VOLUME-8, ISSUE-1, JANUARY-2019 • PRINT ISSN No 2277 - 8160

Original Research Paper

Anaesthesiology

COMPARISON OF 0.5% BUPIVACAINE WITH NALBUPHINE AND 0.5% BUPIVACAINE WITH NORMAL SALINE FOR POST-OPERATIVE EPIDURAL ANALGESIA IN LOWER ABDOMINAL SURGERY

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ABSTRACT

Aim: This study was undertaken to compare the efficacy of 0.5 % Bupivacaine with Nalbuphine and 0.5% Bupivacaine with normal saline by epidural route for providing analgesia in patients undergoing lower abdominal surgeries.

Methods: 60 adult patients of ASA grade I and II of both sexes, aged between 18-50 years posted for elective lower abdominal surgeries were selected for the study using 0.5% Bupivacaine 19ml with0.2 mg/kg of Nalbuphine (made to 1ml) in study group epidurally with control group 0.5% Bupivacaine 19ml with 1ml normal saline.

Results: Epidural Bupivacaine with Nalbuphine produces early onset of sensory blockage significantly at 07.27±1.11 minutes(control group 13.77±1.07 minutes),and prolongs the duration of postoperative analgesia significantly upto 398.33±21.18 minutes (control group 187±10.47 minutes).

Conclusion: In conclusion epidural 0.5% Bupivacaine with Nalbuphine 0.2mg/kg produces early onset of analgesia and prolonged duration of analgesia compared with 0.5% Bupivacaine with Normal saline

KEYWORDS : Nalbuphine ,epidural analgesia,Bupivacaine

Introduction :

Pain is defined by International association for the study of Pain as "an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage". Pain has its effects on every system of the body affecting both physiological and psychological functions of the individual. Autonomic nervous system is stimulated by pain leading to various stress responses which are deleterious to the patient.

Many drugs are tried by various routes including inhalational, intravenous, parenteral, intrathecal and epidural for the pain relief.

Regional anesthesia and analgesia has the potential to provide excellent operating conditions and prolonged post operative pain relief.[1]

Epidural anaesthesia is more versatile than spinal anaesthesia , giving the clinician the opportunity to provide anaesthesia and analgesia ,as well as enabling chronic pain management. It helps in early mobilization by relieving postoperative pain thereby, decreased the incidence of thromboembolic events.[2]

Bupivacaine is a long acting, effective local anaesthetic, commonly administered by the epidural route for surgical anaesthesia as well as for the relief of postoperative pain.Despite its popularity, it is associated with cardiotoxicity and neurotoxicity at higher doses.[3]

Nalbuphine (a derivative of 14-Hydroxymorphine) is an opioid with mixed kappa agonist and mu antagonist properties. Its action on the kappa receptors attributes for the good sedative properties, whereas, partial agonism at the mu receptors induces a ceiling effect on respiratory depression. It is also known to potentiate the action of local anaesthetics. Administered epidurally, it exerts its action by its interaction with opioid receptors present on the spinal cord.[4]

The anaesthetic & analgesic requirement of local anaesthetics got reduced by the use of adjuvants because of their analgesic properties & augmentation of local anaesthetic effects.[5] The ability of the Nalbuphine to provide strong analgesia with mixed kappa agonist and mu antagonist properties, acts principally on kappa receptors. The site of action in spinal cord is substansia gelatinosa.[6]

Aim of study:

Comparison of 0.5% Bupivacaine with Nalbuphine and 0.5%Bupivacaine with normal saline by epidural route for post-operative analgesia in lower abdominal surgery to observe the onset and duration of sensory and motor blockade, efficacy of post-operative analgesia, effects on vital parameters, incidence of complications and side effects.

Material & Methods:

After obtaining approval by the Institutional Ethical committee written informed valid consent was taken.

Total number of 60 patients allocated randomly 30 in each group were selected for study. A detail history and thorough general and systemic examination was done. Patients ASA grade I and II status, aged between 18-50 years belonging to both sexes ,height between 150-170 cm, weight between 40-80 kg undergoing lower abdominal surgeries were included in the study. Patients with ASA grade III,IV and V, history of hypersensitivity to local anaesthetic, dependent on opioid ,local infection at puncture site and patient refusal to participate in study were excluded from the study.

A detail history and thorough general and systemic examination was done. All routine investigations were performed prior to surgery. Patients was kept NBM for 6 hr prior to procedure. Basic demographic data like age, sex, height and weight were recorded.

To monitor vital parameters blood pressure cuff, pulse oximeter, ECG leads were attached.

Baseline pre operatively pulse rate, systolic and diastolic pressure, mean arterial pressure, $SP0_2$, ECG, respiratory rate, $ETCO_2$ were noted.

Venous access with 18 G cannula was secured in all patients and preloaded with 10 ml/kg of ringer lactate solution.

Linear visual analogue scale (VAS) was explained to all patients using a 10 cm scale. All the patients were pre medicated with inj. Midazolam 0.02 mg/kg I.V 45 - 60 mins prior to procedure. For all patients epidural anaesthesia was administered with 18G epidural needle at L2-L3 intervertebral space. The epidural catheter was inserted, placed at about 4 cm in epidural space. Epidural catheter

was fixed aseptically.

After exclusion of blood in the epidural catheter with negative aspiration, test dose of 3 ml inj. Lignocaine with Adrenaline (1:2,00,000) was administered to exclude intrathecal or intravascular placement of the catheter. Patient then turned to supine position.

This study was designed as prospective, randomized, double blind study. Patients were randomly allocated to two groups of 30 each. Group A were given 19ml of 0.5% Bupivacaine with 1 ml of normal saline epidurally. Group B were given 19 ml of 0.5% Bupivacaine with 0.2 mg/kg Nalbuphine (made as 1 ml) epidurally.

Data collection was done by anaesthesiologist who was unaware of group allocation. Level of sensory block was assessed by pinprick and the onset of blockde was noted.

In both the groups the time of injection was recorded as zero hour and onset of blockade, level of sensory blockade, quality of motor blockade by bromage scale, two segment regression time, time at which rescue analgesia was given were noted.

Cardiorespiratory parameters (pulse rate, respiratory rate, non-invasive blood pressure, SpO_2) were monitored continuously. Recordings were made every 5 minutes until 30 min, every 10 min until 2 hours and every 30 minutes thereafter till the completion of surgery. Postoperatively, patients were shifted to recovery room for further monitoring and monitored for 24 hours.

Rescue analgesia was provided with epidural top up by 8 ml of 0.125 % Bupivacaine when patient complained of pain for the first time postoperatively with visual analogue score 4. Subsequent epidural top ups were given with 8 ml of 0.125 % Bupivacaine.

Appropriate statistical software, including but not restricted to MS Excel, SPSS ver. 20 were used for statistical analysis. Graphical representation was done in MS Excel 2010.

Observations and Results

The demographic characteristics of patients were comparable between the two groups regarding mean age, weight, height, BMI, ASA grading, duration of surgery and there was no stastical significance (table no 1).There was no significant difference in heart rate, systolic BP, diastolic BP and SpO2 between the two groups.

Table no 1: Demographic Characteristics

Demographic character		Group A (n=30)	Group B (n=30)	P value
Age (years)	Mean ± S.D.	37.07±6.7	37.13±7.78	0.425
	Range	24-48	24-48	
Weight (kg)	Mean ± S.D.	56±2.62	57.04±3.15	0.457
	Range	50-60	52-64	
Height (cm)	Mean ± S.D.	156.67±2.69	156.73±2.54	0.759
	Range	154-164	152-162	
BMI	Mean ± S.D.	22.82±1.10	23.35±0.878	0.3
	Range	19.53-24.65	21.63-24.45	
ASA classification	Class I	27 (90%)	27 (90%)	1
	Class II	03 (10%)	03 (10%)	

(P Value: Not significant > 0.05, Significant < 0.05, highly significant < 0.001)

Onset of sensory block:

The mean (±SD) time of onset of sensory block in group A (Bupivacaine with normal saline) was 13.77±1.07 minutes and in group B (Bupivacaine with Nalbuphine) was 07.27±1.11 minutes(p<0.000001). (figure no 1).Onset of sensory block was significantly earlier in group B than group A.

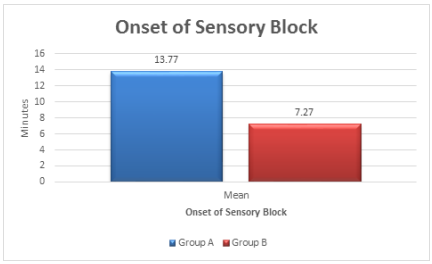

Figure no 1: Distribution of Participants according to Onset of Sensory Block (min)

Time to Achieve Maximum Sensory level

The mean (±SD) time to reach maximum sensory level in group A was 26.47± 1.79 minutes and in group B was 17.37±1.62 minutes(figure no 2). The difference between time to reach maximum sensory analgesia in group A and group B was statistically significant (p<0.000001).Time to achieve maximum level was significantly earlier in group B(Bupivacaine with Nalbuphine) than group A (Bupivacaine with normal saline) .

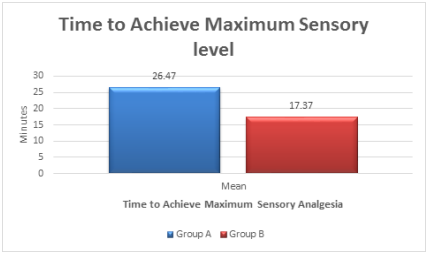

Figure no 2: Distribution of Participants according to Time to Achieve Maximum Sensory level (min)

Time for Two Segment Regression of Sensory Level

The mean (±SD) time for two segment regression in group A was 96±7.92 minutes and in group B was 128.06±5.56 minutes(figure no 3). There was significant difference between time for two segment regression of sensory level in group A and group B was statistically significant (p<0.00001) . Mean time required for two segment regression was significantly higher in group B than group A.

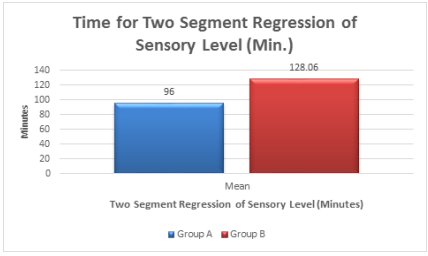

Figure no 3: Distribution of Participants according to Time for Two Segment Regression of Sensory Level (min)

Duration of analgesia

The mean (±SD) duration of analgesia in group A (Bupivacaine with normal saline) was 187±10.47 minutes and in group B (Bupivacaine with Nalbuphine) was 398±21.18 minutes(table no 2). The difference between the duration of analgesia in group A and group B was statistically highly significant (p<0.000001) (HS). Hence, a longer duration of analgesia was achieved in group B as compared to group A.

Table no 2: Distribution of Participants according to Duration of Analgesia (min)

Groups	Duration of Analgesia (min)			Significance	
	Mean	SD	Range	t – value	p – value
Group A	187	10.47	165-210	-48.99	<0.000001
Group B	398.33	21.18	360-430		

(P Value: Not significant > 0.05, Significant < 0.05, highly significant < 0.001)

Number of epidural top up:

The mean number of epidural top up in group A(6±0.643) (Bupivacaine with normal saline) were more as compared to group B(3.50±0.509) (Bupivacaine with Nalbuphine).

Side effects :

Hypotension was noted in 3 (10%) patients in group A and 3 (10%) patients in group B.

Nausea and vomiting was noted in none of the patients in group A and 2(6.66%) patients in group B

Urinary retension was observed in 1(3.33%) patients in group A and 2(6.66%) patients in group B

None of the patients, in either group had pruritus, respiratory depression (table no 3)

Table no 3: Comparison between the groups according to Side Effects

Side effects	Group A (n=30) (%)	Group B (n=30) (%)	Total (%)	P value
Hypotension	03 (10)	03 (10)	06 (10)	-
Respiratory depression	00 (00)	00 (00)	00 (00)	
Pruritis	00 (00)	00 (00)	00 (00)	
Nausea/ Vomiting	00 (00)	02 (6.66)	02 (3.33)	
Urinary Retention	01 (3.33)	02 (6.66)	03 (5.00)	

(P Value: Not significant > 0.05, Significant< 0.05, highly significant < 0.001)

Discussion

Pain management is one of the important task to the anaesthesiologist. Post -operative pain is acute pain, which starts with the surgical trauma and usually ends with tissue healing. It diminishes with time after surgery and responds to analgesics. The effective relief of pain to the patients undergoing surgery is essential and is of paramount importance both on humanitarian grounds and also in reducing post-operative morbidity ,hence should be duly imparted by treating anaesthesiologist.

The use of epidural opiods had become an increasing popular techinique for management of acute post operative pain in recent times. Considerable evidence exists to implicate the role of opioids in the spinal inhibition of nociceptive transmission. Dorsal horn nociceptive neurons exhibit wind up – a frequency dependent potentiation of their responses to repeated "C" fibre stimulation. Opioids reduce the release of primary afferent transmitters via inhibitory pre synaptic opioid receptors on "C" fibre terminals. Thus reducing or blocking "C" fiber stimulation of the dorsal horn nociceptive neurons and delaying the onset of wind up. In combination with a small dose of opioids, threshold doses of local anaesthetics markedly reduce the "C" fibers evoked response compared with either drug alone.

Nalbuphine is a drug with mixed μ antagonist and k agonist properties. Nalbuphine has the potential to maintain or even enhance μ-opioid based analgesia while simultaneously mitigating the μ-opioid related side effects. Nalbuphine and other k agonists have provided potent analgesia in certain models of visceral nociception. They demonstrate complicated interactions with μ opiates that suggest dose-dependent synergies and significant antagonisms at larger doses.

Hence, Nalbuphine was considered as an adjuvant drug in terms of its ability to produce an antagonism of the side effects attendant to spinal opiates, e.g. respiratory depression, pruritus and urinary retention.[6]So nalbuphine was the choice of drug for the present study.

This study was undertaken to compare the efficacy of 0.5 % Bupivacaine with Nalbuphine and 0.5% Bupivacaine with normal saline by epidural route for providing analgesia in patients undergoing lower abdominal surgeries.60 adult patients of ASA grade I and II of either sex, aged between 18-50 years posted for elective lower abdominal surgeries were selected for the study.

The demographic characteristics of patients were comparable between the two groups regarding mean age, weight, height, BMI, ASA grading, duration of surgery

The mean (±SD) time of onset of sensory block in group A was 13.77±1.07 minutes and in group B was 07.27±1.11 minutes (p<0.000001).Onset of sensory block was significantly earlier in group B than group A.

Sonali M khobragade,Jagdish Kalbhor et al(2017)[7] found that onset of sensory blockade was 10.06 (±4.42) minutes in group D (Dexmedetomidine) which showed significant difference from group N (Nalbuphine) where the mean time for onset of sensory blockade was 13.88 (±7.83) minutes (p=0.014). In our study the mean time of onset of sensory block in group B was 07.27±1.11 minutes.This finding was comparable to the studies conducted by Sonali M khobragade,Jagdish Kalbhor et al.

The mean (±SD) time for two segment regression in group A was 96±7.92 minutes and in group B was 128.06±5.56 minutes. The statistical analysis showed that the difference between time for two segment regression of sensory level in group A and group B was statistically significant (p<0.00001)

Sonali M khobragade,Jagdish Kalbhor et al (2017)[7] observed that the mean (±SD) time to two segment regression in group N (Nalbuphine) was 93.43 (±20.28) minutes and in group D (Dexmedetomidine) was 93.71 (±20.16) minutes. In our study time for 2 segment regression in group B was 128.06±5.56 minutes. This findings were comparable with the studies conducted by Sonali M khobragade,Jagdish Kalbhor et al.

The mean (±SD) duration of analgesia in group A was 187±10.47 minutes and in group B was 398±21.18 minutes. The difference between the duration of analgesia in group A and group B was statistically highly significant (p<0.000001) (HS).

In our study the mean (±SD) duration of analgesia in group B was 398±21.18 minutes. These finding were similar to studies conducted by Swarna Banerjee,Shaswat Kumar Pattnaik (2017)[8], Sonali M khobragade,Jagdish Kalbhor et al(2017)[7] , Chatrath V, Attri JP et al (2015)[4]

Hypotension was noted in 3 (10%) patients in group A and 3 (10%) patients in group B

Nausea and vomiting was noted in none of the patients in group A and 2(6.66%) patients in group B

Urinary retension was observed in 1(3.33%) patients in group A and 2(6.66%) patients in group B

Sonali M khobragade,Jagdish Kalbhor et al (2017)[4] observed that nausea was observed in 3 (8.57%) patients and vomiting was observed in 1 (2.8%) patient in group N while no patient in group D had nausea and vomiting.

The finding of our study were comparable with Sonali M khobragade, Jagdish Kalbhor.

In our study we found that 0.5% Bupivacaine with Nalbuphine (0.2 mg/kg) provides had faster onset of sensory and motor block and also prolongs duration of sensory and motor block. Bupivacaine

with Nalbuphine significantly prolongs duration of postoperative analgesia with minimal hemodynamic alterations and very minimal incidence of adverse effects.

CONCLUSIONS

After the clinical comparative study of 0.5% Bupivacaine with Nalbuphine (0.2 mg/kg) and 0.5% bupivacaine with normal saline for post- operative epidural analgesia in lower abdominal surgery following conclusions were drawn.Bupivacaine with Nalbuphine had faster onset of sensory and motor block as compared to bupivacaine with normal saline .Bupivacaine with Nalbuphine had prolonged duration of sensory block and significantly prolongs duration of postoperative analgesia as compared to bupivacaine with normal saline .Hemodynamic alterations in the two groups were found to be minimal with very minimal incidence of adverse effects.

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