



A Randomized Comparative Study of Oral Pregabalin 150 mg and 300 mg on Postoperative Analgesia Following Spinal Anesthesia for Lower Abdominal Surgeries

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KEYWORDS

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ABSTRACT:

Background: Postoperative pain following spinal anesthesia can delay recovery and increase patient discomfort. Pregabalin, a gamma-aminobutyric acid analogue, has been shown to enhance postoperative analgesia when used as a premedicant. However, the optimal dose for achieving effective analgesia with minimal adverse effects remains uncertain.

Objectives: To compare the efficacy of oral pregabalin 150 mg and 300 mg in prolonging postoperative analgesia following spinal anesthesia in patients undergoing lower abdominal surgeries.

Methods: This randomized, double-blind, controlled study included 90 patients aged 20-60 years (ASA I-II) undergoing elective lower abdominal surgeries under spinal anesthesia. Patients were randomly allocated into three groups: Group C (placebo), Group P150 (pregabalin 150 mg), and Group P300 (pregabalin 300 mg). The study drug was administered orally one hour before spinal anesthesia. All patients received 3 mL of 0.5% hyperbaric bupivacaine intrathecally. Parameters assessed included onset and duration of sensory and motor block, duration of postoperative analgesia, sedation scores, and hemodynamic variables.

Results: The duration of postoperative analgesia was significantly prolonged in Group P150 (326.83 ± 29.49 min) and Group P300 (669.00 ± 34.87 min) compared to Group C (183.66 ± 19.02 min) ($p < 0.001$). Time to two-segment regression and duration of motor block were also significantly longer in pregabalin groups, with the greatest effect observed in the 300 mg group. Sedation scores were higher in pregabalin-treated patients but remained within clinically acceptable limits. No significant hemodynamic instability or serious adverse effects were observed.

Conclusion: Oral pregabalin administered preoperatively significantly enhances postoperative analgesia in patients undergoing lower abdominal surgeries under spinal anesthesia. A dose of 300 mg provides superior analgesic efficacy compared to 150 mg, with acceptable sedation and safety profiles. Pregabalin can be considered a useful adjunct in multimodal analgesia strategies.

INTRODUCTION

Spinal anesthesia is one of the most commonly employed regional anesthetic techniques for lower abdominal and lower limb surgeries owing to its rapid onset, reliability, cost-effectiveness, and minimal airway manipulation. It

provides profound sensory and motor blockade with excellent intraoperative conditions while allowing patients to remain conscious. However, the relatively limited duration of postoperative analgesia following subarachnoid block remains a significant limitation,



often necessitating early rescue analgesics, which may be associated with undesirable side effects.^[1]

The management of postoperative pain is a critical component of perioperative care, as inadequate analgesia can result in sympathetic overactivity, delayed mobilization, increased morbidity, prolonged hospital stay, and development of chronic pain syndromes. Central sensitization caused by persistent nociceptive input may lead to exaggerated pain responses and poor functional recovery. Therefore, extending postoperative analgesia without increasing adverse effects has become a major goal in modern anesthetic practice.^[2]

Various adjuvants such as opioids, clonidine, neostigmine, ketamine, and benzodiazepines have been used intrathecally or systemically to enhance the quality and duration of spinal anesthesia. Although intrathecal opioids are effective, they are associated with side effects such as pruritus, nausea, vomiting, urinary retention, and respiratory depression. Hence, attention has shifted toward non-opioid adjuncts with a more favorable safety profile.^[3]

Pregabalin, a structural analogue of gamma-aminobutyric acid (GABA), exerts its analgesic action by binding to the $\alpha 2\text{-}\delta$ subunit of voltage-gated calcium channels, thereby reducing excitatory neurotransmitter release including glutamate, substance P, and norepinephrine. It possesses analgesic, anxiolytic, and anticonvulsant properties and demonstrates predictable pharmacokinetics with high oral bioavailability and rapid absorption. Unlike opioids, pregabalin does not act on opioid receptors and therefore avoids opioid-related adverse effects.^[4]

AIM

To compare the effect of oral pregabalin 150 mg and 300 mg on postoperative analgesia following spinal anesthesia in patients undergoing lower abdominal surgeries.

OBJECTIVES

1. To compare the duration and quality of postoperative analgesia following preoperative administration of oral pregabalin 150 mg and 300 mg.

2. To evaluate the effect of pregabalin on sensory and motor block characteristics and sedation levels.
3. To assess hemodynamic stability and incidence of adverse effects in both study groups.

MATERIALS AND METHODS

Source of Data

Patients undergoing elective lower abdominal surgeries under spinal anesthesia at a tertiary care teaching hospital were included in the study after obtaining written informed consent.

Study Design

Prospective, randomized, double-blind, placebo-controlled comparative study.

Study Location

Department of Anaesthesiology, tertiary care teaching hospital.

Study Duration

The study was conducted over a period of 12 months.

Sample Size

A total of 90 patients were enrolled and randomly allocated into three equal groups:

- **Group C (Control):** Placebo (n = 30)
- **Group P150:** Pregabalin 150 mg (n = 30)
- **Group P300:** Pregabalin 300 mg (n = 30)

Inclusion Criteria

- Patients aged 20-60 years
- ASA physical status I and II
- Scheduled for elective lower abdominal surgeries under spinal anesthesia
- Provided written informed consent

Exclusion Criteria

- ASA physical status \geq III
- Pregnancy or lactation
- Known hypersensitivity to pregabalin
- BMI > 28 kg/m²



- Chronic analgesic or sedative use
- Neurological or psychiatric disorders
- Renal or hepatic impairment
- Emergency surgeries

Procedure and Methodology

All patients underwent pre-anesthetic evaluation on the day prior to surgery and received oral alprazolam 0.5 mg and ranitidine 150 mg the night before surgery. On the day of surgery, baseline vitals were recorded. Patients received either placebo, pregabalin 150 mg, or pregabalin 300 mg orally one hour prior to spinal anesthesia according to random allocation.

After standard monitoring and intravenous access, spinal anesthesia was administered at the L3-L4 interspace using 3 mL of 0.5% hyperbaric bupivacaine with a 25G Quincke needle. Sensory and motor block characteristics were assessed using pin-prick method and modified Bromage scale, respectively. Hemodynamic parameters were recorded at regular intervals.

OBSERVATION AND RESULTS

Table 1: Comparison of Baseline Demographic Characteristics Among Study Groups

Variable	Group C (n=30)	Group P150 (n=30)	Group P300 (n=30)	Test of Significance	Effect Size (95% CI)	p-value
Age (years)	39.17 ± 10.00	36.60 ± 11.00	36.36 ± 10.76	One-way ANOVA	$\eta^2 = 0.02$ (-3.1 to 6.8)	0.512
Sex (M/F)	18/12	17/13	16/14	$\chi^2 = 0.22$		0.896
Height (cm)	156.83 ± 7.95	158.77 ± 7.28	159.00 ± 6.71	One-way ANOVA	$\eta^2 = 0.04$ (-2.3 to 4.1)	0.384
Weight (kg)	57.70 ± 8.35	60.20 ± 5.96	58.27 ± 7.70	One-way ANOVA	$\eta^2 = 0.06$ (-2.1 to 4.8)	0.291
BMI (kg/m ²)	23.69 ± 2.26	23.93 ± 2.32	22.78 ± 2.18	One-way ANOVA	$\eta^2 = 0.05$ (-1.1 to 1.6)	0.417

Table 1 compares the baseline demographic parameters among the three study groups: Control (Group C), Pregabalin 150 mg (Group P150), and Pregabalin 300 mg (Group P300). The mean age of participants was comparable across all groups, with values of 39.17 ± 10.00 years in Group C, 36.60 ± 11.00 years in Group P150, and 36.36 ± 10.76 years in Group P300. The

Postoperative pain was assessed using the Visual Analog Scale (VAS). Time to first rescue analgesic was recorded as the duration of postoperative analgesia. Sedation was evaluated using the Ramsay Sedation Score. Any adverse effects such as hypotension, bradycardia, nausea, vomiting, or dizziness were noted.

Sample Processing

All observations were recorded in a structured proforma and entered into a computerized database.

Statistical Methods

Data were analyzed using SPSS software (version 17). Continuous variables were expressed as mean ± standard deviation and categorical variables as frequencies and percentages. Intergroup comparisons were made using one-way ANOVA for continuous variables and Chi-square test for categorical variables. A p-value <0.05 was considered statistically significant.

difference was not statistically significant ($p = 0.512$), indicating effective randomization. Gender distribution was also comparable, with no significant difference observed between groups ($p = 0.896$).

Similarly, anthropometric parameters including height, weight, and body mass index (BMI) showed no



statistically significant differences across the three groups. Mean height ranged from 156.83 ± 7.95 cm to 159.00 ± 6.71 cm ($p = 0.384$), while mean body weight

ranged from 57.70 ± 8.35 kg to 60.20 ± 5.96 kg ($p = 0.291$). Mean BMI values were also comparable ($p = 0.417$).

Table 2: Comparison of Postoperative Analgesic Outcomes

Parameter	Group C (n=30)	Group P150 (n=30)	Group P300 (n=30)	Test of Significance	Effect Size (95% CI)	p-value
Duration of analgesia (min)	183.66 ± 19.02	326.83 ± 29.49	669.00 ± 34.87	One-way ANOVA	$\eta^2 = 0.89$ (Δ C-P300: 450-520)	<0.001*
Time to 2-segment regression (min)	67.83 ± 10.31	86.83 ± 12.69	121.53 ± 10.36	One-way ANOVA	$\eta^2 = 0.81$ (Δ C-P300: 45-58)	<0.001*
Total duration of motor block (min)	148.00 ± 15.40	208.66 ± 27.38	380.00 ± 54.89	One-way ANOVA	$\eta^2 = 0.87$ (Δ C-P300: 205-255)	<0.001*

Table 2 illustrates the comparison of postoperative analgesic parameters among the three study groups. The duration of postoperative analgesia showed a highly significant increase with increasing doses of pregabalin. Group C demonstrated a mean analgesia duration of 183.66 ± 19.02 minutes, whereas Group P150 and Group P300 exhibited significantly prolonged durations of 326.83 ± 29.49 minutes and 669.00 ± 34.87 minutes, respectively ($p < 0.001$). The large effect size ($\eta^2 = 0.89$) indicates a strong dose-dependent analgesic effect.

Similarly, the time to two-segment regression was significantly prolonged in the pregabalin groups compared to control. Group C showed a mean regression time of 67.83 ± 10.31 minutes, which increased to 86.83 ± 12.69 minutes in Group P150 and further to 121.53 ± 10.36 minutes in Group P300 ($p < 0.001$).

The total duration of motor blockade also followed a similar pattern, with the shortest duration observed in Group C (148.00 ± 15.40 minutes), followed by Group P150 (208.66 ± 27.38 minutes), and the longest in Group P300 (380.00 ± 54.89 minutes).

Table 3: Sensory-Motor Block Characteristics and Sedation Profile

Parameter	Group C (n=30)	Group P150 (n=30)	Group P300 (n=30)	Test	Effect Size (95% CI)	p-value
Onset of sensory block (min)	2.56 ± 0.45	2.60 ± 0.63	2.60 ± 0.61	ANOVA	$\eta^2 = 0.01$	0.91
Onset of motor block (min)	3.08 ± 0.45	2.81 ± 0.43	2.78 ± 0.43	ANOVA	$\eta^2 = 0.12$	0.021*
Time to max sensory block (min)	5.01 ± 0.60	5.00 ± 0.50	5.10 ± 0.50	ANOVA	$\eta^2 = 0.01$	0.74
Time to max motor block (min)	6.46 ± 0.86	6.26 ± 0.69	6.33 ± 0.84	ANOVA	$\eta^2 = 0.02$	0.63
Bromage 3-4 n (%)	13/17	13/17	7/23	χ^2		0.11
Ramsay Sedation Score ≥ 3 n (%)	0 (0%)	24 (80%)	27 (90%)			



Table 3 presents the comparison of sensory and motor block characteristics and sedation levels among the three groups. The onset of sensory block was comparable across groups, with no statistically significant difference ($p = 0.91$). Similarly, the time required to achieve maximum sensory block did not differ significantly between groups ($p = 0.74$), indicating that pregabalin did not influence the onset or peak sensory blockade.

However, the onset of motor block occurred significantly earlier in the pregabalin groups compared to the control group ($p = 0.021$), although the time to reach maximum motor blockade did not differ significantly ($p = 0.63$). The distribution of Bromage scores (3-4) was comparable across groups, suggesting no clinically meaningful difference in the depth of motor block.

A significant difference was observed in sedation levels. None of the patients in the control group had a Ramsay Sedation Score ≥ 3 , whereas 80% of patients in Group P150 and 90% in Group P300 achieved sedation scores ≥ 3 , indicating increased sedation with pregabalin use.

DISCUSSION

Baseline Demographic Characteristics: The baseline demographic parameters in the present study were comparable across the three study groups (Control, Pregabalin 150 mg, and Pregabalin 300 mg), as evidenced by the absence of statistically significant differences in age, sex distribution, height, weight, and body mass index ($p > 0.05$). This homogeneity indicates successful randomization and minimizes confounding variables that could influence postoperative analgesic outcomes. Similar demographic comparability has been reported in previous studies evaluating pregabalin as a premedicant in spinal anesthesia, including those by da Silva FG et al. (2023)^[5]. Maintaining equivalent baseline characteristics strengthens the internal validity of the study and ensures that observed differences in analgesic outcomes are attributable primarily to the pharmacological effect of pregabalin rather than patient-related confounders.

Postoperative Analgesic Outcomes: The present study demonstrated a clear dose-dependent improvement in postoperative analgesia with oral pregabalin. The duration of analgesia increased significantly from 183.66 ± 19.02 minutes in the control group to 326.83 ± 29.49 minutes in the P150 group and further to 669.00 ± 34.87

minutes in the P300 group ($p < 0.001$). This substantial prolongation of analgesia supports the analgesic efficacy of pregabalin as a preoperative adjuvant.

These findings are consistent with the results reported by Mohan SK et al. (2023)^[6], who observed significantly prolonged analgesia with pregabalin 300 mg compared to placebo. Similarly Panse NA et al. (2021)^[7] demonstrated a dose-dependent increase in postoperative analgesia with pregabalin, and Sharma A et al. (2020)^[8] reported reduced analgesic consumption and prolonged pain-free intervals in patients receiving pregabalin premedication.

The time to two-segment regression was also significantly prolonged in the pregabalin groups, with the longest duration observed in the 300 mg group. This suggests a sustained sensory blockade and delayed regression of spinal anesthesia. Comparable findings were reported by Abdelsami Aiad A et al. (2024)^[9], who demonstrated prolonged sensory regression with pregabalin, though the magnitude was lower in their study possibly due to differences in dosing and timing of administration.

Similarly, the total duration of motor block was significantly prolonged in a dose-dependent manner, with the longest duration observed in the 300 mg group. These findings align with studies by da Silva FG et al. (2023)^[5], who reported prolonged motor blockade with higher doses of pregabalin without clinically significant motor impairment.

Sensory-Motor Block Characteristics and Sedation Profile: The onset of sensory block and time to achieve maximum sensory block were comparable among all three groups, indicating that pregabalin does not influence the onset kinetics of spinal anesthesia. These findings are consistent with observations by Lakshminarasimhaiah G et al. (2023)^[3], who also reported no significant effect of pregabalin on sensory onset.

However, the onset of motor block was significantly faster in both pregabalin groups compared to control, suggesting a facilitative effect of pregabalin on motor blockade onset. Despite this, the time to maximum motor block and overall quality of motor block (Bromage scale) did not differ significantly, indicating that pregabalin enhances onset without exaggerating motor impairment.



Sedation scores demonstrated a clear dose-dependent increase, with 80% of patients in the P150 group and 90% in the P300 group achieving Ramsay Sedation Scores ≥ 3 , compared to none in the control group. Importantly, none of the patients experienced excessive or clinically concerning sedation. These findings are in agreement with those of Hossain SM et al. (2023)^[10], who reported increased sedation with pregabalin without respiratory compromise.

CONCLUSION

This randomized comparative study demonstrates that oral pregabalin administered preoperatively significantly enhances postoperative analgesia following spinal anesthesia for lower abdominal surgeries. Both 150 mg and 300 mg doses of pregabalin effectively prolonged the duration of analgesia, delayed two-segment regression, and increased the duration of motor blockade when compared to the control group. However, the magnitude of analgesic prolongation was dose dependent, with the 300 mg dose producing significantly longer analgesia and motor block than the 150 mg dose.

Pregabalin also contributed to improved perioperative comfort by providing mild to moderate sedation without causing excessive sedation, respiratory depression, or hemodynamic instability. Importantly, sensory block onset and maximum sensory level remained unaffected, indicating that pregabalin does not interfere with the quality of spinal anesthesia but enhances its postoperative efficacy.

Overall, oral pregabalin particularly at a dose of 300 mg can be considered a safe and effective adjuvant to spinal anesthesia for improving postoperative analgesia in patients undergoing lower abdominal surgeries. Its use may reduce the need for additional postoperative analgesics and improve patient comfort without significant adverse effects.

LIMITATIONS OF THE STUDY

1. The study was conducted at a single center with a relatively small sample size, which may limit the generalizability of the findings.
2. Only two doses of pregabalin (150 mg and 300 mg) were evaluated; lower or intermediate doses were not assessed.

3. Long-term postoperative outcomes such as chronic pain development or functional recovery were not evaluated.
4. Sedation was assessed using the Ramsay Sedation Scale, which is subjective and observer-dependent.
5. Plasma concentrations of pregabalin were not measured, preventing correlation between serum levels and clinical effects.
6. The study population included only ASA I and II patients; results may not be applicable to higher-risk patients.
7. Postoperative analgesic consumption beyond the first rescue dose was not quantitatively assessed.

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