Original Article ISSN (O):2395-2822; ISSN (P):2395-2814

A Clinical Comparison between Intrathecal and Intravenous Infusion of Magnesium Sulphate as an Adjuvant to Hyperbaric 0.5% Bupivacaine in Spinal Anaesthesia for Elective Infraumbilical Surgeries.

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Received: January 2017
Accepted: January 2017

ABSTRACT

Background: This study was conducted to compare the effects of intrathecal magnesium and intravenous infusion of magnesium sulphate as adjuvants to bupivacaine for intrathecal anaesthesia. **Methods**: A prospective, randomized, double-blinded, placebo controlled study was planned in 90 patients of physical status ASA I and II, aged between 18 to 55 years, scheduled to undergo elective surgery below the level of umbilicus. Patients were randomly assigned into three equal groups A,B & C (n=30 per group) according to a computer generated list. Group A received 15mg of 0.5% bupivacaine + 0.15ml of 50% magnesium sulphate (75mg) + 0.35ml of sterile water, Group B received 15mg of 0.5% bupivacaine + 0.5ml sterile water + a bolus dose of magnesium sulphate 50mg/kg in 100ml saline over 10 minutes followed by a continuous infusion of 15mg/kg/hr until the end of the surgery and group C received 15mg of 0.5% bupivacaine + 0.5ml sterile water (Placebo). Preoperative serum magnesium levels were checked, and repeated at 6h and 24hrs postoperatively. **Results:** Time to 2 segment regression of sensory block, duration of spinal anaesthesia as well as duration of effective analgesia were significantly prolonged in intrathecal as well as intravenous magnesium as compared to placebo. Intrathecal or intravenous magnesium were not associated with significant side effects.**Conclusion**: Co-administration of intravenous or intrathecal Mg given to patients undergoing spinal anesthesia for elective infraumbilical surgeries could improve pain control for the first 24 h after surgery. Intrathecal as well as intravenous magnesium sulphate significantly prolonged the time for the first analgesic request, thus substantiating their use in postoperative analgesia.

Keywords: Analgesia, Intrathecal, Magnesium Sulphate.

INTRODUCTION

Spinal anaesthesia is the primary anaesthetic technique for many types of surgery. Recent developments in spinal anaesthesia have led to greater patient satisfaction and accelerated functional recovery[1]. Currently new ways of decreasing postoperative analgesic requirements are of special interest.

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Adjuvants are drugs that increase the efficacy or potency of other drugs when given concurrently. Neuraxial adjuvants are used to improve or prolong analgesia and to decrease the adverse effects associated with high doses of a single local anaesthetic agent. In addition to their dose sparing effects neuraxial adjuvants are also utilized to increase the speed of onset of neural blockade (reduce latency), improve the quality and prolong the duration of neural blockade[2].

The suggestion that regionally applied opioids might be effective as analgesics dates back to the mid nineteenth century. Since then a number of other adjuvants have been introduced to improve the efficacy of neuraxial analgesia, including NMDA antagonists (Ketamine), GABA agonists (midazolam), adrenergic agonists (clonidine, dexmedetomidine and adrenaline), acetyl-choline esterase inhibitors (neostigmine) etc[3]. The direct application of receptor specific therapeutics at the spinal cord can potentially interrupt pain pathways and limit systemic side effects[4]. However, each drug has its own limitations. Our specialty is still looking for the ideal adjuvant – long acting and without side effects and the search continues!

Magnesium has a non-competitive N-methyl D-Aspartate (NMDA) receptor antagonist activity with

antinociceptive effects in animals and human models[5]. Magnesium has been used as an anticonvulsant for the treatment of preterm labour, preeclampsia and eclampsia, myocardial protection after ischemia, hemodynamic stability during endotracheal intubation, and severe attacks of bronchial asthma. However, intravenous magnesium even at higher doses has limited passage across the blood brain barrier to act on NMDA channels[6].
Intrathecal as well as intravenous administration of magnesium has been reported to prolong duration of anaesthesia[7], potentiate opioid nociception[8] and reduce postoperative opioid consumption[9]. Unlike opioids it is not associated with pruritus, respiratory depression, sedation etc[10]. Keeping this in mind, this study was conducted to compare the effects of intrathecal magnesium and intravenous infusion of magnesium sulphate as adjuvants to bupivacaine for intrathecal anaesthesia.

MATERIALS AND METHODS

Hospital ethics committee clearance was obtained for this study. Informed written consent was taken from all patients.

Source of Data
Adult patients (18-55yrs) of physical status ASA I & II scheduled to undergo elective surgical procedures below the level of umbilicus under spinal anaesthesia at M.K.C.G Medical College during the period November 2013 to October 2015.

Study Design
A prospective, randomized, double-blinded, placebo-controlled study was planned in 90 patients of physical status ASA I and II, aged between 18 to 55 years, scheduled to undergo elective surgery below the level of umbilicus and who satisfy all the inclusion criteria.

Inclusion Criteria
- ASA I & II
- Aged between 18 and 55 years
- Patients giving informed consent
- Patients scheduled to undergo elective surgical procedures below the level of umbilicus under spinal anaesthesia.

Exclusion Criteria
- Contraindications to regional anaesthesia
- Extremes of age (<18 &>55years)
- ASA III & ASA IV
- History of seizures
- History of allergy to magnesium sulphate or bupivacaine
- History of magnesium therapy prior to surgery
- History of central or peripheral neuropathies
- Unwillingness to regional anaesthesia

METHODS
- All the patients satisfying the inclusion criteria were assessed before the day of surgery with a detailed history, general physical examination and systemic examination. Airway assessment and spinal column examination were done. Informed written consent was obtained. Patients were pre-medicated with Tab. Diazepam (0.2mg kg-1) orally on the night before the surgery and were kept fasting overnight. Patients were randomly assigned into three equal groups A,B & C (n=30 per group) according to a computer generated list. The procedure was double blinded and randomization was maintained by the pharmacist.
- In the operation theatre, standard monitoring equipment such as pulse oximetry, ECG and NIBP were applied, and baseline recordings were obtained. Intravenous access was obtained by cannulating a peripheral vein with an 18G IV cannula and the patient was preloaded with Normal Saline (10ml/kg body weight)
- Ampoules of 0.5% hyperbaric bupivacaine (Sensorcaine, AstraZeneca Laboratories, Bangalore, India) and Magnesium sulphate 50% (MagNeon, Neon Laboratories, Mumbai, India) were used in this study.
- Patients in group A received 15mg of 0.5% heavy bupivacaine + 0.15ml of 50% magnesium sulphate (75mg) + 0.35ml of sterile water.
- Patients in group B received 15mg of 0.5% heavy bupivacaine + 0.5ml sterile water + a bolus dose of magnesium sulphate 50mg/kg in 100ml of isotonic saline IV over 10 minutes followed by a continuous infusion of 15mg/kg/hr until the end of the surgery
- Patients in group C received 15mg of 0.5% heavy bupivacaine + 0.5ml of sterile water (Placebo)
- The total drug volume in all three groups was the same (3.5ml). All injections were done at the rate of 0.2ml/sec and solutions were at room temperature. The drugs were loaded by an independent colleague and both the patient and the anaesthetist were blinded to the procedure. After injection of the drug, the patient was made supine, the head end was tilted 5 degrees down, and the parameters were observed and recorded by the anaesthetist.
- In patients who developed hypotension, which was defined as a fall in BP>20% of the basal value or <90mmHg of systolic BP or in the presence of symptoms like nausea, vomiting and dizziness, increments of Inj.

Ephedrine 5mg were administered intravenously. If patients developed bradycardia (HR< 60bpm), increments of Inj. Atropine 0.3mg were administered intravenously. Rescue analgesia was given using Inj. Paracetamol 1gm/6hrs intravenously if the Visual Analogue Scale (VAS) score for pain was greater than three. After completion of the study, the drug solutions were revealed to the anaesthetist.

The Parameters Observed Were:

1. **Sensory Blockade:** assessed by pinprick bilaterally along the mid clavicular line every 15 sec till 30 min and every 10 minutes thereafter
   - Onset of analgesia(min): defined as onset of analgesia to T6
   - Duration of analgesia/sensory block: defined as time taken to two segment regression from the maximum height(T6)
   - Maximum level of sensory block
   - Time taken to attain maximum level of sensory block
   - Need for rescue analgesia during surgery
2. **Motor Blockade:** every 15sec till Bromage 3
   - Estimation using Modified Bromage Scale (0-3)
     [0 – No paralysis (able to flex hip, knee and ankle);
     1 – Able to flex knee, unable to raise leg;
     2 – able to flex ankle, unable to flex knee;
     3 – unable to flex ankle, knee or hip]
   - Time of onset of complete motor block (min)
   - Time to recovery from complete motor block (min)
3. **Duration of effective analgesia:** defined as time from intrathecal/intravenous administration of drug to tie of first analgesic request
4. **Assessment of postoperative pain using Visual Analogue Scale:** the patient was asked to mark on a 10cm horizontal scale with no pain corresponding to zero at one and the worst unbearable, excruciating pain at the other end. This was explained to the patient in his/her vernacular language. The time when VAS score reached 3 was noted, and rescue analgesic was administered.
5. All time durations were calculated from the time of injection of spinal anaesthetic considered as time zero
6. Pulse rate, blood pressure and respiratory rate were recorded every 5 min for the initial 30 min, every 15 min thereafter until the end of the surgery, and every 30 minutes during the first 6 hours of the postoperative period.
7. Other side effects like hypotension, bradycardia, respiratory depression, drowsiness, nausea, vomiting, pruritus were noted.
8. Preoperative serum magnesium levels were checked in each patient on the day before surgery, and then blood samples for measuring serum magnesium were obtained, at 6h and 24hrs after surgery.

Statistical Analysis

Statistical analysis was done using Prism 5.0a (GraphPad Soft- ware, Inc.)One-way analysis of variance (ANOVA) was used for comparisons between groups. A p value of <0.05 was considered statistically significant.

RESULTS

Table 1: Demographic Data (mean & SD) between the three groups was not found to be statistically significant.

	Group A (IT Mg)(n=30)	Group B (IV Mg)(n=30)	Group C (Control)(n=30)
Age (Years)	42.23 (9.19)	42.63 (9.21)	37.80 (9.73)
Weight (kg)	55.50 (6.56)	56.10 (6.32)	54.63 (7.54)
Height (cm)	161.47 (5.42)	161.37 (4.45)	163.53 (6.18)
Sex (male/ female)	17/13	16/14	17/13
ASA (I /II)	22/8	20/10	23/7
Duration of surgery	75.00 (26.42)	71.00 (25.31)	72.50 (23.59)

Table 2: Comparison of three groups with respect to maximum sensory level attained.

Level	Gp A	%	Gp B	%	Gp C	%	Total
T4	4	13.3	6	20.0	4	13.3	14
T5	12	40.0	13	43.3	6	20.0	31
T6	5	16.7	9	30.0	9	30.0	23
T7	9	30.0	2	6.7	11	36.7	22
T8	0	0.0	0	0.0	0	0.0	0
Total	30	100.0	30	100.0	30	100.0	90
Chi – square = 16.3362, p = 0.0378*							

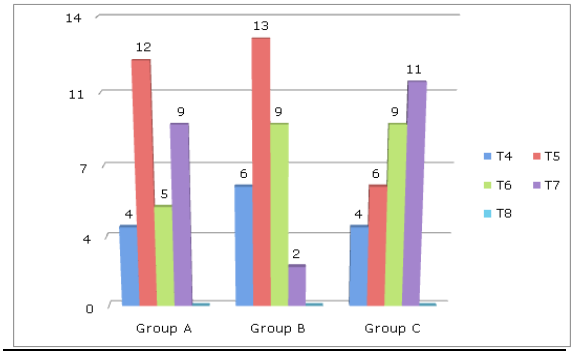

Figure 1: With respect to highest level of sensory block attained, the median was T5 for Group B and Group C, and T6 for Group A. The range was T4-T6 for Group B and Group C, and T5-T7 for Group A. On pairwise comparison, the difference in levels obtained between group B and Group C was found to be statistically significant.

Table 3: Comparison of three groups with respect to time to 2 segment regression(min).

Groups	Mean	SD
Group A	127.2	10.32
Group B	131.6	11.46
Group C	77.84*	8.65*

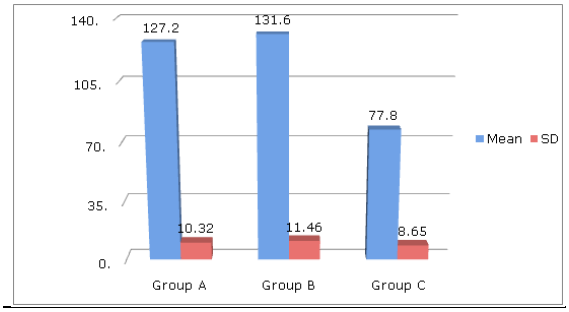

Figure 2: The mean duration of regression of sensory block by 2 segments from the highest level attained was 127.2 minutes in Group A with a SD of 10.32, 131.6 minutes in Group B with a SD of 11.46 and 77.84 minutes with a SD of 8.65 in Group C. After applying ANOVA, the difference in mean duration between Group C and Group A as well as Group B was found to be statistically significant.

Table 4: Comparison of three groups with respect to duration of spinal anaesthesia (min).

Groups	Mean	SD
Group A	299.7	18.31
Group B	303.7	21.77
Group C	227.1*	16.26*

The mean duration of spinal anaesthesia was 299.7 minutes in Group A, 303.7 minutes in Group B and 227.1 minutes in Group C. After applying ANOVA, the difference in mean between Group C and Group A as well as Group B was found to be statistically significant.

Table 5: Comparison of three groups with respect to time to first analgesic request (min).

Groups	Mean	SD
Group A	242	9.78
Group B	238	9.5
Group C	185*	6.44*

The mean time to first analgesic request was 242 minutes in Group A, 238 minutes in Group B and 185 minutes in Group C. After applying ANOVA, the difference in mean between Group C and Group A as well as Group B was found to be statistically significant.

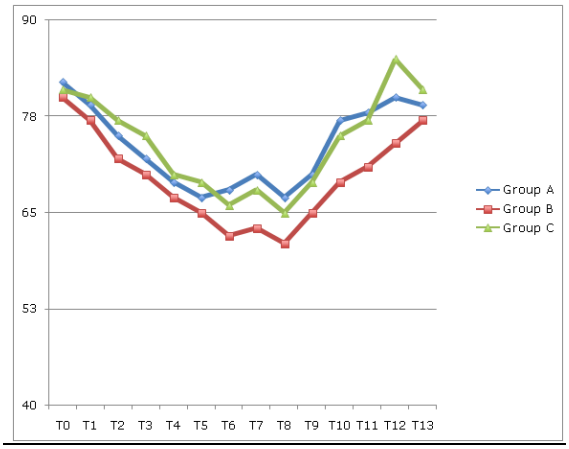

Figure 3: Comparison of perioperative heart rate between three groups (beats/min) Perioperative heart rate (beats/min) T0 (preinduction); T1 (postinduction); T2 (5min); T3 (10min); T4 (15min); T5 (30min); T6 (60min); T7 (90min); T8 (120min); T9 (30min postoperative); T10 (1hr postoperative); T11 (4hr postoperative); T12 (12hr postoperative), T13 (24hr postoperative).

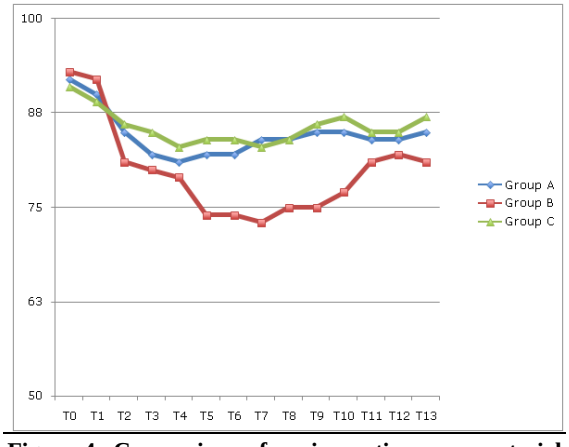

Figure 4: Comparison of perioperative mean arterial pressure between three groups (mmHg)Perioperative mean arterial pressure (mmHg) - T0 (preinduction); T1 (postinduction); T2 (5min); T3 (10min); T4 (15min); T5 (30min); T6 (60min); T7 (90min); T8 (120min); T9 (30min postoperative); T10 (1hr postoperative); T11 (4hr postoperative); T12 (12hr postoperative), T13 (24hr postoperative).

Baseline MAP and HR were insignificantly different in the three groups. However, MAP values were significantly lower in group B compared to the other 2 groups at 30 min after spinal anesthesia and up to 1 h postoperative [Figure 4]. HR variables were insignificantly different between the three study groups throughout the study [Figure 3].

Table 7: Perioperative VAS at different times during the study {median (range)}.

	Group A	Group B	Group C
Immediate postop	0 (0-1)	0 (0-1)	0 (0-2)
1hr postop	0 (0-2)	0 (0-2)	0 (0-3)
2hr postop	2 (0-3)	2 (0-3)	4 (3-5)*
6hr postop	3 (2-4)	3 (1-4)	5 (4-6)*
12hr postop	1 (0-3)	1 (0-2)	4 (3-5)*
24hr postop	2 (1-3)	2 (1-3)	2 (2-3)

Table 8: Perioperative adverse effects in the three groups.

Adverse Effects	Group A	Group B	Group C	Total
Hypotension	2	6	1	9
Nausea	1	0	0	1
Vomiting	0	0	1	1
Shivering	3	1	2	6
Sedation	0	2	0	2
Total	6	8	4	19

The incidence of nausea and vomiting was insignificantly different between the three groups during the study. Intraoperative blood loss was reduced significantly among patients of Group B compared to the other 2 groups, possibly due to the higher incidence of perioperative hypotension seen in patients of Group B.

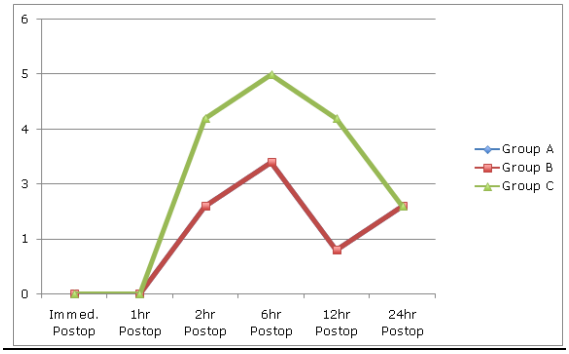

Figure 5: The pain scores (VAS) were significantly lower in group A and B compared to group C at 2 h, 6 h, and 12 h postoperatively (p<0.05). Insignificant differences between group A and B were recorded throughout the study.

Table 9: Perioperative serum Mg concentrations(mmol/L) at different times during the study {mean(SD)}.

Serum Mg	Group A	Group B	Group C	P value
Preop	1.16(0.24)	1.04(0.20)	1.17(0.25)	0.0912
6hr postop	1.10(0.13)	1.66(0.40)*	1.04(0.18)	0.0001*
24hr postop	1.08(0.14)	1.05(0.21)	0.98(0.13)	0.1167

Postoperative serum Mg in group B was significantly higher than the other 2 groups at 6hr postoperatively (p = 0.0001). Serum Mg levels returned to the normal values at 24 h postoperatively.

DISCUSSION

The use of conventional local anaesthetics like bupivacaine has been unable to provide analgesia for an extended duration[11]. Most patients require further analgesics during the postoperative period. Various adjuvants are added to local anesthetics for this purpose. Among the myriad list of LA adjuncts, magnesium seems to have several advantages[1].

Safety of intrathecal magnesium sulphate has been studied in animal models. Though earlier studies encouraged the use of intrathecal magnesium concurrent animal research published recently has raised questions regarding safety of intrathecal magnesium[12-15]. However, IT magnesium has been used in significant number of humans and there were no documented neurological complications[16]. Histopathological and ultra-structural human spinal cord studies may sound interesting but are practically next to impossible. In such circumstances off label use of magnesium intrathecally is supposed to thrive because of its advantages.

Optimum dose and concentration of IT magnesium for antinociceptive action is an untrodden area in research. In the first human study on IT magnesium the dose was fluked out from within the safety range extrapolated from animal studies[9] Recently, few studies have used higher doses and shown antinociceptive action but regression analysis[10] of dose response relationship has not been performed and there is still scope for further higher doses.

Seyhan et al.[17] studied the effect of three different doses of Mg on postoperative consumption of morphine, and a single dose of 40 mg/kg was found to decrease postoperative morphine consumption, when this dose was followed by a continuous infusion of 10 mg/kg/hr, the effect was enhanced. However, increasing the infusion dose to 20 mg/kg/hr led to hemodynamic instability without additional analgesic effect. Perioperative

administration of Mg sulphate (50 mg/kg) and continuous infusion of (15 mg/kg/hr) in gynecology patients receiving total i.v. anesthesia decreased rocuronium requirements and improved postoperative analgesia without significant side effects[18]. Several studies have investigated the effect of intrathecal and i.v. Mg as adjuvant to bupivacaine and fentanyl spinal anesthesia on postoperative pain and analgesic consumption and have shown that both intrathecal and i.v. Mg are safe and prolong the time to first analgesic requirement. Based on the previous studies, a bolus dose of magnesium sulfate (50mg/kg) and continuous infusion of (15mg/kg/hr) in group B and a dose of 75 mg magnesium sulphate as intrathecal adjuvant to bupivacaine in group A was used. In the present study, the incidence of complications was very minimal. Others studies conducted using 50mg of intrathecal magnesium did not show any increased incidence of complications[7,19]. However Jabalameli et al[20] showed that 100mg of intrathecal magnesium is associated with increased incidence of intraoperative and postoperative complications like hypotension, nausea, vomiting compared with lower doses and with placebo. However, he did not find any difference in the requirements of ephedrine or atropine. Nevertheless, IT magnesium has been used in significant number of humans and there have been no documented neurological complications[16].

Onset of analgesia at T6 was delayed with intrathecal magnesium sulphate compared to intravenous magnesium and placebo. Time to 2 segment regression of sensory block, duration of spinal anaesthesia as well as duration of effective analgesia were significantly prolonged in intrathecal as well as intravenous magnesium as compared to placebo. Duration and onset of motor block was similar across all three groups. Intrathecal or intravenous magnesium were not associated with significant side effects. In the present study, serum Mg concentrations in group B were significantly higher than the other 2 groups, at 6 h postoperative. These high levels, however, were safely less than the toxic levels (Mg toxicity begins at serum concentration of 2.5–5mmol/L, cardiac arrest occurs at 12.5mmol/L). An inverse relationship has been found between the severity of postoperative pain and serum magnesium level. Accordingly, prevention of perioperative hypomagnesaemia is an important factor for antinociceptive mechanism[18].

Co-administration of intravenous Mg sulfate or intrathecal Mg given to patients undergoing spinal anesthesia for elective infraumbilical surgeries could improve pain control for the first 24 h after surgery. While there was no significant difference between the two modalities as regard pain scores, however, i.v. Magnesium led to relative hypotension and decreased blood loss. Intrathecal as well as intravenous magnesium sulphate significantly prolonged the time for the first analgesic request, thus substantiating their use in postoperative analgesia.

The present study has the following limitations:

1. In the inclusion criteria, patients undergoing infraumbilical surgeries including lower limb surgeries were selected. This was done to have a larger sample size. This could have been narrowed down to specific surgeries like hip replacement surgery, arthroscopy, etc.
2. Postoperative opioid consumption was not compared between the groups due to technical problems.
3. Prolonged follow up of patients for neurological deficits was not done.

Comparison of magnesium with other agents was not studied.

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How to cite this article: Dalai HK, Nanda S, Chavali S. A Clinical Comparison between Intrathecal and Intravenous Infusion of Magnesium Sulphate as an Adjuvant to Hyperbaric 0.5% Bupivacaine in Spinal Anaesthesia for Elective Infraumbilical Surgeries. Ann. Int. Med. Den. Res. 2017; 3(2):AN23-AN29.

Source of Support: Nil, **Conflict of Interest:** None declared