Section: Anaesthesiology

Original Research Article

A PROSPECTIVE, RANDOMIZED PLACEBO-CONTROLLED STUDY EVALUATING THE EFFECTIVENESS OF ORAL PREGABALIN AND TRAMADOL FOR POSTOPERATIVE PAIN MANAGEMENT IN PATIENTS UNDERGOING LUMBAR LAMINECTOMY

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ABSTRACT

Background: The aim of my study is to assess and compare the efficacy and safety of preoperative administration of pregabalin and tramadol in patients undergoing elective lumbar laminectomy.

Materials and Methods: This prospective, randomised, single blinded placebo-controlled study evaluated the efficacy of preoperative administration of pregabalin and tramadol for postoperative pain management in patients undergoing lumbar laminectomy.Seventy-five patients belonging to ASA1 and 2, between 20 to 60 years of either sex, satisfying inclusion criteria were randomised into three groups containing 25 patients each.These drugs were administered to the patients 1 hour before anaesthetic induction. The heart rate, systolic blood pressure, diastolic blood pressure, mean arterial blood pressure were recorded preoperatively(baseline and 1 hour after drug administration), intraoperatively and postoperatively. Respiratory rate and saturation were also recorded preoperatively and postoperatively. Pain scores, anxiety scores, sedation scores were recorded 1 hour after drug administration, after extubation and postoperatively. Fentanyl consumption in the postoperative period and any adverse effects were also noted. The data was analysed using SPSS software version 20. The demographic profiles of the three groups were matched and the baseline hemodynamic variables in all three groups were comparable.

Results: The pain scores and anxiety scores were significantly reduced in pregabalin and tramadol groups when compared to the placebo group but the reduction in scores in the pregabalin group is significantly less than that of the tramadol group. The sedation score is higher in tramadol group when compared to placebo and pregabalin; however, there was no significant difference in sedation between pregabalin and tramadol immediately after extubation and at 1 hour postoperatively. The sedation scores remained significantly higher in the pregabalin group when compared to the placebo group. Further the systolic, diastolic and mean arterial blood pressures were significantly lower in the tramadol group when compared to the placebo group at 1 & 3 minute after intubation and after extubation whereas in pregabalin group these parameters were significantly lower than placebo group at 1 minute after intubation and after extubation. Heart rate changes in tramadol and pregabalin groups were significantly lower than the placebo group at 1 & 3 minutes after intubation and at 30, 60 and 120 minutes and after extubation. The mean requirement of fentanyl is significantly lower in pregabalin and

tramadol groups when compared to placebo group. Side effects in tramadol and placebo group were significantly higher than the pregabalin group.
Conclusion: Pregabalin has a statistically significant effect when compared to placebo, but this effect is less when compared to tramadol.The need for rescue analgesia is in the least in tramadol patients followed by pregabalin and it increases maximum in the placebo group.
Keywords: Pregabalin, Tramadol, VAS SCORE, Anxiety, Fentanyl, Lumbar Laminectomy.

INTRODUCTION

Postoperative pain is one of the most feared problems among patients coming for surgery. Postoperative pain management includes pain management,[1]prevention and treatment of postoperative complications and restoring preoperative function.[2]

Preventing pain and treating it is a big deal despite significant advancements in pain assessment and therapy.[3]By mobilising patients at the earliest, postoperative complications are reduced. It has been reported that roughly 80% of patients undergoing surgical procedures experience postoperative pain[3] . Pain on movement is comparatively resistant to opioids than the pain during rest and can lead to postoperative pulmonary, cardiac, and thromboembolic complications.[4]

The guidelines for postoperative pain treatment has been revised and drugs like s-ketamine, pregabalin, metamizole, oxycodone are used as new methods of preventing postoperative pain.

Prolonged chronic pain after surgery has been under recognised until recently which is actually a very common phenomenon. A number of risk factors and predictors including the age, gender, surgical procedure, pre and postoperative pain, genes, psychosocial factors and pain modulation variables have been identified.

Together with an increased knowledge about the pathophysiology of chronic pain after surgery it may be possible to develop successful drugs and interventions in the near future.

Post-surgical pain is normally perceived as nociceptive pain. Surgical trauma causes central and peripheral sensitization and hyperalgesia which when untreated can lead to chronic postoperative pain after surgery. Indeed pain is one among the three most common causes of delayed discharge after ambulatory surgery next to drowsiness and nausea/vomiting.

Antihyperalgesic drugs improve the postoperative pain by preventing the development of central sensitisation. The recent advance in postoperative pain management includes finding out the exact mechanism of action of drugs at molecular level, newer routes and modes of analgesic delivery.

For years opioids have been the cornerstone of postoperative pain management in spite of their side effects. Hence the search for newer analgesics and combination of analgesics and other non-opioid drugs continues in order to improve postoperative analgesia and reduce opioid related side effects.[5]

In this context, the gabapentinoids (gabapentin and pregabalin) have been extensively studied. Gabapentinoids were successfully used in the treatment of trigeminal neuralgia, diabetic neuropathy, post herpetic neuralgia.[6]In addition their usefulness for postoperative pain relief is also studied.[7] The present study was thus taken up to test the efficacy of pregabalin for pain management in lumbar laminectomy.

Aims and Objectives

Aim

The aim of my study is to assess and compare the efficacy and safety of preoperative administration of pregabalin and tramadol in patients undergoing elective lumbar laminectomy.

MATERIAL AND METHODS

After obtaining institutional ethical commmitee approval and informed consent, the study was conducted in 75 patients belonging to American Society of Anaesthesiology- 1 (ASA) and ASA- 2 of either sex and age group between 20-60 years undergoing elective decompressive lumbar laminectomy.

This is a prospective, randomised, single blinded study.

The study was conducted in Rajiv Gandhi Government General Hospital, Madras Medical College.

The patients were randomised into three groups of 25 patients each by closed envelope method. The patients were blinded to the group they belong.

Inclusion Criteria

- Age – 20 years to 60 years
- Weight - 40 to 70 kilograms
- BMI - < 30 kilograms/metre square
- ASA- 1 & 2
- Surgery- elective lumbar decompressive laminectomy
- Patients who have given valid informed written consent.

Exclusion Criteria

- Patients not satisfying inclusion criteria
- Patients posted for emergency surgery
- Patients with renal insufficiency
- Patients with liver disease
- History of allergy or sensitivity to the drugs used
- History of seizure disorder
- Chronic therapy with opioids.

Primary and Secondary Outcome

The primary outcome of the study was to measure the analgesic and anxiolytic efficacy of pregabalin and tramadol for postoperative pain while the secondary outcome was to assess the intraoperative hemodynamics and adverse effects of these drugs.

Materials

Pregabalin capsules 100mg
Tramadol capsules 100mg
Placebo capsules
Drugs- Injection Midazolam, Injection Glycopyrrolate, Inj Fentanyl, Inj.Thiopentone Sodium, Inj. Vecuronium, Inj. Neostigmine, Sevo flurane, emergency drugs, Normal Saline and Ringer Lactate.
Monitors- ECG, NIBP, SPO2, EtCo2.

Study Design

The patients satisfying inclusion criteria were randomly allocated into three groups each containing 25 patients. Randomisation was done by closed envelope method.
Group 1(placebo)- received a placebo capsule orally 1 hour before anaesthetic induction.
Group 2 (tramadol)- received a tramadol capsule 100mg orally 1 hour before anaesthetic induction.
Group 3(pregabalin)- received a pregabalin capsule 100mg 1 hour before anaesthetic induction.
All patients were visited the evening before surgery. They were explained about the study methods, the visual analogue scale chart and were provided with information sheet. All were orally premedicated with alprazolam 0.5mg at 10.00 pm, the previous night of surgery.

Anaesthesia Protocol

The patients were premedicated with an injection of midazolam (0.03mg/kg) i.v. and an injection of glycopyrolate (0.005mg/kg) i.v. Analgesia was provided with Injection fentanyl 2mic/kg and induction was done with thiopentone sodium (5 mg/kg of 2.5% solution).Endotracheal intubation was facilitated by using vecuronium bromide as muscle relaxant in the dosage of 0.1mg/kg. Anaesthesia was maintained with N2O:O2 (66:33) and with sevoflurane.
Standard monitoring included noninvasive blood pressure monitoring, electrocardiogram, end tidal concentration of carbon dioxide and pulse oximetry.
Intravenous fluids, Normal Saline and Ringer's Lactate, were administered at the rate of 100 ml/hour. There was minimal blood loss in the surgery.
All patients were given antiemetic ondansetron 4mg i.v.
At the end of the surgery, patients were extubated after the reversal of the residual neuromuscular blockade with inj.neostigmine (0.05 mg/kg) and inj. glycopyrrolate (0.01 mg/kg).
Postoperatively, whenever patients complained of pain (Visual Analog Score of more than 3) they received 0.5mic/kg of fentanyl as rescue analgesia, which was repeated until the pain subsided.

Pain quantification was done on a modified Visual Analog Scale Score between 0 and 10 (0 = no pain to 10 = worst imaginable pain.[8]

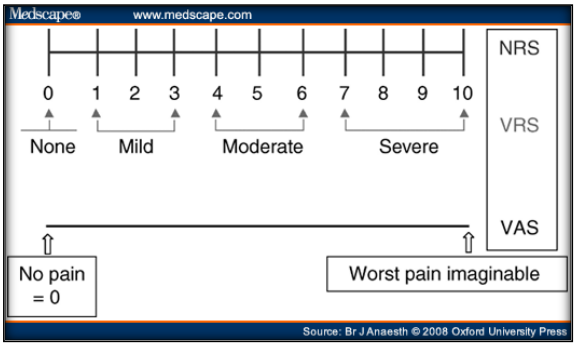

Figure 1: Visual Analog Scale Scoring

Sedation scores were based on Ramsay Sedation Scale.
Ramsay Sedation Scale,[9]

1. Patient anxious, agitated or restless or both
2. Patient co-operative, oriented and tranquil
3. Patient responds to commands only
4. Patient sedated with brisk response to stimulus
5. Patient sedated with sluggish response to stimulus
6. Patient sedated with no response to stimulus

[Stimulus indicates a light glabellar tap or loud command at ears]
Anxiety Scores,[10] were given by
4. Feeling nervous/panic
3. Can't stop worrying/worrying too much
2. Trouble relaxing/restless
1. Easily annoyed
0. calm and comfortable
The pain scores, sedation scores, anxiety scores were recorded preoperatively, after extubation then at 1, 2, 4 and 6 hours.
Baseline heart rate, systolic bloood pressure, diastolic blood pressure, mean arterial pressure, respiratory rate, saturation were recorded. Heart rate, systolic and diastolic blood pressure, mean arterial pressure were recorded preoperatively and during various time intervals intraoperatively and after extubation.
Postoperative blood pressure, heart rate, respiratory rate, postoperative pain, sedation, anxiety, total analgesic consumption were recorded at the end of 6 hours.
Side effects like nausea, vomiting, drowsiness, constipation and other complications, if any, were also recorded preoperatively, as well as 1 hour, 2 hour, 4 hours and 6 hours after extubation.

Statistical Analysis

Sample size was estimated by conducting a pilot study in 5 patients. The sample size needed was 50 for the power of the study to be 50% and alpha error to be 0.05. hence, considering the drop outs the sample size was chosen as 75.
The statistical analysis was done using SPSS software version 20. Qualitative analysis between

three groups were done by ANOVA and quantitative analysis by chi- square test.

RESULTS

The study was done in 75 patients of either sexes in the age group of 20 to 60 years, belonging to ASA class-1 and ASA class- 2, undergoing elective lumbar
laminectomy under general anaesthesia.
The patients were categorised into three groups
Group 1 - placebo
Group 2 - tramadol
Group 3 - pregabalin

Demographic Profiles

The demographic profiles like age, sex, weight, height, BMI, ASA status were comparable between the three groups as shown in table 11.1.

The mean age of patients in group1 is 44.04 with a standard deviation of 7.44 and in group 2 the mean age are 44.12 with a standard deviation of 8.52 and in group 3 the mean age is 45.96 with a standard deviation of 8.5. The p value is 0.645, which is insignificant. So all the three groups are comparable in terms of age. [Table 1]

The mean weight of the patients in group 1 is 56.44 with a standard deviation of 7.19 and in group 2 are 57.44 with a standard deviation of 7.49 and in group 3 are 56.88 with a standard deviation of 6.18. The p value is found to be 0.828 which is not significant. Therefore, the three groups are comparable in their weight.

The mean height of patients in group1, group 2 and group 3 are 1.56, 1.57and 1.59 with a standard deviation of 0.07, 0.07 and 0.09 respectively. The p value is found to be 0.404 which is not significant. This implies that there is no significant difference in height among the three groups and they are comparable.

The mean body mass index among group 1, group 2 and group 3 are 23.35, 23.20 and 22.53 with a standard deviation of 1.74, 2.04 and 1.14 respectively. The p value is 0.192 which is not significant. Therefore, the body mass index is comparable among all three groups.

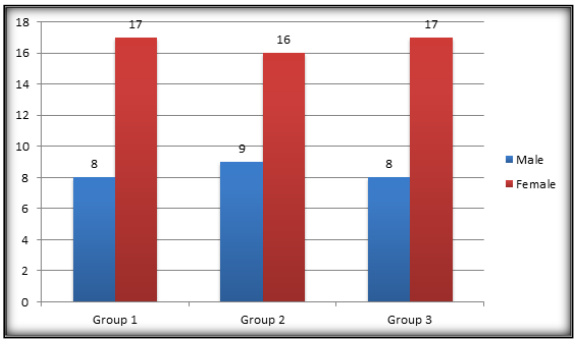

Figure 2: Comparison of demographic data (gender distribution)

The figure 11.2 shows the gender distribution among all three groups. The sex ratio (male: female) among group1, group 2 and group 3 are 8:17, 9:16 and 8:17 respectively. The p value is found to be 0.942 which is not significant which shows the gender distribution among all three groups is comparable.

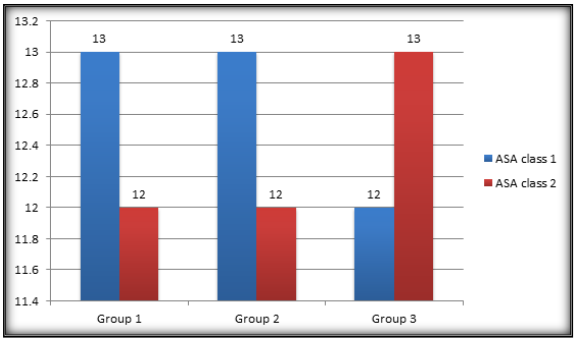

Figure 3: Comparison of ASA status among all groups

The figure 11.3 shows the ASA status among all three groups. The ASA class1:2 ratios among the three groups 1, 2& 3 are 13:12, 13:12 & 12:13 respectively. The p value is found to be 0.948 which is not significant. This implies that the ASA status among all three groups is comparable.

The mean duration of surgery in minutes among group 1, group 2 and group 3 are 148±15, 148.80±11.3 and 146.40±17.29 respectively. The p value is found to be 0.63 which is insignificant. This shows that the mean duration of surgery among the three groups are comparable. [Table 2]

The mean baseline heart rate of group 1, group 2 and group 3 are 75.12±4.49, 74.84±7.11 and 74.28±6.60 respectively with a p value of 0.422 which is insignificant. The mean baseline systolic blood pressures of group 1, group 2 and group 3 are 122±11.09, 122.24±9.18 and 122.64±8.41 respectively with a p value of 0.381 which is not significant. The mean baseline diastolic blood pressure of group1, group 2 and group 3 are 78.92±6.32, 78.92±9.10 and 78.04±5.19 respectively with a p value of 0.117 which is insignificant. The mean baseline MAP of group 1, 2 &3 are 93.16±7.64, 93.24±8.151and 93.16±5.41 respectively with a p value of 0.101 which is insignificant. [Table 3]

The mean Visual Analog Scale scoring in group 2 is less than group 3, which is less than group 1. This difference is significant ($p<0.05$). [Table 4]

The mean anxiety scores in group 2 is less than group 3 which is less than group 1 and this difference is statistically significant. [Table 5]

The sedation score in group 2 is greater than that of group 3 which is greater than that of group 1 preoperatively, after extubation and 1, 2, 4 and 6 hours postoperatively. [Table 6]

The mean fentanyl requirement in group 1 is 128±17.40, in group 2 is 40.40±9.17 and in group 3 it is 60.40±17.29. Fentanyl requirement is more in group 1 compared to group 3, which itself is more

than group2. These differences are statistically significant. [Table 7]

From the above table it's clear that the adverse effects like nausea, vomiting and drowsiness in group 3 is less than that of group 1 and group 2. [Table 8]

Table 1: Demographic profiles of the three groups

Demographic profile	Group1 (Mean±SD)	Group 2 (Mean±SD)	Group3 (Mean± SD)	P value
Age (years)	44.04 ± 7.44	44.12 ± 8.52	45.96 ± 8.5	0.645
Sex (M:F)	8:17	9:16	8:17	0.942
Weight (Kg)	56.44 ± 7.19	57.64 ± 7.49	56.88 ± 6.18	0.828
Height (metre)	1.56 ± 0.07	1.57 ± 0.07	1.59 ± 0.09	0.404
BMI (kg/m^2)	23.35 ± 1.74	23.20 ± 2.04	22.53 ± 1.14	0.192
ASA class 1:2	13:12	13:12	12:13	0.948

Table 2: Duration of surgery and Spinal levels

	Group-1 Mean±SD)	Group-2 (Mean±SD)	Group-3 (Mean±SD)	P value
Duration of surgery (minutes)	148.00±15.00	144.80±11.3	146.40±17.29	0.63
Spinal levels (1:2)	12:13	11:14	13:12	0.852

Table 3: Baseline hemodynamic parameters of the three groups

Heart rate	75.12 ± 4.49	74.84 ± 7.11	74.28 ± 6.60	0.422
Systolic blood pressure	122.00 ±11.09	122.24 ± 9.18	122.64 ±8.41	0.381
Diastolic blood pressure	78.92± 6.32	78.92 ± 9.10	78.04± 5.19	0.117
Mean arterial blood pressure	93.16± 7.64	93.24 ± 8.151	93.16 ± 5.41	0.101

Table 4: Pain scores in the three groups

VAS	Group-1 (Mean±SD)	Group-2 (Mean±SD)	Group-3 (Mean±SD)	P-value
Pre-op	1.52 ± 0.510	0.68± 0.476	1.48± 0.510	0.000#
AE	4.84± .624	1.48± .510	3.12 ± 0.332	0.000#
1 hr	5.52± 0.510	2.00± 0.408	2.84± 0.374	0.000#
2 hr	6.48± 0.510	2.40± 0.500	3.40± 0.500	0.000#
4 hr	5.80± 0.408	2.32± 0.476	4.12± 0.332	0.000#
6 hr	5.72 ± 0.458	2.52 ± 0.510	4.08± 0.277	0.000#

 # - p value significant

Table 5: Anxiety scores in the three groups

AS	Group-1 (Mean±SD)	Group-2 (Mean±SD)	Group-3 (Mean±SD)	P-value
Pre-op	1.84± 0.37	0.20 ± 0.41	1.16 ± 0.37	0.000#
AE	1.72 ± 0.46	0.48± 0.51	1.16 ± 0.37	0.000#
1 hr	2.80± 0.41	0.40± 0.50	1.60± 0.50	0.000#
2 hr	3.52± 0.51	0.56± 0.51	1.96± 0.20	0.000#
4 hr	3.32± 0.48	0.60± 0.50	1.60± 0.50	0.000#
6 hr	3.32± 0.48	0.64 ± 0.49	1.64± 0.49	0.000#

 # - p value significant

Table 6: Sedation scores in the three groups

RSS	Group-1	Group-2	Group-3	P-value
Pre-op	1.00± 0.00	2.32± 0.48	1.52± 0.51	0.000#
AE	1.28 ± 0.46	2.64 ± 0.49	2.48± 0.51	0.000#
1 hr	1.48± 0.51	3.60± 0.51	3.52± 0.50	0.000#
2 hr	1.48± 0.51	3.80 ± 0.41	3.52 ± 0.51	0.000#
4 hr	1.56 ± 0.51	3.92± 0.28	3.44± 0.51	0.000#
6 hr	1.60± 0.50	3.72± 0.46	3.40± 0.50	0.000#

 # - p value significant

Table 7: Mean fentanyl requirement in the 3 groups

	Group 1 (Mean±SD)	Group 2 (Mean±SD)	Group 3 (Mean±SD)	P value
Fentanyl requirement (micrograms)	128.80±17.40	40.40±9.17	60.40±17.29	0.004#

 # - p value significant

Table 8: Adverse effects in the three groups

	Group 1 N(%)	Group 2 N (%)	Group 3 N (%)
Nausea	2 (8%)	5 (20%)	1 (4%)
Vomiting	3 (12%)	5 (20%)	1 (4%)
Drowsiness	1 (4%)	8 (32%)	1 (4%)

DISCUSSION

In the present study, the pain scores of the patients who received tramadol and pregabalin were significantly decreased in comparison to placebo group. The tramadol group had the least pain scores when compared to the pregabalin and placebo groups. It was also observed that the analgesia provided by tramadol was superior to that of pregabalin, but pregabalin was more effective in reducing the pain when compared to placebo.

The amount of rescue analgesia required was more in control group and hence the total dose of fentanyl given during the first six hours of the postoperative period was relatively more when compared to tramadol and pregabalin groups.

In a study by Pandey CK ET al,[11] fentanyl requirement is decreased in patients undergoing lumbar discectomy in gabapentin group. Similar results were obtained by Turan A et al,[12] for spinal surgeries. Pandey CK et al,[13] used 600 mg gabapentin and obtained similar results. Turan An et al,[14] found a decrease in tramadol comsumption in patients who were given gabapentin for abdominal hysterectomy. In other studies by Fassoulaki A et al,[15] and Gianesello et al,[16] opioid consumption is decreased as with above studies.

Hence, the opioid sparing effect of pregabalin as per my study is in agreement with the above studies.[11]

Pregabalin has previously been shown to have good analgesic efficacy in patients with post herpetic neuralgia, spinal cord injury, gynaecological surgery, dental surgery and in patients following lumbar laminectomy and discectomy.[17] However, the doses in these studies varied from 75 mg to 300 mg per day.

In this study, the anxiety scores in pregabalin and tramadol groups were significantly lower when compared to the placebo group. However, the anxiety scores were significantly lower in the pregabalin group in comparison to the placebo group, whereas it is significantly higher than the tramadol group. This observation shows that pregabalin also has an anxiolytic effect additionally although it is to a lesser extent when compared to tramadol.

Ozgencil E et al,[17] in their study found that pregabalin 300 mg per day and gabapentin 1200 mg per day had more analgesic, anxiolytic and also opioid sparing effects. Patient satisfaction is also high and is also more effective in preventing postoperative shivering than the placebo following lumbar laminectomy and discectomy.

Menigaux C et al,[18] in their study concluded that premedication with gabapentin 1200mg improved preoperative anxiolysis, postoperative analgesia and early knee mobilization after arthroscopic anterior cruciate ligament repair.

The above two studies shows the anxiolytic effect of pregabalin which is in line with my study.

The preoperative sedation scores in my study were significantly greater in tramadol group when compared to the pregabalin and placebo groups. After extubation and postoperatively the level of sedation increased in both pregabalin and tramadol. However, this increase in sedation in pregabalin group was more after extubation and 1 hour postoperatively (but less than tramadol insignificantly); rest all time intervals it was significantly lower than the tramadol group though the sedation was significantly higher than the placebo group.

From this, we infer that pregabalin has a good anxiolytic effect without resulting in excessive sedation.

Yoon MH et al,[19] in their animal study, administered gabapentin intrathecally to rats. In their study they concluded that spinally delivered gabapentin has no effect on resting heart rate or blood pressure. But it attenuated the enhanced pain behaviour and cardiovascular response otherwise produced by the injury.

Van Den Berg AA et al,[20] studied the obtundation of stress response to laryngoscopy and intubation by opioids. In this study they found that the increase in heart rate(1 minute after intubation) that occurred with laryngoscopy and intubation is not attenuated by tramadol but rather it returned at a faster rate to baseline in tramadol group(5 minutes after intubation) when compared to placebo group (7 miutes after intubation).

In my study, the increase in heart rate is significantly lower in tramadol group while compared to placebo at 1 and 3 minutes after intubation and at 30, 60 and 120 minutes and after extubation. The decrease in heart rate is insignificant preoperatively and 3 minutes after intubation.

Similarly, in the pregabalin group, the increase in heart rate is significantly lower at 1&3 minutes after intubation, at 30, 60& 120 minutes and after extubation when compared to placebo group.

The systolic blood pressure, diastolic blood pressure and mean arterial blood pressure in tramadol group is significantly lower when compared to placebo group at 1 & 3 minutes after intubation and after extubation. In pregabalin group the systolic, diastolic and mean arterial blood pressure are significantly lower at 1 minute after intubation and after extubation.

Thus both pregabalin and tramadol given preoperatively, apart from preventing pressor response to laryngoscopy and intubation also helps to maintain a stable hemodynamics throughout surgery.

Drowsiness was less frequent in the pregabalin group (4%) compared to the tramadol group (32%). Fewer patients had nausea (4%) and vomiting (4%) with pregabalin when compared to placebo (nausea 8%, vomiting 12%) and tramadol (nausea 20%, vomiting 20%). This implies that the incidence of

nausea and vomiting is more with tramadol and placebo than with pregabalin.

Edwards JE et al,[21]studied the efficacy of oral tramadol and tramadol with acetaminophen combination for acute postoperative pain. According to their study the adverse effects with tramadol were dizziness, drowsiness, nausea, vomiting and headache.

Moore RA et al,[22] did a meta-analysis to assess the safety and efficacy of oral tramadol when compared with standard analgesics. They found that the adverse effects with tramadol was higher at higher doses due to dose-response effect.

In a study by Ozgencil et al,[17] it was found that pregabalin is well tolerated at all doses and has higher patient satisfaction. All these studies are in agreement with my study regarding the adverse effects of pregabalin and tramadol.

CONCLUSION

Pregabalin has a statistically significant effect when compared to placebo, but this effect is less when compared to tramadol.The need for rescue analgesia is in the least in tramadol patients followed by pregabalin and it increases maximum in the placebo group.Pregabalin has a statistically significant anxiolytic effect when compared to the placebo group.The anxiolytic effect of pregabalin is associated with less sedation when compared to that of tramadol.Pregaalin reduces the pressor response to laryngoscopy and intubation and also maintains a stable hemodynamics similar to tramadol Pregabalin has lowest number of postoperative complications like nausea, vomiting and drowsiness when compared to tramadol.

Conflict of Interest: None

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