BJHS
Birat Journal of Health Sciences

**ISSN:**

2542-2758 (Print) 2542-2804 (Online)

**ARTICLE INFO:**

Received Date: 29 March, 2025
Accepted Date: 1 July, 2025
Published Date: 31 August, 2025

**KEYWORDS:**

Gabapentin, lower limb surgery, Postoperative analgesia, Pregabalin.

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Access the article online

**DOI:** 10.62065/bjhs681

**CITATION:**

Bhattarai R, Shah P, Dev R, Sarraf S, Khadka NK. A comparison of the preemptive effects of oral pregabalin and gabapentin on acute postoperative pain following lower limb surgery. 2025; 10 (2): 14-18.



# A comparison of the Preemptive Effects of Oral Pregabalin and Gabapentin on Acute Postoperative Pain Following Lower Limb Surgery

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## ABSTRACT

Introduction: Postoperative pain after orthopedic surgery limits the patient's functional status in postoperative period. Therefore, optimal Postoperative pain has to be addressed to decrease perioperative morbidity and functional impairment. Both pregabalin and gabapentin has been used to treat neuropathic pain but its use in treatment of acute postoperative pain following lower limb surgery has also been advocated recently. We aimed to study the preemptive effects of oral pregabalin and gabapentin on acute postoperative pain following lower limb surgery.

Objectives: To compare effects of oral pregabalin and gabapentin for postoperative acute pain, total analgesic consumptions, sedation and postoperative nausea and vomiting following spinal anesthesia for lower limb surgeries.
Methodology: This prospective observational study was done in 90 patients divided into Group G receiving Gabapentin 600mg & Group P receiving Pregabalin 150mg one hour before surgery. The duration of postoperative analgesia, total doses of rescue analgesics, sedation score and postoperative complications at 1, 2, 6, 12 and 24 hours were recorded.

Results: Patients in Group P had significantly prolonged duration of postoperative analgesia as compared to Group G with 270±64.88min vs 232±42.62 minutes respectively. Rescue analgesics requirement was more in Group G 80.32±19.24 mg vs Group P 61.25 ±24.12 mg. The postoperative nausea & vomiting, Dizziness, Somnolence, Headache, Dry mouth and Mean Ramsay sedation score were comparable between two groups and were statistically insignificant.

Conclusion: Though sedation being observed as a minimal perioperative side effect, the pregabalin 150 mg orally as pre-emptive increases the postoperative analgesia duration when compared with gabapentin 600mg orally following lower limp surgery under spinal anesthesia.

## Introduction

Postoperative Pain plays an important role in early mobilization and functional impairment of surgical patients. It is one of the major challenges for anesthesiologists and orthopedic surgeons to provide subjective comfort and alleviate the suffering of the postoperative patients.[1] Allodynia and hyperalgesia leading due sensitization of neurons in dorsal horn is considered for increasing in pain in postoperative period.[2,3]

The most commonly drugs used as preemptive analgesia includes non-steroidal anti-inflammatory (NSAID) drug, Cyclooxygenase -2 inhibitors, local anesthetics, opioids, pregabalin, gabapentin, dexmedetomidine, clonidine etc. Both Pregabalin and gabapentin is a structural analog of gamma amino butyric acid and are commonly used for the treatment of peripheral neuropathic pain, seizures, postherpetic neuralgia and reflex sympathetic dystrophy.[4,5]

Thus, gabapentin and pregabalin affirm to be effective in decreasing the

postoperative pain by inhibiting the calcium channels influx and decreasing excitatory neurotransmitter release within pain pathways, therefore reducing the use of opioid requirement in the postoperative period.[6]

Today's era, most of the anesthesiologist tends to use multimodal analgesia in postoperative pain , using adjuvants like pregabalin and gabapentin adds on valuable support in not only maintaining the efficacy of analgesia but also decreases the occurrence of post- surgical chronic pain. There are numerous studies which has evaluated the efficacy of pregabalin and gabapentin in reducing the postoperative pain after breast surgery, spine surgeries & laparoscopic surgeries but there are lesser number of studies done under spinal anesthesia for lower limb surgeries.

Therefore, the present study aims to evaluate the effects of preemptive Pregabalin and Gabapentin in reducing the postoperative pain following lower limb surgeries under spinal anesthesia.

## Methodology

This prospective, comparative, double blinded observational study was done on March 2024 to March 2025 , for a period of one year after approval from the Ethical committee of Nobel Medical College Teaching Hospital, Biratnagar, Nepal (reference number : 20/2024). The study was conducted in 90 patients. Patients aged 18-60 years, either sex, American Society of anesthesiologist (ASA) physical status I or II scheduled for orthopedic surgery involving lower limb under spinal anesthesia were included in the study. Patients with contraindications to spinal anesthesia, impaired liver or renal functions, cardiovascular or respiratory disease and coagulation abnormalities were excluded from the study. The patients were randomized using computer generated randomized number and allocated into two groups. The anesthesiologist who was involved in providing preemptive study drugs was not involved in intraoperative and postoperative data collections.

Group G: Received a capsule Gabapentin 600mg with a sip of water one hour before surgery

Group P: Received a Capsule Pregabalin 150mg with a sip of water one hour before surgery

All patients were kept at the preoperative room before the procedure where they were briefed and explained about the visual Analogue Scale[7] for pain assessment and was only taken for procedure once they understood it properly. Preoperative assessment with all routine laboratory investigations were done one day before the surgery and informed consent was obtained. Tablet lorazepam 1mg was given on the night before surgery as premedication.

Pain intensity was measured by using a Visual analogue scale at rest and on movement as,

- 0: No Pain
- 1–3: Mild Pain
- 4–6: Moderate Pain
- 7–10: Severe Pain

In the orthopedic routine operation theatre, the intravenous line was secured with 18-gauge iv canula and baseline electrocardiography (ECG), Non-Invasive blood pressure (NIBP}, Heart rate (HR), Pulse oximetry (SPO2) were monitored. A ringer lactate solution was used as preloading at the rate of 15 ml/kg/hour. Spinal anesthesia was performed at L3-L4 interspace in sitting position with 3 ml of 0.5% bupivacaine heavy. All patients were kept on nasal prongs for oxygen administration at 2 liters/min throughout the surgery. A reduction of blood pressure below 20% from baseline were treated with injection Mephentermine 6mg. A heart rate below 50 beats/min were treated with injection atropine.

Intraoperative heart rate (HR), Systolic blood pressure (SBP), Diastolic blood pressure (DBP), Mean arterial blood pressure (MAP) and SpO2 were monitored and recorded for the first hour after spinal anesthesia at every 5 minutes intervals. Once the adequate level of sensory and motor block achieved surgeon were asked to commence the surgery

Immediately once the patients were transferred to post anesthesia care unit (PACU), pain assessment was done and thereafter at 1 hour, 2 hours, 6 hours, 12 hours and 24 hours respectively. Injection tramadol 50 mg was given if the visual analogue score was 4 or more and also as a rescue analgesia on patient's demand. This VAS score or the first demand of rescue analgesia by patient was recorded and considered as an extent of postoperative analgesic effects of study drugs. Total dose of rescue analgesic needed in the first 24 hours of postoperative period were recorded. Ramsay sedation scale was used for assessing sedation. Any other side effects like Nausea, vomiting, dizziness, somnolence, headache and dry mouth if present were recorded.

Postoperative sedation was assessed by the Modified Ramsay's sedation scale (MRSS)[8] as : 1= anxious, agitated, restless, 2= co-operative, oriented, tranquil, 3= responds to command only, 4= response to brisk light glabellar tap or to loud noises, 5= response sluggishly to light glabellar tap or to loud noise, 6= no response.

The sample size calculation was done based on the previous study[9] as a mean difference of effective analgesia in pregabalin and gabapentin and assuming alpha error of 0.05, with a 95% confidence interval and 80% power for finding difference between two groups. The sample size thus calculated was 41 in each group. Therefore, to reduce a bias 10% of total sample size was added and actual sample size taken as 45 in each group.

The statistical analysis was performed with statistical package for social sciences (SPSS) version 21 for windows. Categorical date was analyzed using Chi-square test and independent T test. Shapiro- wilk test and Man Whitney U test were used to analyze normally distributed and not normally distributed data respectively. The Descriptive variables expressed as mean ± SD. All P value less than or equal to 0.05 were considered as significant.

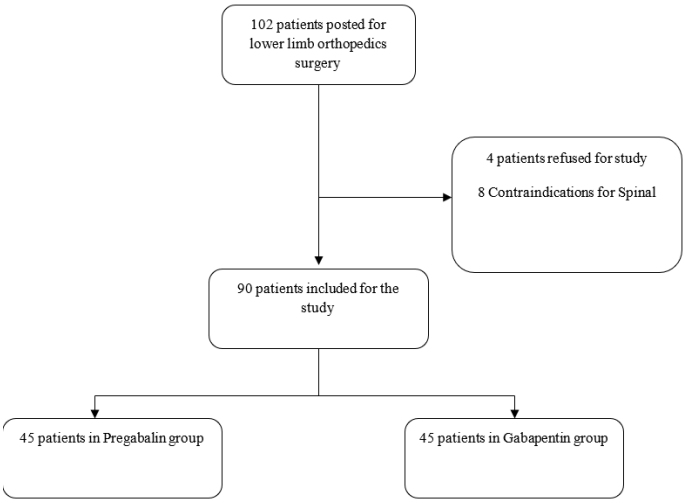


**Figure 1:** Flow chart of patient's selection

## Results

In this study, a total of 102 candidates for lower limb orthopedic surgery were assessed for eligibility. Out of which 12 patients did not fulfill the study criteria, therefore excluded from the study. Of these 45 patients were enrolled in each group. Both Gabapentin and Pregabalin group were comparable in terms of patient's variables like gender, age and ASA physical status (Table 1). The intraoperative and post operative hemodynamics like Heart Rate (HR), Mean arterial blood pressure (MAP), Oxygen Saturation (SPO2) were similar in both groups.

The duration of surgery was similar in both the groups. Whereas the duration of postoperative analgesia and the total Tramadol consumption were significantly lower in the Pregabalin group (Table 2). The Modified Ramsay Sedation scores (Figure 2) as well as side effects profile were similar in between the groups (Table 3).

**Table 1:** Comparison of Patients variables

| Variables | Group G | Group P | p value |
|---|---|---|---|
| Gender (M/F) (n=45) | 23/22 | 25/20 | 0.368 |
| Age (years) [Mean ±SD] | 47.54±14.28 | 48.69±12.62 | 0.862 |
| ASA Physical status(I/II) (n=45) | 36/9 | 35/10 | 0.882 |

**Table 2:** Comparison of the duration of surgery among the two groups

| Observation | Group G (n=45) [Mean ±SD] | Group P (n=45) [Mean ±SD] | P value |
|---|---|---|---|
| Duration of surgery (minutes) | 91.63±11.24 | 90.45±12.35 | 0.782 |
| Duration of Postoperative analgesia (minutes) | 232±42.62 | 270±64.88 | 0.008* |
| Total Tramadol Consumption (mg) | 80.32±19.24 | 61.25±24.12 | 0.007* |

*p-value significant

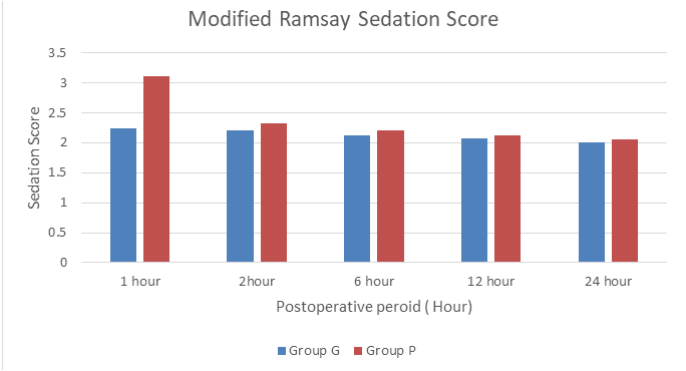


**Figure 2:** Comparison of Modified Ramsay sedation score between two groups

**Table3:** Side effects observed between the two groups

| Side Effects | Group G (n=45) | Group P(n=45) | P Value |
|---|---|---|---|
| Nausea & Vomiting | 0 | 0 | p>0.05 (NS) |
| Dizziness | 4 | 3 | p>0.05 (NS) |
| Somnolence | 5 | 4 | p>0.05 (NS) |
| Headache | 1 | 2 | p>0.05 (NS) |
| Dry Mouth | 1 | 1 | p>0.05 (NS) |

## Discussion

Both Gabapentin and Pregabalin possess antiallodynic and anti -hyper-analgesic features, therefore commonly used for neuropathic pain. But recently it has also seen beneficial in treating acute postoperative pain. The use of preemptive analgesia helps by decreasing the intensity of postoperative pain caused by the effects of surgical stimuli which may result in hyperalgesia.[9-11]

Thus, the present study compared the Gabapentin and Pregabalin as preemptive analgesia for postoperative pain. We used the dose as 600 mg of gabapentin and 150 mg of pregabalin and similar dose was taken by various authors. Bafna et al demonstrated the effects of oral pregabalin and gabapentin for postoperative pain and used the similar doses as our study.[12] Similarly, Pandey CK et al[13], Ashem Jack Meital et al[14] also used similar doses of gabapentin and pregabalin. This dose of gabapentin and pregabalin seems rational as given 1 hour before the surgery to attain maximal plasma concentration. Acharya U[15] did a similar study from Nepal where he used 300 mg of gabapentin and 150 mg of pregabalin as preemptive use for acute postoperative pain but we used 600mg of gabapentin in our study. Another study done in Nepal by Gyawali N et al [16] also used a similar dose of pregabalin and gabapentin but his study was on acute postoperative pain following laparoscopic cholecystectomy. There are number of studies where different doses of gabapentin viz. 600 mg, 900 mg, 1200mg and dose of 150mg, 300 mg of pregabalin were used as preemptive for acute postoperative pain following surgery and we chose to study the lower dose among those studies. Moreover, most of the previously done studies was done on either laparoscopic

gynecological or laparoscopic cholecystectomy whereas in our study we used in patients who were undergoing orthopedic surgery under spinal anesthesia.[16,17]

The patient's variables like gender, Age and ASA physical status were comparable among the groups and were statistically insignificant. The mean duration of surgery in gabapentin versus pregabalin was 91.63±11.24 and 90.45±12.35 respectively and was statistically insignificant.

The mean duration of postoperative analgesia in gabapentin group were 232±42.62 whereas in pregabalin group were 270±64.88 and was statistically significant showing the prolonged duration of analgesia in pregabalin group when used as a preemptive oral route one hour before the surgery. Similar studies done by Bafna et al[12], where they also observed the longer duration of effective postoperative analgesia in pregabalin group when compared with gabapentin and placebo following surgery under spinal anesthesia. The study done by Acharya U et al[15] , Basavareddy et al[18] and V Saraswat et al[19] also observed similar finding in relation to duration of postoperative analgesia when compared between gabapentin and pregabalin group following surgery under spinal anesthesia although the dose of gabapentin used was higher in our study.

In the present study, the total tramadol consumption as rescue analgesia were lower in pregabalin group (61.25±24.12) mg when compared with gabapentin group (80.32±19.24) mg and was statistically significant. This finding was consistent with the study done by Basavareddy et al[18], Acharya U et al[15] & Bafna et al[12] where they also observed the need of rescue analgesia was more in gabapentin group when compared with pregabalin group.

The mean Ramsay sedation score between the gabapentin and pregabalin were comparable in 2 hours, 6 hours, 12 hours & 24 hours however postoperative sedation was seen more in pregabalin group in the first hour. Study done by Acharya U et al. [15], Sebastein et al[20], Mishra et al 8 favored our study in terms of postoperative Ramsey sedation score with more sedation seen in first hour in pregabalin group.

The other side effects like Headache, dry mouth, dizziness, somnolence & nausea and vomiting were comparable among the gabapentin and pregabalin groups and were statistically insignificant in present study. The study done by Bafna et al[12] also found that the side effects like headache, dry mouth, and dizziness were insignificant and consistent with our study. Similar findings with statistically insignificant regarding side effects were also observed with the study done by Saraswat et al[19], Acharya U et al.[15]

## Conclusion

The preemptive oral dose of pregabalin 150 mg is more effective in increasing the postoperative analgesia duration and need of rescue analgesia when compared with oral gabapentin 600mg following orthopedic surgery under spinal anesthesia.

## Limitations of the study

In our study, only a single dose of pregabalin and gabapentin was used .More study on different doses of both gabapentin and pregabalin needs to be done to arrive at an appropriate analgesic dose. Tramadol as rescue analgesic was used in our study which could hinder assessment of PONV as tramadol itself can cause nausea and vomiting. Moreover, our sample size is small. Studies with larger sample sizes are warranted to validate the results of our study

**Acknowledgements:** None

**Conflict of Interest:** There are no conflicts of interest.

**Financial Disclosure:** None

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