International Journal of Science and Research (IJSR)
ISSN: 2319-7064
Impact Factor 2025: 7.089

# Effect of Oral Pregabalin on the Characteristics of Spinal Anaesthesia and Postoperative Pain in Patients Undergoing Lower Limb Orthopaedic Surgeries

**Dr. Shivani Makhecha[1], Dr. Jignasa Patel[2], Dr. Rakesh Jalandhara[3]**

[1]MD Anaesthesiology Resident, Department of Anaesthesiology, Government Medical College, Surat, Gujarat, India (Corresponding Author)

[2]Assistant Professor, Department of Anaesthesiology, Government Medical College, Surat, Gujarat, India

[3]Department of Anaesthesiology, Government Medical College, Surat, Gujarat, India

**Abstract:** ***Background**: Spinal anaesthesia is the technique of choice for lower limb orthopaedic surgeries, yet its limited postoperative analgesic duration remains a significant clinical challenge. Pregabalin, a structural analogue of gamma-aminobutyric acid (GABA), has shown promise in multimodal pain management through its action on presynaptic voltage-gated calcium channels. **Aim**: To evaluate the effect of a single oral dose of pregabalin 150 mg on the characteristics of spinal block, duration of postoperative analgesia, and total analgesic requirement in patients undergoing lower limb orthopaedic surgeries. **Methods**: This prospective observational study was conducted at a tertiary care centre, South Gujarat. Eighty adult patients (ASA I-III, aged 18-65 years) scheduled for lower limb orthopaedic surgeries under spinal anaesthesia were enrolled. Group P (n=40) received oral pregabalin 150 mg one hour before spinal anaesthesia; Group C (n=40) received no premedication analgesic. Sensory and motor block characteristics, postoperative VAS scores, first rescue analgesia time, total analgesic consumption, and sedation (Ramsay Sedation Score) were assessed. **Results**: Both groups were demographically comparable. The onset of sensory and motor block was not significantly different between groups (p>0.05). However, two-segment regression time (Group P: 93.2±5.5 min vs Group C: 83.1±6.9 min), total sensory block duration (195.2±17.9 vs 167.5±10.1 min), and total motor block duration (183.2±14.7 vs 158.47±9.57 min) were all significantly prolonged in Group P (p<0.001). VAS scores were significantly lower in Group P at all intervals except 3 hours. First rescue analgesia was significantly delayed in Group P (353.7±38.3 vs 265.3±39.7 min, p=0.003). Total tramadol (115±36.2 vs 152.5±50.57 mg) and paracetamol requirements were significantly reduced in Group P (p<0.001). Mild sedation was noted in Group P; no adverse effects were observed. **Conclusion**: Pre-emptive oral pregabalin 150 mg significantly prolongs sensory and motor blockade of spinal anaesthesia, delays first analgesic requirement, and reduces total postoperative analgesic consumption without increasing adverse effects. It represents a safe and effective component of multimodal analgesia in lower limb orthopaedic surgeries.*

**Keywords:** Pregabalin, Spinal Anaesthesia, Postoperative Analgesia, Orthopaedic Surgery, Pre-emptive Analgesia, VAS Score, Bromage Scale

## 1. Introduction

Spinal anaesthesia is the preferred anaesthetic technique for lower limb orthopaedic surgeries, valued for its reliability, rapid onset, excellent muscle relaxation, and favourable safety profile. Despite these advantages, its limited duration of action and restricted postoperative analgesia remain major clinical concerns. Inadequately managed postoperative pain not only causes patient distress but also leads to systemic effects including tachycardia, hypertension, impaired wound healing, and prolonged hospital stay. Persistent untreated pain is also associated with the development of chronic post-surgical pain, depression, and delayed rehabilitation.

Contemporary pain management increasingly relies on multimodal analgesic strategies that combine agents with different mechanisms to achieve superior analgesia while minimising individual drug side effects. Pre-emptive analgesia, wherein analgesics are administered prior to surgical insult, has emerged as an effective strategy to prevent central sensitisation and reduce postoperative pain intensity.

Pregabalin (α-amino-3-hydroxy-5-methyl-4-isoxazole propionic acid analogue) is a second-generation gabapentinoid that binds selectively to the α2-δ subunit of presynaptic voltage-gated calcium channels. This binding inhibits the release of excitatory neurotransmitters including glutamate, norepinephrine, substance P, and calcitonin gene-related peptide, thereby reducing neuronal excitability and modulating pain transmission. Its established role in neuropathic pain, fibromyalgia, and generalised anxiety disorder has motivated investigators to explore its perioperative application.

Evidence from multiple randomised controlled trials suggests that a single oral dose of pregabalin (75-150 mg) administered preoperatively can prolong the duration of spinal anaesthesia, reduce postoperative pain scores, and decrease rescue analgesic consumption. The proposed mechanism involves calcium channel-mediated reduction in potassium-evoked excitatory transmitter release, thereby decreasing postsynaptic excitability and effectively prolonging the local anaesthetic block. Despite this evidence, the clinical practice varies widely and institutional data from South Gujarat tertiary care settings are limited. The present prospective

observational study was, therefore, designed to systematically evaluate the effect of oral pregabalin 150 mg on spinal anaesthesia characteristics and postoperative analgesia in patients undergoing lower limb orthopaedic surgeries.

## 2. Aims and Objectives

**Primary Aim:**
To study the effect of a single oral dose of pregabalin 150 mg on the characteristics of spinal block and the duration and quality of postoperative analgesia.

**Primary Objective:**
To assess the onset and regression time of sensory and motor block in both groups.

**Secondary Objectives:**
To assess the quality and duration of postoperative analgesia up to 12 hours; to observe patients for occurrence of any pregabalin-related adverse effects; and to compare total rescue analgesic consumption between groups.

## 3. Material and Methods

**Study Design and Setting:** A prospective observational cohort study was conducted at a tertiary care centre in South Gujarat following approval from the Institutional Research and Ethical Committee. The study was conducted over the academic year 2023-24.

**Study Population:** Eighty adult patients of ASA physical status I, II, and III between the age group of 18-65 years, scheduled for lower limb orthopaedic surgeries under spinal anaesthesia, were enrolled. Patients allergic to pregabalin, pregnant women, those with BMI >30, history of chronic pain, or regular use of analgesic drugs were excluded.

**Study Groups:** Patients were assigned to two groups based on the consulting anaesthesiologist's practice: Group P (n=40) received oral pregabalin 150 mg approximately one hour before spinal anaesthesia, and Group C (n=40, control) did not receive any preoperative oral or intravenous analgesic.

**Anaesthetic Protocol:** All patients underwent detailed pre-anaesthetic evaluation. Written informed consent was obtained. Patients were kept nil by mouth for at least 6 hours preoperatively. Intravenous access was secured (18G or 20G cannula), and all patients were preloaded with Ringer's Lactate 10 ml/kg. Premedication included injection Midazolam 1 mg intravenously. Spinal anaesthesia was administered with injection Bupivacaine Heavy (0.5%) at 0.3 mg/kg body weight.

**Assessment Parameters:** Sensory block was assessed by pin-prick method every minute from caudal to cranial. Motor block was assessed using the Modified Bromage Scale. Postoperative pain was evaluated using the Visual Analogue Scale (VAS, 0-10) at recovery room admission and at 30, 60, 90 minutes, 2, 3, 6, and 12 hours postoperatively. Rescue analgesia (injection Tramadol 100 mg IV) was administered when VAS >3; injection Paracetamol 1 g IV was given if VAS remained >3 within 6 hours of tramadol. Sedation was evaluated by the Ramsay Sedation Score (RSS) at PACU discharge.

**Table 1:** Modified Bromage Scale

| Grade | Description |
|---|---|
| 0 | No motor block |
| 1 | Can flex knee, move foot, but cannot raise leg |
| 2 | Can move foot only |
| 3 | Cannot move foot or knee |

**Table 2:** Ramsay Sedation Score

| Score | Description |
|---|---|
| 1 | Anxious, agitated, restless |
| 2 | Oriented, tranquil |
| 3 | Responds to command |
| 4 | Brisk response to light glabellar tap |
| 5 | Sluggish response to light glabellar tap |
| 6 | No response |

**Statistical Analysis:** Data are presented as mean ± standard deviation. Continuous variables were analysed using Student's t-test. Chi-square test was used for categorical data. Paired t-test was used for within-group comparisons and unpaired t-test for inter-group comparisons. A p-value <0.05 was considered statistically significant and p<0.001 as highly significant. SPSS software (IBM, version 25) was used for all analyses.

## 4. Results

### 4.1 Demographic Data

A total of 80 patients were enrolled and divided into two groups of 40 each. The groups were well-matched for age and weight with no statistically significant differences (Table 3).

**Table 3:** Demographic Data (Mean ± SD)

| Variable | Group P (Pregabalin, n=40) | Group C (Control, n=40) | p-value |
|---|---|---|---|
| Age (years) | 36.2 ± 10.59 | 36.3 ± 11.9 | 0.961 (>0.05) |
| Weight (kg) | 60.0 ± 6.2 | 60.0 ± 4.9 | 1.000 (>0.05) |

### 4.2 Surgery Distribution

**Table 4:** Distribution of Surgery Type

| Fracture Type | Group P (n=40) | Group C (n=40) |
|---|---|---|
| Femur | 13 (32.5%) | 8 (20.0%) |
| Tibia | 27 (67.5%) | 32 (80.0%) |

### 4.3 Characteristics of Sensory Block

Onset of sensory block (time to achieve L1 level) and time to highest sensory level (T8/T10) were comparable in both groups (p>0.05). However, pregabalin significantly prolonged both the two-segment regression time and the total duration of sensory block (Table 5).

**Table 5:** Sensory Block Characteristics (Mean ± SD, in minutes)

| Parameter | Group P | Group C | p-value |
|---|---|---|---|
| Time to L1 sensory level (onset) | 2.61 ± 0.6 | 2.83 ± 0.4 | 0.060 (NS) |
| Time to highest sensory level (T8/T10) | 3.8 ± 0.65 | 4.0 ± 0.76 | 0.338 (NS) |
| Two-segment regression time | 93.2 ± 5.5 | 83.1 ± 6.9 | <0.001 (HS) |
| Complete regression of sensory block | 195.2 ± 17.9 | 167.5 ± 10.1 | <0.001 (HS) |

NS = Not Significant; HS = Highly Significant

### 4.4 Characteristics of Motor Block

Onset of motor block (time to Bromage grade 2) was comparable between groups (p>0.05). The time to achieve maximum motor block (Bromage grade 3) was significantly shorter in Group P, and the total duration of motor block was significantly prolonged (Table 6).

**Table 6:** Motor Block Characteristics (Mean ± SD, in minutes)

| Parameter | Group P | Group C | p-value |
|---|---|---|---|
| Time to Bromage Grade 2 (onset) | 3.37 ± 0.69 | 3.5 ± 0.59 | 0.338 (NS) |
| Time to maximum motor block (Grade 3) | 6.01 ± 1.0 | 7.0 ± 0.7 | <0.001 (HS) |
| Complete regression of motor block (Grade 0) | 183.2 ± 14.7 | 158.47 ± 9.57 | <0.001 (HS) |

### 4.5 Postoperative Pain Scores (VAS)

Visual Analogue Scale scores were significantly lower in Group P at all postoperative time intervals except at 3 hours. This exception was attributed to the administration of rescue tramadol in control group patients by 2 hours, equalising scores temporarily at 3 hours (Table 7).

**Table 7:** Mean VAS Scores at Various Postoperative Intervals (Mean ± SD)

| Time Interval | Group P | Group C | p-value |
|---|---|---|---|
| Immediately at recovery room | 0.075 ± 0.27 | 0.425 ± 0.5 | <0.001 |
| 30 minutes | 0.10 ± 0.3 | 0.65 ± 0.5 | <0.001 |
| 60 minutes | 0.32 ± 0.47 | 1.10 ± 0.75 | <0.001 |
| 90 minutes | 0.78 ± 0.65 | 1.80 ± 1.0 | <0.001 |
| 2 hours | 1.5 ± 0.78 | 2.8 ± 1.04 | <0.001 |
| 3 hours | 3.0 ± 1.2 | 2.98 ± 1.2 | 0.93 (NS) |
| 6 hours | 2.5 ± 0.87 | 3.3 ± 1.0 | <0.001 |
| 12 hours | 2.6 ± 0.74 | 3.3 ± 0.85 | <0.001 |

### 4.6 Patients with VAS >3 at Various Intervals

**Table 8:** Number of Patients with VAS >3 at Various Intervals

| Time Interval | Group P (n=40) | Group C (n=40) |
|---|---|---|
| Up to 60 minutes | 0 (0%) | 0 (0%) |
| 90 minutes | 0 (0%) | 5 (12.5%) |
| 2 hours | 1 (2.5%) | 15 (37.5%) |
| 3 hours | 20 (50.0%) | 21 (52.5%) |
| 6 hours | 8 (20.0%) | 26 (65.0%) |
| 12 hours | 6 (15.0%) | 23 (57.5%) |

### 4.7 Rescue Analgesia and Sedation

The time to first rescue analgesia was significantly longer in Group P compared to Group C (353.7 ± 38.3 min vs 265.3 ± 39.7 min; p=0.003). Total tramadol and paracetamol requirements within 12 hours were significantly lower in Group P. Sedation was mildly higher in Group P, though RSS scores were clinically insignificant. No adverse effects were recorded in either group (Table 9).

**Table 9:** Rescue Analgesia and Sedation Data (Mean ± SD)

| Parameter | Group P (n=40) | Group C (n=40) | p-value |
|---|---|---|---|
| First rescue analgesia time (min) | 353.7 ± 38.3 | 265.3 ± 39.7 | 0.003 (<0.05) |
| Total tramadol within 12 hrs (mg) | 115 ± 36.2 | 152.5 ± 50.57 | <0.001 |
| Total paracetamol within 12 hrs (g) | 0.35 ± 0.48 | 0.90 ± 0.30 | <0.001 |
| Patients requiring paracetamol | 14 (35%) | 36 (90%) | <0.001 |
| Ramsay Sedation Score | 1.65 ± 0.58 | 1.15 ± 0.36 | <0.001 |
| Adverse effects | None | None | — |

## 5. Discussion

This prospective observational study assessed the pre-emptive analgesic effect of a single oral dose of pregabalin 150 mg on spinal anaesthesia characteristics and postoperative pain in patients undergoing lower limb orthopaedic surgery. The results demonstrate that pregabalin significantly prolongs the duration of both sensory and motor blockade without affecting the onset time, delays the need for rescue analgesia, and reduces total analgesic consumption over 12 postoperative hours.

Both groups demonstrated statistically similar demographic profiles, confirming adequate group comparability. The onset time to achieve L1 sensory level (Group P: 2.61 min; Group C: 2.83 min; p=0.06) and highest sensory level T8/T10 (Group P: 3.8 min; Group C: 4.0 min; p=0.338) were not significantly different, which is consistent with earlier work by Park et al. (2016), Patil et al. (2017), and Omara et al. (2019), all of whom reported similar onset times between pregabalin and control groups.

The two-segment regression time was significantly prolonged in Group P (93.2 min vs 83.1 min; p<0.001), and total sensory block duration was substantially extended (195.2 min vs 167.5 min; p<0.001). These findings corroborate those reported by Sebastian et al. (2016), Omara et al. (2019), and Panse et al. (2021). The proposed mechanism is that gabapentinoids, by binding to α2-δ subunits of voltage-gated calcium channels, reduce potassium-evoked excitatory transmitter release and thereby decrease postsynaptic excitability, effectively potentiating the action of intrathecal bupivacaine.

Motor block onset (Bromage grade 2) was comparable between groups (p=0.338), consistent with the literature. The time to achieve maximum motor block (Bromage grade 3) was significantly shorter in Group P (6.01 vs 7.0 min; p<0.001), suggesting that pregabalin accelerates the progression of motor block without affecting its onset. The

total duration of motor block was also significantly prolonged in Group P (183.2 vs 158.47 min; p<0.001), consistent with the results of Park et al. (2016) and Patil et al. (2017), who reported similar prolongation in motor block duration.

Mean VAS scores were significantly lower in Group P at all intervals except 3 hours (p=0.93), the exception explained by tramadol administration in control group patients by 2 hours, which transiently equalised pain scores. Notably, no patients in Group P required rescue analgesia within 90 minutes, whereas 5 patients (12.5%) in Group C had VAS >3 at this time point. At 12 hours, only 15% of Group P patients had VAS >3 compared to 57.5% in Group C, underscoring the prolonged analgesic benefit of pregabalin.

The mean time to first rescue analgesia was significantly longer in Group P (353.7 min vs 265.3 min; p=0.003), representing an approximate 88-minute delay in analgesic demand. This aligns with the half-life of pregabalin (5.5-6.7 hours) and its mechanism of action. Total tramadol consumption (115 vs 152.5 mg; p<0.001) and paracetamol consumption (0.35 vs 0.9 g; p<0.001) were significantly reduced in Group P. Only 35% of patients in Group P required second-line paracetamol rescue compared to 90% in Group C.

Mild sedation (RSS 1.65 vs 1.15; p<0.001) was noted in the pregabalin group, consistent with the known CNS effects of gabapentinoids. However, this difference, though statistically significant, was not clinically meaningful on the 1-6 RSS scale. No adverse effects including dizziness, dry mouth, nausea, vomiting, or respiratory depression were recorded in either group during the 12-hour observation period.

## 6. Conclusion

Pre-emptive administration of oral pregabalin 150 mg one hour before spinal anaesthesia significantly prolongs the duration of both sensory and motor blockade without affecting onset time. It effectively delays the first request for postoperative rescue analgesia and substantially reduces total analgesic consumption within the first 12 postoperative hours in patients undergoing lower limb orthopaedic surgery. The mild perioperative sedation observed was clinically insignificant. No adverse effects were encountered.

Pregabalin may thus serve as a valuable component of multimodal perioperative analgesia in orthopaedic practice, offering a safe, orally administered, cost-effective option to enhance the quality and duration of spinal anaesthesia and postoperative pain control. Further randomised controlled trials with larger sample sizes and extended follow-up are recommended to consolidate these findings.

## References

[1] Park M, Lee H, Jeon Y. Preoperative pregabalin prolongs duration of spinal anesthesia and reduces early postoperative pain: A double-blind, randomized clinical CONSORT study. Medicine. 2016;95(36): e4828.
[2] Miller's Anaesthesia, 9th Edition. Gropper MA, Cohen NH, eds. Chapter 45; p.1421-1435.
[3] Collins VJ. Spinal Analgesia – Physiologic effects. In: Principles of Anaesthesia. Philadelphia: Lea & Febriger. 1993; chapter 55.
[4] Cullin BF, Stoelting RK, eds. Bernards CM: Epidural and Spinal Anaesthesia. Lippincott Williams & Wilkins; 2009; chapter 24; p.928-937.
[5] Sebastian B, et al. Effect of oral pregabalin as pre-emptive analgesic in lower limb orthopaedic surgeries under spinal anaesthesia. Int J Sci Res. 2016.
[6] Patil V, et al. Effect of premedication with oral pregabalin in patients posted for lower limb orthopaedic surgeries under spinal anaesthesia. 2017.
[7] Abdou AM, et al. A comparative study of postoperative effects of two doses of pre-emptive pregabalin after tibial fracture fixation under spinal anaesthesia. 2017.
[8] Omara AF, et al. Effect of pre-emptive oral pregabalin on the postoperative spinal analgesia in patients presented for orthopaedic surgeries. 2019.
[9] Sahni G, et al. The role of preoperative oral pregabalin on acute postoperative pain after orthopaedic lower limb surgeries. 2019.
[10] Kavak Akelma F, et al. The effects of pregabalin and adductor canal block on postoperative pain in arthroscopic anterior cruciate ligament reconstruction. 2019.
[11] Panse NA, et al. Comparative evaluation of two different doses of pre-emptive oral pregabalin on duration of spinal anaesthesia and postoperative pain. 2021.
[12] Mishra A, et al. Perioperative anxiolysis and analgesic effect after premedication with melatonin and pregabalin in total hip arthroplasty under spinal anaesthesia. 2023.
[13] Bafna U, et al. Comparison of effect of pre-emptive use of oral gabapentin and pregabalin for acute postoperative pain after elective gynaecological surgery under spinal anaesthesia. 2014.