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A Comparative Study Between Epidural Ropivacaine With Magnesium Sulfate And Ropivacaine For Lower Limb Surgeries

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Abstract

Introduction. Epidural analgesia is one of the entities practised to provide post-operative pain relief. Central neuraxial blockade with a "combination therapy" of local anesthetics and non-opiates yields a near total pain relief while diminishing or avoiding side effects from each component alone. This newer dimension in pain management can be called as "balanced epidural analgesia". It offers the most complete form of analgesia. Ropivacaine is a new long acting amide local anesthetic. Though it has similar structure, pharmacology and pharmacokinetics as that of bupivacaine it has lower potential for toxic effect. On milligram basis ropivacaine shows greater selectivity for sensory blockade and a lower systemic toxicity as compared to bupivacaine.It is worth studying the role of magnesium in providing perioperative analgesia because it is a relatively harmless molecule, inexpensive and its biological basis for potential antinociceptive action is promising. Although there have been many studies about magnesium, there is little clinical experience on its intrathecal and epidural application. The beneficial effects of magnesium in literature were not unequivocal.

Aim Of The Study: 1. To compare the effects of epidural Ropivacaine and Ropivacaine with Magnesium sulphate for lower limb surgeries. 2. To study the effect of addition of Magnesium sulphate on the time of onset and duration of action of Ropivacaine. 3. To study the other effects of Epidural Magnesium sulphate.

Materials And Methods: This Randomized Prospective comparative study was done Department of Anesthesiology, Department Of Anesthesiology & Critical Care, Government Medical College, Kallakurchi from January to April 2022.. Inclusion Criteria: Patients between (16-60yrs) of either gender belonging to American Society of Anesthesiologists status I and II with + 20% of ideal body weight and height undergoing lower limb surgeries.: After obtaining institutional ethical committee approval and written informed consent, 60 patients were randomly selected and allocated into two groups. Group R (n=30): 0.75% Ropivacaine (16ml) + 0.9% saline (1ml) Group RM (n=30): 0.75% Ropivacaine (16ml) + Magnesium sulfate (1ml) 50mg. After establishing an intravenous access, an infusion of ringer's lactate (20 ml/kg) comprised preloading. Standard monitoring was instituted after shifting the patient on the operating table. Baseline measurements of pulse rate, blood pressure and SpO2 were recorded. The following parameters were monitored Heart Rate, Noninvasive Arterial Blood Pressure, SPO2were recorded every 5 min for the first 20 minutes, every 10 minutes for the next one hour and every hour for the next 6 hours. Sensory block was assessed bilaterally, by analgesia to pinprick with a short bevelled hypodermic needle, in mid-clavicular line. The time of onset of sensory analgesia was defined as the time taken from the administration of local anesthetic to the absence of pin-prick pain at T10 level.

Results : The preoperative pulse rate and mean arterial pressure of both groups were compared. The mean pulse rate of R group was 84.9 +/- 9.9 and that of RM group was 89.4 +/- 8.5. The difference between the two groups was 4.6 and was not statistically significant (p>0.05). Similarly the mean MAP of R group was 80.5 and RM group was 77.1 +/- 7.8. The difference between the two groups was 3.4 and was not statistically significant (p>0.05). pulse rate of groups intraoperatively at different time intervals of 5, 15, 30, 45, 60 minutes and end of surgery and they were not statistically significant (p>0.05). the time of onset of sensory and motor block of the two groups R and RM. Mean time of onset of sensory of R group was 16.9+/-3.8min. And the same of RM group was 14.6+/-3.6min with difference of mean 2.3 minutes. The result was statistically significant (p<0.05). Similarly the time of onset of motor block of R group and RM group were 18.6+/-3.8min and 16.5+/-2.6minrespectively. The difference of mean was 2.1 minutes which was statistically significant (p<0.05). the level of initial sensory block and 2 segment regression time of the two groups R & RM. Mean level of initial block of R was T9.80 and that of RM was T9.95, with difference of mean 0.60; which was statistically not significant (p>0.05).Time to 2 segment regression was 209.7 and 206.7 for R and RM group respectively. Difference of mean was 20, which was not statistically significant (p>0.05).

Conclusion: Epidural magnesium 50 mg with 0.75% ropivacaine for lower limb surgeries shortens the time of onset of sensory and motor blockade with stable hemodynamics. There is no effect in prolonging duration of analgesia. No significant adverse effects were noted with epidural magnesium .Co-administration of magnesium as an adjuvant to epidural ropivacaine reduces the latency of central neuraxial blockade in adults. The lack of any side/adverse effects of epidural magnesium would promote its extensive use in the field of regional anesthesia over the years to come.

Keywords: Epidural, ropivacaine, magnesium sulfate, sensory, and motor block

Introduction

Pain is an unpleasant subjective sensation which can only be experienced. It is a fundamental biological phenomenon. The aim of anesthesiology as a science is the removal of pain temporarily, started initially with pain relief for surgeries and now extends to post-operative pain relief, relief of chronic pain and cancer pain.The International Association for the study of pain, defines pain as an “unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage”.[1] A revolution in the management of acute postoperative pain has occurred in the past few years. Anesthesiologists are continually in the vanguard of clinical and research advances in acute postoperative pain management.An ideal technique should provide effective pain relief with minimal side effects and reasonable level of patient satisfaction in the post-operative period. Epidural analgesia is one of the entities practised to provide post-operative pain relief.Central neuraxial blockade witha “combination therapy” of local anesthetics and non-opiates yields a near total pain relief while diminishing or avoiding side effects from each component alone. This newer dimension in pain management can be called as “balanced epidural analgesia”. It offers the most complete form of analgesia.Ropivacaine is a new long acting amide local anesthetic. Though it has similar structure, pharmacology and pharmacokinetics as that of bupivacaine it has lower potential for toxic effect. On milligram basis ropivacaine shows greater selectivity for sensory blockade and a lower systemic toxicity as compared to bupivacaine.[2] It is worth studying the role of magnesium in providing perioperative analgesia because it is a relatively harmless molecule, inexpensive and its biological basis for potential antinociceptive action is promising.[3] Although there have been many studies about magnesium, there is little clinical experience on its intrathecal and epidural application. [4]The beneficial effects of magnesium in literature were not unequivocal. The study was undertaken in the light of these data so as to evaluate the effect of magnesium as an adjuvant to epidural ropivacaine on the time of onset sensory and motor block, duration of analgesia and associated adverse effects.[5]

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Materials And Methods: This Randomized Prospective comparative study was done Department of Anesthesiology, Department Of Anesthesiology & Critical Care, Government Medical College, Kallakurchi from January to April 2022.. Inclusion Criteria: Patients between (16-60yrs) of either gender belonging to American Society of Anesthesiologists status I and II with + 20% of ideal body weight and height undergoing lower limb surgeries.: After obtaining institutional ethical committee approval and written informed consent, 60 patients were randomly selected and allocated into two groups. Group R (n=30): 0.75% Ropivacaine (16ml) + 0.9% saline (1ml) Group RM (n=30): 0.75% Ropivacaine (16ml) + Magnesium sulfate (1ml) 50mg. After establishing an intravenous access, an infusion of ringer's lactate (20 ml/kg) comprised preloading. Standard monitoring was instituted after shifting the patient on the operating table. Baseline measurements of pulse rate, blood pressure and SpO2 were recorded. The following parameters were monitored Heart Rate, Noninvasive Arterial Blood Pressure, SPO2were recorded every 5 min for the first 20 minutes, every 10 minutes for the next one hour and every hour for the next 6 hours. Sensory block was assessed bilaterally, by analgesia to pinprick with a short bevelled hypodermic needle, in mid-clavicular line. The time of onset of sensory analgesia was defined as the time taken from the administration of local anesthetic to the absence of pin-prick pain at T10 level.

Exclusion Criteria:

1. Hepatic, renal or cardiovascular dysfunction.
2. Patients in whom central neuraxial block is contraindicated.
3. History of hypersensitivity/ adverse reaction to any of the study medication.
4. History of chronic analgesic use.
5. Chronic pain syndrome.
6. Cases where communication difficulties prevent reliable assessment.
7. Psychological disorders.

Statistical Analysis

Statistical analysis and interpretations were performed using PASW (Predictive Analysis Software 18). Numerical variables were presented as Mean and Standard deviation and categorical variables were presented as frequency (%). All continuous variables were analyzed using "student's independent t test". Discontinuous variable gender was matched by "Chi-square test". The onset of sensory and motor block was analyzed by Kaplan-Meyer survival function.

Results

Table 1.Comparison Of Age Group Between Both Groups

Age group (years)	Group R		Group RM	
	Frequency	Percentage	Frequency	Percentage
20-29	8	26.7	13	43.3
30-39	4	13.3	6	20.0
40-49	5	16.7	7	23.3
50-59	9	30.0	3	10.0
60-69	4	13.3	1	3.4

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Total	30	100.0	30	100.0
Mean +/- SD	41.8 +/- 13.9		35.6 +/- 12.2	
Significance	p>0.05			

TABLE :1The mean age of R group was 41.8 +/- 13.9 years and the RM group was 35.6 +/- 12.2 years. The difference of mean age between the two groups was 6.2 years and was not statistically significant (p>0.05).

Table 2. Comparison Of R And RM Group In Respect To Their Preoperative Pulse Rate And Mean Arterial Pressure

Variable	Group R		Group RM		Difference of mean	't'	Significance
	Mean	S.D	Mean	S.D			
Mean PR	84.9	9.9	89.4	8.5	4.6	1.908	p>0.05
Mean MAP	80.5	7.4	77.1	7.8	3.4	1.693	p>0.05

TABLE :2 The preoperative pulse rate and mean arterial pressure of both groups were compared. The mean pulse rate of R group was 84.9 +/- 9.9 and that of RM group was 89.4 +/- 8.5. The difference between the two groups was 4.6 and was not statistically significant (p>0.05). Similarly the mean MAP of R group was 80.5 and RM group was 77.1 +/- 7.8. The difference between the two groups was 3.4 and was not statistically significant (p>0.05).

Table 3. Comparison Of Duration Of Surgery In Both Groups

Variable	Group R		Group RM		Difference of mean	't'	Significance
	Mean	S.D	Mean	S.D			
Duration of surgery	2.9	0.56	2.86	0.41	0.04	0.261	p>0.05

TABLE :3 The duration of surgery between the two groups were compared. The mean duration of R group was 2.90 +/- 0.56 hours and the RM group was 2.86 +/- 0.41 hours. The difference between the two groups was 0.4 and it was not statistically significant (p>0.05).

Table 4. Comparison Of Type Of Surgery In Both Groups

Type of surgery	**Group R**	**Group RM**

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Trendelenberg	5	7
DHS fixation	5	2
ORIF- Femur	5	5
IL nailing- Femur/Tibia	8	7
Implant exit - Tibia	3	2
Others	4	7

The type of surgeries between the two groups were compared, but was not statistically significant (p>0.05).

Table 5 Comparison Of Intra-Operative Pulse Rate Of Both Groups

Time Interval	**Group R**		**Group RM**		't'	Significance
	Mean	S.D	Mean	S.D		
5 min	93.1	13.0	93.2	7.5	0.660	p>0.05
15 min	91.5	11.5	90.7	10.3	0.756	p>0.05
30 min	87.4	9.4	91.1	10.6	1.754	p>0.05
45 min	86.4	9.6	81.2	10.6	0.653	p>0.05
60 min	79.4	10.7	79.4	11.0	1.544	p>0.05
EOS	81.3	13.8	79.9	12.0	1.048	p>0.05

TABLE :5 Above table compares the pulse rate of groups intraoperatively at different time intervals of 5, 15, 30, 45, 60 minutes and end of surgery and they were not statistically significant (p>0.05).

Table 6. Comparison Of Intra-Operative MAP Of Both Groups

Time Interval	**Group R**		**Group RM**		't'	Significance
	Mean	S.D	Mean	S.D		
5 min	79.1	9.5	74.6	9.9	0.741	p>0.05
15 min	75.9	9.1	70.5	9.4	1.733	p>0.05

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30 min	76.5	7.8	70.2	9.9	0.135	p>0.05
45 min	72.6	7.0	70.9	8.1	0.035	p>0.05
60 min	74	7.6	74	7.6	0.432	p>0.05
EOS	75	6.9	76.8	7.7	0.683	p>0.05

TABLE :6 Above table compares the mean arterial pressure of groups intraoperatively at different time intervals of 5, 15, 30, 45, 60 minutes and end of surgery and they were not statistically significant (p>0.05).

Table 7. Comparison Of Time Of Onset Of Sensory And Motor Block In Both Groups

	Group R		Group RM		Difference of mean	't'	Significance
	Mean	S.D	Mean	S.D			
Sensory	16.9	3.8	14.6	3.6	2.3	2.494	p<0.05
Motor	18.6	3.8	16.5	2.6	2.1	2.498	P<0.05

The above table shows the time of onset of sensory and motor block of the two groups R and RM. Mean time of onset of sensory of R group was 16.9+/-3.8min. And the same of RM group was 14.6+/-3.6min with difference of mean 2.3 minutes. The result was statistically significant (p<0.05). Similarly the time of onset of motor block of R group and RM group were 18.6+/-3.8min and 16.5+/- 2.6minrespectively. The difference of mean was 2.1 minutes which was statistically significant (p<0.05).

Figure 1.Kaplan meir survival curve for time of onset of Sensory block in both

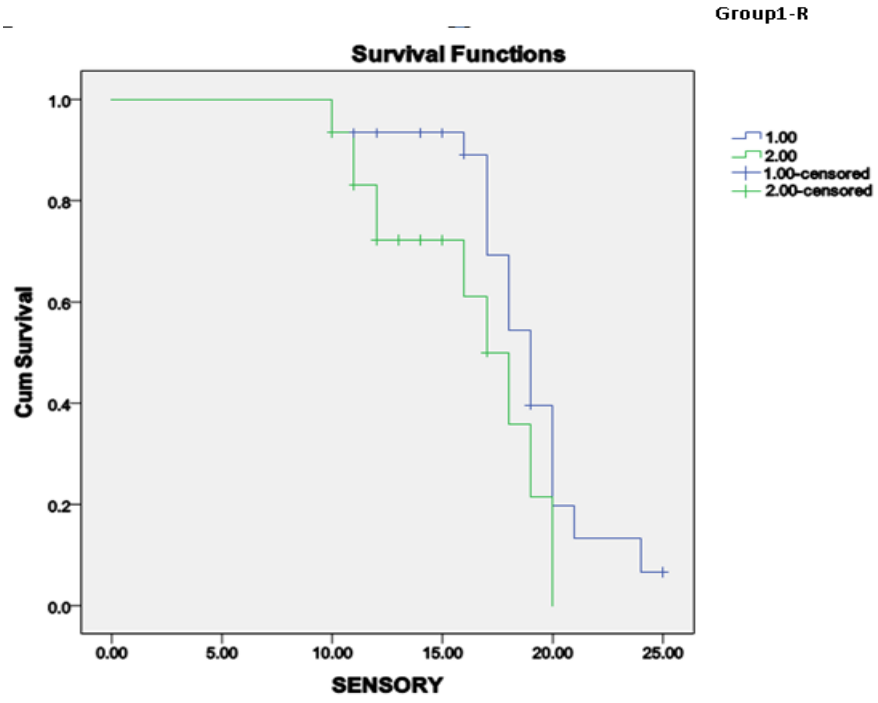

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Table 8. Comparison of duration of analgesia between both groups

Variable	Group R		Group RM		Difference of mean	't'	Significance
	Mean	S.D	Mean	S.D			
Duration of analgesia	3.8	0.60	4.0	0.90	0.20	1.181	p>0.05

TABLE :8 The above Table shows mean duration of analgesia of R group 3.8 +/- 0.6 hours and that of RM group 4 +/- 0.9 hours. The difference of mean was 0.2 hours which was not statistically significant (p>0.05).

TABLE :9 Two segment regression Time and initial level of block

Variable	Group R		Group RM		Difference of Mean	Significance
	Mean	SD	Mean	SD		
Initial level of sensory block	T9.80	0.77	T9.95	0.83	0.60	p>0.05
Time to 2 segment Regression (min)	209.7	60	206.7	40	20	p>0.05

The above table show the level of initial sensory block and 2 segment regression time of the two groups R & RM. Mean level of initial block of R was T9.80 and that of RM was T9.95, with difference of mean 0.60; which was statistically not significant (p>0.05).Time to 2 segment regression was 209.7 and 206.7 for R and RM group respectively. Difference of mean was 20, which was not statistically significant (p>0.05).

Table 10. Postoperative complications

	Group R	**Group RM**
Hypotension	3	2
Bradycardia	Nil	Nil

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Nausea & vomiting	Nil	Nil
Shivering	Nil	Nil
Respiratory depression	Nil	Nil

TABLE :10 No episode of clinically significant postoperative complication such as bradycardia, nausea and vomiting, shivering or respiratory depression were noted.

Discussion

Regional anesthesia is a safe and inexpensive technique with the advantage of providing surgical anesthesia and prolonged postoperative pain relief. Effective treatment of post-operative pain attenuates autonomic, somatic and endocrine responses. Research continues concerning different techniques and drugs that could prolong the duration of regional anesthesia and postoperative pain relief. [6]Recently the importance of magnesium in anesthetic practice has been highlighted. Magnesium is known to be an NMDA receptor antagonist and it is assumed that NMDA receptors play an important role in the development of central sensitization after noxious peripheral stimulation. Its antinociceptive effects in animal and human models of pain have been proved. It is worthwhile to further study the role of supplemental magnesium in providing perioperative analgesia because this is a harmless molecule, inexpensive and the biological basis for its potential antinociceptive effect is promising.[7]There are studies concerning different routes of magnesium administration such as intravenous or intrathecally that improve anesthetic and analgesic quality. To my knowledge this is the first clinical study that has examined the effect of Magnesium as an adjunct to epidural ropivacaine. effect of addition of magnesiumVsulphate 50 mg as an adjunct to 19 ml of 0.5% bupivacaine epidurally for patients undergoing lower abdominal and lower limb surgeries and found thatVthe time to achieve T_6 block was 11.80+/-3.21 minutes in magnesium adjuvant group and 18.73+/ -2.79 minutes in control group. In the present study the mean time to achieve T_{10} block was 14.6+/-3.6 minutes in the RM group and that of R group was 16.9+/-3.8 minutes. They also made an observation that in the magnesium group no patients suffered from shivering during the study, whereas shivering occurred in four patients belonging to control group. In the present study no patients had suffered from shivering in the RM group.[8] effect of epidural ropivacaine and ropivacaine clonidine combination for elective cesarean section.20 ml of 0.75% ropivacaine was the control group, compared with ropivacaine and clonidine 75 micrograms as adjunct . The onset time of analgesia, sensory and motor block levels were compared and they concluded that the mean time of onset of sensory block at T_6 level and complete motor block was 15.12 +/- 4.36 minutes and 21.70 +/- 4.20 minutes respectively. In the present study the mean time of onset of T_{10} and complete motor block was 14 .6+/-3.6minutes and 16.9+/-3.8 minutes respectively. The early onset in the control group of their study can be due to the effect of pregnancy which alters the onset and spread of epidural blockade [9] the effect of addition of 50 mgs of magnesium sulphate as an adjunct to caudal ropivacaine 0.25% compared with ropivacaine alone on post-operative analgesic requirements, analgesic duration and adverse effects. They concluded that the addition of magnesium sulphate as an adjuvant to caudal ropivacaine has no beneficial effect. [10]VIn the present study the duration of analgesia was 3.8+/-0.6 hours and 4+/-0.9 hours in the R group and RM group respectively which was not statistically significant.[11] studied the effect of co-administering 50mg of magnesium sulphate epidurally as an initial bolus dose followed by a continuous infusion of 100 mg per day with fentanyl for patients undergoing hip surgery. Although the time to first analgesic requirement was slightly longer when magnesium was co- administered, there was no statistical difference between the two groups (37.1 vs 51.6 min). No difference between the qualities of sensory or motor block was observed. [12]The cumulative

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fentanyl consumption in 24 hrs was 437 micrograms in control group when compared to 328 micrograms in magnesium group. In the present study the duration of analgesia was slightly longer in RM group as compared to R group but this was not statistically significant.[13,14] One limitation of the study was that serum magnesium and CSF magnesium concentration was not measured. However it has been studied that most of the total body magnesium (99%) is intracellular and estimation of plasma magnesium does not represent magnesium content of the body tissues. There is lack of correlation between plasma magnesium concentration and total body magnesium content[15]

Conclusion: : Epidural magnesium 50 mg with 0.75% ropivacaine for lower limb surgeries shortens the time of onset of sensory and motor blockade with stable hemodynamics. There is no effect in prolonging duration of analgesia. No significant adverse effects were noted with epidural magnesium .Co-administration of magnesium as an adjuvant to epidural ropivacaine reduces the latency of central neuraxial blockade in adults. The lack of any side/adverse effects of epidural magnesium would promote its extensive use in the field of regional anesthesia over the years to come.

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