

A COMPARATIVE STUDY OF DEXMEDETOMIDINE AND MAGNESIUM SULFATE AS ADJUVANTS WITH ROPIVACAINE FOR SPINAL ANAESTHESIA IN INFRAUMBILICAL SURGERIES AND POSTOPERATIVE ANALGESIA

Nirmal Kumar. M¹, R. Vimal², R. Madhusudhanan³

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Corresponding Author:
Dr. R. Vimal,
Email: yulawreegan@gmail.com

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¹Assistant Professor, Department of Anaesthesiology, Srinivasan, Medical College and Hospital, Tamilnadu, India

²Associate Professor, Department of Anaesthesiology, Srinivasan Medical College and Hospital, Tamilnadu, India

³Assistant Professor, Department of Anaesthesiology, Srinivasan, Medical College and Hospital, Tamilnadu, India

Abstract

Background: Neuraxial anaesthesia is superior to general anaesthesia, and intrathecal adjuvants prolong the duration of the block, leading to a better success rate and patient satisfaction. The study evaluated and compared the efficacy of intrathecally administered dexmedetomidine, magnesium sulphate, and ropivacaine in patients undergoing infraumbilical surgeries. **Materials and Methods:** This prospective randomized double-blinded study was conducted at Srinivasan Medical College from January 2023-June 2023 on 50 patients undergoing infra umbilical surgeries. Fifty patients were selected and randomly divided into groups, Group D and Group M, containing 25 patients each. Group D patients received 3 ml of 0.75% isobaric ropivacaine hydrochloride with 10µg of dexmedetomidine in 0.5 ml of Normal Saline. Group M patients received 3 ml of 0.75% isobaric ropivacaine hydrochloride with 75 mg of MgSO₄ in 0.5 ml of Normal Saline. **Result:** No significant difference in gender and age between groups. There was a statistically significant association in the mean onset time sensory block at the T10 level, time to achieve a maximum sensory level and mean time to regression to L1 dermatome in Group D with a p-value of <0.001. There was a significant association in time for complete motor block and the total duration of motor block, the total duration of analgesia and total doses of tramadol in 24 hours between groups (<0.001). Regarding side effects, 3 (12%) patients in group D and 3 (12%) patients in group M had hypotension, which was statistically insignificant (p>0.05). **Conclusion:** Dexmedetomidine is a better adjuvant for intrathecally administered ropivacaine in infraumbilical surgeries.

INTRODUCTION

Neuraxial anaesthesia is the preferred technique for lower abdominal and lower limb surgeries. Spinal anaesthesia is considered superior to general anaesthesia. It minimizes or avoids the problem associated with general anaesthesia, such as airway management, inhibits stress hormone release, decreases intraoperative blood loss, provides postoperative analgesia, and lowers the incidence of thromboembolic events.^[1-3] Using intrathecal adjuvants prolongs the duration of the block, leads to a better success rate and patient satisfaction, and provides adequate pain management. Several adjuvants have been studied to prolong the effect of spinal anaesthesia, such as opioids (morphine,

fentanyl, nalbuphine, buprenorphine), sodium bicarbonate, vasoconstrictors (epinephrine), N-methyl-d-aspartate antagonists (ketamine, magnesium sulfate), centrally acting α -2 adrenoceptor agonists (clonidine and dexmedetomidine), and γ -aminobutyric acid receptor agonists (midazolam). Thus, an intrathecal additive is reliable for prolonging spinal anaesthesia's duration and postoperative analgesia.^[4,5]

Dexmedetomidine is an agonist on the α 2receptor found in the peripheral and central nervous system. Stimulation of the alpha receptors in the brain and spinal cord inhibits neuronal firing, causing hypotension, bradycardia, sedation, and analgesia. The analgesic action of the intrathecal α 2-adrenoceptor agonist is depressing the release of C fiber transmitters and hyperpolarising postsynaptic

dorsal horn neurons.^[6-8] This antinociceptive effect may explain the prolongation of the sensory block. Still, prolonging the motor block may result from the binding of α_2 adrenoceptor agonists to motor neurons in the dorsal horn.

Magnesium sulfate may block calcium influx, non-competitively antagonizes N-methyl-d-aspartate receptor channels, and prevents central sensitization from peripheral nociceptive stimulation, leading to analgesia.^[9] The analgesic action of intrathecal Mg+2 is primarily based on regulating calcium influx into the cell, which is natural physiological calcium antagonism. The study evaluated and compared the efficacy of intrathecally administered dexmedetomidine, magnesium sulphate, and ropivacaine in patients undergoing infraumbilical surgeries.

MATERIALS AND METHODS

This prospective randomized double-blinded study was conducted at Srinivasan Medical College from January 2023- June 2023 on 50 patients undergoing infra umbilical surgeries. Fifty patients were selected and randomly divided into groups, Group D and Group M, containing 25 patients each. Group D patients received 3 ml of 0.75% isobaric ropivacaine hydrochloride with 10 μ g of dexmedetomidine in 0.5 ml of Normal Saline. Group M patients received 3 ml of 0.75% isobaric ropivacaine hydrochloride with 75 mg of MgSO₄ in 0.5 ml of Normal Saline. Ethical committee approval and informed consent from the patients were obtained.

Inclusion Criteria

Patients aged 20 to 65 years of either sex with ASA grades I and II undergoing infraumbilical surgeries under spinal anaesthesia were included.

Exclusion Criteria

Patients with clinically significant cardiovascular, respiratory, hepatic, renal, neurological, psychiatric, and metabolic diseases; patients with coagulation disorders, any life-threatening disease, signs of sepsis, previous injury, deformity, or previous surgery of the spine, anticipated difficulty in regional anaesthesia, patients allergic to study drugs, pregnant and lactating women and the patients who were unwilling to take part in the study were excluded.

A thorough pre-anaesthetic checkup of all patients, including all routine investigations, was done. Pain Visual Analog Scale (VAS) scores were explained to all patients. Premedication was given as a tablet of Alprazolam 0.25 mg a night before surgery, an injection of glycopyrrolate 0.2 mg, and an injection of Midazolam 0.04 mg/kg body weight by the intravenous route just before the procedure in the preop room. Preoperatively, the patient's pulse rate and noninvasive systolic and diastolic blood pressure were recorded. In the operation theatre, the intravenous line was secured with an 18-gauge intricate, and all the patients were preloaded with 10 ml/kg body weight of Ringer lactate solution over 15

to 20 min. Multipara monitors were connected, and baseline pulse rate, noninvasive systolic and diastolic blood pressure, oxygen saturation (SpO₂), and electrocardiogram (ECG) were recorded. Oxygen was routinely administered through an oxygen mask at 5 L/min.

Patients were put in the lateral decubitus position. After scrubbing, washing, and wearing a sterile gown and gloves, the back of the patient was cleaned with povidone-iodine scrub and then painted with povidone-iodine solution. The area was draped with a sterile sheet, and L3 and L4 spaces were located. Skin wheal was raised with 2% lignocaine, and then a 23-gauge spinal needle was inserted in the space with a midline approach. The drug was injected into the space after the free flow of cerebrospinal fluid.

Readings were recorded preoperatively, intra-operatively every 3 min for the first 15 min, and after that, every 15 min till the end of surgery in both groups. The time interval between the end of the administration of the drug and the onset of the sensory block to the T10 level was evaluated by eliciting a pinprick test every minute till the complete sensory block to T10. Sensory block was assessed by the loss of sensation to pinprick in the midline using a 22-gauge blunt hypodermic needle every 3 min interval until no level change occurred. The time taken to achieve the maximum level was noted. The time taken for the sensory level to recede by the L1 dermatome from the maximum sensory level was evaluated by eliciting a pinprick test. The degree of motor block was assessed every 3 min for the first 30 min by the modified Bromage scale. Duration of motor block was recorded from onset time to time when the patient was able to lift the extended leg.

After completion of the surgery, the patient was monitored postoperatively for sensory block, motor block, and analgesia (according to VAS) every 30 min for 1h and then hourly till the first rescue analgesia was given in the form injection of tramadol 50–100 mg intravenously when VAS >3. Bradycardia (heart rate <60 beats/min) was treated with intravenous atropine 0.5 mg. Hypotension (systolic blood pressure <20% of baseline value) was treated with intravenous ephedrine as required and additional Ringer's lactate solution. In the case of failed neuraxial block, the patient was given general anaesthesia, and the case was excluded from the study.

Statistical Analysis

The statistical analyses were performed using SPSS version 21. Data were presented as mean with Standard deviation for normal distribution (Age, Heart rate, blood pressure, and various time durations). Data were presented as the frequency with proportion (%) for categorical data (Type of surgery, maximum sensory level, etc.). The unpaired 't' test was used to compare the means following between dexmedetomidine and MgSO₄ group. The chi-Square test (Fisher's exact test) was used to compare the categorical variables between the groups. p<0.05

and $p < 0.0001$ were considered statistically significant.

RESULTS

Among 50 patients in Group D, 15 (60%) are male, and 10 (40%) are female. In Group M, 18 (72%) are male, and 7 (28%) are female.

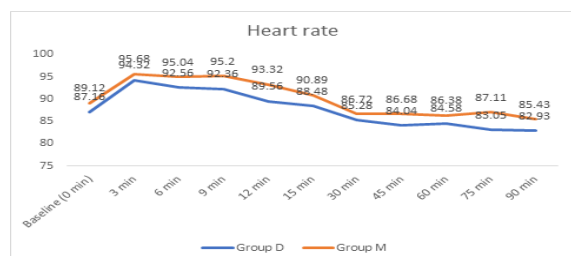


Figure 1: Heart rate between groups

The mean age in average years was 42.04 ± 10.16 (years) in group D and 42.52 ± 11.68 (years) in group M. There was statistically no significant difference in gender and age between groups [Table 1].

There was a statistically significant association in the mean onset time sensory block at the T10 level, time to achieve a maximum sensory level and mean time to regression to L1 dermatome in Group D with a p-value of < 0.001 [Table 2].

The mean time for the motor block was 8.40 ± 0.645 (minutes) in group D and 12.92 ± 1.35 (minutes) in group M. There was a statistically significant association between the two groups in time for complete motor block ($p < 0.001$). No significant

difference in the maximum Bromage scale achieved between groups. There was a statistically significant association in the total duration of motor block in group D ($p < 0.001$) [Table 3].

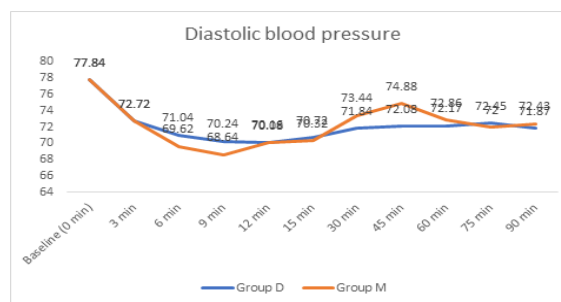


Figure 2: Diastolic blood pressure between groups

There was a statistically significant association between the total duration of analgesia and total doses of tramadol in 24 hours in group D with a p-value of < 0.001 [Table 4].

The heart rate variation between the two groups was significant at 45 and 75 min with a p-value (< 0.05) [Figure 1].

The systolic BP variation between the two groups was not statistically significant, with a p-value of > 0.05 . The diastolic BP variation between the two groups was statistically significant at 45 min with a p-value of < 0.05 [Figure 2].

Regarding side effects, 3 (12%) patients in group D and 3 (12%) patients in group M had hypotension, which was statistically insignificant ($p > 0.05$). No bradycardia and vomiting were noted between groups.

Table 1: Gender and age between groups

		Group D (N=25)	Group M (N=25)	P value
Gender	Male	15 (60)	18 (72)	0.551
	Female	10 (40)	7 (28)	
Age (years)		42.04 ± 10.16	42.52 ± 11.68	0.877

Table 2: Sensory block characteristics between groups

	Group D (N=25)	Group M (N=25)	P value
Mean onset time of sensory block in minutes to T10 level	4.440 ± 0.50	6.680 ± 0.69	< 0.001
Maximum sensory level achieved	T5	T6	0.675
Time to achieve maximum sensory level (min)	8.960 ± 0.78	12.880 ± 0.72	< 0.001
Mean time to regression to L1 dermatome (min)	286.0 ± 23.97	213.30 ± 55.31	< 0.001

Table 3: Motor block characteristics between groups

	Group D (N=25)	Group M (N=25)	P value
Mean onset time of motor block	8.40 ± 0.645	12.92 ± 1.350	0.001
Maximum Bromage scale achieved	3	3	0.786
The total duration of the motor block (mins)	223.60 ± 17.29	168.20 ± 18.30	< 0.001

Table 4: Post-operative parameters between groups

	Group D (N=25)	Group M (N=25)	P value
The total duration of analgesia (mins)	381.60 ± 30.09	223.00 ± 18.20	< 0.001
Total doses of tramadol in 24 hours	1.240 ± 0.435	2.640 ± 0.489	< 0.001

DISCUSSION

The patients in both groups did not show any statistically significant difference in age, gender, ASA classification and type of surgery. Our study

found that the onset of sensory block onset was earlier in Group D compared to Group M, which was statistically significant. This result correlated with the following studies; in the study by Mahala MK et al, adding dexmedetomidine with ropivacaine provided

early onset of sensory block at the T10 level. The mean time to achieve the T10 sensory level (onset of a sensory block) of group Dexmed was 4.85 min, while that of group magnesium sulfate was 6.52 min, which is statistically significant.^[10] Deepika Shukla et al. concluded that the mean time of onset of analgesia at T10 in group dexmedetomidine was 2.27 ± 1.09 min which was faster than group magnesium sulfate 6.46 ± 1.33 . Sunil BV et al. concluded that the time to reach sensory block at T10 in group plain bupivacaine was 4.15 ± 1.14 min, in group magnesium sulfate was 6.46 ± 1.32 min, in group dexmedetomidine was 3.27 ± 0.86 min ($p < 0.05$) which was statistically significant.^[11] Srinivasan et al. conducted a study using dexmedetomidine as an adjuvant with intrathecal ropivacaine in which the onset of sensory block at T10 level was rapid in group dexmedetomidine 5.58 ± 3.56 min when compared with plain ropivacaine group which was 8.0 ± 1.8 min ($P < 0.0001$).^[12]

Our study time to achieve a maximum sensory level in Group D was 8.960 ± 0.78 min, and in Group M was 12.880 ± 0.72 min which was statistically significant ($p < 0.001$). Similar results were observed in a study conducted by Tyagi et al. While comparing dexmedetomidine and magnesium sulfate as adjuvants with bupivacaine, the time to taken to reach a maximum sensory level in Group D (Dexmedetomidine) was 6.8 ± 2.27 min, while in Group M (Magnesium sulfate), 9.73 ± 1.8 , which was statistically significant ($p < 0.001$).^[13] Sethi S et al. also concluded that the highest level of sensory block achieved was significantly earlier in Group D (Dexmedetomidine) 9.98 ± 0.54 min as compared to Group M (Magnesium sulfate) 17.35 ± 0.52 min ($p < 0.001$).^[14,15]

In our study, the mean onset time of motor block in Group D was 8.40 ± 0.645 min, while in Group M was 12.92 ± 1.350 min with $P < 0.001$. Similar results were observed in a study conducted by Mahala MK et al. in which the mean time to onset of motor block in group A (isobaric ropivacaine with Dexmed) was 9.93 min, while in group B (isobaric ropivacaine with magnesium sulfate) was 12.11 min, which is statistically significant ($p < 0.001$).^[10] Eloraby, Rawada et al. reported that the onset time of motor block in group S (plain Bupivacaine) was 5.50 ± 0.61 min, in group DXM (Bupivacaine with Dexmedetomidine), was 3.95 ± 1.47 min and in group Mg (Bupivacaine with Magnesium sulfate) was 5.80 ± 1.47 min.^[16] Tyagi et al. reported the mean time to onset of motor block was rapid in Group D (5.92 ± 1.48 min) and delayed in Group M (8.8 ± 1.54 min) in comparison with the control Group B (6.33 ± 1.37 min).^[13]

A similar result was observed in the study conducted by Sethi S et al., where the meantime for the onset of motor block in Group Dexmedetomidine was 3.73 ± 0.43 min and in Group Magnesium sulphate was 7.72 ± 0.48 min where there was the faster onset of the motor block by adding dexmedetomidine with hyperbaric bupivacaine.¹⁵ In our study, the

maximum Bromage scale achieved was 3 in both groups, which was statistically insignificant. Similar results were observed in studies conducted by Deepika et al, Mahala MK et al, Sunil BV et al, and Vani VK et al.^[4,10,11,17]

In our study, the total duration of the motor block was 223.60 ± 17.29 min in Group D and 168.20 ± 18.30 min in Group M, with a significant difference ($p < 0.001$). Mahala MK et al. and Vani VK et al. also reported a significant difference in the mean duration of the motor block between groups.^[10,17] Similar results were observed in the study conducted by Shukla D et al., that the regression time of the motor block was prolonged in the group Dexmed (331 ± 35 min).^[4] A study by Sunil BV et al. showed that adding dexmedetomidine with hyperbaric bupivacaine prolonged the duration of motor blockade.^[11]

In our study, the total duration of analgesia in Group D was 381.60 ± 30.09 min and in Group M was 223.00 ± 18.20 min with a p-value of < 0.001 . Similar results by Mahala MK et al. showed that adding dexmedetomidine with isobaric ropivacaine prolonged the duration of analgesia, which was statistically significant ($p < 0.001$).^[10] Vani VK et al. observed that the mean duration of analgesia was 204.7 ± 20.61 minutes in Group R (plain ropivacaine) and 430.9 ± 33.08 minutes in Group D (ropivacaine with dexmedetomidine). There was a statistically significant difference between the two groups in the mean duration of analgesia ($P < 0.05$).^[17] Sethi S et al. also concluded that adding dexmedetomidine with hyperbaric bupivacaine prolonged the total duration of analgesia, which was statistically significant.^[15]

In our study, the total number of doses of tramadol required in Group D was 1.240 ± 0.435 , and in Group M was 2.640 ± 0.489 with a p-value of < 0.001 . The total number of rescue analgesics required was less in Group D. Similar results were observed in the studies conducted by Srinivasan et al. and Eloraby, Rawadaa et al, where there were lesser requirements for rescue analgesics in 24 hrs while using dexmedetomidine as an adjuvant.^[12,16]

There was not much difference between the two groups regarding heart rate, systolic BP and diastolic BP. But, the two groups' heart rates and diastolic BP variation were significant at 45 min and 75 min, which is comparable. Significant hypotension and bradycardia were not observed, and hemodynamic stability was maintained in both groups, which correlated with the studies conducted by Shukla D et al. and Shah A et al.^[4,18]

In our study, although hypotension was observed in 12% of the patients in both groups, it was clinically and statistically insignificant ($p > 0.05$). There were no reports of bradycardia and vomiting in both groups. Similar results were observed in studies conducted by Raviprakash Tyagi et al. and Eloraby, Rawadaa et al., as they concluded that adding dexmedetomidine did not produce any significant side effects.^[13,16]

CONCLUSION

The study concluded dexmedetomidine seems to be a better adjuvant to intrathecally administered ropivacaine in infraumbilical surgeries when compared with magnesium sulfate about the early onset of sensory and motor block, a maximum level of sensory block achieved, faster onset of the highest level of the sensory block with better hemodynamic stability and also prolonging the total duration of analgesia with minimal side effects.

Limitations of the study

Only ASA 1 and 2 patients were included in the study. Since blood loss varies with different types of surgeries, comparisons of hemodynamic changes were less reliable, as hemodynamic parameters can vary with blood loss.

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