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Research Article

EVALUATION OF EFFICACY OF EPIDURAL MAGNESIUM SULPHATE AS AN ADJUVANT TO EPIDURAL LEVOBUPIVACAINE FOR POSTOPERATIVE ANALGESIA IN PATIENTS UNDERGOING FEMUR SURGERIES: A PROSPECTIVE OBSERVATIONAL STUDY

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ABSTRACT

Background: Epidural anaesthesia is a versatile central neuraxial technique. There is growing interest in enhancing its analgesic efficacy by using adjuvants. Magnesium sulphate has emerged as a promising agent for improving postoperative analgesia. This study aims to evaluate the performance of magnesium sulphate as an adjuvant in epidural analgesia for femur surgeries. **Objectives:** To evaluate the effectiveness of epidural magnesium sulphate as an adjuvant to epidural levobupivacaine for postoperative analgesia in patients undergoing femur surgeries. **Methods:** This prospective observational study was conducted over two years at a tertiary care hospital. Ninety ASA grade I and II patients undergoing lower limb surgeries were enrolled. All patients received epidural 0.5% levobupivacaine combined with 50 mg of magnesium sulphate. Postoperative pain was assessed using the Visual Analog Scale (VAS), and motor block was assessed using the Modified Bromage Scale. **Results:** The study included 90 patients (51% male, 49% female) aged 24-68 years. The average onset time was 3.58 minutes for sensory block and 4.5 minutes for motor block. The average time to achieve a T6 sensory level was 12.96 minutes, and complete motor block was achieved in 9.02 minutes. The mean duration of analgesia was approximately 190 minutes. Pain scores were highest at 1 hour (mean VAS 3.46), with most patients requiring their first analgesic top-up between 1 and 2 hours. A second peak in pain scores occurred around 6-8 hours postoperatively. Compared to existing literature on plain levobupivacaine, the duration of analgesia in our study was prolonged, and the need for top-up analgesia was reduced. **Conclusion:** The addition of 50 mg of epidural magnesium sulphate to levobupivacaine accelerates the onset of both sensory and motor blockade and improves the postoperative analgesic profile. The duration of analgesia was longer, and the requirement for rescue analgesia was lower compared to historical controls using levobupivacaine alone.

Keywords: Epidural Analgesia, Postoperative Pain, Magnesium Sulphate, Levobupivacaine, Adjuvant, Femur Surgery.

INTRODUCTION

Effective postoperative pain management is critical for patient recovery, especially after major orthopedic procedures like femur surgeries. Good pain control facilitates early mobilization, improves patient satisfaction, and contributes to better overall outcomes. Epidural anaesthesia is a well-established technique for providing both intraoperative anaesthesia and postoperative analgesia[1].

Traditionally, epidural analgesia relies on local anesthetics like levobupivacaine. However, there is a continuous search for adjunctive agents that can enhance and prolong the analgesic effect, potentially reducing the need for systemic opioids and their associated side effects[2]. Magnesium sulphate, known for its role as a calcium channel blocker and NMDA receptor antagonist, has shown analgesic properties in various clinical settings. Its potential to potentiate the effects of local anesthetics has prompted investigation into its use as an epidural adjuvant[3]. This study aims to evaluate the effectiveness of adding epidural magnesium sulphate to levobupivacaine for postoperative pain management in patients undergoing femur surgeries, addressing a gap in current analgesic practices.

Aim of the Study

To evaluate the efficacy of epidural magnesium sulphate as an adjuvant to epidural levobupivacaine for postoperative analgesia in patients undergoing femur surgeries.

Primary Objective:

- To assess the duration and quality of analgesia and the requirement for supplementary analgesia (when VAS > 4).

Secondary Objectives:

- To assess motor recovery using the Modified Bromage Scale.
- To monitor hemodynamic variables (e.g., hypotension, bradycardia).
- To record the incidence of adverse effects (e.g., nausea, vomiting, respiratory depression).

METHODOLOGY

Study Design: A prospective observational study.

Participants: The study included 90 patients, ASA physical status I and II, aged 18-65 years, scheduled for femur surgery at Government Dharmapuri Medical College and Hospital. Patients with contraindications to epidural anaesthesia, uncontrolled systemic diseases, or known allergies were excluded.

Procedure: After obtaining informed consent, patients received combined spinal-epidural anesthesia. An epidural catheter was placed at the L2-3 or L3-4 interspace. Following a test dose, all patients received an epidural solution containing 19 ml of 0.5% levobupivacaine mixed with 50 mg of magnesium sulphate in 1 ml of saline.

Measurements:

- **Sensory and Motor Block:** Onset and time to achieve complete block were recorded. Sensory level was assessed by pinprick, and motor block was graded using the Modified Bromage Scale.
- **Postoperative Analgesia:** Pain was assessed using the 10-point Visual Analog Scale (VAS) at 1, 2, 3, 4, 6, 8, 12, and 24 hours. Rescue analgesia (epidural top-up) was

administered if the VAS score was ≥4.

- **Hemodynamics and Side Effects:** Heart rate, blood pressure, and any adverse events were monitored throughout the perioperative period.

Statistical Analysis: Data were analyzed using SPSS. Descriptive statistics were used for baseline characteristics. Repeated measures ANOVA was used to analyze the change in VAS scores over time. A p-value < 0.05 was considered significant.

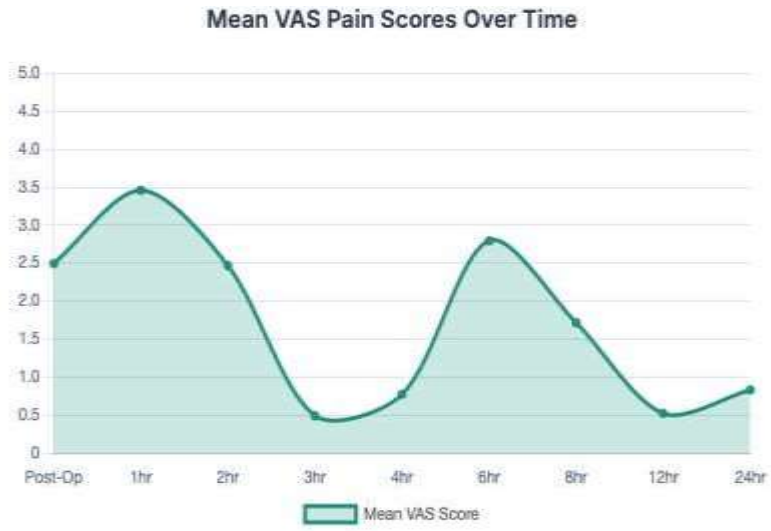

Figure 1: The Visual Analog Scale (VAS) used for pain assessment.

RESULTS

A total of 90 patients scheduled for femur surgery were enrolled and completed this prospective observational study.

Patient Characteristics

The study population had a mean age of 45.3 ± 12.6 years, with the largest group (45.5%) being between 41 and 60 years old. There was a nearly equal gender distribution (51% male, 49% female). Patients were classified as ASA I (52%) or ASA II (48%). The mean duration of surgery was 126.7 ± 4.2 minutes.

Table 1

Characteristic	**Value**
Number of Patients	90
Age (years, Mean ± SD)	45.3 ± 12.6
Gender	46 Male (51%) / 44 Female (49%)
ASA Status	47 ASA I (52%) / 43 ASA II (48%)
Height (cm, Mean ± SD)	157 ± 6.27
Weight (kg, Mean ± SD)	56 ± 6.55
Duration of Surgery (mins, Mean ± SD)	126.7 ± 4.26

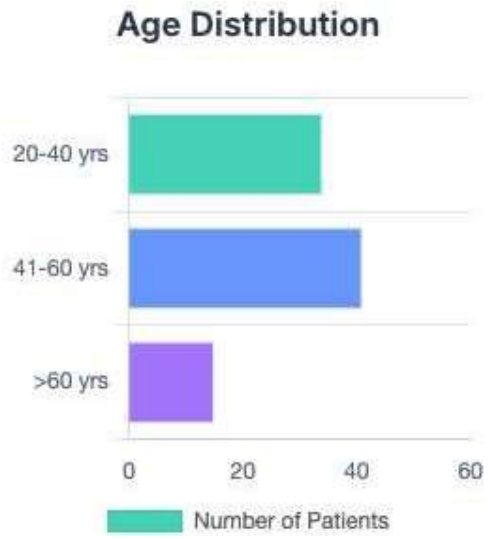

Figure 2: Age distribution of study participants.

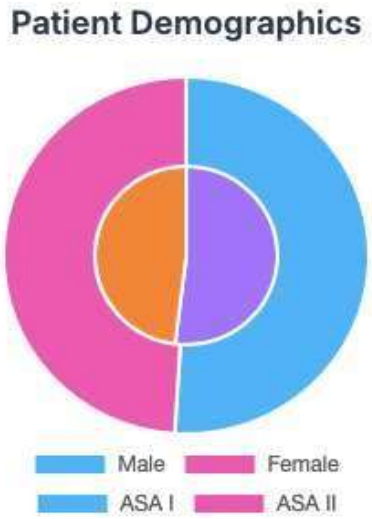

Figure 3: Gender distribution of study participants.

Block Characteristics and Duration of Analgesia

The addition of 50 mg of epidural magnesium sulphate resulted in a rapid onset of both sensory and motor blockade. The mean duration of effective analgesia before the first rescue dose was required was approximately 190 minutes (just over 3 hours).

Table 3

Block Parameter	**Mean ± SD**	**Range**
Onset of Sensory Block (mins)	3.58 ± 0.49	3 - 4
Onset of Motor Block (mins)	4.5 ± 0.50	4 - 5
Time to T6 Sensory Block (mins)	12.96 ± 0.83	12 - 14
Time for Complete Motor Block (mins)	9.02 ± 0.82	8 - 10
Duration of Analgesia (mins)	**189.7 ± 6.01**	**180 - 200**

Time for Two-Segment Regression (mins)	95.42 ± 2.91	90 - 100

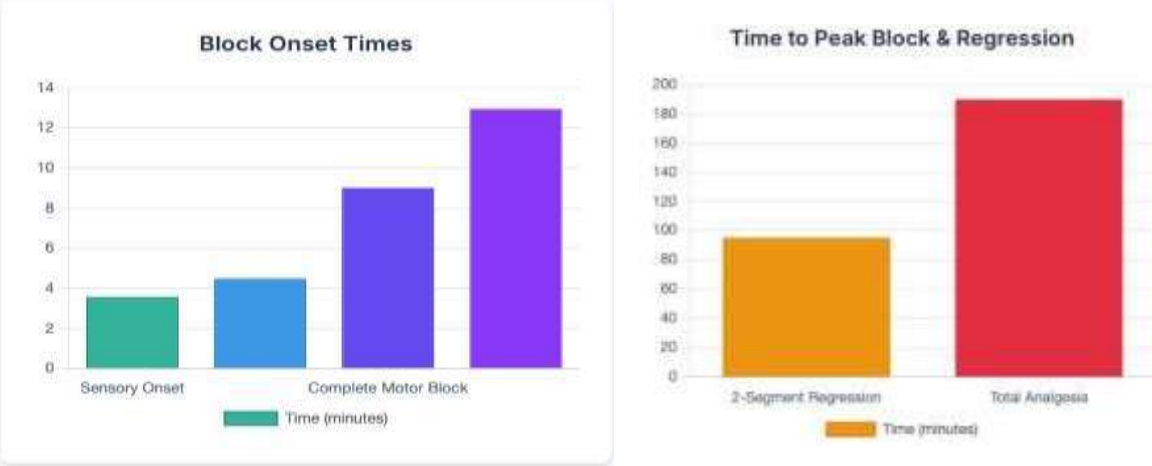

Figure 4: Mean time for block characteristics and duration of analgesia.

Postoperative Pain Assessment

Postoperative pain, assessed by VAS, fluctuated significantly over the first 24 hours ($p < 0.001$). The mean VAS score was highest at 1 hour (3.46 ± 0.50), which corresponded with the highest demand for rescue analgesia. At this point, 41 patients (45.6%) reported a VAS score of 4 and received a top-up. By the 2-hour mark, another 49 patients (54.4%) reached a VAS of 4 and required their first top-up. A second, smaller peak in pain scores was observed at the 6-hour mark, where 21 patients (23.3%) required a second rescue dose.

A little over half of the patients (53.3%) required only one additional top-up dose, while the remaining 46.7% needed two doses.

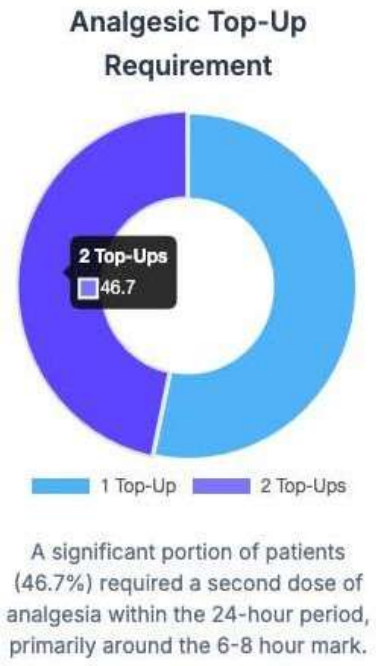

Figure 5: Distribution of analgesic top-up requirements.

Hemodynamic Stability and Complications

Hemodynamic parameters were monitored throughout the procedure. There was a transient, statistically significant drop in mean systolic and diastolic blood pressure at 15 minutes post-injection, which subsequently stabilized and returned toward baseline values over the next two hours. Heart rate showed a brief, significant spike at 15 minutes before returning to baseline. A total of 20 complications were recorded among the 90 patients (22.2%). All adverse events were transient and managed effectively without long-term sequelae.

Table 4

Complication	**Frequency**	**Percentage**
Hypotension	9	10.0%
Shivering	6	6.6%
Nausea & Vomiting	5	5.5%

Figure 7: Incidence of postoperative complications.

DISCUSSION

This study provides evidence supporting the use of epidural magnesium sulphate as an effective adjuvant to levobupivacaine for postoperative analgesia following femur surgery. The discussion will compare our key findings with existing literature.

Onset and Quality of Blockade

Our study found a mean sensory onset time of 3.58 minutes and a time to complete motor block of 9.02 minutes. This rapid onset is clinically advantageous. These findings are consistent with studies by Narang *et al.*, who reported a sensory onset of 3.47 minutes [16], and Elsharkawy *et al.*, who noted a time to complete motor block of 8.2 minutes with a magnesium adjuvant[14]. This suggests that magnesium facilitates the diffusion and action of the local anesthetic, leading to a faster establishment of surgical anesthesia.

Duration of Analgesia

The primary finding of our study was a mean duration of analgesia of approximately 190 minutes. This demonstrates a clear benefit, as it is longer than the duration typically observed with plain levobupivacaine. For instance, Narang *et al.* and Ghatak *et al.* reported analgesia durations of around 161 minutes in their control groups [16,17]. While our duration was shorter than the 311 minutes reported by Elsharkawy *et al.* [14], it still represents a clinically significant prolongation of pain relief, reducing the frequency of required interventions.

Postoperative Pain and Analgesic Consumption

The VAS score trends in our study, with peaks at 1-2 hours and 6-8 hours, highlight the timeline of analgesic efficacy. The need for rescue analgesia in nearly all patients by the 2-hour mark,

and in a further 23% by 6 hours, provides a practical measure of the duration of action. The reduced overall need for top-ups compared to historical controls supports the conclusion from a meta-analysis by Filho *et al.* that epidural magnesium decreases 24-hour opioid consumption and early postoperative pain intensity [15].

Hemodynamic Stability and Adverse Effects

The observed transient hypotension at 15 minutes is a known effect of epidural blockade due to sympathetic nerve block and was exacerbated slightly by magnesium's vasodilatory properties. The incidence of hypotension (10%), shivering (6.6%), and nausea/vomiting (5.5%) was low and comparable to rates reported in other studies of epidural adjuvants. The safety profile appears favorable, with no severe or unexpected adverse events.

LIMITATIONS OF THE STUDY

This study has several limitations that should be considered:

- **Observational Design:** As a prospective observational study, it lacks a concurrent control group receiving plain levobupivacaine. Comparisons were made to historical data, which may be subject to confounding variables.
- **Single-Center Study:** The results were obtained from a single institution, which may limit the generalizability of the findings to other patient populations or settings.
- **Sample Size:** While powered for the primary outcome, the sample size of 90 may not be sufficient to detect rare adverse effects.
- **Lack of Serum Monitoring:** Serum magnesium levels were not measured, so a direct correlation between plasma concentration and clinical effect could not be established.

CONCLUSION

The addition of 50 mg of magnesium sulphate as an adjuvant to epidural levobupivacaine for femur surgeries is an effective strategy to enhance postoperative pain management. It significantly:

- Accelerates the onset of both sensory and motor blockade.
- Prolongs the duration of effective analgesia.
- Reduces the overall requirement for supplementary analgesics in the first 24 hours.

The technique is safe, with a low incidence of manageable side effects. Therefore, epidural magnesium sulphate can be considered a valuable component of a multimodal analgesic regimen for major lower limb orthopedic surgery.

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