Original Research Article

Comparison of nalbuphine and fentanyl as an epidural adjuvant to bupivacaine for post-operative analgesia

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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 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 T10, 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 with lesser hemodynamic alterations and very minimal side effects for patients undergoing lower limb surgeries.

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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[1] which can increase cost of care[2] Poor postoperative pain management may lead to Chronic post-surgical pain (CPSP) [3] 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 [4,5].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 [6] .A growing body of evidence suggests that neuraxial anaesthesia are associated with less morbidity and mortality than general anaesthesia [7]. 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

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

METHODS

After Institutional Ethics Committee approval and written informed consent, 60 patients admitted in Rajah Muthiah Medical College for elective lower limb surgeries were enrolled for this randomized, double blinded comparative study.

Inclusion Criteria:

1. ASA grade I and II
2. Age -18-60 years
3. Patients scheduled for elective lower limb surgeries

Exclusion criteria:

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

The patients were randomized in to two group of 30 each into Group N and Group F. All patients were evaluated in preanesthetic clinic. Detailed history and examination were done. Routine blood investigations viz 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. Ranitidine 150mg PO and T. Alprazolam 0.5mg PO 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 (SpO2) and electrocardiography of patients were recorded. Under standard Sterile precautions neuraxial anaesthesia were performed in sitting or Lateral position. Local anaesthetics 2% lignocaine was infiltrated in L2-3 and L3-4 space. 18G 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 and test dose on 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 3ml of 0.5% bupivacaine heavy was administered intrathecally. Epidural catheter was fixed over the back with plaster. 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 T10 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 Sp02, 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 >5) when rescue medication was given. Post-operative follows up was carried out in the recovery and post-operative ward. Rescue analgesic (1g paracetamol infusion or tramadol 2 mg/kg intravenously) was given.

Data Analysis: Data was entered in MS Excel and analysed using SPSS21 software. A p value <0.05 was considered statistically significant.

RESULTS

The demographic factors and operative factors were comparable between the two groups (Table 1) and were not statistically significant. The mean duration of analgesia was longer in Group N (387.83 $\pm$ 38.32 mins) compared to group F (343.60 $\pm$ 25.64 min) and was statistically highly significant, 'p' value =0.001. Between 3 to 8 hours Nalbuphine group has significantly lower VAS score compared to fentanyl group. The Differences in VAS Score between two groups between 3 to 8 hrs statistically significant. ($p<0.05$). Mean SBP, DBP, MAP in Fentanyl group is significantly lower than nalbuphine during 1-8hrs postoperatively.($p<0.05$). Incidence of PONV were 23.3% in Group F and 13% in group N.

Table 1: Demographic data

Variable	Group N	Group F	P Value
Age (yrs)	35.8 + 12.9	36.6 + 11.5	p >0.05
Weight (kgs)	57.50± 10.18	60.80 ±9.48	p>0.05
Males : Females (%)	86.7% : 13.3%	80.0% : 20.0%	p >0.05
ASA I : II	56.7% : 43.3%	53.3% : 46.7%	p>0.05
Duration of surgery	137.87 ±35.75	139.17 ±46.71	p>0.05

Table 2: Duration of Post-Operative Analgesia

	Group N	Group F	P
Duration of post-Operative Analgesia	387.83 ± 38.32	343.60 ± 25.64	t = 5.255 p = .0001 *

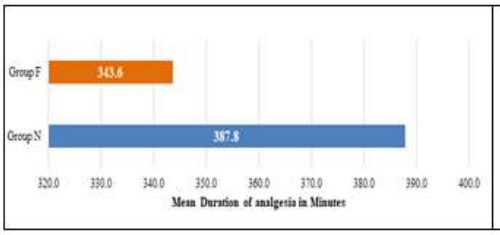

Figure 1

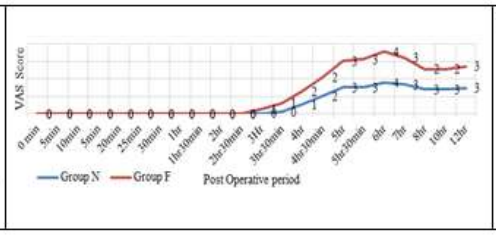

Figure 2

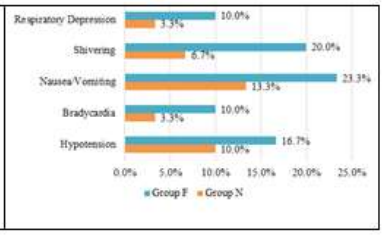

Figure 3

Figure 1: Duration of Post OP Analgesia among Study Groups; **Figure 2:** VAS Score in study groups in postoperative period; **Figure 3:** Side effects among study group

DISCUSSION

Post operative analgesia

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 at al* [8] found that an intrathecal adjuvant of nalbuphine 0.8mg to hyperbaric bupivacaine for cesarean delivery intensified postoperative analgesia compared to fentanyl 25mch and hyperbaric bupivacaine mixture. *Swarna Banerjee at* [9] concluded that addition of nalbuphine 10mg to 0.125% hyperbaric bupivacaine prolonged duration of postop analgesia compared to 100mcg fentanyl with 0.125% bupivacaine.*Veena Chatrath et al.* [10] found that 10mg nalbuphine as epidural adjuvant to 0.25% bupivacaine has significant larger duration of analgesia compared to 100mg 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 at 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 postop analgesia at equipotent doses.

Post-operative haemodynamic status

In our study nalbuphine group had significantly lesser changes in haemodynamic parameters viz heart rate, systolic blood pressure, diastolic blood pressure perioperatively.

Similar results were observed in

Quality of postoperative analgesia

In our study between 3 to 8 hours Nalbuphine group has significantly lower VAS score compared to fentanyl group (p<0.05(. Similar results were observed by Babu S at al [12] and Verma D *et al.* [13]

Postoperative side-effects

In our study incidence of bradycardia (10%) and hypotension (16.7%)was higher in fentanyl group compared to Nalbuphine group (3%,10%). Similar incidence of bradycardia in fentanyl group compared to nalbuphine group was observed by Babu S at al [12.].Nalbuphine group has lesser incidence of shivering compared to fentanyl group. Nalbuphine as a Mu antagonist used for treatment of Spinaland epidural anaesthesia induced shivering [31]. Nalbuphine has ceiling effect on respiratory depression. In our study nalbuphine group has very less incidence of respiratory depression than fentanyl group.

CONCLUSION

Epidural Nalbuphine with bupivacaine is more effective than epidural fentanyl with bupivacaine for postoperative analgesia during the immediate postoperative period of first 6 hours. Nalbuphine in comparison to as an epidural

adjuvant to bupivacaine provides better postoperative analgesia with lesser hemodynamic alterations and very minimal side effects for patients undergoing lower limb surgeries.

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