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Pre-emptive gabapentin versus pregabalin for acute postoperative pain management in head and neck surgeries under general anaesthesia

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Abstract

Background: Gabapentin and pregabalin are antiepileptic drugs which are being used in the treatment of neuropathic pain as well as postoperative pain. However there is paucity of studies in comparison with each other in patients undergoing head and neck surgeries under general anaesthesia.

Objectives: To evaluate and compare the efficacy of gabapentin and pregabalin with respect to increase in duration of analgesia, reduction in postoperative pain scores, total postoperative analgesic requirements and side effects in patients undergoing head and neck surgeries under general anaesthesia.

Settings and design: A prospective, double-blinded, randomized controlled trial.

Methods: 100 patients of either gender in ASA I and II were randomly allocated to one of the two groups of fifty each. Patients in group G received single dose of gabapentin 1200mg while in group P received pregabalin 300mg, 1 hour before induction of anaesthesia. Postoperatively, rescue analgesic was administered at visual analogue scale (VAS) >4. The VAS score, sedation score, time to rescue analgesia, total analgesic consumption and side effects were recorded.

Results: In the 24 hours of postoperative period, the mean VAS score of group P was significantly less than group G. Time for rescue analgesic requirement was more with group P than group G. Mean dose of tramadol administered in group P was significantly less when compared to group G. Sedation score was similar in both the groups. No significant difference was observed among the two groups regarding side effects.

Conclusion: Pregabalin group had lower VAS score, prolonged timing of first rescue analgesic, and less analgesic consumption than the gabapentin group. Both the groups had similar sedation score with very negligible side effects.

Keywords: pregabalin, gabapentin, preemptive analgesia, head and neck surgeries, general anaesthesia

Introduction

Acute postoperative pain management is a challenging clinical problem and if inadequate, may result in increased morbidity, mortality and affect patient's quality of life [1]. Traditionally, opioid analgesics have been the mainstay of treatment of postoperative pain. However, opioid analgesics are not devoid of their share of side effects such as respiratory depression, bradycardia, hypotension, nausea and vomiting. Hence, a multimodal approach is used to manage postoperative pain and reduce opioid related side effects [2].

Surgical stimulation causes peripheral and central sensitization. Anti-hyperalgesic drugs act by relieving postoperative pain by preventing central nervous system (CNS) hypersensitivity [3]. Examples of these drugs are pregabalin and gabapentin, which are anti-seizure, anti-hyperalgesic, anti-anxiety drugs.

Gabapentin, introduced in 1994 as an antiepileptic drug is a structural analogue of gamma-aminobutyric acid (GABA). Currently, used for neuropathic pain, diabetic neuropathy, postherpetic neuralgia, complex regional pain syndrome [4].

It acts by binding to $\alpha 2\text{-}\delta 1$ subunit of presynaptic voltage gated calcium (Ca^{+2}) channels which inhibit Ca^{+2} entry and subsequent release of excitatory neurotransmitters in the pain pathways. Thus, has an anti-nociceptive, anti-hyperalgesic and anti-allodynic properties [5].

Pregabalin, another analogue of GABA, introduced in 2004 has a superior pharmacokinetic profile when compared to its predecessor Gabapentin [6]. It is used in the treatment of peripheral neuropathic pain [7]. Several clinical trials have demonstrated the efficacy of

Pregabalin for treating symptoms of generalised anxiety disorder [8].

Based on the knowledge available regarding post-operative pain management, this study was designed to compare the pre-emptive analgesic efficacy of oral gabapentin versus oral pregabalin for acute postoperative pain management in head and neck surgeries under general anaesthesia.

Methods

After obtaining the ethical clearance, 50 patients received gabapentin and 50 patients received pregabalin about one hour prior to the induction of general anaesthesia for elective head and neck surgeries lasting less than 4 hours. Patients participated in the study by giving a written consent form for the same. Patients were randomly allocated to one of the following two groups by using sealed envelope technique.

Group G: Single dose of oral gabapentin (1200mg) about 1 hour prior to the induction of anaesthesia.

Group P: Single dose of oral pregabalin (300mg) about 1 hour prior to the induction of anaesthesia.

Inclusion criteria

1. Age group between 18 and 60 years.
2. Patients belonging to American Society of Anaesthesiologists (ASA) physical status I and II.
3. Patients posted for elective head and neck surgeries under general anaesthesia.
4. Anticipated duration of surgery less than 4 hours.
5. Patients who give informed consent for the study.

Exclusion criteria:

1. Patients with history of uncontrolled or labile hypertension, diabetes, and liver disease.
2. Patient with known psychiatric disorders.
3. Patients using regular analgesics or corticosteroids, sedatives, hypnotics, antidepressants, and drugs with effects on the nervous system.
4. Patients already taking oral gabapentin or pregabalin for other indications.
5. Intake of paracetamol or nonsteroidal anti-inflammatory drugs 24 hours prior to surgery.
6. Patients with known hypersensitivity to the study drug, opioids and tramadol.
7. History of drug and/or alcohol abuse.
8. Pregnancy and breast-feeding mothers.

Patients meeting the inclusion criteria were randomly allocated by sealed envelope technique into one of the following two groups: Group P (Pregabalin group) and Group G (Gabapentin group). Patients in Group P received oral pregabalin 300mg and Group G received oral gabapentin 1200mg with sip of water about 1 hour prior to the induction of anaesthesia.

Patients were visited in their respective wards on the day prior to the surgery for preanaesthetic check-up. A thorough history, general and systemic examination was done, routine investigations were noted. Procedure regarding general anaesthesia and postoperative follow-up were explained. Written informed consent was taken after explaining the plan and intention of the study in the language best known to them.

Patients were explained about visual analogue scale (VAS) score and were advised to take premedication with tablet

alprazolam (0.25mg) and capsule omeprazole (20mg) on the night prior to the surgery. Patients were kept nil per oral (NPO) for at least 8 hours.

On the day of surgery patients were visited in the preoperative ward about 1 hour prior to the induction of anaesthesia and depending on their position in the random number tables, they were given one of the two study drugs (oral gabapentin or pregabalin) with sip of water. Later were shifted to operation theatre.

In the operating room, monitors (ECG, NIBP, pulse oximeter) were connected. Baseline recordings of pulse rate, respiratory rate, blood pressure (BP) and peripheral oxygen saturation (SpO₂) were noted. Intravenous access was established with 18G cannula and all patients were preloaded with 10mL/kg of Ringer's lactate solution.

Similar premedication was given to all the patients under the study consisting of injection glycopyrrolate (0.004mg/kg) IV, injection ondansetron (4mg) IV, and injection fentanyl (2µg/kg) IV. After adequate preoxygenation for 3minutes, anaesthesia was induced with injection propofol (1.5-2.5mg/kg) IV and injection vecuronium bromide (0.1mg/kg) IV to facilitate endotracheal intubation.

Intraoperatively, ECG, NIBP, SpO₂, pulse rate and end-tidal CO₂ (ETCO₂) were monitored. Anaesthesia was maintained using 60% N₂O in O₂, injection vecuronium bromide (0.02mg/kg) IV and isoflurane that were titrated according to BP. At the end of the surgery, residual neuromuscular blockade were antagonised using injection neostigmine (0.05mg/kg) IV and injection glycopyrrolate (0.01mg/kg) IV. After pharyngeal suctioning and adequate recovery of spontaneous respiration, patients were extubated and were shifted to the recovery room.

Pulse rate, respiratory rate, BP, SpO₂, pain scores [VAS score] and sedation score [Ramsay sedation score] were recorded on arrival to the recovery room and was taken as 0th hour. After stabilisation, patients were shifted to the postoperative ward. The VAS and sedation scores of the patients were recorded at 1st hour, 2nd hour, 3rd hour, 6th hour, 9th hour, 12th hour, 18th hour and 24th hour. In addition to this, pulse rate, respiratory rate, NIBP, SpO₂ were recorded. Injection tramadol (1mg/kg) IV as rescue analgesia (T1) was given if patient had a pain score of ≥4. The total amount of tramadol given in first 24 hours in both the groups were compared.

Any side effects, such as nausea and vomiting, headache, dizziness, sedation, somnolence, respiratory depression and pruritis were noted in first 24 hours of the postoperative period. Patients with sedation score of ≥2 were considered sedated, and respiratory rate of <8 breaths/minute were considered in respiratory depression.

Patients were asked to rate nausea on a scale of 4 as none, mild, moderate and severe. Injection ondansetron (4mg) IV was given in case of moderate to severe nausea or an episode of vomiting.

Statistical analysis: The data collected was analysed using the computer software Statistical Package for the Social Sciences (SPSS) version 17.0. Data was analysed using one way analysis of variance (ANOVA), T- test, Mann-Whitney U test, chi-square test and Fisher exact test. The results were expressed in terms of mean and standard deviation (SD). For all analyses, probability value (P-value) <0.05 was considered as statistically significant.

Results

The groups were comparable with respect to demographic variables like age, gender, height, weight, BMI, ASA physical status, co-morbidities and duration of surgery.

Table 1: Demographic data

	Group G	Group P	P Value
Age (Yrs)	39.62 ± 11.94	39.22 ± 11.82	0.867
Weight (kg)	60.12 ± 3.33	61.12 ± 4.66	0.220
Height (cm)	156.96 ± 2.03	157.58 ± 3.00	0.229
BMI (Kg/m ²)	24.37 ± 1.06	24.55 ± 1.35	0.451
Duration of surgery (min)	125.5 ± 17.649	127.2 ± 18.075	0.635

Outcome Measures: Include VAS score, Ramsay sedation

Table 2: Visual analogue scale (VAS) score

Time interval	Group G		Group P		Mean Difference	P-value	Result
	Mean ± SD	Median	Mean ± SD	Median			
0 hour	0 ± 0	0	0 ± 0	0			
1 hour	0.66 ± 0.479	1	0.16 ± 0.370	0	0.5	<0.0001	Significant
2 hour	1.12 ± 0.328	1	0.78 ± 0.507	1	0.34	<0.0001	Significant
3 hour	2.06 ± 0.586	2	1.34 ± 0.519	1	0.72	<0.0001	Significant
6 hour	2.96 ± 0.925	3	2.04 ± 0.832	2	0.92	<0.0001	Significant
9 hour	3.64 ± 1.601	4	3.00 ± 1.195	3	0.64	0.018	Significant
12 hour	3.28 ± 1.262	3	2.46 ± 1.417	2	0.82	0.039	Significant
18 hour	2.42 ± 0.499	2	1.76 ± 0.797	2	0.66	<0.0001	Significant
24 hour	3.94 ± 0.793	4	2.42 ± 0.835	2	1.52	<0.0001	Significant

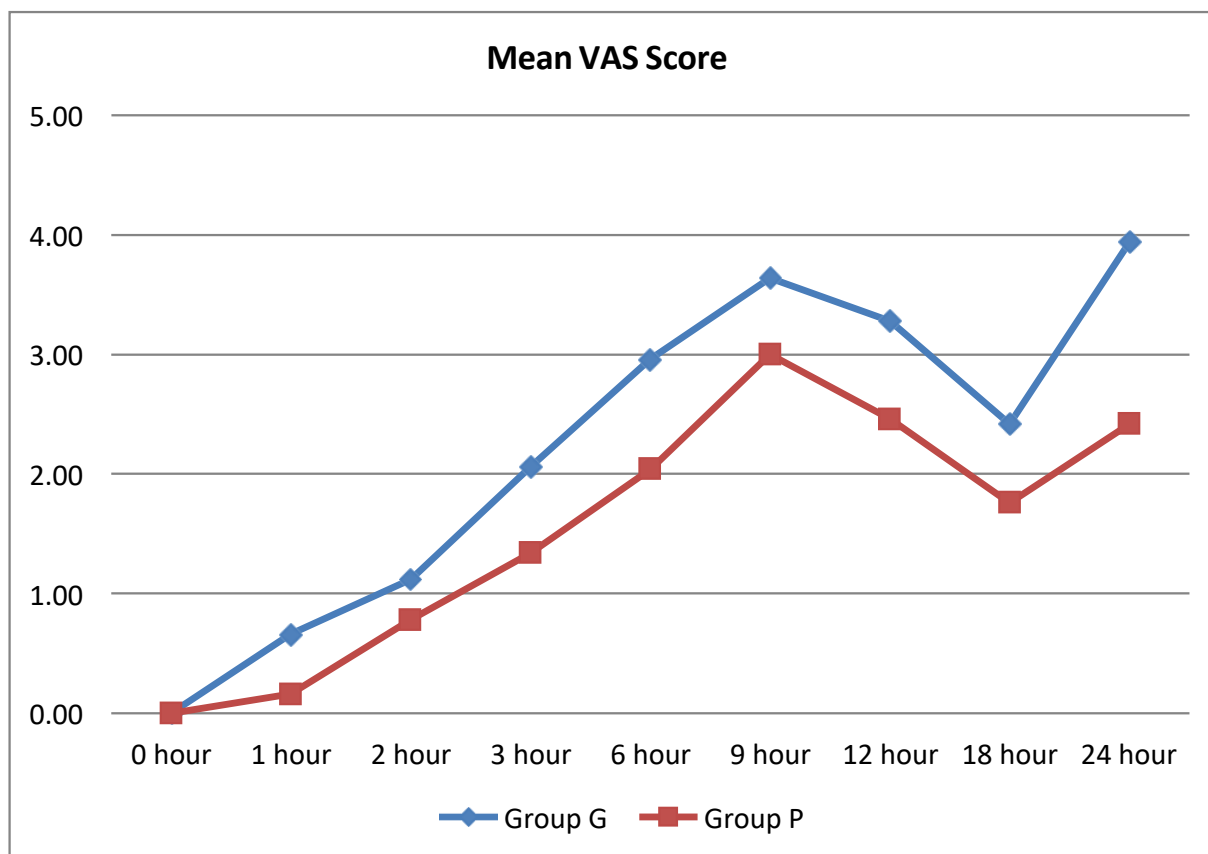


Fig 1: Comparison of Visual analogue scale (VAS) score between study groups

Ramsay sedation score: Level of sedation was analyzed in the postoperative period using Ramsay sedation score at 0th h, 1st h, 2nd h, 3rd h, 6th h, 9th h, 12 h, 18th h, and 24th h following surgery. There was no statistically significant

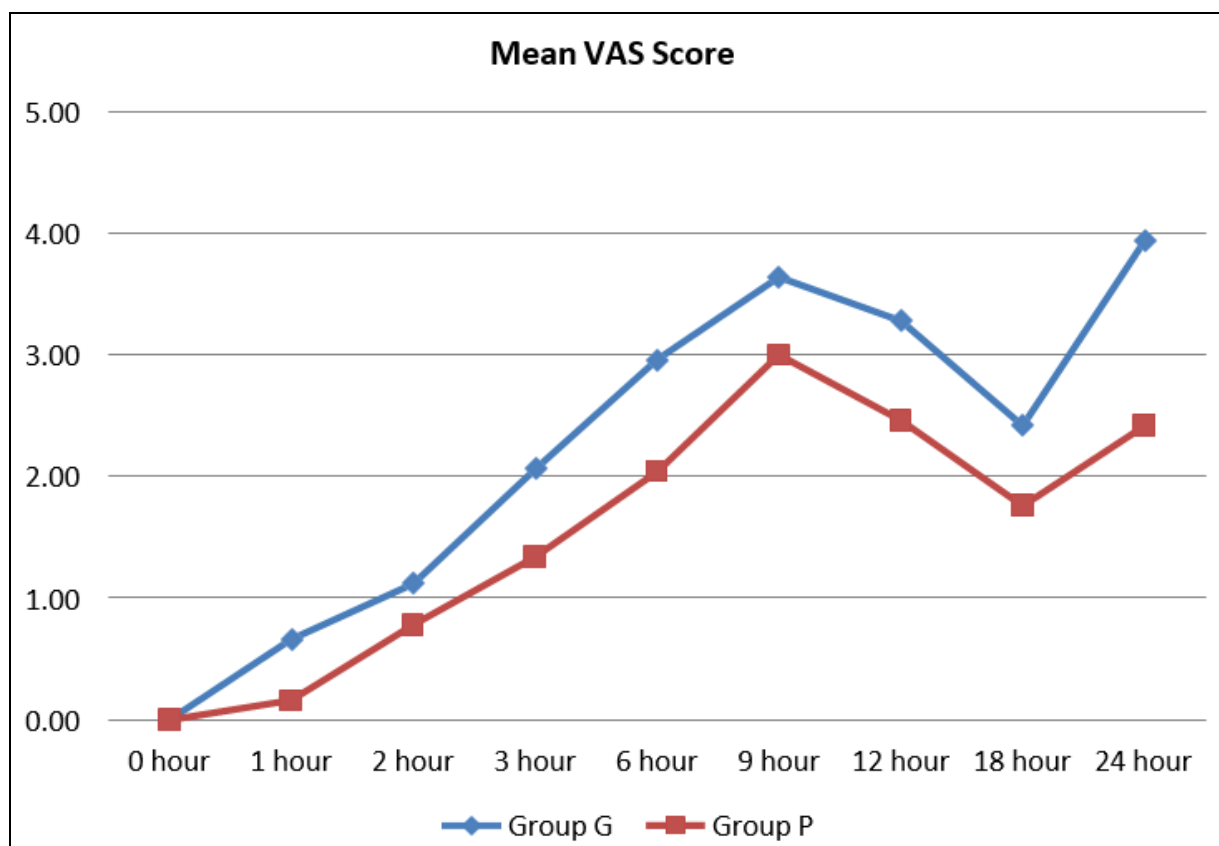
score, time of first rescue analgesia (T1), mean dose of tramadol administered (mg) in first 24 hours post-surgery and the incidence of adverse effects.

1. VAS score: Assessment of VAS score was done in the immediate postoperative period (0th hour), followed by 1st h, 2nd h, 3rd h, 6th h, 9th h, 12 h, 18th h, and 24th h following surgery. The mean VAS score showed no statistically significant difference between the two groups at 0th hour. Overall, the VAS score was significantly reduced in group P when compared to group G in the postoperative period ($p < 0.05$). This indicates pregabalin (300mg) provided better postoperative pain relief when compared to gabapentin (1200mg).

difference in sedation score between the two groups ($p > 0.05$). This indicates both the drugs cause similar sedation.

Table 3: Ramsay sedation score

Time interval (min)	Ramsay Sedation Score	Group				P- value	Result
		Group G		Group P			
		Count	%	Count	%		
0 hour	2	47	94.0	45	90.0	0.715	Not Significant
	3	3	6.0	5	10.0		
1 hour	2	50	100.0	47	94.0	0.242	Not Significant
	3	0	0.0	3	6.0		
2 hour	2	50	100.0	49	98.0	>0.999	Not Significant
	3	0	0.0	1	2.0		
3 hour	1	7	14.0	6	12.0	>0.999	Not Significant
	2	43	86.0	44	88.0		
6 hour	1	12	24.0	10	20.0	0.810	Not Significant
	2	38	76.0	40	80.0		
9 hour	1	17	34.0	15	30.0	0.830	Not Significant
	2	33	66.0	35	70.0		
12 hour	1	20	40.0	17	34.0	0.679	Not Significant
	2	30	60.0	33	66.0		
18 hour	1	24	48.0	22	44.0	0.841	Not Significant
	2	26	52.0	28	56.0		
24 hour	1	25	50.0	23	46.0	0.841	Not Significant
	2	25	50.0	27	54.0		

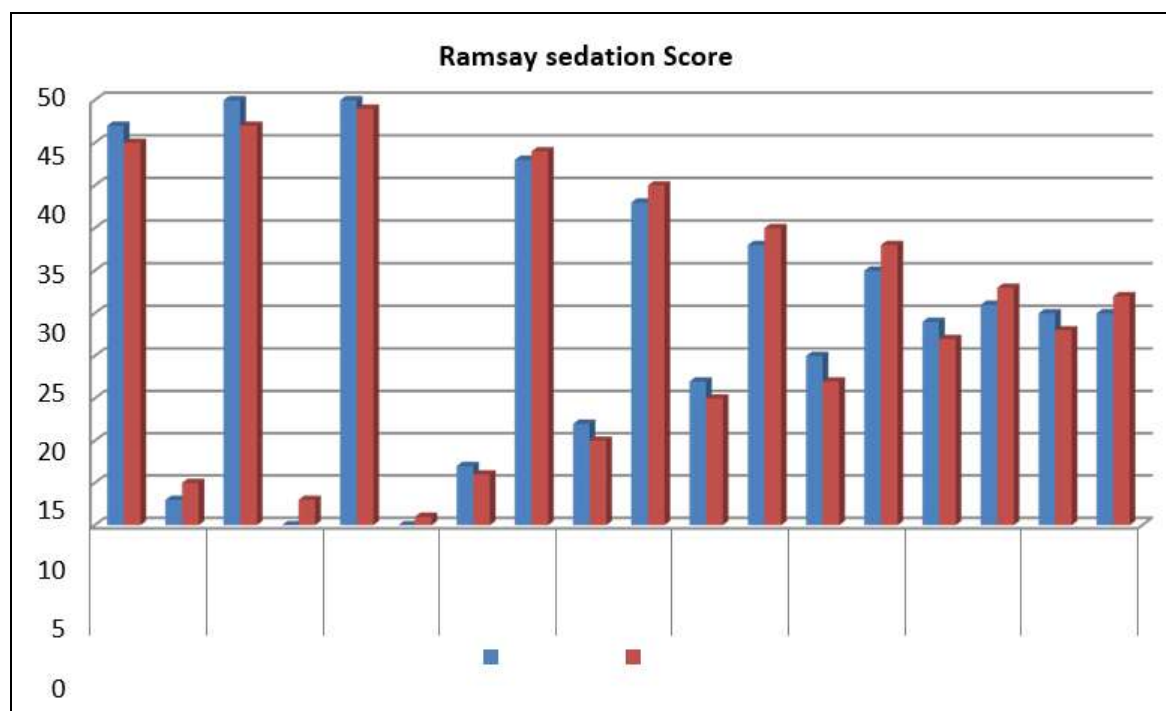
**Fig 1:** Comparison of Visual analogue scale (VAS) score between study groups

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difference in sedation score between the two groups ($p > 0.05$). This indicates both the drugs cause similar sedation.

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24 hour	1	25	50.0	23	46.0	0.841	Not Significant
	2	25	50.0	27	54.0		

**Fig 2:** Comparison of Ramsay sedation score between study group

Time of first rescue analgesic (T1): Injection tramadol (1mg/kg) IV was given as rescue analgesic if patient had VAS score ≥ 4 . In this study, 9 patients in group P did not require any rescue analgesic in the postoperative period. The timing of first rescue analgesic postoperatively was $522 \pm$

121.974 minutes in group G (n=50) while it was 623.41 ± 114.534 minutes in group P (n=41), which was highly significant (P-value <0.0001). This indicates that pregabalin provides longer pain relief when compared to gabapentin.

Table 4: Time of rescue analgesic-T1 (min)

T1 (min)	Group G	Group P
N	50	41
Mean \pm SD	522 ± 121.974	623.41 ± 114.534
Range	180 - 720	360 - 720
Mean Difference	-101.415	
P-value	<0.0001	

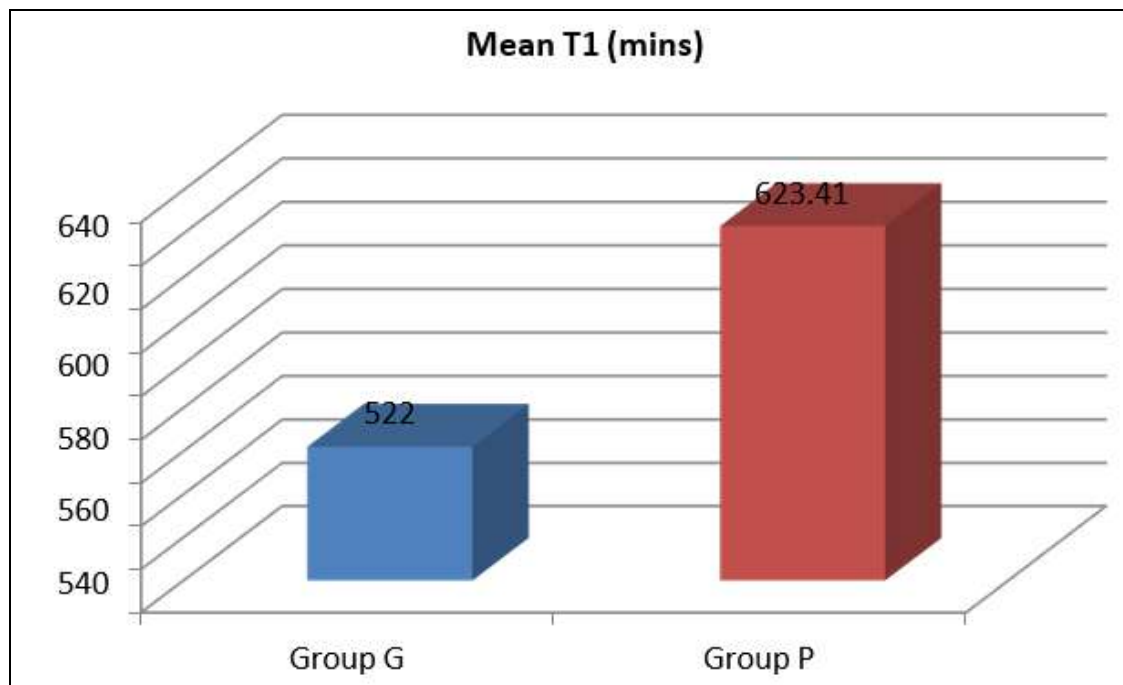


Fig 3: Time of rescue analgesic-T1(min)

Dosage of tramadol administered in 24hours post-surgery: In this study, group P (109.14 ± 27.814 mg) consumed less tramadol when compared to group G (147 ± 33.746 mg) and the difference between both the groups was highly significant (P- value <0.0001). Total of 9 patients in pregabalin group did not require any rescue analgesia in the first 24 hours of the postoperative period.

Table 5: Mean dose of Tramadol administered (mg) in 24 hours post surgery

Tramadol in 24hrs (mg)	Group G	Group P
N	50	41
Mean \pm SD	147 ± 33.746	109.14 ± 27.814
Range	100 - 200	75 - 200
Mean Difference	37.854	
P-value	<0.0001	

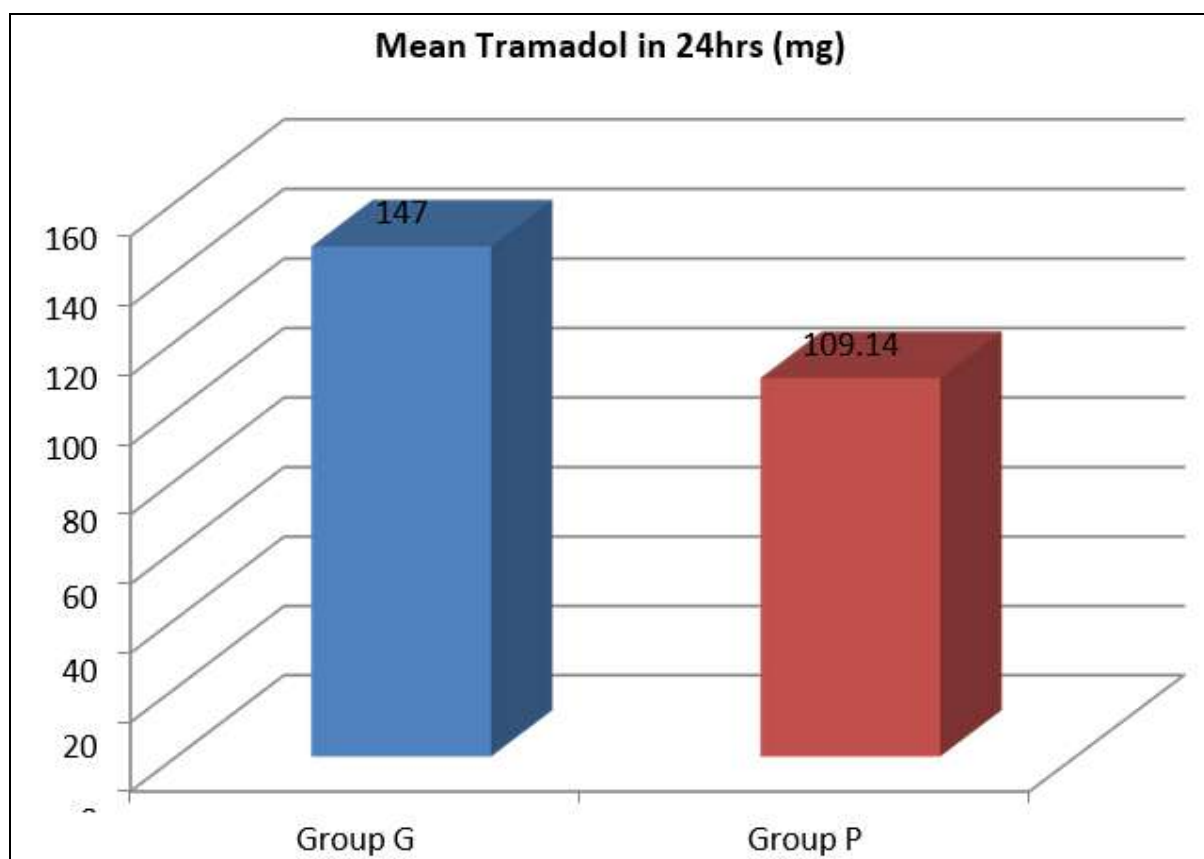


Fig 4: Mean dose of Tramadol administered (mg) in 24 hours post surgery

Incidence of adverse effects: The adverse effects seen in this study were nausea, dizziness, sedation and somnolence in both the groups. There was no statistically significant

difference in number of patients with adverse effects among both the groups.

Table 6: Incidence of adverse effects

Incidence of adverse effects	Group G		Group P	
	No. of Subjects	Percentage	No. of Subjects	Percentage
Nausea	4	8.0	1	2.0
Vomiting	0	0.0	0	0.0
Headache	0	0.0	0	0.0
Dizziness	1	2.0	3	6.0
Sedation	3	6.0	5	10.0
Somnolence	1	2.0	2	4.0
Respiratory Depression	0	0.0	0	0.0

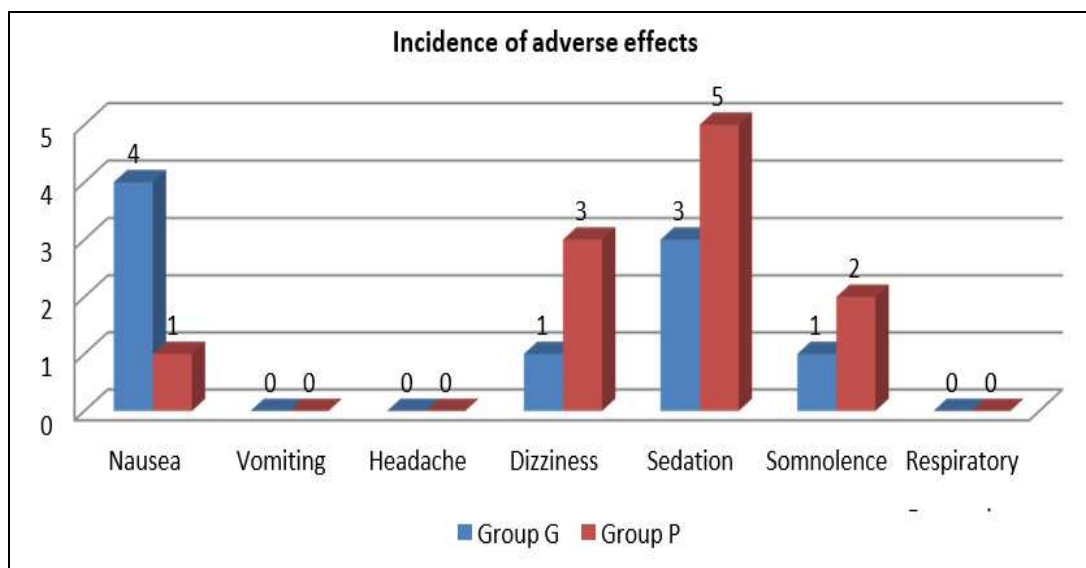


Fig 5: Incidence of adverse effects

Discussion

The most distressing and common symptom, which follows surgery is pain. High-quality pain control following surgery is still a major challenge. The clinical concept of pre-emptive analgesia first introduced by Crile in 1913 and further developed by Wall and Woolf revolutionized postoperative pain relief.⁹ It involves introduction of an analgesic regimen before the onset of noxious stimuli to prevent sensitization of the nervous system to subsequent stimuli that could increase pain. In 1993, Kehlet and Dahl introduced the concept of multimodal analgesia to improve outcome following surgery.¹⁰ This method involves combining 2 or more drugs that act by different mechanism so as to provide adequate analgesia with lower drug doses and with reduced incidence of side effects. Gabapentinoids have been found to be very effective in this role and this forms the basis of this study.

In this study, gabapentin was given in the dosage of 1200mg and pregabalin in the dosage of 300mg orally 1 hour prior to the induction of anaesthesia similar to previous studies [11-14].

Drugs were given preoperatively 1 hour prior to the induction of anaesthesia.¹⁵ In this study, VAS score was used to assess postoperative pain which was explained to the patient preoperatively. Assessment of VAS score was done in the immediate postoperative period (0th hour), followed by 1st h, 2nd h, 3rd h, 6th h, 9th h, 12 h, 18th h, and 24th h following surgery. The mean VAS score showed no

statistically significant difference between the two groups at 0th hour. Postoperatively, the mean VAS score in group G at 1, 2, 3, 6, 9, 12, 18 and 24 hours were 0.66, 1.12, 2.06, 2.96, 3.64, 3.28, 2.42 and 3.94 respectively. Whereas, in group P the mean VAS score were 0.16, 0.78, 1.34, 2.04, 3.00, 2.46, 1.76 and 2.42 respectively. This shows that the VAS score was significantly reduced in pregabalin group compared to gabapentin group in the postoperative period. Possibly no previous study of gabapentin and pregabalin had compared VAS score, sedation score and the timing of first rescue analgesic postoperatively in head and neck surgeries under general anaesthesia. However, a study was conducted by Pal S, *et al.* in 2016 comparing the analgesic efficacy of gabapentin and pregabalin in surgery below the umbilicus under spinal anaesthesia. They concluded that a single dose of pregabalin (300mg) given preoperatively had better postoperative pain control when compared to a single dose of gabapentin (1200mg),¹⁶ which is similar to the results of our study. Mishra R, *et al.* in 2016 did a comparative clinical study of gabapentin (900mg) and pregabalin (150mg) as premedication to evaluate postoperative analgesic benefits and efficacy in patients undergoing laparoscopic cholecystectomy under general anaesthesia and concluded that the pregabalin group had lower VAS score than the gabapentin group.¹⁷ In contrast, our study used gabapentin 1200mg and pregabalin 300mg in head and neck surgeries under general anaesthesia but the results obtained were similar.

There was no statistically significant difference in sedation score between group G (gabapentin, 1200mg) and group P (pregabalin, 300mg) throughout 24 hours of the postoperative period. But this was not in concordance with Gautam A, *et al.* who conducted a study in 2016 to evaluate the efficacy of gabapentin (600mg) and pregabalin (300mg) for acute postoperative pain relief in patients scheduled for surgery under general 74 anaesthesia. They concluded that pregabalin causes more sedation than gabapentin [18] that may be due to different dosage of gabapentinoids used. Mishra R, *et al.* in 2016 did a comparative clinical study on gabapentin (900mg) and pregabalin (150mg) for postoperative pain relief in laparoscopic cholecystectomy under general anaesthesia. They found that sedation score in pregabalin group was significantly higher as compared to gabapentin and placebo group but there was no significant difference between pregabalin and gabapentin group [18]. Even though different dosage of gabapentinoids were used, this finding correlates with our study except no placebo group was included.

All patients were monitored for VAS score periodically in the postoperative period. Injection tramadol (1mg/kg) IV was given as rescue analgesic if patient had VAS score ≥ 4 . In this study, 9 patients in pregabalin group did not require any rescue analgesic in the postoperative period. The timing of first rescue analgesic postoperatively was 522 ± 121.974 minutes in gabapentin group (n=50) while it was 623.41 ± 114.534 minutes in pregabalin group (n=41), which was highly significant (P-value <0.0001). This indicates that pregabalin provides longer pain relief when compared to gabapentin. This finding correlates with the study conducted by Saraswat V, *et al.* in 2008 in which the total postoperative analgesic duration (time from spinal anaesthesia to first rescue analgesic) in group G (gabapentin, 1200mg) was 8.98 hours whereas in group P (pregabalin, 300mg) was 14.17 hours, which was highly significant (P-value <0.001) except that the study was conducted in patients undergoing surgery under spinal anaesthesia [19]. Ghai A, *et al.* in 2011 conducted a comparative study on gabapentin (900mg) and pregabalin (300mg) for postoperative pain relief in patients undergoing abdominal hysterectomy under general anaesthesia and observed that the time to first request for analgesia was longer in pregabalin group when compared to gabapentin group [20] which is similar to the results obtained in our study.

In this study, injection tramadol (1mg/kg) IV was administered as rescue analgesic if patient had VAS score ≥ 4 . The mean dosage of rescue analgesic administered in first 24 hours post-surgery was calculated. It was found that the pregabalin group (109.14 ± 27.814 mg) consumed less tramadol as compared to the gabapentin group (147 ± 33.746 mg) and the difference between both the groups was highly significant (P-value <0.0001). Total of 9 patients in pregabalin group did not require any rescue analgesia in the first 24 hours of the postoperative period. But this was not in concordance with Saraswat V, *et al.* who conducted a study in 2008 and found that the total dose of analgesic (injection diclofenac 1mg/kg IM) in first 24 hours post-surgery was 62.5mg in pregabalin group and 72.5 mg in gabapentin group and the difference was not statistically significant [19] in contrast to the present study. The difference in these two studies might be due to different type of anaesthesia provided (spinal versus general

anaesthesia) and the type of rescue analgesic used (injection diclofenac 1mg/kg IM versus injection tramadol 1mg/kg IV) and also the timing of rescue analgesic being administered (VAS score ≥ 3 versus VAS score ≥ 4 , in the present study). Mishra R, *et al.* conducted a study in 2016 and found that the total dose of analgesic (injection tramadol 1mg/kg IV) requirement in first 24 hours post-surgery in 76 pregabalin (150mg) group was 64.67 ± 16.69 mg while in gabapentin (900mg) group was 116.13 ± 14.08 mg and was statistically significant. This indicates that the total postoperative analgesic requirements in pregabalin group were less when compared to gabapentin group, 26 which correlates with the results obtained in our study.

The adverse effects seen in this study were nausea, dizziness, sedation and somnolence in both the groups. Statistical difference in number of patients with adverse effects among both the groups was not significant and was negligible. In a study conducted by Ghai A, *et al.* in 2011 in patients undergoing abdominal hysterectomy under general anaesthesia also showed no significant difference in the incidence of side effects between pregabalin and gabapentin group.²⁰ The common side effects observed in their study were nausea and vomiting, dizziness, somnolence which is similar to the present study.

The limitation of present study is that single dose of gabapentin (1200mg) and pregabalin (300mg) was used. Conclusions about the optimal dose and duration of treatment cannot be made.

To conclude, a single oral dose of pregabalin 300mg given preoperatively provides better postoperative pain control, prolongs timing of first rescue analgesic requirement and decreases the postoperative rescue analgesic consumption compared to a single oral dose of gabapentin 1200mg with negligible adverse effects.

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