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ASSESSMENT OF EFFECTS OF EPIDURAL BUPIVACAINE VS EPIDURAL BUPIVACAINE WITH MAGNESIUM SULPHATE FOR PERIOPERATIVE ANALGESIA IN PATIENTS UNDERGOING LOWER LIMB SURGERY: A COMPARATIVE CLINICAL STUDY

Anaesthesiology

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ABSTRACT

BACKGROUND AND OBJECTIVES: Epidural anaesthesia is very safe and has the advantage of giving surgical anaesthesia and prolonged post operative analgesia. Common practice is to use polypharmacy and no drug is found to cause antinociceptive action without any side effects. The current study is to observe the role of supplemental magnesium a non expensive and relatively non harmful molecule for perioperative epidural analgesia.

MATERIALS AND METHODS: Sixty patients from either sex (age-20 to 60 years) undergoing lower limb surgery selected randomly in two groups each. Group : B (n=30) patients with height >160cm received total volume of 20ml(19ml of plain 0.5% Bupivacaine + Normal saline 1ml of 0.9%) and those with height <160cm received a total volume of 15ml(14ml of 0.5% Bupivacaine + Normal saline 1ml of 0.9%).On the other hand Group BM patients (n=30) with height>160cm received a total volume of 20ml (19ml of 0.5% bupivacaine + Magnesium sulphate 1ml containing 50 mg) and those with height <160cm received a total volume of 15ml (14ml of 0.5% Bupivacaine+ Magnesium sulphate 1ml containing 50mg) through the epidural route

RESULTS: Onset time, duration of anaesthesia, hemodynamics, side effects are measured. The time for onset of sensory block was significantly less in group BM compared to group B (p- value < 0.05).

CONCLUSION: The current study establishes that magnesium sulphate to epidural bupivacaine is very safe and can provide a rapid onset of anaesthesia.

KEYWORDS

Epidural anaesthesia, Bupivacaine, magnesium sulphate, analgesia

INTRODUCTION:

Epidural anaesthesia is a safe technique for surgical anaesthesia as well as well as for post operative analgesia. It has become a common practice to use polypharmacy approach for treatment of intra and post operative pain, because no drug has yet been identified that specifically inhibits nociception without associated side effects[1].

Noxious stimulus produces an influx of calcium ion through both voltage sensitive calcium channels that facilitates presynaptic release of neurotransmitters and post synaptic N-methyl D-aspartate calcium channels which triggers the sequence of events leading to cellular hyper excitability [2]. Studies in animal models of persistent pain in which central sensitization is present also support this theory [3].

Bupivacaine hydrochloride is one of the most widely used long acting anaesthetic drugs. When used in 0.5% and 0.75% concentration, it provides adequate surgical anaesthesia while analgesia can be obtained with concentrations as low as 0.125% to 0.25% [4].

Supplemental magnesium may provide perioperative analgesia because of its easy availability, less expenses and potential antinociceptive effect [5] that is based on physiological calcium antagonism and noncompetitive antagonism of N-methylD-aspartate (NMDA) receptors [6].

As, there is no ideal drug or combination of drugs for perioperative epidural analgesia and few studies are available, the present study is designed to compare epidural Bupivacaine vs Bupivacaine with magnesium sulphate to compare the efficacy in terms of onset, duration of sensory analgesia, anaethesia and motor block as well as safety regarding adverse drug reactions in two groups of patients undergoing elective lower abdominal surgery .

MATERIALS AND METHODS:

The present study was conducted in the Department of Anaesthesiology, of a tertiary care hospital of West Bengal for 1 year. It was an open randomized parallel group study. The Inclusion criteria were 1) Patients of ASA grade I and II, 2) age between 20-60 years, 3) both sexes, 4) undergoing elective lower limb surgery. The Exclusion criteria were 1) patients unwilling to give informed consent, 2) Local infection in the lumbar region, 3) Known hypersensitivity to amide local anaesthetic, 4) Bleeding diathesis, 5) Spinal deformity, 6) Diabetes Mellitus, 7) Known neurological, cardiac, renal, metabolic and psychological disorder.

Initially, 80 patients were enrolled; out of which 5 did not give consent, 8 did not follow inclusion and exclusion criteria and 7 failed to report on subsequent visits.

Informed consent was collected prior to inclusion in the study and the study protocol was approved by the institutional ethics committee.

Patients were visited on the pre-operative day for pre-anaesthetic checkup. Detailed history of present illness, past illness was recorded. Clinical examination of respiratory system, cardiovascular system, central nervous system and vertebral spine was done. Laboratory investigations were noted.

All the patients were kept fasting overnight after a light meal and received Tab Diazepam 10 mg orally night before surgery. Inj Metoclopramide 10 mg and Inj Ranitidine 50mg intramuscularly were administered 1 to 2 hours before operation.

All the patients were prepared with an intravenous line preloaded with 15ml-20ml/kg of Ringer's Lactate solution over 15 minutes before administering epidural block. Anaesthetic machine, breathing circuits, monitors, full range of drug and equipments including laryngoscope blade, endotracheal tubes and airways were kept in hand. A base line pulse rate, blood pressure, ECG, respiratory rate, SpO_2 was noted in OT.

Patients were randomized at a ratio of 1:1, according to the table generated by random allocation software into two groups.

After proper antiseptic dressing and draping in sitting position, 2ml of inj lignocaine 2% with adrenaline was used to infiltrate the skin and subcutaneous tissue at L_{2-3} or L_{3-4} interspace. After identification of epidural space properly, a test dose was administered with 3 ml of inj. Lignocaine hydrochloride 2% with adrenaline. Monitoring was done to note any haemodynamic changes.

After ensuring proper epidural placement of the needle tip, the study drug was slowly injected in small increments with repeated aspiration test as per protocol. The patients were made supine. No other analgesic was given to the patients intraoperatively. The patients were administered O_2, 3 L/min through face mask. The surgery was allowed after 20 minutes of epidural injection.

Group : B (n=30) patients with height >160cm received total volume of

20ml(19ml of plain 0.5% Bupivacaine + Normal saline 1ml of 0.9%) and those with height <160cm received a total volume of 15ml(14ml of 0.5% Bupivacaine + Normal saline 1ml of 0.9%).On the other hand Group : BM patients (n=30) with height>160cm received a total volume of 20ml (19ml of 0.5% bupivacaine + Magnesium sulphate 1ml containing 50 mg) and those with height <160cm received a total volume of 15ml (14ml of 0.5% Bupivacaine+ Magnesium sulphate 1ml containing 50mg) through the epidural route.

A. Efficacy assessment:

1. **Onset of Sensory Block:** Assessed by pin prick every 3 minutes. Time duration (minute) was assessed from local anaesthetic solution injection to start of loss of pain sensation to pin prick.
2. **Duration of Sensory Block:** Assessed every 15 minutes postoperatively by pin prick. Time duration (minute) was assessed from onset of sensory block to regression of dermatome of two segments.
3. **Duration of Analgesia :**

a) Assessed every 15 minutes postoperatively by four point verbal rating scale to record observer measurement of pain. The scores are as follows: 1 - comfortable (no pain), 2 - mild pain (elicited only by close questioning), 3 - moderate pain (bothering the patients but often controlled by lying still, analgesic accepted gladly), 4 - severe pain (dominating consciousness and calling out for urgent relief). Time duration (minute) was assessed from onset of sensory block to first request for rescue analgesic (i.e. pain score 3 or more).

Rescue analgesic injection Diclofenac sodium 1.5mg/kg was given intramuscularly. The number of rescue analgesics in 24 hours from administration of epidural anaesthesia was also noted.

b) Assessed by 10 cm Visual Analogue Scale (VAS) at the time of request of analgesic by the patients. Numeric pain scale 0-10. 0 - no pain, 10 - worst possible pain.

4. Height of Block: Assessed by pin prick over dermatomal segments.
5. Postoperative Analgesia : Assessed by using Four point Verbal Rating Scale and Visual Analogue Scale (VAS) which is essentially a numeric pain scale - 0 - 10. 0 - no pain, 10 - worst pain possible.
6. Onset of Motor Block : Assessed every 3 minutes by modified Bromage scale as follows: 0 - no paralysis, 1- inability to raise extended leg, 2- inability to flex knee, 3- Inability to flex ankle and first toe. Time duration (minute) was assessed from the time of injection of local anaesthetic solution to achieve motor scale 2 or more.
7. Duration of Motor Block: Assessed by modified Bromage scale every 15 minutes post operatively. Time duration (minute) was assessed from onset of motor block to regaining of full motor power and joint movement.
8. Haemodynamic parameters: Heart rate, Systolic BP, Diastolic BP, Respiratory rate were noted at 0, 15, 30, 60, 75, 90, 120, and at 240 mins from administration of epidural anaesthesia.

B. Tolerability assessment: Nausea, vomiting, hypotension, shivering, headache, etc were noted.

Finally, all the data were analyzed by using SPSS version-12 for Mean±SD, unpaired student t test, chi-square test and Fisher exact t test. P value <0.05 was taken to be statistically significant.

RESULT:

Total 60 patients of both sexes were studied and randomly placed into two groups. The demographic parameters like age, weight, height and duration of surgery were presented in terms of mean ± SD in table-1.

Table-1: showing demographic parameters & duration of surgery in two groups

Features	Group-1	Group-2	p-value
Age (yrs)	34.2667±11.63506	34.2000±11.35751	0.982160
Weight (kg)	58.4333±8.58500	57.1000±9.16647	0.563159
Height (cm)	151.7000±7.45168	151.9667±8.19370	0.895538
Duration of surgery (min)	96.8333±17.93106	96.6667±19.71055	0.972788

Table-2 showed inter group comparison of onset and duration of sensory and motor block, duration of analgesia, visual analogue score, verbal rating score and number of rescue doses. Onset of sensory block and number of rescue doses were significantly lower in group- BM patients (p-value <0.05).

Table-2: showing onset and duration of sensory and motor block, duration of analgesia, visual analogue score, verbal rating score and number of rescue doses in two groups.

Features	Group-1	Group-2	p-value
Onset of sensory block (min)	15.57± 2.27	12.93 ±1.14	0.0001
Onset of motor block (min)	22.9333 ± 2.19613	22.4333 ± 2.22344	0.384477
Duration of sensory block (min)	137.17 ± 22.40	142.17 ± 20.71	0.59
Duration of motor block (min)	191.0000 ± 15.16575	192.1667 ± 15.06785	0.766082
Duration of analgesia (min)	236.17± 21.28	241 ± 10.62	0.27
Visual analogue scale score	5.0667±0.82768	5.0333 ± 0.80872	0.875183
Verbal rating scale score	3.3667± 0.49013	3.2000 ± 0.40684	0.157193
Rescue doses (number)	2.6 ± 0.82	2.0 ± 0.86	0.005

Intergroup comparison of adverse effects (nausea/vomiting, shievering, sedation and headache) was presented in table -3. There was no significant change in two groups.

Table-3: showing adverse effects in two groups

Side effects	Group 1	Group 2	Significance (p value)
Nausea and vomiting	4 (13.33%)	7(23.33%)	0.506
Shievering	2(6.67%)	3(10.00%)	1.000
Sedation	2(6.67%)	1(3.33%)	1.000
Headache	2(6.67%)	1(3.33%)	1.000

Figure: 1,2,3,4 showed hemodynamic parameters (heart rate, systolic and diastolic blood pressure and respiratory rate). A decreasing trend in heart rate, systolic and diastolic blood pressure was observed in both the groups initially during intra operative period. But this fall were within normal range.

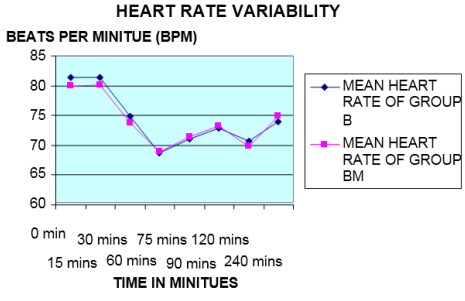

Fig-1: showing heart rate variability between two groups

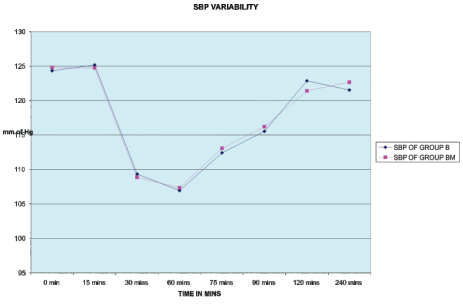

Fig- 2: showing systolic BP variability between two groups

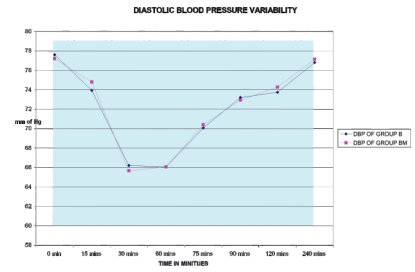

Fig-3: showing diastolic BP variability between two groups

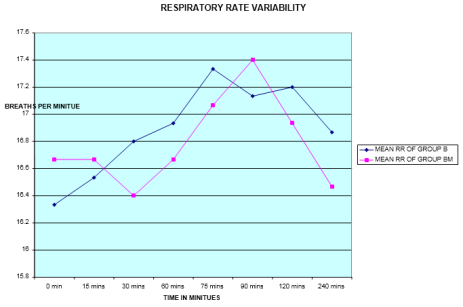

Fig-4: showing respiratory rate variability between two groups

DISCUSSION:

The demographic profile (Age, height, weight) and duration of surgery (mins) were comparable in two groups of the patients (p- value > 0.05). There were no significant differences in onset of motor block, duration of sensory and motor block and height of the block achieved in two groups of patients. But the time for onset of sensory block was significantly less in group 2 compared to group 1 (p- value < 0.05). This finding is corroborative with the study done by ghatak et al (7).

So far analgesia is concerned, the duration of analgesia (mins), the visual analogue scale (VAS) score and the verbal rating scale (VRS) score were comparable in two groups of patients. But, the number of rescue doses of analgesics after 24 hours of administration of epidural anaethesia is significantly less for group- 2 patients compared to group-1 (p-value <0.005). This is quite similar to other studies (8, 9, 10, 11, 12).

The primary mechanism of action of MgSO4 being antagonism of NMDA receptors, it can be postulated that quicker onset of sensory block and reduction of number of rescue doses of analgesics after 24 hours of administration of epidural anaethesia in the patients of group-2 (MgSO4 with Bupivacaine) may be due to the direct effects on the nerve roots in the epidural space alone.

Regarding hemodynamic parameters, a decreasing trend in heart rate, systolic and diastolic blood pressure was observed in both the groups initially during intra operative period. But this fall were within normal range. No case of hypotension (reduction of blood pressure > 20% of base line) was found. However hypovolemia was not allowed during perioperative period with infusion of Ringer's Lactate solution (as hypovolemia is not tolerated in patients with sympathetic block). The fall in blood pressure, often accompanied by reduction in heart rate, is usual after epidural block. The gradual fall of blood pressure in epidural block may be due to slow spread of block and there is more time for auto compensation to occur.

There was no significant difference in respiratory rate in the two groups in the peri - operative period.

Regarding adverse effects, incidence of nausea and vomiting, shivering is less in group-1 compared to group-2 whereas incidence of headache and sedation was less in geoup-2 patients. But the difference is comparable in both the groups (p-value >0.05).

CONCLUSION:

So, it may be concluded that, 1) Magnesium sulphate is quite effective in the field of epidural anaesthesia as add on therapy to Bupivacaine hydrochloride. 2) A single dose epidural administration of 0.5% Bupivacaine hydrochloride with 50 mg Magnesium sulphate produces predictable rapid onset sensory block with less number of rescue doses of analgesics required after 24 hours of administration of epidural anaesthesia than plain 0.5% Bupivacaine hydrochloride.

These findings also paves the way for further studies in perioperative analgesia of patients undergoing major abdominal or lower limb surgery.

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