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Original Research Article

A COMPARATIVE STUDY OF MAGNESIUM SULPHATE VERSUS TRAMADOL AS ADJUVANTS TO INTRATHECAL HYPERBARIC BUPIVACAINE IN PATIENTS UNDERGOING INFRAUMBILICAL SURGERIES

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ABSTRACT

Background: Regional anaesthesia is safe and inexpensive technique. It reduces the risk of airway complications and avoids hemodynamic changes associated with laryngoscopy and intubation. Subarachnoid block provide adequate anaesthesia for patients who are undergoing infraumbilical surgery. The objective is to compare the efficacy and safety parameters using magnesium sulphate and Tramadol as adjuvants to intrathecal hyperbaric bupivacaine in subarachnoid block in terms of Onset and duration of sensory and motor block and Duration of analgesia.

Materials and Methods: 80 patients of ASA I/II physical status undergoing elective infraumbilical surgeries were randomised into 2 groups receiving one of the following for the subarachnoid block: 1. Group M (n=40) Bupivacaine (0.5% H) 2.5ml with Magnesium sulphate 50mg. 2. Group T (n=40) Bupivacaine (0.5% H) 2.5ml with Tramadol 25mg. Quality of block in terms of Time of Onset and total Duration of Sensory and Motor Blockade, 2 Segment regression time, Total analgesia time were recorded.

Results: Patients in Magnesium(M) had a significantly earlier onset of sensory block than in Tramadol(T). Mean onset of sensory block in group M was 6.51±0.97 min and in group T was 7.65 ± 0.98 min (P< 0.01). Mean onset of motor block in group M was 8.27 ± 1.12 min and in group T were 7.8 ± 1.03 min (P- 0.053). Magnesium group (M) had a significantly longer duration of sensory block than in Tramadol group (T). Mean total duration of sensory block in group M was 149.45 ± 13.6 min and in group T was 138.75 ± 7.98 min (P< 0.01). Mean duration of motor block in group M was 171.13 ± 13.61 min and in group T was 167.75 ± 7.06 min (P- 0.169).

Conclusion: Intrathecal Magnesium Sulphate is a better adjuvant than intrathecal Tramadol as it provides earlier onset and prolonged sensory block.

Keywords: Spinal anaesthesia, Intrathecal adjuvants, Tramadol, Magnesium sulphate.

INTRODUCTION

Regional anaesthesia is safe and inexpensive technique. It reduces the risk of airway complications and avoids hemodynamic changes associated with laryngoscopy and intubation.[1] Subarachnoid block provide adequate anaesthesia for patients who are undergoing infraumbilical surgery.[2]

The Subarachnoid block is a simple technique that provides a deep and fast surgical block through the injection of small doses of local anaesthesia solution in subarachnoid space.[3] The use of lidocaine in spinal anaesthesia has been declined over the years and has become Virtually non-existent because of the high incidence of transient neurological syndrome (TNS). The Most common alternative to lidocaine is

Bupivacaine, which has a low Incidence of TNS (0-1%).[4]

The role of spinal anaesthesia is restricted in prolonged surgeries, for its shorter duration of action and less postoperative analgesia when only local anaesthetics are used. This is overcome by adding adjuvants to local anaesthetics.[5]

Various adjuvants like opioids, magnesium sulphate, clonidine, and dexmedetomidine were added to prolong spinal anaesthesia.

Tramadol is a centrally acting opioids, it has a minimal respiratory depressant effect because it has 6000-fold less affinity for μ receptors compared to morphine.

Therefore, tramadol has the potential to provide effective post-operative analgesia with no risk of respiratory depression after central neuraxialadministration.[6]

Magnesium sulphate exerts its analgesic action as a non-competitive N-Methyl-D-aspartate (NMDA) receptor antagonist. This study is undertaken to evaluate and compare the characteristics of subarachnoid block with either Bupivacaine with Magnesium or Bupivacaine with Tramadol in adult patients undergoing infraumbilical surgeries.

MATERIALS AND METHODS

This Randomized controlled trial, double blinded study was conducted among Patients admitted to hospital attached to Bangalore Medical College and Research Institute, Bangalore undergoing infraumbilical surgeries under general subarachnoid block during the period Nov 2019 to May 2021.

Inclusion criteria:

1. Patients who are willing to give written informed consent.
2. Age group 18-60 years of either sex.
3. Patients who are posted for infraumbilical surgeries.
4. American Society of Anesthesiology (ASA) grade 1 and 2.

Exclusion criteria:

1. Patients who are not willing to give informed written consent for study.
2. Know allergy to local anaesthetics, opioids and magnesium sulphate.
3. Pregnancy
4. Height < 150cm and >190 cm
5. BMI >30
6. Contraindication /relative contraindications to spinal anaesthesia.
7. Psychiatric disorders

Sample Size: Based on study7 the minimum expected difference will be, the sample size calculated as $n= 2(Z\alpha+ Z1-\beta)2\ \sigma\ 2 / d2$

Where Zα= standard table value for 95% CI =1.96

Z1-β = Standard table value for 80% Power = 0.84 σ = Standard Deviation = 1.55

d=Effect Size= 5.9-4.9=1

n= 2(1.96+ 0.84)2 (1.55) 2 / (1)2 n=37.63

n~40 in each group.

Methodology: After obtaining institutional ethical committee clearance, patients of physical status American Society of Anaesthesiologists grade 1 and grade 2 of either sex undergoing infraumbilical surgeries lasting more than 30 minutes fulfilling inclusion criteria patient is selected.

A detailed preanesthetic evaluation will be carried out on day before surgery. After explaining the procedure written and informed consent will be taken.

Patient will be randomized to two group of receiving one of the following for subarachnoid block.

Group T (n = 40): 2.5mlof 0.5% hyperbaric bupivacaine plus 25mg tramadol.

Group M (n = 40): 2.5ml of 0.5% hyperbaric bupivacaine plus 50mg magnesium sulphate.

All patient will be advised to be fasting for 8hours for solids prior to surgery and are premedicated with T.Alprazolam 0.5mg and T. Ranitidine 150mg given in the night before the day of surgery.

In the operating room, a venous access will be secured with 18G or 20G intravenous cannula and patients will be preloaded with ringer's lactate/ normal saline (15ml/kg) solution.

Baseline heart rate, non-invasive blood pressure, oxygen saturation (spo2), respiratory rate and electrocardiogram will be connected and monitored using multi-parameter monitor before starting the procedure.

Under strict aseptic precautions the patient is placed in lateral/sitting position, subarachnoid block will be performed using 23/25G quinke's spinal needle in L3-L4interspace, the study drug will be injected intrathecally over 10-15 seconds after confirming clear flow of cerebrospinal fluid.

The time at which injection given will be considered as zero time of the study and all measurements will be recorded from this point. Patient will be placed in supine position immediately after spinal injection.

Intraoperative sensory loss is assessed by pin prick test using 23G sterile hypodermic needle for onset and dermatomal level at every 2 minutes for 20 minutes after spinal injection.

Intraoperative nausea or vomiting is treated with 5mg ondansetron /metoclopramide 10mg.Shivering will be managed using warmed fluids, covering with more drapes, switching off the air conditioner in the operating room.

Postoperative period heart rate, blood pressure, respiratory rate and SPO2 will be monitored until the sensory and motor block weans off.

Assessment tools:

1. Assessment of sensory blockade- Sensory blockade tested using hypodermic needle every 2mins interval for onset and every 5mins till the maximum level of sensory blockade achieved.
2. Duration of motor blockade- Assessed by Modified Bromage Scale
3. Pain intensity- Assessed by Visual Analog Scale (VAS)
4. Sedation-Assessed by Ramsay Sedation Scale.

5. Duration of Analgesia- Assessed by onset of analgesia and till the patient complaints of pain for first time
6. Rescue Analgesia- Analgesics with injection Paracetamol 1gm iv.

Statistical analysis: Data were entered into the Microsoft excel data sheet and were analysed using SPSS 22 version software. Categorical data were represented in the form of Frequencies and proportions. Chi square test was used as test of significance for qualitative data.Continuous data were represented as mean and standard deviation. Independent t test or Mann Whitney U test was used as test of significance to identify the mean difference between two quantitative variables and qualitative variables respectively. MS Excel and MS word was used to obtain various types of graphs such as bar diagram, Pie Diagram. P value (Probability that the result is true) of < 0.05 were considered statistically significance after assuming all the rules of statistical test.

RESULTS

Mean age(years) in group M were37.08 ± 10.98 years and in group Twere37.68 ± 8.90 years.

There was no significant difference in mean age(years) comparison between two groups.

In Group M, 52.5% were Female and 47.5% were Male. In Group T, 45% were Female and 55% were Male.

There was no significant difference in Sex distribution between two groups.

Table 1: Mean Onset of sensory block(min) comparison between two groups

	Group				P-value
	Group M		Group T		
	Mean	Sd	Mean	Sd	
Onset of sensory Block	6.513	0.977	7.65	0.981	0.00

Mean onset of sensory block(min) in Group M were 6.513 ± 0.977 and in Group T was 7.65 ± 0.981.

There was significant difference in mean onset of motor block(min) comparison between two groups.

Table 2: Maximum Height of Sensory Block (Dermatome) Distribution between two groups

		Group			
		Group M		Group T	
		Count	%	Count	%
Maximum Height of Sensory Block(dermatome)	T10	0	0.00%	0	0.00%
	T4	0	0.00%	0	0.00%
	T6	19	47.5 %	29	72.5%
	T7	9	22.5%	0	0.00%
	T8	12	30%	11	27.5%

Maximum Height of Sensory Block in Group M were T6 in 47.5%, T7in 22.5% and T8 in30%. Maximum Height of Sensory Block in Group T were T6 in 72.5%, and T8 in 27.5%.

There was a significant difference in Maximum Height of Sensory Block (Dermatome)distribution between two groups.

Table 3: Mean Two dermatome regression time(min) comparison between Two groups

	Group				P Value
	Group M		Group T		
	Mean	Sd	Mean	Sd value	
Total duration of sensory block	114.23	17.238	100.55	7.906	0.00

Mean two dermatome regression time(min) in Group M were 114.23 ±17.238 and in Group T were 100.55 ± 7.906.

There was a significant difference in mean two dermatome regression time(min) comparison between two groups.

Table 4: Mean Total duration of sensory block(min) comparison between Two groups

	Group				P Value
	Group M		Group T		
	Mean	Sd	Mean	Sd	
Total duration of sensory block	149.45	13.623	138.75	7.986	0.00

Mean total duration of sensory block(min) in Group M were 149.45 ± 13.623 and in Group T were 138.75 ± 7.986.

There was a significant difference in mean total duration of sensory block(min) comparison between two groups.

Table 5: Mean Onset of motor block(min) comparison between two groups

	Group				P value
	Group M		Group T		
	Mean	Sd	Mean	Sd	
Onset of motor Block	8.275	1.12	7.8	1.03	0.05

Mean onset of motor block(min) in Group M were 8.275 ± 1.12 and in Group T was 7.8 ± 1.03.

There was no significant difference in mean onset of motor block(min) comparison between two groups.

Table 6: Mean Duration of motor block(min) comparison between Two groups

	Group				P value
	Group M		Group T		
	Mean	Sd	Mean	Sd	
Duration of Motor block	171.13	13.61	167.75	7.06	0.168

Mean duration of motor block(min) in Group M were 171.13 ± 13.61mins and in Group were 167.75 ± 7.06 mins. There was no significant difference in mean duration of motor block(min) comparison between two groups.

Table 7: Mean Time to first request of analgesic dose(min) comparison Between two groups

	Group				P value
	Group M		Group T		
	Mean	Sd	Mean	Sd	
Time to first request of analgesia Dose	189.13	14.58	193.88	8.58	0.08

Mean time to first request of analgesic dose(min) in Group M were 189.13 ± 14.58 and in Group T was 193.88 ± 8.58.

There was no significant difference in mean time to first request of analgesic dose(min) comparison between two groups.

Table 8: Mean VAS Comparison between two groups at different intervals of Time

VAS	Group				P value
	Group M		Group T		
	Mean	Sd	Mean	Sd	
Im post op	0.70	0.46	0.65	0.48	0.638
1 Hour	1.58	0.54	1.58	0.54	1.000
2 Hour	2.75	0.67	2.75	0.58	1.000
6 Hour	6.23	0.69	6.10	0.77	0.452
12 Hour	5.88	0.64	5.88	0.64	1.000
24 Hour	6.00	0.81	6.00	0.81	1.000

There was no significant difference in Mean VAS Comparison between two groups.

DISCUSSION

The demographic profile of the subjects such as Age, Gender, Weight, Height, BMI and ASA grade showed no statistically significant difference among the two groups.

Sensory block: Maximum Height of Sensory Block in Group M was T6 in 47.5%, T7 in 22.5% and T8 in 30%. Maximum Height of Sensory Block in Group T was T6 in 72.5%, and T8 in 27.5%. There was a significant difference in Maximum Height of Sensory Block (Dermatome) distribution between two groups.

Mean total duration of sensory block(min) in Group M were 149.45 ± 13.623 and in Group T were 138.75 ± 7.986.

There was a significant difference in mean total duration of sensory block(min) comparison between two groups.

Mean two dermatome regression time (min) in Group M were 114.23 ± 17.238 and in Group T were 100.55 ± 7.906.

There was a significant difference in mean two dermatome regression time(min) comparison between two groups.

Mean time to first request of analgesic dose (min) in Group M were 189.13 ± 14.58 and In Group T was 193.88 ± 8.58.

There was no significant difference in mean time to first request of analgesic dose(min) comparison between two groups.

Khezri et al8, The NMDA channels are involved in pain modulation and hence NMDA blockers may not be expected to prolong sensory block. But it has been shown that intrathecal injection of a large dose of magnesium sulphate (1260 mg) causes a complete sensory and motor lasting for 60 minutes. However, the mechanisms weren't elucidated. Sanad et al9 showed in his study that 50mg of magnesium prolonged the regression of sensory block.

However, a satisfactory explanation for this prolongation cannot be suggested and hence, further studies and clinical trials are required.

Dandona S et al,[10] Studied the comparison of Intrathecal Tramadol and Fentanyl as adjuvant in abdominal and lower limb surgeries.50 patients was randomized to the Group A and Group B. Group A Received 2.5ml 0.5% Bupivacaine + 0.5ml (25mcg)

Fentanyl and Group B received 2.5ml 0.5% Bupivacaine + 0.5 ml (25mg) of Tramadol. Fentanyl is better alternative to Tramadol as an adjuvant to spinal bupivacaine in surgical procedures as it provides prolonged Duration of the sensory block, longer duration of postoperative Analgesia and lesser number of doses of rescue analgesia are Required.[10]

Motor block: Mean onset of motor block(min) in Group M were 8.275 ± 1.12 and in Group T was 7.8 ± 1.03. There was no significant difference in mean onset of motor block(min) comparison between two groups. Mean duration of motor block(min) in Group M were 171.13 ± 13.61mins and in Group were 167.75 ± 7.06 mins. There was no significant difference in mean duration of motor block(min) comparison between two groups.

Paul et al, Shukla et al and Khezri et al. They demonstrated a delay in onset of motor block by using 50mg of magnesium sulphate. The difference in mean values of onset of sensory block and complete motor block obtained by Khezri was 3.16 minutes and 4.37 (Mg vs control) respectively.[8,9,11,12]

Studies done by Sanad et al and Khezri et al and have demonstrated that 50mg of intrathecal magnesium does not affect duration of motor block but Shukla et al using a similar dose contrasted these results. In both human and animal studies, intrathecal magnesium sulphate has produced spinal anaesthesia including motor blockade, but the dose which was used was extremely high and the mechanism of action could not be elucidated.[8,9]

Dalvi NP et al, conducted the study of Intrathecal Fentanyl – Bupivacaine and Tramadol- Bupivacaine combination on Postoperative Analgesia in Lower Abdominal Surgeries. 60 patients were randomized to Group F(n=30) and Group T (n=30).

Duration of Sensory block significantly prolonged in Group F (314+/- 49.25 mins) Compared to Group T (261+/- 27.92mins), Duration of motor Block were longer in Group F (263.66 +/- 40.97mins) compared to Group T (214.66 +/- 26.61mins). Total duration of analgesia was Significantly prolonged (p > 0.001) in Group F (412 +/-97.888 mins) Compared to Group T (301+/- 38.75 mins).[13]

CONCLUSION

From our study, we conclude that Magnesium Sulphate 50mg as an adjuvant to spinal Bupivacaine is better than Tramadol 25mg as it provides prolonged duration of sensory blocks without any significant hemodynamic alterations and provides good quality of post-operative analgesia. Thus, Intrathecal Magnesium sulphate can be desirable as an adjuvant to bupivacaine compared to tramadol(25mg).

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