

Original Research Article

A STUDY TO COMPARE THE EFFICACY OF EPIDURAL BUPRENORPHINE WITH ROPIVACAINE AND FENTANYL WITH ROPIVACAINE FOR POST OPERATIVE ANALGESIA IN LOWER LIMB ORTHOPEDIC SURGERY

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ABSTRACT

Background: Ropivacaine is an amide local anesthetic with a long duration of action^[2] For analgesia dose, 0.1-0.2% is used. It is associated with superior safety profile compared to bupivacaine. Buprenorphine is a thebaine derivative and it is a mu receptor partial agonist and antagonist. It was introduced in 1976. It is most commonly used for orthopedic surgeries. **Objective:** to compare postoperative epidural analgesia in lower limb orthopaedic surgeries between two opioid adjuvants to the local anesthetic Ropivacaine – Buprenorphine and Fentanyl.

Materials and Methods: This case control study was conducted on patients with lower limb fractures in Department of Anaesthesiology, Basaveshwar Teaching and General Hospital attached to Mahadevappa Rampure Medical College, Kalaburagi. Ethical committee clearance (IEC:-Reg no:ECR/899/Inst/2017) was taken. Study Duration of study was 18 months (01 August 2022 TO 31st January 2024)

Results: This study included 60 patients, of which 30 patients in each group. In this study patient characteristics were comparable. The onset of analgesia was significantly faster ($p < 0.001$) in Fentanyl Group (14.50 \pm 3.36 mins) as compared to Buprenorphine group (16.43 \pm 3.44mins). While the duration of analgesia was 10.93 hours with Buprenorphine as compared to 5.56 hours with Fentanyl and was statistically significant ($p < 0.001$). Side effects such as nausea and vomiting, hypotension, pruritis, sedation was seen in 4, 2, nil, nil patients respectively in the Buprenorphine group and 2, 2, nil, nil patients respectively in the Fentanyl group.

Conclusion: Buprenorphine and Fentanyl are both safe and effective epidural adjuvants to Ropivacaine. Because of its faster onset of action and fewer side effects, we concluded that Fentanyl is a preferable choice. However, the duration of analgesia is longer with Buprenorphine.

Keywords: Epidural, Ropivacaine, Fentanyl, Buprenorphine, VAS score.

INTRODUCTION

Regional anaesthesia is a safe, inexpensive technique with the advantage of prolonged postoperative pain relief. Post operative epidural analgesia with local anesthetic solutions is known to have beneficial effects on patient outcome after major abdominal surgery, lower limb orthopedic

surgeries improving recovery of normal bowel and ambulatory function.^[1]

Epidural anaesthesia is becoming one of the most useful and versatile procedures in modern anaesthesiology. 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.^[2]

Orthopedic surgeries are indicated for musculoskeletal dysfunction like fractures, trauma, tumors, joint disorders, deformities or infections. The goal includes to improve movement and stability and alleviate pain. Regional Anesthesia by Spinal and Epidural Anesthesia is the most widely used technique for orthopedic lower limb surgeries. The purpose of this study was to compare postoperative epidural analgesia in lower limb orthopaedic surgeries between two opioid adjuvants to the local anesthetic Ropivacaine – Buprenorphine and Fentanyl.

MATERIALS AND METHODS

This case control study was conducted on patients with lower limb fractures in Department of Anaesthesiology, Basaveshwar Teaching and General Hospital attached to Mahadevappa Rampure Medical College, Kalaburagi. Ethical committee clearance (IEC:-Reg no:ECR/899/Inst/2017) was taken. Study Duration of study was 18 months (01 August 2022 TO 31st January 2024)

Sample size calculation:

$$\text{Sample size} = (Z \alpha/2 + Z \beta)^2 \times 2\sigma^2 / \mu^2 - \mu^1^{(3)}$$

$$= (1.96 + 0.82)^2 \times 2 \times (2)^2 / 3$$

$$= 20.8 \text{ samples in each group}$$

$$= \text{So, 30 samples are considered in each group}$$

Sample size = Total samples 60 (30 samples were taken in each group)

Sample size: 60 cases.

Inclusion Criteria

1. Patients posted for lower limb orthopedic surgery.
2. Patients who belongs to American Society of Anaesthesiology(ASA) grade I and II
3. Age group 18-80 years

Exclusion Criteria

1. Patients on opioid or sedative medication in the week prior to the surgery.
2. Patients with history of alcohol or drug abuse.
3. History of coagulation disorders or on anti coagulant drug.
4. Patients who have known allergies to any of test drugs.
5. Known case of respiratory diseases.
6. Contraindications for epidural anaesthesia

Study methodology:

EQUIPMENT USED FOR EPIDURAL INSERSTION:-

- LOSS OF RESISTANCE SYRINGE
- 18G TUOHY EPIDURAL NEEDLE
- 25G QUINCKE SPINAL NEEDLE
- 18G EPIDURAL CATHETER WITH FILTER



Pre-operative planning

When the patient arrived, a brief history was taken, patient's vitals including pulse rate, BP, temperature were recorded. Routine investigations were done which included CBC, PT INR, RFT, LFT, Serum Electrolytes, Urine Routine, Blood Grouping, HIV, HBsAg, RBS, ECG, Chest X-ray.

DRUGS USED

- LIGNOCAINE 2%
- 2% LIGNOCAINE WITH ADRENALINE
- BUPIVACAINE HEAVY
- ROPIVACAINE HYDROCHLORIDE 0.1%
- Inj FENTANYL 100mcg ampoule
- Inj BUPRENORPHINE 300mcg ampoule



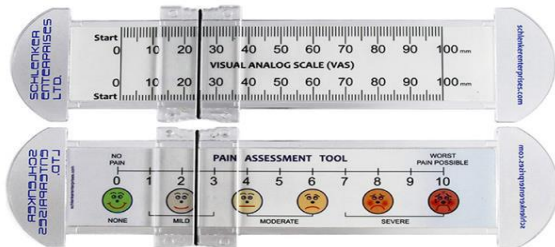
DRUGS USED IN THE STUDY

Pre-anaesthetic evaluation: Patients included in the study underwent thorough pre-operative evaluation which included the following :

- History: History of any underlying medical illness, drug history, previous history of surgery, previous anaesthetic exposure and hospitalization.
- Physical examination :
 1. General condition of the patient.
 2. Vital signs- heart rate, blood pressure, respiratory rate, room air saturation
 3. Height(in cms), Weight (in kgs)
 4. Systemic examination: Examination of cardiovascular system, respiratory system, central nervous system and per abdomen.

5. Airway assessment by Modified Mallampati grading, cervical spine movement, mouth opening, teeth, neck movements and spine.

Visual analog scale (VAS)^[4] consists of a 10 cm scale with markings at 1cm distance on which the patient indicates the line that represents the intensity of pain he/she is experiencing. Mark '0' represents no pain and mark '10' represents worst possible pain. The numbers indicated by the patient is used to assess the pain intensity.



**VAS SCALE
VAS SCORE INTERPRETATION**

0-2	No/slight pain
2-5	Mild pain
5-7	Moderate Pain
7-9	Severe pain
10	Worst possible pain

Statistical Methods: The quantitative variables are expressed as mean±sd and compared between groups using unpaired t test. Qualitative variables are compared between groups using Chi-square test

(SPSS 20.0 software). A p value < 0.05 is considered statistically significant.

The data was compiled meticulously and statistical analysis performed.

RESULTS

In the present study; Out of 60 sample cases were divided in to two groups.

Group-A: 7ml inj. Ropivacaine 0.1% with 1ml of 20mcg fentanyl were randomly divided 30 (50.0%) of samples

Group-B: 7ml inj. Ropivacaine 0.1% with 1ml of 60mcg buprenorphin were randomly divided 30 (50.0%) of samples.

Study observes that, majority of patients in the two groups 20 (33.3%) cases were belongs to the age group of 51—60, followed by each 15 (25.0%) were belongs to 20—30 years and 41—50 years. Mean age of Group-A was 42.26 and mean age of Group-B was 42.67. But there was statistically no significant difference of mean age between the groups Group-A and Group-B (P>0.05).

Study observed that; in the group-A male cases were 18 (60.0%) and in Group-B male cases were 18 (60.0%) and Female cases in Group-A were 12 (40.0%) and Group-B were 30 12 (40.0%). There was statistically no significant difference of distribution of gender between the Groups A and Group B (P>0.05).

Table 1: ASA grades wise distribution of cases in the groups

ASA grades	Group-A		Group-B	
	No.	%	No.	%
I	12	40.0	12	40.0
II	18	60.0	18	60.0
Total	30	100.0	30	100.0
χ ² -Test value, P-value	χ ² = 0.000, P = 1.000, NS			

NS= not significant, S=significant, HS=highly significant

ASA grade I in Group-A were 12 (40.0%) cases in Group-B were 12 (40.0%) cases and ASA grade II Group-A were 18 (60.0%) cases in Group-B were 18 (60.0%) cases. There was statistically no significant difference in the distribution of ASA status between Group-A and Group-B (P>0.05) The mean weight of Group-A was 64.83 kg and group-B was 66.10 kg, mean weight was statistically

not significant difference between Group-A and Group-B (P>0.05).

The mean height of Group-A was 158.00 cm and group-B was 160.33 cm, mean height was statistically not significant difference between Group-A and Group-B (P>0.05).

Table 2: Comparison of diagnosis between the groups

Diagnosis	Group-A		Group-B	
	No.	%	No.	%
RT or LT IT #	8	26.7	4	13.3
RT or LT ACL TEAR	3	10.0	3	10.0
RT or LT FEMUR #	6	20.0	12	40.0
TIBIA FIBULA COMPOUND #	3	10.0	2	6.7
RT or LT TIBIA #	3	10.0	4	13.3
TRIMALLEOLAR #	3	10.0	1	3.3
RT NOF#	2	6.7	1	3.3
HIP OSTEOARTHRITIS	1	3.3	2	6.7
PCL AVULSION	1	3.3	0	0.0
KNEE OSTEOARTHRITIS	0	0.0	1	3.3
Total	30	100.0	30	100.0

Fisher exact test	P = 0.431, NS
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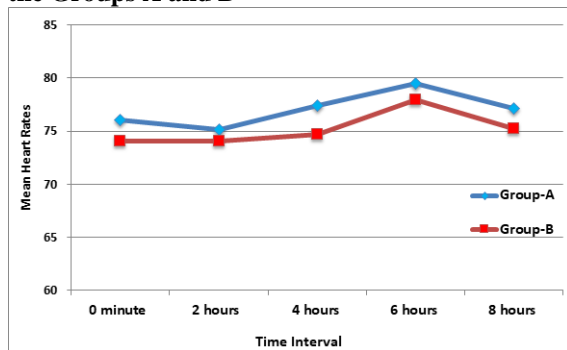
Study reveals that; There was statistically no significant difference in the distribution of diagnosis between Group-A and Group-B (P>0.05).

Table 3: Comparison of procedure between the groups

Procedure	Group-A		Group-B	
	No.	%	No.	%
CRIF & PFN	3	10	8	26.8
CRIF & TFN	4	13.3	1	3.3
ARTHROSCOPIC REPAIR	4	13.3	3	10
CRIF WITH NAILING	3	10	2	6.7
HEMIARTHROPLASTY	5	16.8	3	10
ORIF & PLATING	7	23.4	7	23.4
ORIF WITH CC SCREW AND DHS	1	3.3	0	0
TOTAL HIP REPLACEMENT	1	3.3	1	3.3
IMPLANT REMOVAL	1	3.3	1	3.3
THR	1	3.3	1	3.3
EXTERNAL FIXATION WITH LIMB RECONSTRUCTION	0	0	1	3.3
ORIF WITH IMIL WITH BONE GRAFTING	0	0	1	3.3
TOTAL KNEE REPLACEMENT	0	0	1	3.3
Total	30	100.0	30	100.0
Fisher exact test	P = 0.431, NS			

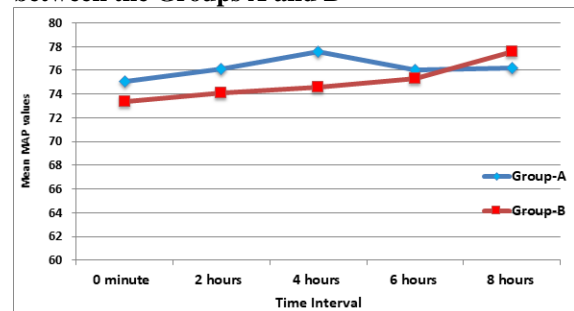
Study reveals that; There was statistically no significant difference in the distribution of procedure between Group-A and Group-B (P>0.05). Study reveals that; The mean HR values were seen higher at 0 min, 2 hours, 4 hours, 6 hours and 8 hours in Group-A as compare Group-B. But statistically not significant difference of mean heart rate at 0 minute, 2 Hours, 4 Hours, 6 Hours and 8 Hours between group-A and Group-B (P>0.05).

Line diagram shows comparison of HR between the Groups A and B



Study observed that; Most of the patients in Group-A had the mean MAP ranging from 75.07 to 77.60 between intra-operative at 0 minutes to 8 hours. Similarly patients in Group-B had the mean intra-operative men MAP from the range of 77.60 to 73.76. There was statistically not significant difference of mean MAP at 0 minutes, 2 hours 6 hours and 8 hours between group-A and Group-B (P>0.05). There was statistically significant difference of mean MAP at 4 hours between Group-A and Group-B. In Group-A seen higher mean MAP at 0 minute, 2 hours, 4 hours and 6 hours compare to Group-B

Line diagram shows comparison of MAP between the Groups A and B



There was statistically significant difference of mean VAS score at 0 minute, 2 hours and 4 hours between group-A and Group-B (P<0.001) and (P<0.05) respectively. The mean VAS score was seen higher in Group-A as compare to Group-B. And there was statistically not significant difference of mean VAS at 3, 5 hours between Group-A and Group-B (P>0.05).

Line diagram shows comparison of VAS score between the Groups A and B

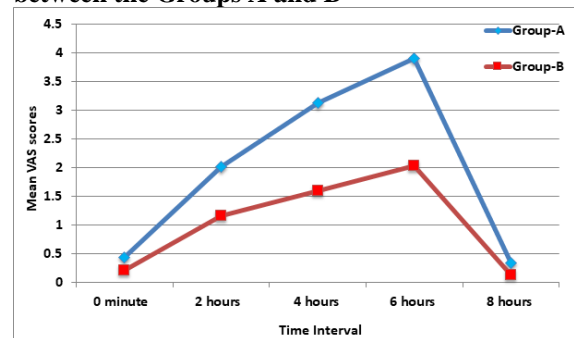


Table 4: Comparison of side effects between the Groups A and B

SIDE EFFECTS	Group-A		Group-B	
NAUSEA & VOMITING	4	13.3	2	6.7
HYPOTENSION	2	6.7	2	6.7
BRADYCARDIA	0	0.0	0	0.0
BLEEDING	0	0.0	0	0.0
χ^2 –Test value, P-value	$\chi^2_{\text{vates}} = 2.731$ P = 0.731, NS			

Study reveals that; There was statistically not significant difference of distribution of side effects between the Groups A and Group B (P>0.05).

Table 5: Comparison of Time of Rescue Analgesia between the Groups A and B

Groups	No. of cases	Mean	SD	Test Value, P-Value & Significance
Group-A	30	5.56	0.817	t = 22.560, P = 0.000 HS
Group-B	30	10.93	1.014	
Total	60	--	--	--

Study observes that, Mean time rescue analgesia in Group-A was 5.56 hours and mean time rescue analgesia in Group-B was 10.93 hours. But there was statistically highly significant difference of

mean time rescue analgesia between the groups Group-A and Group-B (P<0.001) In Group-B the mean time rescue analgesia significantly higher as compare to Group-A.

Table 6: Comparison of Time of Onset Sensory in min between the Groups A and B

Groups	No. of cases	Mean	SD	Test Value, P-Value & Significance
Group-A	30	14.50	3.36	t = 2.202, P = 0.032 S
Group-B	30	16.43	3.44	
Total	60	--	--	--

Study observes that, Mean time of onset sensory in Group-A was 14.50 minutes and mean time of onset sensory in Group-B was 16.43 minutes. But there was statistically significant difference of mean time of onset sensory between the groups Group-A and Group-B (P<0.05). In Group-B the mean time of onset sensory significantly higher as compare to Group-A.

Fentanyl group we observed was comparable with the results obtained from the study done by Suraj Dhalae and his colleagues in 2000.^[2] They studied epidural analgesia with 0.5% Bupivacaine and 50mcg Fentanyl and found that the mean onset of analgesia was 9.53±1.12 minutes, when compared to 0.5% Bupivacaine alone which was 11.26±0.79 minutes (p<0.01).

DISCUSSION

60 patients undergoing orthopedic lower limb surgeries under spinal anesthesia with epidural catheter in situ for postoperative analgesia were randomly selected for the study. The patients were randomly divided in two groups of 30 each.

In our study the demographic profile of the two groups were comparable in terms of age, gender, weight and ASA grade distribution. The baseline parameters such as pulse rate, systolic and diastolic blood pressure, respiratory rate and spo2 were comparable in both the groups.

In the postoperative period when the patient complained of pain (VAS score of >4), the study began. The following observations were made:

MEAN ONSET OF ANALGESIA

The mean onset of analgesia (VAS score less than 4) was 16.43±3.44 minutes in Group B (Buprenorphine) as compared to 14.50±3.36 minutes in Group A (Fentanyl) and there was a significant statistical difference (p<0.001). The faster onset of pain relief in Fentanyl group can be attributed to its high lipid solubility. The faster onset of analgesia in the

Boas RA et al evaluated the opioid receptor binding properties of fentanyl and buprenorphine in their study. Fentanyl receptor binding reached equilibrium fast (within 10 minutes) and dissociated rapidly (T 1/2 = 6.8 minutes) and entirely (100 percent by 1 hr). Buprenorphine, on the other hand, demonstrated sluggish receptor association (30 minutes) with high affinity for numerous sites, and slow (T 1/2 = 166 minutes) and incomplete dissociation (50 percent binding after 1 hr). These findings offer an explanation for the difference in onset of analgesia with fentanyl and buprenorphine.^[5]

DURATION OF ANALGESIA:-

In our study the duration of analgesia is taken as the time from administration of study drugs epidurally upto the time when patient complains of pain and VAS Score is more than equal to 4. We observed that patients who received Buprenorphine as adjuvant did not require rescue analgesia for more than 10 hours (mean 10.93±1.014 hours) as compared to 4-5 hours (mean 5.56 ± 0.817 hours) in those who received Fentanyl.

This could be correlated with

1. D.Kumar, N.Dev, and N.Gupta found that 0.15mg Buprenorphine with 10 ml of 0.9 percent saline had a longer duration of action 13.1 hours (range 8-12 hours) than 10mg Ketamine with 10 ml of 0.9 percent saline, which had a mean duration of 5.2 hours in their study comparing epidural buprenorphine and epidural Ketamine for postoperative pain relief.^[6]

VAS SCORES:-

The visual analogue pain score (VAS) was noted at 0, 5, 10, 15, 30, 45, 60 mins and then hourly after administration of study drugs.

At the end of first hour, Group A and Group B had excellent pain scores with mean VAS scores of 2.01 ± 0.58 and 1.16 ± 0.37 respectively.

The mean VAS scores remained less than 4 for upto 10 hours in Group B as compared to upto 4 hours in Group A. The increase in VAS Score above 4 indicated the need for rescue analgesia.

The findings were comparable with the study conducted by Arun Kumar Gupta et al in 2015. They assessed pain quality by VAS scores and observed that within 15 minutes 100% of the patients in the fentanyl group had complete pain relief and it lasted till 2 hours. In Buprenorphine group within 15 minutes 60% patients had satisfactory analgesia, but within 30 minutes all patients (100%) had satisfactory analgesia which lasted beyond 6 hours (upto 24-30 hours).^[7]

HEMODYNAMIC STABILITY

Pulse rate remained stable in the range of 64-101/min in Group A and 68-110/min in Group B. Mean arterial pressure decreased from the baseline in both the groups but never went below 65mm of Hg.

Gough 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, systolic BP, diastolic BP and Respiratory rate varied negligibly from basal recordings.^[8]

UshaRathi, M. Singh, M.Pramanik in 1993 conducted a study on postoperative analgesic efficacy with different doses of extradural buprenorphine for herniorrhaphy, where Group A (control) received 2 percent lignocaine plain, Group B received 0.15 mg buprenorphine with 2 percent lignocaine and Group C received 0.3 mg buprenorphine with 2 percent lignocaine. They reported that 0.3mg dose of Buprenorphine was preferable for single shot epidural injection which provided both good quality anaesthesia and postoperative analgesia with hemodynamic stability which correlates with our observation.^[9]

SIDE EFFECTS

Nausea and vomiting, pruritis, Urinary retention and respiratory depression are the four main side effects of opioids.^[8,9] These can be attributed to the presence of drug either in CSF or in the systemic circulation. Most of these side effects are dose dependant.

Opioids cause nausea and vomiting by directly stimulating the CTZ in the medulla. However, this is dose-dependent, and tolerance develops quickly. Anticholinergics and phenothiazines, particularly those that are antagonists at dopamine receptors, can be used to treat this emetic effect.^[9,10]

One of the most frequent side effects of neuraxial opioids is pruritus. The mechanism of pruritus is probably due to the cephalad migration of the opioids within the CSF and their interaction with opioid receptors in trigeminal nucleus rather than the histamine release from mast cells. Opioid antagonist Naloxone is effective in relieving this pruritus.

Urinary retention due to effect of opioids on sacral spinal nerve receptors. This leads to inhibition of sacral parasympathetic nervous system outflow, causing detrusor muscle relaxation and an increase in maximum bladder capacity, finally resulting in urinary retention. The patients in our study were observed for any side effects like nausea and vomiting, pruritis, respiratory depression, hypotension and sedation in both the groups.

Nausea and vomiting

In our study 4 patients had nausea and vomiting in group A whereas in group B only 2 patients (6.67 %) had nausea and vomiting. Morphine and related opioid congeners induce nausea by direct stimulation of CTZ and are reported to cause delay in gastric emptying.

Hayashi H, Nishiuchi T, and Tamura H studied postoperative pain relief with epidural buprenorphine and fentanyl in 1993 and found no difference in their analgesic efficacies, but the incidence of nausea and vomiting was significantly lower in fentanyl compared to buprenorphine, which was comparable to our study.

Pruritus

In our study, Group A and B showed no incidence of pruritis. It can be generalized, but it's more likely to affect the face, neck, or upper thorax. The incidence varies greatly; severe pruritis is uncommon, but maybe seen in obstetric patients. In a study by SA Lytle et al in 1991 using epidural fentanyl 50µg, they reported that 4% of patients had pruritis which correlates with our study.^[11]

Respiratory depression

In 1994, Koshi et al studied postoperative analgesia and side effects of epidural morphine versus epidural buprenorphine and reported that with epidural buprenorphine, the incidence of respiratory depression was zero.^[12]

Sedation- was observed no sedation in fentanyl group and in buprenorphine group. Drowsiness with fentanyl has been reported in many studies. Stephen Naulty et al, reported drowsiness as one of the common side effects in a study of extradural fentanyl. Scott et al,^[13] and Sylvie Rostening et al (1991) have also reported similar findings in their studies.

In our study 2 patients in each group had hypotension, which is not statistically significant.

CONCLUSION

In this comparative study between Buprenorphine and Fentanyl used as adjuvants to Ropivacaine for postoperative Epidural Analgesia in lower limb orthopaedic surgeries we conclude that Buprenorphine has profound and prolonged analgesia for epidural analgesia. Fentanyl is a better adjuvant to Bupivacaine with faster onset of analgesia. The duration of analgesia is longer with buprenorphine as compared to fentanyl. Fentanyl had lesser side effects compared to buprenorphine.

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