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## Comparison of Epidural Nalbuphine/fentanyl as adjuvant to Bupivacaine for postoperative analgesia in infraumbilical surgeries

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### Abstract

**Background:** Alleviation of post-operative pain will reduce the surgical stress response and improve outcome of surgery. About 10% of patients undergoing surgeries can develop chronic pain postoperatively. Neuraxial analgesia found to better alternative than other mode of analgesia. This study was designed to compare the effect of Nalbuphine Vs Fentanyl as an adjunct to bupivacaine for post-operative analgesia, haemodynamic variations, side effects after epidural injection on patients undergoing elective lower limb surgeries.

**Methods:** Double blinded comparative study was conducted on 60 patients of ASA I,II category admitted for elective lower abdominal & lower limb surgeries under combined spinal epidural anaesthesia were enrolled for this study. Surgery was done under spinal anaesthesia. At the end of surgery, once sensory regression to T<sub>10</sub>, post op analgesia was administered via study drug epidurally. Group N patients will be received Nalbuphine 10 mg with Bupivacaine 0.125% diluted to 10ml in Normal saline. Group F patients received Fentanyl 100 mcg with Bupivacaine 0.125% diluted to 10ml in Normal saline.

**Results:** The mean duration of analgesia was longer in Group N (387.83 +/- 38.32 mins) compared to group F (343.60 +/- 25.64 min) and was statistically highly significant, ' p ' value =0.001.

**Conclusion:** Nalbuphine as an epidural adjuvant to bupivacaine provides better postoperative analgesia and very minimal side effects for patients undergoing infraumbilical surgeries.

**Keywords:** Epidural bupivacaine, epidural fentanyl, epidural Nalbuphine, postoperative analgesia

### Introduction

Postoperative pain is acute that is often undertreated. Inadequate pain relief has been shown to result in increased length of stay, time to discharge, time for ambulation <sup>[1]</sup> which can increase cost of care <sup>[2]</sup> Poor postoperative pain management may lead to Chronic post-surgical pain (CPSP) <sup>[3]</sup>, Chronic post-surgical pain is difficult and costly to treat, with wider costs associated with increased health service use as well as reduced quality of life and economic productivity <sup>[4, 5]</sup>. The management of acute pain is a unique challenge to the physician and can often lead to chronic problems for the surgical patient. About 10% of patients undergoing different types of surgeries can develop chronic pain postoperatively. Alleviation of post-operative pain will reduce the surgical stress response and improve outcome of surgery. Neuraxial analgesia found to better alternative than other mode of analgesia <sup>[6]</sup>. A growing body of evidence suggests that neuraxial anaesthesia are associated with less morbidity and mortality than general anaesthesia <sup>[7]</sup>. Epidural opioid drugs will reduce post-operative pain and provides longer duration of post-operative analgesia. Nalbuphine is an agonist at kappa-opioid receptors and an antagonist at Mu receptors; it thus produces analgesia (A kappa effect), whilst antagonizing both the respiratory depressant effects and the potential for dependency that are associated with the mu-receptor. Fentanyl is a highly selective mu-agonist acts on G protein receptors and decreases cAMP production thereby decrease in membrane excitability of neurons and produces analgesia. Intrathecal Nalbuphine provides better analgesia with lesser side effects than fentanyl <sup>[8]</sup>. Till date, there are very few studies which used nalbuphine as an epidural adjuvant.

### Objectives

This study was designed to compare the effect of Nalbuphine Vs Fentanyl as an adjunct to

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bupivacaine for post-operative analgesia, haemodynamic variations, side effects after epidural injection on patients undergoing elective lower limb surgeries.

### Methods

After taking written informed consent, 60 patients admitted in tertiary care center for elective lower limb surgeries were enrolled for this randomized, double blinded comparative study.

#### Inclusion Criteria

- ASA grade I and II
- Age -18-60 years
- Patients scheduled for elective lower abdominal & lower limb surgeries

#### Exclusion criteria

- ASA III-VI
- Weight >95 kg,
- Age >60 years,
- Patients on tricyclic anti-depressants, alpha-2 adrenergic agonists or opioids.
- Any contra-indications to epidural anaesthesia.
- Patients refusing consent

#### Randomization

The patients were randomized in to two group of 30 each into Group N and Group F by odd & even numbers put in sealed opaque envelopes. Execution if randomisation at time of giving epidural drug.

All patients were evaluated in preanesthetic clinic. Detailed history and examination were done. Routine blood investigations, CBC, LFT, RFT, ECG, Chest Xray, Serum Electrolytes were done. Patient were given counselling about postoperative pain and informed written consent was obtained. Patients were kept nil per oral for 6 hours. Tablet Ranitidine 150 and T. Alprazolam 0.5 mg tablets were given night day before surgery. On the Day of surgery patients were connected to multipara monitor. 18G IV cannula was secured and preloaded with Ringer's lactate solution at 10– 15 ml/kg. Preoperative baseline respiratory rate, pulse rate, blood pressure (BP), oxygen saturation (SpO<sub>2</sub>) and electrocardiography of patients were recorded. Under standard Sterile precautions neuraxial anaesthesia were performed in sitting or Lateral position. Local anaesthetic 2% lignocaine was infiltrated in L2-3 and L3-4 space. 18 G Tuohy needle was introduced in L2-3 space, after 2– 3 cm insertion, stylet withdrawn and air-filled glass syringe was attached to the hub of the needle. Epidural space was identified with Loss of resistance technique. Epidural catheter was threaded about 5 cm in the epidural space after negative aspiration of CSF & Blood and test dose of 3ml of 2% Xylocaine with adrenaline was given through epidural

catheter and observed for Motor block or raise in Heart Rate (HR). Spinal anaesthesia was given in L3-4 space and 3.5ml of 0.5% bupivacaine heavy was administered intrathecally. Epidural catheter was fixed over the back. Surgery was carried over under spinal anaesthesia. Level of sensory blockade was checked by pinprick and motor blockade by modified Bromage scale. If the surgical procedure is prolonged and patient requires further blockade 0.5% Bupivacaine is given by epidural route. At the end of surgery once sensory regression to T<sub>10</sub> post op analgesia was administered via study drug epidurally. Group N patients will be received Nalbuphine 10 mg with Bupivacaine 0.125% diluted to 10ml in Normal saline. Group F patients received Fentanyl 100 mcg with Bupivacaine 0.125% diluted to 10ml in Normal saline. ECG, Pulse oximetry SpO<sub>2</sub>, NIBP, Heart Rate, Respiratory Rate, Pupil Size, VAS Score were monitored postoperatively. Study parameters were observed for every 5 mins till 30 mins, every 30 minutes till hours, every 1hour till 8 hours, every 2 hours till 12 hours in both groups. Duration of Post-operative analgesia is the time between the injection of the first epidural bolus to till patient complained of pain (VAS score >4) when rescue medication was given. Post-operative follows up was carried out in the recovery and post-operative ward. Rescue analgesic same as gr.allocated was given. Number of analgesic requests within 24 hrs were noted. Haemodynamic parameters like HR, SBP, DBP, MAP were measured periodically in both groups. Patients were monitored for PONV, shivering & other complications of spinal & epidural anaesthesia & treated by standard protocol.

**Data Analysis:** Data was entered in MS Excel and analysed using SPSS21 software. Numerical data was analysed by unpaired t-test. Categorical data was analysed by chi-square test.

A p value <0.05 was considered statistically significant (S). p=0.001 was highly significant (HS), p>0.05 was non-significant (NS).

### Results

**Table 1:** Demographic characteristics

Demographic parameter	Group N	Group F	P value	Inference
Age(yrs)	42+/-4	40+/-2	>0.05	NS
Male: Female	15:15	14:16	>0.05	NS
ASA grade I:II	16:14	15:15	>0.05	NS
Duration of surgery (mins)	126+/-20	120+/-26	>0.05	NS

The demographic factors and operative factors were comparable between the two groups (Table 1) and were not statistically significant. (p>0.05).

**Table 2:** Postoperative analgesia

Parameter	Group N	Group F	P value	Inference
Mean Duration of analgesia	387.83 +/- 38.32	343.60 +/- 25.64	0.001	HS
Mean VAS upto 8 hrs	1.5+/-05	3.8+/-0.2	<0.05	S
Total number of analgesic requests in 24 hrs	2+/-0.2	3+/-0.8	<0.05	S

The mean duration of analgesia was longer in Group N (387.83 +/- 38.32 mins) compared to group F (343.60 +/- 25.64 min) and was statistically highly significant, ' p' value =0.001. Upto 8 hours Nalbuphine group has

significantly lower VAS score compared to fentanyl group. (p<0.05). Total number of analgesic requests were less in group N in compare to gr. G with on, 24 hrs (p<0.05). Haemodynamic parameters like HR, SBP, DBP, MAP,

Spo2 were stable & comparable in both groups ( $p > 0.05$ ). Incidence of PONV were 23.3% in Group F and 13% in group N.

### Discussions

Modern anaesthesia recommends multimodal analgesia for enhanced recovery after surgery. Epidural analgesia is gold standard Post-operative analgesic technique. Nalbuphine & fentanyl are opioids used for same in present study.

The duration of post-operative analgesia was significantly prolonged in the nalbuphine group when compared to fentanyl group. (N vs F - 387.83 + 38.32 vs 343.60 + 25.64)  $p < 0.001$ .

Hala Mostafa Gomaa *et al.* [8] found that an intrathecal adjuvant of nalbuphine 0.8 mg to hyperbaric bupivacaine for cesarean delivery intensified postoperative analgesia compared to fentanyl 25mcg and hyperbaric bupivacaine mixture. Swarna Banerjee *et al.* [9] concluded that addition of nalbuphine 10 mg to 0.125% hyperbaric bupivacaine prolonged duration of postoperative analgesia compared to 100mcg fentanyl with 0.125% bupivacaine. Veena Chatrath *et al.* [10] found that 10 mg nalbuphine as epidural adjuvant to 0.25% bupivacaine has significant larger duration of analgesia compared to 100 mg tramadol. Oinam Bisu Singh *et al.* [11] demonstrated that nalbuphine as epidural adjuvant to ropivacaine had prolonged duration of postoperative analgesia for more than 6 hours. Babu S *et al.* [12] found that addition of nalbuphine as epidural adjuvant to ropivacaine has duration of analgesia for more than 6 hours. The above observations were similar to our study results. Hence, we conclude that nalbuphine has an advantage of prolonged duration of post-operative analgesia when used as adjuvant to bupivacaine compared to fentanyl for epidural postoperative analgesia at equipotent doses.

### Post-operative haemodynamic status

In our study nalbuphine group had significantly lesser changes in haemodynamic parameters heart rate, systolic blood pressure, diastolic blood pressure perioperatively. Similar results were observed in Quality of postoperative analgesia

In our study between upto 8 hours Nalbuphine group has significantly lower VAS score compared to fentanyl group ( $p < 0.05$ ). Similar results were observed by Babu S *et al.* [12] and Verma D *et al.* [13].

### Conclusion

We summarize that both epidural Nalbuphine and epidural fentanyl both are good adjuvants to Epidural Bupivacaine for effective postoperative analgesia.

In nutshell, Epidural Nalbuphine is more effective than Epidural Fentanyl as adjuvant with Epidural Bupivacaine, in terms of mean duration of postoperative analgesia, total analgesic requests in 24 hours, and very minimal side effects for patients undergoing infraumbilical surgeries.

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