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

M Sathesha	Associate professor, Department of Anaesthesiology, Bangalore Medical College and Research Institute, Bengaluru.
Divakar S R	Assistant professor, Department of Anaesthesiology, Mandya Institute of Medical Sciences, Mandya.
Priyanka Krishnamurthy	Senior resident, Department of Anaesthesiology, Bangalore Medical College and Research Institute, Bengaluru.
P K Dileep*	Senior resident, Department of Anaesthesiology, Bangalore Medical College and Research Institute, Bengaluru.*Corresponding Author

ABSTRACT **INTRODUCTION:** Lower abdominal and lower limb surgeries can be performed under local, regional or general anaesthesia. Spinal anaesthesia is the most common technique of regional anaesthesia used for infra-umbilical surgeries because of its rapid onset, superior blockade, lower risk of infection, less failure rates and cost effectiveness. Magnesium and Dexmedetomidine are used as adjuvants for spinal anaesthesia in our study. Magnesium possesses a property of NMDA receptor antagonist. NMDA receptor antagonist plays an important role in the prevention of central sensitization of pain. Glutamate and aspartate neurotransmitters are released in response to noxious stimuli and bind to the NMDA receptors and various other excitatory amino acid receptors. Dexmedetomidine is a highly selective α2-adrenergic agonist which has been used for premedication and as an adjunct to general anaesthesia. It reduces opioid and inhalational anaesthetics requirements. Intrathecal α2-receptor agonists are found to have antinociceptive action for both somatic and visceral pain. Activation of post synaptic alpha 2 receptors in the substantia gelatinosa of the spinal cord is presumably how it produces analgesia. **Material and Methods:** This is a Prospective randomized control study, double blind study The study will be conducted on inpatients of hospitals attached to Bangalore Medical College and Research Institute, Bangalore. 90 patients of physical status American society of Anaesthesiologists (ASA) grade 1 and grade 2 (ANNEXURE 1) of either sex, undergoing infraumbilical surgeries lasting more than 30 minutes fulfilling inclusion criteria will be included in the study after ethical committee clearance. Patients will be randomized to two groups of 45 each, receiving one of the following for the subarachnoid block: Group M (n=45) Bupivacaine (0.5% H) 2.5ml with magnesium sulphate 50mg. Group D (n=45) Bupivacaine (0.5% H) 2.5ml with dexmedetomidine 5 µg. **Result** Mean age(years) in group m was 40.89 ± 11.95 years and in group d was 42.8 ± 12.07 years. In Group M, 44.44% were Female and 55.56% were Male. In Group D, 51.11% were Female and 48.89% were Male. Maximum Height of Sensory Block in Group M was T4 in 2.22%, T6 in 42.22%, T7 in 17.78% and T8 in 37.78%. Maximum Height of Sensory Block in Group D was T10 in 20.00%, T6 in 33.33%, and T8 in 46.67%. Mean total duration of sensory block(min) in group m was 144.24 ± 25.9 and in group d was 234.36 ± 43.4. Mean duration of motor block(min) in group m was 163.91 ± 28.43mins and in group d was 216.67 ± 42.87 mins. In Group M Hypotension was there in 26.67% and 35.56% had in Group D. There was no significant difference in hypotension distribution between two groups. In Group M Bradycardia was there in 6.67% and 44.44% had in Group D. **CONCLUSION:** From our study, we conclude that Dexmedetomidine 5 µg as an adjuvant to spinal Bupivacaine is better than Magnesium Sulphate 50 mg as it provides earlier onset and prolonged duration of sensory and motor blocks without any significant hemodynamic alterations and provides good quality of post-operative analgesia.

KEYWORDS : Magnesium Sulphate, Dexmedetomidine, Intrathecal Hyperbaric Bupivacaine, Infraumbilical Surgeries

Introduction

Lower abdominal and lower limb surgeries can be performed under local, regional or general anaesthesia. Spinal anaesthesia is the most common technique of regional anaesthesia used for infra-umbilical surgeries because of its rapid onset, superior blockade, lower risk of infection, less failure rates and cost effectiveness. [1]

Lignocaine and Bupivacaine are the local anaesthetic drugs used to achieve the subarachnoid block. Use of Lignocaine is limited by its short duration of action and its implication in causation of transient neurological symptoms and cauda equina syndrome following intrathecal injection. [2] Bupivacaine is the commonest local anaesthestic used for spinal anaesthesia but its relatively shorter duration of action may lead to early analgesic intervention in postoperative period. [3]

Adjuvants are a different pharmacological class of drugs, which are used to prolong and enhance analgesia, to lower the dose requirements and to reduce the dose dependent side effects. Many drugs have been tried as spinal adjuvants. They are Opioids, Sodium bicarbonate, Ketamine, Neostigmine, Midazolam, Clonidine and the latest inclusion is Dexmedetomidine. Opioids are commonly used as intrathecal adjuvants as they improve the quality of intraoperative analgesia and prolong it in postoperative period without significant motor or autonomic blockade.[4] But since there are many side effects and complications like early and late depression of ventilation, pruritus, nausea, vomiting, urinary retention, central nervous system excitation, delayed gastric emptying and ocular dysfunction, there is an active search for an alternative ideal adjuvant which is devoid of these side effects and complications. [5]

Magnesium and Dexmedetomidine are used as adjuvants for spinal anaesthesia in our study. Magnesium possesses a property of NMDA receptor antagonist. NMDA receptor antagonist plays an important role in the prevention of central sensitization of pain. Glutamate and aspartate neurotransmitters are released in response to noxious stimuli and bind to the NMDA receptors and various other excitatory amino acid receptors. NMDA receptors activation leads to calcium and sodium influx into the cell, efflux of potassium and initiation of central sensitization, and wind-up [6,7]

Dexmedetomidine is a highly selective α2-adrenergic agonist which has been used for premedication and as an adjunct to general anaesthesia. It reduces opioid and inhalational anaesthetics requirements. [8] Intrathecal α2-receptor agonists are found to have antinociceptive action for both somatic and visceral pain. [9] Activation of post synaptic alpha 2 receptors in the substantia gelatinosa of the spinal cord is presumably how it produces analgesia.

This study is undertaken to evaluate and compare the characteristics of subarachnoid block with either Bupivacaine with Magnesium or Bupivacaine with Dexmedetomidine in adult patients undergoing infraumbilical surgeries.

MATERIALS AND METHODS

This is a Prospective randomized control study, double blind study The study will be conducted on inpatients of hospitals attached to Bangalore Medical College and Research Institute, Bangalore.

Inclusion Criteria:
a) Patients who are willing to give written informed consent
b) Patients posted for infraumbilical surgeries.
c) Age group- 18- 60 years, of either sex.
d) American Society of Anaesthesiologists (ASA) grade 1 and 2.
e) Weight 50-80 kg.
f) Height 150cm to 190cm.

F) Exclusion Criteria:
a) Patients who are not willing to give informed written consent for study.

b) Allergy to local anesthetics, opioids and Dexmedetomidine.

c) Uncontrolled diabetes mellitus, hypertension, recent myocardial infarction.

d) Pregnancy.

e) Contraindications/relative contraindications to spinal anaesthesia.

f) Hypovolemic shock, Bleeding diathesis and coagulopathy.

g) Psychiatric disorder.

90 patients of physical status American society of Anaesthesiologists (ASA) grade 1 and grade 2 (ANNEXURE 1) of either sex, undergoing infraumbilical surgeries lasting more than 30 minutes fulfilling inclusion criteria will be included in the study after ethical committee clearance.

Patients will be randomized to two groups of 45 each, receiving one of the following for the subarachnoid block:

Group M (n=45) Bupivacaine (0.5% H) 2.5ml with magnesium sulphate 50mg.

Group D (n=45) Bupivacaine (0.5% H) 2.5ml with dexmedetomidine 5 µg.

Under strict aseptic precautions with patient in lateral/sitting position, 25G/26G Quincke spinal needle will be introduced into L3-L4 space, after confirming clear flow of cerebrospinal fluid and negative aspiration for blood, study drug will be injected intrathecally over 10-15seconds. The time at which injection is completed will be considered as zero time of the study and all measurements will be recorded from this point. Following subarachnoid block, patients will be made to lie supine. Sensory testing will be assessed by loss of pinprick sensation to 23 G sterile hypodermic needle for onset and dermatomal levels were tested every 2 minutes until the highest level has been achieved and stabilized for four consecutive tests. Intraoperatively, vital parameters like heart rate, non-invasive blood pressure and percentage of oxygen saturation (SPO2) will be recorded every 2 minutes for the first 10 minutes, then every 5 minutes till 1 hour of surgery and then every 15 minutes till the end of surgery. Postoperatively, every 1 hour till the patient complaints of pain.

A 20% fall in Systolic Blood Pressure from baseline, will be treated with intravenous fluids and intravenous Injection ephedrine 6 mg. And a 20% fall in heart rate from baseline and will be treated with intravenous Injection Atropine 0.6 mg.

Post-operatively the haemodynamic variables and oxygen saturation will be recorded in the post anaesthesia care unit (PACU) until complete recovery from sensory and motor blockade. The incidence of any adverse effects such as hypotension, bradycardia, shivering, nausea, vomiting, pruritus, respiratory depression will be noted and treated accordingly.

RESULTS

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

			Group		P value
	Group M	Group D			
	Mean	Sd	Mean	Sd	
Age(years)	40.89	11.95	42.8	12.07	0.452

Mean age(years) in group m was 40.89 ± 11.95 years and in group d was 42.8 ± 12.07 years. There was no significant difference in mean age(years) comparison between two groups.

Table 2: Sex Distribution between two groups

		Group			
		Group M		Group D	
		Count	%	Count	%
Sex	Female	20	44.44%	23	51.11%
	Male	25	55.56%	22	48.89%

$\chi 2 = 0.401$, df = 1, p = 0.527

In Group M, 44.44% were Female and 55.56% were Male. In Group D, 51.11% were Female and 48.89% were Male. There was no significant difference in Sex distribution between two groups.

Table 3: Maximum Height Of Sensory Block (Dermatome) Distribution between two groups

		Group			
		Group M		Group D	
		Count	Column n %	Count	Column n %
Maximum height of sensory block (dermatome)	T10	0	0.00%	9	20.00%
	T4	1	2.22%	0	0.00%
	T6	19	42.22%	15	33.33%
	T7	8	17.78%	0	0.00%
	T8	17	37.78%	21	46.67%

$\chi 2 = 18.892$, df = 4, p = 0.001*

Maximum Height of Sensory Block in Group M was T4 in 2.22%, T6 in 42.22%, T7 in 17.78% and T8 in 37.78%. Maximum Height of Sensory Block in Group D was T10 in 20.00%, T6 in 33.33%, and T8 in 46.67%. There was a significant difference in Maximum Height of Sensory Block(Dermatome) distribution between two groups.

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

	Group				P value
	Group M		Group D		
	Mean	Sd	Mean	Sd	
Total duration of sensory block(min)	144.24	25.9	234.36	43.4	< 0.001*

Mean total duration of sensory block(min) in group m was 144.24 ± 25.9 and in group d was 234.36 ± 43.4. There was a significant difference in mean total duration of sensory block(min) comparison between two groups.

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

	Group				P value
	Group M		Group D		
	Mean	Sd	Mean	Sd	
Duration of Motor block(min)	163.91	28.43	216.67	42.87	< 0.001*

Mean duration of motor block(min) in group m was 163.91 ± 28.43mins and in group d was 216.67 ± 42.87 mins. There was a significant difference in mean duration of motor block(min) comparison between two groups.

Table 6: Mean SBP Comparison between two groups at different intervals of time

Sbp	Group				P value
	Group M		Group D		
	Mean	Sd	Mean	Sd	
Baseline	131.98	10.62	130.51	13.66	0.571
2mins after SAB	117.2	11.06	118.69	16.19	0.612
4 mins	105.36	8.81	112.51	12.4	0.002*

6 mins	101.07	8.66	107.49	14.73	0.013*
8 mins	97.13	8.49	105.29	12.11	< 0.001*
10 mins	96.73	8.05	103.27	13.7	0.007*
20 mins	96.56	10.6	103.33	13.56	0.01*
30 mins	101.69	9.64	103.73	12.39	0.385
40 mins	104	11.18	105.24	13.27	0.632
50 mins	105.02	11.85	106.33	13.12	0.62
60 mins	106.87	9.2	106.84	12.24	0.992
90 mins	107.49	9.14	106.31	8.84	0.536
120 mins	108.44	7.17	107.96	9.4	0.782
Immediate post op	113.69	13.76	116.76	12.84	0.277
1hour	118.33	9.32	116.89	12.91	0.544
2hours	121.13	8.38	118.27	13.24	0.223
3hours	122.62	8.36	117.51	13.85	0.037*
4hours	123.91	10.49	119.09	12.15	0.047*
8hours	124	9.89	119.67	11.31	0.056
12hours	119.36	17.71	120.09	10.41	0.811
16hours	122.93	10.38	119.04	10.58	0.082
20hours	124.8	8.96	120.96	10.43	0.064
24hours	128.49	9.2	123.82	9.16	0.018*

There was a significant difference in Mean SBP between two groups from 4mins to 20mins and at post op from 3 hours – 4hours and at 24 hours. At other intervals there was no significant difference.

Table 7: Mean DBP Comparison between two groups at different intervals of time

Dbp	Group				P value
	Group M		Group D		
	Mean	Sd	Mean	Sd	
Baseline	76.71	8.44	70.53	12.19	0.006*
2mins after SAB	65	6.49	65.18	10.8	0.925
4 mins	60.47	5.95	61.84	11.18	0.468
6 mins	58.13	6.18	59.96	10.83	0.33
8 mins	55.84	5.9	57.67	9.5	0.277
10 mins	55.98	8.09	56.51	11.23	0.797
20 mins	53.64	9.48	54.96	8.53	0.492
30 mins	53.38	9.26	55.53	7.5	0.228
40 mins	53.71	9.34	56.87	7.21	0.076
50 mins	55.84	8.92	59.16	6.85	0.051
60 mins	56.36	8.53	58.64	7.04	0.169
90 mins	56.29	7.22	59.51	6.55	0.029*
120 mins	56.13	5.83	60.02	6.21	0.003*
Immediate post op	62.2	6.7	63.09	8.55	0.584
1hour	65.93	5.33	67.31	6.73	0.285
2hours	67.51	5.87	68.71	6.52	0.362
3hours	67.42	6.22	68.49	8.97	0.514
4hours	67.13	6.2	67.31	7.91	0.906
8hours	69.71	6.38	67.87	8.79	0.258
12hours	69.69	5.27	68.89	8.19	0.583
16hours	72.07	7.08	70.2	7.1	0.215
20hours	74.51	8.63	71.16	7.89	0.058
24hours	79.91	10.19	72.62	7.83	0.001*

There was a significant difference in Mean DBP between two groups at Baseline, 45mins, from 90 mins – 120mins and at post op 24 hours. At other intervals there was no significant difference.

Table 8: Mean Respiratory Rate Comparison between two groups at different intervals of time

RR	Group				P value
	Group M		Group D		
	Mean	Sd	Mean	Sd	
Baseline	14.36	1.63	15.27	1.34	0.005*
Immediate Post OP	13.36	1.17	13.71	1.27	0.171

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

Table 9: Mean VAS Comparison between two groups at different intervals of time

	Group				P value
	Group M		Group D		
	Mean	Sd	Mean	Sd	
Immediate Post OP	0.62	0.75	0.22	0.42	0.002*
1 hour	2.71	0.97	1.93	0.65	< 0.001*
2 hours	4.78	1.02	3.02	0.92	< 0.001*
6 hours	6.49	0.51	6.2	0.73	0.031*
12 hours	5.4	0.58	5.73	0.84	0.0318
24 hours	5.24	0.53	5.64	0.91	0.012*

At all intervals there was a significant difference in Mean VAS Comparison between two groups.

Table 10: Side Effects Distribution between two groups

		Group				Chi Square
		Group M		Group D		
		Count	Column n %	Count	Column n %	
Hypotension	Absent	33	73.33%	29	64.44%	χ^2 = 0.829, df = 1, p = 0.362
	Present	12	26.67%	16	35.56%	
Bradycardia	Absent	42	93.33%	25	55.56%	χ^2 = 16.879, df = 1, p = < 0.001*
	Present	3	6.67%	20	44.44%	
Nausea	Absent	43	95.56%	39	86.67%	χ^2 = 2.195, df = 1, p = 0.138
	Present	2	4.44%	6	13.33%	
Shive ring	Absent	41	91.11%	38	84.44%	χ^2 = 0.932, df = 1, p = 0.334
	Present	4	8.89%	7	15.56%	

In Group M Hypotension was there in 26.67% and 35.56% had in Group D. There was no significant difference in hypotension distribution between two groups. In Group M Bradycardia was there in 6.67% and 44.44% had in Group D. There was a significant difference in bradycardia distribution between two groups. In Group M Nausea was there in 4.44% and 13.33% had in Group D. There was no significant difference in nausea distribution between two groups. In Group M Shivering was there in 8.89% and 55.56% had in Group D. There was no significant difference in shivering distribution 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.

Mean onset of sensory block at L1 in group M was 6.11 ± 1.34 min and in group D was 2.13 ± 0.63 min. There was a significant difference in mean onset of sensory block at L1 comparison between two groups. Mean onset of motor block in group M was 7.4 ± 1.29 min and in group D was 3.27 ± 0.91 min. There was a significant difference in mean onset of motor block(min) comparison between two groups.

Mean total duration of sensory block in group M was 144.24 ± 25.9 min and in group D was 234.36 ± 43.4 min. Mean two dermatome regression time in group M was 109.78 ± 18.81 min and in group D was 152.89 ± 40.89 min. There was a significant difference in mean total duration of sensory block and mean two dermatome regression time comparison between two groups.

Mean duration of motor block in group M was 163.91 ± 28.43 min and in group D was 216.67 ± 42.87 min. There was a significant difference in mean duration of motor block comparison between two groups.

Mean time to first request of analgesic dose in group M was 182.04 ±

34.48 min and in group D was 311.82 ± 56.14 min. There was a significant difference in mean time to first request of analgesic dose comparison between two groups.

Shukla D et al (2011) [10] conducted a study to compare the effects of dexmedetomidine and Magnesium Sulphate given intrathecally with Bupivacaine for spinal anaesthesia. 90 patients were randomly allocated to receive intrathecally either 15 mg bupivacaine plus (10 µg) dexmedetomidine (group D, n=30) or 15 mg bupivacaine plus (50 mg) magnesium sulphate (group M, n=30) or 15 mg bupivacaine plus saline (group C, n=30) as control.

They found that onset of anaesthesia was rapid and of prolonged duration in the dexmedetomidine group (D). In the magnesium sulphate group (M), onset of block was delayed, the duration was significantly prolonged as compared with the control group (C), but to a lesser degree than in the dexmedetomidine group (D), which supports our study.

Farooq, et al (2017) [11] conducted a similar study and concluded that addition of Dexmedetomidine to Bupivacaine for spinal anaesthesia shortens the onset time whereas addition of Magnesium delays onset. This supports the findings of our study.

Sur D et al (2017) [12] evaluated the effects of subarachnoid administration of bupivacaine with clonidine, magnesium, dexmedetomidine and saline group. 120 patients were allocated into four groups with each group including 15 mg bupivacaine with various adjuvants (30 µg clonidine, 50 mg magnesium sulphate and 3µg dexmedetomidine) compared with saline group (group S). Time of onset was earlier in groups D and C but delayed in group M. The duration of motor block in group D (250.8±18.87), group M (235.23±24.66) and group C (242.70±25.98) were significantly delayed($p<0.05$) as compared with group S (180.07±18.53). Here, the duration of motor blockade is comparable between Magnesium and Dexmedetomidine, unlike our study where duration of motor blockade was significantly more with Dexmedetomidine.

M Ozalevli et al (2005) [13] used magnesium (group M) and normal saline (group S) as adjuvants to bupivacaine plus fentanyl for subarachnoid block and they concluded that group receiving magnesium as adjuvant showed significant delay in onset of both sensory and motor block.

The delayed onset may be due to difference in pH of the solution of magnesium sulphate. Also, increase in metabolism of bupivacaine due to the activation of cytochrome P450 (CYP) by magnesium may be responsible for the delayed onset.

There was a significant difference in Mean SBP between two groups from 4mins to 20mins and at post op from 3 hours - 4hours.
There was a significant difference in Mean DBP and MAP between two groups at 8 min, 45mins, from 90 mins - 120mins and at post op 24 hours.

Shukla D et al (2011)[10] found that there was no significant difference in the mean values of heart rate and MAP in the first hour after performing the spinal anaesthesia.

Sur D et al (2017)[12] found the heart rate (HR), systolic blood pressure (SBP) and diastolic blood pressure (DBP) in all groups remains similar but comparatively lower in groups Clonidine and Dexmedetomidine groups as compared to group Magnesium group. This was similar to our study.

CONCLUSION

From our study, we conclude that Dexmedetomidine 5 µg as an adjuvant to spinal Bupivacaine is better than Magnesium Sulphate 50 mg as it provides earlier onset and prolonged duration of sensory and motor blocks without any significant hemodynamic alterations and provides good quality of post-operative analgesia.

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