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Original Research Article

COMPARISON OF DEXAMETHASONE AND MAGNESIUM SULPHATE FOR PREVENTION OF POST SPINAL SHIVERING IN PATIENTS UNDERGOING INFRA UMBILICAL SURGERIES: A RANDOMIZED CONTROLLED STUDY

Asma Rahat[1], Akash Gupta[2], Praful Kumar Srivastava[3], Uma Rani Purohit[2]

[1]Assistant Professor, Department of Anaesthesiology, Rohilkhand Medical College & Hospital, Bareilly, Uttar Pradesh, India.
[2]Professor, Department of Anaesthesiology, Rohilkhand Medical College & Hospital, Bareilly, Uttar Pradesh, India.
[3]3rd year Post Graduate, Department of Anaesthesiology, Rohilkhand Medical College & Hospital, Bareilly, Uttar Pradesh, India.

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Corresponding Author:
Dr. Praful Kumar Srivastava,
3rd year Post Graduate, Department of Anaesthesiology, Rohilkhand Medical College & Hospital, Bareilly, Uttar Pradesh, India.
Email: pra.srivastava.777@gmail.com

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ABSTRACT

Background: Dexamethasone and magnesium sulphate are commonly used drugs in anaesthesia. The efficacy of both drugs in prevention of post spinal anaesthesia shivering remains optimistic. The objective is to compare the preventive effect of intravenous dexamethasone and intravenous magnesium sulphate usage in mitigating shivering following spinal anaesthesia in patients undergoing infraumblical surgeries.

Materials and Methods: This Randomized, double blinded study was carried out among patients posted for elective infra-umbilical surgeries under spinal anesthesia in Department of Anesthesiology, Rohilkhand Medical College and Hospital, Bareilly.

Results: The mean age, gender, weight, and type and duration of surgery were similar across both groups, with no significant differences. The overall incidence of PSAS was 35% in magnesium sulphate group and 57.5% in dexamethasone group which was statistically significant (p value - 0.043) in current study. Post-spinal shivering was more frequent in Group B (dexamethasone) compared to Group A (magnesium sulfate), with statistical significance at 15, 30, and 45 minutes after spinal anesthesia.

Conclusion: Magnesium sulphate group had a higher percentage of patients with no shivering (Grade 0) and a lower percentage of moderate (Grade 2) and severe (Grade 3) shivering compared to Dexamethasone group.

Keywords: dexamethasone, magnesium sulphate, post spinal shivering, infra umbilical surgeries.

INTRODUCTION

Significant advancements have been made in the field of anesthesiology in recent years, with a focus on improving patient care and comfort across a variety of surgical procedures. Essential elements of anaesthesia management include the avoidance and control of undesirable side effects, such as post-spinal anaesthesia shivering (PSAS). This phenomenon, characterized by involuntary muscle spasms and a sense of cold, has the potential to produce discomfort as well as serious ramifications.[1] Shivering is a prevalent adverse consequence of spinal anaesthesia, with recorded incidences ranging from 50 to 65%. The mechanism governing shivering after spinal anaesthesia is vasodilation, which causes rapid heat loss and leads to the transfer of body heat to the extremities from the core, resulting in hypothermia.[2]

Shivering is the optimal physiological reaction in core hypothermia, as it increases metabolic heat synthesis. Parameters like age of patient, type and length of surgery, baseline body core temperature and any accompanying co-morbidity all independently affect shivering and its severity.[1]

Post-spinal anaesthesia shivering not only induces discomfort but also carries the potential for

unexpected sequel, including heightened oxygen demand, instability in hemodynamic, increased intracranial pressure, increased intra-occular pressure, lactic acidosis and prolonged recovery from anaesthesia.[3] It has also been observed that movements that are caused because of shivering interfere with monitoring of Electrocardiography, pulse oximetery and blood pressure estimation.[4] Post spinal shivering is problematic for patient, surgeon as well as anaesthetist. Therefore, prevention of post spinal shivering is very important and not to be taken lightly. As a result, numerous treatment have been investigated in order to avoid and effectively manage this condition.[1]

Shivering can be prevented and treated using pharmacological and non-pharmacological approaches. Warm fluid, warm clothing, radiant heating, forced air warmers, and raising the operating room's ambient temperature are examples of non-pharmacological techniques.[5]

The usage of Dexamethasone for prevention of PSAS is widely accepted as it regulates immune response and decrease the temperature gradient via its anti-inflammatory action and vasodilation effects. The use of dexamethasone (4 mg) can be used as an alternative for prevention of post spinal shivering in procedures like TURP.[6]

In addition to the physiological reasons, environmental factors including the operating room's humidity and temperature might also affect the incidence of PSAS. The onset of PSAS may also be influenced by a number of patient-related factors, such as age, gender, and body temperature prior to surgery. Therefore, understanding the complex nature of PSAS is essential to developing successful preventative and treatment strategies.[7]

MATERIALS AND METHODS

This Randomized, double blinded study (CTRI Number: REF/2024/05/084315) was carried out among Patients posted for elective infra-umbilical surgeries under spinal anesthesia in Department of Anesthesiology, Rohilkhand Medical College and Hospital, Bareilly after approval by Institutional Ethical Committee. Duration of study was 1stAugust, 2023 - 31st July, 2024.

Inclusion Criteria:

Patients fulfilling the Following

- American Society of Anesthesiologist (ASA) grade I or II.8
- Age between 20-60yrs of either sex.(11)
- Patient undergoing elective infra-umbilical surgeries.

Exclusion Criteria:

Patients fulfilling the Following

- Patients with contraindications to Spinal anaesthesia.[9]
- Obesity (BMI >30kg/m2).
- Allergy to study drugs.
- Baseline temperature >38 C and <36 C.
- Expected massive blood loss or blood transfusion.
- Surgeries lasting more than 3 hours.

Sample Size: In our study a total of 80 patients were included which was statistically calculated by using the software, power and sample size program G power version 3.1. The sample size calculated in each group is 40.[10]

Informed and written consent of patients for participation in the study was taken.

Thorough per-anaesthetic checkup was done one day prior to the surgery. A total of 80 patients posted for infra-umbilical surgeries were enrolled and the patients were randomly split into 2 groups.

Group A: Intravenous Magnesium Sulphate 30mg/kg was given immediately after block.

Group B: Intravenous Dexamethasone 4mg was given immediately after block.

Under all aseptic techniques, spinal anaesthesia was administered at the L2-L3 inter-vertebral space using a 25-gauge spinal needle in sitting position with 15 mg of 0.5% Hyperbaric Bupivacaine. The onset and duration of the motor & sensory blockade was assessed by the Modified Bromage scale and pinprick test (using 24-gauge hypodermic needle), respectively. The block level was evaluated to make sure that it is between T6-T8. The motor blockade was assessed using the Modified Bromage Scale.[11] Patients were draped, and IV fluids was maintained at room temperature (kept at 24 °C). No warming devices were used. A blinded observer recorded the frequency and intensity of shivering after the block is administered, every five minutes for the first 15 minutes, and then every 15 minutes for the next four hours using the Crossley and Mahajan scale.[12] All the patients were monitored for post-spinal shivering during intraoperative and post operative period for incidence and severity and so was recorded. Also the incidence of complication of spinal anaesthesia and adverse effects of both drugs were also be monitored and recorded.

Bradycardia (HR <50) was treated with a bolus of 0.6mg of Injection Atropine. Hypotension (20% reduction in SBP from baseline) was treated with 200ml of Ringer lactate when it was not responsive to i.v. bolus then 6 mg of injection mephentermine was given. 10 mg of Injection Metoclopramide was used to relieve nausea and vomiting. 1 mg/kg of Injection Tramadol was given when patients presents with shivering of grade 2 or more. Following surgery, patients were moved to the post-anaesthesia care unit (PACU), where they were watched over and a cotton sheet was given to cover themselves. After 2 hours of observation in PACU, patients were shifted to respective ward.

Statistical Analysis: Descriptive statistics was performed by calculating mean and standard deviation for the continuous variables. The software used for the statistical analysis was SPSS (statistical package for social sciences) version 23.0, The p-value was taken significant when less than 0.05 ($p<0.05$) and Confidence interval of 95% was taken.

RESULTS

In our study mean age of cases in group A was 38.50 years and in group B, it was 40.37 years. Out of 40 patients in group A, 31 were male and 9 were female. 31 were male and 9 were female in group B. (p-value >0.05)

In Our study, the mean weight of cases in group A was 63.23 kg and in group B, it was 65.43 kg. (p-value >0.05).

Table 1: Comparison of Type Of Surgery Conducted In Between Groups.

Surgery	Group A (Magnesium sulphate)	Group B (Dexamethasone)	p- value
General Surgery	20	18	>0.05
Urosurgery	6	5	
Orthopaedics Surgery	10	10	
Obstetric & Gynecological Surgery	4	7	
TOTAL	40	40	

There were total 38 patients who underwent general surgery among which 20 patients were in Group A and 18 patients were in Group B. Total 11 patients underwent urological surgeries among which 6 patients were in group A and 5 patients were in group B. 20 patients were scheduled for orthopaedics surgery and 10 patients were in group A and 10 patients were in group B. There were total 11 patients who underwent Obstetric and gynaecology surgeries in which 4 patients were in group A and 7 patients were in group B. (p-value >0.05)

The mean time period of the surgery of patients in group A was 95.87 minutes, and in group B, it was 97.37 minutes. The mean time period of the motor block of patients in group A was less as compared to group B. (p-value >0.05)

In our study mean time period of the beginning of sensory block of patients in group A was 6.65 minutes and in group B, it was 6.30 minutes. (p-value >0.05)

In our study, T6 was the most common peak height for the sensory block in 29 patients in group A and 30 patients in group B, T8 was in 8 patients in group A and 2 patients in group B and T4 was in 3 patients in group A and 8 patients in group B.

In our research mean time period of the onset of motor blockade of patients in group A was 9.85 minutes and in group B, it was 9.30 minutes. (p-value >0.05).

Table 2: Comparison Of Sensory Block Duration Between Magnesium Sulphate And Dexamethasone Groups.

Duration of Sensory Block (in minutes)	Group A (Magnesium Sulphate)	Group B (Dexamethasone)
140 minutes or less	4	1
141-160 minutes	11	2
161-180 minutes	15	11
180 minutes or more	10	26
TOTAL	40	40

In our research mean duration of the sensory blockade of patients in group A was 162.30 minutes and in group B, it was 185.90 minutes. The mean duration of the sensory block of cases in group B was more as compared to group A. (p-value <0.05)

Mean heart rate was noted down from preoperative period to 240mins postoperatively. In group A it varied from 70.47±8.18 (lowest reading) to 74.55 ± 5.40 (highest reading). In group B it varied from 72.13 ± 4.77 (lowest reading) to 75.73 ± 12.54 (highest reading). (p-value <0.05)

Mean SBP was noted down from preoperative period to 240mins postoperatively. In group A it varied from 113.70 ± 10.29 (lowest reading) at 18 mins to 124.95 ± 6.28 (highest reading) at pre-op. In group B it varied from 114.00 ± 10.77 (lowest reading) at 18 mins to 123.75 ± 5.42 (highest reading) at preop. (p-value >0.05)

Mean diastolic blood pressure was noted down from preoperative period to 240 mins post-operatively. In group A it varied from 71.88 ±7.65 (lowest reading) at 12 mins to 76.40 ± 7.12 (highest reading) at 55 mins. In group B it varied from 74.18 ± 11.22 (lowest reading) at 15 mins to 78.68 ± 8.10 (highest reading) at 45 mins. (p-value >0.05) except at 12 minute and 120 minute where diastolic blood pressure in Group A was less than that of in group A.

Mean MAP was noted down from preoperative period to 240 mins postoperatively. In group A it varied from 86.04 ± 5.90 (lowest reading) at 12 mins to 91.89 ± 4.71 (highest reading) at 27 mins. In group B it varied from 87.45 ± 8.39 (lowest reading) at 15 mins to 92.77 ± 4.87 (highest reading) at 3 mins. (p-value <0.05)

Post spinal shivering was not seen in patients 5 min and 10 min after block in group A and group B. In group A post spinal shivering was in 12 patients 15 min after block in group A and in 17 cases in group Bat 15 mins post block. Post spinal shivering was in 9 patients at 30 min after block in group A and in 16 patients in group B. Post spinal shivering was evident in 4 patients 45 min after block in group A and present in 7 patients in group B. There was significant difference in Post spinal shivering after 15min, 30 min and 45 min duration in between group A and group B. There was no Post spinal shivering after 60 min in both group A and group B. Overall the incidence of PSAS was seen more in Group B as

compared to group A at 15 minutes, 30 minutes, and 45 minutes which is also statistically significant with p-value of 0.013, 0.001, and 0.001, respectively.

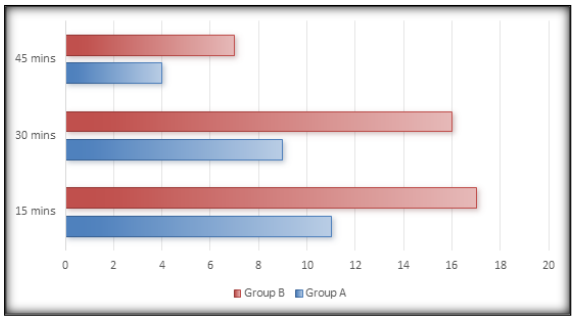

Figure 1: Post Spinal Shivering

In our research, the incidence of post spinal anaesthesia shivering was observed in 14 patients in group A and in 23 patients in group B. Incidence of PSAS of was seen less in group A when compared with to group B and there was a noteworthy statistical difference, with p value 0.043, in incidence of post spinal anaesthesia shivering in patients between group A and group B. In Group A (Magnesium Sulfate), 8 patients had Grade 1 shivering at 15 minutes, 5 at 30 minutes, and 4 at 45 minutes. In Group B (Dexamethasone), 9 patients had Grade 1 shivering at 15 minutes, 12 at 30 minutes, and 7 at 45 minutes. For Grade 2 shivering, 4 patients in Group A experienced it at both 15 and 30 minutes, while in Group B, 7 patients had Grade 2 shivering at 15 minutes, and 4 at 30 minutes. No patients in Group A had Grade 3 shivering, but 1 patient in Group B experienced Grade 3 at 15 minutes. Most patients in both groups had shivering no higher than Grade 2.The Fisher's Exact Test results comparing the shivering grades between Group A (Magnesium Sulfate) and Group B (Dexamethasone) at different time points are as follows:- At 15 minutes: Odds Ratio = 1.37, p-value = 0.589 (not significant), - at 30 minutes: Odds Ratio = 3.10, p-value = 0.094 (not significant) and at 45 minutes: Odds Ratio = 2.33, p-value = 0.326 (not significant). (p-value >0.05)

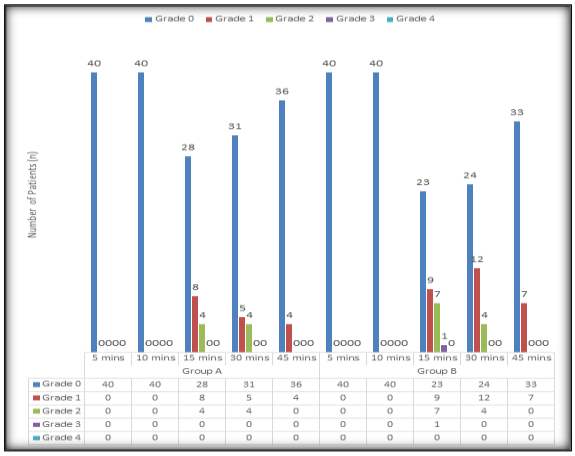

Figure 2: Comparision of Crossley & Mahajan Grade Distribution at Different Time Interval Between Group A & Group B

In our study: Grade 0 (No Shivering): In Group A (Magnesium Sulfate), 26 participants (65%) had no shivering, while in Group B (Dexamethasone), 17 participants (42.5%) had no shivering. This suggests that a higher percentage of participants in Group A experienced no shivering, indicating Magnesium Sulfate might be more effective at preventing shivering.

- Grade 1 (Mild Shivering): In Group A, 9 participants (22.5%) experienced mild shivering, compared to 15 participants (37.5%) in Group B. This suggests that Dexamethasone was less effective in preventing mild shivering than Magnesium Sulfate.-
- Grade 2 (Moderate Shivering): Group A had 5 participants (12.5%) with moderate shivering, while Group B had 7 participants (17.5%) with moderate shivering.- Grade 3 (Severe Shivering): No participants in Group A had severe shivering, but 1 participant (2.5%) in Group B experienced severe shivering. Neither group had participants with Grade 4 (Very Severe Shivering), showing that both treatments were effective in preventing the most severe forms of shivering.

Overall, Group A (Magnesium Sulfate) had a higher proportion of participants with no shivering (Grade 0) and a lower proportion with mild shivering (Grade 1) compared to Group B (Dexamethasone). Group B had a higher percentage of mild and moderate shivering, as well as 1 case of severe shivering. These findings suggest that Magnesium Sulfate may be more effective than Dexamethasone in preventing or reducing shivering, especially mild and moderate shivering. (p-value <0.05)

- In our study, shivering was categorized into two groups: mild shivering (clinically insignificant, grades 0 and 1 on the Crossley-Mahajan scale) and severe shivering (clinically significant, grades 2 and above on the same scale).
- Mild shivering was observed in 35 patients in Group A (Magnesium Sulfate) and 32 patients in Group B (Dexamethasone).
- Severe shivering (grades 2 and above) was seen in 5 patients in Group A and 8 patients in Group B.

Overall, the prevalence of mild shivering was higher in Group A (Magnesium sulphate) and severe shivering was higher in Group B (Dexamethasone). However, there was no statistically significant difference between the two groups.

In our study, the following adverse events were observed:- Hypotension occurred in 7 patients in Group A (Magnesium Sulfate) and 6 patients in Group B (Dexamethasone).

- Bradycardia was noted in 3 patients in Group A and 2 patients in Group B.
- Nausea and vomiting were experienced by 2 patients in each group.
- Tramadol was required for the management of shivering (Grade ≥2) in 5 patients in Group A and 8 patients in Group B.

DISCUSSION

There were no significant differences in mean age, gender and mean weight between the groups. the gender makeup of both groups was identical, ruling out gender as a confounding variable. Additionally, weight did not significantly differ between the groups, further reducing the likelihood that this factor affected the study outcomes.

Furthermore, no significant differences were observed regarding type of surgery ($p = 0.797$) and duration of surgery ($p = 0.424$). This suggests that the type of surgical procedure and the length of surgery did not vary significantly between the groups.

These findings align with Ibrahim et al. (2014), in a study evaluating the efficacy of magnesium sulfate for shivering prevention, found no significant demographic differences between groups receiving magnesium sulfate as prophylaxis or therapy, reinforcing the validity of the study's design.[13] Similarly, Bhatnagar S et al. (2007), who compared pethidine and tramadol for post-spinal shivering, also observed no significant demographic variations, suggesting that these factors did not influence their study outcomes.[14]

In our study, we evaluated the time of onset and the peak level of both sensory and motor blocks, as well as the duration of sensory blockade, in relation to the effectiveness of pharmacological interventions in preventing shivering. (p-value >0.05) This suggests that the timing of sensory and motor blockade was consistent across the intervention groups, indicating that any differences in shivering prevention were not due to differences in the onset or depth of the spinal anesthesia itself.

However, we observed a significant difference in the duration of the sensory block between the groups. Specifically, the dexamethasone group exhibited a significantly longer duration of sensory block (Mean = 185.90 ± 18.3) compared to the magnesium sulfate group (Mean = 162.3 ± 20.77). This difference was statistically significant ($p < 0.001$) The extended duration of sensory block can contribute to prolonged analgesia and potentially reduce the need for additional analgesic interventions during the perioperative period, which might also indirectly affect the occurrence and severity of shivering.

Our findings are consistent with Priyanka et al. (2017), who investigated the effects of dexamethasone on spinal anesthesia in a cohort of patients and found a significantly longer duration of sensory block in those receiving dexamethasone compared to the control group. Their study demonstrated that dexamethasone prolongs the sensory block significantly ($p < 0.001$), which aligns with our results and supports the idea that dexamethasone can have a modifying effect on the duration of sensory blockade.[15]

A significant difference in heart rate was observed at 30 minutes ($p = 0.048$) and 90 minutes ($p = 0.040$) post-administration of subarachnoid blockade between the dexamethasone and magnesium sulfate groups. The magnesium sulfate group showed a lower heart rate at both time points, which may indicate a mild depressive effect of magnesium sulfate on sympathetic outflow. Magnesium sulfate is known for its properties as a calcium antagonist, which can reduce the release of norepinephrine, thus leading to lower heart rates. This finding is consistent with Sachidananda et al. (2018), who reported a reduction in heart rate in the magnesium sulfate group compared to controls.[16]

The magnesium sulfate group exhibited significantly lower diastolic blood pressure (DBP) at both 12 minutes ($p = 0.009$) and 120 minutes ($p = 0.005$) post-spinal anesthesia, compared to the dexamethasone group. These results align with Ibrahim et al. (2014), who found that magnesium sulfate reduced DBP compared to a placebo group in patients undergoing spinal anesthesia.[13]

Significant differences in MAP were observed at 12 minutes ($p = 0.014$), 35 minutes ($p = 0.047$), and 120 minutes ($p = 0.030$), with the magnesium sulfate group showing consistently lower MAP values compared to the dexamethasone group. Ibrahim et al. (2014) also noted similar findings in their study, where magnesium sulfate administration resulted in lower MAP. The observed reduction in MAP in the magnesium sulfate group likely reflects the combined effects of its vasodilatory and calcium channel-blocking properties.[13] However, despite the statistically significant differences, the MAP in both groups remained within clinically acceptable ranges.

Our findings are in agreement with Ismail et al. (2020), who evaluated hemodynamic parameters after administering dexamethasone and dexmedetomidine to patients undergoing spinal anesthesia. They found that while both drugs maintained stable hemodynamics, dexmedetomidine led to slight reductions in heart rate and blood pressure.[17]

In conclusion, while both dexamethasone and magnesium sulfate were effective in managing hemodynamics during the perioperative period, magnesium sulfate exhibited a more pronounced effect in reducing heart rate and blood pressure. This effect, although statistically significant, was generally mild and did not lead to clinically significant complications. Both agents offer a safe option for preventing post-spinal anesthesia shivering, but attention should be given to potential mild hemodynamic changes, especially in patients with preexisting comorbidities.

In our research we observed the overall incidence of PSAS was 35% in magnesium sulphate group and 57.5% in dexamethasone group which was statistically significant (p value - 0.043). Additionally, when the severity of shivering was assessed, 20% of patients in the dexamethasone group experienced Grade 2 or higher shivering (moderate to severe), compared to 12.5% of patients in the magnesium sulfate group ($p = 0.02$).

When shivering grades were categorized into clinically insignificant (Grade 0 & 1) and clinically significant (Grade 2 or more), we found no statistically significant difference in the incidence of clinically significant shivering between the two groups (p value - 0.363). This suggests that while magnesium sulfate was superior in preventing severe shivering, dexamethasone did not differ significantly from magnesium sulfate in its ability to reduce clinically significant shivering. This may indicate that both drugs are effective, but magnesium sulfate has a more potent effect in preventing severe episodes.

Our study's findings align with several key studies that have evaluated the efficacy of magnesium sulfate and dexamethasone in preventing post-spinal anesthesia shivering. In study by Ibrahim et al. (2014) when magnesium sulphate was used prophylactically, there were only 5% of patients who developed severe grades of shivering when compared to therapeutic and control group, which was statistically significant as well having value of p less than 0.05.[13] This result mirrors our findings, where magnesium sulfate demonstrated a notable reduction in the severity of post-spinal shivering.

Azeem AE et al. (2016) also provided compelling evidence supporting the use of dexamethasone for shivering prevention. Their study directly compared dexamethasone to pethidine, a drug often used to manage post-neuraxial anesthesia shivering.[8] They observed a significant reduction in both the incidence and severity of shivering in patients who received dexamethasone, which is consistent with the results of our own study. When related to our study it suggests that dexamethsone is not only effective but also more reliable than pethidine, which is associated with potential side effects such as sedation, respiratory depression, and nausea.

CONCLUSION

Magnesium sulfate was more effective in reducing the incidence and severity of post-spinal shivering compared to dexamethasone. Additionally, both drugs had comparable safety profiles and are readily available in limited resource settings, with no significant differences in complications such as hypotension, bradycardia, nausea, or vomiting.

Overall, magnesium sulfate proved to be a superior option for shivering prevention without causing significant hemodynamic instability and magnesium sulfate showed a faster onset of action and provided better control of shivering in the perioperative period, further supporting its use as a more effective agent for managing post-spinal anesthesia shivering. These results highlight the potential of magnesium sulfate as a preferred pharmacological intervention for post-spinal shivering management. It was also found that when dexamethasone was administered intravenously it significantly increased the duration of sensory blockade when compared to magnesium sulphate.

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