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LOWER ABDOMINAL SURGERIES- A RANDOMIZED DOUBLE BLINDED CONTROLLED TRIAL

ABSTRACT Background; Intrathecal administration of magnesium sulphate produces spinal anaesthesia that includes profound motor and sensory blockage without any permanent and untoward effects.

Aim of this study is to evaluate the effect of intrathecal magnesium sulphate as an adjuvant to bupivacaine-fentanyl in patients undergoing elective lower abdominal surgeries.

Materials and Methods; This randomized controlled trial conducted among 50 patients belongs to ASA I and II, age ranged from 23-68 years, weighing 35-65 kg and height ranging from 150-168 cms. Patients were randomly allocated to two groups of 25 each GROUP S received 2ml 0.5% Bupivacaine(10mg) and 0.5 ml fentanyl (25 mcg) and 1 ml NS, GROUP M received 2ml 0.5% Bupivacaine and 0.5ml fentanyl (25 mcg) and 1 ml NS, GROUP M received 2ml 0.5% Bupivacaine and 0.5ml fentanyl (25 mcg) and 1 ml NS, GROUP M received 2ml 0.5% Bupivacaine and 0.5ml fentanyl (25 mcg) and 1 ml NS, GROUP M received 2ml 0.5% Bupivacaine and 0.5ml fentanyl (25 mcg) and 1 ml NS, GROUP M received 2ml 0.5% Bupivacaine and 0.5ml fentanyl (25 mcg) and 1 ml NS, GROUP M received 2ml 0.5% Bupivacaine and 0.5ml fentanyl (25 mcg) and 1 ml NS, GROUP M received 2ml 0.5% Bupivacaine and 0.5ml fentanyl (25 mcg) and 1 ml NS, GROUP M received 2ml 0.5% Bupivacaine and 0.5ml fentanyl (25 mcg) and 1 ml NS, GROUP M received 2ml 0.5% Bupivacaine and 0.5ml fentanyl (25 mcg) and 1 ml NS, GROUP M received 2ml 0.5% Bupivacaine and 0.5ml fentanyl (25 mcg) and 1 ml NS, GROUP M received 2ml 0.5% Bupivacaine and 0.5ml fentanyl (25 mcg) and 1 ml NS, GROUP M received 2ml 0.5% Bupivacaine and 0.5ml fentanyl (25 mcg) and 1 ml NS, GROUP M received 2ml 0.5% Bupivacaine and 0.5ml fentanyl (25 mcg) and 1 ml NS, GROUP M received 2ml 0.5% Bupivacaine and 0.5ml fentanyl (25 mcg) and 1 ml NS, GROUP M received 2ml 0.5% Bupivacaine and 0.5ml fentanyl (25 mcg) and 1 ml NS, GROUP M received 2ml 0.5% Bupivacaine and 0.5ml fentanyl (25 mcg) and 1 ml NS, GROUP M received 2ml 0.5% Bupivacaine and 0.5ml fentanyl (25 mcg) and 1 ml NS, GROUP M received 2ml 0.5% Bupivacaine and 0.5ml fentanyl (25 mcg) and 1 ml NS, GROUP M received 2ml 0.5% Bupivacaine and 0.5ml fentanyl (25 mcg) and 1 ml NS, GROUP M received 2ml 0.5% Bupivacaine and 0.5ml fentanyl (25 mcg) and 1 ml NS, GROUP M received 2ml 0.5% Bupivacaine and 0.5ml fentanyl (25 mcg) and 1 ml NS, GROUP M received 2ml 0.5% Bupivacaine and 0.5ml

Results; The age, sex, height, weight, were similar in both groups. There is no statistical difference between two groups in onset of sensory, motor blockade and duration of motor blockade. Duration of analgesia was prolonged in Group M when compared to Group S (P VALUE 0.083). P Value <0.05 was considered significant.

Conclusion; In this study, it is inferred that intrathecal magnesium when added to Bupivacaine and Fentanyl prolonged period of analgesia without increasing the incidence of side effects in patients undergoing elective abdominal surgeries.

KEYWORDS: Motor block, Sensory block, Mgso₄, Fentanyl.

INTRODUCTION:

Spinal analgesia was first performed by august bier on 16^{th} august 1898 when he injected 3ml of 0.5% cocaine intrathecally. spinal anaesthesia, is easy to perform and has got a definite end point for successful positioning of needle. The spinal analgesia is rapid in onset and the spread of analgesic can be controlled. It requires a small dose of local anaesthetic yet produces profound sensory and motor blockade.

Ever since the introduction of local anaesthetics, diverse classes of drugs such as epinephrine, opioids, clonidine, neostigmine, and benzodiazepines have been added as adjuvants to LA in an attempt to prolong analgesia and reduce incidence of side effects.^(1,2,3)

Magnesium has been called "Nature's physiological calcium channel blocker". Parenteral magnesium has been used for many years on an empirical basis for intraoperative and postoperative analgesia.⁽⁴⁾

Although systemic magnesium decreases postoperative opioid requirement, its intrathecal use has not been evaluated clinically. However it has been safely used in humans and its safety profile has been documented by histopathological analysis in experimental studies.⁽⁵⁾

In 1906 Haubold and Meltzer showed that intrathecal administration of magnesium sulphate produces spinal anaesthesia that includes profound motor and sensory blockage without any permanent and untoward effects.

Spinal (SAB/intrathecal) anaesthesia is a form a central neuraxial block in which a temporary interruption of nerve transmission of nerve transmission is achieved following injection of LA and/or adjuvant solutions into SA space.^(6,7) Spinal anaesthesia is most frequently employed methods of Regional anesthesia.^(8,9)

Injection of LA solution into spinal CSF allows access to sites of action both within spinal cord and peripheral nerve roots. The nerve roots leaving spinal canal are not covered by epithelium and are readily expose to LA within CSF. Therefore afferent impulse leaving via venteral nerve roots are blocked during spinal anesthesia.^(10,11,12) LA block Na channel and electrical conduction in spinal nerve roots. There are also multiple potential actions of LA within spinal cord at different sites.^(13,14) LA can exert Na channel block within the dorsal and ventral horns inhibiting generation and propagation of electrical activity.⁽¹⁵⁾

In this prospective randomised double blind controlled study we evaluated the effect of adding intrathecal magnesium sulphate to bupivacaine and fentanyl in patients undergoing elective lower abdominal surgeries.

AIM OF THE STUDY:

To evaluate the effect of intarthecal magnesium sulphate as an adjuvant to bupivacaine-fentanyl in patients undergoing elective lower abdominal surgeries.

METHODS AND MATERIALS:

After approval of the study by institutional ethical committee, the study was conducted in Govt. Theni Medical College, Theni. Fifty patients belonging to ASA I and II, age ranging from 23-68 years, weighing 35-65 kg and height ranging from 150-168 cms. Patients with significant coexisting diseases, long term opioid use, contraindication to RA were excluded from this study. VAS was explained to the patients and patients were randomly allocated to two groups of 25 each,

GROUP S: 2ml 0.5% Bupivacaine(10mg) 0.5 ml fentanyl (25 mcg) 1 ml NS GROUP M: 2ml 0.5% Bupivacaine 0.5ml fentanyl (25mcg) 1 ml MgSO4(50 mg)

Total volume of injected solution was 3.5 ml in both groups. Onset of sensory blockage was defined as time between injection of drug and absence of pain at T10 dermatome.

Motor block; Motor block was assessed by using Modified bromage scale.

Modified bromage scale;

0- No block. Able to raise extended lega against gravity.

- 1- Unable to raise extended leg, able to flex knees
- 2- Unable to flex knees, able to flex ankle
- 3- Total block. Inability to flex ankle/move leg.

The onset of motor block defined as time to achieve bromage score of 1 from time of injection. Duration of motor block is taken as time from drug injection to return of 0 scale.

Vitals signs and side effects:

BP, PR, SpO2 were recorded 2 minutes for first 10 minutes, and thereafter every 5 minutes till immediate postoperative period. Hypotension was defined as fall in SBP>30% from baseline. This was managed with IV ephedrine in incremental dose of 6mg. Bradycardia was defined as HR< 60/min and managed with IV atropine in titrated doses.

Respiratory depression was defined as RR <8/minute or SpO2 <85% and this was planned to be managed with mask ventilation and IPPV.

Table-8 INCIDENCE OF SIDE EFFECTS

Vomiting was managed with Inj.Ondansetrone 8 mg IV. Pruritis was managed with Inj.Pheneramine maleate 22.75mg IV. Urinary retention monitored postoperatively and catheterised was planned, if retention was more than 6 hours.

Patents were monitored for 24hrs to detect any side effects like respiratory depression, urinary retention, pruritis, nausea and vomiting. Motor block was assessed till bromage score of 0 was reached.

DURATION OF ANALGESIA:

The time at which patient first complaints of pain is noted. Duration of effective analgesia defined as from drug injection to first when patient complaints of pain in the postoperative period.

The collected data was analysed with SPSS 16.0 version. Percentage analysis were used for categorical data and for continuous variables mean and SD were used. Chi square and student t test were used to find the significance. P value < 0.05 was considered significant.

OBSERVATION AND RESULTS: Table-1 AGE DISTRIBUTION

AGE (YEARS)	GROUP S	GROUP M
MINIMUM	24	23
MAXIMUM	65	68
MEAN	41.36	41.92

Table-2 SEX DISTRIBUTION:

SEX	GROUP S	GROUP M
MALE	14	13
FEMALE	11	12
TOTAL	25	25

Table-3 WEIGHT DISTRIBUTION:

WEIGHT(KG)	GROUP S	GROUP M
RANGE	35-64	35-65
MEAN	47.96	47.28

Table-4 HEIGHT DISTRIBUTION:

HEIGHT(CM)	GROUP S	GROPU M
RANGE	150-164	150-168
MEAN	155.76	155.32

Of fifty patients, 25 belongs to Group S and other 25 belongs to Group M. Mean Age distribution (group S 41.36 and group M 41.92), Sex distribution (group S 25 and group M 25), Weight distribution (group S 47.96 and group M 47.28), Height distribution (group S 155.76 and group M 155.32) were statistically comparable in both groups.

Table-5 SENSORY BLOCKAGE:

SENSORY BLOCKAGE (MINUTES)	GROUP S	GROUP M	P VALUE
ONSET	4.28+/-0.98	4.48+/-0.96	0.470

There is no statistically significant difference between two groups in onset of sensory block (P Value 0.470).

Table-6 MOTOR BLOCKAGE:

MOTOR BLOCK(MINUTES)	GROUP S	GROUP M	P VALUE
ONSET	5.08+/-0.86	5.24+/-0.78	0.494
TIME FOR MOTOR	130.36+/-10.4	131.4+/-10.5	0.936
RECOVERY			

There is no statistically significant difference between two groups in onset of motor block (P Value 0.494) and duration of motor block (P Value 0.936).

Table-7 DURATION OF ANALGESIA:

	GROUP S	GROUP M	P VALUE
DURATION OF	141.48+/-11	154.56+/-11.1	0.083
ANALGESIA			
(MINUTES)			

Duration of analgesia in Group M was significantly prolonged when compared to Group S (P Value 0.083).

SIDE EFFECTS GROUP S GROUP M			
GROUP S	GROUP M		
4	3		
3	3		
5	6		
3	4		
-	-		
-	-		
12	13		
	GROUP S 4 3 5 3 - - 12		

From the above finding it is clear that the incidence of side effects were similar in both the groups.

DISCUSSION:

The primary aim of this study was to evaluate the effect of adding magnesium sulphate to bupivacaine and fentanyl spinal anaesthesia. Simpson et al and Kroin et al demonstrated in animals that intrathecal magnesium has safety profile. M.Ozalevli et al and Buvendran et al demonstrated no delirious effects in humans on administartion of intarthecal magnesium sulphate.

The dose of magnesium used in this study was based on data from M.Ozalevli et al and Buvendran et al where 50 mg of magnesium potentiated opioid analgesia. The dose of magnesium was based on data from rat model of postoperative pain in which 188 mcg of intrathecal magnesium sulphate potentiated morphine antinociception done by Kroin et al. Based on relative diffrences between human and rat CSF volume and body weight, the 188 mcg dose was conservatively extrapolated to 50 mg for humans.

The results in this study correlates with study done by M.Ozalevli et al who concluded that addition of intrathecal magnesium sulphate to Bupivacaine and Fentanyl prolonged period of analgesia.

This also correlates with study done by Buvendran et al who concluded that magnesium when administered intrathecally prolonged duration of spinal opioid analgesia in humans.

CONCLUSION:

This study concludes that intrathecal magnesium sulphate when added to Bupivacaine and Fentanyl prolonged period of analgesia without increasing the incidence of side effects in patients undergoing elective abdominal surgeries.

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