# To Study the Efficacy of Intrathecal Fentanyl plus MgSo4 on the onset and duration of Hyperbaric Bupivacaine Induced Spinal Block.

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Abstract	

**Background:** Aim: To compare the duration of analgesia on addition of MgSO4 and Fentanyl with Bupivacaine and to study their haemodynamic effects and complications. **Subjects and Methods:** 50 patients undergoing elective lower limb surgeries were randomized into one of the two groups with 25 patients in each group. Group F received 2.5 cc of 0.5% hyperbaric bupivacaine + 50mcg (1ml) of fentanyl and Group (F+ M) received 2.5 cc of 0.5% hyperbaric bupivacaine + 50mcg (1ml) of fentanyl + 50 mg (0.1ml) Magnesium. Parameters were statistically analyzed using student t test. **Results:** The recovery of motor blockade was found to be statistically insignificant in both the groups. The hemodynamic parameters (blood pressure, heart rate) wereomparable in the peri operative period. The incidence of side-effects in both the groups was also comparable. **Conclusion:** Addition of fentanyl (50mcg) plus MgSO4 (50mg) to 2.5ml (12.5mg) bupivacaine increased the duration of analgesia and also reliability of sensory blockade without increasing the motor block.

Keywords: Fentanyl, MgSO4, Bupivacaine, Intrathecal additives.

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#### Introduction

Regional anaesthesia is the ideal technique for most Orthopedic procedures. As the duration of spinal anaesthesia is limited, adding the adjuvant, to some extent, offer a benefit over using plain local anaesthetic. Various agents have been tried intrathecally to study their efficacy in prolonging the duration of spinal anaesthesia. Recently, Magnesium Sulphate has gained popularity among the adjuvants owing to its safety. Opioids are other commonly used additives to local anaesthetics. During surgery, noxious stimulation leads to the release of glutamate and aspartate neurotransmitters, which bind to various subclasses of excitatory amino acid receptors, including the N-methyl D-aspartate (NMDA) receptor. Activation of NMDA receptors leads to calcium and sodium influx into the cell, with an efflux of potassium and initiation of central sensitization and wind-up.<sup>[1,2]</sup> NMDA receptor signalling may be important in determining the duration and intensity of postoperative pain.<sup>[</sup> Magnesium sulfate block the N- methyle -D- aspartate (NMDA) channels in a voltage-dependent way to be improve the quality and duration of spinal block.<sup>[3]</sup> The safety of intrathecal magnesium administration has been evaluated in animal and human studies.<sup>[4]</sup> No neurological deficit or other major complication was observed in any patient receiving magnesium sulfate or saline in the first postoperative week after surgery.<sup>[5]</sup>

anaesthetics improves the quality of intraoperative analgesia and also provide postoperative pain relief for longer duration.<sup>[6,7]</sup> Fentanyl, a lipophilic opioid, has rapid onset of action following intrathecal administration. It does not tend to migrate to the fourth ventricle in sufficient concentration to cause delayed respiratory depression when administered intrathecally.<sup>[8]</sup> Hence, in our study we set the following objectives. To compare the duration of analgesia on addition of MgSO4 and fentanyl with bupivacaine. To study the haemodynamic effects and the incidence of complications like respiratory depression, nausea, vomiting, shivering, and pruritis.

## Subjects and Methods

After approval from the institutional ethical committee and obtaining consent from the patients, 50 patients undergoing elective lower limb surgeries were randomized into one of the two groups with 25 patients in each group. Spinal anaesthesia was used for all patients. Spinal anaesthesia with 2.5 cc of 0.5% hyperbaric bupivacaine + 50mcg (1ml) of fentanyl (Group F) or 50 mg (0.1ml) Magnesium (Group F+M). The following parameters were be noted every 5min in each group for first 30 min, then every 15 min till the patient complains of pain.

Blood pressure, pulse rate, Time taken for maximum sensory block, Time taken for maximum motor block, Regression of sensory level by two dermatomes, Complete motor recovery.

Neuraxial administration of opioids along with local

## Gopal & Sangitha: Onset and duration of Hyperbaric Bupivacaine Induced Spinal Block

#### **Inclusion Criteria:**

- ASA Grade I and II patients
- Patients coming with single lower limb fracture
- Patients age between 20-60 years

#### **Exclusion Criteria:**

- ASA Grade III and IV patients
- Underlying neurological and lower limb motor deficits
- Hypotension
- CNS Tumors
- Spinal deformities
- Raised ICT
- Local and systemic infection
- Patient refusal
- Multiple fractures involving upper limb
- Patients with chronic headache

**Pre anaesthetic Examination and Preparation:** The study protocol was approved by Hospital Ethics committee. Then all patients who were included, consented to the terms of this study during the preoperative evaluation. Pre-anaesthetic checkup was done one day prior to the surgery. Patients were evaluated for any systemic diseases and laboratory investigations recorded. The procedure of spinal anesthesia was explained to the patients and written informed consent was obtained. Patients advised overnight fasting and premeditated with Tab. Ranitidine 150 mg.

Preparation of OT: Boyle's anesthesia machine was checked. Appropriate size endo tracheal tubes, working laryngoscope with medium and large size blades, stylet and working suction apparatus were kept ready before the procedure. After shifting the patient to operating theatre, IV access was obtained with 18 Gauge IV cannula. IV fluids (NS/RL) were given according to Holiday Segar rule. Patients were monitored for heart rate (HR), noninvasive blood pressure (NIBP), percentage oxygen saturation (SpO2), ECG rhythm. Under all aseptic precautions spinal anaesthesia was performed with the patient in the sitting position using a 25-gauge Quincke needle at the L4 - L5 interspace. Patient was allowed to lie-down gently and placed supine without elevation of extremities and tested every 1 minute until maximal sensory and motor blockade achieved, then every 15 minute during the surgery.

**Group F** - 25 patients received 2.5ml (12.5 mg) of 0.5% hyperbaric Bupivacaine plus 50 mcg fentanyl intrathecally.

**Group F+M** - 25 patients received 2.5 ml (12.5mg) of 0.5% hyperbaric Bupivacaine plus 1ml (50mcg) fentanyl intrathecally plus 50mg (0.1ml) of MgSO4.

#### **Parameters Evaluated:**

Sensory Block: Assessed using pin-prick test on each side and patients were asked about the sensation.

**Onset time of sensory block:** Defined as the time between injection of the drug to loss of sensation at L1 level.

Sensory block to reach till t10: Defined as the period between injection of the drug to loss of sensation at T10 level.

Motor block assessed using 'Bromage Scale'

- 0. No block
- 1. Impaired movements at the hip, with normal knee & ankle movements.

- 2. Impaired movements at hip & knee with normal ankle movements.
- 3. Impaired movements at hip, knee & ankle.
- a. Onset time of motor blockade: defined as the time between injection and complete block.
- b. Motor Block Duration: Defined as the time between injection and complete recovery of motor block.

Time taken for 2-segment regression (sensory block): time between injections of the drug to regression of sensory level by two segments from highest sensory level (T10).

Duration of analgesia: Defined as the period between injections of the drug till patient Complained of pain. Hypotension (H) was defined as a mean arterial pressure decrease of more than 20% from baseline, and was treated with injection Mephentermine 6 mg intravenously, dose titrated according to response. A decrease in the heart rate of more than 20% from baseline was considered as bradycardia (Br) and treated with injection atropine 0.02 mg/kg intravenously. Mean arterial pressure and Heart rate was recorded every 5 minute for the first fifteen minutes and then every 15 min throughout the surgery. All the above observed intraoperatively parameters were and postoperatively.

Complications such as nausea (N) vomiting (V), pruritis (P), respiratory depression (R.D) (decrease in SpO2, difficulty in breathing), shivering (S) were noted down. Urinary retention was not assessed as all the patients were catheterized after the surgery. Rescue analgesia/ sedation was given if patient complained of mildpain/ discomfort. Post-operative observation done for a period for 6 hours.

#### **Statistical Analysis:**

To detect a significant difference between the parameters of two groups and for type 1 error of 5% and a power of 80% a group size of 20 in each group is sufficient from previous studies. Data was presented in terms of mean (+/-SD) or frequencies as appropriate. Demographic data and block characteristics were compared using student t-test. P-value obtained from these tests was considered as significant if p < 0.05 and not significant if p > 0.05.

### Results

Table 1: Demographic data						
	Group F	Group F+M				
Age	$34.1 \pm 2.3$	$34.3 \pm 2.4$				
Sex (M:F)	17.8	16.9				
Height	$153.2 \pm 5.5$	$152.9 \pm 6.1$				
No statitically signific	cant (P>0.5) difference among	two group in terms of demographic				

No statificanty significant (r>0.5) difference among two group in terms of demographic data.

Complications in both the groups were comparable. However, the recovery of motor blockade was found to be statistically insignificant in both the groups. The hemodynamic parameters (blood pressure, heart rate) were comparable in the peri operative period (P>0.05). The incidence of side-effects in both the groups was also comparable (P>0.05) [Table 3].

Table 2: Sensory and Motor Black						
Parameter	Group F	Group F+M	P-value			
Onset of sensory	2.88	2.8	>0.05			
block (min)						
Time taken to achieve T <sub>10</sub> (min)	5.06	4.9	>0.05			
Onset of motor block (min)	5.23	5.3	0.6			
Duration of motor block (min)	135	136.6	0.6			
Time taken for two segment regression (min)	85.1	90.5	0.00			
Duration of analgesia (min)	171.8	237	0.00			

Time taken for two segment regression and duration of analgesia were significantly prolonged in Group F+M.

Table 3: Complications						
No of patients with side effects	Group F	Group F+M	P-Value			
Nausea	3	2	P=0.981			
Vomiting	1	1	P=1.00			
Pruritis	4	2	P=314			
Respiratory depression	Nil	Nil				
Shivering	2	3	P=0.981			

# Discussion

Regional anaesthesia is commonly employed for orthopaedic procedures and is also better choice. The technique is simple, rapid onset & is reliable. The risk of aspiration or mishaps of airway and polypharmacy associated with general anaesthesia are avoided by this technique. Bupivacaine is used routinely for the most of the lower abdominal & lower limb surgeries because of its high potency and minimal neurological symptoms.

As orthopaedic procedures are long procedures low dose of intrathecal local anaesthetic (L.A) is insufficient, addition of fentanyl plus MgSO4 gives a reliable block and also decreases the analgesics in early postoperative period. Combination of L.A and opiods and MgSO4 is a better choice for orthopaedic surgeries compared to the use of L.A and opiods alone.<sup>[9]</sup> Subarachnoid block with 2.5 ml Bupivacaine 0.5% heavy and 50 mcg fentanyl and 50mg MgSO4 is better in terms of maintaining hemodynamic stability and lower incidence of complications without compromising the surgical blockade in elderly patients.

Demographic parameters: Present study results showed that both the groups are comparable with respect to Age, Sex, Height as the p-value > 0.05

Pre–Operative haemodynamics: Present results showed that preoperative haemodynamics like HR, SBP, DBP, MAP were statistically comparable between two groups as p>0.05 Sensory block and Motor block characteristics: Onset of sensory blockade in group F was 2.88 min and group F+M was 2.8 min. with p-value >0.05. Many studies showed that addition of fentanyl do not enhance the onset of blockade as in study done by Jeong-eun Kim.<sup>[10]</sup> Time taken to reach till T10 in group F was 5.06 min, in group F+M was 4.9 min with p-value >0.05, this also coincides with the study done by Jeong-eun.<sup>[10]</sup> Onset of motor blockade in group F was

5.23 min, in group F+ M was 5.3min with p-value 0.6, so addition of fentanyl plus MgSO4 did not enhance the onset of motor blockade. Time taken for 2 segment regression in group F was 85.1min, in group F+M was 90.5 min with pvalue 0.000, hence it was longer in group F+M, which coincides with the findings of the study done by S Neeta, MadhusudanUpadya,<sup>[11]</sup> where they showed that fentanyl with bupivacaine delayed two-segment regression. It also coincides with the study done by HübanDayioğlu et al.<sup>[12]</sup> Duration of motor block in group F was 135 min, in group F+M was 136.5 min with p-value 0.6, hence no significant difference was seen in both the groups. Numerous clinical studies have demonstrated that intrathecal fentanyl does not prolong the duration of motor blockade. This also coincides with the study done by Harbhejsingh.<sup>[13]</sup>Intrathecal fentanyl + MgSO4 prolongs sensory bupivacaine spinal block. Duration of analgesia in group F was 171.8 min, in group F+ M was 237 min with p-value 0.00. Hence addition of fentanyl + MgSO4 prolonged the duration of analgesia. This finding was similar to that of the study done by S Neeta, MadhusudanUpadya,<sup>[11]</sup> where they showed that Fentanyl with bupivacaine prolongs the duration of analgesia. Addition of magnesium sulphate at 100 mg dose or fentanyl 50 µg as adjuvants to intrathecal bupivacaine significantly prolongs the duration of analgesia. At these doses, magnesium provides better haemodynamic stability than fentanyl, with fewer side effects.<sup>[14]</sup>

## Conclusion

Addition of fentanyl (50 mcg) plus MgSO4 (50mg) to 2.5ml (12.5mg) bupivacaine increased the duration of analgesia and also reliability of sensory blockade, without affecting the duration of motor block. There were no adverse affects on hemodynamic profile and also no complications. Hence it is a better choice in elderly patients undergoing orthopaedic procedures.

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21

#### Gopal & Sangitha: Onset and duration of Hyperbaric Bupivacaine Induced Spinal Block

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