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# EFFICACY OF ONDANSETRON, GRANISETRON AND PALONOSETRON ON POSTOPERATIVE NAUSEA AND VOMITING IN PATIENTS UNDERGOING ELECTIVE NEUROSURGICAL PROCEDURE

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**Abstract**

**Background :**Neurosurgery is associated with high incidence of post operative nausea and vomiting. $5HT_3$ Antagonists are highly specific for the treatment of nausea and vomiting. They are preferred antiemetic agents in neurosurgical patients due to lack of sedation and extrapyramidal reactions. The aim of the study is to compare the effect of ondansetron, granisetron and palonosetron on postoperative nausea and vomiting in patients undergoing elective neurosurgical procedure under general anaesthesia.

**Material and methods**

Seventy- five adult patients, of either sex, age group of 18-60 years, ASA I, II and III, scheduled to undergo elective neurosurgical procedure, under general anaesthesia, were enrolled in the prospective, randomized, double blind study. Anaesthesia was induced with fentanyl 2 $\mu gkg^{-1}$ and propofol 2 $mgkg^{-1}$ and vecuronium bromide 0.1 $mgkg^{-1}$ was given to facilitate endotracheal intubation. At the time of dura closure, patients were randomly allocated to one of the three groups (n=25 each) Group O: to receive injection ondansetron 4mg i/v, Group G: to receive injection granisetron 1mg i/v and Group P: to receive injection palonosetron 0.075mg i/v. Observer recorded each episode of nausea and vomiting, the use of rescue antiemetics, degree of satisfaction and variation in ECG postoperatively

**Results**

The cumulative incidence of PONV in 0 to 48 hrs postoperatively was 57.33%. The incidence of PONV Among the three groups is statistically significant with the least incidence in Group P. The use of RAE for the first time, in each of the individual group was noted and was found to be least in Group P. The study indicated that patients were most satisfied with palonosetron, followed by granisetron and least satisfied with ondansetron for the antiemetic efficacy.

**Conclusion**

Palonosetron is an excellent choice for PONV prophylaxis with good safety profile for patients undergoing neurosurgical procedures in comparison to granisetron and ondansetron.

**Keywords**

Neurosurgery, Antiemetic, 5HT3 Antagonist

## Introduction

Neurosurgery is associated with high incidence and prevalence of PONV because of multiple factors such as use of volatile anaesthetics, the prolonged duration of surgery, use of high doses of intraoperative and postoperative opioids.[1] Postcraniotomy, PONV incidence ranges from 44-70% with higher incidence in infratentorial procedures. It is the most common complication observed following neurosurgery with an overall incidence of 39% in the first 4 hours after surgery. [1,2]

$5HT_3$ Antagonists are highly specific and selective for the treatment of nausea and vomiting.[3,4] They are preferred antiemetic agents in neurosurgical patients due to the lack of sedation and extrapyramidal reactions.[1] First generation $5HT_3$ antagonists have been categorized into three major classes, on the basis of their chemical structures i.e. carbazole derivatives i.e. ondansetron, indazoles i.e. granisetron and indoles i.e. dolasetron. Palonosetron is the first second generation serotonin antagonist and is highly selective for $5HT_3$ receptor.[3] It has been used for prophylaxis of PONV in various surgical procedures like middle ear surgery, laparoscopic cholecystectomy, thyroidectomy, gynaecological procedures.[5,6] However this drug has not been compared with other $5HT_3$ antagonists (ondansetron and granisetron) for their efficacy in neurosurgical patients. Taking null hypothesis in consideration that all of these three drugs would have no difference in efficacy, when given with dexamethasone, we proposed to study the effect of ondansetron, granisetron and palonosetron on postoperative nausea and vomiting in patients undergoing craniotomy under general anaesthesia.

The primary aim of the study is to assess and compare the efficacy of i/v ondansetron, granisetron and palonosetron in addition to dexamethasone on episodes of nausea and vomiting postoperatively. The secondary objectives include requirement of rescue antiemetics, adverse effects on ECG, if any and patient satisfaction.

## Material and methods

This prospective, randomized, double blind study was conducted in the Department of Anaesthesiology and Critical Care in a tertiary care hospital in North India. A total of 75 adult patients, of either sex, in the age group of 18-60 years, belonging to American society of Anaesthesiologists (ASA) physical status I, II and III, scheduled to undergo elective neurosurgical procedure, under general anaesthesia, were enrolled in the study. Informed and written consent was obtained from all the patients. The patients with previous history of PONV/motion sickness, refusal of consent, gastro esophageal reflux disease, history of allergy to $5HT_3$ antagonists, Glasgow coma scale <14, not extubated at the end of surgery,

pregnant or lactating women and on preoperative antiemetic therapy were excluded from the study.

Patient was preoxygenated with 100% $O_2$ for 3 minutes. After preoxygenation, anaesthesia was induced with fentanyl 2 $\mu gkg^{-1}$ and propofol 2 $mgkg^{-1}$ intravenously. Mask ventilation was checked and vecuroniun bromide 0.1 $mgkg^{-1}$ was given to facilitate endotracheal intubation. All patients were given injection dexamethasone 8 mg intravenously as a routine neurosurgical protocol after the induction. Anaesthesia was maintained with isoflurane, nitrous oxide (50%) in oxygen (50%) to maintain MAC of 1. Ventilation was controlled to maintain $EtCO_2$ between 30 and 35 mmHg. At the time of dura closure, patients were randomly allocated to one of the three groups (n=25 each) using sealed envelopes.

Group O (n=25): to receive injection ondansetron 4 mg i/v

Group G n=25): to receive injection granisetron 1 mg i/v

Group P (n=25): to receive injection palonosetron 0.075 mg i/v

These 3 drugs were administered approximately 30 minutes before anticipated extubation. Study medications were prepared by an anaesthetist, not involved in PONV monitoring, in identical 2 ml syringes, to the volume of 2 ml. At the end of surgery, residual neuromuscular blockade was reversed with injection neostigmine 0.05 mg $kg^{-1}$ and injection glycopyrrolate 0.008 mg $kg^{-1}$ and trachea was extubated after signs of adequate neuromuscular reversal.

Postoperatively, patients were managed in the ICU for the first 48 hrs. Observer, who was blinded to the group allocation, recorded each episode of nausea and vomiting. An episode of PONV was defined as Nausea (subjective feeling of the need to vomit), Retching (an involuntary attempt to vomit but not productive of stomach contents) or Vomiting (expulsion of stomach contents). Investigator assessed the severity of PONV according to predetermined nausea vomiting scores[7] (0 = no nausea, 1 = nausea, 2 = retching / 1 vomitus, 3 >1 vomitus) by direct questioning of the patients at the postoperative times: 0, 1, 2, 4, 8, 12, 24, and 48 hours. No antiemetic was given in postoperative period. The rescue antiemetic used was ondansetron in dose of 4 mg i.v and was used in patients with PONV score >2. At 24 hours, the investigator recorded the use of rescue antiemetics and degree of satisfaction[7] (1 = very unsatisfied, 2 = unsatisfied, 3 = satisfied, 4 = very satisfied). At 24 hours postoperatively, an ECG was performed and compared with the baseline ECG and any variation was noted.

**Sample size**

Based on previous study (Gupta et al[4]), it was found that the complete control of postoperative nausea and vomiting for first

12 hours was achieved in 30% patients of ondansetron group, 55% patients of granisetron group, and 90% patients of palonosetron group. Assuming the same, with power 80% and at alpha 0.05, sample size of 25 patients per group was required to ensure statistical significance.

**Statistical analysis**

Statistical testing was conducted with the statistical package for the social science system version SPSS 17.0. Continuous variables were presented as mean±SD or median (IQR) for non-normally distributed data. Categorical variables were expressed as frequencies and percentages. The comparison of normally distributed continuous variables was performed using ANOVA with appropriate post-hoc test. Nominal categorical data between the groups was compared using Chi-square test. Non-normal distribution continuous variables were compared using Kruskal Wallis test and further paired comparisons were done using Mann Whitney U-test. For all statistical tests, a p <0.05 was taken as a significant difference.

## Results

The demographic profile of the patients in all the three groups is demonstrated in table I. All the patients were comparable in terms of their demographic profile.

**Table I**

**Demographic variables**

| Variables | Granisetron | Ondansetron | Palonosetron | P value |
|---|---|---|---|---|
| Age (years) | 41.60±16.23 | 43.88±10.89 | 38.16±13.02 | 0.303* |
| Weight (kgs) | 59.92±6.72 | 61.08±6.93 | 60.80±7.77 | 0.837* |
| Height (cm) | 162.56±6.83 | 161.72±7.51 | 162.56±7.07 | 0.891* |
| Gender (Male/Female) | 15/10 | 11/14 | 13/12 | 0.527** |
| ASA grade (I/II/III) | 8/13/4 | 7/16/2 | 10/10/5 | 0.522** |

*ANOVA test, **Chi-square test

The incidence of PONV in each individual group is demonstrated in table II. When using chi - square test, the difference in the incidence of PONV amongst the three groups is statistically significant (p=0.001).

**Table II**

**Incidence of PONV**

| Drug | Incidence (%) | P value* |
|---|---|---|
| Granisetron | 13/25 (52%) | 0.001 |
| Ondansetron | 22/25 (88%) | |
| Palonosetron | 9/25 (36%) | |

*Chi-square test

The incidence of PONV across various time periods in all the three groups is demonstrated in table III. The cumulative incidence of PONV in 0 to 48 hrs postoperatively was 57.33%. In the time period of 0 to 4 hours postoperatively, eight patients in group G, twenty two patients in group O and seven patients in group P had experienced PONV and this difference amongst the three groups is statistically significant ($p < 0.001$). In the time period of 0 to 12 hours postoperatively, 13 patients in group G, 22 patients in group O and 7 patients in group P had experienced PONV and this difference amongst three groups is statistically significant ($p<0.001$). In the time period of 0 to 24 hrs postoperatively, 14 patients in group G, 22 patients in group O and 7 patients in group P had suffered from PONV and this difference in terms of incidence of PONV amongst the three groups is statistically significant ($p < 0.001$).

**Table III**

**Incidence of PONV across various time periods**

| Time period | Granisetron | Ondansetron | Palonosetron | P value* |
|---|---|---|---|---|
| 0-4 hours | 8 (32%) | 22 (88%) | 7 (28%) | <0.001 |
| 0-12 hours | 13 (52%) | 22 (88%) | 7 (28%) | <0.001 |
| 0-24 hours | 14 (56%) | 22 (88%) | 7 (28%) | <0.001 |

*ANOVA test

The use of RAE for the first time, in each of the individual groups is depicted in table IV. In group G, out of 25 patients, one patient received first RAE at the time of shifting to recovery room, two patients received it at the 8$^{th}$ hour postoperatively and four patients received it at the 12$^{th}$ hour postoperatively. In group O, out of 25 patients, ten patients received first RAE at the time of shifting to recovery room, two patients received it at the 2$^{nd}$ hour postoperatively, four patients received it at the 4$^{th}$ hour postoperatively and two patients received it at the 8$^{th}$ hour postoperatively. In group P, out of 25 patients, one patient received the first RAE at the time of shifting to recovery room and one patient received it at the 48$^{th}$ hour postoperatively.

**Table IV**

**First rescue antiemetic dose in three groups**

| | Shifting | 1 hr | 2 Hr | 4 Hr | 8 Hr | 12 Hr | 24 Hr | 48 Hr |
|---|---|---|---|---|---|---|---|---|
| Granisetron | 1 | 0 | 0 | 0 | 2 | 4 | 0 | 0 |
| Ondansetron | 10 | 0 | 2 | 4 | 2 | 0 | 0 | 0 |
| Palonosetron | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 1 |

The incidence of RAE use across various time periods in the three groups is depicted in table V. In 0 to 4 hrs postoperatively, the incidence of RAE use was 4% in group G, 64% in group O and 4% in group P and this difference was found out to be statistically significant amongst the three groups. In 0 to 12 hrs postoperatively, the incidence of RAE use was 28% in group G, 72% in group O and 4% in group P and this difference was found out to be statistically significant amongst three groups ($p < 0.05$). The incidence of RAE use remained same in all three groups across the period of 0 to 24 hrs. In 0 to 48 hours, the incidence of RAE use was 28% in group G, 72% in group O and 8% in group P and this difference was found out to be statistically significant ($p < 0.05$).

**Table V**

**RAE use across various time periods**

| Time interval | Group G | Group O | Group P | P value |
|---|---|---|---|---|
| 0 - 4 hrs | 1/25 (4%) | 16/25 (64%) | 1/25 (4%) | <0.001 |
| 0 - 12 hrs | 7/25 (28%) | 18/25 (72%) | 1/25 (4%) | <0.001 |
| 0 - 24 hrs | 7/25 (28%) | 18/25 (72%) | 1/25 (4%) | <0.001 |
| 0 - 48 hrs | 7/25 (28%) | 18/25 (72%) | 2/25 (8%) | <0.001 |

*Chi square test

The incidence of 24 hour ECG changes amongst the three groups was observed. Only 4 patients out of 75 had experienced variation from baseline ECG. Two patients in group O and 2 patients in group P had sinus bradycardia in their 24 hour ECG. None of the patients showed any other changes like QTc prolongation, as described in literature with the use of ondansetron and other $5HT_3$ antagonists. This was found out to be statistically insignificant ($p=0.348$). There was no complication due to PONV, amongst all the three groups.

**Table VI: Patient Satisfaction Score**

| | Group G | Group O | Group P | P value |
|---|---|---|---|---|
| Patient satisfaction score I/II/III/IV | 1/3/9/12 | 12/7/3/3 | 0/0/7/18 | |
| Poor (I+II)/Good (III+IV) | 4/21 | 19/6 | 0/25 | <0.001** |

**Chi square test

The patient's satisfaction score in the three groups is demonstrated in table 6. I and II indicates poor satisfaction among patients regarding the effectiveness of antiemetics given to them whereas satisfaction scores III and IV indicates good satisfaction. By using chi-square test, the differences in patients satisfaction score amongst all the three groups were statistically significant ($p < 0.001$) with good level of satisfaction in Group P and least satisfaction in Group O.

## Discussion

The mean age, weight, height and gender were comparable with no statistical difference between three groups ($p > 0.05$) and this provided us the uniform platform to evenly compare the results observed. Our result is similar to the results of the study conducted by Gupta et al[8], Madenoglu et al[9], and Kathirvel et al[10], but this is in contrast to the studies conducted by Gan et al[11], and Fabling et al[12], which had shown that female patients were more prone to post-craniotomy PONV. This difference might be due to small sample size and a study with a larger sample size is required to conclude more definitely on risk factors for PONV following craniotomy.

### Incidence of PONV

The incidence of PONV in 0 to 4 hrs, 0 to 12 hours and 0 to 48 hours postoperatively amongst the three groups was statistically significant ($p<0.001$). In our study, the cumulative incidence of PONV was 57.33%, which was falling in the range of 43% to 70% incidence as reported in the literature and previous studies.

The present study showed that the palonosetron and granisetron were statistically superior to ondansetron for prophylaxis of PONV across all the time periods of 0 to 4 hrs, 0 to 12 hrs and upto 48 hrs postoperatively. They also concluded that palonosetron was also statistically superior to granisetron for control of both early upto 4 hours and delayed PONV upto 48 hours. This result is in accordance with the study by Selcuk et al[14] who conducted the study to compare the effects of granisetron and ondansetron on PONV in patients undergoing supratentorial craniotomies, using steroids. Selcuk et al[14] observed that the existence of vomiting in the control group for first 4 hours, and in the ondansetreon group for the first 2 hours, were significantly higher than the other times, whereas no vomiting was observed in granisetron group. Bhattacharya and Banerjee[15] found 2 mg granisetron to be more

effective than 4 mg ondansetron in preventing PONV following gynaecological laparoscopy. Similarly, Ayden et al[16] reported a significantly lower incidence of PONV in palonosetron group (38.2%) than the ondansetron (63.6%) and tropisetron (61.8%) group following middle ear surgeries. Our result is in contrast to the results of studies conducted by Jain et al[13] who concluded that 4 mg ondansetron and 1 mg granisetron were comparably effective at preventing PONV after supratentorial craniotomy. We had inculcated some measures to decrease the baseline risk of nausea and vomiting in our study like the restriction of opioid use to fentanyl, propofol as induction agent and use of $N_2O$ in lower concentration 50:50 and the use of 8 mg dexamethasone after the induction of anaesthesia. Dexamethasone has a biological half-life of 36 to 48 hours and used in higher doses of 8 to 10 mg and is effective for delayed PONV. Basu et al[17] conducted a similar study to compare the same three antiemetics for prevention of PONV in patients undergoing middle ear surgery. Seventy five adult patients were included and they concluded that a single dose of palonosetron 0.25 mg was a superior antiemetic to granisetron 3 mg or ondansetron 8 mg in complete prevention of PONV after middle ear surgery during the first 24 hours period, inspite of the fact that the doses of granisetron and ondansetron used were higher than our study drugs. Gupta et al[4] conducted a similar study in 120 patients undergoing elective laparoscopic cholecystectomy under general anaesthesia and compared palonosetron, granisetron and ondansetron for antiemetic prophylaxis. They observed that the incidence of PONV was maximal during the first four hours postoperatively and the complete control of PONV for first 12 hours was achieved in 30% patients of ondansetron group, 55% patients of granisetron group and 90% patients of palonosetron group and finally, concluded that palonosetron was comparatively highly effective to prevent PONV after anaesthesia than ondansetron and granisetron.[4]

In our study, out of 7 patients who had experienced PONV in group P, 5 had nausea or retching and 2 patients had more than 1 episode of vomiting, who further required RAE and incidence of PONV was maximum in the initial 4 hours. Thus, palonosetron was found out to be very effective for delayed PONV.

**Use of RAE**

In 0 to 4 hrs and 0 to 12 hrs postoperatively, the incidence of RAE use was found out to be statistically significant amongst three groups ($p<0.05$). The incidence of RAE use remained same in all three groups across the period of 0 to 24 hrs. In 0 to 48 hours, the incidence of RAE use was 28% in group G, 72% in group O, and 8% in group P and this difference was found out to be statistically significant ($p<0.05$). RAE use was maximum in initial 4 hours postoperatively in group O and this may

be due to the shorter half-life i.e. 3 hrs whereas, in group G, RAE use was maximum in 0 to 12 hrs postoperatively and this may be attributed to the elimination half life of approximately 9 hrs of granisetron, which might lead to the decrease in its plasma level. Moreover, need for RAE is least in group P upto 48 hrs postoperatively and could be due to its long t1/2 of approximately 40 hrs. This result is in accordance with the result of study conducted by Bergese et al[18] on 40 patients undergoing elective craniotomy under general anaesthesia and used the combination therapy of palonosetron, dexamethasone and promethazine. They observed that the incidence of RAE use was 10% in initial 2 hrs postoperatively and 5% across the time period of 24 to 120 hrs.[17] Jain et al[13] conducted a study to compare ondansetron, granisetron and placebo after supratentorial craniotomy under general anaesthesia and observed that the requirement of RAE was significantly reduced in patients receiving ondansetron 14.8% and granisetron 13.3%, as compared with placebo 53.3% ($p<0.001$). The results of study by Singh et al[19] are in concordance with our results in terms of decrease in RAE use.

**Satisfaction score**

In terms of satisfaction score, the present study indicated that patients were most satisfied with palonosetron, followed by granisetron and least satisfaction was seen with ondansetron for the antiemetic efficacy. Our results are in disconcordance to the study conducted by Bestas et al[7] which concluded that mean satisfaction scores were comparable in ondansetron and granisetron for PONV prophylaxis in adult patients undergoing laparoscopic cholecystectomy, but higher than the placebo group, during 24 hr period. This difference might be due to the use of a larger dose of ondansetron i.e. 100 $\mu gkg^{-1}$ by them, whereas we have used only 4 mg of ondansetron and also because the different set of patient's surgery was included. Kathirvel et al[10] used 4 mg ondansetron in elective craniotomy patients and observed higher patient satisfaction scores as compared to placebo and thus, in concordance with our study. To best of our knowledge, no study comparing palonosetron, granisetron, and ondansetron had involved patients satisfaction criteria as the secondary outcome of the study, instead they used the complete control i.e. No nausea, retching, vomiting or RAE use, as their objective.

**24 hour ECG**

Only 4 patients out of 75 had experienced variation from baseline ECG. Two patients in group O and 2 patients in group P had sinus bradycardia in their 24 hour ECG. This was found out to be statistically insignificant. All $5HT_3$ antagonists except palonosetron are known to affect $QT_c$ interval. In our study, we had used the minimum and safe dose of three drugs. Our results are in concordance with the

study by Bergese et al[17] who used the triple combination therapy of palonosetron, dexamethasone and promethazine in patients undergoing elective craniotomy and observed that there were no clinically important changes in the baseline, 24 hr period and discharge ECG on 5th day postoperatively.

## Conclusion

We concluded that palonosetron is an excellent choice for PONV prophylaxis with good safety profile for patients undergoing neurosurgical procedures in comparison to granisetron and omdansetron and provides satisfaction to patients and requires very less frequent dosing. Granisetron is a better antiemetic than ondansetron in terms of PONV prophylaxis and patient satisfaction.

## Limitations

Inclusion of small sample size; inclusion of all types of intracranial neurosurgical procedures and the routine use of dexamethasone, which itself has an antiemetic role.

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**Authors' Contributions:**

1. Govil Vasudha, 2. Malik Richa,3. Kummar Prashant, 4. Rani Anju, 5. Puhal Sudha,
Work concept and design 1,2
Data collection and analysis 1,2,3
Responsibility for statistical analysis 1
Writing the article 1,2,3,4,5
Critical review, 1,2,3,4,5
Final approval of the article 1,2,3,4,5

Each author believes that the manuscript represents honest work and certifies that the article is original, is not under consideration by any other journal, and has not been previously published.

**Availability of Data and Material:** The corresponding author is prompt to supply datasets generated during and/or analyzed during the current study on wise request.

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