Section: Anaesthesiology

Original Research Article

EPIDURAL LABOUR ANALGESIA: EVALUATION OF THE EFFICACY OF MAGNESIUM SULPHATE AS AN ADJUVANT TO ROPIVACAINE AND FENTANYL MIXTURE

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Received *: 26/02/2025*
Received in revised form *: 10/05/2025*
Accepted *: 29/05/2025*

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DOI: 10.70034/ijmedph.2025.2.316

Source of Support: Nil,
Conflict of Interest: None declared

Int J Med Pub Health
2025; 15 (2); 1764-1768

ABSTRACT

Background: Aim: To compare the efficacy of magnesium sulphate as an adjuvant to a ropivacaine-fentanyl mixture for epidural labour analgesia in terms of onset time, duration of analgesia, maternal satisfaction, and neonatal outcomes.

Materials and Methods: A prospective, randomized, double-blind clinical study was conducted on parturients in active labour. Two groups were formed: Group RF received 0.1% ropivacaine with 2 mcg/ml fentanyl, and Group RFM received 0.1% ropivacaine with 2 mcg/ml fentanyl plus 50 mg magnesium sulphate. Epidural analgesia was initiated and maintained with intermittent boluses. Pain was assessed using a visual analog scale (VAS), and onset time, duration, total drug consumption, side effects, and Apgar scores were recorded.

Results: The onset of analgesia was significantly faster in the RFM group. Duration of effective analgesia was longer in Group RFM, and total drug consumption was lower. VAS scores were significantly reduced at multiple intervals. Maternal hemodynamic stability and neonatal Apgar scores were comparable between groups.

Conclusion: Magnesium sulphate, when added to ropivacaine-fentanyl epidural mixture, significantly enhances the onset and duration of analgesia without adverse maternal or neonatal effects. It is a promising adjuvant for labour analgesia.

Keywords: Magnesium Sulphate, Ropivacaine, Fentyl Mixtures, Adjuvant, Epidural Labor Analgesia.

INTRODUCTION

Childbirth is a deeply emotional and complex experience involving both physiological and psychological dimensions. Labor is widely recognized as one of the most painful events in a woman's life, with the intensity of pain often raising concern for its potential impact on both maternal and fetal outcomes.[1] Uncontrolled labor pain may lead to adverse physiological effects, influencing the overall course and success of delivery.

To mitigate labor pain, a variety of pharmacological and non-pharmacological strategies have been employed. These include systemic opioids and non-opioids, epidural and combined spinal-epidural analgesia, inhalation agents, pudendal block, transcutaneous electrical nerve stimulation, massage, acupuncture, water immersion, yoga, music therapy, biofeedback, continuous emotional support, maternal positioning, ambulation, hypnosis, and breathing techniques.[2] Among these, epidural analgesia stands out as the gold standard due to its superior efficacy. It provides near-complete pain relief, reduces the maternal stress response,

enhances satisfaction with the birthing experience, and can also serve as an effective anaesthetic technique in the event that surgical intervention becomes necessary.[3]

Ropivacaine, a long-acting local anaesthetic, is preferred for labor analgesia because of its greater affinity for sensory fibers, resulting in reduced motor blockade. A concentration of 0.125% ropivacaine has demonstrated an optimal balance between effective analgesia and minimal motor impairment, thus preserving maternal mobility and the ability to actively participate in the labor process.[4] The addition of opioids such as fentanyl further enhances the quality of analgesia.[5]

Magnesium sulphate, when used epidurally along with bupivacaine and fentanyl, has shown promise in improving postoperative analgesia in patients undergoing elective caesarean sections under combined spinal-epidural anaesthesia. Although several adjuvants, including alpha-2 agonists (clonidine, dexmedetomidine), neostigmine, and tramadol have been investigated for enhancing neuraxial analgesia, many are associated with undesirable side effects. In contrast, magnesium sulphate, with its NMDA receptor antagonist and calcium channel blocking properties, emerges as a potentially safer and effective adjunct. These considerations form the basis for evaluating magnesium sulphate as an adjuvant to ropivacaine and fentanyl in epidural labor analgesia.[4,6]

MATERIALS AND METHODS

This study was conducted at Government General Hospital, Kadapa, over a period from October 2022 to March 2024 (18 months). The study was a prospective, randomized, double-blinded trial involving 80 primigravid parturients, with 40 participants in each group. Randomization was performed using computer-generated numbers, and both the participants and the observer were blinded to the study group allocations.

The inclusion criteria for participants included being a primigravida aged 18-33 years with an American Society of Anaesthesiologists (ASA) physical status II and 3 cm cervical dilation. Exclusion criteria included hypersensitivity to study drugs, bleeding disorders, spinal deformities, pregnancy complications (e.g., pregnancy-induced hypertension, gestational diabetes, or multiparity), or any existing sepsis or significant systemic conditions.

Written informed consent was obtained from all participants after thoroughly explaining the study procedure and its significance. The procedure began after obtaining institutional ethics approval (05/GMC/KDP/ /2022) and registered with the Clinical Trials Registry of India (CTRI/ 2025/03/081977) and securing the participants' consent. Intravenous access was established using a 20G cannula without any preload, and standard monitoring with pulse oximetry, blood pressure, ECG, and fetal heart rate was applied throughout the procedure.

For the epidural procedure, an 18G Tuohy needle was used to place a 22G epidural catheter at the L2-L3 interspace following the standard midline technique. Participants were randomly assigned to receive either: Group A, which received 12 ml of 0.125% Ropivacaine and 25 µg Fentanyl; or Group B, which received 12 ml of 0.125% Ropivacaine, 25 µg Fentanyl, and 50 mg Magnesium Sulphate. Doses were administered in small aliquots, with additional top-ups given if the Numerical Rating Scale (NRS) score exceeded 3.

During the study, the participants' vital signs were continuously monitored, including SpO2, pulse rate, non-invasive blood pressure, and fetal heart rate. Motor blockade was assessed using the Bromage scale, which evaluated the range of joint movement. Epidural top-ups were administered based on NRS scores, and maternal expulsive efforts were subjectively assessed by the obstetrician. The parturients were allowed to change positions every hour to enhance comfort during labor.

Post-delivery assessments focused on the onset and duration of analgesia. The onset was defined as the time taken to achieve an NRS score of less than 3 after the initial bolus dose, while the duration was determined as the time between T = 0 and the occurrence of breakthrough pain (NRS >3). Delivery outcomes were categorized into normal vaginal delivery, assisted vaginal delivery, and LSCS. After delivery, the epidural catheter was removed, and a sterile dressing was applied to the puncture site. Participants were monitored for 24 hours for any complications, such as urinary retention, backache, or neurological symptoms.

Adverse effects were noted, including pruritis, nausea, vomiting, hypotension, respiratory depression, and urinary retention. Statistical analysis of the data was performed using Unpaired t-tests for quantitative variables and Chi-square tests for qualitative data, with a p-value of <0.05 considered statistically significant. The data were analyzed using SPSS version 29.0.2.0.

RESULTS

The present study aimed to evaluate the efficacy of magnesium sulphate as an adjuvant to a ropivacaine and fentanyl mixture in epidural labor analgesia. Participants were divided into two groups: Group A (ropivacaine and fentanyl) and Group B (ropivacaine, fentanyl, and magnesium sulphate). Demographic characteristics, including age, weight, and height, were comparable between the two groups, with no significant differences observed ($p > 0.05$).

Regarding the primary outcomes, the onset of analgesia was significantly faster in Group B. The mean onset time for Group B was 4.45 ± 0.55

minutes, compared to 7.20 ± 0.60 minutes in Group A ($p < 0.001$). This finding suggests that the addition of magnesium sulphate accelerates the onset of analgesia. The duration of analgesia was also significantly prolonged in Group B, with a mean duration of 101.23 ± 8.97 minutes, compared to 84.35 ± 8.25 minutes in Group A ($p < 0.001$), indicating that magnesium sulphate extends the duration of pain relief.

Pain intensity, as measured by the Numerical Rating Scale (NRS), was significantly lower in Group B at various time intervals. At 5 minutes post-administration, Group B reported a mean NRS score of 1.12 ± 0.40, compared to 3.18 ± 0.45 in Group A ($p < 0.001$). At 15 minutes, Group B maintained lower pain scores (1.05 ± 0.38) compared to Group A (2.92 ± 0.44) ($p < 0.001$). At 30 minutes, Group B reported a mean NRS score of 0.95 ± 0.35, whereas Group A had 2.65 ± 0.42 ($p = 0.0004$). However, by 45 minutes and beyond, pain scores between the two groups were comparable, with no significant differences at 60 minutes ($p = 0.25$), 90 minutes ($p = 0.17$), or 180 minutes ($p = 0.12$).

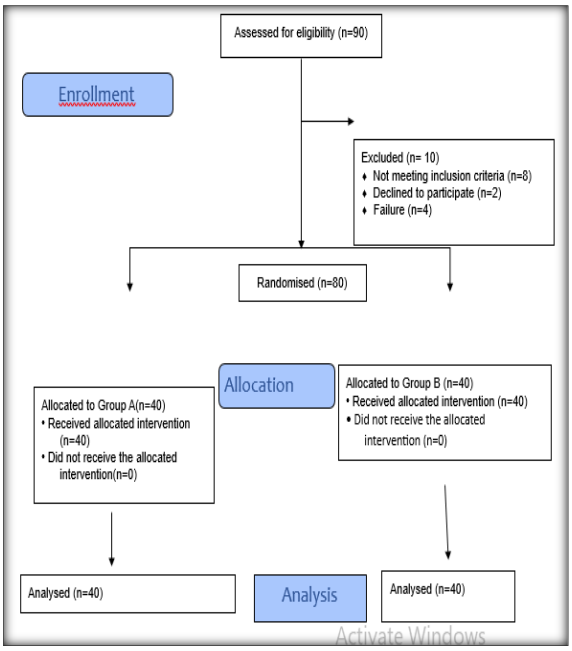
In terms of labor progression, all participants in both groups delivered vaginally, with no significant differences in the mode of delivery ($p = 0.98$). The mean duration of labor during the first, second, and third stages was similar between the groups (first stage: $p = 0.23$; second stage: $p = 0.25$; third stage: $p = 0.16$).

Maternal and fetal outcomes were also similar between groups. No significant differences were observed in maternal vital signs (pulse rate, systolic, diastolic, and mean arterial blood pressure) or fetal heart rates. Furthermore, APGAR scores at both 1 and 5 minutes were comparable, indicating no adverse effects on neonatal health.

Complications were rare in both groups, with hypotension occurring in one participant from each group. No significant differences were observed in the occurrence of other complications, such as pruritus, vomiting, respiratory depression, or urinary retention ($p = 0.99$). Additionally, the motor block, assessed using the Modified Bromage Scale, was similar between the groups, with no significant differences (Chi-Square = 1.6, $p = 0.206$).

These findings suggest that the addition of magnesium sulphate to a ropivacaine and fentanyl mixture in epidural labor analgesia provides a faster onset and longer duration of analgesia, with a reduction in pain intensity in the initial stages of labor. Furthermore, magnesium sulphate appears to be a safe adjunct, with no significant differences in maternal or neonatal outcomes and minimal complications.

Consort flow chart



CONSOLIDATED STANDARDS OF REPORTING TRIALS (CONSORT) FLOW CHART FOR RECRUITMENT

Table 1: Demographic data and duration of labour

Parameter	Group A	Group B	p-value
Age (years)	23.80 ± 3.49	23.33 ± 3.24	0.08
Weight (kg)	63.71 ± 6.29	63.07 ± 6.07	0.391
BMI	Normal – 15	Normal – 12	0.08
	Overweight–23	Overweight – 24	
	Obese – 2	Obese – 4	
Duration of Labor	First – 237.57 ± 30.72	First – 229.56 ± 28.64	> 0.05
	Second – 49.42 ± 6.36	Second – 51.02 ± 6.12	
	Third – 17.62 ± 4.02	Third – 16.40 ± 3.79	

Table 2: Analgesic characteristics

Parameter	Group -A	Group- B	P value
Mean onset of analgesia (min)	7.2 ± 0.6	4.45 ± 0.545	<0.001
Mean duration of analgesia (min)	84.35 ± 8.25	101.225 ± 8.97	<0.001
NRS AT 0MIN	9.5±0.54	9.475±0.49	0.83
NRS AT 5 MIN	4.475±0.63	2.525±0.49	<0.001
NRS AT 15 MIN	2.775±0.41	1.1±0.3	<0.001

Table 3: Neonatal outcomes

Time Point	Mean APGAR Score (Group A)	Mean APGAR Score (Group B)	p-value
1 minute	7.55±0.495	7.575±0.489	0.824
5 minutes	8.35± 0.5	8.43± 0.59	0.569

DISCUSSION

Pain during labor leads to significant physiological changes in both the mother and fetus, affecting respiratory, cardiovascular, hormonal, and metabolic functions. These changes can result in complications like hyperventilation, blood gas alterations, uterine involution, increased cardiac output, and hormonal fluctuations, potentially compromising maternal and fetal health. The goal of labor analgesia is to minimize these adverse effects and ensure a safe delivery for both mother and child.

Lumbar epidural analgesia is the most commonly used and effective method for managing labor pain. It provides substantial pain relief without impairing key sensations such as the urge to push, allowing labor to progress naturally. Although alternative techniques like combined spinal-epidural approaches exist, epidural analgesia remains the preferred option due to the avoidance of complications like dural puncture.

Ropivacaine, a local anaesthetic that selectively targets sensory fibers, is favored for labor analgesia due to its superior safety profile. Compared to Bupivacaine, Ropivacaine causes less motor blockade and has fewer systemic side effects, including a reduced risk of cardiotoxicity. Its pharmacokinetics ensure minimal effects on uterine blood flow and fetal heart rate, making it an ideal choice for labor. Although it transfers across the placenta similarly to Bupivacaine, its lower protein binding reduces the likelihood of adverse fetal effects.[7]

Fentanyl, a lipid-soluble opioid, is often used in combination with Ropivacaine for enhanced analgesia. By acting on the spinal cord's dorsal horn, Fentanyl blocks nociceptive impulses, extending the duration of pain relief without hindering the mother's ability to move or push. Despite crossing the placenta, studies suggest that Fentanyl does not significantly impact fetal heart rate or outcomes during labor.[8]

Magnesium sulfate has emerged as a promising adjunct to epidural analgesia. It does not cause motor weakness, ensuring minimal interference with maternal mobility and the ability to push. Research suggests that Magnesium sulfate enhances opioid effects, prolongs analgesia, and improves pain relief without impairing motor function. By antagonizing NMDA receptors involved in pain perception, Magnesium sulfate enhances analgesic effects and reduces opioid requirements.[9]

In our study, demographic factors such as age, body mass index (BMI), mode of delivery, and labor duration were similar between the two groups. Group A (Ropivacaine and Fentanyl) had a mean age of 23.80 ± 3.49 years, while group B (Ropivacaine, Fentanyl, and Magnesium sulfate) had a mean age of 23.33 ± 3.24 years, with no significant difference ($p = 0.08$). BMI values were also similar across both groups ($p = 0.329$).

The addition of Magnesium sulfate in group B significantly reduced the onset time of analgesia, with a mean of 4.45 ± 0.55 minutes compared to 7.2 ± 0.6 minutes in group A ($p < 0.001$). This result is consistent with prior studies, such as Megha et al., which reported a faster onset of analgesia with Magnesium sulfate.[4]

There were no significant differences in labor duration or mode of delivery between the groups, as both had 100% normal vaginal deliveries. Our findings align with studies like Priyadarshi et al., where no differences in labor duration or delivery mode were observed between Ropivacaine alone and Ropivacaine with Fentanyl.[10]

Group B also experienced a significantly longer duration of analgesia, with a mean of 101.22 ± 8.97 minutes, compared to 84.35 ± 8.25 minutes in group A ($p < 0.001$). This finding is consistent with Megha et al., which demonstrated that Magnesium sulfate extended the duration of analgesia.[4]

Numerical Rating Scale (NRS) scores, measuring pain intensity, were significantly lower in group B at 5, 15, and 30 minutes post-administration. While scores remained lower in group B at later time points, the difference was not statistically significant. These results mirror those of Hasanein et al., who observed reduced VAS scores in the first 30 minutes with the addition of Magnesium sulfate to Bupivacaine and Fentanyl.[9]

Both groups maintained a modified Bromage score of 0 or 1, indicating no significant motor blockade. Romberg's sign was negative, and the straight leg-raising test showed no motor impairment. These findings align with studies by Chhetty YK et al. (2013) and Hasanein R et al. (2013), who attributed the absence of motor blockade to the use of low concentrations of local anesthetics. Magnesium sulfate did not affect motor function, consistent with Megha et al. (2020), who also reported no motor blockade with the addition of Magnesium sulfate.[4,9,11]

There were no differences in expulsive efforts between the two groups, with excellent expulsive efforts observed in 52.5% of parturients in group B and 50% in group A. The incidence of good expulsive efforts was similar between the groups, with no statistically significant difference ($P > 0.05$). This aligns with Megha et al. (2020), where no difference in expulsive efforts was found between groups.[4]

Top-up analgesia was required by 75% of participants in group A (two top-ups) and 25% (three top-ups), while in group B, 82.5% required

two top-ups, and 17.5% needed three. This is consistent with findings by Arun Ahirwar et al., who reported fewer additional analgesic doses required when adjuvants like Magnesium sulfate were used.[6]

Maternal pulse rate and mean arterial pressure (MAP) showed no significant differences between the groups at various time points. Both were comparable across groups, with p-values greater than 0.05, suggesting no clinically significant variations. Similar results were reported by Megha et al. (2020) 4 and Avni Thacker et al. (2021).[12]

Fetal heart rate (FHR) measurements and APGAR scores at 1, 5, and 10 minutes were comparable between the groups, indicating that the addition of Magnesium sulfate did not adversely affect neonatal well-being. These findings are consistent with studies by Hasanein R et al. (2013)9 and Chhetty YK et al. (2013).[11]

Maternal satisfaction was higher in group B, with 55% rating their experience as "Excellent" and 45% as "Good." In group A, 40% rated it as "Excellent" and 30% as "Good." These results align with Megha et al. (2020), who found greater satisfaction in the Magnesium sulfate group, with 86.7% rating their analgesia as excellent.[4]

There were no major complications in our study, with only one patient in each group experiencing hypotension, which responded to a 200 mL fluid bolus. This low incidence of hypotension contrasts with studies using higher concentrations of Ropivacaine. Megha et al. (2020) also reported no significant adverse effects with Magnesium sulfate.[4]

Our study does have limitations. We did not use techniques like PCEA, continuous epidural infusion, or programmed intermittent epidural bolus, which may influence analgesia effectiveness. Additionally, we did not evaluate a dose-response relationship for Magnesium sulfate, which could help determine the optimal dosing. Although APGAR scores were recorded, direct fetal outcomes like umbilical artery pH were not measured, which could provide more detailed information on fetal well-being.

CONCLUSION

The addition of 50 mg of Magnesium sulfate to the Ropivacaine and Fentanyl mixture for epidural labor analgesia significantly shortens the onset time and extends the duration of analgesia, without causing any adverse effects in either the mother or fetus. Throughout the study, no significant differences were observed in hemodynamic parameters or maternal expulsive efforts between the two groups. Additionally, the mode of delivery remained comparable in both groups.

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