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Research Article

COMPARISON OF GABAPENTIN V/S PREGABALIN FOR PREEMPTIVE ANALGESIA FOR ACUTE POSTOPERATIVE PAIN AFTER SURGERY UNDER SPINAL ANAESTHESIA

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Abstract

Introduction: Pain is defined as an unpleasant sensory and emotional experience associated with actual or potential tissue damage. Postoperative pain is an inevitable consequence of surgical trauma and remains one of the major concerns in perioperative patient care.

Materials and Methods: This was a prospective, randomized double blinded study, conducted in Department of Aneasthesia, KMCRI, Hubli. Inclusion criteria included patients of ASA grade I or II, of either sex, aged 20-50 years, having body weight 50-70 kg, scheduled for elective infra-umbilical surgeries under spinal anaesthesia. While those patients with uncontrolled or labile hypertension, allergic to the study drugs, pregnant and lactating women, patients with psychiatric illness, hepatic impairment, or renal impairment and patients having any contra indication to spinal anaesthesia were excluded.

Results: In Group G rescue analgesic was needed after 10.00 ± 2.02 hours, while in Group P rescue analgesic was required after 14.48 ± 4.48 hours. In Group G subsequent rescue analgesic was required in only three cases while in Group P, subsequent rescue analgesic was required in only two cases. The incidence of somnolence and dizziness was less with Pregabalin than with Gabapentin.

Conclusion: Single oral dose of Pregabalin (300 mg) given preoperatively provides better postoperative pain control and decreases postoperative rescue analgesic consumption compared to a single dose of Gabapentin (1200 mg) with fewer side effects.

Key Words: Pain, Pregabalin, Gabapentin, spinal anaesthesia, surgical trauma.

INTRODUCTION

Pain is defined as an unpleasant sensory and emotional experience associated with actual or potential tissue damage. Postoperative pain is an inevitable consequence of surgical trauma and remains one of the major concerns in perioperative patient care.[1]

Effective management of postoperative pain is important for early ambulation, reduction

in postoperative complications, shorter hospital stay, and improved patient satisfaction. Inadequately treated postoperative pain may lead to various physiological and psychological complications such as tachycardia, hypertension, pulmonary complications, delayed wound healing, anxiety, and chronic pain syndromes.[2]

Spinal anaesthesia is commonly employed for lower abdominal, pelvic, and lower limb surgeries because of its rapid onset, reliable sensory blockade, reduced blood loss, and lower incidence of airway complications. However, pain following regression of spinal anaesthesia can be severe and requires effective postoperative analgesia. [3]

Traditionally, postoperative pain has been treated using opioids, non-steroidal anti-inflammatory drugs (NSAIDs), and local anaesthetic techniques. However, opioid use is associated with adverse effects such as nausea, vomiting, pruritus, respiratory depression, urinary retention, and sedation.[4]

Preemptive analgesia refers to administration of analgesic interventions before surgical incision in order to prevent central sensitization caused by nociceptive stimuli. By blocking pain pathways before tissue injury occurs, postoperative pain intensity and analgesic requirements can be reduced.[5]

Gabapentin and pregabalin are anticonvulsant drugs belonging to the gabapentinoid group. These drugs bind selectively to the alpha-2-delta subunit of voltage-gated calcium channels in the central nervous system and inhibit release of excitatory neurotransmitters such as glutamate, substance P, and norepinephrine. Gabapentin has been widely used for neuropathic pain and postoperative analgesia. Pregabalin, a newer analogue of gabapentin, possesses superior pharmacokinetic properties including higher bioavailability, rapid absorption, and predictable plasma concentrations. Although both drugs have shown efficacy in postoperative pain management, there remains uncertainty regarding the superior agent for preemptive analgesia.

The aim of present study was to evaluate the postoperative analgesic benefit of Gabapentin or Pregabalin, administered as premedication for surgery under spinal anaesthesia and to compare their postoperative efficacy with respect to increase in duration of analgesia, reduction in total postoperative requirements of analgesics and to study their side effects and complications, if any attributable to these drugs.

MATERIALS AND METHODS

This was a prospective, randomized double blinded study, conducted in Department of Aneasthesia, KMCRI, Hubli.

Inclusion criteria:

Inclusion criteria included patients of ASA grade I or II, of either sex, aged 20-50 years, having body weight 50-70 kg, scheduled for elective infra-umbilical surgeries under spinal anaesthesia.

Exclusion Criteria: While those patients with uncontrolled or labile hypertension, allergic to the study drugs, pregnant and lactating women, patients with psychiatric illness, hepatic impairment, or renal

impairment and patients having any contra indication to spinal anaesthesia were excluded.

As calculated from a previous study, to get a clinically relevant difference in the duration of postoperative analgesia, we needed 62 patients in each group, with a power of study 80% at 95% confidence interval (alpha = 0.05). Total 124 patients were randomly allocated in two groups using an online randomizer-Group G (n = 62) received tablet Gabapentin 1200 mg while Group P (n = 62) received tablet Pregabalin 300 mg, 1 hour prior to spinal anaesthesia. A day before surgery, PAC (Pre-anaesthetic check up) was done. The patients were explained about the procedures of spinal anaesthesia and postoperative pain relief; along with details about VAS (0-10). A pharmacologist of our institution, not involved in this study, prepared the drug containing bags, which had gelatin capsules of similar size and shape. In group G, the bag contained four capsules of Gabapentin (300 mg each); in group P, the bag contained four capsules of Pregabalin (75 mg each capsule). The medication was given to the patient by an anaesthesiologist not involved in the study, 1 hour before giving the spinal anaesthesia. No other premedication was instituted. On OT arrival, routine monitoring (NIBP, pulse oximetry and ECG) was started. All the patients were preloaded with 10 mL/kg lactated Ringer's solution, before spinal anaesthesia. Spinal anaesthesia was instituted with 3 mL of 0.5% bupivacaine (15 mg) at L3 -L4 /L4 -L5 level. Fluid administration was continued intraoperatively and hypotension, if any, was treated with fluid replacement and intravenous (IV) Mephentermine and this whole procedure was conducted by another anaesthetist. Pain was assessed by VAS scale in the immediate postoperative period and every 2 h there after postoperatively; where 0 = no pain and 10 = most severe pain. Time lapsed after the surgery when the patient needs rescue analgesic was noted. For sedation: Filos' numerical scale was used (Scale 1 = awake and nervous, Scale 2 = awake and relaxed, Scale 3 = sleepy but easy to awake, Scale 4 = sleepy and hard to awake). Adverse events were also noted in the first 24 hours postoperatively, which included: dizziness/somnolence; diplopia; vomiting [the severity of PONV was 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 noncatheterized patient; respiratory depression (defined as ventilatory frequency <8 bpm and oxygen saturation <90% without oxygen supplementation).In the ward, other anaesthesiologist (unaware of the premedication) was responsible for charting the pain score by VAS scale. Pain charting was done separately and anaesthetic chart was not attached with the case sheet, so the observer was unable to know the group of the patient. Patient with VAS score of more than 3 received diclofenac 1 mg/kg intramuscularly. Time since spinal anaesthesia to the first dose of analgesic and total dose of analgesic in the first 24 hours was recorded.

Statistical analysis: The computer software SPSS (Statistical Package for the Social Sciences Inc. released 2007, version 16.0. Chicago, Illinois, USA) was used for analysis of data. For all analyses, probability values (P value) <0.05 were considered as statistically significant and p value <0.01 were considered as statistically highly significant.

RESULTS

A total of 124 patients were enrolled in our study. Maximum number of participants belonged to the age group of 40 years and above. The male: female ratio was 1:1.38. Both the groups were comparable in respect to demographic data, ASA physical status, the mean duration of surgery and the type of surgeries performed. The groups did not vary significantly with respect to the average time required for the surgical maneuver (as shown in Table 1).

Groups	Duration of surgery (minutes) (Mean ± SD*)	P value
Group P (n-62)	70.10 ± 25.48	0.3818
Group G (n-62)	64.76 ± 22.13	

Table 1: Comparison of duration of surgery in both the groups

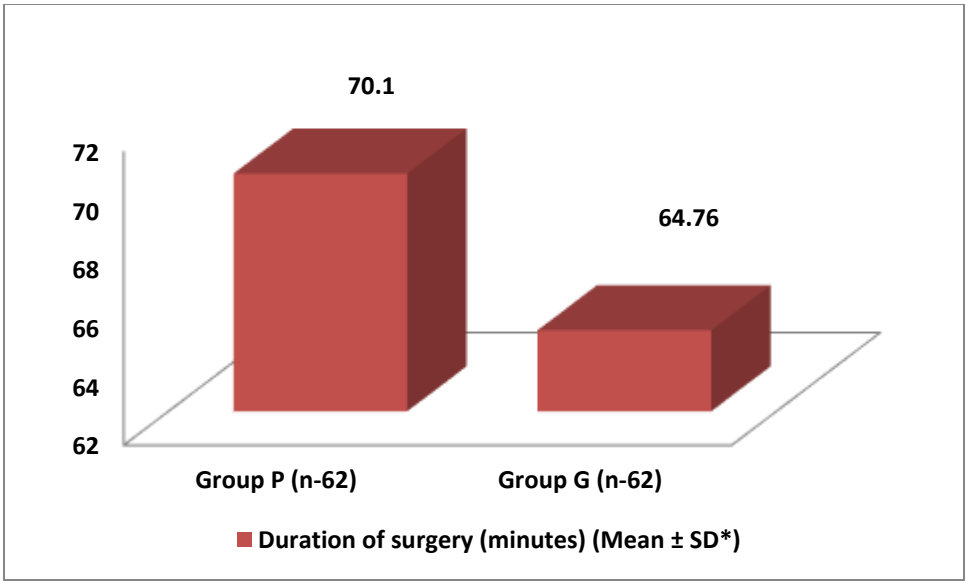

Figure 1: Comparison of duration of surgery in both the groups

Groups	Hours after surgery when VAS > 3 (Mean ± SD)	P value
Group P (n-62)	14.48 ± 4.08	0.0001
Group G (n-62)	10.00 ± 2.22	

Table 2: Comparison of time elapsed after surgery when VAS score > 3

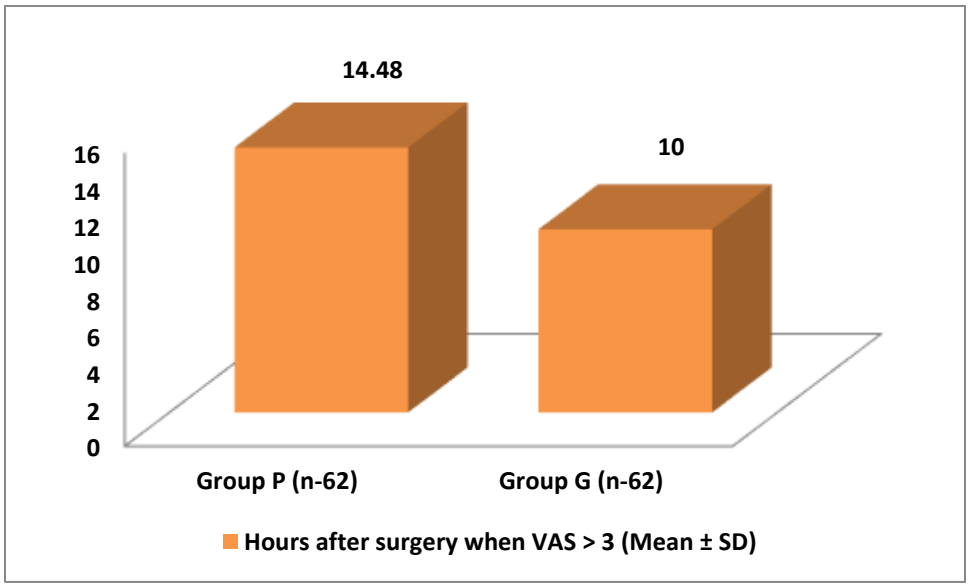

Figure 2: Comparison of time elapsed after surgery when VAS score > 3

Groups	Somnolence	Dizziness
Group P (n-62)	12.90%	9.68%
Group G (n-62)	22.59%	19.35%

Table 3: Comparison of percentage of adverse events seen in both the groups

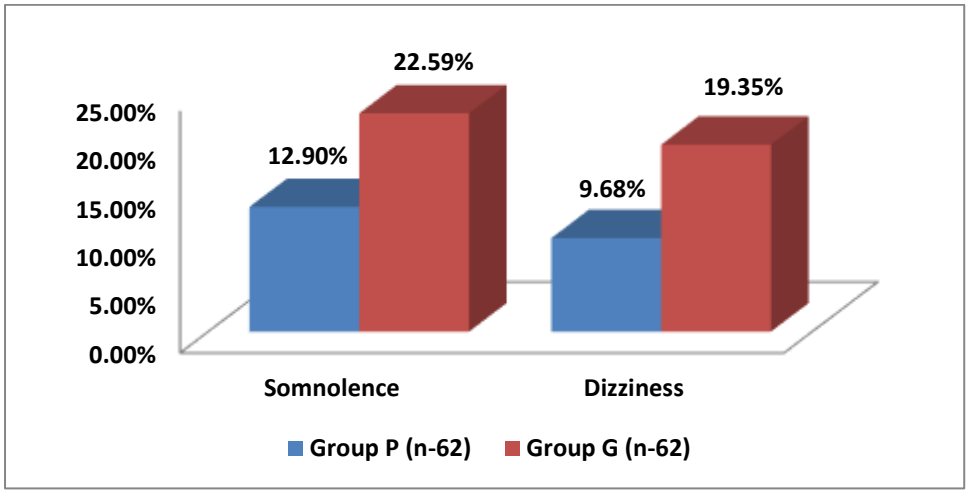

Figure 3: Comparison of percentage of adverse events seen in both the groups

DISCUSSION

Several studies have reported the usefulness of Gabapentin and Pregabalin in perioperative settings, resulting in reduced postoperative pain, postoperative analgesic requirement, side effects, prolongation of analgesia and higher patient satisfaction. Management of pain and its complications in the postoperative period still is a major challenge. Preemptive analgesia prevents establishment of the altered sensory processing that amplifies postoperative pain. Pre-incisional analgesia has been shown to be more effective in the control of postoperative pain by protecting the central nervous system from deleterious effects of noxious stimuli and resulting allodynia, and increased pain.[6]

Gabapentin and Pregabalin have antiallodynic and anti-hyperalgesic properties useful for treating neuropathic pain and may also be beneficial in acute postoperative pain. In a recent review of 22 RCTs, analysis suggested that the Gabapentin induced reduction in the 24 hour opioid consumption was not significantly dependent on the Gabapentin dose.[7] Hence, single highest safe dose of Gabapentin (1200 mg) and Pregabalin (300 mg) was selected for this study, which is same as used in most of the studies. In some of the studies conducted with Pregabalin as preemptive analgesic, like minor gynaecological surgery involving the uterus by Paech et al., day-case gynaecological laparoscopic surgery by Jokela et al. and laparoscopic cholecystectomy by Agarwal et al., a single dose of 100-150 mg was used.[8]

The pain scores in the placebo group of the earlier studies mentioned were substantially low, however the present study used a single preemptive 300 mg dose of Pregabalin, as lower dose would have been sub therapeutic because more painful procedures like laminectomy, discectomy, and instrumentation were involved in the present study. The duration after surgery, when rescue analgesic was required was 14.48 ± 4.08 hours in case of Pregabalin and 10.00 ± 2.02 hours in case of Gabapentin, which was statistically and significantly lower in the case of Gabapentin. Subsequent dose required in the case of Pregabalin was 6.45% and in the case of Gabapentin was 9.68%.[9]

Paech et al. in 2007 conducted the study in 90 women having minor gynaecological surgery involving the uterus. Patients received either oral Pregabalin 100 mg or placebo approximately 1 hour before surgery. There was no significant difference between the groups regarding pain experienced in the recovery room or thereafter or for recovery room Fentanyl

requirement (42% group Pregabalin versus 27% group placebo, P value = 0.12) or the quality of recovery at 24 hours postoperatively.[10]

CONCLUSION

Thus, we concluded that preemptive use of single oral dose of Pregabalin (300 mg) provides better and prolonged postoperative pain control and therefore, decreases postoperative rescue analgesic administration as compared to preemptive single oral dose of Gabapentin (1200 mg). Gabapentin and Pregabalin both can be an effective tool in the armamentarium of anaesthesiologist in treatment of perioperative pain. They can be used as part of multimodal therapy if not as sole analgesic.

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