



EPIDURAL ANAESTHESIA USING 0.5% BUPIVACAINE WITH NALBUPHINE AND 0.5% BUPIVACAINE WITH FENTANYL IN INFRA UMBILICAL SURGERIES:AN ANALYTICAL OBSERVATIONAL STUDY

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ABSTRACT Epidural anaesthesia^(1,2) offers a wide range of applications than the spinal anaesthesia. Epidural opioids have unique advantages over conventional, intermittent IV/IM administration, in that patients given epidural opioids have fewer respiratory complications and can be mobilized sooner in the postoperative period. Though pure opioid agonists like morphine and fentanyl have already established their role in epidural administration for pain relief, their side effects like respiratory depression, nausea, vomiting, urinary retention etc., have made physician to search for a better drug for epidural use. The agonist/antagonist opioid agent NALBUPHINE can be expected to offer some promise in this respect, since the respiratory depression reaches ceiling level at higher dose of this drug.⁽³⁾

KEYWORDS : Epidural anaesthesia, Bupivacaine, Nalbuphine, Fentanyl, Postoperative Analgesia.

INTRODUCTION

Pain is one of the primary concerns for patients after surgery. It can cause distress to patients, hamper their breathing pattern, mobilization and finally prolong their hospital stay. The use of opioids as adjuvants in regional analgesia techniques has been one of the cornerstones in postoperative pain management.^(4,5)

Epidural technique is widely used for operative anaesthesia, obstetric analgesia, postoperative pain control, and chronic pain management. It can be used as a single shot technique or with a catheter that allows intermittent boluses and/or continuous infusion.^(1,2) Analgesia with neuraxial opioids is dose-related and specific for visceral rather than somatic pain.

Additives used to prolong the duration and Analgesic effect of local anaesthetics are clonidine, dexmedetomidine, buprenorphine, fentanyl, nalbuphine and others. This study is conducting to compare the effect of fentanyl and nalbuphine as adjuvants with the bupivacaine in epidural anaesthesia in infraumbilical surgeries.

AIMS AND OBJECTIVES

The aim is to observe and study the efficacy of nalbuphine and fentanyl as adjuvant with bupivacaine for analgesia in epidural anaesthesia in patients undergoing infraumbilical surgeries.

The objectives are to study the onset and duration of sensory and motor blockade, hemodynamic parameters and adverse effects.

MATERIALS AND METHODS

After obtaining approval from institutional ethics committee, all the patients were fully explained about the study procedure. Then written informed consent obtained from patients.

INCLUSION CRITERIA

1. Posted for elective infra umbilical surgeries
2. ASA grade I and II
3. Age group of 20 – 55 years of either sex

EXCLUSION CRITERIA

1. Patient refused to give written informed consent
2. Systemic diseases with ASA grade 3 and 4
3. Skin infection near injection site
4. Patients above 55 years
5. Coagulopathy
6. Patients with history of drug allergy

DETAILED PROCEDURE OF STUDY CONDUCT

A detailed history and pre anaesthetic evaluation was done on the previous day of the surgery.

Routine investigations like haemoglobin, blood grouping, serum electrolytes, blood sugar were measured.

Written informed consent taken prior to scheduled operation from the patients.

Patients were kept nil oral for 6 hrs before the surgery.

All patients were monitored with electrocardiography, pulse oximetry and blood pressure. Baseline heart rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial blood pressure (MAP) and oxygen saturation (SpO₂) will be measured.

A peripheral intravenous line secured with 18 Gauge intravenous cannula and ringer lactate solution started as maintenance fluid(10ml/kg) over 30minutes.

Premedication: Inj. Ranitidine (1mg/kg)

Inj. Ondansetron (0.1mg/kg) i.v.

Procedure:

After thorough aseptic precautions L1-L2 or L2L3 Space located and using a 18 gauge Huber point Tuohy needle epidural space was identified with loss of resistance technique. 18G Epidural catheter was inserted and aspirated to rule out subarachnoid or intravascular placement of the catheter. The placement was confirmed by 3 ml of 2% lidocaine with adrenaline 1:2,00,000 and fixed.

Group A- patients were given 15 ml of 0.5% bupivacaine with 1 ml of nalbuphine (10 mg) into the epidural catheter as a single bolus dose.

Group B- patients were given 15 ml of 0.5% bupivacaine with 1ml of fentanyl (50 mcg) into the epidural catheter as a single bolus dose.

Patients monitored for onset of sensory and motor blockade, hemodynamic parameters like pulse rate, blood pressure, saturation and ECG changes at an interval of 1min, 5min, 15min, 30min, 45min, 60min, 90min and 2hour till end of surgery. Post operative monitoring done up to 24hrs and requirement of rescue analgesia noted.

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 T10 level on the dependent side. Time taken for maximum motor blockade according to modified Bromage scale were noted.

The duration of analgesia was taken as the period from the time of giving epidural analgesia till the patient's first requirement of systemic analgesic medication. Supplementary analgesia was given when VAPS was more than 4.

The total number of rescue analgesics (inj. Diclofenac 75 mg IM) in the first 24 hours was noted down to assess the quality of analgesia. The side effects due to opioids like nausea, vomiting, pruritis, urinary retention were noted down.

Chi-square test and Independent t test were used for statistical analysis.

OBSERVATION AND RESULTS

Mean age, mean weight, gender, ASA status, ECG and SpO2, Mean duration of surgery, heart rate and blood pressure were comparable and there was no significant difference between two groups.

Table 1: Mean time to sensory regression at S1 (min) Comparison between two groups

	Group				p value
	Bupivacaine and Nalbuphine		Bupivacaine and Fentanyl		
	Mean	SD	Mean	SD	
Mean time to sensory regression at S1 min	278.4	14.91	245.25	13.62	< 0.001*

Mean time to sensory regression at S1 in Group A was 278.4 ± 14.91 and in Group B was 245.25 ± 13.62. There was significant difference in Mean time to sensory regression between two groups.

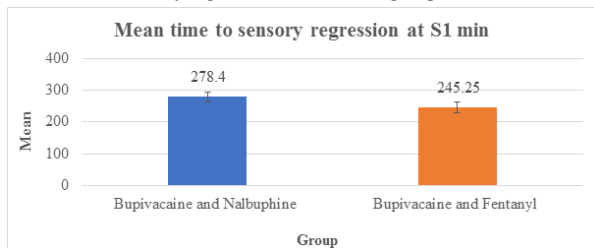


Figure 1: Bar diagram showing Mean time to sensory regression at S1 (min) Comparison between two groups

Table 2: Mean First Rescue Analgesia Given Comparison between two groups

	Group				p value
	Bupivacaine and Nalbuphine		Bupivacaine and Fentanyl		
	Mean	SD	Mean	SD	
First Rescue Analgesia Given (hours)	14.4	3.79	8.93	2.09	< 0.001*

First Rescue Analgesia Given in Group A was at 14.4 ± 3.79 hrs and in Group B was 8.93 ± 2.09 hrs. There was significant difference in First Rescue Analgesia Given between two groups.

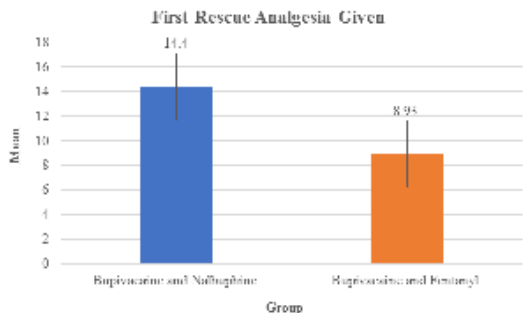


Figure 2: Bar diagram showing Mean First Rescue Analgesia Given (in hrs) Comparison between two groups

Table 3: Mean Number of rescue analgesia in 24hrs Comparison between two groups

	Group				p value
	Bupivacaine and Nalbuphine		Bupivacaine and Fentanyl		
	Mean	SD	Mean	SD	
Number of rescue analgesia in 24hrs	1.63	0.49	2.73	0.45	< 0.001*

Number of rescue analgesia in 24hrs in Group A was 1.63 ± 0.49 and in Group B was 2.73 ± 0.45. There was significant difference in Number of rescue analgesia in 24hrs between two groups.

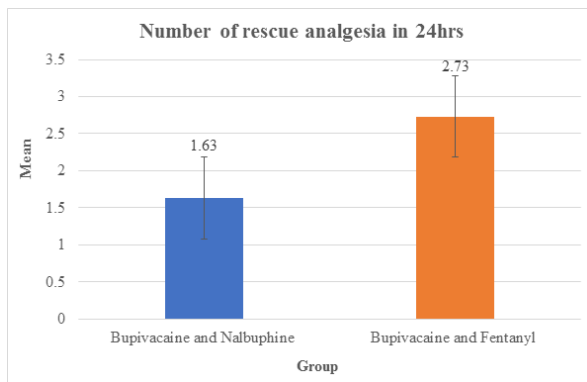


Figure 3: Bar diagram showing Mean Number of rescue analgesia in 24hrs Comparison between two groups

Table 4: Mean VAS Comparison between two groups at different intervals of time

	Group				p value
	Bupivacaine and Nalbuphine		Bupivacaine and Fentanyl		
	Mean	SD	Mean	SD	
3hr	2.48	0.55	2.5	0.51	0.834
6hr	2.75	0.49	3.95	1.22	< 0.001*
9hr	3.7	0.72	4.25	1.28	0.02*
12hr	4.13	1.11	3.55	1.22	0.031*
18hr	4.9	0.9	4.8	0.9	0.458
24hr	5.0	1.0	4.9	0.9	0.733

In the study there was significant difference in mean VAS Score between two groups from 6 hrs to 12 hr. Mean VAS Score at these intervals was high in Group B compared to Group A. At 3 hr, 18 hr and 24 hrs there was no significant difference in mean VAS score between two groups.

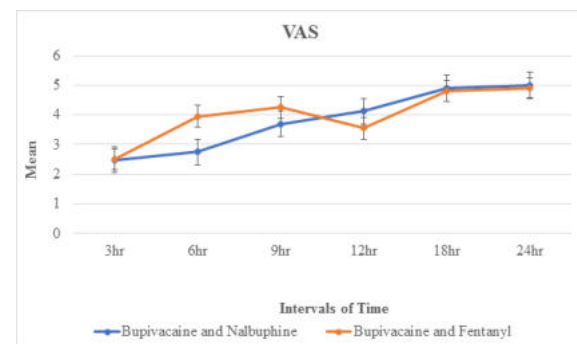


Figure 4: Line diagram showing Mean VAS Comparison between two groups at different intervals of time

Table 5: Mean sensory onset at T10 (min), mean motor onset (min), motor max (min) and mean time to modified bromage scale 0 (min) comparison between two groups

	Group				p value
	Bupivacaine and Nalbuphine		Bupivacaine and Fentanyl		
	Mean	SD	Mean	SD	

Mean Sensory Onset at T10(min)	5.45	1.4	5.63	1.19	0.548
Mean Motor Onset (min)	12.85	1.19	13.1	1.1	0.333
Motor max(min)	22.58	2.68	23.3	2.74	0.235
Mean time to modified bromage scale 0 (min)	168.9	8.02	165.5	8.86	0.076

Table 6: Side Effects Distribution between two groups at different intervals of time

Side Effects	No	Group			
		Bupivacaine and Nalbuphine		Bupivacaine and Fentanyl	
		Count	%	Count	%
		38	95.00%	32	80.00%
Nausea and vomiting		1	2.50%	3	7.50%
Pruritus		0	0.00%	3	7.50%
Shivering		1	2.50%	2	5.00%

$\chi^2=4.848, df=3, p=0.183$

Mean sensory onset at T10(min), mean motor onset(min), motor max(min) and mean time to modified bromage scale 0(min) and side effects were comparable between two groups and insignificant.

DISCUSSION

Epidural anaesthesia is superior to Spinal anaesthesia as the desired block levels can be achieved without significant hemodynamic 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. Traditionally epidural bupivacaine was used for post-operative analgesia. The epidural bupivacaine 0.5% causes motor, sensory and autonomic blockade, 0.25%-0.125% causes sensory and autonomic blockade. Epidural administration of narcotics for postsurgical analgesia gained increasing popularity following the discovery of opioid receptors in the spinal cord capable of producing potent analgesia.

Duration of sensory block

It is the time taken for sensory regression at S1 and There was significant difference in Mean time to sensory regression between two groups.

Minimum duration of sensory block in group A is 246 minutes and in group B it is 218 minutes. maximum duration of sensory block in group A is 320 minutes and that of group B is 280 minutes. Mean time to sensory regression at S1 that is duration of sensory block in Group A was 278.4 ± 14.91 and in Group B was 245.25 ± 13.62. This result is in agreement with other studies.

Nama Nagarjuna Chakravarthy et al^[6] in their study of epidural 0.5% bupivacaine with nalbuphine and 0.5% bupivacaine with fentanyl in lower abdominal and lower limb surgeries found that the duration of sensory blockade was highly significant ($p < 0.01$) and duration was longer in bupivacaine and nalbuphine group.

Manisha Sapate, et al^[7] compared the effects of addition of nalbuphine to intrathecal bupivacaine. The duration of sensory blockade was significantly prolonged in nalbuphine group compared to bupivacaine group.

Arghya Mukherjee, et al^[8] compared intrathecal bupivacaine alone with three different doses of nalbuphine added to bupivacaine. The duration of sensory blockade was significantly and progressively prolonged in all the three groups of nalbuphine when compared with bupivacaine group.

In 2011 study by Tiwari and Tomar^[9] showed that nalbuphine hydrochloride (400 µg) significantly prolongs the duration of sensory when introduced intrathecally along with hyperbaric bupivacaine.

QUALITY OF ANALGESIA

It was one of main aims of this study to measure the quality of analgesia.

The duration of analgesia was taken from the time of epidural drug administration to the time of first supplementation with rescue

analgesic. It was measured using VAS and Rescue analgesics were given when the VAS score was 5 or more. Quality of analgesia is taken as number of rescue doses in first 24 hours.

In this study there was significant difference in mean VAS Score between two groups from 6 hrs to 12 hr. Mean VAS Score at these intervals was high in Group B compared to Group A. At 3 hr, 18 hr and 24 hrs there was no significant difference in mean VAS score between two groups.

Minimum time at which first rescue analgesia was given in group A is 9 hours and in group B was 6 hours. and maximum time in group A was 18 hours and in group B was 12 hours. mean time for First Rescue Analgesia in Group A was at 14.4 ± 3.79 hrs and in Group B was 8.93 ± 2.09 hrs. There was significant difference in First Rescue Analgesia Given between two groups.

Minimum number of rescue analgesia in group A was 1 and in group B it was 2. maximum number of rescue analgesia in group A was 2 and that in group B was 3. mean number of rescue analgesia in 24 hrs in Group A was 1.63 ± 0.49 and in Group B was 2.73 ± 0.45. There was significant difference in Number of rescue analgesia in 24 hrs between two groups. This observation is comparable with other studies.

Nama Nagarjuna Chakravarthy et al^[6] in their study of epidural 0.5% bupivacaine with nalbuphine and 0.5% bupivacaine with fentanyl in lower abdominal and lower limb surgeries found that the total number of rescue analgesics required in the first 24 hours in the post-operative period was statistically significant. ($p < 0.01$) and it was lesser in nalbuphine group than fentanyl group.

Paul et al^[10] compared the effects of dexmedetomidine and fentanyl as an adjuvant to epidural bupivacaine in lower limb surgeries, where the duration of analgesia was longer in bupivacaine and dexmedetomidine (group BD) than bupivacaine and fentanyl group ($p < 0.001$). Postoperative visual analogue scale was reduced statistically significantly in Group BD ($P < 0.001$)

Mishra et al^[11] compared the effects of epidural bupivacaine (group 1) epidural bupivacaine clonidine (group 2) Vs Epidural bupivacaine fentanyl (group 3) for Postoperative Analgesia and found that Duration of analgesia was prolonged in Group II in comparison to Group III & Group I which is statistically significant.

LIMITATIONS

There are very few studies comparing nalbuphine and fentanyl with bupivacaine epidurally and these studies evaluated only the duration of post-operative analgesia and the incidence of side effects with opioids. Most of the studies which evaluated the sensory and motor blockade were done in intrathecal route of administration. So, few parameters in this study were not in agreement with other studies where nalbuphine and fentanyl was given intrathecally.

CONCLUSION

From the results of our study, duration of sensory blockade and analgesia were prolonged with epidural 0.5% bupivacaine with nalbuphine. Onset of sensory and motor blockade, peak sensory blockade, time for maximum motor blockade and duration of motor blockade were comparable in both the groups.

Therefore it is concluded that epidural 0.5% bupivacaine with nalbuphine significantly prolongs the total duration of sensory blockade with better postoperative analgesia when compared to Epidural Fentanyl with 0.5% bupivacaine, with stable hemodynamics and less side effects.

REFERENCES

- Andres J, Valia JC, Gill A, Bolinches R. Predictor of patient satisfaction with regional anesthesia. Reg Anesth., 1995; 20: 198-505.
- Bernards CM. Epidural and spinal anesthesia. In: Barash PG, Cullen BF, Stoelting RK, editors. Clinical anesthesia. 6th edition. Philadelphia: Lippincott Williams and Wilkins; 2009. p.928-37.
- Romagnoli A, Keats AS. Ceiling effect for respiratory depression by nalbuphine. Clin Pharmacol Ther. 1980 Apr; 27(4):478-85.
- Buvanendran A, Kroin JS. Useful adjuvants for postoperative pain management. Best Pract Res Clin Anaesthesiol 2007; 21:31-49.
- Hindle A. Intrathecal opioids in the management of acute postoperative pain. Continuing education in anaesthesia, critical care and pain. Br J Anaesth 2008; 8:81-5.
- Nama Nagarjuna Chakravarthy, A Sagar, G. Venkateshwarlu. A comparative study of epidural 0.5% bupivacaine with nalbuphine and 0.5% bupivacaine with fentanyl in lower abdominal and lower limb surgeries. IAIM. 2018; 5(2): 124-134.
- Sapate M, Sahu P, Thatte WS, Dubey R. A randomized, double blind, control study of the effects of adding nalbuphine to spinal bupivacaine for lower abdominal surgeries in

- elderly patients. *Anaesth Pain & intensive Care*, 2013; 17(2): 145-148.
8. Mukherjee A, Pal A, Agrawal J, Mehrotra A, Dawar N. Intrathecal nalbuphine as an adjuvant to subarachnoid block: What is the most effective dose? *AnesthEssays Res.*, 2011; 5: 171-5.
 9. Tiwari AK, Tomar GS, Agrawal J. Intrathecal bupivacaine in comparison with a combination of nalbuphine and bupivacaine for subarachnoid block: a randomized prospective double-blind clinical study. *Am Jther.*, 2013 NovDec; 20(6): 592-5.
 10. Paul A, Nathroy A, Paul T. A comparative study of dexmedetomidine and fentanyl as an adjuvant to epidural bupivacaine in lower limb surgeries. *J Med Sci* 2017;37:221-6.e-blind clinical study. *Am Jther.*, 2013 NovDec; 20(6): 592-5.
 11. Mishra SK, Mishra PR, Satapathy R. Epidural Fentanyl Vs Epidural Clonidine for Postoperative Analgesia: A Comparative Study. *Ann. Int. Med. Den. Res.* 2017; 3(3):AN54-AN57.