Original Article

Compare The Hemodynamic Parameters Using Magnesium Sulphate and Tramadol as Adjuvants to Intrathecal Hyperbaric Bupivacaine in Subarachnoid Block

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Abstract

Background: Spinal anesthesia is a type of regional anesthesia achieved by obstructing the spinal nerves roots within the subarachnoid space through the injection of a local anesthetic solution into the cerebrospinal fluid, mostly affecting the spinal nerve roots. The objective is to evaluate the safety and effectiveness of intrathecal hyperbaric bupivacaine in subarachnoid block utilizing magnesium sulfate and tramadol as adjuvants in terms of hemodynamic parameters and potential adverse effects. **Material and Methods:** Eighty patients with ASA I/II physical status undergoing elective infraumbilical procedures were randomly divided into two groups and administered one of the following subarachnoid blocks: 1. Group M (n = 40) 50 mg of magnesium sulfate and 2.5 ml of bupivacaine (0.5% H). 2. Group T (n = 40) Tramadol 25 mg and Bupivacaine (0.5% H) 2.5 ml. Side effects and hemodynamic parameters were noted **Results:** There was a significant fall in intraoperative Blood pressure in Tramadol group compared to Magnesium group. But this did not require any intervention. Other hemodynamic parameters were comparable between two groups. There was no significant difference in the degree of sedation between two groups. **Conclusion:** Intrathecal Magnesium Sulphate is a better adjuvant than intrathecal Tramadol as it provides no significant hemodynamic variations and side effects.

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

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Introduction

For many kinds of surgery, the main anesthetic technique is spinal anesthesia. Increased patient satisfaction and faster functional recovery are the among the benefits of recent advancements in spinal anesthesia. New approaches to reducing the need for post-operative analgesics are currently of great interest. Long-lasting analgesia has not been possible with the use of local anesthetics such bupivacaine. During the post-operative phase, the majority of patients need additional analgesics. For this reason, different adjuvants are added to intrathecal local anesthetics.[1-3]

The order of nerve fiber blockade is autonomic preganglionic b fibers, followed by temperature, proprioception, pain, and finally motor fibers. The injection site,needle angulation, density, specific gravity, baricity, and local anesthetic dosage are some of the variables that may affect the level of block. The degree of blockade is further influenced by the patient's height, position, and elevated abdominal pressure caused by obesity, ascites, and pregnancy. Pregnancy and dehydration might have an impact on CSF volume. There are multiple effects of spinal anesthesia on different systems of our body: Sympathetic denervation is one of the impacts on the cardiovascular system. The local anesthetic, its volume and dosage, and the degree of neural block all have an impact. Blood pressure decreases as a result of arteriolar dilatation and venous circulation vasodilatation brought on by sympathetic denervation. Bradycardia is linked to a drop in blood pressure because of the Bainbridge reflex. Bradycardia may also result from blockage of cardiac sympathetic fibers from T1 to T4.

Magnesium sulfate affects the myocardium's calcium channels and indirectly affects the heart muscle by preventing the myocyte's troponin C from absorbing Ca2+, which affects myocardial contractility. Because Mg2+ activates CAMP, it has a vasodilatory effect.

Systolic blood pressure is lowered as a result. There is no change in pulmonary vascular resistance. Vasodilation results from a decrease in coronary vascular resistance.

Since it doesn't lead to tolerance or addiction, tramadol 3 mg/kg is an excellent treatment for moderate to severe pain and chronic pain. It can be given orally, intramuscular or intravenously. It can

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be administered via caudal, intrathecal, epidural, or intravenous methods. Ampoules containing a 100 mg/2 ml solution of tramadol are available; it has also been used to treat perioperative shivering. Another antishivering medication, tramadol, can promote the production of 5-HT and prevent the reuptake of dopamine, nor-epinephrine, and 5-hydroxy tryptamine.

Tramadol may induce drowsiness, ambulatory dizziness, nausea, and vomiting. Patients on tricyclic antidepressants and monoamine oxidase inhibitors shouldn't use tramadol. Patients with epilepsy should not use it because tramadol might trigger seizures in these people.

Therefore, the purpose of this study was to examine the safety and efficacy of intrathecal hyperbaric bupivacaine in subarachnoid block with magnesium sulfate and tramadol as adjuvants in terms of hemodynamic parameters and any side effects.

Materials and Methods

Patients admitted to the hospital affiliated with Bangalore Medical College and Research Institute, Bangalore, undergoing infraumbilical procedures under general subarachnoid block between November 2019 and May 2021 were included in this double-blind, randomized controlled trial.

Duration of study: From Nov 2019 to May 2021.

Inclusion criteria:

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

Exclusion criteria:

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

Methodology: Patients of physical status American Society of Anesthesiologists grade 1 and grade 2 of either sex undergoing infraumbilical procedures lasting more than 30 minutes who meet the inclusion criteria are chosen after receiving institutional ethical committee clearance.

The day prior to surgery, a thorough preanesthetic assessment will be performed. Written and informed consent will be obtained following an explanation of the process.

Patients will be randomly assigned to one of two groups and given a 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 patients will be advised to be fasting for 8hours for solids prior to surgery and are pre medicated with T. Alprazolam 0.5mg and T. Ranitidine 150mg given in the night before the day of surgery.

An 18G or 20G intravenous cannula will be used to secure a venous access in the operating room, and patients will be preloaded with a 15ml/kg mix of ringer's lactate and normal saline.

Before the procedure begins, a multi-parameter monitor will be used to connect and track baseline heart rate, non-invasive blood pressure, oxygen saturation (spo2), respiratory rate, and electrocardiogram.

The patient is positioned in a lateral or sitting posture under strict aseptic measures. A 23/25G Quinke's spinal needle will be used to perform a subarachnoid block in the L3-L4 interspace. After confirming a clear flow of cerebrospinal fluid, the study drug will be given intrathecally over a period of 10-15 seconds.

All measurements will be taken starting at the moment the injection is administered, which will be regarded as the study's zero time. After receiving a spinal injection, the patient will be put in a supine position right away.

Using a 23G sterile hypodermic needle, the pin prick test is used to measure intraoperative sensory loss at the dermatomal level every two minutes for 20 minutes following spinal injection.

For the first ten minutes of the procedure, vital signs such as heart rate, non-invasive blood pressure, and percentage of oxygen saturation will be checked every two minutes. After that, they will be checked every five minutes until the procedure is finished, then every fifteen minutes until the patient reports pain.

Hypotension is defined as a systolic blood pressure drop of more than 30% from baseline or a systolic blood pressure drop of less than 90 mmHg. It is treated with quick intravenous fluid infusion and intravenous injection of mephentermine (6 mg) and ephedrine (6 mg).

Intravenous atropine 0.01 mg/kg will be used to treat bradycardia, which is defined as a drop in heart rate of more than 30% from baseline or less than 50 beats per minute.

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.

Sample Size: Based on study43 the minimum expected difference will be, the sample size calculated as n= 2(Zα+ Z1-β)2 σ 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.

Statistical analysis: Data were inputted into the Microsoft Excel spreadsheet and subsequently analyzed utilizing SPSS version 22 software. Categorical data were depicted as frequencies and proportions. The chi-square test was employed as a significance test for categorical data. Continuous data were expressed as the average and standard deviation. The Independent t-test or Mann Whitney U test was employed as a significance test to ascertain the mean difference between two quantitative and qualitative variables, respectively. MS Excel and MS Word were utilized to generate diverse forms of graphs, including bar charts and pie charts. P values less than 0.05 were deemed statistically significant, provided that all statistical testing protocols were adhered to.

Figure 1: ?

Results

Table 1: Mean age(years) comparison between two groups

	Group			
	Group M		Group T	
	Mean	Sd	Mean	Sd
Age(years)	37.08	10.98	37.68	8.90

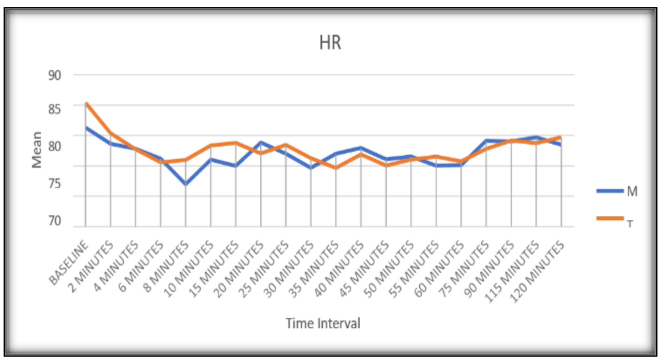
Mean age(years) in group M were37.08 ± 10.98 years and in group Twere37.68 ±8.90 years.

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.

There was a significant difference in Mean Heart Rate between two groups at 15mins. At other intervals there were no significant difference.



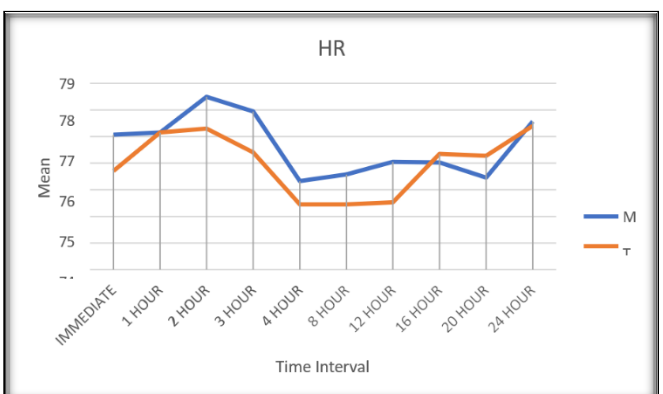
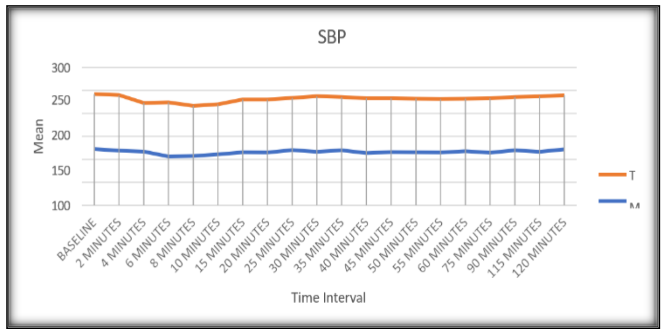


Figure 1: line diagram showing mean heart rate comparison between two groups at different intervals of time

There was a significant difference in Mean SBP between two groups at 6mins,8mins,30mins,40mins,75mins,115mins, Immediate post op, 4hour and 24hours. At other intervals there were no significant difference.



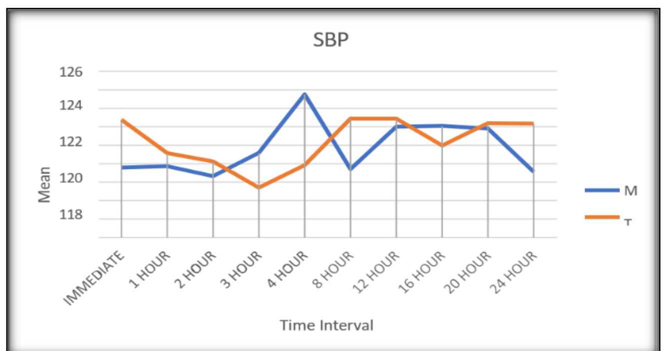


Figure 2: Line Diagram Showing Mean SBP Comparison Between Two Groups At Different Intervals Of Time

There was a significant difference in Mean DBP between two groups at 4mins,6mins,15mins and 25mins. At other intervals there were no significant difference.

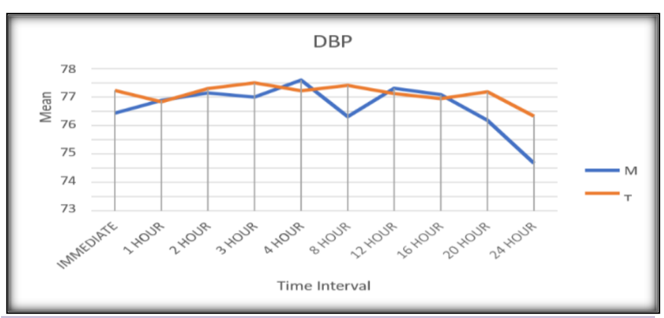


Figure 3: line diagram showing mean DBP comparison between two groups at different intervals of time

There was a significant difference in Mean SpO2 between two groups at 4mins, 6mins and Immediate post op.
At other intervals there were no significant difference.

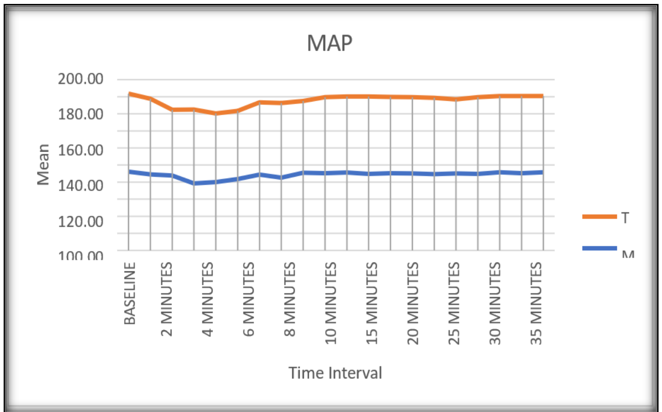


Figure 4: line diagram showing mean map comparison between two groups at different intervals of time

There was a significant difference in Mean MAP between two groups at 4mins,6mins,25mins and 4hour. At other intervals there were no significant difference.

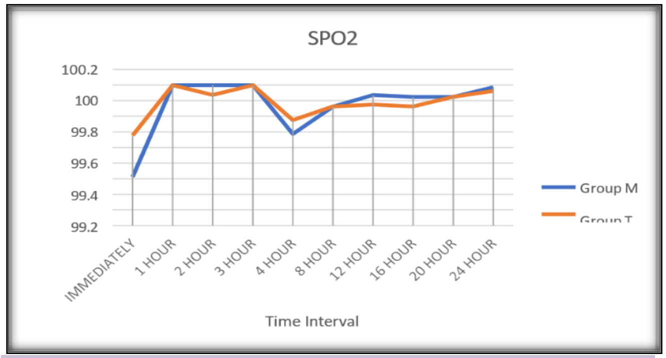


Figure 5: line diagram showing mean SPO2 comparison between two groups at different intervals of time

Table 2: Mean Respiratory Rate Comparison between two groups at Different intervals of time

RR	Group				P Value
	Group M		Group T		
	Mean	Sd	Mean	Sd	
Baseline	14.58	0.95	14.8	1.04	0.184

There was no significant difference in Mean Respiratory Rate between two groups at Baseline.
At other intervals there were no significant difference.

Table 3: Mean Sedation Score Comparison between two groups at different Intervals of time

Sedation Score	Group			
	Group M		Group T	
	Mean	Sd	Mean	Sd
Baseline	2.00	0.00	2.00	0.00
5mins	2.00	0.00	2.00	0.00
10mins	2.00	0.00	2.00	0.00
20mins	2.00	0.00	2.00	0.00
40mins	2.00	0.00	2.00	0.00
60mins	2.00	0.00	2.00	0.00
80mins	2.00	0.00	2.00	0.00
100mins	2.00	0.00	2.00	0.00
120mins	2.00	0.00	2.00	0.00
Im post op	2.00	0.00	2.00	0.00
1hour	2.00	0.00	2.00	0.00
2hour	2.00	0.00	2.00	0.00
6hour	2.00	0.00	2.00	0.00
12hour	2.00	0.00	2.00	0.00
24hour	2.00	0.00	2.00	0.00

There was no significant difference in Mean Sedation Score between two groups.

Table 4: Side Effects Distribution between two groups

		Group				P value
		Group M		Group T		
		Count	Percentage	Count	Percentage	
Hypotension	Absent	30	75%	29	72.5%	0.799
	Present	10	25%	11	27.5%	
Bradycardia	Absent	40	100%	40	100%	
	Present	0	0.00%	0	0.00%	
Nausea	Absent	36	90%	37	92.5%	0.692
	Present	4	10%	3	7.5%	
Shivering	Absent	38	95%	40	100%	0.152
	Present	2	5%	0	0.00%	

In Group M, hypotension was observed in 25%, while in Group T, it was present at 27.5%. There was no notable disparity in the distribution of hypotension between the two cohorts.

In Group M, the incidence of nausea was recorded at 10%, but in Group T, it was observed in 7.5%. There was no notable disparity in the distribution of nausea between the two groups.

In Group M, the incidence of shivering was recorded at 5%, whereas Group T exhibited a rate of 0.00%. There was no notable disparity in shivering distribution between the two cohorts.

Discussion

The demographic attributes of the subjects, encompassing Age, Gender, Weight, Height, BMI, and ASA grade, revealed no statistically significant discrepancies between the two groups.

A considerable variation in Mean Heart Rate existed between the two groups after 15 minutes. At different intervals, there was no notable distinction.

A considerable variation in Mean SBP existed between the two groups at 6, 8, 30, 40, 75, and 115 minutes, as well as immediately after surgery, and at 4 and 24 hours. During other periods, there was no noticeable distinction.

There was a significant difference in Mean DBP between two groups at 4mins,6mins,15mins and 25mins. At other intervals there were no significant difference.

There was a significant difference in Mean MAP between two groups at 4mins,6mins,25mins and 4hour. At other intervals there were no significant difference.

There was a significant difference in Mean SpO2 between two groups at 4mins, 6mins and Immediate post op. At other intervals there were no significant difference.

There was no significant difference in Mean Respiratory Rate between two groups at Baseline. At other intervals there were no significant difference.

The distinctions were not statistically significant, which substantiates the hemodynamic stability of intrathecal magnesium. The investigation by Katiyar et al. revealed that 100mg of intrathecal MgSO4 was linked with improved hemodynamic stability when juxtaposed with 25µg of intrathecal fentanyl. Other investigations carried out by Shukla D and Khezri MB exhibited similar conclusions.[7-9]

Dhimar A A et al, stated that haemodynamic stability was better in magnesium sulphate compared to tramadol group without significant difference in incidence of peri- operative complications.[10]

Limitation of the Study: Our study is done on ASA I and ASA II patients only. The effects of drugs in Patients with uncontrolled comorbid conditions are not studied. Total dose of rescue analgesia is not calculated. Long term effects of Magnesium Sulphate and Tramadol are not evaluated.

Conclusion

A notable decline in intraoperative blood pressure was observed in the Tramadol group vs to the Magnesium group. However, this did not necessitate any intervention. Other hemodynamic metrics were similar between the two cohorts. There was no notable disparity in the level of sedation between the two groups.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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