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"Comparison of Analgesic Effect of Epidural Clonidine and Magnesium Sulphate as an adjuvant to bupivacine In Orthopaedic Lower Limb Surgeries.

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ABSTRACT:-Introduction:-Clonidineand Magnesium Sulphate usedas adjuvant to epidural 0.5% isobaric bupivacaine for patients undergoing orthopaedic lower limb surgeries to shorten the onset of sensory and motor block and prolonging the duration of block.**Aims and Objective**:-we evaluated
the onest and duration of analgesia and first pain complain by patient and to establish the ideal combination of drug for epidural anaesthesia with least side effects.**Material and methods:-**This analytical comparative study was conducted in the Department of Anaesthesia and Critical Care, NIMS UNIVERSITY Jaipur Rajasthan with prior permission of ethical committee of the institute and informed patient consent.The sample size of 90 patients aged 20 to 60 years belonging to ASA physical status 1 & 2 undergoing orthopaedic lower limb surgeries were randomly allocated to three groups in double blind manner.**Group 1**Received epidural isobaric bupivacaine 0.5% (20 ml) with 5 ml normal saline (0.9%) 25 ml,**Group2**Received isobaric bupivacaine 0.5% (20 ml) with 50 mg magnesium sulphate (which was diluted in 1 ml normal saline) with 4 ml normal saline (0.9%) keeping total volume 25 ml,**Group3** Received isobaric bupivacaine 0.5% (20 ml) with 50 microgram clonidine (diluted in 1 ml normal saline) with 4 ml normal saline (0.9%) 25 ml.Onset and Duration of Sensory and motor blockade and time taken for regression of analgesia to L1.**Results:-**The present study showed that both clonidine and magnesium sulphate shorten the onset and prolonged the duration of block.However with respect to onset time,clonidine has shorter onset of blockade than magnesium sulphate.**Conclusion**:-Both the modalities independently assured quicker onset and prolonged duration of block,suggesting that adjuvant use of either of two could be beneficial.

Keywords :- Epidural,Clonidine,Magnesiumsulphate,Bupivacaine.

I. INTRODUCTION:-

Regional anaesthesia is the most frequently used anaesthesia for orthopaedic lower limb surgeries. Epidural anaesthesia offers advantages, which are difficult to duplicate with general anaesthesia. Complication of epidural anesthesia is preventable. If the technique is employed meticously under all aseptic precautions skillfully, in properly selected cases. Epidural anaesthesia has been used all over the world and is widely accepted. Epidural Blockade is the armamentarium of Modern anaesthesiologist. It Includes less physiological disturbances than spinal anaesthesia, has low incidence of Neurological sequelae and postdural puncture headache although onset of action is much slower (10-20 min) than spinal blockade. Epidural Techniques are widely used for operative anesthesia, obstetric analgesia, post operative pain controls and chronic pain management.

Bupivacaine :- It is most widely used long acting local anesthetic, it is used in 0.5% and 0.75% concentration for surgical anesthesia. Analgesic technique can be performed with concentration from 0.125% to 0.25%. Bupivacaine was three to four times more potent and possessed longer duration of action than lignocaine.

Clonidine Hydrochloride:- Isan imidazoline derivatives with alpha -2adregenic agonistic activity. US FDA approved preservative free Clonidine formulation meant for epidural use in1996. It has variety of actions including

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antihypertensive effects as well as the ability to potentiate the effects of local anesthetic. It can provide pain relief by an opoid-independent mechanism.

Magnesium:-Is the fourth most plentiful cations in the body. It has antinociceptive effects in animal and human models of pain. It has been reported that intrathecal or epidural magnesium enhances opoidantinociceptive in an acute incisional model. These effects have prompted the investigations of magnesium as an postoperative analgesic.

II. AIMS AND OBJECTIVES:-

The Present Study will be undertaken to evaluate the effect of epidural administration Bupivacaine alone, Bupivacaine with Clonidine, Bupivacaine with magnesium on onset and duration of analgesia and first pain complain by patient and to establish the ideal combination of drug for epidural anaesthesia with least side effects.

Material and methods:-

Material required:-

Anaestheiamachine,Monitors such as pulse oximeter, ECG, sphygmomanometer,Intravenous infusion set, blood infusion set,Ringer lactate, 5% dextrose, normal saline,Epidural set (18G epidural needle),Syringe 5 ml, 10 ml,Suctionmachine,Drugs :Bupivacaine isobaric (0.5%),Injectable Clonidine (50 microgram),Injectable $MgSO_4$ (50mg),Povidine iodine, spirit, adhesive plaster, Autoclaved sponges, cotton, towel sheet, apron and surgical gloves,Sponge holding forceps,Laryngoscope,Endotracheal tubes of different sizes,Ventimask, masks of different sizes.

Emergency Drugs were kept ready

Method:

This study is carried out in patients undergoing orthopedics' lower limbs surgeries in Department of Anaesthesia and Critical Care, NIMS UNIVERSITY Jaipur Rajasthan with prior permission of ethical committee of the institute.

Sample size: Total 90 patients were selected and these patients were divided in 3 groups.

Study Design:-

This was a prospective Double blind, Randomized Controlled Trial. Randomization was done according to days of week, in which patient appointed for surgery on Monday, was included in group I, patient appointed for surgery on Tuesday was included in group II, patient appointed on Wednesday was included in group III respectively and so on.

(a) Eligibility criteria of patients:-

Every patient was screened a day before surgery after applying inclusion and exclusion criteria.

i. **Inclusion Criteria**:

a) Patients with ASA grade I & II
b) Patient belongs to age group 20 – 60 yrs. Of either sex.
c) Undergoing Orthopedics Lower Limb Surgery.

ii. **Exclusion Criteria:** Patients suffering from following disease were excluded:-

a) Diabetes Mellitus
b) Hypo or hypertension.
c) Respiratory Disease.
d) Epilepsy.
e) Cardiac disease.
f) Spinal Injuries.
g) Spinal Defects or Spinal Surgeries.
h) Emergency surgeries.
i) Patient on Beta Blockers.
j) Patient on antidepressants.
k) Psychatric patients.
l) Dumb and Deaf Patient.
m) Impair LFT and RFT.

Pre-Anaesthetic Check Up:

Pre-anaesthetic check up was done a day before, which was include:-

- Complete history of patient.
- General Physical and systematic examination of Lumbosacral region, any cardiac or pulmonary pathology are significant nature.
- Pulse rate, blood pressure, respiratory rate were noted.

Routine Investigation: Hb, TLC, DLC, BT, CT, Skiagram, Chest PA view, ECG, Blood Urea, Sr. Creatinine, SGOT, SGPT, Fasting and random Blood Sugar.

A written informed consent was taken from patient for epidural block and drugs which were used, Procedure was explained to the patient.

(e) Groups :-The patients are randomly divided into three groups:-

Group -1:-These patients were injected epidural isobaric bupivacaine 0.5% (20 ml) with 5 ml normal saline (0.9%) keeping the total volume 25 ml.

Group -2:-These patients were injected isobaric bupivacaine 0.5% (20 ml) with 50 mg magnesium sulphate (which was diluted in 1 ml normal saline) with 4 ml normal saline (0.9%) keeping total volume 25 ml.

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Group -3:-These patients were injected with isobaric bupivacaine 0.5% (20 ml) with 50 microgram clonidine (diluted in 1 ml normal saline) with 4 ml normal saline (0.9%) keeping total volume 25 ml.

Epidural techniques

No premedication was given. all patients were preloaded with 500ml of ringer lactate. Epidural block was performed with 18g touhy needle at the L3-L4 or L4-L5 interspaces in the sitting position after back of patient painted with Povidineiodine,a subcutaneous wheal was raised by injecting 5ml of 2% lignocaine in supraspinous and interspinous ligaments. By using loss of resistance technique tuohy needle is placed in epidural space, under all aseptic precaution,after conforming the position of the touhy needle ,test dose given,then after 2 to 3 minutes, total dose of the desired solution was given slowly. Patients were injucted according to the random assignment. Then patients were placed in supine position with pillow under their shoulders. No head down tilt was given .The time of injection, onset of analgesia, level of sensory &motor block were noted.

- **Sensory blockade:-**sensory blockade was examined by pin prick method on abdomen, perineum, &lower limb by 25G disposable needle. The onset &leval of sensory blockade were noted
- **Motor blockade** was noted using modified bromage criteria

Intraoperative monitoring:-Following parameters were monitored every 5 minutes for first 30 minutes fallowed by every 10 minutes up to completion of surgery:-Pulse,Bloodpressure,Respiration (spo2:-saturation of blood pressure with oxygen),Sedation and Side effects.

Post operative monitoring: The following parameters such as pulse,BP,respiration and VAS score were monitored during early post operative period. These paremeters were noted at 30 minutes& then at1,2,3,8,12hrs up to 1st dose requirement of analgesic by patient (VAS socre>4)

End point of study:-

Time at which first dose of analgesia supplemented (with VAS score<4):-

Pain Scoring Scale (VAS scoring):-

It will be done by visual analogue technique which involves use of 10cm line divided into 10 equal parts, where in one end of the line represent "worst pain imaginable" while the other end represents "No pain at all". The patient related pain will be noted accordingly.

Visual Analogue Scale (VAS)
Score 0 : No Pain
Score 1,2,3, : Mild Pain
Score 4,5,6,: Moderate Pain
Score 7,8,9,: Severe Pain
Score 10: Worst Imaginable Pain

Motor Power Grading Scale:-

The Degree of Motor blockade of lower limbs will be assessed by modified bromage scale as follows:-

0. No Paralysis
1. Inability to raise the extended Knee,
2. Inability to flex the knee,
3. Inability to flex the ankle joint.
4. Complete paralysis.

Table no.1

The mean time of onset of sensory analgesia in three groups

Group	Mean+/-S.D.
Group 1	18.67+/-2.54
Group 2	17.33+/-2.86
Group 3	13.67+/2.54

The mean time of analgesia is least in Colonidine group. Table no. 1 shows that there is no statically significant difference between 1&2 group, but there is highly significant difference 1&3 group 2&3 groups

Time of onset of motor block:-The mean time for onset of motor block is least in Colonidine group. After comparing statistically, it shows that there is highly significant difference between group 1&2, 1&3, 2&3.

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Grade of motor block in three groups:-

Table 2

Compared groups	P value	interferance
1 & 2	0.73	Not Significant
1 & 3	0.04	Significant
2 & 3	0.04	Significant

Table no.2 shows that there is significant difference between group 1&3 and 2&3 but there is no significant difference between group 1&2 regarding motor block grade.

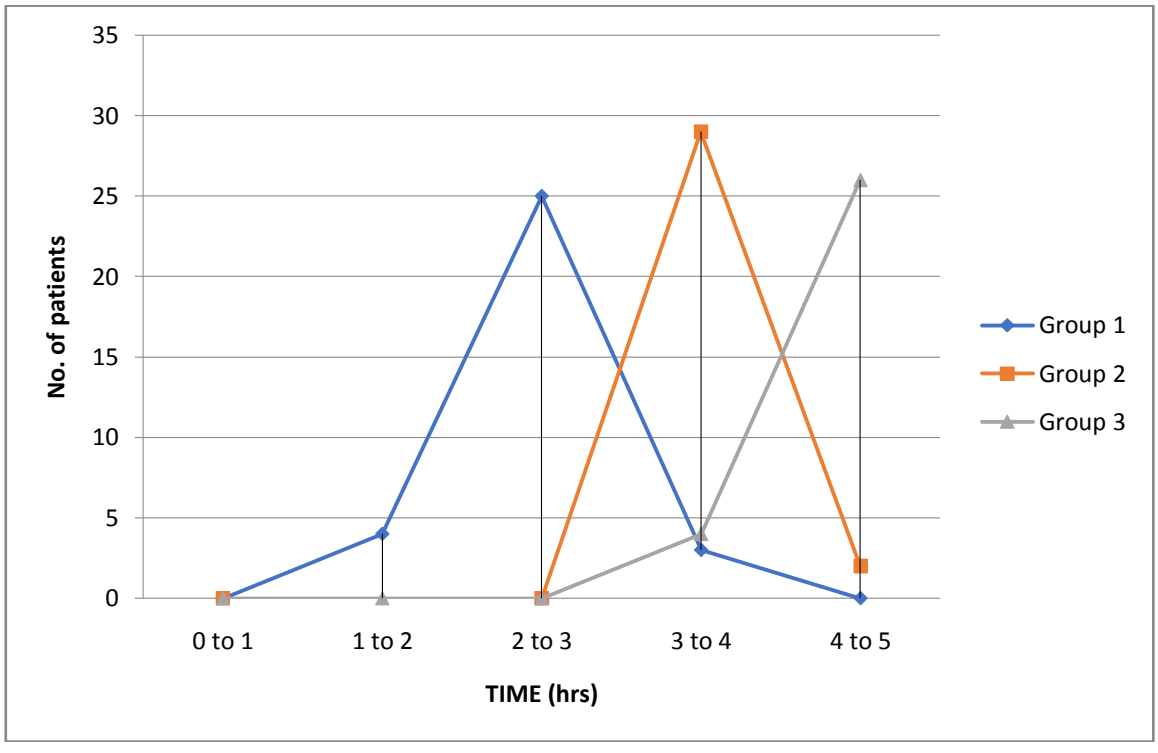
TIME FOR REGRESSION OF ANALGESIA TO L1

The mean time for analgesia to L1 segment in three groups

Table No.3

Group	Mean +/-S.D
Group 1	148+/-24.83
Group 2	196.9+/-10.95
Group 3	218+/-20.74

"p" value and significant in between three groups regarding time for regression of analgesia to L1 segment



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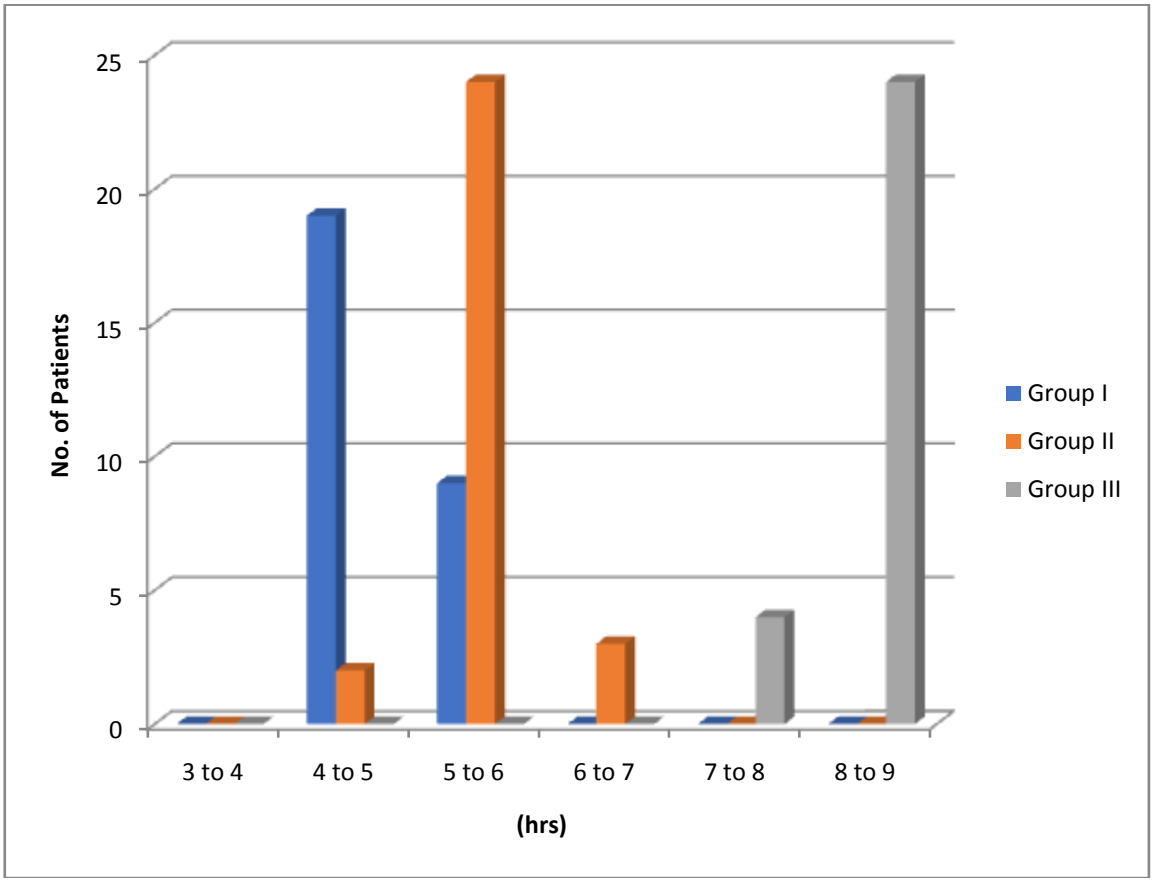
Total duration of analgesia:- The mean time of total duration of analgesia is maximum with Clonidine group. Table no 3 shows there is highly significant difference between three groups with least duration in Bupivacaine group.

P Value and its significance between three groups regarding total duration of analgesia:

Table no. 4

Compared Group	P Value	Interference
1 & 2	0.000	Highly significant
1 & 3	0.000	Highly significant
2 & 3	0.000	Highly significant

DURATION OF ANALGESIA



III. DISCUSSION:-

Epidural analgesia. Studies have proved that epidural analgesia for post operative analgesia are safe than parental route Pain during and also into the early post operative period is a problem of great concern to both patient and doctor. Pain not only misery to the patient but may also increase pulmonary complication and hypoxemia. (Spence and alekander1971).

Now a day's lot of surgery is done under epidural aneasthesia because less infection risk, Dural punctures headache and potential neurological toxicity as compared to spinal aneasthesia. It is convenient to administer epidural with local aneasthesia agents so as to prolong the analgesic effects into post operative period with advantage. This study was under taken to assess and compare the onset and duration of complete analgesia with epidural Bupivacaine alone and with epidural magnesium sulphate-Bupivacaine combination and Colonidine –Bupivacaine combination in patient undergoing major orthopedic lower limb surgeries. 90 patients were given epidural block; the patients were divided into three groups of 30 each, in control group 5ml normal saline was given with 20ml of 0.5% Bupivacaine. In group2,20ml 0.5% Bupivacaine with 50mg magnesium sulphate diluted in 1ml normal saline with 4ml additional normal saline. In group 3,20ml 0.5% Bupivacaine with 50mic.Colonidine diluted in 1ml normal saline with

additional 4ml normal saline. Total injected volume in three groups was 25ml.

Earlier studies with 10-20ml of 0.125% Bupivacaine, reports suggest a quite unacceptably high failure rate and brief duration of action, despite the addition of adrenaline (bleyart et al 1979).hence in our study we used 0.5% Bupivacaine. Besides this (tunsletall and ostheimer 1989) conclueded that a single dose of Bupivacaine upto 150mg may be given and doses upto 50mg two hourly may be added subsequently

Scott D,McclureJ,Giasi R et al 1980 concluded that increase in the concentration of epidural Bupivacaine in surgical patients from 0.5% to 0.75% with a concomitant increased in dosage from approximately 100 to 150 mg produced more rapid onset and prolong sensory aneasthesia, a grater frequency of satisfactory sensory aneasthesia and more profound motor blockade. so in our study by using high concentration and grater volume, we mask two major epidural drawback i.e late onset of analgesia and less motor block.

Our study showed similar result as seen in previous study done by Rucci et al, Reynolds et al (1989) , Klimscha et al (1985), Reynolds et al (1989)

andStrebel S(2004) et al and in respect of onset of analgesia ,duration of analgesia and regression of sensory analgesia to L1and gradeof motor blockade.

IV. CONCLUSION:-

After comparing the results of the three groups we see that by addition of magnesium sulphate and Colonidine to Bupivacaine in epidural aneasthesia, we have quicker time of onset of sensory and motor blockade, grater duration of analgesia, with no significant increase in side effects the effects are more pronounced with Colonidine group than the magnesium sulphate group. Thus Colonidine 50 microgram found to be an ideal and reliable combination for quicker onset of maximum duration of analgesia with minimal acceptable side effects , compared to 50mg of magnesium sulphate and Bupivacaine alone, however, the optimum drug and dose combination needed for maximum safe results perhaps demand more study on large scale so that more individualization can be achieved and the quality of aneasthesia improved further.

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