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Anesthesiology

COMPARISON OF MOTOR BLOCKADE AND COMPLICATION OF EPIDURALLY ADMINISTERED BUPIVACAINE - FENTANYL COMBINATION AS INTERMITTENT AND CONTINUOUS INFUSION IN PATIENTS WITH REST PAIN- CHRONIC LIMB ISCHEMIA

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ABSTRACT This study comparing the motor blockade and complication of intermittent doses and continuous infusion of 0.125% Bupivacaine with Fentanyl.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 except one case had intrathecal catheter migration. 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.

KEYWORDS : Bupivacaine, Fentanyl, Motor Blockade, Infusion

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.

AIM OF STUDY

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

1. Motor blockade
2. Complications

MATERIALS AND METHODS

Grouping

Patients with rest pain were grouped into A and B.

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

Group B- patients received continuous infusion of 0.125% Bupivacaine with Fentanyl 2 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).

EXCLUSION CRITERIA

- Refusal of patient
- Patients with Diabetes Mellitus, Systemic Hypertension, Ischemic Heart Disease,CerebrovascularAccident
- 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

METHODS:

Patients with rest pain were assessed by taking good history, physical examination and investigations pre procedure.

Cardiovascular System-Degree of Coronary Artery Disease, ventricular function valvular disease, ECG, ECHO.

Respiratory System-History of smoking habits, breath holding time, Chest x ray PA view, Pulmonary Function Test.

Central Nervous System-History of Transient Ischemic Attacks, declining mental function, and tested for cognitive function .Spine and motor power of lower limbs were documented.

Renal system-to rule out renal failure and renal artery stenosis
Hematological System-Hemoglobin, cell counts, viscosity platelets, Bleeding Time, Clottiiig Time.

General examination included general condition, blood pressure measurement, pulse rate, respiratory rate, Sp02, 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
- 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:

- 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

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PROCEDURE:

- Patient shifted to operation theatre
- Monitors were connected - NIBP, Sp02, ECG
- Pre-procedure Heart Rate, Blood Pressure, Respiratory Rate, Sp02, 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.

TECHNIQUE

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 L3, L4 and fixed in position. Randomly patients were given intermittent bolus or continuous infusion. Drug used in intermittent bolus dose was 0.125% Bupivacaine with 50 mcg 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 2 mcg/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 10 mcg Fentanyl, 5ml was given through epidural catheter.

MONITORING

Heart rate, Blood Pressure (systolic and diastolic), respiratory rate, Sp02 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, 6th hourly for 72 hours. VAS scores were recorded 2 hourly.

Motor blockade : assessed with Bromage Scale
0- No paralysis
1- inability to raise extended leg
2- inability to flex knee
3- inability to flex ankle and big toe

COMPLICATIONS:

Patients were monitored for hypotension, bradycardia, urinary retention, respiratory depression, pruritis and nausea, vomiting 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 motor blockade and complication of 0.125% Bupivacaine with 50 meg Fentanyl as intermittent bolus-6ml (Group A) with continuous infusion of 0.125% Bupivacaine with 10 meg Fentanyl- 5ml /hour (Group B) administered epidurally was done.

ANALYSIS

The parameters Blood Pressure (BP), Respiratory Rate (RR), Pulse Rate (PR), SP02, visual analogue Scale(VAS) have been evaluated on the 20 patients each admitted to the two treatment programmes (intermittent and continuous infusion). The parameters are compared at different time points within the same treatment group and between the treatment groups. Giving due considerations to the two treatment groups and setting up a null hypothesis that both groups offer the same benefit; the parameters are tested for statistical significance. The paired t-test statistics was used.

The parameters Heart Rate , Blood Pressure , Respiratory Rate and SP02 were recorded every 1 minute for initial lO mins , every 5 minutes for next 30 minutes , every 30 minutes for 1 hour , every I hour for 12 hours and 6th hourly there after. For statistical calculations the observations at 30 min, 1 hr., 12 hrs. 24 hrs., 36 hrs., 48 hrs., and 72 hrs time points have been considered. This was assessed using subjective and objective parameters.

MOTOR BLOCKADE

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.

Systolic blood pressure at different point time in Group A and Group B

Group	*Time points*	*Mean*	*Standard Deviation*	*P value*
Group A	Vi Hr.	129.1	6.69	N.S
	1 Hr.	127.8	6.48	N.S
	12 Hrs.	129.1	5.59	N.S
	24 Hrs.	128.6	5.98	N.S
	36 Hrs.	128.1	5.04	N.S
	48 Hrs.	130	5.54	SIG
	72 Hrs. '	128.2	4.89	SIG
	Vi Hr.	126	5.94	SIG
	1 Hr.	124.25	6.60	SIG
	12 Hrs.	122.7	5.99	N.S
Group B	24 Hrs.	121.3	6.06	N.S
	36 Hrs.	121.2	4.78	N.S
	48 Hrs.	121.9	4.42	N.S
	72 Hrs.	121.1	4.65	SIG

Diastolic blood pressure at different point time in Group A and Group B

Group	**Time points**	**Mean**	**Standard Deviation**	**P value**
Group A	Vi Hr.	84.2	8.28	SIG
	1 Hr.	82.0	7.73	N.S
	12 Hrs.	81.1	7.41	N.S
	24 Hrs.	80.3	5.66	N.S
	36 Hrs.	80.5	5.68	N.S
	48 Hrs.	80.0	5.94	N.S
	72 Hrs.	79.6	6.73	SIG
a	Vi Hr.	82.5	6.38	SIG
	1 Hr.	79.5	5.83	N.S
	12 Hrs.	78.6	4.30	N.S
Group B	24 Hrs.	77.2	5.67	N.S
	36 Hrs.	76.5	5.26	N.S
	48 Hrs.	76.4	5.82	N.S
	72 Hrs.	77.3	5.70	SIG

Heart Rate at different point time in Group A and Group B

Group	*Time points*	*Mean*	*Standard Deviation*	*P value*
Group A	% Hr.	95.3	4.61	SIG
	1 Hr.	92.5	5.26	SIG
	12 Hrs.	90.2	5.10	SIG
	24 Hrs.	88.0	5.73	N.S
	36 Hrs.	87.5	5.94	N.S
	48 Hrs.	87.3	4.78	N.S
	72 Hrs.	87.4	4.50	SIG
	'A Hr.	100.5	6.03	SIG
t	1 Hr.	95.25	5.63	SIG
	12 Hrs.	90.3	4.99	SIG
Group B	24 Hrs.	87.5	3.83	N.S
	36 Hrs.	87.1	3.40	SIG
	48 Hrs.	85.6	2.39	SIG
	72 Hrs.	84.7	2.53	SIG

Respiratory Rate at different point time in Group A and Group B

Group	*Time points*	*Mean*	*Standard Deviation*	*P value*
Group A	Vi Hr.	17.5	2.13	SIG
	1 Hr.	16.9	1.65	N.S
	12 Hrs.	16.3	1.56	N.S
	24 Hrs.	16.0	2.05	N.S
	36 Hrs.	16.3	1.49	N.S

	48 Hrs.	15.9	1.51	N.S
	72 Hrs. *i*	15.9	1.20	SIG
	Vi Hr.	17.0	1.65	SIG
	1 Hr. "	16.3	1.17	N.S
	12 Hrs.	15.7	1.17	SIG
Group B	24 Hrs.	14.9	1.20	SIG
	36 Hrs.	14.4	1.04	N.S
	48 Hrs.	14.2	0.89	N.S
	72 Hrs.	14.1	0.78	SIG

DISCUSSION

This randomized, prospective, blinded study has been done to compare the motor blockade and complication of 0.125% Bupivacaine with Fentanyl 50mcg as intermittent bolus with 0.125% Bupivacaine with Fentanyl 10mcg as continuous infusion administered epidurally. 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 . 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. The mean heart rate which has been found to be statistically significant ($P<0.05$) in group B when compared with group A. 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. In this study, Sp02 measurements did not show significant difference in groups A and B

COMPLICATIONS

The accidental dural puncture which occurs by epidural needle during the technique has not been reported in our study. One case of probable catheter migration was encountered in our study in group A. The patient presented with motor blockade of Bromage Scale 2. He was treated by supporting circulation with crystalloids and oxygen by mask till effect of block wore off.

In this study we did not encounter any case of respiratory depression, cardiovascular collapse, seizures, pruritis in either group A or B. In our study none of the cases had nausea, vomiting or urinary retention in either group A or B. The patients in our study had ill localized, burning pain because malperfusion of small sensory nerves which was relieved by hanging the diseased limb over the edge of the bed or by limping around, which increased the dependent edema and ischemia. As these patients were relieved off their pain by epidural analgesia, they were able to lie recumbent and keep their limbs elevated. This reduced the dependent edema, improved circulation and thus reduction of ischemic effects. In this study, 2 patients in group B and 1 patient in group A went in for revascularization procedures. The rest in addition to epidural analgesia responded to anticoagulants and abstinence from smoking with better compliance and quality of life.

CONCLUSION

We conclude that, epiduraly adminstered intermittent bolus and continuous infusion of 0.125% Bupivacaine and Fentanyl have no motor blockade and almost nil complication in both the groups.The continuous infusion of 0.125% Bupivacaine and Fentanyl has been found to be better than the intermittent bolus doses, with stable hemodynamics and minimal side effects.

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