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A Prospective Randomized Comparative Study Of The Effect Of Single Preemptive Dose Of Oral Pregabalin Versus Oral Gabapentin On Sensory And Motor Blockade On Sub Arachnoid Block In Patients Undergoing Elective Infra Umbilical Surgeries

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Abstract

Introduction: Acute pain accompanies almost all surgical procedures. The goal of postoperative pain relief is to achieve optimal analgesia, facilitating a quick return to normal physiological function. Gabapentinoids have been shown to reduce post-operative pain and opioid analgesic requirement in various studies involving general anaesthesia.

Objectives: This study was being done to evaluate and compare the efficacy of single preemptive dose of oral Pregabalin (300mg) versus oral Gabapentin (1200mg) on the time of onset and quality of sensory and motor blockade and on the duration of postoperative analgesia in patients undergoing elective infra umbilical surgeries under Sub Arachnoid block.

Methodology: This prospective randomized comparative study was conducted on 90 subjects. Subjects were divided into 3 groups, and the sensory and motor blockade were assessed.

Results: The time taken to achieve a sensory level of T6 was 7.4±0.6min in group G, 7.3±0.7min in group P and 7.4±0.6 min in group C, with no statistically significant difference between the groups. Motor blockade characteristics was compared and there was no statistically significant difference (p value=0.12).

Conclusion: Preemptive oral Pregabalin and Gabapentin provide longer duration of post-operative analgesia and reduced requirement of rescue analgesics in patients undergoing infra umbilical surgeries under sub arachnoid block. Preemptive oral pregabalin and gabapentin also prolong the period of sensory and motor blockade.

INTRODUCTION

Pain is defined by the International Association for the study of pain as an “unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage.” Acute pain accompanies almost all surgical procedures. In addition to immediate unpleasantness, painful experiences can imprint themselves indelibly on the nervous system, amplifying the response to subsequent noxious stimuli (Hyperalgesia) and causing a typically painless sensation to be experienced as pain (Allodynia). The goal of postoperative pain relief is to achieve optimal analgesia, facilitating a quick return to normal physiological function.[1]

The gabapentinoids, pregabalin and gabapentin, are both indicated for the treatment of post herpetic neuralgia and as adjuvant therapy for seizure disorder. Pregabalin is additionally approved for the treatment of fibromyalgia and neuropathic pain associated with diabetes mellitus or spinal cord injury. Although both of the gabapentinoids are structural analogs of γ-aminobutyric acid, neither has any activity at the γ-aminobutyric acid receptors. Instead, they bind to the α-2δsubunit of presynaptic P/Q-type voltage- gated calcium channels, modulating the traffic and function of these channels. This, in turn, is thought to modulate the subsequent release of excitatory neurotransmitters from activated nociceptors. By modulating calcium- induced release of glutamate from activated pain transmitting neurons, these drugs may inhibit pain transmission and central sensitization. The principal differences between these two drugs arise not from different modes of action but rather from differing bioavailability.[2] Pregabalin is several times more potent than gabapentin. It is rapidly absorbed orally, achieves peak plasma levels within 30 minutes to 2 hours. Pregabalin has fewer side effects, with the most common adverse events being dizziness and somnolence.[3] Gabapentinoids have been shown to reduce post-operative pain and opioid analgesic requirement in various studies involving general anaesthesia. As yet, not many patients undergoing surgery under regional anaesthesia have been exposed to Gabapentin and Pregabalin in the perioperative period.[1]

Hence the present study was being undertaken to evaluate and compare the efficacy of single preemptive dose of oral Pregabalin (300mg) versus oral Gabapentin (1200mg) on the time of onset and quality of sensory and motor

blockade and on the duration of postoperative analgesia in patients undergoing elective infra umbilical surgeries under Sub Arachnoid Block.

Objectives: This study was being done to evaluate and compare the efficacy of single preemptive dose of oral Pregabalin (300mg) versus oral Gabapentin (1200mg) on the time of onset and quality of sensory and motor blockade and on the duration of postoperative analgesia in patients undergoing elective infra umbilical surgeries under Sub Arachnoid block.

METHODOLOGY

This prospective randomized comparative study was conducted on 90 subjects aged between 18 and 60 years of ASA grade I and II, who underwent elective infra umbilical surgeries under spinal anesthesia at our institute during March 2021 to December 2022. Simple Random Sampling was used to select the study samples. Subjects were divided into 3 groups- Group G – received 1200mg of Gabapentin capsule, Group P – received 300mg of Pregabalin capsule, and Group C – received identical placebo capsule.

Under strict aseptic precautions, in left lateral or sitting position, at the L3-L4 intervertebral space, lumbar puncture was done using a 27 Gauge Quincke's Spinal needle and a volume of 3.0ml of Hyperbaric solution of 0.5% Bupivacaine was injected intrathecally. The patients were then placed in supine position with head end at lower level to ensure that a sensory block of atleast T6 was achieved. The level of sensory block was assessed and recorded as a loss of sensation to pin prick using a 26-gauge hypodermic needle, checking in a caudal to cranial direction. Mean time for sensory blockade onset to achieve a T10 and a T6 level was noted. Onset of motor block was assessed and recorded according to the Modified Bromage Scale. The patients' sedation was assessed and noted, using Ramsay Sedation score, in the immediate postoperative period and at 1, 2, 4, 6, 9, 12 and 24 hours after completion of surgery. After confirmation of successful blockade, sedation score was also assessed and noted. Maximum level of sensory blockade achieved and time taken for sensory block to regress by 2 segments from the maximum level was also noted.

RESULTS

The present study included a total number of 90 patients. Among them, 30 patients in Group G, 30 patients in Group P and 30 patients in Group C were distributed randomly. In our study, the mean age of group G is 39.1±12 years, group C is 40.2±11 years and group C is 38.5±10.7 ears. There was no statistical difference, with respect to age of the patients, between the three groups (p value= 0.956). In our study, 53.3% were males and 46.7% were females in group G, 50.0% were males and 50.0% were females in group P and 53.3% were males and 46.7% were females in group C. There was no statistically significant difference in sex distribution amongst the three groups (p value = 0.95). In our study, in each of the groups, 60% of patients were of ASA I and 40% of the patients were of ASA II grading. There was no significant difference between the three groups in terms of ASA grading (p value=0.98). The mean duration of surgery was 80.8±22.4 minutes in group G, 81.3±21.2 minutes in group P and 80.9±24.9 minutes in group C respectively. There was no statistically significant difference between the groups with respect to duration of surgery (p value=0.99). (Table 1)

The time taken to achieve a sensory level of T6 was 7.4±0.6min in group G, 7.3±0.7min in group P and 7.4±0.6 min in group C, with no statistically significant difference between the groups (p values between groups G and P, groups G and C, and groups P and C being 0.99, 0.99, and 0.99 respectively) (Table 2). There was no statistically significant difference between the groups in the maximum level of sensory blockade achieved (p values between groups G and P, groups G and C, and groups P and C being 0.63, 0.89, and 0.88 respectively). (Table 3) Motor blockade characteristics was compared and there was no statistically significant difference between the groups G and P (p value=0.12). (Table 4)

There was no statistically significant difference observed between the groups preoperatively and immediate postoperatively (may be due to the effect of spinal anaesthesia). But from 2 hours postoperatively till 24 hours, the VAS scores both group G and group P were statistically significantly lower compared to group C($P<0.05$). (Figure 1) There was no statistically significant difference between RSS values of group G and group P at all measured intervals ($p>0.05$). Statistically significant RSS values were observed between groups G and C, and groups P and C (p value <0.05 at 2 hours after drug, after motor block, after surgery, and at 1,2,4,6,9 hours postoperatively), except at 12 and 24 hours postoperatively. The RSS scores were higher in group G and group P compared to group C.

Table 1: ASA grading by groups

	Group G Number (%)	Group P Number (%)	Group C Number (%)	p value
ASA I	18 (60.0)	18 (60.0)	18 (60.0)	0.98
ASA II	12 (40.0)	12 (40.0)	12 (40.0)	
Total	30 (100.0)	30 (100.0)	30 (100.0)	

Table 2: Sensory Blockade characteristics by groups

	Group G Minutes (SD)	Group P Minutes (SD)	Group C Minutes (SD)	G & P p value	G & C p value	P & C p value
Time to achieve T10 level	4.3 (0.7)	4.3 (0.7)	4.4 (0.7)	0.99	0.99	0.99
Time to achieve T6 level	7.4 (0.6)	7.3 (0.7)	7.4 (0.6)	0.99	0.99	0.99
Time for 2 segment sensory regression	88.3 (7.7)	97.2 (7.6)	74.9 (7.4)	**<0.001**	**<0.001**	**<0.001**

Table 3: Maximum level of Sensory Blockade achieved by groups

	Group G Number (%)	Group P Number (%)	Group C Number (%)	G & P p value	G & C p value	P & C p value
T4	5 (16.7)	3 (10.0)	4 (13.3)			
T5	4 (13.3)	6 (20.0)	5 (16.7)			
T6	21 (70.0)	21 (70.0)	21 (70.0)			
Total	30 (100.0)	30 (100.0)	30 (100.0)	0.63	0.89	0.88

Table 4: Motor Blockade characteristics by groups

	Group G Minutes (SD)	Group P Minutes (SD)	Group C Minutes (SD)	G & P p value	G & C p value	P & C p value
Mean time for onset of Motor block	12.4 (0.8)	12.3 (0.8)	12.5 (0.9)	0.99	0.99	0.99
Mean duration of Motor block	225.3 (10.0)	221.8 (13.0)	216.2 (11.3)	0.12	**0.02**	**0.031**

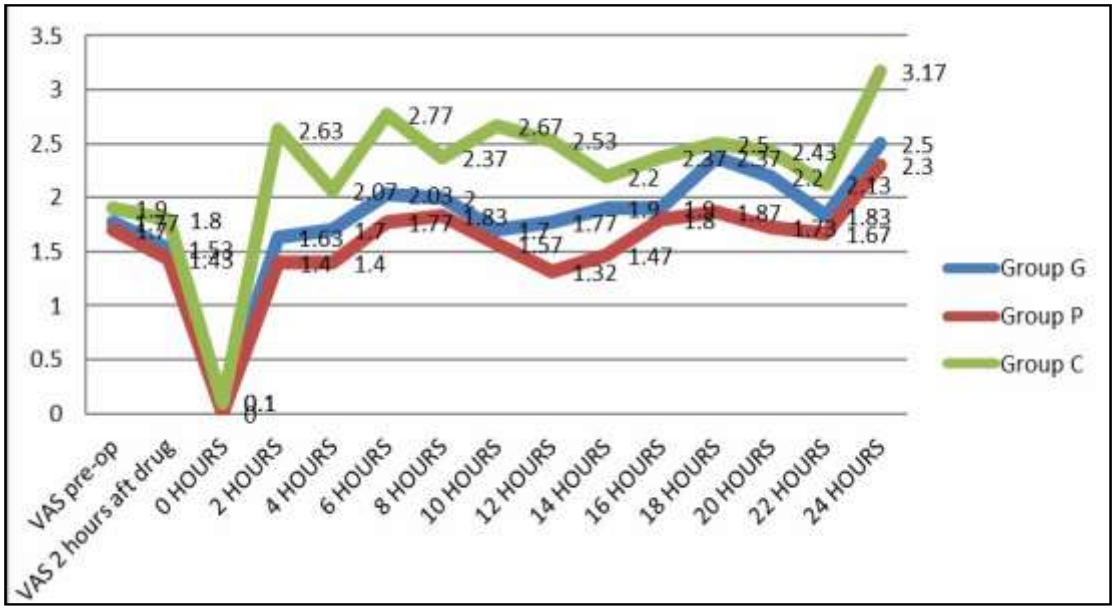

Figure 1: VAS scores between groups.

DISCUSSION

This study titled 'A prospective randomized comparative study of the effect of single preemptive dose of oral Pregabalin versus oral Gabapentin on Sub arachnoid block in patients undergoing elective infra umbilical surgeries' was conducted at our institute from March2021 to December 2022.

Schmidt et al,[2] after analysis of many studies, concluded that gabapentinoids have to be given atleast 2 hours preoperatively as the time to peak plasma concentration of gabapentin after an oral dose is approximately 2 hours and the same is about 1 hour for pregabalin. Tiippana et al,[4] after a meta-analysis, also concluded that a single dose of gabapentin (300-1200mg) given 1-2 hours preoperatively, significantly reduced the postoperative pain scores and postoperative opioid consumption and opioid related side effects. So, in our study, the drugs were given 2 hours before the surgery with sips of water.

In the study conducted by Usha Bafna et al,[5] the mean duration of surgery was 57.2 minutes, 56.8 minutes and 57.8 minutes in the gabapentin, pregabalin and placebo group respectively, while the in the study by Induja et al,[6] it was 46.7 minutes, 48.1 minutes and 45.6 minutes respectively.

In our study, when the patients' postoperative VAS score was 4 or more. This shows that both Pregabalin and Gabapentin provide prolonged pain relief when compared to the control, with pregabalin providing longer duration of analgesia compared to gabapentin. This is comparable to the results obtained in a study done by Saraswat V et al[7] where the time to first rescue analgesic was 8.985.38 hours and 14.17±6.67 hours in the gabapentin and pregabalin groups respectively(P<0.001). Our results were also comparable to those obtained in a study by Swarup P et al[8], in which the time to first rescue analgesic was 9.41±1.84 hours and 15.38±3.52 hours in the gabapentin and pregabalin groups respectively(P<0.001).

Time taken to achieve sensory block of level T10

There is no significant difference in the time to T10 sensory block between Group P and Group C(p value=0.99). This correlates with the results obtained in the studies done by MiHye Park et al[9] (P=0.79), Galal Adel et al[10](P=0.79) and Amany F et al[11](P=0.602).

Our study also observed no significant difference in the time to T10 sensory block between group G and Group C (p value 0.99). There are not many studies available to correlate this, but a study done by Upasana Bhatia et al[12] showed significant difference between the two groups (P<0.001). Our study also observed no significant difference between Group G and Group P (p value=0.99), with respect to the same.

A) Time taken to achieve sensory block of level T6

Our observations are comparable to that seen in the study by Usha Bafna et al,[5] where the time taken was 9.96±1.79 min, 9.96±1.24min and 9.83±1.55min in the gabapentin, pregabalin and control group respectively(P>0.928).

B) Time to Two Segment Regression

The study done by Galal Adel et al[10] showed the time for 2 segment regression was 91.46±13.49min and 69.11±11.23min in the pregabalin and control groups, which was significant(P<0.001), and which also correlates with our study(P<0.001). Other studies by MiHye Park et al[9] and Amany F et al[11]also showed similar significant time difference between the pregabalin and control group (P=0.00 and P=0.002 respectively), which also correlates with our study.

C) Maximum Level of Sensory block achieved

There was no statistically significant difference between the groups in the maximum level of sensory blockade achieved showing that preemptive gabapentin and pregabalin does not affect the level of block after spinal anesthesia. The study by Usha Bafna et al[5] also shows that at 5min and 10 min after subarachnoid block, similar levels of sensory block (T9 and T6 respectively) was achieved in all the three groups(pregabalin, gabapentin and control), which is similar to the observation in our study.

MOTOR BLOCKADE CHARACTERISTICS

A) Onset of motor blockade

There was no statistically significant difference noted between the three groups (p values between groups G and P, groups G and C, and groups P and C being 0.99, 0.99, and 0.99 respectively), suggesting that both preemptive gabapentin and pregabalin does not have any effect on the duration of onset of motor blockade, which is comparable with the results obtained in a study by Usha Bafna et al[5] (P>0.20).

B) Duration of motor blockade

Our study showed that both pregabalin and gabapentin prolong the duration of motor blockade as compared to the control group, while there was no significant superiority found between pregabalin and gabapentin in this aspect. Our observations with respect to difference between pregabalin and control group correlate with the studies done by MiHye Park et al[9] (P=0.00), Galal Adel et al[10] (P<0.001) and Amany F et al[11] (P=0.007).

VAS SCORE

Our study results were similar to the results obtained in a study by Induja R et al,[6] which showed significant reduction in the VAS scores of the pregabalin and gabapentin group as compared to the placebo group. Tiippana et al,[4] in her meta-analysis of 22 studies, also revealed that there was a significant reduction in post operative pain scores in patients receiving preoperative gabapentin and pregabalin.

RAMSAY SEDATION SCORE (RSS)

The results of our study was comparable to the results obtained in a study by Induja R et al,[6] which showed significantly lower sedation scores in control group as compared to the pregabalin and gabapentin group (P<0.001) up to 12 hours postoperatively.

LIMITATIONS OF THE STUDY

1. This study was conducted in patients of age group of 18-60 years, belonging to ASA class I and II, coming for elective infra-umbilical surgeries. So, correlating the results of this study to other population groups with significant comorbidities needs further research.
2. We compared only one dose of pregabalin and gabapentin our study. This was arrived at after analyzing other previous studies, which showed that higher doses had more incidence of adverse effects while lower doses were not as efficient in offering analgesia. If varying doses of pregabalin and gabapentin were compared, we would have been able to come to a conclusion of what the best dose of each drug, with maximum efficacy and minimum side effects, would have been.

CONCLUSION

From the observations of this study, we conclude that preemptive oral Pregabalin and Gabapentin provide longer duration of post-operative analgesia and reduced requirement of rescue analgesics in patients undergoing infra umbilical surgeries under sub arachnoid block. Preemptive oral pregabalin and gabapentin also prolong the period of sensory and motor blockade. Pregabalin (300mg) provided longer post-operative analgesia with lesser requirement of rescue analgesics as compared to gabapentin (1200mg).

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