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Original Research Article

A Comparative Analysis Evaluating the Prolongation of Postoperative Pain Relief after Spinal Anesthesia with Oral Pregabalin versus Gabapentin

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Abstract

Background: Pre-emptive analgesia entails administering an analgesic regimen before the onset of noxious stimuli, aiming to prevent sensitization of the nervous system to subsequent stimuli that may exacerbate pain. This study aimed to compare the efficacy of pregabalin and gabapentin as pre-emptive analgesics in surgeries below the umbilicus under spinal anesthesia.

Methods: Fifty patients undergoing elective infraumbilical surgeries were randomly assigned to two groups using an online randomizer. Group I (n =25) received a single dose of gabapentin 1,200 mg, while Group II (n = 25) received a single dose of pregabalin 300 mg. Various parameters were assessed to compare the quality of intraoperative and postoperative analgesia, sedation, and complications.

Results: Throughout the 24-hour postoperative period, the mean visual analog scale (VAS) scores at rest were consistently lower in Group I compared to Group II. Rescue analgesia was required after a significantly longer duration in Group P (14.37 ± 1.92 h) compared to Group G (8.54 ± 3.25 h). The incidence of subsequent rescue analgesic requirement was lower in both groups, with fewer cases in the pregabalin group. Additionally, the pregabalin group exhibited a significantly lower incidence of somnolence and dizziness compared to the gabapentin group.

Conclusion: Administration of a single preoperative oral dose of pregabalin (300 mg) offers superior postoperative pain management and reduces postoperative rescue analgesic consumption compared to a single dose of gabapentin (1,200 mg) in infraumbilical surgeries under spinal anesthesia.

Keywords: Complications, gabapentin, pregabalin, pre-emptive analgesia

Introduction

Pain, frequently undertreated, is a common accompaniment to the over 23 million surgical procedures conducted annually and can persist long after tissue healing. [1] Postoperative pain has the potential to induce autonomic disturbances and hemodynamic imbalances, which can adversely impact the patient's recovery. Therefore, it needs to be addressed before the commencement of surgery. Postoperative pain encompasses not only nociceptive components but also inflammatory, neurogenic, and visceral elements. [2] Surgical stimulation induces sensitization of dorsal horn neurons, contributing to pain augmentation. [3] Pre-emptive analgesia, an evolving clinical approach, entails administering analgesics before the onset of noxious stimuli to prevent nervous system sensitization and subsequent pain amplification. Surgery, with its predictable timing of noxious stimuli, presents an ideal setting for pre-emptive analgesia. Administering adequate drug doses to appropriately selected patients before surgery, such as intravenous opiates, local anesthetic infiltration, nerve block, subarachnoid block, and epidural block, has demonstrated benefits lasting up to 1-year post-surgery. [3-5]

Gabapentin, initially an antiepileptic drug introduced in 1994, has since been utilized for chronic pain conditions including neuropathic pain, diabetic neuropathy, postherpetic neuralgia, and complex regional pain syndrome. [4, 5] Its

mechanism involves binding with the alpha 2 delta subunit of presynaptic voltage-gated Ca^{2+} channels, conferring antinociceptive, antihyperalgesic, and antiallodynic effects. [6, 7] Numerous studies have evidenced the efficacy of gabapentin in reducing postoperative analgesic requirements across various surgical procedures like abdominal hysterectomy, spinal surgery, radical mastectomy, and laparoscopic cholecystectomy. [8-11] Pregabalin, a structural analog of GABA with a superior pharmacokinetic profile compared to gabapentin, has established roles in treating peripheral neuropathic pain associated with diabetes mellitus and postherpetic neuralgia. [12] Recent literature suggests pregabalin's potential efficacy in relieving acute pain akin to gabapentin, albeit with fewer studies directly comparing them. [13 – 15] Considering the aforementioned findings, this study was designed to compare the pre-emptive analgesic efficacy of pregabalin and gabapentin in infraumbilical surgeries under spinal anesthesia in elective surgeries undertaken in our hospital.

Material and Methods

This prospective study was carried out at the Department of Anesthesiology, Kakatiya Medical College, and MGM Hospital in Warangal, Telangana. Ethical approval for the study was obtained from the institutional review board. Written consent was obtained from all participants after explaining the study's nature in the local language. Only those who voluntarily agreed to participate were included.

Inclusion Criteria

1. Elective infraumbilical surgeries under spinal anesthesia
2. Males and females
3. Aged 20 – 50 years
4. ASA I and II categories
5. Voluntarily willing to participate in the study.

Exclusion Criteria

1. Any known allergy to local anesthetics or study medications.
2. History of liver disease, including hepatitis B or C, cirrhosis, or elevated liver enzymes.
3. Significant renal impairment (Estimated glomerular filtration rate < 60 mL/min/1.73 m^2).
4. Uncontrolled cardiovascular disease (Recent heart attack, unstable angina, uncontrolled hypertension).
5. History of bleeding disorders or taking anticoagulant medications.

A total of n=50 patients were selected and analyzed during the study period. They were distributed equally to two groups of n=25 each. Group I received a single dose of gabapentin 1,200 mg; Group II received a single dose of pregabalin 300 mg.

The parameters studied for comparing the quality of intraoperative and postoperative analgesia and sedation: For pain: Visual analog scale (VAS)[14] between 0 cm and 10 cm; 0 = no pain; 10 = most severe pain. Time lapsed after the operation when the patient needs rescue analgesia for sedation: Filos' numerical scale. Scale 1 = awake and nervous Scale 2 = awake and relaxed Scale 3 = sleepy but easy to awake Scale 4 = sleepy and hard to awake

The parameters studied for comparing adverse effects: Dizziness/somnolence; diplopia; vomiting [the severity of PONV will be graded on a 4-point ordinal scale; (0 = no nausea/vomiting; 1 = mild nausea; 2 = moderate nausea; 3 = severe nausea with vomiting)]; confusion (assessed by asking time, place, person); urinary retention in a non-catheterized patient; respiratory depression [defined as ventilatory frequency <8 bpm and oxygen saturation <90% without oxygen supplementation].

Patients in Group I (n = 25) received a single dose of gabapentin 1,200 mg, whereas, in Group II (n = 25), patients were administered pregabalin 300 mg per oral 1 h prior to the administration of spinal anesthesia. No other premedication was instituted. A day before the scheduled operation the patients were visited preoperatively in their wards for pre-anesthetic checkups. A thorough clinical history was obtained. They were physically examined; laboratory investigations were reviewed and details about VAS [15] (0-10 cm) were explained on the day before the operation. The patients were also explained about the procedures of spinal anesthesia and postoperative pain relief and all queries and doubts were answered to get their confidence and support. A pharmacologist of our institution not involved in this study prepared the drug-containing bags, each containing four hard gelatin capsules. In group I, the bag contained four 300 mg hard gelatin capsules of gabapentin belonging to one particular pharmaceutical company; in group P the bag contained four 75 mg hard gelatin capsules of pregabalin belonging to the same pharmaceutical company (size and shape looked similar). The medication was given to the patient by an anesthesiologist not involved in the study 1h before the induction of anesthesia. Routine monitoring in the form of a non-invasive blood pressure amplifier (NIBP), pulse oximetry, and electrocardiogram (ECG) was instituted on arrival in the operation theater. All the patients were preloaded with 10 mL/kg lactated Ringer's solution before being administered spinal anesthesia. Spinal anesthesia was instituted with 3 mL of 0.5% bupivacaine (15 mg) at L_3 - L_4 /L_4 - L_5 level. Fluid administration was continued intraoperatively and hypotension, if any, was treated with fluid replacement and intravenous (IV) mephentermin, and this whole procedure was conducted by another anesthetist.

Pain was assessed postoperatively by VAS in the immediate postoperative period and every 2h thereafter, which was explained to the patient during the preoperative visit. When the patient was shifted to the ward anesthesiologists, were unaware that premedication was responsible for charting the pain score by the VAS scale. Pain charting was done separately, and an anesthetic chart was not attached to the case sheet, so the observer was not able to assess to which group the patient belonged. Any patient with a VAS score of more than 3 received diclofenac 1 mg/kg intramuscularly. Time since spinal anesthesia to the first dose of analgesic and the total dose of analgesic in the first 24 h was recorded. Any complications such as dizziness, somnolence, diplopia, vomiting, confusion, respiratory depression, pain, and urinary retention were recorded in the first 24-h postoperative period.

Statistical analysis All the results were tabulated and analyzed statistically using software SPSS version 17 for Windows Statistical Software Package (SPSS Inc., Chicago, IL, USA). Comparison of quantitative data was done by one-way analysis of variance(ANOVA) and an independent sample t-test was used for the comparison between the groups. The Chi-square test was used for the non-parametric data. A p-value of less than 0.05 was considered statistically significant and 0.001 was highly significant.

Results

Table 1 shows the age distribution of patients in two groups who received different medications during elective infraumbilical surgeries under spinal anesthesia. The age range across both groups is 20-50 years. The distribution of patients across age groups is relatively similar in both groups: No age group has more than 24% of patients in either group. The largest difference is in the 31-35 age group, where Group II has 1 more patient than Group I (6 vs. 5). There is no statistically significant difference in the average age between the two groups

Table 1: Age-wise distribution of cases included in the study

Age in years	*Group I*	*Group II*
20 - 25	4(16%)	3(12%)
26 - 30	5(20%)	5(20%)
31 - 35	5(20%)	6(24%)
36 - 40	3(12%)	4(16%)
41 - 45	5(20%)	4(16%)
46 - 50	3(12%)	3(12%)
Total	25(100%)	25(100%)

The mean age of the cohort was 37.25 ± 5.5 years in group I and 36.19 ± 6.5 in group II. In group I out of n=25 cases n=10 were males and n=15 were females. Similarly in group II out of n=25 cases, n=12 were males and n=13 were females. The mean weight of group I was 62.29±2.11 Kgs and similarly the mean weight of group II was 60.25 ± 6.8 Kgs. The mean height of group I was 159.28 ± 6.5 cm and group II was 161.22 ± 5.5 cm. The mean BMI of group I was 21.95 ± 2.4 Kg/m^2 and for group II mean BMI was 22.34 ± 1.92 kg/m^2. The mean duration of surgery in group I cases was 69.25 ± 10.51 min and 66.17 ± 12.37 min in group II cases.

Table 2: Mean vas scores at different intervals of time in two groups

Mean VAS Scores at different intervals	*Group I*	*Group II*	*P value*
3 hours post-operative	6.25 ± 1.20	6.01 ± 1.10	0.952
6 hours post-operative	5.17 ± 0.92	4.99 ± 0.81	0.199
12 hours post-operative	4.55 ± 0.86	3.82 ± 0.75	0.043
18 hours post-operative	3.2 ± 0.785	2.14 ± 0.62	0.031
24 hours post-operative	2.27 ± 0.27	1.92 ± 0.23	0.001

Table 2 compares the mean pain scores (measured using the Visual Analog Scale, VAS) at different time intervals after surgery in two groups of patients. Both groups experience a decrease in mean VAS scores over time, indicating a reduction in pain intensity. At 3 and 6 hours post-operative, there is no statistically significant difference ($p>0.05$) in VAS scores between the groups. From 12 hours onwards, Group II consistently shows lower mean VAS scores compared to Group I. This difference becomes statistically significant at 12 hours ($p=0.043$), 18 hours ($p=0.031$), and 24 hours ($p=0.001$). The findings suggest that the pain relief medication or intervention administered to Group II might be more effective than that given to Group I, particularly at later time points after surgery.

Table 3: Description and Analysis of Rescue Analgesic Used

	Group I	Group II	P values
The mean time for the demand of first rescue analgesic post-operatively	8.54 ± 3.25	14.37 ± 1.92	0.001*
Total number of rescue analgesics required	2.58 ± 0.89	1.02 ± 0.64	0.012*

*Significant

Table 3 compares the use of rescue analgesic medication between two groups of patients after surgery. *Time to first rescue analgesic:* Group I required rescue medication significantly earlier (mean 8.54 hours) than Group II (mean 14.37 hours) after surgery (p=0.001). *Number of rescue analgesics:* Group I required a significantly higher number of rescue medications (mean 2.58) compared to Group II (mean 1.02) (p=0.012). These findings suggest that Group I experienced more pain and required pain medication sooner and more frequently than Group II after surgery. The earlier need for and higher number of rescue medications in Group I indicate potentially less effective pain management compared to Group II.

Table 4: Distribution of adverse events in both groups of patients

Attributes		Group I	Group II	P value
Adverse events	Present	11(44%)	5 (20%)	0.0129*
	Absent	14(66%)	15(80%)	

*Significant

Table 4 compares the occurrence of adverse events in two groups of patients who received different medications after elective infraumbilical surgery under spinal anesthesia: *Adverse events:* 44% of patients in Group I experienced adverse events compared to 20% in Group II. The common adverse events were dizziness nausea and vomiting. The p-value (0.0129) indicates a statistically significant difference in the proportion of patients experiencing adverse events between the groups, suggesting this difference is unlikely due to chance. This finding suggests that *Gabapentin (Group I)* might be associated with a higher risk of adverse events compared to *Pregabalin (Group II)* in this population and surgical setting.

Discussion

Pre-emptive analgesia refers to a therapeutic approach aimed at preventing the development of heightened sensory responses that can exacerbate pain after surgery. This treatment strategy seeks to address the entirety of the period characterized by intense noxious stimuli, which can induce both central and peripheral sensitization resulting from surgical incisions or inflammation during and immediately following surgery. The focus on a pre-operative approach as opposed to a post-operative one has resulted in the exclusion of the potential sensitization that may occur during the initial postoperative period due to inflammatory injuries [2]. Preoperative administration of analgesia has demonstrated greater effectiveness in controlling postoperative pain by shielding the central nervous system from the adverse effects of noxious stimuli, thereby mitigating allodynia and heightened pain perception. Gabapentin and pregabalin, known for their antiallodynic and antihyperalgesic properties in neuropathic pain management, have shown promise in alleviating acute postoperative pain as well. Various studies have highlighted the utility of gabapentin and pregabalin in perioperative settings, leading to reduced postoperative pain intensity, decreased need for postoperative analgesics, minimized adverse effects, prolonged analgesic duration, and enhanced patient satisfaction [16-19]. Gabapentin, an analog of gamma-aminobutyric acid (GABA), initially introduced as an antiepileptic medication in 1994, has demonstrated antinociceptive, antihyperalgesic, and antiallodynic effects [10]. Numerous studies have underscored the efficacy of gabapentin in providing acute postoperative pain relief, resulting in decreased requirements for postoperative analgesics. There is emerging evidence suggesting that pregabalin may be effective in alleviating acute pain similar to gabapentin [20, 21], although studies directly comparing the two are relatively scarce. Considering these observations, the present study was designed as a randomized, double-blinded trial to compare the efficacy of pregabalin and gabapentin as preemptive analgesics for surgeries conducted below the umbilicus under spinal anesthesia.

This study, conducted by the Department of Anesthesiology, involved fifty patients aged between 20-50 years, classified as ASA grade I and II, scheduled to undergo infraumbilical surgery. They were randomly divided into 2 groups: Group I (n=25) received 1200 mg of gabapentin, and Group II (n=25) received 300 mg of pregabalin capsules orally with sips of water one hour before anesthesia induction. All groups were comparable regarding demographic data. There were no significant differences in the mean duration of surgery or the types of surgeries performed between the groups. The recommended starting dose of gabapentin for neuropathic pain is 300 mg on day 1, followed by 300 mg twice daily on day 2, and then 300 mg three times daily thereafter. However, this dose may often be inadequate,

necessitating doses of up to 1800 mg. Administering a first dose of 1200 mg or 600 mg immediately before anesthesia and surgery contradicts this recommendation. In a recent review comprising 22 randomized controlled trials (RCTs), meta-regression analysis indicated that the reduction in 24-hour opioid consumption induced by gabapentin was not significantly dependent on the dosage [22]. Consequently, for this study, we opted for the single highest safe dose of gabapentin (1200 mg) and pregabalin (300 mg), consistent with dosages used in the majority of studies. While animal models have suggested that gabapentin may be more effective when administered preoperatively, Pandey et al. [23] found in their study that pre-emptive administration of gabapentin (600 mg) did not significantly differ from post-incision administration in terms of fentanyl consumption. Nonetheless, we chose to administer gabapentin and pregabalin preoperatively based on the observation of lower analgesic consumption in the preoperative regimen. The mean VAS scores at rest in the 0-10 cm scale were recorded at the following time points: 3, 6, 12, and 18 hours in the first 24 hrs of the postoperative period. Analysis of Table 3 shows *Group I (gabapentin)* required rescue medication significantly earlier and more frequently, indicating less effective pain control compared to Group II. In the study by Saraswat et al. [15], the time to rescue analgesia was reported as 8.98 ± 5.38 hours for the gabapentin group, significantly shorter ($p < 0.001$) than that of the pregabalin group (14.17 ± 6.67 hours). However, the total dose of rescue analgesic (mg) administered during the 24-hour postoperative period was 62.5 ± 28.43 mg for pregabalin, which was lower than the 5 ± 23.99 mg for gabapentin, although this difference was not statistically significant between the groups. These findings indicate that pregabalin exhibited superiority over gabapentin in the aforementioned criteria, aligning with the results of the current study. The requirement for subsequent rescue analgesic doses during the 24-hour postoperative period between the groups (see Table 4) further supported this observation in both group I (gabapentin group) and group II (pregabalin group). Dirks et al. [10] conducted a study comparing the effects of a single pre-emptive oral dose of gabapentin versus placebo on postoperative pain and morphine consumption after mastectomy, whereas our study focused on surgeries below the umbilicus. Similar to their approach, we administered 1200 mg of gabapentin. Their findings indicated a substantial reduction in movement-related pain at 2 and 4 hours post-radical mastectomy in the gabapentin group, whereas our study did not record movement-related pain. Additionally, they observed a significant decrease in morphine consumption at 4 hours post-surgery in the gabapentin group compared to the control group, whereas we utilized diclofenac as the rescue analgesic, required in the gabapentin group as subsequent rescue analgesic in only 9.68% of cases. However, unlike our study, their results showed a statistically significant reduction in pain at rest with gabapentin, which was not observed in our study. Turan et al. [9] in a similar study comparing preemptive administration of 1200 mg gabapentin versus a placebo given 1 hour before lumbar spine surgery under general anesthesia (GA), similar to our study design. They utilized patient-controlled analgesia with morphine postoperatively. Their findings revealed significantly lower pain scores at 1, 2, and 4 hours, as well as total morphine consumption, in the gabapentin group compared to the placebo group. They concluded that preoperative oral gabapentin reduces pain scores in the early postoperative period in spinal surgery patients, a conclusion aligned with our study's results.

Conclusion

In conclusion, administering a single oral dose of pregabalin preoperatively offers superior postoperative pain control and reduces rescue analgesic consumption compared to gabapentin, as evidenced by lower mean VAS scores at rest in elective infraumbilical surgeries. Additionally, pregabalin demonstrates a lower incidence of adverse effects compared to gabapentin, with percentages aligning with literature findings and minimal distress to patients. This suggests that pregabalin could be effectively integrated into a multimodal analgesic approach to prevent acute postoperative pain.

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