Original Article

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Anaesthesia Section

Effect of i.v. Magnesium Sulphate versus i.v. Dexamethasone on Intraoperative Haemodynamic and Postoperative Analgesia after Spinal Anaesthesia in Lower Limb Surgeries: A Randomised Clinical Study

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ABSTRACT

Introduction: Intrathecal adjuvants have gained favour in recent years with the goal of extending the duration of a block. Among these, Dexamethasone possesses anti-inflammatory and analgesic action and can be given as an adjuvant to local anaesthetics to enhance the efficacy of regional anaesthesia, as well as to decrease the intensity of shivering. The addition of Magnesium sulphate ($MgSO_4$) to spinal anaesthesia helps in improving postoperative analgesia in an orthopaedic setting.

Aim: To compare the effects of Intravenously (i.v.) $MgSO_4$ and i.v. dexamethasone on intraoperative haemodynamics, the time to achieve dermatome T10 intraoperatively, and to compare postoperative Visual Analogue Scale (VAS) scores between the two groups at 1, 3, 6, 12, and 24 hours after surgery.

Materials and Methods: This randomised clinical trial was conducted, and patients were randomly divided into two groups. Group M (n=40): $MgSO_4$ 40 mg/kg given 15 minutes before spinal anaesthesia in 100 mL normal saline infusion i.v. Group D (n=40): Dexamethasone 8 mg given 15 minutes before spinal anaesthesia in 100 mL normal saline infusion i.v. The parameters assessed included haemodynamic parameters, time to achieve dermatome T10 intraoperatively, postoperative VAS score at 1, 3, 6, 12, and 24 hours after surgery, and any side-effects like sedation, respiratory depression, nausea, vomiting, pruritus, urinary retention, bradycardia, and hypotension. Statistical testing was conducted using the statistical software Statistical Package for Social Sciences (SPSS) 28.0.

Results: There was no significant difference in demographic variables (age and gender) between the two groups (p-value >0.05). However, the decrease in mean heart rate, Systolic Blood Pressure (SBP), Diastolic Blood Pressure (DBP), and Mean Arterial Blood Pressure (MAP) was greater in group D compared to group M at different time intervals (p-value <0.05). Additionally, dermatome level T10 was achieved earlier in group D by approximately two minutes compared to group M (6.95±0.39 minutes versus 5.03±0.16 minutes, respectively, p-value <0.001).

Conclusion: An i.v. infusion of 8 mg dexamethasone in 100 mL normal saline was more effective compared to an i.v. infusion of 40 mg/kg $MgSO_4$ in terms of achieving more stable haemodynamics intraoperatively and achieving the T10 dermatome level earlier.

Keywords: Analgesics, Bupivacaine, Injections, Postoperative pain, Subarachnoid block

INTRODUCTION

Spinal anaesthesia is considered a secure, reliable, and cost-effective procedure with the advantage of providing surgical anaesthesia and prolonging postoperative pain management through the use of various local anaesthetics. It offers a rapid onset and a potent sensory and motor blockade. The first spinal anaesthesia was administered by August Bier on August 16, 1898, by intrathecally injecting 3 mL of 0.5% cocaine [1]. Intrathecal adjuvants have gained favour in recent years with an aim of extending the duration of the block. The addition of opioids (morphine, fentanyl, and sufentanil) and other medications (dexmedetomidine, clonidine, neostigmine, ketamine, and midazolam) has been found to enhance the quality of spinal anaesthesia, leading to an early onset of sensory and motor block and prolonging the block. They are generally considered safe but may have minimal side-effects such as vomiting, nausea, bradycardia, and hypotension [2]. Dexamethasone possesses anti-inflammatory and analgesic actions by inhibiting the transmission of nociceptive C-fibres and neural discharge [3]. It can be safely injected into the cerebrospinal fluid and can be used as an adjuvant to local anaesthetics to enhance the efficacy of regional anaesthesia and reduce the intensity of shivering [4].

Magnesium is an N-methyl-D-aspartate (NMDA) antagonist. It blocks the NMDA channel in a voltage-dependent manner, resulting in a reduction in NMDA-induced currents. The addition of magnesium to spinal anaesthesia has been shown to improve postoperative analgesia in orthopaedic settings [5,6]. Most studies have compared intrathecal dexamethasone and $MgSO_4$, but there are limited studies comparing (i.v.) dexamethasone and $MgSO_4$ [2,3,5,6-11]. Therefore, present study aimed to compare the effects of i.v. $MgSO_4$ and i.v. dexamethasone on intraoperative haemodynamics, time to achieve dermatome T10, and also to compare postoperative VAS scores between the two groups at 1, 3, 6, 12, and 24 hours after surgery and any side-effects such as sedation, respiratory depression, nausea, vomiting, pruritus, urinary retention, bradycardia, and hypotension.

MATERIALS AND METHODS

This randomised double-blind clinical trial was conducted in the Department of Anaesthesiology and Intensive Care, MMIMSR,

Mullana, Ambala, Haryana, India over a period of five months (June 2023 to October 2023). Approval from the Institutional Ethics Committee and CTRI (CTRI/2023/06/053435) was obtained before conducting the study. Informed consent was obtained from all the patients.

Inclusion criteria: Patients aged 18 to 65 years of either gender belonging to American Society of Anaesthesiologists (ASA) 1 or 2 and scheduled to undergo lower limb surgeries were included in the study.

Exclusion criteria: Patients' refusal, any contraindication to spinal anaesthesia, and any drug allergies in the patient were excluded from the study.

Sample size: Referring to previous studies [12,13], a sample size of 35 per group was required to detect a difference of atleast 10, with an effect size of 0.67 at any time point between the two groups, with a power of 80% at the 5% significance level. To enhance the power of the study and to compensate for any possible dropouts, patients were enrolled in each group.

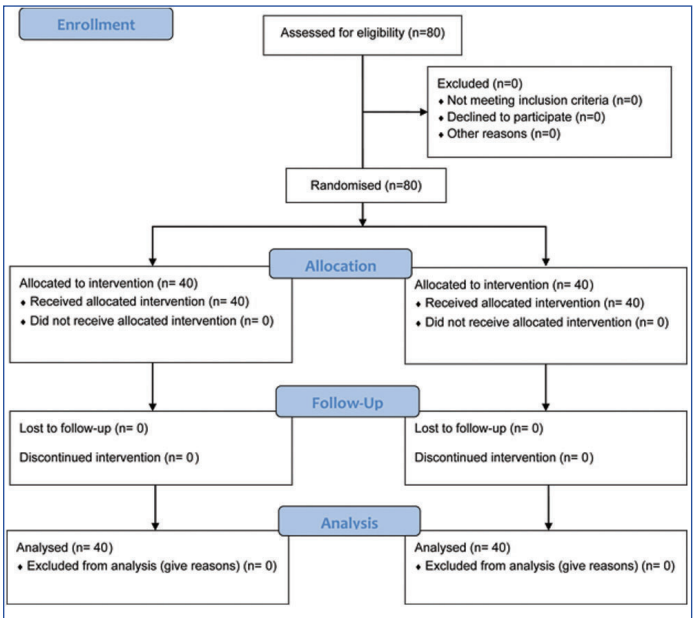
Formula used:

$$n=\frac{(\sigma 1^2+\sigma 2^2) \times (Z1-\alpha/2+Z1-\beta)^2}{(M1-M2)^2}$$

Where $Z_{\alpha/2}$ represents the critical value of the normal distribution at $\alpha/2$ (e.g., for a confidence level of 95%, α is 0.05 and the critical value is 1.96), and Z_{β} is the critical value of the normal distribution at β (e.g., for a power of 90%/80%, β is 0.1/0.2 and its critical value is 1.282/0.842). $\sigma 1$ and $\sigma 2$ are the standard deviations of the two groups, while M1 and M2 are the means of the two groups.

Study Procedure

The patients were randomly divided into two groups using the chit method [Table/Fig-1]. Group M (n=40): $MgSO_4$ 40 mg/kg was administered 15 minutes before spinal anaesthesia in a 100 mL normal saline infusion via a syringe infusion pump i.v. This dosage was selected based on a study by Benevides ML et al., [14] where 50 mg/kg $MgSO_4$ was used. Group D (n=40): Dexamethasone 8 mg was administered 15 minutes before spinal anaesthesia in a 100 mL normal saline infusion via a syringe infusion pump i.v. as same dose used in study done by Shalu PS and Ghodki PS [15]. The individuals administering the infusion and collecting data (primary assessors) were unaware of the drug being administered in the 100 mL saline.



[Table/Fig-1]: Consort flow diagram showing distribution of patients.

Preoperative routine investigations were conducted (Electrocardiogram (ECG), Complete Blood Count (CBC), coagulation profile, and liver and kidney functions). Patients were kept nil per oral for eight hours. The patients were premedicated in the induction room with midazolam 0.02 mg/kg i.v. Upon arrival in the operating theatre, 500 mL of lactated Ringer's solution was infused i.v., and basic monitors were applied (ECG, pulse oximeter, non invasive blood pressure). Patients in group M received $MgSO_4$ 40 mg/kg in a 100 mL infusion over 15 minutes approximately 15 minutes prior to spinal anaesthesia. Subsequently, spinal anaesthesia was administered using a 25G Quincke's spinal needle in the sitting position at the L3-L4 interspace. The drug solution contained 0.5% hyperbaric bupivacaine 3 mL.

Patients in group D received dexamethasone 8 mg 15 minutes prior to spinal anaesthesia and received spinal anaesthesia with the same drug solution as group M. Haemodynamic parameters such as heart rate, SBP, DBP, MAP, and SpO_2 levels were recorded at baseline, 1 min, 3 mins, 5 mins, 10 mins, 30 mins, 1 hour, 1.5 hours, and 2 hours postspinal anaesthesia throughout the entire surgery duration.

Sensory block assessment began immediately by the primary assessor after turning the patient to the supine position and continued every minute until the loss of sensation to pinprick at the T8 level was observed. Two-segment regression of sensory block was also noted. Motor block was bilaterally assessed using the Modified Bromage scale [16] starting immediately after turning the patient to the supine position and continuing every minute until a Bromage score of 3 was reached. The VAS was assessed after 1, 3, 6, 12, and 24 hours after surgery [17]. Time to rescue analgesia, defined as the time until the first demand for rescue analgesia in the form of i.v. tramadol 2 mg/kg, was also noted. Any side-effects due to the study drugs were also recorded.

STATISTICAL ANALYSIS

Statistical testing was carried out using the Statistical Package for the Social Sciences (SPSS) system version 28.0. Continuous variables are expressed as mean±SD, while categorical variables are presented as absolute numbers and percentages. The comparison of normally distributed continuous variables between the groups was conducted using Student's t-test. Nominal categorical data between the groups were compared using the Chi-squared test or Fisher's exact test as appropriate. A p-value of <0.05 was considered statistically significant, while a p-value of <0.001 was considered statistically highly significant.

RESULTS

There was no significant difference in mean age, gender, ASA grade, and mean duration of surgery (p-value >0.05) [Table/Fig-2].

Parameter	Group M Mean±SD	Group D Mean±SD	p-value
Age $ (years)	46.13±14.81	51.48±12.95	0.890
Gender (M:F)#	58:42	67:33	0.42
ASA grade (I/II)#	37/3	40/0	0.241
Duration of surgery$ (hours)	1.94±0.52	1.96±0.57	0.838

[Table/Fig-2]: Demographical and surgical characteristics of the two groups. $Unpaired t-test. #Chi-square test

A significant difference in mean HR was found in group M compared to group D at one minute (p-value=0.026), at three minutes (p-value 0.001), five minutes, 10 minutes, 30 minutes (p-value <0.001), one hour (p-value <0.001), and 1.5 hours (p-value=0.001), respectively [Table/Fig-3].

Heart rate	Group M Mean±SD	Group D Mean±SD	p-value
Baseline	81.35±4.25	80.15±2.50	0.298
1 min	74.15±5.88	71.68±3.59	0.026*
3 mins	75.65±4.63	71.15±5.88	0.001*
5 mins	73.2±4.97	68.15±5.88	<0.001**

10 mins	73.33±3.11	65.15±5.88	<0.001**
30 mins	74.5±4.38	63.15±5.88	<0.001**
1 h	74.13±3.77	65.15±5.88	<0.001**
1.5 hrs	73.37±3.41	69.31±6.13	0.001*
2 hrs	74.94±2.38	73.46±6.41	0.216
End of surgery	74.65±3	73.28±6.41	0.244

[Table/Fig-3]: Comparison of heart rate at various time points between the two groups.
p-value <0.05-statistically significant, p-value <0.001-statistically highly significant

A significant difference in mean SBP was found in group M compared to group D at one minute, three minutes, five minutes, 10 minutes, 30 minutes, one hour, and 1.5 hours (p-value <0.001) [Table/Fig-4].

SBP	Group M Mean±SD	Group D Mean±SD	p-value
Baseline	120.75±9.64	124±4.78	0.060
SBP 1 min	124.23±5.16	118.88±4.71	<0.001**
SBP 3 mins	123.03±6.08	116.98±4.78	<0.001**
SBP 5 mins	120.3±7.02	115.2±4.96	<0.001**
SBP 10 mins	118.13±6.62	113.35±5.14	<0.001**
SBP 30 mins	116.93±4.83	112.5±5.48	<0.001**
SBP 1 h	117.68±6.28	110.98±6.02	<0.001**
SBP 1.5 hrs	115.63±4.41	109.77±6.59	<0.001**
SBP 2 hrs	112.67±3.59	110.94±6.49	0.091
End of surgery	113.2±4.73	111.13±6.75	0.058

[Table/Fig-4]: Comparison of mean SBP at various time points between the two groups.
p-value <0.001-statistically highly significant

A significant difference in mean DBP was found in group M compared to group D at one minute (p-value=0.001), three minutes (p-value=0.030), five minutes, 10 minutes, 30 minutes, one hour, and 1.5 hours (p-value <0.001), respectively [Table/Fig-5].

DBP	Group M Mean±SD	Group D Mean±SD	p-value
Baseline	72.15±3.49	71.28±5.09	0.373
1 min	71.97±6.75	67.45±5.37	0.001*
3 mins	68.33±5.16	65.65±5.64	0.030*
5 mins	72.9±2.32	62±6.27	<0.001**
10 mins	72.53±2.09	60.33±6.88	<0.001**
30 mins	72.5±2.22	58.6±7.26	<0.001**
1 hr	71.18±3.23	61.3±6.59	<0.001**
1.5 hrs	70.14±3.05	62.92±6.02	<0.001**
2 hrs	67.3±1.85	65.73±5.66	0.058
End of surgery	67.33±1.98	65.7±6.03	0.056

[Table/Fig-5]: Comparison of mean DBP at various time points between the two groups.
p-value <0.001-statistically highly significant

A significant difference in MAP was found in group M compared to group D at one minute, three minutes, five minutes, 10 minutes, 30 minutes, one hour, and 1.5 hours (p-value <0.001), respectively [Table/Fig-6]. There was a significantly longer time to achieve dermatome T10 in group M compared to group D (p-value=0.001) [Table/Fig-7]. SpO_2 was 100% at all-time points in both groups, which was comparable.

MAP	Group M Mean±SD	Group D Mean±SD	p-value
Baseline	89.98±4.4	88.85±4.19	0.242
1 min	89.39±4.37	84.59±4.3	<0.001**
3 mins	86±3.66	82.76±4.54	<0.001**
5 mins	88.7±3.15	79.73±5.06	<0.001**
10 mins	85.39±2.5	78±5.56	<0.001**
30 mins	87.31±1.89	76.57±5.95	<0.001**
1 h	86±2.4	68±5.81	<0.001**
1.5 hrs	87.97±2.39	76.56±10.69	<0.001**
2 hrs	82.42±1.68	79.80±11.9	0.214
End of surgery	82.61±1.94	80.84±5.94	0.065

[Table/Fig-6]: Comparison of mean MAP at various time points between the two groups.
p-value <0.001-statistically highly significant

Variable	Group M Mean±SD	Group D Mean±SD	p-value
Time to achieve dermatome T10 (minutes)	6.95±0.39	5.03±0.16	0.001*

[Table/Fig-7]: Comparison of mean time to achieve dermatome T10 between two groups.
p-value <0.001-statistically highly significant

The mean onset of sensory block was almost similar in both the groups with a p-value of 0.851 [Table/Fig-8]. 100% of the patients had a Modified Bromage Scale of 3 in both groups [Table/Fig-9]. There was no significant difference in VAS scores when comparing group M to group D [Table/Fig-10]. There was no significant difference in the mean time to rescue analgesia when comparing group M to group D (p-value=0.704) [Table/Fig-11].

Variable	Group M Mean±SD	Group D Mean±SD	p-value
Onset of sensory block	5.06±0.32	5.08±0.27	0.851

[Table/Fig-8]: Comparison of mean onset of sensory block between two groups.

Modified bromage scale	Group M n (%)	Group D n (%)	p-value
3	40 (100)	40 (100)	-

[Table/Fig-9]: Comparison of Modified Bromage scale distribution between two groups.

Time interval (Hours)	Group M VAS score	Group D VAS score	p-value@
1	0	0	–
3	0	0	-
6	1.82±0.79	1.80±0.75	0.912
12	2.7±1.25	2.5±1.23	0.381
24	2.65±1.27	2.59±1.26	0.657

[Table/Fig-10]: Comparison of Visual Analogue Scale (VAS) between two groups.
@Mann-Whitney U test

Variable	Group M Mean±SD	Group D Mean±SD	p-value
Time to rescue analgesia (minutes)	149.33±27.74	160.00±28.28	0.704

[Table/Fig-11]: Comparison of mean time to rescue analgesia between two groups.

There was no significant difference in the distribution of nausea among patients when comparing group M to group D (p-value=1.000) [Table/Fig-12].

Nausea	Group M n (%)	Group D n (%)	p-value
No	40 (100)	40 (100)	1.000
Yes	0	0	

[Table/Fig-12]: Comparison of the proportion of patients having nausea within the two groups.

DISCUSSION

While comparing the effects of i.v. dexamethasone and $MgSO_4$, no statistically significant differences were observed in baseline haemodynamic characteristics, demographic profile, ASA status, and duration of surgery in present study. Similar results were obtained in studies conducted by Sharma M et al., and Farouk I et al., [18,19]. A significant difference in mean HR was found at one minute (p-value=0.026), three minutes, five minutes, 10 minutes, 30 minutes, one hour (p-value <0.001), and 1.5 hours p-value=0.001 in present study. However, Agrawal A et al., observed that heart rate was comparable across the two groups receiving intravenous infusions of $MgSO_4$ and bupivacaine in patients undergoing lower limb orthopaedic surgery [20]. This difference may be attributed to the fact that they compared $MgSO_4$ with normal saline and not with dexamethasone, which was the drug compared in present study.

A significant difference in mean SBP was observed in group M when compared with group D at one minute, three minutes, five minutes, 10 minutes, 30 minutes, one hour, and 1.5 hours (p-value <0.001). Additionally, a significant difference in mean DBP was found in group M when compared with group D at one minute (p-value=0.001), three minutes (p-value=0.030), five minutes, 10 minutes, 30 minutes, one hour, and 1.5 hours (p-value <0.001) in present study. In contrast, Farouk I et al., observed no significant differences in SBP and DBP at all time intervals [19]. Shahadah HH et al., observed no difference in MAP between the preoperative and intraoperative periods [21]. This difference may be due to variations in the dosage of $MgSO_4$ used by the authors and differences in the study drugs being compared. Significant differences were observed in MAP for group M compared with group D at one minute, three minutes, five minutes, 10 minutes, 30 minutes, one hour, and 1.5 hours (p-value <0.001) in present study. Conversely, Benevides ML et al., reported that MAP was comparable between the two groups, potentially because they compared $MgSO_4$ with normal saline [14]. Pyasetska N observed that patients who received intrathecal dexamethasone maintained a precise baseline MAP measured before spinal anaesthesia and prevented a drop to 80% of the baseline [22].

There was no significant difference between the two groups in arterial oxygen saturation at various time intervals. Similar results were obtained by Shahadah HH et al., [21]. A significantly longer time to achieve dermatome T10 was observed in group M compared with group D in present study (p-value=0.001). All patients had a Modified Bromage scale three in both groups. Furthermore, no significant difference was observed in the mean duration of surgery when comparing group M with group D (p-value=0.838). There was no significant difference in the distribution of nausea among patients when comparing group M with group D (p-value=1.000). In contrast, Farouk I et al., observed that 3% of patients experienced nausea in group M [19]. Additionally, no significant difference was observed in the mean time to rescue analgesia when comparing group M with group D (p-value=0.704).

Based on these findings, as discussed, dexamethasone demonstrates better results compared to $MgSO_4$ in terms of better haemodynamic stability and various other parameters.

Limitation(s)

Normal saline was not used as a control to analyse the haemodynamic and other parameters. The effects of $MgSO_4$ and dexamethasone were only measured i.v. while their efficacy as intrathecally administered was not analysed. Therefore, magnesium sulphate and dexamethasone could be compared for their efficacy when administered via the intrathecal route in future studies.

CONCLUSION(S)

The present study concluded that i.v. dexamethasone is more effective compared to i.v. $MgSO_4$ during spinal anaesthesia in lower limb surgeries in terms of achieving better haemodynamic stability in patients. Moreover, i.v. dexamethasone was found to be more efficient in achieving dermatome level T10 earlier as compared to i.v. $MgSO_4$. Since limited data is available on the comparison between dexamethasone and $MgSO_4$, this study could be helpful in selecting i.v. dexamethasone over $MgSO_4$ for administration during spinal anaesthesia in patients operated for various surgical procedures.

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