

Original Research Article

A PROSPECTIVE RANDOMIZED DOUBLE-BLIND COMPARATIVE STUDY OF TWO DIFFERENT DOSES OF PREGABALIN (150 MG VS 300 MG) ON POSTOPERATIVE ANALGESIA IN PATIENTS UNDERGOING ELECTIVE LOWER ABDOMINAL SURGERIES UNDER SUBARACHNOID BLOCK

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ABSTRACT

Background: Effective postoperative pain management is a key determinant of perioperative quality of care and patient satisfaction. Pregabalin, a gabapentinoid, has gained attention as a pre-emptive analgesic due to its opioid-sparing properties and anxiolytic effects. However, the optimal dose that balances analgesic efficacy with adverse effects remains unclear. The objective is to compare the analgesic efficacy, quality of blockade, sedation profile, and adverse effects of oral pregabalin 150 mg versus 300 mg administered preoperatively in patients undergoing elective lower abdominal surgeries under subarachnoid block.

Materials and Methods: This prospective, randomized, double-blind study was conducted over 1.5 years in 70 ASA physical status I–II patients aged 20–60 years undergoing elective lower abdominal surgeries. Patients were randomly allocated into two groups: Group P150 received oral pregabalin 150 mg and Group P300 received oral pregabalin 300 mg, one hour before surgery. Spinal anesthesia was administered using 0.5% hyperbaric bupivacaine. Parameters assessed included onset and duration of sensory and motor blockade, time to two-segment regression, duration of postoperative analgesia, Visual Analog Scale (VAS) scores at 4, 8, and 12 hours, Ramsay sedation score, and incidence of adverse effects. Statistical analysis was performed using SPSS version 22.0, with $p < 0.05$ considered significant.

Results: There was no statistically significant difference between the groups in terms of onset of sensory and motor blockade, time to maximum block, or duration of surgery. The 300 mg pregabalin group demonstrated a significantly prolonged duration of postoperative analgesia, longer motor blockade, delayed two-segment regression, lower VAS scores at all postoperative intervals, and higher sedation scores compared to the 150 mg group ($p < 0.001$). However, the incidence of dizziness was significantly higher in the 300 mg group ($p = 0.02$).

Conclusion: Preoperative oral pregabalin 300 mg provides superior postoperative analgesia and better sedation compared to 150 mg in patients undergoing elective lower abdominal surgeries under spinal anesthesia, albeit with a higher incidence of dizziness. Clinicians must balance enhanced analgesic benefits against increased side effects when selecting the appropriate dose. Larger, procedure-specific studies are recommended for broader generalization of results.

Keywords: Pregabalin; Postoperative analgesia; Subarachnoid block; Spinal anesthesia; Lower abdominal surgery; Visual Analog Scale; Pre-emptive analgesia.

INTRODUCTION

Post operative pain relief is now an emerging basis for deciding the quality of care provided to the patients.^[1] According to the American Society of Anesthesiologist practice guidelines for acute pain management in the perioperative setting, acute pain is defined as pain present in a surgical patient after a procedure.^[2] The World Health Organization and International Association for the Study of Pain have recognized pain relief as a human right.^[3] Poorly managed postoperative pain can lead to complications and prolonged rehabilitation.^[4] Uncontrolled acute pain is associated with the development of chronic pain with reduction in quality of life.^[5]

The Hospital Consumer Assessment of Health Providers and Systems (HCAHPS) scores measures patient satisfaction with in-hospital pain management and may have implications in regards to reimbursements.^[6]

Many drugs such as local anesthetics, opioids, non-steroidal anti-inflammatory drug, cyclooxygenase-2 inhibitor, gabapentin, pregabalin, clonidine and dexmedetomidine have been used as post operative analgesics. Preemptive analgesic modalities have been used as single entities and in combination. The most important side effect is respiratory depression that could result in hypoxia and respiratory arrest. Hence, regular monitoring of respiration and oxygen saturation is essential in patients on opioids postoperatively. Pregabalin is claimed to be more effective in preventing neuropathic component of acute nociceptive pain of surgery, to produce more opioid sparing effect and for amelioration of perioperative anxiety.^[7] Pregabalin has been used in a dose range of 75 mg to 300 mg, and higher doses of pregabalin were associated with an increased incidence of dizziness.^[8] Hence the present study was carried out to compare 2 different doses of 150mg and 300 mg of Pregabalin in cases with lower abdominal surgeries; to assess the clinical outcome in terms of better pain control.

MATERIALS AND METHODS

Ethical clearance was obtained from the institution before the start of the study. It was a prospective randomized double blinded study among Patients of either sex aged 20-60 scheduled for lower abdominal surgeries belonging to ASA class I and II undergoing elective lower abdominal surgeries were included in the study for a period of 1.5 years

Sample Size

$$N = \frac{(Z\alpha/2 + Z 1-\beta)^2 \times 2 \times (SD)^2}{d^2}$$

SD = Pooled Standard deviation obtained from previous study = 1.2 (Mean time of onset of analgesia (min))

d = accuracy of the estimate = 1

$Z\alpha/2$ = Normal deviate for two tailed hypothesis = 1.96
 $Z 1-\beta$ = 0.84

N = Sample size = 35

Substituting the above formula we got a sample size of 35 in each group patients of either sex, scheduled for lower abdominal surgeries belonging to ASA class I and II were included in the study. The study population was randomly divided into two groups.

1. Group P150 : received oral 150mg of pregabalin 1hr preoperatively
2. Group P300 : received oral 300mg of pregabalin 1hr preoperatively

Inclusion Criteria

- 1 Normal adult patients of either sex, aged between 20–60 years
- 2 ASA class I and II posted for elective lower abdominal surgeries.
3. Patients undergoing elective lower abdominal surgeries

Exclusion Criteria

1. Age group less than 20 and more than 60 years
2. Patient refusal to participate in the study
3. Patients belonging to ASA class III, IV and V
4. Pregnant females
5. Patients posted for emergency surgeries
6. Patients with body mass index more than 30kg/m²
7. Patients with comorbid diseases like diabetes, hypertension, neurological, psychiatric or neurovascular disorder.
8. Patients having absolute contraindication for spinal anaesthesia like raised intracranial pressure, severe hypovolaemia, bleeding diathesis and local infection.
9. Patients with history of taking pregabalin or gabapentin

All patients underwent a detailed Pre Anaesthetic Check up including examination of back for feasibility of spinal anaesthesia, after which they were explained about the study protocol in detail. Written and informed consent was obtained from all participants in the study. Weight, height and Body Mass Index was recorded. After thorough PAC workup patients were randomly allocated to one of the group by allocation sequence generated by computer generated random number table. Group allocation and drug administration was carried done by anaesthesiologist who was not a part of study design to avoid any bias. Also for all the cases 0.5% 3ml bupivacaine local anaesthetic was administered. Sedation was assessed preoperatively by using Ramsay's sedation score.^[9]

Other parameters which were recorded were as follows:

- Induction of spinal anaesthesia: The time at which the intrathecal injection was completed.
- Onset of sensory blockade: From the time of induction of spinal anaesthesia till the time the level of sensory blockade reach T10 dermatome.

- Maximum sensory blockade: Time required to attain the maximum level of sensory blockade from the time of induction of spinal anaesthesia.
- Motor onset: Time required for the development of Bromage grade 1 motor block from the time of induction of spinal anaesthesia.

Postoperatively the patients were shifted to Post Anaesthesia Care Unit for monitoring and observation. All patients were given Inj. Diclofenac 1.5mg/kg intramuscular as rescue analgesic once VAS exceeded 4. The patients were subsequently shifted to ward. Postoperatively one resident anaesthetist who was unaware as to which group the patient belonged to recorded the following data.

- Time taken to two segment regression from the highest dermatomal level of sensory block (in minutes) was assessed by pin prick method.
- Time to VAS >4 (time to rescue analgesics in minutes).
- Total number of times VAS >4 in 12 hours duration.

Statistical analysis: The data was entered in Microsoft excel 2013 and cleaned. It was checked for normality of distribution using the Shapiro Wilk test.

Paired means were compared using the t- test. All p-values <0.05 was considered to be statistically significant. SPSS 22.0 (IBM Analytics, New York U.S.A) was used for the analysis process.

RESULTS

Of the total 70 cases enrolled for the study, each group comprised of 35 cases. Among the total 22(31.4%) cases of hernioplasty; 12(54.5%) were administered with Pregabalin 150 mg and 10(45.5%) were given 300 mg of Pregabalin. Of the 17(24.3%) of the URS cases; 09(52.9%) were administered with Pregabalin 150 mg and rest 08(47.1%) were administered with Pregabalin 300 mg. Of the 18(25.7%) cases with appendicectomy; 07(38.9%) were administered with Pregabalin 150 mg and 11(61.1%) cases with Pregabalin 300 mg. Of the 13 cases with ORIF; 07(53.85%) were administered with Pregabalin 150 mg and the remaining 06(46.15%) were administered with Pregabalin 300 mg.

Table 1: Distribution of cases based on the type of surgery and the dosage of pregabalin administered

Type of surgery	Pregabalin 150 mg	Pregabalin 300 mg	Total
Hernioplasty	12(54.5%)	10(45.5%)	22(31.4%)
URS	09(52.9%)	08(47.1%)	17(24.3%)
Appendicetomy	07(38.9%)	11(61.1%)	18(25.7%)
ORIF	07(53.9%)	06(46.1%)	13(18.6%)
Total	35(50%)	35(50%)	70(100%)

Table 2: Mean of height, weight, and BMI among the two Pregabalin groups (150 mg and 300 mg)

Mean	Pregabalin 150mg	Pregabalin 300mg	t-test	p- value
Age	38.42(±9.08)	36.48(±11.49)	0.8	0.42
Weight	59.31(±7.18)	60.62(±5.56)	-0.86	0.39
Height	158.62(±7.79)	158.94(±6.64)	-0.18	0.85
BMI	23.5(±2.01)	23.97(±2.02)	-0.98	0.32

There was no significant difference in the mean age height; weight or BMI among the two groups.

Table 3: Distribution of the cases based on the mean change in time to t10 sensory levels

Parameter	Pregabalin 150 mg	Pregabalin 300 mg	t- test value	p- value
Time to t10 sensory level (min)	2.57(±0.60)	2.62(±0.59)	-0.40	0.69
Time to maximum sensory level	4.82(±0.56)	5.11(±0.83)	-1.68	0.09
Onset of motor blockade	3.94(±0.68)	3.85(±0.64)	0.54	0.59
Time for maximum motor blockade	6.65(±0.72)	6.88(±0.67)	-1.36	0.17
Total duration of surgery (min)	54.2(±9.78)	55.42(±11.65)	-0.44	0.65
Total duration of analgesia	280.14(±28.06)	564.42(±32.42)	-39.22	0.000
Total duration of motor blockade	181.57(±20.71)	344.14(±29.96)	-26.40	0.000
Time taken to two segment regression	76.71(±11.62)	105.14(±20.20)	-7.22	0.000

Significantly there was no difference in the time taken to t10 sensory level, time for maximum sensory levels, the onset of motor blockade, time taken for maximum motor blockade, the total duration of surgery. Significantly higher score were seen with the Pregabalin 300 mg group; where the total duration of analgesia was more than the 150 mg group. More

time duration of motor blockade was seen in the 300 mg group and also the time taken for the two segment recession was higher with the 300 mg group. Thus the duration of analgesia, motor blockade and segment recession was achieved significantly more with the 300 mg of dosage than with 150 mg.

Table 4: Distribution of cases based on the quality of blockade:

Quality of Blockade	Pregabalin 150 mg	Pregabalin 300 mg	Total	Chi-square	p-value
Bromage 2 – Patient is unable to move the hip and knee but is able to move the ankle	11 (55%)	9 (45%)	20 (28.6%)	0.28	0.59

Bromage 3 – Patient is unable to move the hip, knee, and ankle	24 (48%)	26 (52%)	50 (71.4%)		
Total	35 (50%)	35 (50%)	70 (100%)		

There were more cases with Bromage 3 in 300 mg group than in the 150 mg group; but this difference was not found to be statistically significant ($p=0.59$).

Table 5: Distribution of the cases based on the dizziness index

Dizziness	Pregabalin 150 mg	Pregabalin 300 mg	Total	Chi square	p- value
Yes	0(0.0)	5(100%)	5(7.1%)	5.38	0.02
No	35(53.9%)	30(46.1%)	65(92.9%)		
Total	35(50%)	35(50%)	70(100%)		

More dizziness was seen with the Pregabalin 300 mg group than the pregabalin 150 mg group significantly

($p=0.02$). This shows that the side effects of a higher dosage was more with the 300 mg group.

Table 6: Distribution of cases based on the Ramsay Sedation scoring

Ramsay Sedation Score – Criteria	Pregabalin 150 mg	Pregabalin 300 mg	Total	Chi-square	p-value
1 – Awake (Anxious or restless or both)	9 (100%)	0 (0%)	9 (12.9%)	12.90	0.0048
2 – Awake (Cooperative, oriented and tranquil)	21 (48.8%)	22 (51.2%)	43 (61.4%)		
3 – Awake (Responding to commands only)	5 (29.4%)	12 (70.6%)	17 (24.3%)		
4 – Asleep (Brisk response to stimulus)	0 (0%)	1 (100%)	1 (1.43%)		
Total	35 (50%)	35 (50%)	70 (100%)		

Significantly more cases were awake (anxious or restless) with pregabalin 150 mg. Higher number of cases were present in the 300 mg group who were cooperative, oriented and tranquil and also

responding to commands only. Significantly higher scoring criteria was seen with pregabalin 300 mg group.

Table 7: Distribution of cases based on VAS scale over 4, 8 and 12 hours

Time	VAS Scale	Pregabalin 150 mg	Pregabalin 300 mg	Total	Chi-square	p-value
4 hours	< 4	9 (100%)	35 (57.4%)	26 (37.1%)	10.32	0.0005
	> 4	26 (42.6%)	0 (0%)	44 (62.9%)		
8 hours	< 4	4 (10.3%)	35 (89.7%)	39 (55.7%)	55.64	0.0000
	> 4	31 (89.7%)	0 (0.0%)	31 (44.3%)		
12 hours	< 4	7 (20.6%)	27 (79.4%)	34 (48.6%)	22.87	0.0000
	> 4	28 (77.8%)	8 (22.2%)	36 (51.4%)		

We divided the scores of the VAS scale as <4 and more than 4 to assess the pain with regards to the 150mg and 300 mg of Pregabalin. From the above table it is clear that; greater amount of Pregabalin provided with more time of relief and with low VAS scale (<4) i.e., from no to only mild pain. Significantly less pain was seen over 4, 8 and 12 hours of time with 300 mg of pregabalin as compared to 150 mg.

DISCUSSION

The present study was carried out to clinically assess whether Pregabalin 150 mg or at 300 mg can serve as a better analgesic agents in cases of post operative analgesia. The present study had a total of 70 adult cases with 35 each in two arms- Pregabalin 150 mg and Pregabalin 300 mg. In the present study we included different cases of hermioplasty, URS, appendicectomy, ORIF wherein 150 mg and 300 mg of Pregabalin was compared for its efficacy.

We observed that 300 mg dosage gave more blockade (patient was unable to move the hip, knee and ankle) as compared to 150 mg dosage. Also higher score were seen with the Pregabalin 300 mg group; where the total duration of analgesia was more than the 150 mg group. More time duration of motor blockade was

seen in the 300 mg group and also the time taken for the two segment recession was higher with the 300 mg group. Thus the duration of analgesia, motor blockade and segment recession was achieved significantly more with the 300 mg of dosage than with 150 mg. This was also reported by El Rahamawy et al (2013);¹⁰ and Kumari et al (2017).^[11] In the present study; significantly more cases were awake (anxious or restless) with pregabalin 150 mg. Higher number of cases were present in the 300 mg group who were cooperative, oriented and tranquil and also responding to commands only. Significantly higher scoring criteria was seen with pregabalin 300 mg group. A similar conclusion was reported by Kohli et al (2011),^[12] where a significant reduction in anxiety in groups P (150) and P (300) than placebo group P (0) during intraoperative and postoperative period than preoperative period was observed.

Buvanendran et al (2012),^[13] though reported that there is no correlation between neurotransmitters and the analgesia after administration of Pregabalin at any specific dosage. We divided the scores of the VAS scale as <4 and more than 4 to assess the pain with regards to the 150mg and 300 mg of Pregabalin. We observed that; greater amount of Pregabalin provided with more time of relief and with low VAS scale (<4)

i.e. from no to only mild pain. Significantly less pain was seen over 4, 8 and 12 hours of time with 300 mg of pregabalin as compared to 150 mg. This was similar to the reports by Singh et al (2014),^[14] Sebastain et al (2016),^[15] Kumari et al (2017),^[11] the authors concluded that a single preoperative dose of 100 mg pregabalin does not reduce acute pain or improve recovery after minor surgery involving only the uterus.

Kumari et al (2017),^[11] used only 75 mg in their study and found that oral pregabalin 75mg as premedicant has comparable duration of spinal analgesia. However the VAS scores and number of doses of rescue analgesics used were significantly less in the pregabalin group. Hence using a less dosage seems to be ineffective as an adjunct to achieve analgesia. Singh et al (2014),^[14] found the incidence of sedation, dizziness, and visual disturbances was more in group B as compared to group A and was least in group C.

Limitations of the study-

1. We pooled in all forms of surgeries in one study; which could have been the cause of a different result as compared to previous reported literature.
2. The samples selected were not homogenous; which could have resulted in difference in the responses to the drug dosages.

CONCLUSION

The present study demonstrates that while pregabalin at doses of 150 mg and 300 mg showed no significant difference in the onset and attainment of sensory and motor blockade, maximum sensory levels, or total duration of surgery, the 300 mg dose provided superior postoperative analgesia with a longer duration of pain relief. This enhanced analgesic effect was accompanied by a prolonged motor blockade, delayed two-segment sensory regression, and a higher incidence of dense motor block (Bromage 3) in the 300 mg group. However, the higher dose was also associated with a significantly increased incidence of dizziness, despite better patient tranquility, cooperation, and responsiveness to commands. Although VAS scores were reduced across all procedures, the pattern of adverse events differed from previously reported literature. Overall, pregabalin 300 mg offers improved analgesic efficacy at the cost of increased side effects, highlighting the need to balance analgesic benefits against tolerability. Further studies with larger sample sizes are warranted to validate and generalize these findings.

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