group B at Different Time Intervals

Time Intervals	Pulse Rate	
	Mean	SD
Base line	81.7333	9.33
05 min	81.2	9.14
10 min	82.3	8.62
15 min	79.4	7.62
30 min	79.1	6.789
45 min	77.73	6.71
60 min	79.46	6.39
75 min	78.83	6.04
90 min	79.03	5.48
105 min	78.93	5.33
120 min	79.73	5.72
135 min	81.66	6.74
150 min	81.83	6.51
165 min	80.83	5.79
180 min	80	4.82

Variation of pulse rate in group –A and group -B was studied at different time intervals upto 3 hrs. There was moderate change in the pulse rate in 30 min and 45 min in the both the groups which was statically insignificant.

Table 10: Mean of Mean Arterial Pressure in Between Group- A and Group-B at Different Time Intervals

Time Intervals	MAP			
	Group A		Group B	
	MEAN	SD	MEAN	SD
Base line	95.13	6.92	98.1	5.10
05 min	94.73	6.98	97.2	5.25
10 min	92.7	7.64	94.83	6.04
15 min	88.9	7.16	91.66	5.63
30 min	86.4	6.68	88.8	6.01
45 min	84.76	6.00	87.9	4.53
60 min	88.9	7.16	91.66	5.63
75 min	86.4	6.68	88.8	6.01
90 min	84.76	6.00	87.9	4.53
105 min	84.76	5.94	88.2	4.29
120 min	84.66	6.36	86.83	4.19
135 min	87.46	6.16	87.3	4.92
150 min	88	7.16	87.7	5.12
165 min	88.76	7.06	89.66	4.55
1801 min	89.76	8.05	91	5.87

Effect on respiratory system

Table 11: Variation in respiratory rate per minute within each group and in between the groups

Time Intervals	MAP			
	Group A		Group B	
	MEAN	SD	MEAN	SD
Base line	18	1.525	18.4333	2.523
05 min	17.9	1.843	18	1.29
10 min	17.4667	1.32	17.2	0.996
15 min	16.7	1.342	16.2	1.381
30 min	15.5	1.27	16.4333	1.381
45 min	16.6333	1.496	16.9667	1.3767
60 min	17.4333	1.381	18.2667	1.229
75 min	18.7667	1.165	18.5	1.252
90 min	18.0333	1.629	18	1.14
105 min	18.9	1.061	18.6	0.968
120 min	18.3	1.087	18.5333	1.166
135 min	18.9667	0.889	18.4	1.003
150 min	18.2667	0.827	18.4333	0.817
165 min	18.3	0.915	18	1.033
180 min	18.2	0.761	18.2667	0.944

It can be seen from the table no.14 there was significant change in respiratory rate in between two groups at 10, 15, 30 min. This was due to the respiratory depressant action of both the drugs which was statically insignificant in both the groups.

Table 12: VNS Score

Time Intervals	Group A		Group B		t	Significance
	Mean	SD	Mean	SD		
0 min	5.13	0.63	5.9	0.88	-	-
10 min	4.23	0.72	5.55	0.65	4.78	P < 0.05 S
20 min	3.33	0.63	4.10	0.92	0.0006	P > 0.05 NS
30 min	2.7	0.89	2.68	0.855	0.941	P > 0.05 NS
1 hr	1.12	0.715	2.93	0.45	5.17	P < 0.05 S
3 hr	1.3	0.59	4.0	0.91	1.09	P > 0.05 NS
5 hr	1.68	0.61	5.4	0.56	2.49	P > 0.05 NS
7 hr	2.53	0.75	5.76	0.50	3.45	P > 0.05 NS

As seen from table 16 pain score (VNS) was compared between the two groups at different time interval for the first 7 hrs. It was found that VNS was significant at 20 min and 1 hr. This was due to the reduce VNS in group A when compared to group B.

Table 13: Mean Duration of Analgesia

	No of Patients	Mean Duration (inmin)	SD	t	Significance
GROUP A	30	766.6	169.67	7.178	P<0.05 S
GROUP B	30	471	148.68		

Table 14: Side Effects The incidence of side effects like nausea, vomiting, urinary retention, pruritus and hypotension was studied and results were as shown in the table

Side Effects	Group- A		Group- B	
	NO	%	NO	%
Nausea	9	30	2	10
Vomiting	3	10		
Urinary retension	-		-	
Prurites	-		10	33.3
Hypotension	-		-	

Discussion

Pain is a more terrible lord of mankind than death itself. Pain is a complex subjective experience, which has proved difficult to measure in reproducible way.[3] Pain perception can be sensory discriminative aspect that describes the location and quality of the stimulus called fast pain and motivational affective portion that leads to aversive aspect of pain, also known as slow pain. Satisfactory pain relief has always been a difficult problem in clinical practice [4].

The pain in the postoperative period demands relief not only on humanitarian ground but also to reduce physical morbidity following the operation. In postoperative period when the effect of the anaesthetic disappears, the tissue injury persists and pain producing substances which are liberated during the operation greatly reduce the normally high threshold of the nociceptors, so that innocuous stimulation produces pain. Moreover the cut ends of axons further contribute to nociception. A wide range of options exist to combat pain both pharmacologically and nonpharmacologically. However, despite the increasing complex armamentarium that we have at our disposal, the satisfactory alleviation of pain remains difficult goal. Thus the extent of our pharmacological alternatives is rather a reflection of our constant efforts to obtain more effective and safer analgesics.

Epidural anaesthesia is superior to Spinal as the desired block levels can be achieved without significant haemodynamic disturbances and top-up doses of anaesthetics & analgesics can be given. In modern anaesthesia practice Epidural anaesthesia is widely being used especially in patients undergoing surgical procedures involving lower parts of the body. To fulfil this demand, there is a need for local anaesthetic with desirable properties like longer duration of sensory blockade and shorter duration of motor blockade [3].

Traditionally epidural bupivacaine was used for post-operative analgesia. The epidural bupivacaine 0.5% causes motor, sensory and sympathetic blockade, 0.25% causes sensory and autonomic blockade and 0.125% causes autonomic blockade only Epidural and intrathecal opioids are today being used for intraoperative and postoperative analgesia.

A study entitled, a comparative study between epidural**,** **"**Bupivacaine With Buprenorphine and Bupivacaine with Fentanyl In Lower Limb Surgeries‖, was undertaken at Pratima Medical College and Hospital, Karimnagar, Telangana, India to evaluate sensory and motor blocking properties, quality and duration of analgesia and side effects if any.

After informed consent 60 patients of ASA class I and II, posted for various elective lower limb surgeries were grouped randomly into either Buprenorphine with Bupivacaine (A) group or Fentanyl with bupivacaine (B) group. Epidural space was identified with loss of resistance technique to air. Epidural catheter was inserted and secured 3cms inside epidural space and 3 ml of lignocaine 2% with

adrenaline test dose given, observed for 3mins for any intravascular or intrathecal placement of catheter. Later 16 ml of the study drug was injected and various parameters were studied.

In our study all the patients were given epidural block in sitting position, because the patients with lower limb fractures, found sitting position more comfortable.

Demographic data

Demographic data comparing age, sex, weight, height shows no statistically significant difference among both the groups.

Sensory characteristics

Onset of sensory blockade

Onset of sensory blockade is taken as the time from the completion of the injection of the study drug till the patient does not feel the pin prick at T_{12} level on the dependent side.

Mean time of analgesia in our study was

Group-A 7.53 min

Group-B 6.60 min

There was no significant difference in the onset of analgesia between the Group A and Group B.

Zenz M, Pipenbrocks S, did a double blind comparison of epidural Buprenorphine and epidural morphine for postoperative pain relief. Morphine 4 mg and buprenorphine 0.15 mg were given through epidural route. Buprenorphine produced analgesia with short latency 6.8 min. This is close to our observation of 7.53 min.5 High lipid solubility and high potency may explain the faster onset of pain relief in buprenorphine group.

Suraj Dhale and Vaishali Shelgaonkar, in 2000 studied different doses of epidural fentanyl (25µg, 50µg, 75µg) with 0.5% bupivacaine for perioperative analgesia found that 50µg had a quicker onset of analgesia within 9.53 min which is close to our observation [6].

Duration of Analgesia

Duration of analgesia is taken from the time of injection till the patient complains of pain at the site of surgery. Time at which, patients complained of pain more than 5 and above on the verbal numerical scale was noted. That point was taken as the end of fair analgesia and at that point, top up doses were given based on requirement.

In our study mean duration of analgesia in group A was 766 min which was significantly longer compared to group B of mean duration of analgesia was 471 min.

In their comparative study between epidural buprenorphine and epidural Ketamine for postoperative pain relief D.Kumar, N.Dev and N.Gupta found that 0.15mg Buprenorphine with 10 ml of 0.9% saline had longer duration of action 13.1 hours (range 8-12 hours) compared to 10mg of Ketamine with 10 ml of 0.9% saline, which had mean duration of 5.2 hours. In our study mean duration of analgesia in Group A was 766 min (12 hours) [7].

Motor Blockade

The mean time to achieve complete motor blockade was 18.9 min in group A and 18.63 which was statically insignificant in both the groups.

Suraj Dhale and Vaishali Shelgaonkar, in 2000 studied different doses of epidural fentanyl (25µg, 50µg, 75µg) with 0.5% bupivacaine for perioperative analgesia where mean onset of motor blockade was 26.13 ± 1.80 min [6].

On Cardiovascular System

The reduction in MAP was statistically insignificant in both groups. In group A MAP from base line 95.13 mmHg fell to 84.8 mmHg at 45 min. Then picked up to 88 mmhg at 150 min remained same throughout the study. In group B MAP from baseline 98.97 mmHg fell to 87.90 mmHg at 45 min then picking up slowly to 93.7 mmHg at 120 min thereafter remained significantly high throughout the study but the difference was not significant in both the groups ($P > 0.005$).

The mean HR reduction indicating analgesia was also insignificant in both the groups. The mean base line heart rate in group A which was 81.233/ min reduced gradually to 78.966 at 1hr and remained stable throughout the study. The mean base line heart rate which was in group B 81.733/min went up to 78.8 / min at 60 min then significantly remained unchanged throughout the study which was comparable.

On respiratory rate

In our study mean base line respiratory rate in Group A fell from 18/ min to around 15.5 in 30min gradually picking up by 90 min and remained to 18.2 /min. In Group B mean basal respiratory rate which was 18.4/ min fell to 16.43 at 30th min, picked up to 18/ min at 90 min which is again comparable without any significant difference. Following below studies correlates with our observation.

In 1981, Zenz M, Pipenbrock S, Hubner S, Glocke M, did a double blind comparison of epidural buprenorphine and epidural morphine in post-operative pain. Morphine 5 mg and buprenorphine 0.15 mg given by epidural route were compared, in fifty patients, recovering from abdominal surgery. They observed there was decreased respiratory rate and increased tidal volume; however there was no severe respiratory depression [8].

Side Effects

The four classic side effects of neuraxial opioids are Pruritus, Nausea and vomiting, Urinary retention and Depression of ventilation. Side effects are caused by the presence of drug either in CSF or systemic circulation. Most side effects are dose dependant.

Conclusion

In this comparative study an effort was made to study the peri operative analgesic efficacy of Inj. Buprenorphine and Inj. Fentanyl with 0.5% Bupivacaine epidurally for lower limb surgeries. There were no significant hemodynamic and respiratory side effects in either of the groups. The postoperative analgesia was definitely of a longer duration with the buprenorphine group. So it is concluded that epidural buprenorphine is better in providing prolonged satisfactory postoperative analgesia as compared to Inj. Fentanyl. Regarding the side effects, the incidence of nausea and vomiting was more in buprenorphine as compared to fentanyl group, which is easily treated with antiemetic‘s like Ondansetron. Both buprenorphine and fentanyl along with bupivacaine 0.5% can be given epidurally as a single shot injection for perioperative analgesia obviating the need for epidural catheter.

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Conflict of Interest
None

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References

1. Miller's textbook of anaesthesia- 7th edition, Ronald D Miller.
2. Combination of local anaesthetic and an opioid combination- Wheatley RG, Schugg Sa, Watson D; British Journal anaesth. 2001, 87:47.
3. Wheatley RG, Schug SA, Watson D. Safety and efficacy of postoperative analgesia. Br.J Anaesth 2001; 87:47-61.
4. Analgesia by epidural technique– Dolin Sj, Cashman JNBland JM; 2002, 89:409.
5. Zenz M, Pipen brock S, Hubner B, Glocke M. A double blind comparison of epidural Buprenorphine and epidural morphine in post-operative pain'. Anaesth - Intensive therapy – Notfallmed, 1981; 16(6):333-9.
6. Suraj, Dhale, Vaishali Shelgaonkar and V V Akulwar. A comparative study of epidural bupivacaine and epidural bupivacaine with fentanyl for peri operative analgesia. Indian journal anaesthesia.2000, 44:35.
7. Kumar D, Dev Gupta. Comparitive study of Epidural Buprenorphine and Ketamine for postoperative pain relief. Ind. Journal Anaesthesia. 1997; 41:38-49.
8. Zenz M, Pipen Brock S, Hubner B, Glocke M. A double blind comparison of epidural Buprenorphine and epidural morphine in post-operative pain'. Anaesth - Intensive therapy – Notfallmed, 1981; 16(6):333-9.