



Comparative Analysis of Ropivacaine and Fenatanyl with Magensium Sulfate and Without for Labour Analgesia

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KEYWORDS

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MHR,
labour analgesia.

ABSTRACT:

Multiple studies have demonstrated that administering magnesium via intravenous or intrathecal methods improves the anesthetic and analgesic qualities of the treatment. In addition, the start, duration of effect, and breakthrough pain of epidurally injected bupivacaine-fentanyl for labour analgesia were all improved by the addition of a single dose of Mg. So, we thought it would be a good idea to compare the efficacy of Mg₂SO₄, RF, for LP treatment to that of R and F alone in this study. There were a total of 60 patients in our study, and they were split evenly between two groups. Thirty patients in Group RFM received inj.R + F + Mg₂SO₄, whereas thirty patients in Group RF received inj.R + F + NS. Additionally, heart rate, blood pressure, and pain intensity (VAS score) were recorded just before the surgery began. In our study, we found that after applying the GLM to repeated variables, there were no significant variations in MAP between the two groups ($p = 0.502$), and no significant variations in FHR& MHR were observed between the two groups as $p = 0.808$ & $p=0.275$ respectively . Therefore, we conclude that Mg₂SO₄ as an adjuvant is safe for both the mother and the neonate.

INTRODUCTION

Studies have indicated that labour is widely recognized as one of the most distressing experiences in a woman's life. Studies also concluded that, "epidural analgesia (EA) utilizing local anesthetics (LA) is widely regarded as the optimal approach for achieving pain-free labour(PFL) due to its exceptional efficacy in pain management, ability to minimize maternal stress responses, heightened levels of satisfaction reported by participants, and its capacity to provide anesthesia.^{1,2} Various past studies have proven that Mg has postsynaptic N-methyl D-aspartate (NMDA) calcium channel blocker properties and has been used successfully to potentiate opioid analgesia and treat neuropathic pain in animals.³ Furthermore, researchers have also determined that the use of Mg₂SO₄ during the perioperative period has been demonstrated to be linked with reduced analgesic needs

in the postoperative period.⁴ Additional research has determined that the inclusion of Mg in spinal bupivacaine-F anesthesia enhances the duration of spinal A during labour while exhibiting no adverse effects.⁵ Hence, in our study, we have decided to evaluate and compare the effects of Mg₂SO₄, RF, to those of R and F alone for relief from LP.

AIM

To compare the effects of a magnesium sulphate(Mg₂SO₄) with ropivacaine(R) and fentanyl(F) to those of R and F alone for the relief from labour pain (LP).

INCLUSION CRITERIA

1. Patients with ASA physical status I &II.



2. Patients with primigravida with singleton pregnancy aged 20–35 years at gestational maturity of 37–41 weeks with cephalic presentation and spontaneous onset of labour.
3. Active phase of labour with cervical dilatation 3–4 cm & 50% cervical effacement.
4. No identifiable medical or obstetric complication
5. Admission on stress test reactive.

EXCLUSION CRITERIA

Patients with high risk cases like antepartum hemorrhage, preeclampsia, diabetes complicating pregnancy, polyhydramnios, oligohydramnios, cephalopelvic disproportion, malpresentation, and prelabour rupture of membranes.

MATERIAL & METHOD

We have conducted a randomized double-blind comparative study over 18 months, starting in December 2017, with a total of 60 patients in the department of gynecology at KIMS, Karad, after receiving informed written consent. In group RFM, 30 patients received inj. R (0.125%) 9ml + F (25mcg) 0.5ml + Mg2SO4 (50mg) 0.5ml as loading dose (10ml in total), whereas in group RF, 30 patients received inj. R (0.125%) 9ml + F (25mcg) 0.5ml + NS 0.5ml (total 10ml). Furthermore, HR, BP, PI(VAS Score) was noted prior to procedure.

METHOD

There were prerequisites, including a cervix that was 3–4 cm dilated, >50% effaced, and a head position of 0 or -1. Using a 20-gauge canula, we obtained an intravenous reading while gradually infusing a 20-drop/min Ringer's lactate solution. Monitoring for all the patients were done which includes HR, BP, oxygen saturation & ECG before, during, and after the surgery, and supplemental oxygen at 4 L/min was administered. Each group's medication was drawn up in a 10-ml syringe. After painting and draping the patient, subcutaneous infiltration with 2–3 mL of 2% lignocaine at L2-L3 or L3-L4 was performed using all appropriate aseptic measures. Next, an 18-gauge Touhy needle was used to locate the epidural space by using the loss of resistance to air technique. A multi-orifice epidural catheter was then inserted 4 cm into the epidural space in a cephalic direction and aspirated for detection of CSF or After the catheter was fixed, 3 mL of 2% lignocaine with adrenaline as a test dose was injected. Further both the groups received their respective doses. Maternal pain relief was assessed with the help of a visual analog scale and motor blockade by Bromage. Epidural topup was given when VAS ≥ 3 . After which, the duration of the active phase of the 1st stage of labor and the 2nd stage of labor was noted. Neonatal assessment was done with Apgar scores at 1 minute and 5 minutes.

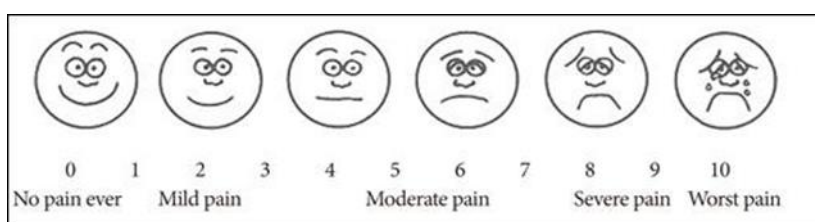


Figure 1: Visual analogue scale (VAS)



STATISTICAL ANALYSIS

SPSS version 2.0 was used to analyze the data. The Fischer exact test, independent sample t-test, and chi-

square test were used. A change in HR and MAP was detected using repeated measures analysis of variance. A P value ≤ 0.05 was considered to be significant.

RESULT

	Minimum	Maximum	Mean	Std. Deviation
Age (Years)	20	34	25.17	3.83
Weight (kg)	49	83	65.70	5.87
Height (cm)	150	174	161.45	4.59
Gestationalage (weeks)	38	41	38.90	0.73

Table 1: Different means of study variables.

In our study, we found that the minimum age observed was 20 years, and the maximum was 34 years. The mean age observed was 25.17 ± 3.83 years. The minimum

weight of the patients observed in our study was 49 kg, and the maximum was 83 kg. The mean weight observed was 65.70 ± 5.87 kg (Table 1).

	Group RFM, RF	N	Mean	Std. Deviation	p Value
Age	RFM	30	25.10	3.670	0.89
	RF	30	25.23	4.049	
Wt (kg)	RFM	30	66.43	6.306	0.34
	RF	30	64.97	5.404	
Ht (cm)	RFM	30	162.27	4.989	0.17
	RF	30	160.63	4.072	
Gestationalage (weeks)	RFM	30	38.93	.785	0.73
	RF	30	38.87	.681	

Table 2: Comparison of variables between groups

In our study, we found that the mean age of group RFM patients was 25.10 ± 3.67 years, while that of group RF patients was 25.23 ± 4.049 years. The mean weight of patients in group RFM was 66.43 ± 6.306 kg, while that of group RF patients was 64.97 ± 5.404 kg. The mean height of patients in group RFM was 162.27 ± 4.989 cm, while that of group RF patients was 160.63 ± 4.072 cm.

The gestational age observed in our study was 38.93 ± 0.785 weeks in group RFM, while it was 38.87 ± 0.681 weeks in group RF. Using an independent sample t-test, we found that age, weight, height, and gestational age were comparable in both groups. No significant difference was seen between these variables ($p > 0.05$) (Table 2).

	Group RFM, RF	N	Mean	Std. Deviation	P Value
Cervical dilatation(cm)	RFM	30	3.90	0.31	0.46
	RF	30	3.83	0.38	
Duration of 1st stage labour (min)	RFM	30	358.50	26.43	0.20
	RF	30	367.00	23.91	



Duration of 2nd stage labour (min)	RFM	30	30.93	6.51	0.002*
	RF	30	36.03	5.76	

Table 3: Cervical Dilatation (CD) & duration of labour

In our study, we found that the MCD in group RFM was 3.9 ± 0.31 cm, while in group RF it was 3.83 ± 0.38 cm. In group RFM, the mean duration of the first stage of labour was 358.50 ± 26.43 min; in group RF, it was 367.00 ± 23.91 min. Using an independent sample t-test, we found that there was no significant difference

between cervical dilatation and the 1st stage of labour between the two groups ($p = 0.46$ and 0.20 , respectively). The duration of the 2nd stage of labour was 30.93 ± 6.51 min in group RFM and 36.03 ± 5.76 min in group RF; this difference was statistically significant ($p = 0.002$) (Table 3).

	Group RFM (n=30)	Group RF (n=30)	p value
Patients with VAS ≤ 3 at 5 min (n, %)	0	0	0.0003
Patients with VAS ≤ 3 at 10 min (n, %)	26 (86.67%)	3 (10%)	
Patients with VAS ≤ 3 at 30 min (n, %)	30 (100%)	30 (100%)	

Table 4: VAS score at different mins

In our study, we found that using the Fischer exact test, when we compared the number of patients having VAS scores less than or equal to 3 in both groups, there were no patients with $VAS \leq 3$ at 5 minutes, 26 patients (86.67%) in group RFM having $VAS \leq 3$ at 10 minutes,

and only 3 patients (10%) in group RF. All 30 patients in each group had attained a VAS of ≤ 3 at 30 min. This showed that the group RFM patients had better analgesia at 10 min as compared to group RF, and this was significant ($p = 0.0003$) (Table 4).

Number of top-ups	Group RFM	Group RF	Total
1 top up	25 (83.33%)	0 (0%)	25 (41.67%)
2 top ups	5 (16.67%)	23 (76.67%)	28 (46.67%)
3 top ups	0 (0%)	7 (23.33%)	7 (11.66%)
Total	30 (100%)	30 (100%)	60 (100%)

Table 5: Comparison

In our study, we found that among all the patients, 25 patients (83.33%) from group RFM required only 1 top-up, while only 5 of them (16.67%) required 2 top-ups. 23 patients (76.67%) from group RF required 2 top-ups, while the rest, 7 patients (23.33%), required 3 top-ups. By applying the chi square test, we found that there was

a significant difference between the two groups in the number of top-ups required, with group RFM requiring a smaller number of top-ups as compared to group RF patients ($p < 0.001$) (Table 5).



	Group RFM,RF	N	Mean	Std. Deviation	p Value
Maternal satisfaction score	Group RFM	30	8.17	0.59	0.007
	Group RF	30	7.70	0.70	

Table 6: Maternal satisfaction score(MSS)

In our study, we found that using an independent sample t-test, there was a significant difference between the maternal satisfaction scores between the two groups (p

= 0.007). The score observed in group RFM (8.17 ± 0.59) was higher than that of group RF (7.70 ± 0.7) (Table 6).

Maternal satisfaction score	Group RFM	Group RF	Total	p value
Excellent	8 (26.67%)	2 (6.67%)	10 (16.67%)	0.079
Satisfactory	22 (73.33%)	28 (93.33%)	50 (83.33%)	
Total	30 (100%)	30 (100%)	60 (100%)	

Table 7: MSS between 2 group

In our study, we found that using the Fischer exact test, the proportion of patients having excellent analgesia (scores 9, 10) and satisfactory analgesia (scores 6, 7, 8) scores between the two groups had no significant difference (p = 0.079). 8 patients (26.67%) from the

group RFM and 2 patients (6.67%) from the group RF had excellent scores, while 22 patients (73.33%) from the group RFM and 28 patients (93.33%) from the group RF had SS (Table 7).

Side effects	Group RFM	Group RF	Total
Nausea	1	1	2
Vomiting	0	0	0
Pruritus	0	0	0
Bradycardia	0	0	0
Hypotension	2	4	6
Respiratory depression	0	0	0

Table 8: Side Effect

In our study, we found that 1 patient in each group complained of nausea, while 2 patients in Group RFM and 4 patients in Group RF had hypotension. There was

no incidence of side effects such as vomiting, pruritus, bradycardia, or respiratory depression (Table 8).

	Hypotension	No Hypotension	Total	p value
Group RFM	2	28	30	0.67



Group RF	4	26	30
Total	6	54	60

Table 9: Frequency of hypotension in group

In our study, we found that, using the Fisher exact test, there was no significant association between the presence of hypotension and the two groups ($p = 0.67$) (Table 9).

	Group RFM, RF	N	Mean	Std. Deviation	P Value
Umbilical ArterypH	RFM	30	7.41	0.025	1
	RF	30	7.41	0.032	
PO2	RFM	30	104.87	3.137	0.16
	RF	30	105.87	2.161	
PCO2	RFM	30	38.50	1.432	0.93
	RF	30	38.53	1.548	
Base excess	RFM	30	-0.73	1.337	1
	RF	30	-0.73	1.574	
Lactate	RFM	30	2.083	0.158	0.123
	RF	30	2.137	0.100	
Birthweight	RFM	30	3.08	0.18	0.333
	RF	30	3.02	0.22	
APGAR score at 1min	RFM	30	7.77	0.430	0.27
	RF	30	7.63	0.490	
APGAR score at 5min	RFM	30	8.87	0.346	0.069
	RF	30	8.90	0.305	

Table 10: Neonatal data

In our study, we found that, using an independent sample t-test, there was no statistically significant difference seen in neonatal parameters (all $p > 0.05$). The mean umbilical artery pH in group RFM patients was 7.41 ± 0.025 , and in group RF it was 7.41 ± 0.032 . The mean lactate in group RFM was 2.083 ± 0.158 and in group RF

was 2.137 ± 0.100 . The mean birthweight of neonates in group RFM was 3.08 ± 0.18 kg, and in group RF it was 3.02 ± 0.22 kg. Apgar scores at 1 minute and 5 minutes in both groups were comparable and statistically insignificant (Table 10).

Descriptive Statistics				
	Group RFM, RF	Mean	Std. Deviation	N
HR0	Group RFM	74.87	6.532	30
	Group RF	77.47	3.963	30
	Total	76.17	5.515	60
HR 5	Group RFM	74.67	6.042	30
	Group RF	74.10	13.231	30
	Total	74.38	10.202	60
	Group RFM	74.00	6.080	30



HR 10	Group RF	75.87	3.360	30
	Total	74.93	4.960	60
HR 15	Group RFM	73.73	5.913	30
	Group RF	75.93	3.216	30
	Total	74.83	4.847	60
HR 30	Group RFM	73.53	5.888	30
	Group RF	75.00	4.026	30
	Total	74.27	5.055	60
HR 60	Group RFM	73.60	6.066	30
	Group RF	74.93	3.513	30
	Total	74.27	4.960	60
HR 120	Group RFM	73.80	6.065	30
	Group RF	74.87	3.550	30
	Total	74.33	4.956	60
HR 240	Group RFM	73.80	5.904	30
	Group RF	75.00	3.514	30
	Total	74.40	4.854	60

Table 11: Maternal (M)HR

Tests of Between-Subjects Effects								
Measure: Heart Rate								
Transformed Variable: Average								
Source	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared	Non-cent. Para	Observed
Intercept	334786.725	1	334786.725	13915.681	.000	.996	13915.681	1.000
Group RF / MRF	29.225	1	29.225	1.215	.275	.021	1.215	.192
Error	1395.378	58	24.058					
a. Computed using alpha = 0.05								

Table 12: Change in MHR

In our study, we found that, after applying the GLM to repeated measures, there were no significant variations in heart rate between the two groups. ($p=0.275$) (Table 12).

Descriptive Statistics				
	Group RFM,RF	Mean	Std. Deviation	N
MAP 0	Group RFM	96.77	3.57	30
	Group RF	97.84	2.45	30
	Total	97.31	3.08	60
MAP 5	Group RFM	94.17	4.19	30
	Group RF	94.42	4.45	30
	Total	94.29	4.29	60
MAP 10	Group RFM	90.08	3.78	30
	Group RF	89.86	3.65	30
	Total	89.97	3.68	60
MAP 15	Group RFM	86.31	4.26	30



MAP 30	Group RF	85.79	3.95	30
	Total	86.05	4.08	60
	Group RFM	84.26	4.31	30
	Group RF	83.86	3.63	30
	Total	84.06	3.96	60
MAP 60	Group RFM	86.71	5.10	30
	Group RF	85.71	3.28	30
	Total	86.21	4.28	60
MAP 120	Group RFM	90.77	4.19	30
	Group RF	89.19	2.73	30
	Total	89.98	3.59	60
MAP 240	Group RFM	94.00	3.87	30
	Group RF	92.42	3.24	30
	Total	93.21	3.63	60

Table 13: MAP

Tests of Between-Subjects Effects								
Measure: Mean_Arterial_Pressure								
Transformed Variable: Average								
Source	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared	Noncent. Parameter	Observed Power ^a
Intercept	487516.181	1	487516.181	60006.442	.000	.999	60006.442	1.000
Group RFM RF	3.708	1	3.708	.456	.502	.008	.456	.102
Error	471.215	58	8.124					

a. Computed using alpha = 0.05

Table 14: Comparison of MAP

In our study, we found that after applying the GLM to repeated variables, there were no significant variations in MAP between the two groups. ($p=0.502$) (Table 14).

Descriptive Statistics				
	Group RFM,RF	Mean	Std. Deviation	N
FHR 0	Group RFM	153.73	3.956	30
	Group RF	153.80	3.167	30
	Total	153.77	3.553	60
FHR 5	Group RFM	152.93	3.269	30
	Group RF	152.20	3.253	30
	Total	152.57	3.254	60
FHR 10	Group RFM	151.27	3.423	30
	Group RF	151.27	2.947	30



	Total	151.27	3.167	60
FHR 15	Group RFM	150.20	2.941	30
	Group RF	150.03	2.710	30
	Total	150.12	2.805	60
FHR 30	Group RFM	149.33	2.695	30
	Group RF	152.20	18.288	30
	Total	150.77	13.040	60
FHR 60	Group RFM	148.67	2.482	30
	Group RF	148.13	2.675	30
	Total	148.40	2.572	60
FHR 120	Group RFM	147.87	1.961	30
	Group RF	147.87	2.515	30
	Total	147.87	2.236	60
FHR 240	Group RFM	147.87	1.961	30
	Group RF	147.83	2.437	30
	Total	147.85	2.193	60

Table 15: Foetal(F) HR

Tests of Between-Subjects Effects								
Measure: Foetal Heart Rate								
Transformed Variable: Average								
Source	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared	Noncent. Param.	Observed Power
Intercept	10846850.700	1	10846850.700	160192.163	.000	1.000	160192.163	1.000
GroupRF / MRF	4.033	1	4.033	.060	.808	.001	.060	.057
Error	3927.267	58	67.711					
a. Computed using alpha = 0.05								

Table 16: FHR comparison

In our study, we found that after applying GLM for repeated measures, no significant variations in FHR were observed between the two groups. (p value = 0.808) (table 16).

DISCUSSION

Studies have been proving that of all labor analgesic techniques, epidural analgesia is considered the most effective form of analgesia. Studies have concluded that bupivacaine is commonly used for labor epidural analgesia because of its longer duration of action and relative motor sparing effect in comparison with other

local anesthetics.⁶ Studies have also concluded that the role of magnesium in preventive analgesia and its safety as a drug have been widely studied. It has been reported that the addition of intrathecal magnesium 50mg to spinal anesthesia is safe and prolongs the anesthesia period without additional side effects.^{7,8} Hasanein et al. found the onset of analgesia to be shorter in the magnesium group; the duration of analgesia was also found to be prolonged with the addition of magnesium sulfate (169 ± 50) min in comparison to only (105 ± 41) min in the control group.⁹ In the study done by Finegold et al., the onset times for analgesia were 10.62±4.9 and



11.3±4.7 min for the bupivacaine and ropivacaine groups, respectively (p =not significant).¹⁰ Dresner et al. compared ropivacaine 0.2% with bupivacaine 0.1% with fentanyl for epidural labor analgesia. Pain relief and satisfaction scores were better in the ropivacaine group, even though they were not statistically significant.¹¹ Purdie et al. found hypotension in 15% of patients in Group Ropivacaine (Group R) vs. 32% of patients in Group Levobupivacaine (Group L). Pruritus was found to be more common in Group R (42%), while 23% of the women in Group R described mild sedation. The incidence of nausea was greater in Group R (65%) than in Group L (25%) ($p = 0.003$).¹²

CONCLUSION

Mg₂SO₄, when added to R & F for labour epidural analgesia, resulted in a faster onset and longer duration of analgesia. Thus, we found that the overall MSS was better with the addition of Mg. Therefore, we conclude that Mg₂SO₄ as an adjuvant is safe for both the mother and the neonate.

REFERENCE

1. Nageotte MP, Larson D, Rumney PJ, Sidhu M, Hollenbach K. Epidural analgesia compared with combined spinal–epidural analgesia during labor in nulliparous women. *New England Journal of Medicine*. 1997 Dec 11;337(24):1715-9.
2. Albers LL, Anderson D, Cragin L, Daniels SM, Hunter C, Sedler KD, Teaf D. The relationship of ambulation in labor to operative delivery. *Journal of Nurse-Midwifery*. 1997 Jan 1;42(1):4-8.
3. Begon S, Pickering G, Eschaliere A, Dubray C. Magnesium increases morphine analgesic effect in different experimental models of pain. *The Journal of the American Society of Anesthesiologists*. 2002 Mar 1;96(3):627-32.
4. Tramer MR, Schneider J, Marti RA, Rifat K. Role of magnesium sulfate in postoperative analgesia. *The Journal of the American Society of Anesthesiologists*. 1996 Feb 1;84(2):340-7.
5. Lysakowski C, Dumont L, Czarnetzki C, Tramèr MR. Magnesium as an adjuvant to postoperative analgesia: a systematic review of randomized trials. *Anesthesia & Analgesia*. 2007 Jun 1;104(6):1532-9.
6. Reynolds F. Does the left hand know what the right hand is doing? An appraisal of single enantiomer local anaesthetics. *International Journal of Obstetric Anesthesia*. 1997 Oct 1;6(4):257-69.
7. Bilir AY, Gulec S, Erkan A, Ozcelik AB. Epidural magnesium reduces postoperative analgesic requirement. *British journal of anaesthesia*. 2007 Apr 1;98(4):519-23.
8. Buvanendran A, McCarthy RJ, Kroin JS, Leong W, Perry P, Tuman KJ. Intrathecal magnesium prolongs fentanyl analgesia: a prospective, randomized, controlled trial. *Anesthesia & Analgesia*. 2002 Sep 1;95(3):661-6.
9. Hasanein R, El-Sayed W, Khalil M. The value of epidural magnesium sulfate as an adjuvant to bupivacaine and fentanyl for labor analgesia. *Egyptian Journal of anaesthesia*. 2013 Jul 1;29(3):219-24.
10. Finegold H, Mandell G, Ramanathan S. Comparison of ropivacaine 0.1%-fentanyl and bupivacaine 0.125%—fentanyl infusions for epidural labour analgesia. *Canadian Journal of Anesthesia*. 2000 Aug;47:740-5.
11. Dresner M, Freeman J, Calow C, Quinn A, Bamber J. Ropivacaine 0.2% versus bupivacaine 0.1% with fentanyl: a double blind comparison for analgesia



- during labour. British journal of anaesthesia. 2000 Dec 1;85(6):826-9.
12. Purdie NL, McGrady EM. Comparison of patient-controlled epidural bolus administration of 0.1% ropivacaine and 0.1% levobupivacaine, both with 0.0002% fentanyl, for analgesia during labour. Anaesthesia. 2004 Feb;59(2):133-7.