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STUDY ON ANALGESIC EFFICACY OF EPIDURALLY ADMINISTERED BUPIVACAINE -FENTANYL COMBINATION AS INTERMITTENTAND CONTINUOUS INFUSION IN PATIENTSWITH REST PAIN- CHRONIC LIMB ISCHEMIA

Anesthesiology

Dr. P. Deepthi Senior Assistant Professor, Institute Of Anaesthesia And Critical Care, Madras Medical College, Chennai.

Dr. C. Pranab Nirmal* Assistant Professor, Institute Of Transplant, Madras Medical College, Chennai. *Corresponding Author

ABSTRACT

In this study, comparing the analgesic efficacy of intermittent doses and continuous infusion of 0.125% Bupivacaine with Fentanyl we foundThe mean time of onset of analgesia was rapid in the intermittent infusion group when compared to the continuous infusion group, though the difference was not significant.The patients included in our study in both groups - the intermittent bolus and the continuous infusion did not have motor blockade which enabled them to be ambulant and do their daily activities. Moreover the disposable continuous infusion pumps were handy enough to be carried. The wide swings in hemodynamics like blood pressure, heart rate and respiratory rate were not encountered in the continuous infusion group and stability was maintained throughout.The quality of analgesia was found to be excellent in both the intermittent bolus and continuous infusion groups, slightly more with stable hemodynamics in the continuous infusion group.

KEYWORDS

bupivacaine, fentanyl, analgesia, infusion

1. INTRODUCTION :

The International Association for study of pain defines pain as 'An unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage".Analgesia delivered through an indwelling epidural catheter is a safe and effective method for management of pain. Epidural analgesia can provide superior analgesia compared with systemic opioids.The local anesthetic - opioid combination in epidural infusion provides superior analgesia, limits regression of sensory block and decreases the dose of local anesthetic administered.Experimental studies demonstrate a synergistic effect between local anesthetics and opioids, however clinical trials suggest an additive effect.Fentanyl has advantages because of rapid onset of action and as preservative free Fentanyl has become available making its epidural administration possible.

2. AIM AND OBJECTIVES:

To compare the efficacy of epidurally administered 0.125% Bupivacaine with Fentanyl as intermittent bolus and continuous infusion in patients with rest pain (chronic limb ischaemia) as analgesia based on following parameters.

1. Visual analogue scale
2. Time of onset of analgesia in intermittent bolus and continuous infusion
3. Motor blockade
4. Hemodynamic changes in intermittent bolus and continuous infusion
5. Quality of Analgesia

3. MATERIALS AND METHODS

Forty patients with rest pain admitted in the Department of Vascular surgery, Government General Hospital, Madras Medical College, have been taken up for study. Period of study was 2018 to 2019. A randomized prospective clinical trial has been conducted after obtaining the informed consent.Grouping Patients with rest pain were grouped into A and B.

Group A- patients received intermittent bolus doses of 0.125% Bupivacaine with Fentanyl 50mcg through epidural catheter.

Group B- patients received continuous infusion of 0.125% Bupivacaine with Fentanyl 12 mcg/ml at 5ml /hr.

Pain scores using Visual Analogue Scale and vitals in both the groups were noted.

Type of study -Randomized clinical trial

Inclusion criteria

- onset of disease before 45 years of age
- current tobacco use or smoking

Distal extremity ischemia such as rest pain, ischemic ulcer and gangrene documented with non invasive testing.

Clinical category of Chronic Limb Ischemia -category 3 (severe claudication), 4 (ischemic rest pain) and 5 (minor tissue loss; non healing ischemic ulcer, focal gangrene with diffuse pedal ischemia). Male or female

Exclusion Criteria

Refusal of patient

Patients with Diabetes Mellitus, Systemic Hypertension, Ischemic Heart Disease ,Cerebrovascular Accident

Clinical category chronic limb ischemia -Category 6 (major tissue loss, extending above TM level, functional foot no longer salvageable)

Spine deformities

Local infection at site of introduction of epidural needle

Allergic to local anesthetic - known history of allergy

Fixed cardiac output states

Raised intracranial tension, Patients with rest pain were assessed by taking good history, physical examination and investigations pre procedure.General examination included general condition, blood pressure measurement, pulse rate and respiratory rate, $Sp0_2$, Visual Analogue Scale using a 10 cm scale marked one to ten with 'no pain' at the zero end and maximum pain at other end.Medications- T.Aspirin, T.Clopilet, Injection Heparin. T.Clopilet was stopped 7 days before. UFH stopped 6 hours before the procedure.

Patient with cardiac,respiratory, Renal, hepatic,
neurological and psychiatric disorders were excluded from study
Investigations included

- Hemoglobin/packed cell volume
- Total count, differential count, ESR, PT,INR
- Random Blood Sugar
- Renal function test
- Serum electrolytes
- ECG
- Chest X-ray, PA, view
- Echo
- Bleeding time, clotting time
- Platelets
- Urine for Albumin and sugar
- No premedications used
- Pre-procedure visit

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To get rapport with patients and reassurance. To make sure the patient

has been completely evaluated and medications like heparin and clopilet have been stopped.

Assessment of airway, neck movements
Patient shifted to operation theater
Monitors were connected - NIBP, $Sp0_2$, ECG

Pre-procedure Heart Rate, Blood Pressure, Respiratory Rate, $Sp0_2$, Visual Analogue Scale, Motor Power of Lower Limbs assessed.

All emergency resuscitative drugs including injection Naloxone were kept ready.

Resuscitative equipments like intubating laryngoscope with suitable blades, appropriate size endotracheal tubes, laryngeal Mask Airways were kept ready.

Boyles machine was checked for proper functioning

Epidural set consisting of sterile tray, sterile gauze and towel, glass syringe 2ml, 5ml, 10ml with hypodermic needles 22/23/24G, sponge holding forceps, epidural Tuohy needle 17G with catheter 90cm (19G) were made available.

Patients cannulated with 18G cannula and preloaded with 15-20ml/kg of crystalloid solution prior to block.

Aseptic precautions were followed throughout the procedure.
After re- explaining to the patient, patient positioned
Patient skin over back was cleansed with betadine and draped.
Intervertebral space using highest point of iliac crest was identified.

Skin and subcutaneous tissue overlying the midline of space was infiltrated with 2ml of 2% lignocaine using 22g hypodermic needle.

17G Tuohy needle was introduced till the interspinous ligament and stylet was removed.

A 5ml glass syringe with air filled upto 2ml was attached to hub of needle and advanced cautiously to identify the epidural space using LOR technique.

After the epidural space was identified, catheter was inserted with the tip at L_3, L_4 and fixed in position.

Randomly patients were given intermittent bolus or continuous infusion.

Drug used in intermittent bolus dose was 0.125% Bupivacaine with 50pg Fentanyl, 6ml was given. Vitals monitored to check for signs of complication. The subsequent bolus doses were repeated when visual analogue scale scores showed five

Continuous infusion - 0.125% bupivacaine with 2mcg/ml of Fentanyl in disposable infusion pump at rate of 5ml/hr. Before the infusion pump was connected a bolus dose of 0.125% Bupivacaine with 10mcg Fentanyl, 5ml was given through epidural catheter.

Heart rate, Blood Pressure (systolic and diastolic), respiratory rate, $Sp0_2$ were initially recorded every minute for 10 minutes, every 5 minutes for next 30 minutes , every 30 minutes for next 1 hour, hourly for 12 hours, 6^{th} hourly for 72 hours. VAS scores were recorded 2 hourly.

Onset of analgesia - Time taken from injection of local anesthetic with opioid to start of loss of sensation to pin prick was noted in the both groups.

4. RESULTS & DISCUSSION

This study was conducted at Madras medical college (MMC), on patients with Rest Pain admitted in Department Of Vascular Surgery MMC, Chennai. The comparison of analgesic efficacy of 0.125% Bupivacaine with 50mcg Fentanyl as intermittent bolus-6ml (Group A) with continuous infusion of 0.125% Bupivacaine with 10mcg Fentanyl- 5ml /hour (Group B) administered epidurally was done.This was assessed using subjective and objective parameters.The subjective parameter was patients' verbal utterance of reduction of pain after perceiving it.The objective parameter was loss of sensation to pin prick.The mean duration of onset of sensory analgesia in Group A using Subjective method is found to be 12.15 ± 0.67 minutes and that in objective method is 7.3 ±1.78 mins.The mean duration of onset of sensory analgesia in Group B using subjective method is found to be 13.25 ± 0.79 minutes and that in objective method is 7.8± 1.39 mins .There was no statistical significance between the Groups A or B regarding this parameter.In our study motor blockade was assessed using Bromage Scale except for one case all other patients in Group A and Group B showed Bromage Score of 0. Both the groups almost produced no motor blockade. In this study the quality of analgesia in group A and group B were compared using Visual Analogue Scale.This parameter is statistically significant ($P<0.05$) in both the groups. The statistical significance was high in group B than group A. This randomized, prospective, blinded study has been done to compare the analgesic efficacy of 0.125% Bupivacaine with Fentanyl 50mcg as intermittent bolus with 0.125% Bupivacaine with Fentanyl 10mcg as continuous infusion administered epidurally.This study was conducted on patients with Rest Pain with Chronic Limb Ischemia admitted to Department Of vascular Surgery, Madras Medical College, Chennai. These patients were categorized as ASA I or II.The mean time of onset of sensory analgesia by using the objective method (loss of sensation to pin prick) is 7.3 ± 1.78 mins and 12.15 ± 0.67 minutes by subjective method (patient's utterance when elicited) in group A and 7.8 ±1.39 minutes and 13.25 ± 0.79 minutes respectively in group B. This result is comparable with Balzaena S.D (1992) who observed that Fentanyl when administered with local anesthetic had faster onset compared with morphine. According to Ionescu et al., (1989) Fentanyl is 800 times as lipid soluble as Morphine. CSF concentration of Fentanyl peak is about 20 minutes, in contrast to Morphine which peaks in 1 to 4 hours. Ionescu et al., (1991) also observed that Fentanyl blood concentrations peak in 5 to 10 minutes.In this study with use of 0.125% Bupivacaine with Fentanyl in intermittent bolus and continuous infusion administered epidurally, no motor blockade was encountered in group A or B except for one case where Bromage Score of 2 was observed in group A. This can be accounted for subarachnoid migration of catheter. The absence of motor blockade indicates that low dose and low concentration of local anesthetics with addition of opioids loses the ability to block motor fibres .Our results are comparable with Badner NH ,Bandari R ,Komar WE (1994) who suggested that 0.125% Bupivacaine improves analgesia of epidural infusions of fentanyl with minimal motor disturbance.The mean systolic blood pressures and diastolic blood pressures have been found to be statistically significant ($P<0.05$) in group B when compared to group A. According to Grass JA (1998), Wheatley RG, Schug SA, Watson D (2001) strategies to prevent noncritical hypotension was to decrease the, overall dose of local anesthetic or decrease the concentration of local anesthetic.Most evidence indicates that Fentanyl produces little or no change in myocardial contractility but has positive inotropic effect. Possible mechanisms of positive inotropic effects of Fentanyl include catecholamine release or direct myocardial adrenergic activation. According to William F Ganong (1995) pain usually causes rise in blood pressure via afferent impulses in the Reticular Formation converging on the Vasomotor area- a group of neurons in medulla oblongata that mainly control blood pressure . Opioids also can modulate the stress response through receptor mediated actions on the hypothalamic - pituitary - adrenal axis.In this study rise in blood pressures were seen in group A, when the effect of bolus dose weaned off and Visual Analog Scales increased. These effects (i.e.) wide swings of blood pressures were not seen in group B. The mean heart rate which has been found to be statistically significant ($P<0.05$) in group B when compared with group A. Murat et al (1988) observed that carotid sinus baroreceptor reflex control of heart rate is markedly depressed by Fentanyl at a rate of lOmcg/kg administered to neonates. In our study low dose of Fentanyl was used to provide analgesia .The rise in heart rate due to pain occurred in group A when the drug effect weaned where as in group B it was significantly maintained. Impulses like pain reaching the Medulla affect the heart rate. The stimuli that increases the heart rate increases blood pressure.In this study the mean respiratory rate which was found to be statistically significant ($P<0.05$) in group B when compared to group A. According to Jaekle KA (1990) et al, opioids by decreasing both pain and central ventilatory drive are effective agents in preventing hyperventilation induced by pain or anxiety.In this study, SpC**>2** measurements did not show significant difference in groups A and B. This result was comparable with Badner NH,Bandari R. Komar WE (1994).The quality of analgesia was compared using Visual Analog Scale has been found to be statistically significant ($P<0.05$) in group A and B .The significance was high in group B when compared with

group A. This result is comparable with Badner NH,Bandari R,Komar WE (1994).Sagakuchi H, Ikuta Y, Seshita M (1995) compared Morphine bolus injection with Bupivacaine -Fentanyl mixture in 100 patients who underwent upper abdominal surgery. They suggested that continuous infusion of Bupivacaine (2.5mg /ml) and Fentanyl (12.5mcg /ml) at rate of 2ml /hour was superior to bolus injection of Morphine for post -operative analgesia. Dhalae ,Shelgoankar ,Akulwar (2000) compared epidural bupivacaine with Fentanyl of 3 different doses 25mcg, 50 and 75mcg with 0.5% bupivacaine for post - operative analgesia in elective lower limb orthopedic procedures and lower abdominal surgeries . They found that 50mcg of Fentanyl with 0.5% Bupivacaine was of better choice with acceptable side effects.In this study, comparing the analgesic efficacy of intermittent doses and continuous infusion of 0.125% Bupivacaine with Fentanyl we summarize as follows:The mean time of onset of analgesia was rapid in the intermittent infusion group when compared to the continuous infusion group, though the difference was not significant.The patients included in our study in both groups - the intermittent bolus and the continuous infusion did not have motor blockade which enabled them to be ambulant and do their daily activities. Moreover the disposable continuous infusion pumps were handy enough to be carried. The wide swings in hemodynamics like blood pressure, heart rate and respiratory rate were not encountered in the continuous infusion groupand stability was maintained throughout.The quality of analgesia was found to be excellent in both the intermittent bolus and continuous infusion groups, slightly more with stable hemodynamics in the continuous infusion group. We conclude that, though both the intermittent bolus and continuous infusion of 0.125% Bupivacaine and Fentanyl have provided equally effective analgesia, the continuous infusion of 0.125% Bupivacaine and Fentanyl has been found to be better than the intermittent bolus doses

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