



Original Research Article

An observational study to compare the effect of intravenous dexmedetomidine versus intravenous magnesium sulphate pretreatment on characteristics of spinal anaesthesia

Akash Gajendra¹, Tripti Vatsalya¹, Vikas Gupta¹, Vandana Pandey^{1,*}, Shikha Mehrotra¹

¹Dept. of Anesthesiology, Gandhi Medical College, Bhopal, Madhya Pradesh, India



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ABSTRACT

Background and Aims: The study was conducted to assess & compare the effect of pretreatment with intravenous Dexmedetomidine and Magnesium sulphate on characteristics of SAB with hyperbaric bupivacaine.

Materials and Methods: 80 ASA grade I and II patients (age: 18-60 years) scheduled for infraumbilical surgery under spinal anesthesia were included & randomly divided into group-D (dexmedetomidine 1 μ gm/kg) and group-M (magnesium sulfate 50 mg/kg). patients were given prefixed doses of either intravenous dexmedetomidine or Magnesium sulfate 15 mins before SAB. Incidence of hypotension, highest level & duration of sensory & motor blockage, duration of analgesia, vasopressor requirement and incidence of sedation, nausea & vomiting were compared.

Results: highest upper level of sensory block after SAB was higher in group-D (p value < 0.001) than group-M. onset of sensory & motor block was earlier & duration of sensory and motor block, time of rescue analgesia was longer in group-D (p value < 0.001). Depth of sedation was higher in group-D though oxygen saturation and respiratory rate was comparable in both groups. Postoperative VAS score (p value < 0.001) was lower in dexmedetomidine group.

Conclusion: Study suggests that Intravenous dexmedetomidine at a dose of 1 μ g/kg is a better adjuvant to 0.5% hyperbaric bupivacaine than MgSO₄ at a dose of 50 mg/kg in infra-umbilical surgeries, with complications of hypotension and bradycardia occurring at acceptable incidences.

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1. Introduction

Spinal anesthesia is an appropriate choice for surgery on the lower extremities, pelvis, or lower abdomen. The use of a short-acting local anesthetic will result in rapid recovery of motor and sensory function and can shorten the time to discharge.^{1,2} Neuraxial anesthesia for patients undergoing infra-umbilical surgery is a well-established safe and effective anesthetic technique. Subarachnoid block is the preferred technique because of its rapid onset, superior

blockade, lower failure rates, and cost-effectiveness, but has the drawbacks of a shorter duration and lack of postoperative analgesia. Recently, the use of intrathecal & intravenous adjuvants has gained popularity with the aim of prolonging block duration, higher success rates, patient satisfaction, and decreased resource utilization without increasing the side effects. Effective management of postoperative pain is essential for rehabilitation and accelerated functional recovery, allowing patients to return to normal activity more quickly.³ Dexmedetomidine being a α_2 agonist provides excellent sedation with

* Corresponding author.

E-mail address: pandeyvandana92@gmail.com (V. Pandey).

minimal respiratory depression, decreases postoperative requirement of analgesics and may also acts as an adjuvant in subarachnoid block (SAB). Intravenous infusion of magnesium sulfate during spinal anesthesia has also been used to improve postoperative analgesia and to reduce total analgesic consumption.⁴ Local anesthetic agents act by blocking sodium channels. Thus, the prolonged effect can be explained by synergism between local anesthetic and α 2-adrenoceptor agonist, while the binding of α 2-adrenoceptor agonists to motor neurons in the dorsal horn leads to prolongation of the motor block of spinal anesthetics.^{5,6} Magnesium Sulphate exerts its analgesic effects as a non-competitive NMDA receptor Antagonist and blocking the ion channel in voltage dependent manner. Noxious stimulation leads to release of Glutamate and Aspartate neurotransmitters which binds to various subclasses of excitatory amino acid receptor including NMDA receptor. Activation of the NMDA receptor results in the influx of calcium and sodium into the cell and the influx of potassium and the onset of a central sensitization and wind phenomenon.⁴ In addition to prolonging the duration of spinal anesthesia, both of these causes a decrease in stress response, heart rate and blood pressure by decreasing the secretion of catecholamines. This can be of great help in the perioperative period when most of the vulnerable hemodynamic changes occur due to stress. In this study we investigated the effect of a single intravenous low dose of dexmedetomidine and MgSO₄ on characteristics of spinal anesthesia using hyperbaric bupivacaine. Therefore, we aimed to study effects of pretreatment of Dexmedetomidine and Magnesium Sulphate intravenously on hyperbaric Bupivacaine (H 0.5%) for spinal Anesthesia in patients undergoing infra-umbilical surgery. We also studied effect on block characteristic, duration of postoperative Analgesia, hemodynamic variation & occurrence of any side effects.

2. Materials and Methods

This comparative observational hospital based study was conducted in a tertiary care Institute from January 2019 to September 2020. Institutional ethics committee approval and written informed consent was obtained and patient related confidentiality was maintained. The study included 80 patients aged 18- 60 years of either sex belonging to ASA 1 and 2 undergoing infra umbilical surgeries under spinal anesthesia. Patients excluded from the study were: patients who refused to give valid informed consent, ASA grades 3, 4 and more, carrying pregnancy, any absolute contraindication to spinal Anesthesia and also those cases which were converted to general Anesthesia due to insufficient spinal Anesthesia.

Pre-anesthetic assessment of the patient was done with a complete history, physical examination, routine investigations and informed written consent was obtained. All patients were kept NBM (nil by mouth) for 6 hrs before

surgery.

In the Operating room each patient received intravenous Ringer lactate solution @ 10ml/Kg before induction of spinal anesthesia and infusion was continued during surgery. Injection Ranitidine 50mg iv. + Injection Ondansetron 4 mg iv. 15 minutes administered as premedicant before induction of anesthesia.

A baseline reading of heart rate, Noninvasive blood pressure (NIBP), and Hemoglobin oxygen saturation were recorded using multipara monitor.

Patients were allocated to two groups on the basis of drugs received. 40 patients received i/v dexmedetomidine 1 mcg/kg in 100ml normal saline given as infusion slowly over 15 minutes and another 40 received i/v Magnesium sulphate 50mg/kg in 100ml normal saline given as infusion slowly over 15 minutes.

Five min following the end of the infusion vitals were recorded & Dural puncture was performed at the L3-L4 interspace using a standard midline approach in sitting position with a 25G Quincke's spinal needle after confirmation of free flow of CSF. Bupivacaine (Heavy) 0.5%, 3ml was injected intrathecally. All Patients received moist oxygen via Hudson mask throughout the procedure @ 4L /min. Level of sensory blockade was checked after 2 minutes with a pin prick in mid axillary line & maximum level of sensory blockade achieved was noted. Recovery time for sensory blockade was defined as two dermatome regression of anesthesia from maximum level. Motor blockade was assessed immediately after sensory block assessment using a Modified Bromage scale. The level of sedation was assessed using Ramsay sedation scale.

Hypotension (defined by a decrease in mean arterial blood pressure [MAP] below 20% of baseline or systolic blood pressure [SBP] <100 mm Hg) was treated with 200ml of bolus Ringer's solution intravenously if not corrected then i.v mephentermine (6 mg) had been administered. Bradycardia (heart rate <50 beats/ min) was treated with intravenous atropine (0.6 mg). Any adverse reaction was noted and treated accordingly. At the end of the procedure patients were sent to the postoperative room. Postoperative analgesia was assessed by visual analogue scale [VAS] pain score (VAS 0 = no pain, 10 = worst possible pain) at 4, 8, 12 and 24 post-operative hours. Rescue analgesia in the form of injection diclofenac 75mg intramuscularly was administered when VAS score > 4 or on demand.

Adverse reactions like episodes of hypotension, bradycardia, desaturation, respiratory depression, nausea, vomiting, shivering, perioperative sedation score, VAS score, perioperative total requirement of mephentermine and atropine was also be noted.

2.1. Statistical analysis plan

Statistical analysis was completed using Statistical Package of Social Science (SPSS Version 20; Chicago Inc., USA).the

data were distributed meaningfully and presented as individual tables with graphs. Quantitative variables were compared using mean values and qualitative variables using proportions. The difference in proportion was analyzed using the chi-square test and the difference in mean was analyzed using Student's t test. Significance level for tests was determined as 95% ($P < 0.05$).

3. Observation & Results

All the enrolled patients completed the study, and none of them were excluded. A total of 80 patients referred for elective intra-umbilical surgeries were divided into two groups equally. There was statistically no significant difference in age, height & weight between the two groups. The group wise distributions of the patients were as follows: group D= (n=40) & group M (n=40). Age of patients included in study were 18-60 years. Mean age was 32.75 years in group M & 34.4 years in group D. Mean height was 161.77 cm in group M & 159.3 cm in group D. Mean weight was 58.42 kg in group M & 52.5 kg in group D. There was statistically no significant difference found in age, height & weight between the two groups.

Out of 80 patients 17(13.6%) were of ASA grade I and 63(86.4%) were of ASA grade II. There was statistically no significant difference found in ASA Grade ($p=0.418$) & duration of surgery between the two groups ($p=0.849$).

Maximum level of sensory blockade achieved in Group D was more (i.e. T6-22.5 %) as compared to group M (i.e. 0). (p value < 0.001). Time of onset of sensory blockade in Group D was less i.e. 3.23 ± 0.37 min as compared to group M i.e. 4.37 ± 0.641 min. The difference was statistically significant (P value= 0.0003). Onset of motor blockade in Group D was early i.e. 4.89 ± 0.292 min as compared to group M i.e. 5.89 ± 1.006 min. The difference was statistically significant (p value= 0.0006). Time for two segment regression was more in group D 144.175 ± 4.18 mins as compared to group M 131.325 ± 4.27 mins. The difference was statistically significant ($p=0.0006$). Duration of analgesia was statistically significantly prolonged in Group D 249.55 ± 51.52 mins as compared to Group M 213.65 ± 70.27 mins. The difference was statistically significant. (p value= 0.010). Duration of motor block was more in group D 191.55 ± 2.85 minutes as compared to Group M 165 ± 23.39 minutes. The difference was statistically significant. (p value= 0.0004).

Baseline vitals of patients of both groups [Heart Rate, Mean arterial pressure (MAP), respiratory rate (RR) and SPO₂] were recorded. There was statistically no significant difference found in baseline vitals between the two groups ($p > 0.05$). There was a decrease in heart rate after administration of study drugs in both the groups. However, the decrease was more in group D as compared to group M. There was a drop in heart rate from baseline in both groups during the first 140 minutes, but it was more in group D as

compared to group M but it was not statistically significant (p value- >0.05) throughout the observation period. There was a decrease in mean arterial pressure after administration of study drugs in both the groups. However, the decrease was more in group D as compared to group M. there was a drop-in mean arterial pressure from baseline in both the groups during first 60 min but it was more in group D as compared to group M but it was not statistically significant (p value- >0.05) throughout the observation period.

The pain scores as assessed on the VAS were lowest for a significant time in the post-operative period in patients receiving i.v Dexmedetomidine (Group D) as compared to the Group M. P value was found to be highly significant ($p < 0.001$). Test of significance (chi square test) showed statistically significant difference of sedation score between the 2 groups at 1 hour and 2 hours, 3 hours & 4 hours ($p < 0.01$). Sedation score was greater in dexmedetomidine group than the MgSo₄ group. However, test of significance could not be applied at rest of the hours of observation. There was no statistical difference in Respiratory Rate and SpO₂ between Group M and Group D at all intervals as p value was >0.05 . Incidence of bradycardia was greater in the dexmedetomidine (12.5%) group as compared to MgSo₄ Group (7.5%). The incidence of hypotension was greater in the dexmedetomidine (25%) group than with MgSo₄ Group (20%). There were no side effects in 35 % patients in group M & 12.5 % patients in group D.

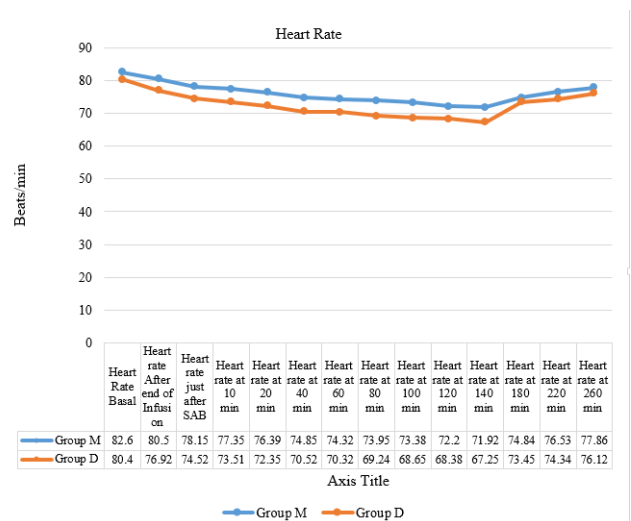


Fig. 1: Comparison of heart rate at various time intervals between the groups.

4. Discussion

Use of intravenous dexmedetomidine before or just after spinal block is not a new concept.⁷ Commonly used method of intravenous dexmedetomidine is either as loading dose just before or after spinal anaesthesia,⁸ loading dose

Table 1: Distribution of patients in two groups according to ASA grade

ASA grade	I	Group		Total	T-Test F-Value	DF(Degrees of freedom)	P value
		Group M	Group D				
	I	10(12.41%)	07(1.19%)	17(13.6%)	0.661	1	0.418
	II	30(18.9%)	33(67.5%)	63(86.4%)			
Total		40(31.31%)	40(68.69%)	80(100%)			

Table 2: Duration of surgery in two groups

Parameters	Group M		Group D		T-test f- value	P- value
	Mean	SD	Mean	SD		
Duration of Surgery (Min)	130.4	24.14	135.15	21.84	0.036	0.849

Table 3: Comparison of maximum level, onset, duration of sensory blockade (time for two segment regression) & duration of analgesia in two groups.

Parameters	Maximum sensory blockade		Frequency	Percentage %	p-value	
	Group M	Group D				
Group D	T6		9	22.5	0.000	
	T8		27	67.5		
	T10		4	10		
Group M	T6		0	0	0.0003	
	T8		12	70		
	T10		28	30		
Parameters	Group M		Group D		p- value	
Onset of sensory block (Min)	Mean 4.37	SD 0.641	Mean 3.23	SD 0.376	0.0003	
Parameters	Group M		Group D		T-test f- value	P -value
Two segment Regression (Min)	Mean 131.325	SD 4.27	Mean 144.175	SD 4.18	83.32005	0.0006
Duration of Analgesia (Min)	Mean 213.65	SD 70.27	Mean 249.55	SD 51.52	6.789235	0.010

Table 4: Comparison of onset & duration of motor blockade (min.) in two groups.

Parameters	Group M		Group D		T-Test F-Value	Df (Degrees of freedom)	P Value
	Mean	SD	Mean	SD			
Onset of motor block (Min)	5.89	1.006	4.89	0.292	83.320	1	0.0006
Duration of Motor block (Min)	165	23.39	191.55	28.5	50.76415	1	0.0004

Table 5: Baseline vitals of patients in groups

Parameters	Group M		Group D		p- value
	Mean	SD	Mean	SD	
Heart rate	82.6	8.77	80.4	7.62	0.279
Mean Arterial pressure	70.95	13.64	68.2	12.67	0.799
Respiratory rate Basal	15.75	0.58	15.67	0.65	0.452
SPO2 rate Basal	98.87	0.40	98.85	0.42	0.78

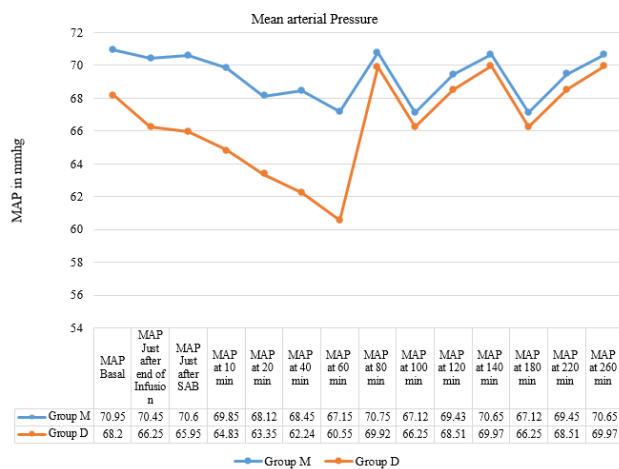
followed by continuous infusion.⁹ Most commonly used loading dose is 0.5 mcg/kg to 1 mcg/kg over 10 min and infusion dose range from 0.2 mcg/kg/hr to 1 mcg/kg/hr were reported to prolong analgesia & sensory blockade.^{10,11} we administered the study drug via infusion over 15 min. to avoid any unwanted side effects like bradycardia, hypotension, respiratory depression etc. It has been shown in previous studies that the dose of 50 mg neuraxial Magnesium Sulphate either as intravenous, intrathecal or

epidural route leads to increase in duration of analgesia and found to be effective. It has been suggested that NMDA blocking agents should be administered before the beginning of nociceptive stimulation to inhibit the process of central sensitization.¹² Hence, in this study, we have used IV 50mg/kg preservative free Magnesium Sulphate 15 min before SAB with 3ml hyperbaric Bupivacaine in Group M. The dosage of Mg chosen by us was in accordance to the study of Hwang et al.¹³

Table 6: Comparison of vas score & sedation score at various time intervals between the groups

Vas score	Group M		Group D		T-test f- value	P -value
	Mean	SD	Mean	SD		
1 hr	0	0	0	0	0	NA
2 hr	0.850	0.2320	0.500	0.0000	72.435	< 0.001
3 hr	1.838	0.3469	1.000	0.0000	97.086	< 0.001
4 hr	2.975	0.3914	2.050	0.2207	85.680	< 0.001

Sedation score	Group m		Group d		T-test f- value	P -value
	Mean	SD	Mean	SD		
30 min.	2.825	0.384	2.975	0.158	5.2	0.025
1 hr.	2.9	0.303	3.05	0.220	6.38	0.013
2 hr.	2.075	0.266	2.225	0.422	5.38	0.022
3 hr.	1.275	0.452	2.05	0.220	102.8	0.0006
4 hr.	1	0	1.75	0.438	117	0.0003
5 hr.	1	0	1	0	NA	NA

**Fig. 2:** Comparison of mean arterial pressure at various time intervals between the groups.

Maximum level of sensory blockade achieved in Group D was more as compared to group M (p value < 0.001). Similar results have been observed by Annamalai A et al¹⁴ & Kiran Kumar S. et al.¹⁵

Time of onset of sensory & motor blockade in Group D (Dexmedetomidine) was early as compared to group M ($MgSO_4$). Which was statistically significant ($P < 0.001$). Vatsalya et al¹⁶ & Zhang H et al¹⁷ concluded that administration of IV dexmedetomidine during subarachnoid block hastens onset of sensory & motor block. We observed statistically significant difference in duration of sensory block & prolongation in duration of motor blockage & time for two segment regression between group D & M ($P < 0.001$). Similar results were observed by Harsoor S.S et al¹⁸ & Lee et al.¹⁹ The degree of prolongation of motor blockade appears to be dose dependent (continuous intraoperative infusion) of alpha 2 agonists.²⁰

Duration of analgesia was maximum in Group D (Dexmedetomidine) & the difference was statistically significant ($P < 0.001$). Dexmedetomidine infusion used as a loading dose has been found to prolong the duration of analgesia in study by Hong et al²¹ similar to present study. The pain scores as assessed on the VAS were lowest for a significant time in the post-operative period in patients receiving i.v Dexmedetomidine (Group D) as compared to the Group M ($p < 0.001$). Prolonged duration of spinal anaesthesia by Dexmedetomidine can be explained by its vasoconstricting and analgesic actions by agonism at spinal alpha 2 receptors in the substantia gelatinosa. Similarly, a bolus of 50 mg/kg magnesium sulphate has been found to prolong the duration of analgesia of spinal block. prolonged duration of analgesia of spinal block can be explained by its inhibition of calcium entry into cells by means of noncompetitive block of dorsal horn NMDA receptor.

Heart rate was monitored from the start of infusion till end point of the study. Mean baseline heart rate was comparable in both groups. The drop-in heart rate was for moderate period, with the hemodynamic perturbations lasting only up to 140 min after beginning of anaesthesia which was more in group D than group M. Decrease in heart rate was clinically significant but not statistically significant, also the decrease was within 10-15% of baseline values.

Blood pressure was monitored from the start of infusion till end point of the study. Baseline MAP was comparable in both groups. The drop-in mean arterial pressure was for moderate period, with the hemodynamic perturbations lasting only up to 60 min after beginning of anaesthesia which was more in group D than group M. Decrease in blood pressure was clinically significant but not statistically significant, also the decrease was within 10-15% of baseline values. The incidence of hypotension was greater in the dexmedetomidine (25%) group than with $MgSO_4$ Group (20%) which was not significantly different.

Dexmedetomidine does not cause much respiratory depression despite providing good sedation resulting in wide safety margins.²² In present study, Sedation scores in Groups D and M were 3 and 2, respectively. Dexmedetomidine had highest sedation scores throughout the observation period. Dexmedetomidine produces sedation by its central effect and seems to be dose dependant.²³ Sedation can be due to the α_2 agonists action of dexmedetomidine on the locus coeruleus.²⁴ Lack of such effect may be the cause of decrease sedation in magnesium sulphate group.

We observed increased incidence of bradycardia in the dexmedetomidine group (12.5%) as compared to MgSO₄ (7.5%) group. Also, the incidence of hypotension, was greater in the dexmedetomidine (25%) groups than with MgSO₄ group (20%). Bradycardia following Dexmedetomidine administration may be due to the central sympatholytic action which is responsible for unopposed vagal tone.²⁵ Incidence of nausea & vomiting was more in the dexmedetomidine (27.5%) group as compared to MgSO₄ Group (25%). Incidences of shivering under spinal anesthesia has been reported as high as 40-60%. Shivering not only cause discomfort to the patient, it increases the oxygen consumption, increases catecholamine level subjecting the patient to a higher risk of cardiovascular complications.²⁶ The Alpha-2 receptor agonists are known to possess anti-shivering property by lowering shivering and vasoconstriction threshold without increasing respiratory depression, nausea-vomiting unlike the other anti-shivering drugs like meperidine. There were few limitations also like VAS score >4 or request for analgesic was used as a therapeutic end point. Twenty-four hours total analgesic requirements were not recorded which would have better demonstrated the analgesic qualities of the studied drugs.

5. Conclusion

Intravenous dexmedetomidine at a dose of 1 μ g/kg is a better adjuvant to 0.5% hyperbaric bupivacaine than MgSO₄ at a dose of 50 mg/kg in infra-umbilical surgeries, with complications of hypotension and bradycardia occurring at acceptable incidences.

6. Conflict of Interest

None.

7. Source of Funding

None.

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Author biography

Akash Gajendra, Senior Resident  <https://orcid.org/0000-0002-0558-2455>

Tripti Vatsalya, Associate Professor  <https://orcid.org/0000-0002-6284-9048>

Vikas Gupta, Associate Professor  <https://orcid.org/0000-0003-3015-9074>

Vandana Pandey, Assistant Professor  <https://orcid.org/0000-0002-5078-9113>

Shikha Mehrotra, Professor and HOD

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