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Magnesium sulfate intravenous infusion versus intrathecal injection for prevention of post-spinal shivering during lower limb fracture surgery: a randomized controlled study

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Abstract: Background: Shivering is a prevalent adverse event after spinal anesthesia, often disturbing to medical staff and hazardous to patients. Intravenous magnesium sulfate [$MgSO_4$] has been proven to be effective in prevention of post-spinal shivering. However, the risk of intravenous route to develop hypermagnesemia in certain patients encouraged us to do this study in order to investigate the effectiveness of intrathecal $MgSO_4$ as an alternative to the intravenous route in prevention of post-spinal shivering. The enrolled 135 patients were allocated to 3 groups, 45 patients each, groups: intrathecal [T], IV $MgSO_4$ infusion [M], and control [C]. Group T (no. = 45) received 50 mg $MgSO_4$ added to heavy bupivacaine 0.5% intrathecally, while group M (no. = 45) received IV $MgSO_4$ as 50 mg/kg in 100 cc saline within 20 min as a loading dose then infused as 2 mg/kg/h after performing spinal anesthesia. The vital signs, duration and shivering grades, temperature, and adverse effects were recorded.

Results: T and M groups showed a significant difference from control as regard the incidence of shivering with 40%, 26.7%, and 64.4% for T, M, and C groups, respectively, patients needed rescue pethidine were 17.7%, 11.1%, and 60% for group T, M, and C, respectively, and shivering duration (min) was 24.86 ± 7.411, 20.47 ± 6.61, and 45 ± 36.2 for groups T, M, and C, respectively with a statistically insignificant difference between group T and M as regards these parameters.

Conclusions: Intrathecal $MgSO_4$ has the potentiality to be used as an alternative to IV route regarding prevention of post-spinal shivering. This makes advantage for intrathecal magnesium use in patients at risk for magnesium toxicity.

Keywords: Shivering, Spinal anesthesia, Intrathecal magnesium, Intravenous magnesium

Background

Shivering is a frequent adverse event of neuraxial block. It is an unintentional, muscular oscillation augmenting metabolic production of heat (Frank et al. 1995). Neuraxial block reduces the control of peripheral and central thermoregulation. Shivering is distressing to both patients and anesthesiologists (Crowley and Buggy 2008).

Intravenous magnesium can decrease shivering incidence in patients receiving neuraxial anesthesia by different mechanisms (Kizilirmak et al. 1997) but may have some lethal effects related to hypermagnesemia (Connolly and Worthley 1999). Some intrathecal adjuvants were effective in prevention of shivering (Eskandr and Ebeid 2016). This encouraged studies for the use of intrathecal $MgSO_4$ administration that proved to be effective in prevention and controlling the perioperative

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shivering with a relatively safe profile (Seyed et al. 2013; Mostafa et al. 2019; Omar et al. 2019).

No enough studies done before that confirmed the effectiveness of intrathecal magnesium sulfate to be used as an alternative to the intravenous route in preventing post-spinal shivering in order to avoid the risk of hypermagnesemia associated with the IV route that may occur in certain cases. So, this double blinded randomized controlled trial [RCT] was done trying to fill this gap in literature.

Methods

This double-blinded RCT was conducted in the orthopedic operating unit during the period from 1 February to 30 May 2020. After obtaining the institutional ethics committee approval, 135 patients between 20 and 45 years age, with grades I and II according to the American Society of Anesthesiologists [ASA] undergoing orthopedic trauma operation for lower limb under spinal anesthesia were involved in the study. A written informed consent was received from the involved patients in the study. Clinicaltrials.gov. registry was done with (ID: NCT04249804, Date of registration: 31 January 2020).

Exclusion criteria was unstable hemodynamics, cardiac, pulmonary, kidney, hepatic, psychiatric illness, thyroid disorders, cerebrovascular inefficiency, coagulopathy, patients on vasoactive medications, body mass index > 35, allergy to $MgSO_4$, height less than 160 cm or more than 190 cm, baseline temperature above 38 °C or below 36 °C, transfused blood of > 2000 mL intra-operatively and surgery lasting > 3 h.

During preoperative assessment, history taking and examination of the patients were done. Investigations such as CBC, coagulation profile, serum urea, and creatinine, liver enzymes were performed. IV metoclopramide 10 mg, midazolam 0.03 to 0.05 mg/kg were given as premedication and a preload of 10 mg/kg Ringer's lactate solution at room temperature in the preparation room was given to all patients.

In the OR, monitoring was done to all patients with pulse oximetry, NIBP, ECG, and axillary thermometer. Operating room temperature was kept in the range of 24–25 °C. The baseline of all vital sign values was recorded.

Patients were randomized according to a computer-generated random number and were allocated to group [T] for intrathecal $MgSO_4$, [M] for IV $MgSO_4$ infusion and [C] for control. M group (no. = 45) , after performing spinal anesthesia, received IV magnesium sulfate as 50 mg per kg in 100 cc isotonic saline within 20 min as a loading dose, after which IV magnesium sulfate, at a concentration of 20 mg/ml, was infused at a rate of 0.2 ml/kg/h in a separate infusion set. Patients in T group (no. = 45) received 50 mg $MgSO_4$ added to heavy bupivacaine 0.5% intrathecally. Control group was given 0.5 % heavy bupivacaine intrathecally without additives. Groups C and T, after performing spinal anesthesia, received IV 100 cc isotonic saline within 20 min as a loading dose, after which an infusion of isotonic saline at a rate of 0.2 ml/kg/h was given in a separate infusion set, to be equivalent to the rate given in the M group. The anesthesiologist who prepared the drugs for spinal anesthesia and the infusion regimens was then replaced by the anesthesiologist who performed the spinal anesthesia and recorded the data so the recording anesthesiologist was blinded to the study.

The spinal block was performed using 25 G Quinke needle in sitting position at L3–4 or L4–5 intervertebral space. The volume administered was based on the height of the patients (160-170 cm receives 3 ml; 171–190 cm receives 3.5 ml) then the sensory and motor block level was evaluated by pinprick and Bromage scale, respectively. Parameters of vital signs were documented every 5 min after receiving spinal anesthesia and up to 2 h. Hypotension was defined as < 20% of the basal mean arterial blood pressure (MAP) or systolic BP < 90 mmHg and was responded to by injection of 5–10 mg IV ephedrine. Atropine 0.5 mg IV was injected when HR became < 45 b/pm.

Shivering duration after spinal block was recoded. Temperature from axilla and shivering grades were recorded every 10 min. Shivering grades were evaluated by the scale of Crossley and Mahajan 1994 as [0, absent shivering; 1, piloerection or peripheral vasoconstriction, i.e., cyanosis, without seen shivering; 2, activity in one group of muscles; 3, activity in > 1 group of muscles without generalized shivering; and 4, whole body shivering]. If grades III and IV shivering sustained for more than 10 min, pethidine 25 mg was given intravenously as a rescue therapy and number of subjects required rescues were recorded. Sedation score was assessed after 30 min of performing spinal anesthesia using the Ramsay sedation scale.

Adverse events were recorded every 10 min during the intra and post-operative period. These adverse events included nausea and vomiting, bradycardia, arrhythmia and hypotension, diminished deep tendon reflexes, depressed respiration, and over-sedation. Deep tendon reflexes were evaluated in upper extremities by testing tendon jerk of brachioradialis *tendon using a hummer.* Depressed respiration was monitored by the respiratory rate and oxygen saturation. Over-sedation was defined as reaching grade III or more. Patients were monitored for all parameters in the unit of post-anesthesia care every 10 min post-operatively until regression of 4 segments of the sensory block and the duration of 4 segments regression and motor block (complete motor block recovery was assumed when the Bromage score was (grade I)) were recorded. Patients were observed for possible neurologic deficits at the time of discharge from the hospital.

Outcomes

The incidence of post-spinal shivering within groups was targeted as the primary aim. Secondary aims targeted were the number of patients needed rescue pethidine, side effects, and changes in temperature, sedation scores, and vital parameters.

Statistical analysis

Data was analyzed by Statistical Package for Social Sciences (SPSS, IBM, USA) version 20.0. Results were illustrated as mean ± standard deviation for quantitative variables. For categorical data as demographics, shivering incidence, and adverse effects, chi-square was used for analysis. Comparison shivering duration was done with the use of one-way ANOVA test. Vital signs trends were assessed using chi-square test. Statistical significance was considered when the P value was < 0.05.

Calculation of the sample size was done by G power software 3.1.9.4. Analysis was done on shivering incidence after spinal anesthesia as the primary outcome of our study. Previous studies reported the incidence as 67.5% where magnesium sulfate decreased the incidence to 39% (Sachidananda et al. 2018). Taking a study power of 80%, an alpha error of 0.05 and an effect size of 0.39, a size of 45 subjects per group was calculated.

Results

One hundred thirty-five participants were involved in the study, 45 in each group (Fig. 1) Patients characteristics are shown in (Table 1).

Shivering incidence in patients receiving both regimens was 40% in the T group and 26.7% in group M, while there was a statistically insignificant difference between groups. Both groups were able to control shivering that only 17.7% and 11.1% of patients in group T and M, respectively needed rescue pethidine to control shivering. There was an insignificant statistical difference between groups either in the number of patients needed rescue pethidine or as regard the duration of shivering (Tables 2 and 3). Yet, both groups were statistically different from the control as regards these parameters (P < 0.05). The grades of shivering were highest in the control group with significant statistical difference from the other groups and highest mean of 1.8 at 40 min. Although group M showed lower grades of shivering with the highest mean of 0.47 and 0.36 for groups T and M, respectively, there was a statistically insignificant difference as regard shivering grades (Fig. 2) (Table 4). HR showed statistically significant difference with a P < 0.05 between both groups and control except for baseline and in 10 min after start of the regimen. Group T was lower than group M throughout the study but with no significant statistical difference (Fig. 3).

As regards MAP, insignificant difference resulted with P > 0.05 either between M and T groups or between both groups and control (Fig. 4). Sedation scores between groups showed no significant difference with no documented cases of over sedation or agitation (Fig. 5). The incidence of complications showed no significant difference between groups (Table 5). Also, there was no statistical difference as regards the duration of 4

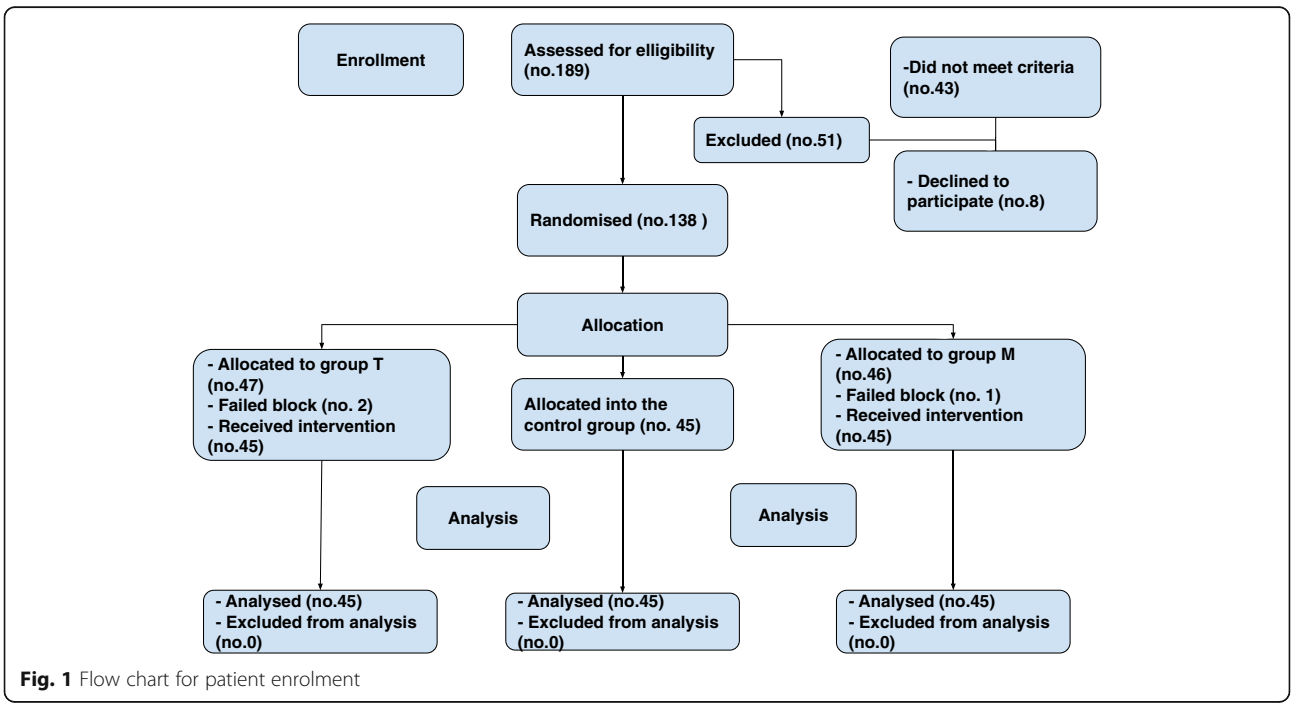

Fig. 1 Flow chart for patient enrolment

Table 1 Patients characteristics

Variables	Group	N	Mean	SD
Age (years)	Group T	45	37.64	6.087
	Group M	45	32.02	6.188
	Group C	45	31.5	8.24
Weight (kg)	Group T	45	77.09	9.095
	Group M	45	73.31	7.486
	Group C	45	74.6	9.85
Height (cm)	Group T	45	174.58	8.327
	Group M	45	172.38	6.308
	Group C	45	175.2	7.33
		N	Percent	
Sex	Male	93	68.8%	
	Female	42	31.2%	
ASA	I	107	79.26%	
	II	28	20.74%	

Data are presented as numbers (*N*), percent (%), means and standard deviation (SD)

segments block regressions and motor block, and no neurological deficits at time of hospital discharge were reported (Tables 3, 4 and 5). There was no relation found between mean change in temperature and incidence of shivering in patients who had shivering and those who did not have shivering (Table 6).

Discussion

This double-blinded RCT was done on 135 patients undergoing orthopedic trauma surgery for the lower limbs under spinal anesthesia. The study was done to compare the effectiveness of intrathecal $MgSO_4$ against intravenous $MgSO_4$ infusion in reducing post-spinal shivering incidence in order to be used as an alternative to the IV route, especially in patients at risk for hypermagnesemia. The hypothesis of this study was that intrathecal $MgSO_4$ is effective as or more than intravenous $MgSO_4$ infusion in prevention of post-spinal shivering. This target was not targeted by enough previous studies. The results supported this hypothesis showing that the pre-emptive administering of magnesium sulfate reduced shivering incidence after spinal from 64.4% in control to 40% in the T group and 26.7% in group M, shivering incidence grades 3 and 4 was 19.9% for group T and 15.5% for group M. Only 17.7% and 11.1% in group M and T, respectively, needed rescue pethidine to control shivering and both groups were able to decrease grades and duration of shivering with a significant difference from the control group. Despite superiority of the IV route, there was no significant statistical difference found between both regimens in the incidence, duration, need for rescue treatment or grades of shivering, or the incidence of complications.

Shivering preserves heat to the body, yet, it is annoying and can be hazardous to patients with limited cardiac or pulmonary reserve due to shivering induced increase in catecholamine, lactic acid, CO_2 production, cardiac output, respiratory work, consumption of oxygen and post-operative pain from stretching of surgical incision. Shivering interferes with patients monitors by artifacts or BP and pulse oximetry recording disruption (De Witte and Sessler 2002). Although there is no relationship linearity between shivering development and body temperature, hypothermia represents an important risk factor for shivering (Bajwa et al. 2012). Shivering may occur in normothermic patients under neuraxial anesthesia (Joris et al. 1994). This can be explained by other mechanisms than heat loss, including reflexes of spinal cord, post-surgical pain, decrease in sympathetic stimulation, pyrogenic production, and adrenal inhibition. So, shivering can be considered both thermogenic and non-thermogenic (Berti et al. 1998).

Neurotransmitter pathway of shivering involves many receptors such as α-2, opioid, anti-cholinergic, and serotonergic. So, various drugs acting on such receptors were studied in many researches for the management of shivering after spinal anesthesia (De Witte and Sessler 2002). Magnesium serves as N-methyl-D aspartate (NMDA) receptor non-competitive antagonist that is fairly safe under hypothermia (Nowak et al. 1984). It can

Table 2 Shivering incidence and rescue treatment within groups

Variables	Incidence of shivering				Patients needed rescue treatment			
	N (%)				*N* (%)			
	No	Yes	*P value		No	Yes	*P value	
Group T	27 (60 %)	18 (40 %)	0.197		36 (80 %)	8 (17.7 %)	0.213	
Group M	33 (73.3%)	12 (26.7%)			40 (88.8%)	5 (11.1%)		
Group C	16 (35.6%)	29 (64.4%)	**P value	***P value	18 (40%)	27 (60%)	**P value	***P value
			0.034	0.006			0.01	0.003

Data are presented as numbers (*N*), percent (%)
**P* value (for group T versus M)
***P* value (for group C vs T)
****P* value (for group C vs M). *P* value < 0.05 is significant

Table 3 Duration of shivering, 4 segments block regressions and motor block

Variable	Group	Mean	SD	*P value	
Duration of shivering (minutes)	T	24.86	7.411	0.092	
	M	20.47	6.61		
	C	45	36.2	**P value	***P value
				0.015	0.008
Duration of 4 segments block regressions (minutes)	T	60.67	7.8	0.15	
	M	57.78	10.14		
	C	58.6	10.4	**P value	***P value
				0.185	0.655
Duration of motor block (minutes)	T	56	5.8	0.09	
	M	54.4	7.93		
	C	55.78	8.13	**P value	***P value
				0.81	0.16

Data are presented as means and standard deviation (SD)
**P* value (for group T versus M)
***P* value (for group C vs T),
****P* value (for group C vs M). *P* value < 0.05 is significant

prevent shivering at multiple levels by reducing the threshold of shivering by modulating thermoregulation (Singewald et al. 1998). In the locus coeruleus, it modulates serotoninergic and noradrenergic neurons enhancing to the effect of NMDA receptors in the dorsal raphe nucleus (Alojado et al. 1994). Magnesium causes peripheral vasodilatation, so, it improves cutaneous circulation and decreases shivering incidence (Gozdemir et al. 2010). It increased the rate of surface cooling in unanesthetized volunteers improving patient's comfort (Zweifler et al. 2004). It not only produces a central effect but also decreases the gain of shivering by peripheral muscle relaxation via calcium antagonist (Lee et al. 1996).

A meta-analysis was done by Kawakamia et al. about the efficacy of magnesium in shivering preventing during surgery. The shivering incidence was 9.9% in the magnesium group and 23% in control. They concluded that giving intravenous magnesium perioperatively decreased shivering effectively and recommended that IV

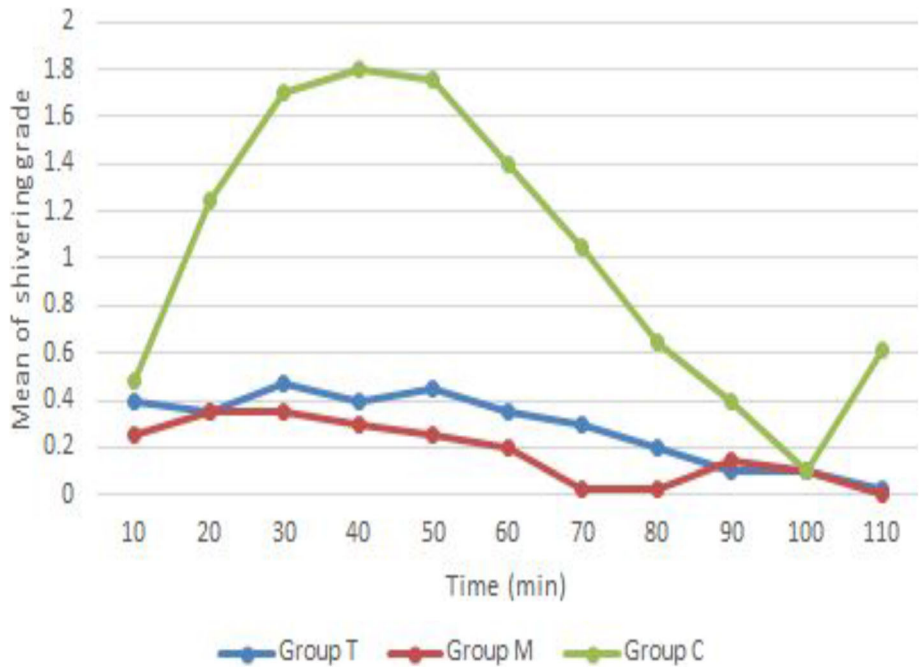

Fig. 2 Grades of shivering per time in minutes

Table 4 Maximumm shivering grades

Grade	Group T (*N*)(%)	Group M (*N*)(%)	Group C (*N*)(%)	**P* value	***P* value	****P* value
0	27(60%)	33 (73.3%)	16 (35.6)			
1	2(4.4%)	3(6.7%)	1(2.2%)	0.416	0.54	0.2
2	7(15.6%)	2(4.4%)	2(4.4%)	0.087	0.045	0.8
3	6(13.3%)	6(13.3%)	12(26.66%)	0.88	0.016	0.016
4	3(6.6%)	1(2.2)	14(31.1%)	0.294	0.007	0.004

Data are presented as numbers (*N*), percent (%)
**P* value (for group T versus M)
***P* value (for group C vs T)
****P* value (for group C vs M). *P* value < 0.05 is significant

magnesium effectiveness to reduce shivering does not need to be confirmed by more studies. Although intrathecal magnesium reduced shivering incidence effectively, it had a low evidence quality as no adequate studies were done to confirm that neuraxial magnesium prevents shivering (Kawakami et al. 2019).

Ibrahim et al. studied the prophylactic magnesium sulfate against the therapeutic use for post-spinal shivering showed a shivering incidence of 15% in prophylactic group and 45% in therapeutic group, meperidine was needed as a rescue in 20% of the prophylactic group and 50% of the therapeutic group, while there was no correlation between prevalence of shivering and temperature. Compared to our results the incidence and the need for rescue were 26.7% and 11.1%, respectively, for the IV infusion group. However, in our study, we did not use $MgSO_4$ boluses and also, there was no temperature-shivering correlation was found (Ibrahim et al. 2014).

Osama et al. compared dexmedetomidine, magnesium, and pethidine on 120 patients under spinal anesthesia. No significant differences in incidence of shivering grades 3–4 were found. They showed significant difference as regard response rate between groups that dexmedetomidine group had the highest while magnesium sulfate group had the lowest. So, IV $MgSO_4$ was comparable to other regimens in prevention of shivering but was worse in controlling shivering as pethidine and dexmedetomidine (Osama et al. 2019).

The validity of intrathecal magnesium sulfate to decrease incidence and control shivering has been studied before in many clinical trials. (Seyed et al. 2013; Mostafa et al. 2019) studied intrathecal $MgSO_4$ with a dose of 25 mg and showed a higher shivering grades in the control

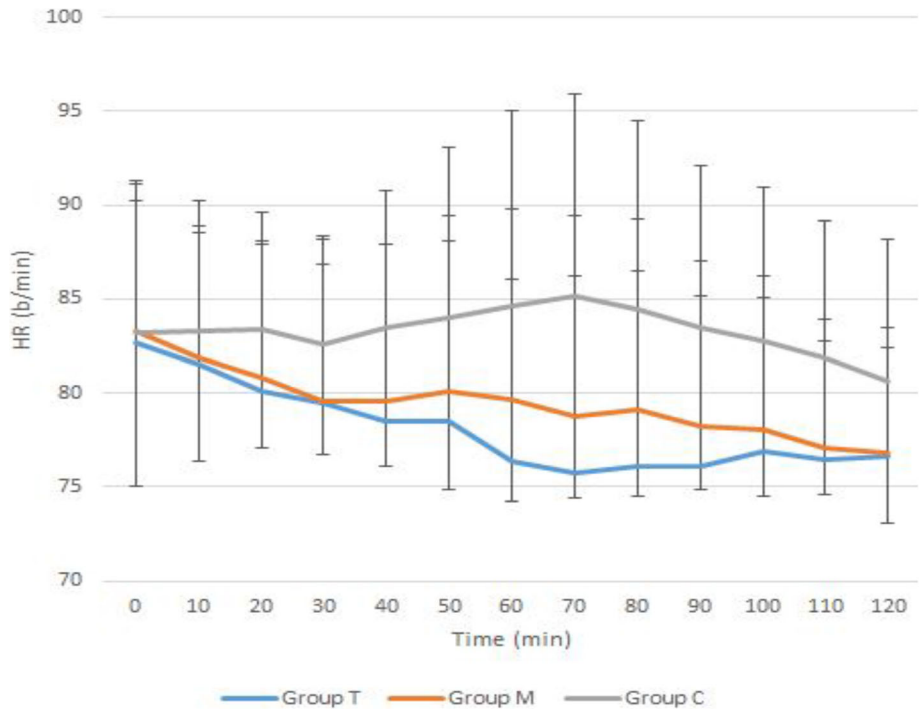

Fig. 3 HR trends in groups. HR: heart rate (beat per minute)

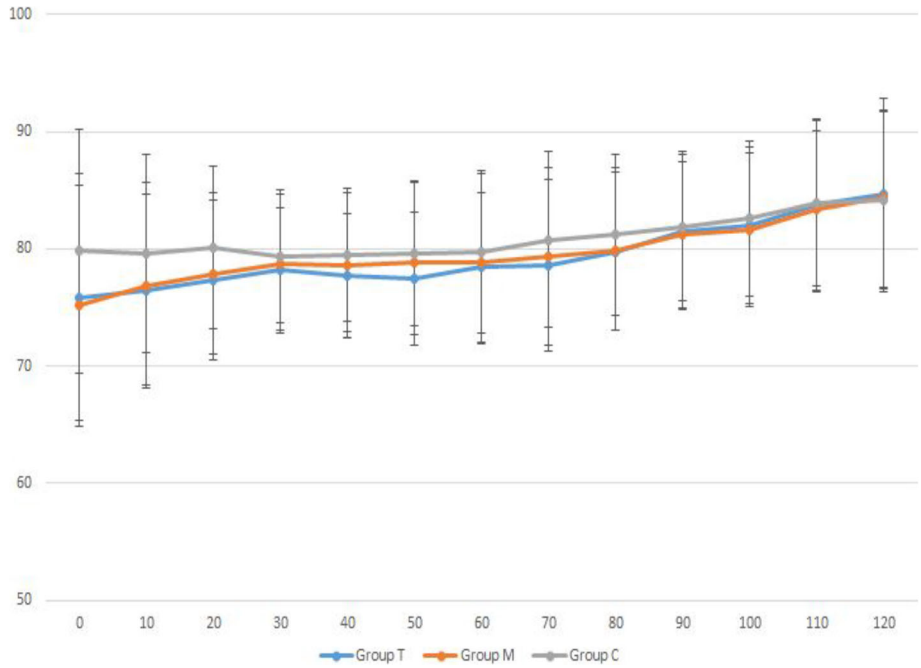

Fig. 4 MAP trends in groups. MAP: mean arterial pressure (mmHg)

and incidence of shivering of 25% and 31% for both studies, respectively. Omar et al. compared the anti-shivering effect of intrathecal $MgSO_4$ and dexmedetomidine against placebo. $MgSO_4$ and dexmedetomidine groups were both effective with non-significant difference between them (Omar et al. 2019).

Lethal effects of hypermagnesemia may develop if IV $MgSO_4$ was given in inappropriate doses or in patients prone to develop hypermagnesemia as renal failure, elderly, and cancer patients with high BUN. These effects comprise respiratory dysfunction, bradycardia, heart block, and asystole (Connolly and

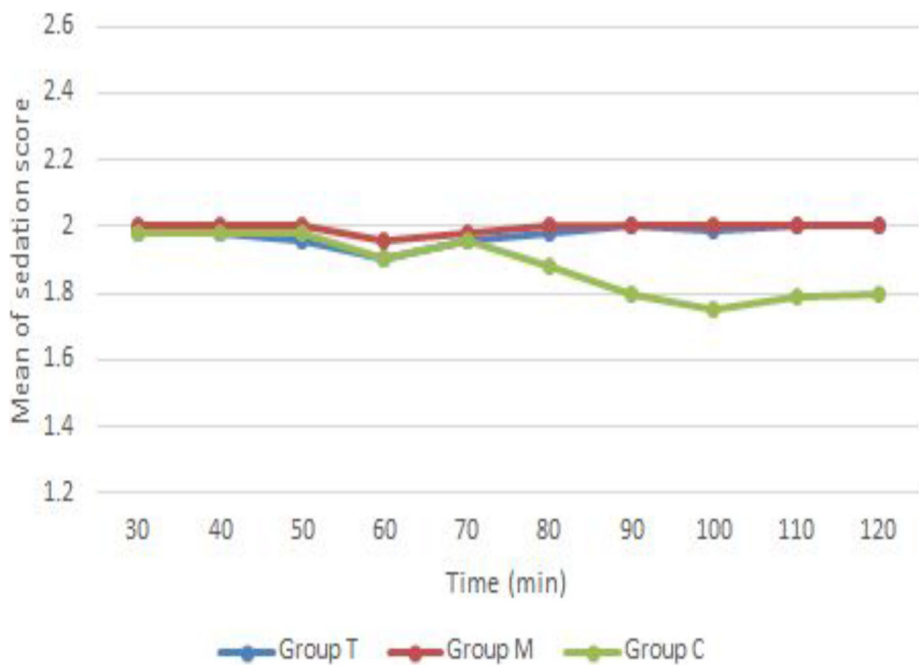

Fig. 5 Sedation score in groups

Table 5 Complications incidence within groups

Complication		Group T		Group M		Group C		*P* value
		N	%	*N*	%	*N*	%	
Respiratory depression	No	45	100.0%	45	100.0%	45	100.0%	
	Yes	0	0.0%	0	0.0%	0	0.0%	
Absence of tendon reflex	No	45	100.0%	45	100.0%	45	100.0%	
	Yes	0	0.0%	0	0.0%	0	0.0%	
Over-sedation	No	45	100.0%	45	100.0%	45	100.0%	
	Yes	0	0.0%	0	0.0%	0	0.0%	
Bradycardia	No	45	100.0%	45	100.0%	45	100.0%	
	Yes	0	0.0%	0	0.0%	0	0.0%	
Arrhythmia	No	45	100.0%	45	100.0%	45	100.0%	
	Yes	0	0.0%	0	0.0%	0	0.0%	
Neurological deficit	No	45	100.0%	45	100.0%	45	100.0%	
	Yes	0	0.0%	0	0.0%	0	0.0%	
Hypotension	No	42	93.3%	38	84.4%	42	84.4%	> 0.05
	Yes	3	6.7%	7	15.6%	3	15.6%	
Nausea	No	37	82.2%	38	84.4%	40	84.4%	> 0.05
	Yes	8	17.8%	7	15.6%	5	15.6%	
Vomiting	No	40	88.9%	38	84.4%	39	84.4%	> 0.05
	Yes	5	11.1%	7	15.6%	6	15.6%	

Data are presented as numbers (*N*), percent (%), *P* value < 0.05 is significant

Worthley 1999; Nakamura et al. 2013; Nakashima et al. 2016).

Two reports of inadvertent Mg sulfate infusion, one epidural, and one intrathecal showed no resulted complications. In the intrathecal one, 1000 mg were injected; there was no sensory loss. However, a 5-h weakness in the legs occurred then a total uneventful recovery followed (Mebazaa et al. 2011). Ninety patients were subjected by Hari et al. to compare intravenous infusion and intrathecal $MgSO_4$ in spinal anesthesia, and they found that complications incidence was negligible and comparable (Hari et al. 2017). Studies that used 50 mg of magnesium intrathecally did not reveal any increased complication incidence. Yet, Jabalameli et al. reported that when magnesium was given in a dose of 100 mg intrathecally, there was an increased intra- and post-operative adverse events incidence like nausea, vomiting, and decreased blood pressure compared with lower doses and placebo (Jabalameli and Pakzadmoghadam 2012). In our study, it seems that intrathecal $MgSO_4$, when given in the current investigated doses, to be safe as there was insignificant difference regarding the duration of 4 segments block regressions and motor block. Besides, no neurological deficits at time of hospital discharge were reported.

Limitations

Studies with larger groups are required to settle our results to completely eliminate the problem of post-spinal shivering. The intrathecal dose needs further modification in order to eliminate the superiority of the IV regimen despite the statistically insignificant difference between both groups in the prevention of shivering. This work did not compare their effects on vulnerable groups as ASA III and IV.

Conclusion

The pre-emptive use of intravenous or intrathecal magnesium sulfate reduced post-spinal shivering incidence and decreased the need for rescue pethidine, grades, and

Table 6 Relation of the mean change in temperature and the incidence of shivering in groups

Variables		Group T		Group M		Group C		*P* value
		N	Mean ± SD	*N*	Mean ± SD	*N*	Mean ± SD	
Temperature change (Celsius)	Shiver-ing	27	1.0538 ± 0.36108	33	0.9637 ± 0.26461	16	0.944 ± 0.224	> 0.05
	No	18	1.0619 ± 0.33834	12	0.9333 ± 0.20587	29	8.92 ± 0.32	

Data are presented as numbers (*N*), means and standard deviation (SD). *P* value < 0.05 is significant

duration of shivering with insignificant statistical difference between both groups. The study results suppose that the intrathecal route can be used as an alternative to IV route, especially in patients with risk for magnesium toxicity.

Abbreviations

ASA: American Society of Anesthesiologists; BP: Blood pressure; CO_2: Carbon dioxide; CBC: Complete blood count; ECG: Electrocardiography; HR: Heart rate; I.V.: Intravenous; $MgSO_4$: Magnesium sulfate; MAP: Mean arterial pressure; NIBP: Non-invasive blood pressure; OR: Operation room; RCT: Randomized controlled trial; SD: Standard deviation

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Not applicable.

Authors' contributions

SA was a major contributor in the conception and designing of the study. NM revised the manuscript. RM collected the data. AS collected the data. MS interpreted and analyzed the data. All authors have read and approved the manuscript.

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Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate

Research ethics committee of Kasr Alainy, Faculty of Medicine, Cairo University gave approval (ID: MS-261-2019), and informed written consent was obtained from all the patients after the description of the intervention and its potential complications.

Consent for publication

Not applicable

Competing interests

The authors declare that they have no competing interests.

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