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Dr. Kavin Kumar
Assistant Professor of
Anesthesiology, Trichy SRM
Medical College Hospital and
Research Centre, Tamil Nadu,
India

Dr. Sivashanmugam
Assistant Professor of
Anesthesiology, Trichy SRM
Medical College Hospital and
Research Centre, Tamil Nadu,
India

Dr. Sundari
Assistant Professor of
Anesthesiology, Trichy SRM
Medical College Hospital and
Research Centre, Tamil Nadu,
India

Corresponding Author:
Dr. Kavin Kumar
Assistant Professor of
Anesthesiology, Trichy SRM
Medical College Hospital and
Research Centre, Tamil Nadu,
India

A double blinded study comparing magnesium sulphate and fentanyl as intrathecal adjuvant to hyperbaric bupivacaine in orthopaedic lower limb surgery

Dr. Kavin Kumar, Dr. Sivashanmugam and Dr. Sundari

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Abstract

Aim: To compare the efficacy of intrathecal magnesium sulphate with fentanyl as adjuvant to 0.5% hyperbaric bupivacaine in orthopaedic lower limb surgery.

Objectives: This was a prospective randomized double blind controlled study conducted in patients undergoing orthopaedic lower limb surgery. Both the observer and the patients were blinded to the study drug. This study was conducted in the Department of Anaesthesiology Trichy SRM Medical College Hospital and Research Centre during June 2019 to October 2020.

Observation: We compared the efficacy and safety of 100 mg (0.5 ml) of intrathecal magnesium sulphate (group 2) with 25 µg (0.5 ml) of fentanyl (group 1) and 0.5 ml of normal saline as control (group 0), as an adjuvant to hyperbaric bupivacaine for the onset, duration, quality of sensory, motor block and for the duration of post-operative analgesia. Duration of post-operative analgesia was assessed by noting the time to first rescue analgesic, the total 24 hour analgesic requirement and by using VAS score. Ramsay sedation score was used to assess the level of sedation. Hemodynamic parameters were noted. Side effects such as nausea, vomiting, bradycardia, hypotension and respiratory depression were also noted.

Conclusion: The result of present study indicates intrathecal MgSO₄ is efficacious as it provides good post-operative analgesia when used as adjuvant to 0.5% hyperbaric bupivacaine in orthopaedic lower limb surgery.

Keywords: Limb surgery, magnesium sulphate, MgSO₄

Introduction

Post traumatic lower limb fracture is the commonest orthopaedic trauma requiring surgery. Orthopaedic lower limb surgeries are preferably done under spinal anaesthesia, which is the primary anaesthetic technique for many type of surgeries. Since spinal anaesthesia has limited duration of block, intrathecal adjuvants are used to prolong the duration of anaesthesia. Opioids are the commonly used intrathecal adjuvant but associated with several adverse effects. Recently magnesium sulphate has been tried as intrathecal adjuvant and found to be promising without any additional side effects. In the present study the effects of 100 mg of intrathecal MgSO₄ will be compared with 25 µg of fentanyl and control as adjuvant to 15 mg of hyperbaric bupivacaine in orthopaedic lower limb surgeries.

Aim: To compare the efficacy of intrathecal magnesium sulphate with fentanyl as adjuvant to 0.5% hyperbaric bupivacaine in orthopaedic lower limb surgery.

Objectives

1. To compare the effect of magnesium sulphate and fentanyl as adjuvant to 0.5% hyperbaric bupivacaine on duration of spinal analgesia.
2. To compare the time of onset, maximum level, time to achieve maximum level and duration of sensory block.
3. To compare the time of onset, intensity and duration of motor block.
4. To compare the duration of postoperative pain relief and total analgesic requirement in first 24 hours in three groups.

Place of study: The study was conducted in the Department of Anaesthesiology trichy SRM medical college hospital and research centre.

Study Design: Randomized double blind controlled study. Both the observer and the patient were blinded to the study drug.

Period of study: June 2019 to October 2020.

Population/participants: Patients belonging to ASA I and II between the age of 18-60 years and the height of 150-180 cm was included in the study.

Sample size: Ninety patients were included in the study. The patients were randomly allocated in three groups of 30 each using a computer generated random number table.

Methods: 90 patients planned for orthopaedic lower limb surgeries were taken up for the study and randomized into 3 groups to receive 3 ml of 15 mg 0.5% hyperbaric bupivacaine either with 0.5ml of 100 mg MgSO₄ or 0.5ml of 25 µg fentanyl or 0.5ml of normal saline. Under continuous monitoring subarachnoid block was performed under all aseptic precautions. A total volume of 3.5 ml study drug solution prepared by anaesthetist not involved in the study was injected intrathecally in all patients. Patients were assessed for characteristics of spinal anaesthesia, sedation score, hemodynamic parameters, pain score and side effects.

Statistical analysis: To obtain the intra and intergroup comparison Generalized Estimating Equation (GEE) was used. The multiple comparisons at different times in the patients were done by Least Significant difference method in GEE. Differences in demography, sensory, motor and analgesic parameters were done by one way ANOVA followed by Tukey’s test at 5%. Adverse effects were

compared by Chi-square and Fisher’s Exact test (FET). A p value of <0.05 was considered as significant.

Outcome measures

Primary: The duration of spinal analgesia following intrathecal magnesium sulphate, fentanyl and saline as adjuvant to 0.5% hyperbaric bupivacaine in orthopaedic lower limb surgery.

Secondary: Time of onset, maximum level, time to achieve maximum level and duration of sensory block. Time of onset, intensity and duration of motor block. Postoperative pain assessment (VAS score) and total analgesic requirement in first 24 hours in three groups.

Results: The demographic profiles among the three groups were comparable with respect to their age, weight, height and duration of surgery. The mean time of onset of sensory block was significantly delayed with MgSO₄ (9.20±1.44 min) as compared to control (7.87±1.27 min) and fentanyl (7.40±1.49 min). The mean height of sensory block was comparable among the three groups. The mean time to reach the maximum height of sensory block was significantly delayed with MgSO₄ (14.93±1.01 min) as compared to control (13.47±0.90 min) and fentanyl group (12.47±1.25 min). The mean duration of sensory block was significantly prolonged with MgSO₄ (112.50±9.44 min) as compared to control (93.00±9.15 min) whereas it was significantly shorter than fentanyl group (127.00±7.61 min). The mean time of onset of motor block was similar for MgSO₄ (7.80±1.42 min) and control group (7.67±1.39 min) whereas it was significantly earlier in fentanyl group (6.53±0.90 min). The mean duration of motor blockade was similar for MgSO₄ (175.00±12.03 min) and control group (179.00±10.37 min) whereas it was significantly prolonged in fentanyl group (208.00±15.79 min).

Table 1: Comparison of Sensory Block Characteristics in the three groups

Parameter		Group 0 (n=30) (Control)	Group 1 (n=30) (Fentanyl)	Group 2 (n=30) (MgSO ₄)	p-value (one way ANOVA)	Significance (Tukey’s Test at 5%)
Time to T10 (min)	mean±SD	7.87±1.27	7.40±1.49	9.20±1.44	0.000*	Group 2 was significantly different from Group 0 & 1
	Range	6-10	6-10	8-12		
Maximum T level	mean±SD	T6.93±0.69	T6.76±0.73	T6.83±0.75	0.669	NS
	Range	T6-T8	T6-T8	T6-T8		
Time to achieve maximum level	mean±SD	13.47±0.90	12.47±1.25	14.93±1.01	0.000*	All three groups were significantly different from each other
	Range	12-14	10-14	14-16		
Time to 2 segment regression	mean±SD	93.00±9.15	127.00±7.61	112.50±9.44	0.000*	All three groups were significantly different from each other
	Range	75-105	120-135	105-135		

* p <0.05 significant
NS = Not Significant.

Block Height: (Table 1)

The maximum block height achieved was T6 and minimum block height was T8 in all three groups. The mean height achieved in group 0 was T6.93±0.69 while it was T6.76±0.73 in group 1 as compared to T6.83±0.75 in group 2. The mean height of sensory block was comparable among the three groups.

Time to reach highest level of block: (Table 1)

The mean time to achieve maximum block height in group 0 was 13.47±0.90 min while it was 12.47±1.25 min in group 1

and 14.93±1.01 min in group 2. The mean time to reach maximum height of sensory block in Group 2 was significantly delayed as compared to group 0 and 1 and also group 0 was significantly delayed as compared to group 1. All three groups were significantly different from each other.

Time to two segment regression: (Table 1)

The mean time to two segment regressions in group 0 was 93.00±9.15 minutes while it was 127.00±7.61 minutes in group 1 and 112.50±9.44 minutes in group 2. The mean

time to two segment regressions was significantly prolonged in group 1 as compared to group 0 and 2 and also significantly prolonged in group 2 as compared to group 0. All three groups were significantly different each other.

Motor Block Characteristics

The comparison between motor block characteristics is shown in table 2.

Onset: (Table 2)

The time to reach Bromage 3 in group 0 was 7.67 ± 1.39 min while it was 6.53 ± 0.90 and 7.80 ± 1.42 min in group 1 and 2

respectively. The mean time of onset was significantly earlier in group 1 as compared to group 0 and 2 (p value 0.000).

Duration: (Table 2)

The mean time to reach Bromage 0 in group 0 was 179.00 ± 10.37 minutes while it was 208.00 ± 15.79 minutes in group 1 as compared to 175.00 ± 12.03 minutes in group 2. The mean duration of motor blockade was significantly prolonged in group 1 as compared to group 0 and group 2 (p value 0.000).

Table 2: Comparison of motor block characteristics

Parameter		Group 0 (n=30) (Control)	Group 1 (n=30) (Fentanyl)	Group 2 (n=30) (MgSO ₄)	p-value (one way ANOVA)	Significance (Tukey's test at 5%)
Time to B3 (min)	Mean \pm SD	7.67 ± 1.39	6.53 ± 0.90	7.80 ± 1.42	0.000*	Group 1 was significantly different from Group 0 & 2
	Range	6-10	6-8	6-10		
Time to B0(min)	Mean \pm SD	179.00 ± 10.37	208.00 ± 15.79	175.00 ± 12.03	0.000*	Group 1 was significantly different from Group 0 & 2
	Range	165-195	180-240	165-195		

*p <0.05 significant

Post-operative pain relief

Duration of spinal analgesia: (Table 3)

Duration of spinal analgesia was the time to first rescue analgesia and VAS score ≥ 3 for the first time. In Group 0 the mean time to first rescue analgesic was 184.00 ± 12.41 min while it was 292.00 ± 22.19 and 194.33 ± 11.87 min in

Group 1 and 2 respectively. The time to the first rescue analgesia was significantly prolonged in group 1 as compared to group 0 and 2, and also significantly prolonged in group 2 as compared to group 0. All three groups were significantly different from each other.

Table 3: Comparison of post-operative analgesia

Parameter		Group 0 (n=30) (Control)	Group 1 (n=30) (Fentanyl)	Group 2 (n=30) (MgSO ₄)	p-value (one way ANOVA)	Significance (Tukey's test at 5%)
Duration of spinal analgesia (min)	Mean \pm SD	184.00 ± 12.41	292.00 ± 22.19	194.33 ± 11.87	0.000*	All three groups were significantly different from each other
	Range	165-210	270-330	180-210		
Total no. of rescue analgesia required in 24 hrs. post-operatively	Mean \pm SD	4.23 ± 0.43	2.37 ± 0.49	3.30 ± 0.45	0.000*	All three groups were significantly different from each other
	Range	4-5	2-3	3-4		

*p <0.05 significant

24 hour rescue analgesic requirement: (Table 3)

The 24 hour rescue analgesic requirement was calculated on the basis of the number of rescue analgesics given in 24 hours. The average number of rescue analgesic requirement in 24 hour for group 0 (4.23 ± 0.43) was found to be significantly more than group 1 (2.37 ± 0.49) and group 2 (3.30 ± 0.45) respectively. Group 1 had significantly lower requirement of rescue analgesic in 24 hours than group 2 (p-value = 0.000). All three groups were significantly different from each other. The mean duration of spinal analgesia was significantly prolonged in MgSO₄ (194.33 ± 11.87) min as compared to control (184.00 ± 12.41 min) whereas it was significantly shorter than fentanyl (292.00 ± 22.19 min). The mean number of rescue analgesic doses requirement in 24 hour was significantly decreased in MgSO₄ (3.30 ± 0.45) as compared to control group (4.23 ± 0.43). However it was significantly more than fentanyl (2.37 ± 0.49). Hypotension was seen in all three groups, but the difference was statistically insignificant. No episodes of bradycardia, sedation, desaturation or respiratory depression.

No patients reported any nausea and vomiting. None of the patients had any other adverse effects

Conclusions

To conclude, the result of present study indicates intrathecal MgSO₄ is efficacious as it provides good post-operative analgesia when used as adjuvant to 0.5% hyperbaric bupivacaine in orthopaedic lower limb surgery.

Intrathecal MgSO₄ significantly prolonged the duration of spinal analgesia. It significantly delayed the onset, time to reach the maximum height and prolonged the duration of sensory block. The onset, intensity and duration of motor blockade were not affected. It significantly decreased the number of rescue analgesic doses requirement in 24 hour without any additional side effects.

Intrathecal fentanyl provided a longer period of spinal analgesia as compared to intrathecal MgSO₄. The onset of sensory and motor block was earlier and its duration was prolonged. Intrathecal fentanyl was found to be superior to intrathecal MgSO₄.

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