Original Article

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Anaesthesia Section

Comparison of the Effect of Two Different Doses of Oral Pregabalin in Reducing Postoperative Analgesia in Patients Receiving Neuraxial Anaesthesia for Surgical Procedures: A Randomised Controlled Trial

NANDITHA PADIKKASU[1], KARTHIK KRISHNAMOORTHY[2], VISHAK MANOJ BHASKAR[3]

ABSTRACT

Introduction: Effective postoperative pain management is vital for patient recovery and comfort. Due to the side effects associated with opioids, alternative strategies such as Pregabalin are being explored. As a Gamma-aminobutyric Acid (GABA) analogue, Pregabalin may reduce pain and analgesic requirements by modulating central sensitisation. The present study evaluates the impact of preoperative oral Pregabalin on enhancing subarachnoid block, prolonging postoperative analgesia and improving recovery in patients undergoing neuraxial surgeries.

Aim: To evaluate the efficacy of oral Pregabalin (150 mg and 300 mg) compared with a placebo in reducing postoperative pain in patients undergoing surgical procedures under spinal anaesthesia.

Materials and Methods: The present double-blinded randomised controlled trial was conducted in the Department of Anaesthesiology at SRM Medical College Hospital and Research Centre, Chennai, Tamil Nadu, India, from September 2024 to February 2025 over a duration of six months. After obtaining written consent, 90 patients undergoing surgery under neuraxial blockade were recruited and randomised into three groups. The study drugs were administered one hour before surgery as follows: Group C (Placebo drug), Group P1 (T. Pregabalin 150 mg), Group P2 (T. Pregabalin 300 mg). The Ramsay Sedation Scale was used to assess sedation levels before and after the procedure. Pain intensity was assessed using the Visual Analogue Scale (VAS). Statistical analysis was performed using Statistical Packages of Social Sciences (SPSS) software (version 26.0), with a significance level set at 0.05.

Results: There was no statistically significant difference in the demographic characteristics of the study participants, such as age, height and weight (Mean=40.01 years, 166.42 cm, 67.3 kg; p=0.537, 0.454, 0.349, respectively). The time to first analgesic requirement after spinal anaesthesia was significantly longer in patients who received pregabalin compared with those who received the placebo (Mean=105.83, 120.33, 126.67 minutes, respectively; p<0.001). Corresponding VAS scores at the time analgesia was administered were also statistically significant (Mean=4.04, 3.08, 2.99, respectively; p<0.001).

Conclusion: Compared with placebo, preoperative oral pregabalin was effective in enhancing sedation, delaying the onset of postoperative pain and reducing the need for early rescue analgesics.

Keywords: Central nervous system sensitisation, Multimodal pain, Opioid, Pain management, Patient comfort

INTRODUCTION

Every surgical patient requires adequate postoperative pain management. Opioids and other strong analgesics are commonly used to treat postoperative pain and maintain patient comfort; however, their use at higher doses is associated with a range of adverse effects. Pregabalin, a Gamma-aminobutyric Acid (GABA) analogue, is known for its antinociceptive and antihyperalgesic properties. Central neuronal sensitisation, which contributes to amplified postoperative pain, may be reduced through preemptive administration of Pregabalin. This may subsequently decrease the need for postoperative analgesics and improve the quality of hospital stay [1,2].

Effective control of postoperative pain remains a crucial component of perioperative care. Inadequate pain management not only causes significant discomfort but also delays ambulation, increases the risk of thromboembolic complications, prolongs hospitalisation and may contribute to the development of chronic postsurgical pain syndromes [3,4]. Although opioids remain widely used for moderate to severe postoperative pain, their adverse effects—such as nausea, vomiting, pruritus, sedation, constipation, respiratory depression and potential dependence—highlight the need for alternative or adjunctive strategies that reduce opioid consumption [5,6].

Multimodal analgesia, which involves using multiple pharmacological agents and techniques targeting different pain pathways, has gained widespread clinical acceptance. Pregabalin, a structural analogue of GABA, binds selectively to the $\alpha 2\delta$ subunit of voltage-gated calcium channels, inhibiting the release of excitatory neurotransmitters and attenuating neuronal hyperexcitability triggered by surgical trauma [7,8]. Its antinociceptive and antihyperalgesic effects make it a promising agent for preemptive analgesia [9].

Preemptive analgesia aims to administer analgesic medications before the onset of nociceptive stimulation to prevent central sensitisation—a process in which the central nervous system shows an exaggerated response to peripheral stimuli. By reducing central sensitisation, preoperative pregabalin may decrease postoperative pain intensity and reduce opioid requirements [8,9]. Numerous clinical trials across various surgical specialties have demonstrated

beneficial effects of pregabalin on postoperative pain control, patient satisfaction and opioid sparing [10,11].

However, the optimal dosing, timing and balance between analgesic efficacy and adverse effects (such as sedation, dizziness and visual disturbances) remain areas of ongoing investigation, with previous studies reporting conflicting results. Moreover, although Pregabalin is well established for chronic pain management, its role in acute postoperative pain—particularly in surgeries performed under spinal anaesthesia—requires further evaluation [10].

The present study focussed to address these gaps by assessing the analgesic efficacy and safety of preoperative pregabalin in terms of opioid-sparing effects, pain intensity, sedation levels and patient comfort using validated assessment scales. The findings may contribute to improved postoperative care and reduced reliance on opioids.

The present study aimed to evaluate the efficacy of preoperative oral Pregabalin in improving the quality and duration of spinal anaesthesia, reducing postoperative analgesic consumption and enhancing patient comfort. These outcomes were assessed using the Visual Analogue Scale (VAS) for pain and the Ramsay Sedation Scale for sedation levels in patients undergoing surgery under subarachnoid block. The primary objective of present study was to compare the duration of postoperative analgesia among the three groups using the VAS score. The secondary objective was to assess sedation levels from one hour after premedication upto six hours post-surgery using the Ramsay Sedation Scale.

MATERIALS AND METHODS

The present double-blinded randomised controlled trial was conducted in the Department of Anaesthesiology at SRM Medical College Hospital and Research Centre, Chennai, Tamil Nadu, India after obtaining approval from the Institutional Ethics Committee (SRMIEC-ST0724-1518) and registration with the Clinical Trials Registry-India (CTRI/2024/10/075846). The study was carried out over six months, from September 2024 to February 2025.

Sample size calculation: A total of 90 patients scheduled for elective surgical procedures under neuraxial blockade were randomly selected. The sample size was calculated based on the study by Kohli M et al., using a significance level of 0.05 and a power of 80% for their primary objective, which compared VAS scores for anxiety [10].

$$\text{Formula: } n = \left(\frac{(1+\sqrt{g-1})(Z_{\alpha/2}+Z_{1-\beta})^2}{d^2}\right) + \frac{(Z^2_{\alpha/2}\sqrt{g-1})}{2(1+\sqrt{g-1})}$$

The calculated sample size was 89; hence, for improved statistical analysis, a final sample size of 90 was selected, with 30 patients in each group.

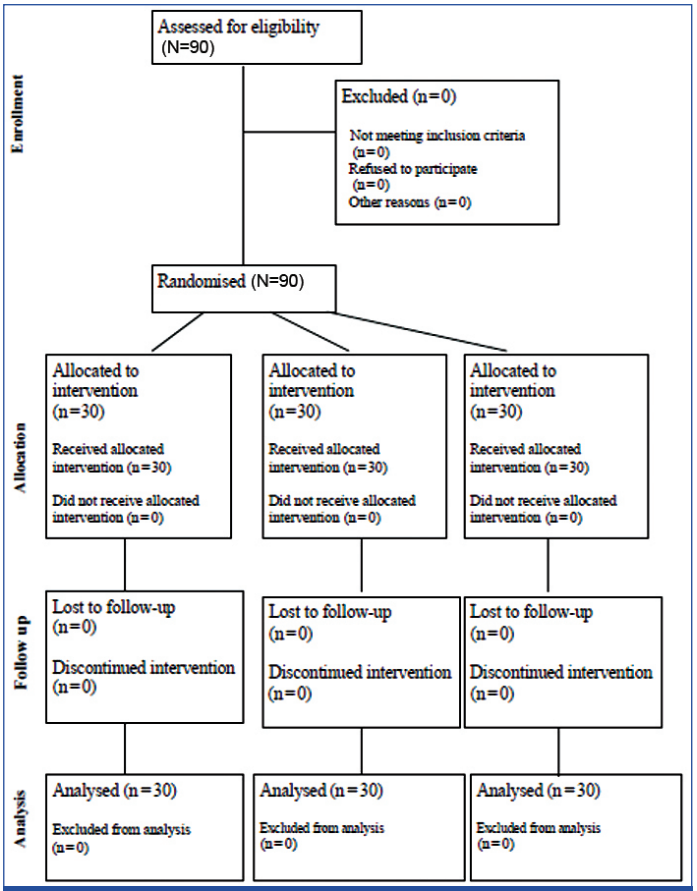
Inclusion criteria: Patients aged 18–65 years, classified as American Soceity of Anaesthesiology (ASA) physical status I or II, with a Body Mass Index (BMI) less than 24.9 kg/m^2 and scheduled for surgeries under neuraxial anaesthesia with an expected duration of less than two hours.

Exclusion criteria: Patient refusal, spinal deformities, raised intracranial pressure, local infection at the site of spinal anaesthesia and coagulation disorders.

Study Procedure

This double-blinded study ensured that both the participants and the anaesthesiologist administering the spinal anaesthesia were unaware of the patient's group allocation, thereby minimising observer bias.

Patients were allocated into Group C, Group P1 and Group P2 using a computer-generated random sequence [Table/Fig-1]. Group assignments were placed in sealed envelopes and opened by a senior anaesthesiologist not involved in the study.



[Table/Fig-1]: Consolidated Standards of Reporting Trails (CONSORT) diagram.

Group C: Placebo capsule containing only inert excipient (microcrystalline cellulose), administered orally one hour before neuraxial blockade.

Group P1: T. Pregabalin 150 mg orally, one hour before neuraxial blockade.

Group P2: T. Pregabalin 300 mg orally, one hour before neuraxial blockade.

The dosing regimen followed the methodology described by Kohli M et al., to maintain consistency [10].

Routine preoperative protocol was followed the night before surgery, and adequate fasting was ensured as per ASA guidelines. Premedication included T. Alprazolam 0.25 mg, T. Ranitidine 150 mg and T. Metoclopramide 10 mg on the previous night, and T. Ranitidine 150 mg and T. Metoclopramide 10 mg on the morning of surgery, administered two hours before transfer to the operating theatre.

On the day of surgery, one hour before being shifted to the operating theatre, all patients received their assigned study medication. After one hour, sedation levels were assessed using the Ramsay Sedation Scale.

Patients were then shifted to the operating theatre, where routine monitors were attached, including Non Invasive Blood Pressure (NIBP), pulse oximetry, Electrocardiogram (ECG) and temperature monitoring.

After ensuring strict asepsis, spinal anaesthesia was administered using a 25-gauge Quincke needle at the L3–L4 interspace. All patients received 3 mL of 0.5% hyperbaric Inj. Bupivacaine. Once adequate sensory and motor blockade was confirmed, surgery commenced.

Following the procedure, sedation levels were reassessed using the Ramsay Sedation Scale. Patients were monitored for six hours postoperatively at 30-minute intervals for sedation assessment.

The time to first analgesic requirement was recorded. Pain intensity at that time was assessed using the VAS immediately before administering the first dose of rescue analgesia.

STATISTICAL ANALYSIS

Data were entered in an MS Excel spreadsheet (2010), and statistical analysis was performed using SPSS software (version 26.0). The readings were compared using the Analysis of Variance (ANOVA) test. Post-hoc analysis among the three groups was performed using Tukey's HSD (Honestly Significant Difference) HSD test. A p-value <0.05 was considered statistically significant.

RESULTS

There was no statistically significant difference among the three groups with respect to age, gender, height or weight [Table/Fig-2].

Demographic parameters	Group C (Mean±SD)	Group P1 (Mean±SD)	Group P2 (Mean±SD)	p-value
Age (in years)	42.10±11.27	39.55±14.12	38.40±13.68	0.537
Height (cm)	165.67±6.86	167.3±5.8	166.3±5.05	0.454
Weight (kg)	69.23±8.29	65.7±9.86	66.97±9.99	0.349
Gender (Male/Female)	20/10	25/5	19/11	0.32
ASA (I/II)	18/12	20/10	17/13	0.78

[Table/Fig-2]: Demographic data across the three groups.
(Age, height and weight were calculated by means of One-way ANOVA test, sex and American Soceity of Anaesthesiology (ASA) status by means of Chi-square test)

The difference in the duration to first analgesic requirement among the groups has been depicted in [Table/Fig-3]. Patients who received the placebo reported pain at an average of 105 minutes after spinal anaesthesia. Patients who received T. Pregabalin 150 mg reported pain at an average of 120 minutes, while those receiving T. Pregabalin 300 mg reported pain at an average of 126 minutes post-spinal anaesthesia. These differences were statistically significant.

Groups	Group C (Mean±SD)	Group P1 (Mean±SD)	Group P2 (Mean±SD)	p-value
Time to requirement of first dose of analgesia (min)	105.83±3.9	120.33±4.94	126.67±7.47	<0.001
VAS score	4.04±0.86	3.08±0.68	2.99±0.65	<0.001

[Table/Fig-3]: Data collected across the three groups using one-way ANOVA test.

At the onset of pain, VAS scores were recorded before administering rescue analgesia. Patients with VAS ≤4 received Inj. Paracetamol 1 g intravenous (i.v.), whereas those with VAS >4 received Inj. Tramadol 100 mg in 100 mL NS. These values were also statistically significant.

Post-hoc analysis (Tukey's HSD) showed that both Group P1 and Group P2 had a significantly longer duration before requiring the first dose of analgesia compared with Group C (p<0.001 for both). A significant difference was also noted between Groups P1 and P2 (p<0.001). Similarly, VAS scores were significantly lower in Groups P1 and P2 compared with Group C (p<0.001 for both) [Table/Fig-3,4].

Measure	Comparison	p-value
Time to analgesia	C vs P1	<0.001
Time to analgesia	C vs P2	<0.001
Time to analgesia	P1 vs P2	<0.001
VAS score	C vs P1	<0.001
VAS score	C vs P2	<0.001
VAS score	P1 vs P2	0.667

[Table/Fig-4]: Post-hoc analysis data amongst the three groups using Turkey's HSD.

The variation in sedation levels of patients has been depicted in [Table/Fig-5]. Sedation was assessed using the Ramsay Sedation Scale one hour after administering T. Pregabalin and every 30 minutes thereafter for six hours. Deep sedation was observed in patients receiving T. Pregabalin 300 mg, while those receiving T. Pregabalin 150 mg exhibited mild sedation compared with the placebo group.

Sedation scale (time)	Group C (Mean±SD)	Group P1 (Mean±SD)	Group P2 (Mean±SD)	ANOVA p-value
1 hr	1.00±0.20	2.87±0.30	3.08±0.25	<0.001
1.5 hr	2.06±0.20	3.05±0.30	3.95±0.25	<0.001
2 hr	1.98±0.20	3.21±0.30	4.00±0.25	<0.001
2.5 hr	1.68±0.20	3.86±0.30	4.05±0.25	<0.001
3 hr	1.47±0.20	3.67±0.30	4.10±0.25	<0.001
3.5 hr	1.53±0.20	3.72±0.30	3.98±0.25	<0.001
4 hr	1.39±0.20	3.59±0.30	3.85±0.25	<0.001
4.5 hr	1.41±0.20	3.42±0.30	3.50±0.25	<0.001
5 hr	1.28±0.20	2.98±0.30	3.21±0.25	<0.001
5.5 hr	1.37±0.20	2.84±0.30	3.02±0.25	<0.001
6 hr	1.25±0.20	2.01±0.30	2.87±0.25	<0.001

[Table/Fig-5]: Sedation levels across the three groups using one-way ANOVA test.

The post-hoc analysis demonstrated a clear gradation in sedation: the control group showed the lowest scores, Group P1 showed intermediate sedation and Group P2 showed the deepest sedation has been depicted in [Table/Fig-6]. Both pregabalin groups had significantly greater sedation than the control group, and Group P2 consistently showed higher sedation than Group P1. These findings indicate that while both doses are effective, Group P2 may be preferable when deeper sedation is desired.

Time	Group	Group	p-value
1 hr	Group C	Group P1	<0.001
1 hr	Group C	Group P2	<0.001
1 hr	Group P1	Group P2	<0.001
1.5 hr	Group C	Group P1	<0.001
1.5 hr	Group C	Group P2	<0.001
1.5 hr	Group P1	Group P2	<0.001
2 hr	Group C	Group P1	<0.001
2 hr	Group C	Group P2	<0.001
2 hr	Group P1	Group P2	<0.001
2.5 hr	Group C	Group P1	<0.001
2.5 hr	Group C	Group P2	<0.001
2.5 hr	Group P1	Group P2	<0.001
3 hr	Group C	Group P1	<0.001
3 hr	Group C	Group P2	<0.001
3 hr	Group P1	Group P2	<0.001
3.5 hr	Group C	Group P1	<0.001
3.5 hr	Group C	Group P2	<0.001
3.5 hr	Group P1	Group P2	<0.001
4 hr	Group C	Group P1	<0.001
4 hr	Group C	Group P2	<0.001
4 hr	Group P1	Group P2	<0.001
4.5 hr	Group C	Group P1	<0.001
4.5 hr	Group C	Group P2	<0.001
4.5 hr	Group P1	Group P2	<0.001
5 hr	Group C	Group P1	<0.001
5 hr	Group C	Group P2	<0.001
5 hr	Group P1	Group P2	<0.001
5.5 hr	Group C	Group P1	<0.001
5.5 hr	Group C	Group P2	<0.001
5.5 hr	Group P1	Group P2	0.1188
6 hr	Group C	Group P1	<0.001
6 hr	Group C	Group P2	<0.001
6 hr	Group P1	Group P2	<0.001

[Table/Fig-6]: Post-hoc analysis data of level of sedation amongst the three groups using Turkey's HSD.

Intraoperative haemodynamic variations among all patients has been depicted in [Table/Fig-7]. These variations were not statistically significant.

Parameters	Time	Group C (Mean±SD)	Group P1 (Mean±SD)	Group P2 (Mean±SD)	p-value
SBP	15 min	120±7	124±7	123±7	0.656
SBP	30 min	121±6	122±6	118±6	0.627
SBP	45 min	123±6	118±6	116±6	0.668
SBP	1 hr	120±7	117±7	114±7	0.345
SBP	1 hr 15 min	118±4	119±4	112±4	0.626
SBP	1 hr 30 min	122±4	120±4	110±4	0.258
SBP	1 hr 45 min	123±4	115±4	111±4	0.72
SBP	2 hr	120±7	112±7	113±7	0.305
DBP	15 min	80±3	78±3	78±3	0.656
DBP	30 min	81±3	77±3	74±3	0.627
DBP	45 min	79±4	79±4	76±4	0.668
DBP	1 hr	82±5	80±5	78±5	0.345
DBP	1 hr 15 min	78±5	81±5	80±5	0.626
DBP	1 hr 30 min	80±4	80±4	79±4	0.258
DBP	1 hr 45 min	81±6	79±6	78±6	0.72
DBP	2 hr	79±2	78±2	76±2	0.305
HR	15 min	88±5	86±5	84±5	0.656
HR	30 min	86±3	78±3	77±3	0.627
HR	45 min	84±9	77±9	72±9	0.668
HR	1 hr	83±5	74±5	70±5	0.345
HR	1 hr 15 min	82±9	76±9	74±9	0.626
HR	1 hr 30 min	84±8	73±8	73±8	0.258
HR	1 hr 45 min	83±9	72±9	75±9	0.72
HR	2 hr	86±4	76±4	72±4	0.305

[Table/Fig-7]: Haemodynamic parameters across the three groups using one-way ANOVA test.
SBP: Systolic blood pressure in mmHg; DBP: Diastolic blood pressure in mmHg; HR: Heart rate in beats per minute

DISCUSSION

Every patient undergoing surgery requires effective postoperative pain management. Opioids and other potent analgesics are commonly used, but their higher doses are associated with adverse effects such as respiratory depression, nausea and excessive sedation. Pregabalin, a gamma-aminobutyric acid analogue, possesses antinociceptive and antihyperalgesic properties that may help attenuate central neuronal sensitisation—an amplifying mechanism that contributes to postoperative pain [12,13]. Consequently, preemptive administration of pregabalin is hypothesised to delay the onset of postoperative pain, reduce analgesic requirements and improve the overall quality of recovery [14].

The present study evaluated the effectiveness of oral pregabalin in prolonging postoperative analgesia, reducing the need for early rescue analgesics and improving recovery quality. Assessment was based on pain scores using the VAS and sedation levels using the Ramsay Sedation Scale.

In present study, deeper sedation levels were observed in patients administered T. Pregabalin 300 mg compared with the other two groups. Additionally, patients who did not receive pregabalin required the first dose of analgesia sooner than those premedicated with pregabalin.

The present findings align with the results of Kohli M et al., who compared the time to first rescue analgesia and sedation among three groups: placebo, T. Pregabalin 150 mg and T. Pregabalin 300 mg [10]. Their study reported significantly higher sedation in patients receiving pregabalin compared with the placebo group, with the longest duration before first rescue analgesia occurring in those receiving 300 mg.

Similarly, Sebastian B et al., evaluated the effectiveness of T. Pregabalin 150 mg compared with placebo for postoperative pain control [14]. They found that pregabalin resulted in a longer duration before the first analgesic requirement and showed better sedation and patient satisfaction scores compared with placebo [15]. The sedation scores and patient satisfaction scores were also better in T. Pregabalin when compared to the placebo" [14].

Similarly, Sebastian B et al., evaluated the effectiveness of T. Pregabalin 150 mg compared with placebo for postoperative pain control [14]. They found that pregabalin resulted in a longer duration before the first analgesic requirement and showed better sedation and patient satisfaction scores compared with placebo [15]. The sedation scores and patient satisfaction scores were also better in T. Pregabalin when compared to the placebo" [14].

In the present study, patients who received T. Pregabalin 300 mg had improved postoperative analgesia compared to the other two groups. Similar findings were reported by Park M et al., who conducted a study comparing the effectiveness of neuraxial blockade in patients who received T. Pregabalin 150 mg versus those who received a placebo [16]. They concluded that the duration of neuraxial blockade was significantly longer in the Pregabalin group than in the placebo group. Postoperative pain scores were also significantly lower, and the need for postoperative analgesics was reduced among patients who received Pregabalin compared to those who received the placebo [16].

A study conducted by Gupta P et al., compared the use of Pregabalin as premedication in patients undergoing laparoscopic surgery under general anaesthesia [15]. They evaluated three groups: one received T. Diazepam as premedication, while the other two groups received different doses of T. Pregabalin. It was observed that perioperative intravenous and inhalational anaesthetic requirements were significantly lower in patients who received Pregabalin compared to the Diazepam group. Additionally, patients who received Pregabalin were more comfortable and experienced a longer pain-free postoperative period than those in the other groups [17].

Another study by Ahiskalioglu A et al., examined the preoperative use of Pregabalin and its effects on postoperative pain and opioid consumption [17]. They found that pain levels were consistently lower in the Pregabalin group than in the placebo group. Furthermore, 24-hour opioid consumption and overall analgesic requirements were significantly lower in the Pregabalin group [17].

These findings collectively indicate that preoperative oral Pregabalin is an effective option for reducing postoperative analgesic requirements and providing adequate sedation, even in cases performed under general anaesthesia.

In the current study, a greater number of patients who received T. Pregabalin 300 mg reported dizziness compared to those who received 150 mg or placebo. Similarly, Kohli M et al., found that dizziness occurred predominantly in the group receiving 300 mg of T. Pregabalin [10].

Although both Pregabalin groups demonstrated superior analgesic and sedative effects compared to the placebo, several drawbacks made the 150 mg dose preferable to the 300 mg dose. The 150 mg dose offered a favourable balance of prolonged analgesia, reduced anxiety, and higher patient satisfaction. While these benefits were also seen with the 300 mg dose, they were accompanied by excessive sedation and pronounced dizziness—effects that posed more risk than benefit in this clinical setting. The 150 mg dose provided sufficient therapeutic advantage with tolerable side effects, whereas the 300 mg dose may be used cautiously in younger patients who prioritise maximal pain control and are willing to accept higher levels of sedation and dizziness.

Limitation(s)

The present study was limited by a short postoperative observation period, and long-term outcomes such as persistent pain, functional recovery, or patient satisfaction beyond the initial 24 hours were not assessed. The subjective nature of sedation scoring and pain assessment may also introduce variability, despite the use of validated scales.

CONCLUSION(S)

Compared to placebo, preoperative oral Pregabalin effectively improved sedation, delayed the onset of postoperative pain, and reduced the need for early rescue analgesics. These findings align with previous research, particularly regarding the effectiveness of the 300 mg dose in enhancing patient comfort and pain relief. However, the higher dose was associated with increased sedation and dizziness, underscoring the importance of individualising the dosage based on patient characteristics and clinical context. Pregabalin appears to be a valuable adjuvant in multimodal pain management. Nevertheless, additional research is needed to optimise dosing strategies and ensure safety.

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PARTICULARS OF CONTRIBUTORS:
1. Postgraduate Student, Department of Anaesthesiology, SRM Medical College Hospital and Research Centre, Chennai, Tamil Nadu, India.
2. Professor, Department of Anaesthesiology, SRM Medical College Hospital and Research Centre, Chennai, Tamil Nadu, India.
3. Assistant Professor, Department of Anaesthesiology, SRM Medical College Hospital and Research Centre, Chennai, Tamil Nadu, India.

NAME, ADDRESS, E-MAIL ID OF THE CORRESPONDING AUTHOR:
Dr. Karthik Krishnamoorthy,
Professor, Department of Anaesthesiology, SRM Medical College Hospital and Research Centre, Kattankulathur, Chennai-603203, Tamil Nadu, India.
E-mail: karthikkrishnamoorthy1981@gmail.com

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