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Comparison of the effect of adding Dexmedetomidine and Magnesium Sulphate to Hyperbaric Bupivacaine in lower abdominal and lower limb surgeries

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Abstract: *Spinal anaesthesia is a safe, inexpensive, commonly performed anaesthetic technique for lower abdominal and lower limb surgeries. It is rapid in onset and provides good analgesia both intraoperatively and post-operatively. Spinal anaesthesia can be performed with a wide range of local anaesthetic drugs. Spinal anaesthesia using only local anaesthetics is associated with relatively short duration of action. Postoperative pain control is major problem with spinal anaesthesia using only local anaesthetics alone and thus early analgesic intervention is needed in the postoperative period. A number of adjuvants such as clonidine, opioids, dexmedetomidine, magnesium sulphate etc. have been studied to prolong the effect of spinal anaesthesia. Various studies showed addition of dexmedetomidine, magnesium sulphate, as adjuvants improves the quality of the block. Till date there are only few studies done to compare the effects of addition of 10 micrograms of dexmedetomidine to 15 mg of hyperbaric bupivacaine and 50 milligrams of magnesium sulphate to 15 mg of hyperbaric bupivacaine.*

This study is designed to compare the effect of adding dexmedetomidine and magnesium sulphate to hyperbaric bupivacaine in lower abdominal and lower limb surgeries in total of 60 adult patients aged between 20-60 years undergoing lower abdominal and lower limb surgeries.

Key words: *Lower abdominal and lower limb surgeries, spinal anaesthesia, Local anaesthetic drugs, hyperbaric bupivacaine, dexmedetomidine, magnesium sulphate*

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I. Introduction

Spinal anaesthesia is a safe, inexpensive, commonly performed anaesthetic technique for lower abdominal and lower limb surgeries. It is rapid in onset and provides good analgesia both intra-operatively and post-operatively. Spinal anaesthesia can be performed with a wide range of local anaesthetic drugs. Using only local anaesthetics is associated with relatively short duration of action. Postoperative control is a major problem with spinal anaesthesia when using local anaesthetics alone and thus early analgesic intervention is needed in the postoperative period. A number of adjuvant such as clonidine, opioids, dexmedetomidine, magnesium sulphate etc.have been studies to prolong the effect of spinal anaesthesia. Various studies showed addition of dexmedetomidine, magnesium sulphate as adjuvants improves the quality of block. Till date there are only few studies done to compare the effects of addition of 10 micrograms of dexmedetomidine of 15 mg to hyperbaric bupivacaine and 50 milligrams of magnesium sulphate to 15 mg to hyperbaric bupivacaine.

***GroupD** – 30 patients received 3 ml of 0.5% bupivacaine (H)(15mg) and 0.1 ml(10mcg) dexmedetomidine.
***GroupM** – 30 patients received 3 ml of 0.5% bupivacaine (H)(15 mg) and 0.1 ml(50mg) of Magnesium Sulphate.
Inclusion Criteria : Patients of both sexes aged between 20-60 years of ASA physical status classification I and II were included. Patients with heights between 150-180 cms; weight between 50-80 kgs were included.
Execlusion Criteria : Patient's refusal, ASA Class III and IV or more, patients with coagulation disorders; patient on anticoagulant therapy; post spinal surgery; emergency surgery; infection at spinal needle insertion site; known hypersensitivity to local anaesthetics, hyperdynamically unstable.

Materials : Inj. Hyperbaric Bupivacaine 0.5% (15mg), Inj. Dexemedetomidine (10mcg); Inj. Magnesium sulphate (50 mg).

.Method of Study: This study is designed to compare the effect of addition dexmedetomidine and magnesium sulphate to hyperbaric bupivacaine in lower abdominal and lower limb surgeries in total of 60 adult patients aged between 20-60 years undergoing lower abdominal and lower limb surgeries. The study population is divided into 2 groups with 30 patients in each group. Group D received 3 ml of 0.5% bupivacaine (H) 15 mg and 0.1 ml (10mcg) dexmedetomidine. Group M received 3 ml of 0.5% bupivacaine (H) (15 mg) and 0.1 ml of magnesium sulphate (50mg). The following parameters were observed, speed of onset and duration of motor block, speed of onset and sensory regression time to 2 segments below. Haemodynamic parameters like pulse, systolic BP, diastolic BP, respiratory rate. Duration of analgesia, time for first voiding and post operative complications like nausea, vomiting, shivering, seizures are observed for. Statically the data was analysed.

This is a prospective, comparative, and interventional study. This study was undertaken at the Department of anaesthesiology, Dr. Pinnamaneni Siddhartha Institute of Medical Sciences & Research Foundation, Chinavutapalli, Gannavaram Madal, Andhra Pradesh, India. The study was approved by the institutional ethical committee and a written informed consent in the local language was obtained from every patient before being included in the study. Total of 60 adult patients who were undergoing lower abdominal and lower limb surgeries were randomly allocated into two groups;

II. Aim And Objectives

The aim of the study is to compare the effects of dexmedetomidine and magnesium sulphate as adjuvants to hyperbaric bupivacaine in spinal anaesthesia for lower abdomen and lower limb surgeries. Objectives of the study are to compare the

1. Time of onset and duration of motor block.
2. Time of onset and sensory regression time to 2 segments below.
3. Perioperative haemodynamic changes.
4. Duration of analgesia.
5. Time of first voiding.
6. Complications – Nausea, vomiting, shivering, seizures.

III. Patients and Methods

This is a prospective, comparative, and interventional study. This study was undertaken at the Department of anaesthesiology, Dr. Pinnamaneni Siddhartha Institute of Medical Sciences & Research Foundation, Chinavutapalli, Gannavaram Mandal, Krishna District, Andhra Pradesh, India. The study was approved by the institutional ethical committee and a written informed consent in the local languages was obtained from every patient before being included in the study. Total of 60 adult patients who were undergoing lower abdominal and lower limb surgeries were randomly allocated into two groups:

Method of Study: A pre-anaesthetic assessment by obtaining detailed history, complete physical examination and routine investigations were done a day before the surgery to the all patients. Procedure SAB was explained to the patient in their language and about the anaesthetic technique and the possible consequences. The patients were instructed to fast for a period of 8 hrs. before the procedure. Patients were pre-medicated with Tab. Rantac 150 mg and Tab. Anxit 0.5 mg H.S. All patients were clinically examined in the preoperative period, In preoperative assessment, patients were asked about any history of drug allergy, previous operations, or prolonged drug treatment.

Inclusion criteria: Patients of both sexes aged between 20-60 years of ASA I and II were included. Patients with heights between 150-180 cms; weight between 50-80 kgs were included.

Exclusion criteria: Patient's refusal, ASA Class II and IV or more, patients with coagulation disorders; patient on anticoagulant therapy; past spinal surgery; emergency surgery; infection at spinal needle insertion site; known hypersensitivity to local anaesthetics, hyperdynamically unstable.

Drugs: Bupivacaine was discovered in 1957 and was introduced in 1963. It is on the WHO Model List of Essential Medicines and is available as a generic medication and is not very expensive. Bupivacaine has probably had the greatest influence on the practice of regional anaesthesia due to the combined properties of an acceptable onset, long duration of action, profound conduction blockade, and significant separation of sensory to motor block.

Dexmedetomidine was approved in 1999 by the Food and Drug Administration (FDA) as a short term sedative and analgesic (<24 hours) for critically ill or injured people on mechanical ventilation in the Intensive Care Unit (ICU). The rationale for its short term use was due to concern over withdrawal side effects, such as rebound high blood pressure. More recently, in 2008 the FDA expanded its indication to non-intubated people requiring sedation.

Dexmedetomidine is most often used in the intensive care setting for light to moderate sedation. A unique feature of it is that it has analgesic properties in addition to its role as a hypnotic, but is opioid sparing, and is therefore not associated with significant respiratory depression. People on it are arousable and cooperative, and as such are able to actively cooperate with various procedures. It has less neurocognitive dysfunction compared to other sedatives.

Magnesium Sulphate: Magnesium was discovered in 1755 by Sir Humpry Davy. It is the fourth plentiful cation in the body and second most abundant intracellular cation after potassium. It is a cofactor in hundreds of enzymatic reactions and is a natural calcium antagonist.

IV. Observations and Results

This study is designed to compare the effect of adding dexmedetomidine and magnesium sulphate to hyperbaric bupivacaine in lower abdominal and lower limb surgeries.

Total of 60 adult patients aged between 20-60 years undergoing lowing abdominal and lower limb surgeries are selected after institutional ethical committee approval and the study population divided into 2 groups with 30 patients in each group.

- Group D-Received 3 ml of 0.5% bupivacaine (H) 15 mg and 0.1 ml (10 mcg) dexmedetomidine.
- Group M-Received 3 ml of 0.5% bupivacaine (H) 15 mg and 0.1 ml of magnesium sulphate (50 mg).

The following parameters were observed:

1. Demographic profile.
2. Baseline hemodynamics.
3. Perioperative hemodynamics.
4. Speed of onset and duration of motor block.
5. Speed of onset and sensory regression time to 2 segments below.
6. Pain and Visual analogue scale (VAS) scores.
7. Time for first voiding.
8. Complications – nausea, vomiting, shivering, seizure.

Number of patients in each group was 30. The number of males in group D was 26 (86%) and group M was 20 (66.7%). The number of females in group D was 4 (13.3%) and group M were 10 (33.3%). The p value of 0.07 ($p>0.05$) showing no statistical significance. Group D containing 30 subjects with 25-60 years age distribution with mean of 40.6 years with SD of 12.55 both groups are compared with t-value of 0.69 and the P value of 0.49 ($p>0.05$) which is statistically not significant.

Group D containing 30 subjects with 152-180 cms distribution with mean of 162.53 with SD of 6.39 and Group M containing 30 subjects with 150-174 cms distribution with mean of 159.53 with SD of 7.02. Both groups are compared with t value of 1.85 and the P value of 0.07 ($p>0.05$) which is statistically not significant.

Group D containing 30 subjects with 54-80 kgs distribution with mean of 62.90 kgs with SD of 7.72 and Group M containing 30 subjects with 50-80 kgs distribution with mean of 64.67 kgs with SD of 8.76. Both groups are compared with t value of 0.83 and the P value of 0.41 ($p>0.05$) which is statistically not significant.

Group D containing 30 subjects with 3-5 min distribution time of highest sensory level from time to injection with mean of 4.2 min with SD of 0.4 and Group M containing 30 subjects with 4-7 min distribution time of highest sensory level from time of injection with mean of 6.3 min with SD of 0.6. Both groups are compared with t value of 17.35 and the P value of $p>0.001$ which is statistically significant.

Group D containing 30 subjects with 94-128 min distribution for sensory regression of 2 segments from time of injection with mean of 112 min with SD of 8.9 and Group M containing 30 subjects with 55-105 min distribution for sensory regression of 2 segments from time of injection with mean of 75 min with SD of 9.3. Both groups are compared with t value of 15.78 and the P value of <0.001 which is statistically significant.

Group D containing 30 subjects with 2-4 min distribution for bromage 3 scale from time of injection with mean of 3 min with SD of 0.5 and Group M containing 30 subjects with 3-8 min distribution for bromage 3 scale from time of injection of 2 segments from time with mean of 7 min with SD of 0.9. Both groups are compared with t value of 20.22 and the P value of >0.001 which is statistically significant.

Group D containing 30 subjects with 320-393 min distribution for bromage 0 scale from time of injection with mean of 357 min with SD of 20.4 and Group M containing 30 subjects with 190-304 min

distribution for bromage 0 scale from time of injection with mean of 235 min with SD of 27.7. Both groups are compared with t value of 19.40 and the P value of <0.001 which is statistically significant.

Patient pain was assessed with VAS at 30 min post operatively and following results were observed. Mean VAS for D group was 4.5 and mean VAS for M group was 5.2. Hence it is observed that addition of dexmedetomidine to bupivacaine had a better analgestic effect that magnesium sulphate.

Group D containing 30 subjects with 315-390 min distribution for analgesia from time of injection with mean of 361.9 min with SD of 18.4 and Group M containing 30 subjects with 194-360 min distribution for analgesia from time of injection with mean of 251.9 min with SD of 30.4. Both groups are compared with t value of 17.07 and the P value of <0.001 which is statistically significant.

Group D containing 30 subjects with 336-408 min distribution for first vioding from time of injection with mean of 374.2 min with SD of 16.7 and Group M containing 30 subjects with 220-382 min distribution for first vioding from time of injection with mean of 274.6 min with SD of 30.9. Both groups are compared with t value of 15.54 and the P value of <0.001 which is statistically significant.

Table No.1 : Gender Distribution

Female	4	13.3%	10	33.3%
Male	26	86.7%	20	66.7%
Total	30	100%	30	100%
Chi -square valu = 0.28;	df =1		P = 0.59	

Table No. 2 : Demographical Distribution

Variable	Group	N	Minimum	Maximum	Mean	SD	T Value	P Value
Age (Yrs)	D	30	25.0	60.0	42.60	9.65	0.69	0.49
	M	30	22.0	60.0	40.60	12.65		
Height (cms)	D	30	152.0	180.0	162.53	6.39	1.85	0.07
	M	30	150.0	174.0	159.33	7.02		
Weight (Kgs)	D	30	54.0	180.0	62.90	7.72	0.83	0.41
	M	30	50.0	80.0	64.67	6.76		

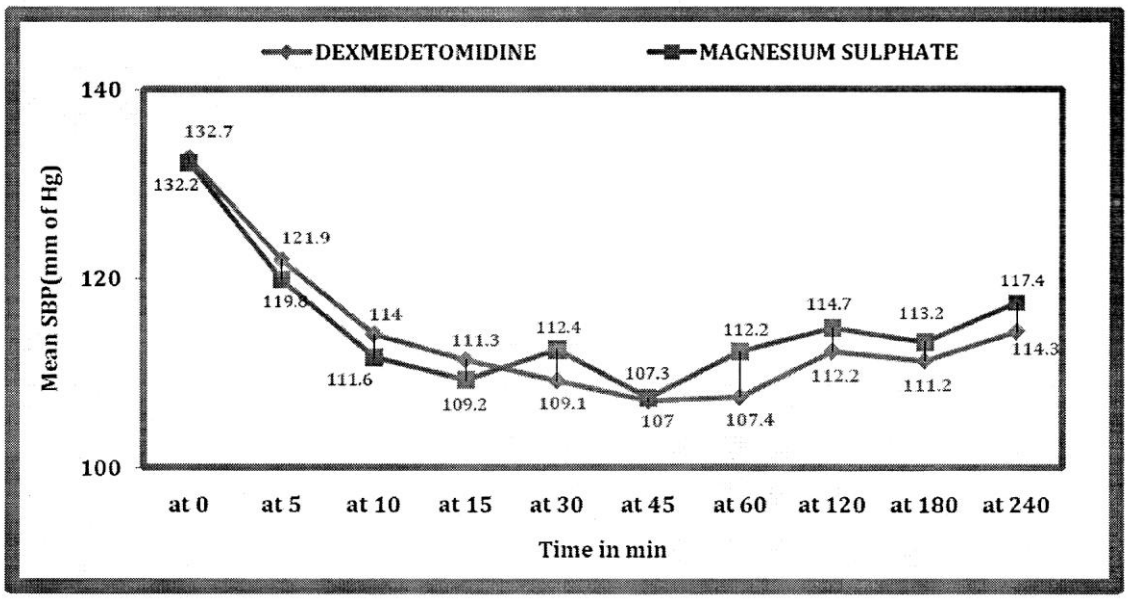
Table No.3 : Intra and Perioperative Parameters

Time from injection to highest sensory level (min)	30	3	5	4.2	0.4	30	4	7	6.3	0.6	17.73	<0.001
Sensory reg time to 2 segment below (min)	30	94	128	112.0	8.9	30	55	105	75	9.3	15.78	<0.001
Time achieve Bromage 3 scale (Min)	30	2	4	3.0	0.5	30	3	8	7	0.9	20.22	<0.001
Time achieve Bromage 0 scale (Min)	30	320	393	357	20.4	30	190	304	233	27.7	19.40	<0.001
Duration of anaglesia (min)	30	315	390	361.9	18.4	30	194	360	251.9	30.1	17.07	<0.001
Time of first voiding (min)	30	336	408	374.2	16.7	30	220	382	274	30.9	15.54	<0.001

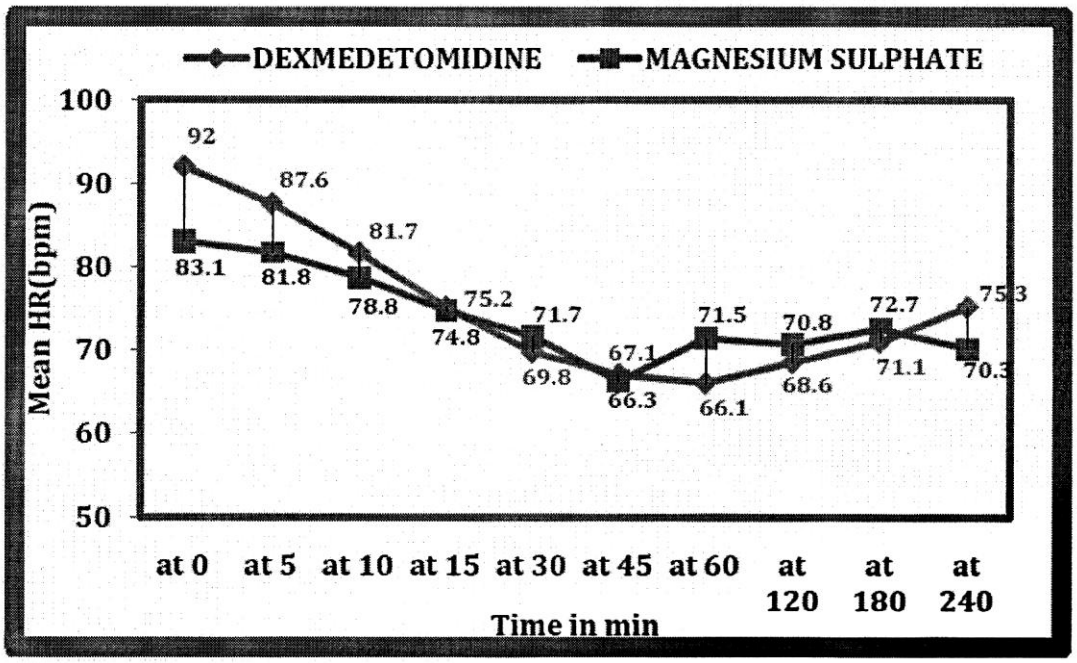
Table No.4 : Adverse Effects

	Count	%	Count	%
No	25	83.3%	28	93.3%
Shivering	5	16.7%	2	6.7%
Total	30	100%	30	100%
Chi square value = 1.6 df = 1 P = 0.02				

GRAPH 15: Systolic Blood Pressure



GRAPH 13: Heart Rate



V. Discussion

Spinal anaesthesia is the most preferred regional anaesthesia technique as it is easy to perform, produces rapid onset of anaesthesia and complete muscle relaxation and is also economical. These advantages are sometimes offset by a relatively short duration of action. The aim of intrathecal local anaesthetic is to provide adequate sensory and motor block necessary for all infra umbilical surgeries. Hyperbaric bupivacaine is the most commonly used intrathecal local anaesthetic. Various adjuvants have been added to bupivacaine to shorten the onset of block and prolong the duration of block. Dexmedetomidine, an 0-2 agonist drug, when given intrathecally, significantly prolongs the duration of spinal anaesthesia. Intrathecal □–2 receptor agonists have been found to have antinociceptive action for both somatic and visceral pain. Dexmedetomidine is more selective, □$_2$ agonists imidazole compound than clonidine. It exhibits a high ratio of specificity for the alpha-2 versus alpha-1 adrenergic receptor. This agent causes sedation, anxiolysis, and analgesia. Dexmedetomidine had been approved for sedation in adults during mechanical ventilation in intensive care unit settings. There are few data addressing the use of this drug for regional anaesthesia.

The mechanism by which intrathecal alpha 2-adrenergic agonists prolong the motor and sensory block of local anaesthetics is not clear. It may be an additive or synergistic effect secondary to the different mechanisms of action of local anaesthetic and alpha 2-adrenergic agonist. The local anaesthetics act by blocking sodium 54 channels, whereas the alpha 2 adrenergic agonist acts by binding to pre synaptic C fibre and post synaptic dorsal horn neurons. Intrathecal alpha 2 adrenergic agonist produce analgesia by depressing the release of C fibre transmission by hyperpolarization of post synaptic dorsal horn neurons.

Li et.al observed that glutamate is involved in excitatory neurotransmission nociception and plays an essential role in relaying noxious stimuli in the spinal cord. Intrathecal injection of alpha 2 adrenergic agonists produces potent anti nociceptive effects by altering spinal neurotransmitter release and effectively treats acute pain.

Recent studies suggest the role of magnesium sulfate as an adjuvant to local anaesthetics in spinal anaesthesia. The biological basis for potential anti nociceptive effect of magnesium is its voltage-dependent regulation of calcium influx into the cell, and non-competitive antagonism of N-methyl-D-aspartate (NMDA) receptors. Efficay and safety of intrathecal magnesium as analgesic adjuvant has been tested by several clinical trails in recent years. Anti nociceptive effect of magnesium appears to be relevant for the management of chronic and post operative pain. These effects are primarily based on regulation of calcium influx in to the cell. Magnesium blocks calcium influx and non competitively antagonized NMDA channels. NMDA receptor signaling plays an important role in determining the duration of acute pain. Addition of magnesium to spinal anaesthesia improved post operative analgesia in orthopaedic setting. Addition of intrathecal magnesium sulfate to 10 mg bupivacaine plus 25 g fentanyl prolonged spinal anaesthesia in patients undergoing lower limb surgeries. Therefore, the present study was performed to compare dexmedetomidine and magnesium sulphate in their efficacy as adjuvants to spinal anaesthesia. In our study, the intrathecal dose of dexmedetomidine and magnesium are selected based on previous studies. In our study design Group D received Inj Hyperbaric bupivacaine 0.5% (15 mg) + Inj. dexmedetomidine (10mcg), Group M received Inj Hyperbaric bupivacaine 0.5% (15 mg) + Inj magnesium sulphate (50 mg).

Kim ENY et al studies the effects of intrathecal dexmedetomidine and low-dose bupivacaine spinal anaesthesia in elderly patients undergoing transurethral prostatectomy. Fifty-four patients undergoing transurethral prostate surgery were randomized into two groups receiving either dexmedetomidine 3 g(n=27) or normal saline (n=27) intrathecally with 6 mg of 0.5% hyperbaric effects were evaluated. Dexmedetomidine 3 g when added to intrathecal bupivacaine 6 mg produced fast onset and a prolonged duration of sensory block and postoperative analgesia in elderly patients for transurethral surgery. However, recovery of motor block could be delayed in dexmedetomidine added patients.

In our study also similar results were observed with dexmedetomidine 10 g when addedto intrathecal bupivacaine 15 mg with fast onset and prolonged duration of sensory block and post operative analgesia. But the mean sensory onset time is 7.9 min in contrast to 4.2 min in our study.

VI. Conclusion and Summary

In our study there was significant difference in highest sensory level onset time (4.2±0.4 min in group D and 6.3±0.6 min in group M) with group D (dexmedetomidine group) rapid in onset. Sensory regression time to 2 segments below the highest sensory level was significantly more (12±8.9 min in group D and 75±9.3 min in group M) with group D. There was significant difference in the onset time to Bromage 3 motor block (3±0.5 min in group D and 7.0+0.9 min in group M) with group D rapid onset. But the regression of motor block to Bromage 0 (357±20.4 min in group D and 235±0.27 min in group M) was significantly slower in group. The duration of analgesia (361.9±18.4 min in group D and 251.9±30.1 min in group M) was significantly longer in group D as compared to group M.

Our study concluded that

1. Onset of sensory and motor block is faster in dexmedetomidine group than magnesium sulphate group.
2. Duration of sensory and motor block is significantly longer in dexmedetomidine group than magnesium sulphate group.
3. Duration of analgesia is significantly prolonged in dexmedetomidine group than magnesium sulphate group with better VAS in dexmedetomidine group.
4. No significant haemodynamic changes except fall in mean SpO2 to 97% in magnesium sulphate group at 1 hr, and 2 hrs interval.

Hence, it is concluded that dexmedetomidine provides rapid onset of block and prolonged duration of block when compared to magnesium sulphate without any clinically significant side effectts.

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