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Original Article

Anaesthesia Section

Effect of Low Dose Intravenous Magnesium Sulphate on Sensory Regression Time in Patients undergoing Spinal Anaesthesia- A Randomised Placebo-controlled Double-blinded Study

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ABSTRACT

Introduction: Adjuvants like intravenous (i.v.) Magnesium Sulphate ($MgSO_4$) are used to improve the efficacy and duration of spinal anaesthesia and postoperative analgesia. But it is unclear, whether this prolongation of duration of analgesia is an independent effect of $MgSO_4$ or it is because of increased duration of spinal anaesthesia itself.

Aim: To evaluate the effect of intraoperative i.v. low dose $MgSO_4$ on two-segment regression time of sensory block, regression time up to L2 dermatome from the highest level of sensory block and postoperative analgesic requirement.

Materials and Methods: This randomised placebo-controlled blinded study was conducted in the Department of Anaesthesia, Fakhruddin Ali Ahmed Medical College and Hospital, Barpeta, Assam, India from September 2020 to August 2021. A total of 60 patients, satisfying American Society of Anaesthesiology (ASA) physical status I and status II, aged between 40-70 years, patients undergoing femur fracture surgery under spinal anaesthesia were enrolled in the present study. Patients in the magnesium group (Group M, n=30) received $MgSO_4$ 5 mg/kg infusion, and control group (Group C, n=30) received at the same volume of saline during operation. Unpaired t-test was used to test the significance in normally distributed continuous variable and Mann-Whitney U test was used to test the significance of the difference between the quantitative variables. The software Predictive Analytics Software (PASW) 18.0 was used for statistical analysis and the graphs have been generated using the Microsoft Excel 2007. A p-value of less than 0.05 has been considered to be significant.

Results: There were no significant differences between the two groups with respect to patient characteristics (age, weight, and height).The mean time for two segment regression in the group M was prolonged by around 13 minutes, as compared to group C (104.96±11.37 minutes versus 91.2±11.86 minutes, respectively, p<0.001). The mean regression time up to L2 dermatome in the group M was prolonged by 15 minutes as compared to the group C. (171.23 minutes versus 156.43 minutes, respectively, p=0.0003). The total consumption of tramadol in the group M was significantly lesser than the control group (192.5±58.03 mg and 245.0±43.74 mg, respectively, p=0.0002).

Conclusion: An i.v. infusion of 5 mg/kg $MgSO_4$ prolongs two segment regression time upto L2 dermatome and reduces postoperative opioid consumption without any complication in patients undergoing femur fracture surgery under spinal anaesthesia.

Keywords: Analgesics, Bupivacaine, Femoral Fractures, Injections, Postoperative pain

INTRODUCTION

Pain is a personal experience and should always be respected. Verbal description is only one of several modes of expression; inability to communicate does not negate the possibility of pain [1,2]. By definition, "Pain is an unpleasant sensory and emotional experience that is related with actual or potential tissue damage, or articulated in such terms" [2].

Postoperative pain is experienced by a vast majority of patients who undergo surgical procedures and is a major concern because it affects postoperative outcome of the patient. Adequate and appropriate pain control plays an essential role in facilitating recover, both physiologically and psychologically. Thus it leads to shorter hospital stays, lower hospital expenses, and more patient satisfaction. Postoperative pain control may be achieved by variety of mechanisms [3]. They may include the use of pharmacological agents and interventional techniques [3]. Various drugs like midazolam, ketamine, Magnesium Sulphate ($MgSO_4$) have been used to prolong postoperative analgesia in patients undergoing spinal anaesthesia. Intravenous (i.v.) use of $MgSO_4$ along with regional anaesthesia and neuraxial anaesthesia prolongs duration of postoperative analgesia [4-6].

$MgSO_4$ has been used patients undergoing spinal anaesthesia and most of the studies reports it analgesic properties [7-12]. It is unclear whether this prolongation of duration of analgesia is an independent analgesic effect of $MgSO_4$ of because of increased duration of spinal anaesthesia itself [7-12]. In some studies, increased two segment regression time and regression of spinal block up to L2 dermatome was observed, but they were secondary outcomes [8-12]. Moreover, these studies have used $MgSO_4$ dose ranging from 20-50 mg/kg [7-11].

Literature has also shown decreased opioid requirement using a much lower dose of $MgSO_4$ [12]. However, the effect of $MgSO_4$ on the duration of spinal anaesthesia has not been properly evaluated. Thus, it is not known whether such doses influence the duration of spinal anaesthesia and contribute to prolongation of postoperative analgesia. Thus, it was intended to evaluate the effect of i.v. 5 mg/kg on duration of spinal anaesthesia. Such low dose has not been used in studies that evaluated systemic analgesic properties of $MgSO_4$.

It was hypothesised that low dose of i.v. $MgSO_4$ infusion increases two segment regression time of sensory block and the regression time up to L2 dermatome in patients undergoing femur fracture surgery under spinal anaesthesia. The present study, also aimed to study the effect on postoperative requirement of opioids.

MATERIALS AND METHODS

This randomised placebo-controlled blinded study was conducted in the Department of Anaesthesia, Fakhruddin Ali Ahmed Medical College and Hospital, Barpeta, Assam, India, from September 2020 to August 2021. The study protocol was approved by the Institutional Ethics Committee (IEC no FAAMC&H/IEC_PG/498/2020/10573) and written informed consent was obtained from all the patients. The procedures followed were in accordance with the ethical standards of the responsible institutional ethics committee on human experimentation and with the Helsinki Declaration of 1975 that was revised in 2013.

Sample size calculation: The formula used for sample size calculation is as below [13]:

$n=(Z_{\alpha/2}+Z_{\beta})^2 *2*\sigma^2/d^2$,

where $Z_{\alpha/2}$ is the critical value of the normal distribution at $\alpha/2$ (for a confidence level of 95%, α is 0.05 and the critical value is 1.96), Z_{β} is the critical value of the Normal distribution at β (for a power of 90%, β is 0.1 and the critical value is 1.28), σ^2 is the population variance, and d is the difference we would like to detect.

According to the study by Fanelli G et al., the two segment regression time was 80±25 minutes [14]. We presumed to detect a difference of 30 minutes between both the groups. Thus, substituting σ with 25 and d with 30.

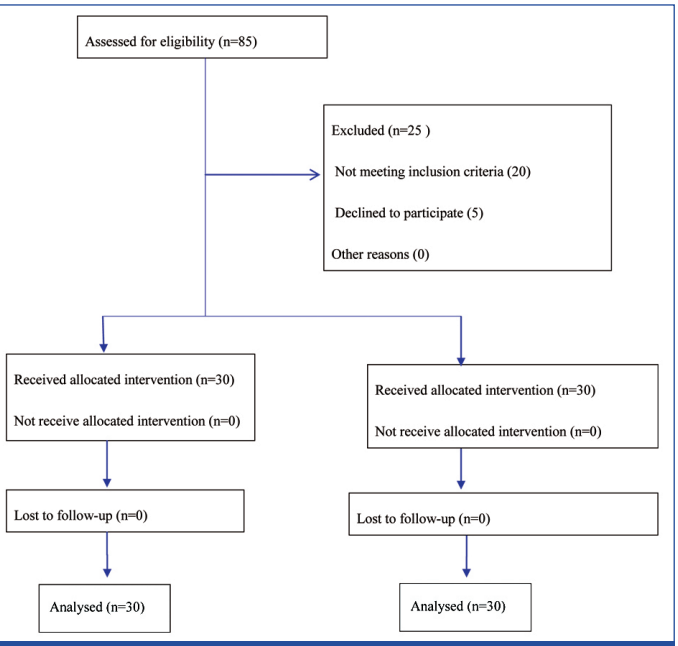
$n=(1.96+1.28)^2*2*\sigma^2/d^2=10.49*2*25^2/30^2=10.49*2*625/900$

$= 10.49*2*0.6944= 14.568$

Thus, to detect a difference of 30 minutes in two segment regression regression time with confidence interval of 95% and power of 90, 15 patients were required in each group. Considering the recommendation of central limit theorem and possible dropout, the authors intended to include 30 patients in each group [15].

Inclusion criteria: The ASA physical status I and status II patients, aged between 40 and 70 years, undergoing femur fracture surgery under spinal anaesthesia were included in the present study [16].

Exclusion criteria: Patients with severe cardiovascular, renal and hepatic dysfunction, neuromuscular diseases, using calcium channel blockers and with contraindications for spinal anaesthesia were excluded [Table/Fig-1].



[Table/Fig-1]: Consolidated Standards Of Reporting Trials (CONSORT) flow diagram.

Study Procedure

The patients were randomly allocated into two groups, M (Case) or C (Placebo) of 30 each by block randomisation, with six patients in each block; a total of 10 such blocks (www.sealedenvelope.com). Concealment of allocation was done by opaque sealed envelope technique. The patients were not informed about their group allocation. On the day of operation, a designated Operation Theatre (OT) technician opened the sealed envelopes, once the patient was shifted to the OT. Accordingly the patients were assigned to their respective groups. The designated OT technician did not take any further part in the study. The anaesthesiologist administering the drug was not aware of the group allocation. After placement of standard monitors including continuous electrocardiogram, pulse oximetry, and non-invasive blood pressure measurements, an 18 Gauge (G) i.v. cannula was placed and patients were premedicated with i.v. midazolam 0.03 mg/kg. Spinal anaesthesia was performed through L3-4 or L4-5 interspace in sitting position. After dural puncture with a 25 G Quincke needle, 0.3 mg/kg of hyperbaric bupivacaine 0.5% solution was injected into the subarachnoid space over 15 seconds. The patients were turned to supine position and maintained to achieve the estimated level of the block.

Following this injection, 5 mg/kg $MgSO_4$ in 250 mL 0.9% saline solution over 15 minutes were given in patients of group M and then patients were allowed for surgery. In control group (group C, n=30) 250 mL of 0.9% saline infusion was administered over 15 minutes during operation in a double-blind randomised manner. Rest of the management was similar to group M. The level of sensory block was evaluated by the loss of pinprick sensation (20-gauge hypodermic needle). Motor blockade was scored using a modified Bromage scale (1= inability to raise extended leg, able to bend knee; 2=inability to bend knee, can flex ankle; and 3=no movement) in the non affected limb [17]. Readiness to surgery was defined as the presence of adequate motor block (Bromage score ≥2) and loss of pinprick sensation at T10. The inability to reach a sensory block at T10 within 30 minutes after spinal injection was considered to be a technical block failure and the patient was converted to general anaesthesia.

Clinically relevant hypotension was defined as a decrease in systolic arterial blood pressure by 20% from baseline values [18]. It was initially treated with a rapid i.v. infusion of 200 mL lactated Ringer's solution; if this proven to be ineffective, an i.v. bolus of 5 mg ephedrine was given. Clinically relevant bradycardia was defined as heart rate decreases to less than 45 bpm, and it was treated with 0.6 mg i.v. atropine [19]. Rescue analgesia with tramadol 75 mg i.v. was available when VAS scores were ≥4. Nausea and vomiting were treated with 4 mg ondansetron intravenously. Age, weight, height, ASA physical status, surgical time, systolic, diastolic, and mean arterial blood pressures, heart rates were noted.

The outcome measures included pain scores (VAS values) two segment regression time, regression time up to L2 dermatome, total opioid consumption and side-effects were recorded for each patient by an investigator. Haemodynamic variables were recorded baseline 0, 15, 30, 60 and 90 minutes after spinal anaesthesia. Pain scores were evaluated using a 0–10 cm VAS (0=no pain, 10=worst pain imaginable) at the postoperative periods (at 0, 1st h, 2nd h, 4th h, 6th h, 12th h and 24th h).

STATISTICAL ANALYSIS

The normality of distribution was evaluated by Kolmogorov-Smirnov test. Continuous variables with normal distribution were analysed with unpaired t-test. For variables with non parametric distribution, Mann-Whitney U test was used to test the significance of the difference between the quantitative variables between both the groups. The software PASW 18.0 has been used to carry out the analysis and the graphs have been generated using the Microsoft Excel 2007. A p-value of less than 0.05 has been considered to be significant in all cases.

RESULTS

The demographic profile and duration of surgeries are depicted in [Table/Fig-2]. There were no significant differences between the two

groups with respect to patient characteristic [Table/Fig-2]. All the sixty patients completed the study. All of the patients were operated for femur fracture surgery under spinal anaesthesia.

Parameters	Group M (n=30)	Group C (n=30)	p-value
Age (years)†	54.46±8.78	50.76±7.71	0.08
Weight (kg)†	59.36±5.41	59.5±6.06	0.92
Height (cm)†	156.86±5.4	156.13±5.95	0.62
Duration of surgery in minutes)†	77±12.49	80±12.31	0.35

[Table/Fig-2]: Demographic and surgical characteristics of two groups.
†Unpaired t-test

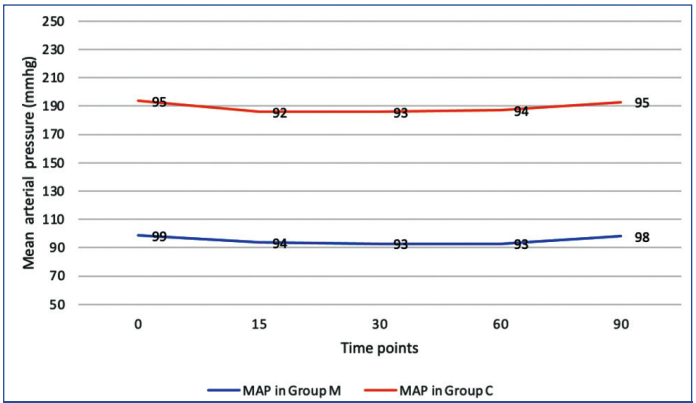
The mean time taken for two segment regression of sensory block in the group receiving $MgSO_4$ was 104.96±11.37 minutes, as compared to 91.2±11.86 minutes in the placebo group [Table/Fig-3].

Variables	Group M n=30	Group C n=30	T score	Degree of freedom	p-value
Two segment regression time (minutes) (mean±SD)†	104.96±11.37	91.2±11.86	4.58	58	<0.0001**
Time for regression up to L2 in both groups (minutes) (mean±SD)†	171.23±12.82	156.43±16.54	3.87	58	0.0003*
Total Tramadol consumption (in mg) 24 h postop (mean±SD)†	192.5±58.03	245.0±43.74	3.9571	58	0.0002*

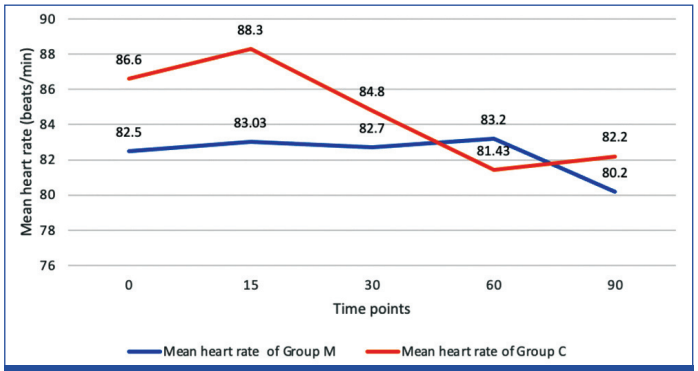
[Table/Fig-3]: Comparison of two segment regression of sensory block, time for regression up to L2 and tramadol consumption in both the groups.
**p-value highly statistically significant; *p-value statistically significant; †Unpaired t-test

Hypothesis testing shows that two segment regression time in the $MgSO_4$ group was significantly prolonged when compared to the control (p<0.001). The details are available in [Table/Fig-3]. The mean time taken for regression up to L2 dermatome from the highest level of sensory block was 171.23±12.82 minutes in the group administered $MgSO_4$ and 156.43±16.54 minutes in the control group [Table/Fig-3]. This duration was significantly prolonged in the $MgSO_4$ group as compared to the placebo group as shown in the [Table/Fig-3]. The total consumption of tramadol in first 24 hours after operation was more in group C [Table/Fig-3] and the difference is statistically significant (p=0.0002).

Two patients in group M and two patients in group C developed nausea, and two patients in group M and one patient in group C experienced vomiting during surgery. Two cases in each group developed headache and two patients in group M and one patient in group C developed dizziness. There were no other side-effects observed. In accordance with the study protocol, all events were treated. Mean arterial blood pressures and heart rates were similar in the two groups [Table/Fig-4,5]. The VAS score of pain was similar till four hours in both the groups. Beyond four hours, the pain was statistically significantly lower in group M [Table/Fig-6].



[Table/Fig-4]: Mean arterial blood pressure in both groups at the given time intervals.



[Table/Fig-5]: Mean heart rates in both study groups at the given time intervals.

VAS	Group M (Mean±SD)	Group C (Mean±SD)	p-value‡
0 h	0	0	-
1 h	0	0	-
2 h	0	0	-
4 h	1.63±0.85	2.43±0.62	<0.001**
6 h	3.35±0.88	4.4±1.54	0.002*
12 h	3.5±1.07	4.26±1.22	0.012*
24 h	2.3±0.95	2.8±1.27	0.08

[Table/Fig-6]: VAS score of pain in both the groups.
‡Mann-Whitney U test

DISCUSSION

Perioperative i.v. $MgSO_4$ has been studied and considered as an efficacious modality of postoperative analgesia in various studies [10,20,21]. In a study by Shah PN and Dhengle Y patients in the study group were given 250 mg of $MgSO_4$ intravenously followed by 500 mg $MgSO_4$ at the rate of 20 mL per hour; same volume of normal saline as bolus and infusion was given in the control group [10]. The duration of both sensory and motor blockade in the magnesium group was prolonged in comparison to the control group, and this prolongation was statistically significant (p=0.001 for both the parameters). The main finding of the present study suggested improved postoperative analgesia in the $MgSO_4$ group with delayed and decreased need of postoperative analgesic; and increased duration of sensory and motor blockade.

In the study by Agrawal A et al., patients in the study group received $MgSO_4$ as infusion in the dose of 50 mg/kg/hour over 15 minutes and 15 mg/kg/hour until the end of the surgery and patients in the control group received 15 mL of normal saline over 15 minutes followed by 100 mL/hour until the end of surgery [8]. The study found that the use of i.v. $MgSO_4$ with spinal anaesthesia decreases postoperative pain and analgesic consumption (p=0.001). The time taken for regression of sensory blockade was extended and need for initial rescue analgesia was also delayed (p=0.001).

Kahraman F and Eroglu A studied the effect of i.v. infusion of $MgSO_4$ during spinal anaesthesia on duration of spinal block and postoperative pain [9]. Patients in the study group (group M) received $MgSO_4$ 65 mg/kg infusion in 250 mL 5% dextrose at 3.5 mL per minute rate and patients in the control group (group C) received the same volume of saline. The authors concluded that $MgSO_4$ i.v. infusion prolongs the spinal sensorial block duration and regression time of sensory block (p<0.01). They also observed a decrease of pain VAS score till four hours after surgery (p<0.01) which is in concurrence with the present study.

In the present study, it was found that the mean time for two segment regression in the group receiving $MgSO_4$ was prolonged by around

13 minutes as compared to those receiving placebo p<0.05. The mean regression time up to L2 dermatome in the $MgSO_4$ group was prolonged by 15 minutes as compared to the control group p<0.05. The authors feel that a prolongation of two segment regressions by an average of 13 minutes and prolongation of regression time up to L2 dermatome by 15 minutes in the group receiving magnesium is of clinical significance.

The rescue analgesic used in the present study was Inj. Tramadol intramuscularly, in a dose of 1.5 mg/kg (with a maximum of 75 mg at once). Analgesia was given whenever the patient demanded or the VAS score was ≥4. The total consumption of Tramadol in the group receiving $MgSO_4$ was significantly lesser than the control group (192.5±58.03 mg and 245.0±43.74 mg, respectively, p=0.0002). The observations made in the present study are similar to the study done by Kayalha H et al., in which they evaluated the effect of i.v. $MgSO_4$ on postoperative opioid requirement [12]. Similar to the present study, Kayalha H et al., had also used i.v. $MgSO_4$ in a dose of 5 mg/kg and the group receiving $MgSO_4$ showed statistically significant reduction in postoperative opioid requirement (group M, 20 mg vs group C, 25 mg, p=0.001). Pain score was also reduced postoperatively in the group receiving group M as compared group C. The endurance of spinal anaesthesia was increased in group M, compared to group C (p<0.001).

Pastore A et al., concluded from their study that i.v. infusion of $MgSO_4$ during spinal anaesthesia improves the quality of analgesia and reduces the postoperative consumption of analgesics [11]. This property is probably related to the competitive antagonism of N-methyl-D-aspartate receptor to the blockade of calcium channel, both involved in the mechanism of central sensitisation of pain. The study conducted by Gao P-f et al., concluded that adjuvant $MgSO_4$ infusion is beneficial to reduce intraoperative fentanyl requirement and postoperative pain without cardiovascular side-effects [20].

Farouk I et al., conducted a study to find out the analgesic and haemodynamic effects of i.v. infusion of $MgSO_4$ versus dexmedetomidine in patients undergoing bilateral inguinal hernia surgeries under spinal anaesthesia. They reported that i.v. infusion of either dexmedetomidine or $MgSO_4$ with spinal anaesthesia improves the quality of spinal anaesthesia. Along with it, they also prolong the duration of postoperative analgesia and decrease the 24 hour postoperative morphine consumption. These findings are in accordance with the present study [21].

Above mentioned studies have employed $MgSO_4$ in a dose ranging from 10-50 mg/kg and has found that decreased opioid requirement but in some studies their outcome has shown that prolongation of spinal analgesia [5,8-12,22]. This is the reason, why the present study was done where regression of spinal anaesthesia was primary outcome and increased duration of spinal anaesthesia was observed. If the data of the previous studies is looked into, it can be seen that the prolongation of postoperative analgesia is far more than the prolongation of duration of spinal anaesthesia. Thus, $MgSO_4$ may have another mechanism of action, where despite prolongation of spinal anaesthesia, it gives analgesia to patient. A study conducted by Kiran S et al., in patients undergoing inguinal surgery found that preoperative administration of i.v. $MgSO_4$ at the dose of 50 mg/kg produces significant reduction in postoperative pain [23].

It is not clear whether decreased opioid requirement was because of intrinsic analgesic activity of $MgSO_4$ or due to its effect of increased duration of spinal analgesia. The present study observes that it increases the duration of spinal anaesthesia. The finding of the present study also suggests that it has analgesic action that is maintained beyond what is provided by the spinal anaesthesia.

Limitation(s)

In the present study, serum magnesium levels were not assessed before and after the surgery. Hence, a correlation between the serum magnesium levels and its effect on duration of blockade and duration of analgesia could not be established.

CONCLUSION(S)

The present study concluded that i.v. use of $MgSO_4$ as an adjuvant along with 0.5% hyperbaric bupivacaine in spinal anaesthesia for patients undergoing femur fracture surgeries at a dose of 5 mg/kg bolus, over 15 minutes prolongs two segment regression time and regression time up to L2 dermatome, thus, accepting the hypothesis. It was also observed that postoperative opioid consumption was reduced. Thus, low dose i.v. $MgSO_4$ can be used to prolong the duration of spinal anaesthesia and duration of postoperative analgesia.

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