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# Effect of 75mg vs 150mg Pregabalin in Postoperative Pain Relief Among Patients Scheduled for Lower Abdominal Surgeries: A Comparative Study

Dr. Nandini Darapaneni[1*,]
[*1](Postgraduate, Department of Anesthesia, NRI Medical College, Andhra Pradesh, India)

***Abstract:***
***Background****: Postoperative pain causes significant physiological and psychological responses and adequate pain relief improves perioperative outcomes. Pregabalin was introduced as a lipophilic GABA (-aminobutyric acid) analogue that has a substitution of '3' position substitution to help in blood-brain barrier diffusion. Studies on the comparison of varying doses of pregabalin for postoperative pain relief in India were less. Hence the current study was undertaken.*
***Objective:****This study was done to know the efficacy and safety of 75mg vs 150mg pregabalin in decreasing postoperative pain, when given as premedication for providing postoperative analgesia in patients scheduled for lower abdominal surgeries under spinal anaesthesia.*
***Materials and Methods****: In this interventional, randomized, single-blinding study, 200 patients scheduled for various lower abdominal surgerieswere included. They were randomized into 2 groups of 100 patients each. Group A received 75mg of pregabalin and group B received 150mg of pregabalin.Age, gender, ASA status,postoperative pain, number of doses of rescue analgesia needed, sedation scores were assessed and compared between two groups.*
***Results****: There is no significant difference in mean age, gender, ASA grade between two groups. Postoperative pain was significantly less in group B patients. Sedation score was significantly more in group B patients. No. of rescue analgesic doses used were significantly less in group B patients. Overall adverse effects were significantly more in group B patients.*
***Conclusion:****Pregabalin was found to be very effecting in providing effective postoperative pain relief. The dose of 150mg is idea in relieving pain but it produced more adverse effects compared to the dose of 75mg.*
***Key Words:*** *Pregabalin, postoperative pain relief, analgesia, lowerlimbsurgeries, spinal anaesthesia*

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## I. Introduction

Postoperative pain causes significant physiological and psychological responses and adequate pain relief improves perioperative outcomes.Pain is defined as "Sensory and emotional experience linked to existing or potential tissue injury or explained in terms of tissue damage."Modern anaesthesia is not just concerned with intraoperative pain relief, but also with pain relief after surgery which in turn helps to decrease the risk of complications, providefast recovery and hence lowers medical expenses. Multiple medications can be used preemptively to reduce postoperative pain. They include using ketamine, non-steroidalanti-inflammatorydrugs (NSAIDs) like ketorolac, diclofenac, lornoxicam, opioids like morphine, fentanyl, steroids like dexamethasone, neuropathic pain relivers like gabapentin, pregabalinbut consistent relief of peri/postoperative pain is a major challenge.[3]But opioids can cause various side effects like urinary retention, constipation, vomiting, and respiratory depression.[4]Local anaesthetic techniques can be short-lived or need certain interventional procedures and usage of NSAIDs and is limited due to known concerns. Pregabalin was introduced as a lipophilic GABA (-aminobutyric acid) analogue that has a substitution of '3' position substitution to help in blood-brain barrier diffusion. It acts like gabapentin but has better pharmacokinetic profile and efficacy compared to gabapentin[5]. It acts by increasing the levels of gamma amino butyric acid (GABA). It is used in various laparoscopic operations as prophylactic and postoperative analgesic with varying success. Pregabalin at low doses provides mild analgesic effect. High doses of pregabalin may provide effective analgesia, but it may cause more adverse effects.[6-9]

Studies on comparison of varying doses of pregabalin for postoperative pain relief in India were less. Hence the current study was undertaken.

**Objective:** This study was done to know the efficacy and safety of 75mg vs 150mg pregabalin in decreasing postoperative pain, when given as premedication for providing postoperative analgesia in patients scheduled for lower abdominal surgeries under spinal anaesthesia.

## II. Material And Methods

This interventional, randomized, single-blinded study was carried out at the Department of anesthesia at NRI Institute of Medical Sciences,Chinakakani, Andhra PradeshfromJune 2022to November 2022.
**Study Design:**Interventional, randomized, single-blinded study
**Study Location**: This study was done at tertiary care teaching hospital in the Department of anesthesia at NRI Institute of Medical Sciences, Chinakakani
**Study Duration:**June 2022 to November 2022.
**Sample size:** 200 patients
**Sample size calculation:** The sample size was estimated on the basis of results of study done by Anand et al using incidence of postoperative pain at 4 to 8 hours. The minimum sample size came to be 186 overall.
At confidencelevel of 95%, taking error as 10%, and incidence of postoperative pain as 44%, the minimum sample size obtained was 93 in each group. So, we included 100 patients in our study, in each group, considering few drop outs.

**Subjects & selection method**: The study population was drawn from patients scheduled for elective lower abdominal surgeries under spinal anesthesia at NRI Institute of Medical Sciences.
Patients were divided into two groups (each group had 100 patients) as per the drug given.
Group A (N=100 patients) –75mg pregabalin was given- it was given 1 hour before surgery orally
Group B (N=100 patients) –150mg pregabalin was given- it was given 1 hour before surgery orally.
The patients who were involved in randomization and drug preparation doesn't know the information about the type of drug that was given to them (single-blinded).

**Inclusion criteria:**
1. Patients belonging to ASA grade I and II
2. Either sex
3. Aged 19 to 65 years,
4. Patients scheduled for various lower abdominal surgeries under spinal anesthesia
5. Patients who provided informed consent

**Exclusion criteria:**
1. Pregnant and lactating women
2. Patients with contraindication to study drugs
3. Patients with severe hepatic and renal disorders
4. Patients with BMI above 35kg/$m^2$.
5. Patients who can't understand visual analogue scale.

**Methodology:**
Patients were randomized into two groups using blind envelope method.
All the patients were given capsule omeprazole 20mg, Tab Alprazolam 0.25 mgnight before the surgery.The patient was asked to fast for minimum of 8 hours. After shifting patients to operation theatre,continuous pulse oximetry, ECG, blood pressure, heart rate monitoring weredone. Spinal anaesthesia was given using 0.5% hyperbaric bupivacaine intrathecally in sitting position, at Lumbar 3rd intervertebral space using 25-gauge needle. All patients received paracetamol injection 1 gram intravenously. Rescue analgesia was given if VAS is more than 4. Tramadol and diclofenac were used as rescue analgesic agents.
All 200 patients accepted to participate in this study and gave written ICF. All the patients underwent proper physical examination and required blood testing. Medical history was taken from all patients as per the case record form (CRF).
During postoperative period, pain was assessed using 0–10-point VAS scale. Pain was assessed at baseline, 8, 12 and 24 hours. Side effects like nausea, vomiting, dizziness, headache was noted.

We have used visual analogue scale (VAS) scoreto identify the severity of pain among patients.

VAS SCALE:[10]
0: No pain
1-3: Mild pain

4 to 6: Moderate pain
7 to 10: Severe pain
Sedation was assessed using Ramsay sedation score. It is assessed as follows:

| Sedation score | Response |
|---|---|
| 1 | Anxious and agitated or restless or both |
| 2 | Co-operative, oriented and tranquil |
| 3 | Responding to commands only |
| 4 | Brisk response to light glabellar tap or loud auditory stimulus |
| 5 | Sluggish response to light glabellar tap or loud auditory stimulus |
| 6 | No response to stimulus |

Image 1 shows Ramsay sedation score[11]

**Parameters assessed**:
Age
Gender
ASA grade
VAS score at baseline, 8, 12 and 24 hours
Sedation score
No of doses of rescue analgesia consumption
Side effects

**Ethical considerations:**
Permission was obtained from the Institutional ethical committee attached to NRI Institute of Medical Sciencesbefore conducting the study. Every patient was explained the whole process and advantages of the study. After he/she accepts, an informed consent form is given in local language or patient understandable language and the person was asked to sign it or put a thumb impression.

**Statistical analysis**
Data was analyzed using Epi info software version 7.2.5. Student's *t*-test was used to compare numerical parameters between two groups.Chi-square test was used to compare categorical values between two groups. P value <0.05 was considered significant.

## III. Results

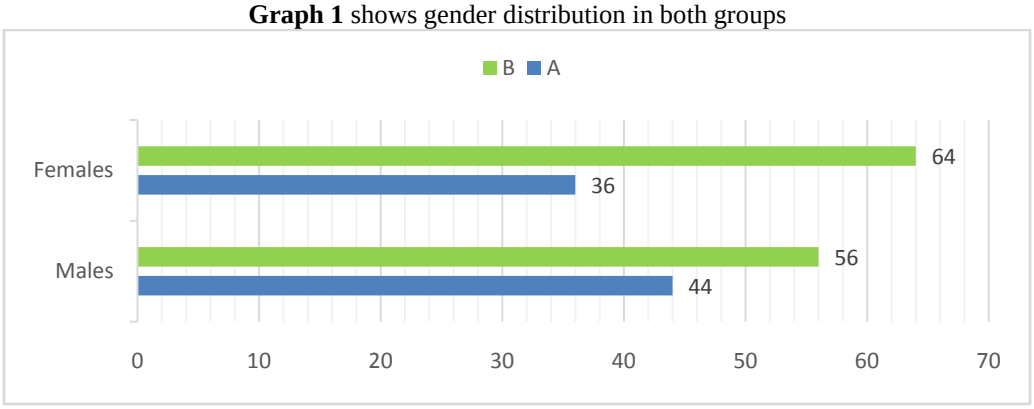
The current study included 200 patients divided into groups A and B.

**Demographic features**
Females were more commonly involved in our study. Most of the patients belonged to ASA grade I. But, there is no significant difference in the mean age, gender and ASA grade of patients of both groups, as per the T-test. Hence the comparison is justifiable without baseline bias.

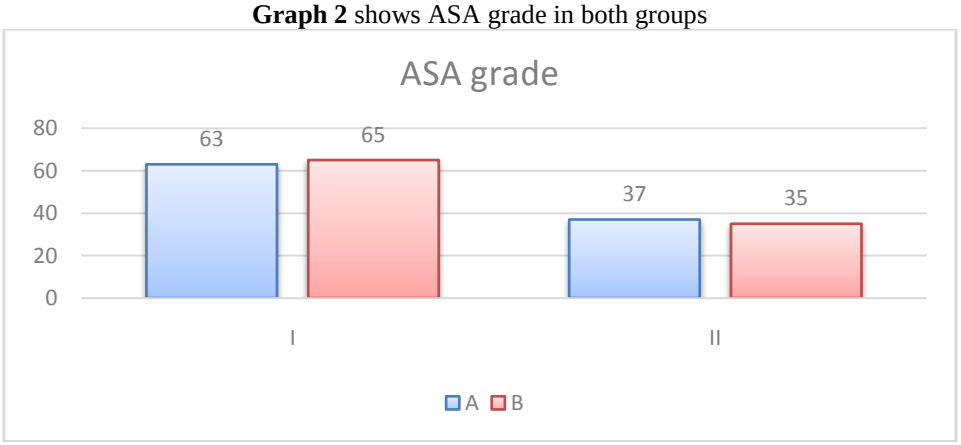
**Table no 1:** Shows the summary of baseline characteristics in each group

| Parameters | Group A | Group B | P Value |
|---|---|---|---|
| Mean age | 52.3±3.4 years | 53.1±3.21 years | 0.08 |
| Gender (% of males) | 44% | 36% | 0.24 |
| ASA grade (% of grade I) | 63% | 65% | 0.086 |

**Graph 1** shows gender distribution in both groups




**Graph 2** shows ASA grade in both groups



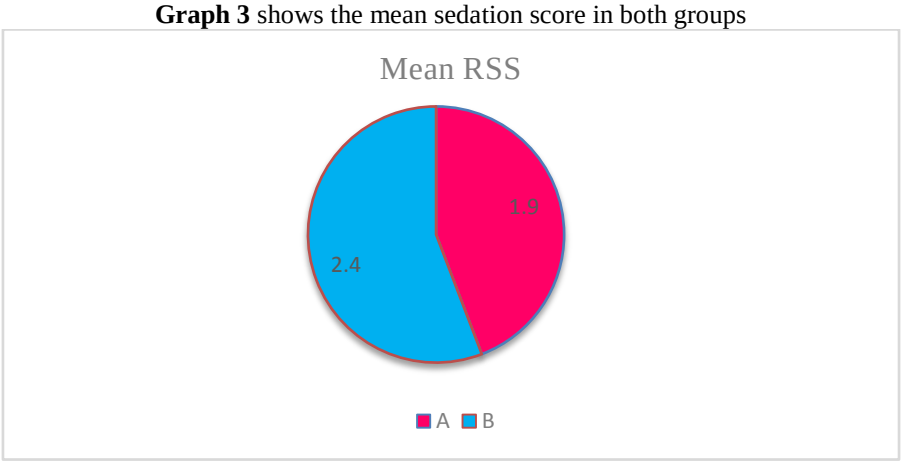

**VAS scores:**VAS score was significantly less in group A patients compared to group B patients at 30min, 8 hours, 12 and 24 hours of postoperative period.

**Table no 2:** Shows VAS score in both groups at various intervals

| Parameters | Group A | Group B | P Value |
|---|---|---|---|
| Mean VAS at 30min | 2.0±0.21 | 1.64±0.6 | 0.001 |
| Mean VAS at 8 hours | 2.7±0.62 | 2.2±0.13 | 0.001 |
| Mean VAS at 12 hours | 3.7±0.4 | 3.2±0.29 | 0.001 |
| Mean VAS at 24 hours | 3.3±0.5 | 2.9±0.41 | 0.001 |

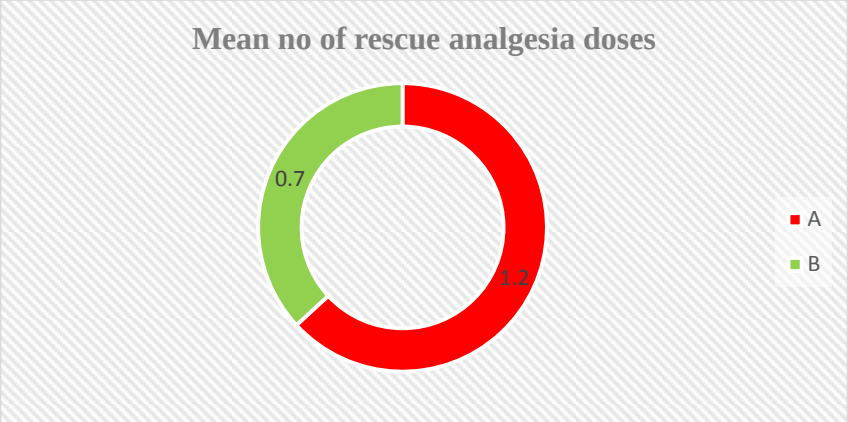
**Sedation score:**
Ramsay sedation score(RSS) was significantly more in group B patients compared to group A patients(p=0.001). It was assessed 6 hours after surgery.

**Graph 3** shows the mean sedation score in both groups



**Number of doses of rescue analgesia needed:**
There is a significant difference in the mean number of rescue analgesic doses consumed by patients in between two groups. It was less in group B patients. (P=0.001).

**Graph 4** shows no. of doses of rescue analgesia




**Side effects:**
Side effects are significantly more common in group B patients compared to group A patients.

**Table 3** shows side effects of patients in both groups

| Parameters | Group A | Group B | P Value |
|---|---|---|---|
| Nausea | 72% | 96% | 0.0001 |
| Vomiting | 20% | 46% | 0.0001 |
| Hypotension | 41% | 92% | 0.0001 |

## IV. Discussion

Pregabalin was previous shown to possess analgesic and antinociceptive properties in various experimental studies done on neuropathic pain. It reduces the discharge of neurotransmitters like noradrenaline, glutamate, dopamine, serotonin, and substance P by binding to calcium channels

In the current study, 100 patients received 75 mg of pregabalin (group A) and 100 patients received 150mg of pregabalin (group B) for postoperative pain reliefamong patients scheduled for lower abdominal surgeries under spinal anesthesia.

Most of the patients belong to ASA grade I. Females were more commonly involved as lower abdominal surgeries more commonly occur in females like hysterectomy etc.

But there is no significant difference in the mean age, gender and ASA grade of patients of both groups in our study.

Both 75mg and 150mg pregabalin reduced the need for rescue analgesia and provided effective pain relief in our study. But since, 150mg pregabalin produced more adverse effects, we recommend using 75mg pregabalin dose.

In the study of**Ajish et al.**[12]**,** theauthors compared 75mg of pregabalin with 150mg along with placebo. They included 129 patients who were scheduled for hysterectomy. They found no significant difference in mean agesimilar to our study. Postoperative pain scores decreased with both doses of pregabalin.Sleep score was better as the dose of pregabalin raises. The need for rescue analgesia reduced with increasing dose of pregabalin, similar to our study findings. Adverse effects like nausea and vomiting, dizziness was more in 150mg dose pregabalin group compared to 75mg pregabalin group, similar to our study findings.

**Anand et al, Agarwal *et al.*, Mishra *et al.*,**showed that postoperative pain was reduced using 150 mg of pregabalin compared to placebo among patients undergoing laparoscopic cholecystectomy.[13-15]

**Sattari et al and Entezary *et al.*** used high dose of pregabalin in their studies. They reported thatpreemptive use of 300 mg of pregabalin decreased post operative pain significantlyafter hysterectomy and thoracotomy.[16-17]

**Paech *et al.***found that a single preoperative dose of 100 mg of pregabalin does not decrease postoperative pain after small surgeries that involve uterus. This is in contrast to our study findings.[18]

**Ghai** et al also found that dizziness as the most common adverse effect in their study when they used pregabalin.[19]

**Park et al** found no effect of pregabalin in reducing postoperative pain in patients scheduled for gastrectomy.[20]

## V. Conclusion

Pregabalin was found to be very effecting in providing effective postoperative pain relief. The dose of 150mg is idea in relieving pain but it produced more adverse effects compared to the dose of 75mg.
The study is self-sponsored and there are no conflicts of interest.

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