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Effectiveness of Oral Pregabalin for Preemptive Analgesia in Infraumbilical Surgeries: A Randomized Controlled Trial

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Abstract

Background: Effective postoperative pain management remains a critical aspect of perioperative care, particularly following infraumbilical surgeries under spinal anaesthesia. Preemptive analgesia using agents like pregabalin may improve outcomes by reducing pain and analgesic consumption in the postoperative period.

Aim: To evaluate and compare the efficacy of preoperative oral pregabalin versus placebo in terms of duration of postoperative analgesia, visual analogue scores (VAS), sedation levels, and rescue analgesic requirement in patients undergoing infraumbilical surgeries under spinal anaesthesia.

Methods: This randomized controlled trial included 60 patients aged 18–60 years, undergoing elective infraumbilical surgeries under spinal anaesthesia. Patients were randomly assigned to two groups: Group A received 150 mg oral pregabalin, and Group C received placebo one hour preoperatively. Intraoperative and postoperative parameters such as onset and duration of sensory block, VAS scores, Ramsay sedation scores, time to first rescue analgesia, total analgesic consumption over 24 hours, and side effects were recorded and analyzed.

Results: Group A demonstrated a significantly longer mean duration of sensory analgesia (287 ± 44.01 minutes) compared to the placebo group (177.33 ± 47.12 minutes) ($p = 0.001$). VAS scores were consistently lower in the pregabalin group across all time intervals postoperatively ($p < 0.05$), except at baseline. The mean total dose of rescue analgesic required over 24 hours was significantly lower in the pregabalin group (2.17 ± 0.66 doses) than in the placebo group (3.07 ± 0.52 doses) ($p = 0.001$). Mild sedation was observed in 20% of patients in the pregabalin group, but no major adverse events occurred.

Conclusion: Preoperative administration of oral pregabalin 150 mg significantly enhances postoperative analgesia, reduces analgesic consumption, and provides better pain control than placebo in patients undergoing infraumbilical surgeries under spinal anaesthesia, with an acceptable safety profile.

Keywords: *Pregabalin*, *Analgesia, Postoperative*, *Spinal Anesthesia*, *Infraumbilical Surgery*, *Visual Analog Scale*, *Preemptive Analgesia*, *Pain Measurement*, *Randomized Controlled Trial*

INTRODUCTION

Pain is defined as an unpleasant sensory and emotional experience which may be associated with actual or potential tissue damage [1]. Surgical trauma induces hyperalgesia which, when left untreated, could lead to development of chronic pain [2]. Postoperative pain may be attributed to inflammation resulting from tissue trauma due to the surgical incision, tissue injury due to cauterization, or direct nerve injury as a result of nerve transection, stretching, or compression. Pro-inflammatory mediators released due to tissue injury — such as prostaglandins, interleukins, cytokines, and neurotrophins — contribute to nociceptor sensitization. Additionally, decreased tissue pH and oxygen tension, and increased lactate concentration, which may persist at the surgical site for several days, play important roles in peripheral sensitization and spontaneous pain behavior following an incision [3].

Inadequately treated postoperative pain may lead to systemic complications such as tachycardia, hypertension, increased blood glucose, delayed wound healing, and anxiety [4], [5], [6]. Anxiety induces a surge of catecholamines due to the stress response, leading to hemodynamic instability. Thus, the relationship between anxiety and pain is well established [5], [7]. Pain has also been recognized as a significant cause for delayed discharge after ambulatory surgery, alongside drowsiness and nausea/vomiting [8].

Depression, psychological stress, and delayed recovery are related to chronic post-surgical pain, which may occur even after minor surgery. Hence, adequate postoperative pain relief must be an integral part of anesthesia administration. The main goal of postoperative pain management is to minimize medication doses, reduce side effects, and provide sufficient analgesia. This can be achieved through a multimodal approach. Drugs such as IV paracetamol, IV diclofenac, COX-2 inhibitors, and opioids do not fully meet the needs of post-surgical patients [9]. Moreover, opioids are limited in postoperative use due to adverse effects such as excessive sedation, respiratory depression, nausea, vomiting, delayed mobilization, and increased risk of thromboembolic events.

Multimodal analgesia includes the use of combinations of local/regional anesthesia, acetaminophen, NSAIDs, gabapentinoids, and other analgesic drugs that act on different receptors along the pain pathway, providing effective pain relief while reducing opioid-related adverse effects. The rationale for preemptive analgesia lies in preventing the development of central sensitization [10]. Preemptive analgesia involves initiating pain control before surgical incision and continuing until after wound healing is complete [1]. Based on current evidence, this study was designed to compare the **preemptive analgesic efficacy of oral pregabalin versus placebo** in patients undergoing infraumbilical surgeries under spinal anesthesia. The primary

objective of this study was to compare the mean duration of postoperative analgesia following spinal anesthesia between patients who received oral pregabalin and those who received placebo. The secondary objectives were to compare the median time to first rescue analgesic requirement, the total dose of rescue analgesics used in the first 24 hours postoperatively, the sedative effects of the two drugs, and any side effects associated with their use.

METHODOLOGY

This randomized controlled trial was conducted at Shridevi Institute of Medical Sciences and Research Hospital, Tumkur, between July 2023 and December 2024. A total of 60 patients scheduled for elective infraumbilical surgeries under spinal anesthesia were enrolled based on predefined inclusion and exclusion criteria. Patients aged between 18 to 60 years, belonging to ASA physical status I or II, and with a body mass index ranging from 18 to 30 kg/m² were included. Patients were excluded if they had known allergies to the study drugs, were pregnant or lactating, or had neuropathy, neurological disorders, or psychiatric illness.

The study was conducted after obtaining institutional ethical clearance, and written informed consent was obtained from all participants. Eligible patients were stratified and randomly allocated into two equal groups of 30 each using a computer-generated closed-envelope method. Group A received oral pregabalin 150 mg one hour preoperatively, while Group B received a placebo (oral multivitamin) under identical conditions.

All patients underwent thorough pre-anesthetic evaluation and relevant laboratory investigations. They were kept nil per overnight and premedicated with tablet alprazolam 0.5 mg and tablet ranitidine 150 mg the night before and two hours prior to surgery, respectively. On the day of surgery, patients were educated on using the Visual Analogue Scale (VAS) for pain assessment.

Upon arrival in the operating room, standard monitors (ECG, pulse oximeter, non-invasive blood pressure) were applied, and intravenous access was secured with an 18G cannula. All patients were preloaded with Ringer’s lactate solution at 10 ml/kg. Under strict aseptic precautions, a subarachnoid block was administered at the L3–L4 interspace using a 25G Quincke spinal needle. Hyperbaric bupivacaine 0.5% (3.5 ml) was injected after confirming free flow of cerebrospinal fluid.

The onset of sensory block was assessed bilaterally using a pinprick test. Surgery commenced once a T10 dermatomal level of sensory block and a Bromage scale motor block of 3 were achieved. Intraoperative monitoring included continuous observation for hypotension (mean arterial pressure drop >20% from baseline), treated with IV mephentermine 6 mg boluses, and bradycardia (heart rate <50 bpm), managed with IV atropine 0.6 mg. No intraoperative sedatives or analgesics were administered.

Postoperatively, patients were monitored in the recovery area for pain onset. Analgesia was provided with intramuscular diclofenac sodium 1 mg/kg if the VAS score exceeded 4. Pain scores (VAS 0–10) and sedation levels (Ramsay Sedation Scale) were assessed at multiple intervals: immediately postoperatively (0 min), and then at 30 min, 60 min, 90 min, 2, 3, 4, 8, 12, 16, 20, and 24 hours. The time taken for two-segment regression of sensory block from its highest level was also recorded using the pinprick method. The time to first rescue analgesia and total dose of rescue analgesic administered within 24 hours were documented.

Data were entered into Microsoft Excel and analyzed using IBM SPSS Statistics version 22. Qualitative variables were presented as frequencies and percentages, and quantitative variables as mean ± standard deviation or median with interquartile range, based on normality. Statistical comparisons between groups were performed using Chi-square and ANOVA tests, with a p-value <0.05 considered statistically significant. Graphs including bar diagrams, pie charts, and scatter plots were prepared using Microsoft Word and Excel.

RESULTS

The demographic characteristics between Group A and Group B were statistically comparable. Mean age was 37.80 ± 12.34 years in Group A and 36.53 ± 8.50 years in Group B (p = 0.26). Similarly, height (159.17 ± 6.41 cm vs. 157.87 ± 7.63 cm; p = 0.42), weight (61.87 ± 10.58 kg vs. 61.10 ± 9.55 kg; p = 0.34), and BMI (24.57 ± 3.75 vs. 24.49 ± 3.30; p = 0.76) showed no statistically significant differences. Group A included 17 males (56.7%) and 13 females (43.3%), while Group B had 14 males (46.7%) and 16 females (53.3%). The gender distribution was not statistically different (p = 0.73), indicating both groups were well-matched demographically (Table 1).

The onset of sensory block was faster in the pregabalin group (2.73 ± 0.78 min) compared to placebo (3.10 ± 0.40 min), with a borderline p-value of 0.06. Similarly, motor block onset was faster in Group A (3.73 ± 1.05 min) vs. Group B (4.33 ± 0.48 min; p = 0.08). The duration of sensory analgesia was significantly longer in the pregabalin group (287.00 ± 44.01 min) compared to placebo (177.33 ± 47.12 min), with a highly significant p-value of 0.001. (Table 2).

Pulse rates were consistently higher in the pregabalin group across all time points. At 30 minutes, the mean pulse rate was 78.13 ± 11.96 beats/min in Group A compared to 67.33 ± 6.55 beats/min in Group B (p = 0.001). This significant difference persisted throughout the 24-hour period, including at 60 minutes (76.87 vs. 64.13; p = 0.001), 3 hours (79.13 vs. 68.73; p = 0.001), and 24 hours (80.27 vs. 73.83; p = 0.005). These findings suggest that pregabalin may blunt autonomic suppression postoperatively, resulting in a sustained elevation in pulse rate relative to placebo.

Systolic blood pressure (SBP) remained consistently higher in the pregabalin group compared to placebo throughout the postoperative period. At 30 minutes, mean SBP was 119.27 ± 12.52 mmHg in Group A versus 112.80 ± 5.55 mmHg in Group B

(p = 0.012), with significant differences also observed at 90 minutes (p = 0.001), 120 minutes (p = 0.012), and 3 hours (p = 0.001). This trend continued at the 4th, 12th, 16th, and 24th hours with p-values < 0.05, though the difference narrowed at the 8th and 20th hours. These findings suggest that pregabalin may modestly elevate SBP, possibly due to reduced sympathetic tone or stress response.

Diastolic blood pressure (DBP) was generally higher in the pregabalin group compared to placebo, though the differences reached statistical significance only at select time points. At 120 minutes, DBP was significantly higher in Group A (79.93 ± 7.82 mmHg) than in Group B (74.27 ± 6.76 mmHg; p = 0.010). Similarly, significant differences were noted at the 3rd hour (79.27 ± 7.76 vs. 74.67 ± 6.99 mmHg; p = 0.040) and the 8th hour (80.47 ± 10.85 vs. 77.67 ± 6.52 mmHg; p = 0.040). While other time points showed a consistent trend of elevated DBP in the pregabalin group, they did not reach statistical significance. Overall, these findings suggest that pregabalin may contribute to mild increases in diastolic pressure postoperatively.

The Visual Analogue Scale (VAS) scores showed significantly lower pain levels in the pregabalin group compared to placebo during the initial postoperative period. At 30 minutes, the mean VAS was 0.07 ± 0.25 in Group A and 0.70 ± 0.79 in the control group (p = 0.001). This difference persisted through 60 minutes (0.23 ± 0.63 vs. 1.40 ± 1.00; p = 0.001), 90 minutes (0.43 ± 0.94 vs. 1.90 ± 0.96; p = 0.001), and 120 minutes (0.80 ± 1.27 vs. 2.83 ± 0.83; p = 0.001), indicating more effective early pain control with pregabalin. Peak pain levels were observed at the 3rd and 4th hours in both groups, but scores remained lower in Group A (1.77 ± 1.48 vs. 3.63 ± 0.89 at 3rd hr; 2.40 ± 1.10 vs. 3.83 ± 0.91 at 4th hr; both p = 0.001). By the 8th to 24th hour, pain scores in both groups began to converge, yet remained slightly lower in the pregabalin group. Notably, at 24 hours, Group A recorded a VAS of 2.30 ± 0.60 versus 2.77 ± 0.57 in the control group (p = 0.002). These results affirm that oral pregabalin significantly reduces early postoperative pain and sustains analgesic efficacy over 24 hours (Figure 4).

The total number of rescue analgesic doses required in the first 24 hours postoperatively was significantly lower in the pregabalin group compared to the control group. Patients in Group A received a mean of 2.17 ± 0.66 doses, while those in the control group (Group B) required 3.07 ± 0.52 doses (p = 0.001). This statistically significant reduction highlights the superior analgesic effect of pregabalin in managing postoperative pain and reducing the need for additional pain medication (Table 3).

Patients in the pregabalin group consistently demonstrated higher sedation scores in the early postoperative period compared to the control group. At 30 minutes, the mean RSS score was 1.23 ± 0.43 in Group A versus 1.00 ± 0.00 in the control group (p = 0.001), with similar significant differences noted at 60 minutes (1.50 ± 0.51 vs. 1.00 ± 0.00; p = 0.001), 90 minutes, and 2 hours. The difference remained statistically significant until the 8th hour (1.10 ± 0.31 vs. 1.00 ± 0.00; p = 0.050). From 12 hours onward, RSS scores between the two groups converged, showing no

significant difference. These results indicate that pregabalin induced mild, transient sedation in the early postoperative period without prolonged sedative effects (Figure 5).

Side effects were more frequently observed in the pregabalin group compared to the control group. Sedation occurred in 6 patients (20.0%) in Group A, while no patients in the control group experienced sedation. One patient (3.3%) in the pregabalin group experienced bradycardia, and another (3.3%) experienced a combination of bradycardia and sedation. No such events were observed in the control group. The majority of patients in Group A (73.3%) reported no side effects, compared to 100% in the control group, and this difference was statistically significant ($p = 0.001$). These findings suggest that pregabalin is associated with a higher incidence of mild side effects, primarily sedation, although none were severe or required intervention (Table 4)

DISCUSSION

Relief of surgical pain with minimal side effects is a major goal during postoperative care and a top priority for patients. Inadequate relief of postoperative pain has adverse physiological effects that can contribute to significant morbidity and mortality, resulting in delayed recovery and return to daily activities [1]. Uncontrolled postoperative pain may produce a range of detrimental acute and chronic effects. Pain signals initiate a cascade of changes in the somatosensory system that increase sensitivity to future stimuli, amplifying the perception of pain [11].

The concept of preemptive analgesia, introduced by Crile and further developed by Wall and Woolf, revolutionized postoperative pain management. Preemptive analgesia is defined as an analgesic regimen administered prior to surgical incision and is more effective at pain relief than the same regimen given after surgery. The goal is to block the development of sustained pain by preventing NMDA receptor activation in the dorsal horn and inhibiting central sensitization [1].

Pregabalin is an antiepileptic and GABA analog that binds to the alpha-2-delta subunit of voltage-sensitive calcium channels, decreasing calcium influx and reducing the release of excitatory neurotransmitters such as glutamate, substance P, and calcitonin gene-related peptide from primary nociceptive afferents, thereby modulating nociceptive transmission [11]. Pregabalin is inactive at $GABA_A$, $GABA_B$ receptors, has an elimination half-life of 5.5–6.7 hours (independent of dose or repeated use), and is effective in treating inflammatory, incisional, and neuropathic pain. Administered preoperatively, pregabalin reduces opioid consumption and its associated side effects in the first 24 hours of the postoperative period.

In this randomized controlled trial conducted at Shridevi Institute of Medical Sciences and Research Hospital, Tumakuru, 60 patients scheduled for elective infraumbilical surgeries under subarachnoid block were randomized into two groups. Group A received oral pregabalin 150 mg, and Group B received placebo, both given one hour preoperatively. Visual Analogue Scale (VAS) scores were assessed at

predefined intervals. We compared the mean duration of postoperative analgesia, the total 24-hour rescue analgesic requirement, sedation levels using Ramsay Sedation Score (RSS), and incidence of side effects between the two groups. Our results showed significantly lower VAS scores in the pregabalin group in the early postoperative period. Pain scores remained lower up to the 4th hour and remained comparable through 24 hours. The total rescue analgesic requirement was significantly lower in Group A (2.17 ± 0.66 doses) compared to the control group (3.07 ± 0.52 doses; p = 0.001), indicating superior pain control with pregabalin. Sedation was higher in Group A during the first few hours but remained within a safe, arousable range and normalized after the 8th hour.

In our study, Group A (pregabalin) had the longest mean duration of sensory analgesia at 287 minutes, compared to 177.33 minutes in Group C (control), a statistically significant difference ($p < 0.05$). These results are consistent with the findings of Anu Prasad et al. [2], who observed a significantly longer sensory block in the pregabalin group compared to placebo. Similarly, Beniwal et al. [12] reported prolonged postoperative analgesia with pregabalin in patients undergoing below-umbilical surgeries under spinal anaesthesia. Bhalavi et al. [13] also demonstrated superior analgesic duration with 150 mg pregabalin compared to oral diazepam.

VAS scores were measured at multiple time points over 24 hours. In the immediate postoperative period (0 hr), there was no significant difference in VAS scores, likely due to the ongoing effect of spinal anaesthesia. However, from 1 hour onwards, Group A consistently showed lower VAS scores than the control group. The scores in Group A were 0.03 at 1 hr, 0.80 at 2 hrs, 2.40 at 4 hrs, 3.70 at 8 hrs, 3.13 at 12 hrs, 2.67 at 16 hrs, and 2.30 at 24 hrs. In contrast, Group C recorded higher scores across time points. These findings are consistent with those of Bhalavi et al. [13] and Beniwal et al. [12], who found that preoperative pregabalin significantly reduced postoperative pain scores.

In terms of the **first rescue analgesic requirement**, the mean time was 287 minutes in the pregabalin group compared to 177.33 minutes in the control group ($p = 0.001$), suggesting prolonged pain relief with pregabalin. Anu Prasad et al. [2] similarly reported delayed analgesic requirements in pregabalin recipients. Saraswat et al. [14] observed that patients given pregabalin 300 mg required significantly less analgesia than those given gabapentin 1200 mg, further affirming the efficacy of pregabalin.

The **total doses of diclofenac** administered as rescue analgesia over 24 hours were significantly lower in the pregabalin group (2.17 ± 0.66) compared to the control group (3.07 ± 0.52), with a highly significant p-value of 0.001. This demonstrates pregabalin's role in reducing analgesic consumption.

Postoperative **sedation** was evaluated using the Ramsay Sedation Scale. Pregabalin showed a higher sedation score in the early hours postoperatively, which

normalized by the 12th hour. Anu Prasad et al. [2] also reported mild sedation with pregabalin that did not compromise patient safety.

In terms of **side effects**, sedation occurred in 20% of patients in the pregabalin group, and a combination of bradycardia and sedation occurred in 3.3% of cases. In contrast, 100% of patients in the control group had no side effects. Although pregabalin was associated with more side effects than placebo, they were mild and self-limiting. This aligns with prior findings by Anu Prasad et al. [2].

CONCLUSION:

Based on the results of this study, it can be concluded that preemptive administration of oral pregabalin 150 mg provides significantly better postoperative analgesia compared to placebo in patients undergoing infraumbilical surgeries under spinal anaesthesia. Pregabalin effectively prolongs the duration of sensory analgesia, delays the time to first rescue analgesic requirement, and significantly reduces the total analgesic consumption in the first 24 hours after surgery. Although mild sedation was observed in a few cases, pregabalin was overall well-tolerated with no major adverse effects. Therefore, pregabalin demonstrates a favorable efficacy-safety profile and can be considered a useful component in multimodal analgesia protocols for infraumbilical surgical procedures under spinal anaesthesia.

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Table 1: Comparison of Demographic Profile Between Group A and Group B

Parameter	Group A (n = 30)	Group B (n = 30)	P-value
Age (years)	37.80 ± 12.34	36.53 ± 8.50	0.26
Male	17 (56.7%)	14 (46.7%)	0.73
Female	13 (43.3%)	16 (53.3%)	
Height (cm)	159.17 ± 6.41	157.87 ± 7.63	0.42
Weight (kg)	61.87 ± 10.58	61.10 ± 9.55	0.34
BMI (kg/m²)	24.57 ± 3.75	24.49 ± 3.30	0.76

Table 2: Comparison of Block Characteristics Between Group A and Group B

Parameter (min)	Group A (n = 30)	Group B (n = 30)	P-value
Onset of Sensory Block	2.73 ± 0.78	3.10 ± 0.40	0.06
Onset of Motor Block	3.73 ± 1.05	4.33 ± 0.48	0.08
Duration of Sensory Analgesia	287.00 ± 44.01	177.33 ± 47.12	0.001

Table 3: Comparison of Total Rescue Analgesic Doses in 24 Hours

Group	Mean ± SD	P-value
Group A (Pregabalin)	2.17 ± 0.66	**0.001**
Group B (Control)	3.07 ± 0.52	

Table 4: Side Effects in Relation to Study Groups

Side Effects	Group A (n = 30)	Group B (n = 30)	P-value
Nil	22 (73.3%)	30 (100.0%)	**0.001**
Sedation	6 (20.0%)	0 (0.0%)	

Bradycardia	1 (3.3%)	0 (0.0%)	
Bradycardia and Sedation	1 (3.3%)	0 (0.0%)	

Figure 1. Comparison of Pulse Rate Over Time

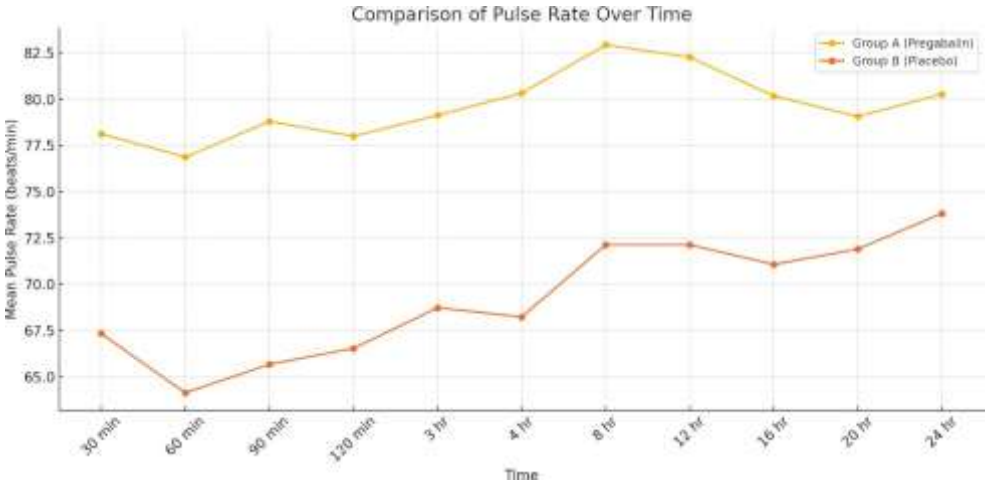

Figure 2. Comparison of Systolic Blood Pressure (SBP) Over Time

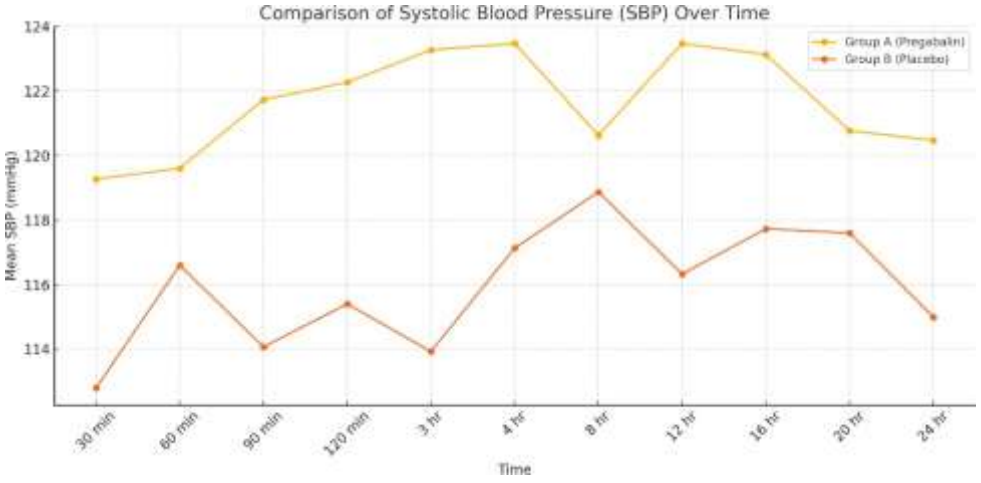

Figure 3. Comparison of Diastolic Blood Pressure (DBP) Over Time

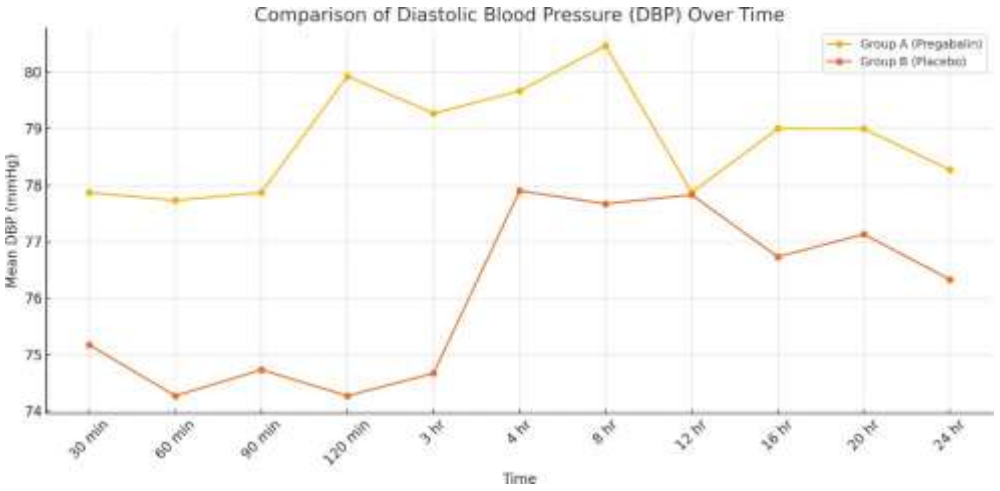

Figure 4: Comparison of Visual Analogue Scale (VAS) Scores Between Groups

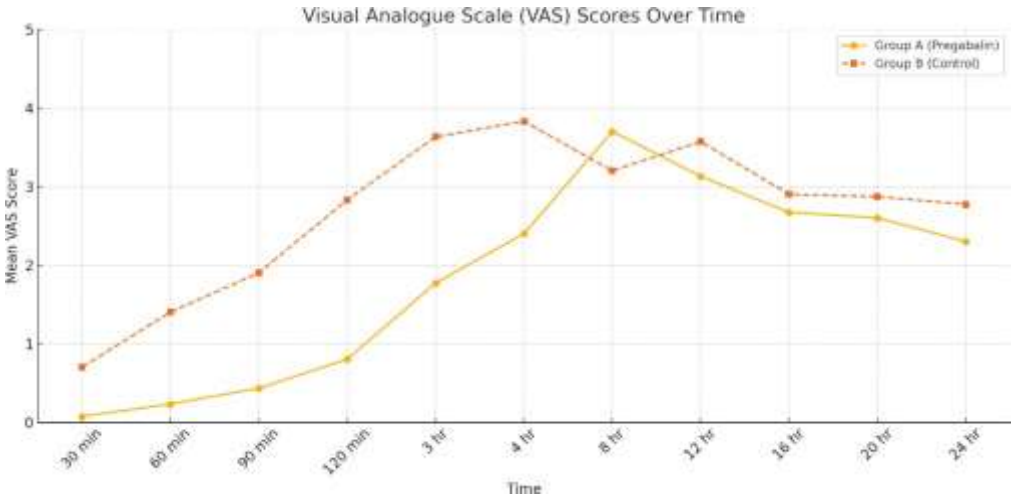

Figure 5: Ramsay Sedation Scale (RSS) Scores Over Time