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## RESEARCH ARTICLE

# POST OPERATIVE NAUSEA VOMITING (*PONV)*: EFFECT OF ONDANSETRON AND PALONOSETRON

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**ABSTRACT**

The most common and distressing symptom following general anaesthesia are nausea and vomitting which occurs in post operative period of 20% to 30% of patients. The aim of this study is to compare the anti emetic eficacy of ondansetron and palonosetron by comparing the incidence of post operative nausea and vomitting using each drug. It was seen in the study that with palonosetron the incidence of post operative nausea and vomitting was significantly lower as compared to the group that received ondansetron.



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## INTRODUCTION

Post operative nausea and vomiting (PONV), (Andrews, 1992), has been associated with general anaesthesia since the introduction of chloroform and the first description was made by John Snow in 1884. During ether era the incidence was as high as 60% -70%. But inspite of advances in antiemetic therapy and changes in anaesthesia procedure including use of non-opioids or supplemented opioids to lighter non ether anaesthesia and improved pre and post operartive medication, refinement of operative technique, still post operative nausea and vomiting (PONV) occurs with unacceptable frequency and has been described as a "big little problem". With change in focus from inpatients to ambulatory anaesthesia, there has been an increase in this big little problem of nausea and vomiting (Patricia, 1991 and Gigilo, 2000). In 1956, halothane was introduced for induction which played an important role in reducing post operative nausea and vomitting (PONV), (Lerman, 1992). The introduction of propofol further declined the incidence of PONV to as low as 19% (Raftery, 1992 and Schulman, 1995). Avoidance of nitrous oxide reduced the incidence by 12 %. The approach for management is both pharmacological and non-pharmacological. The first and second line pharmacological antiemetic for PONV in adults include 5HT3 receptor antagonist (ondansetron, granisetron, palonosetron,tropisetron) (Dua, 2004; Myles, 2000; Helmer, 1993; Rojas, 2008 and Basu, 2011), steroids like dexamethasones, phenothiazines (promethazine), buterophenone (haloperidol, droperidol), antihistaminic like diphenhydramine, dimen hydrinate and anticholinergics like scopolamine (Liu, 1999 and Lee, 2004). Among these the 5HT3 antagonists are the most effective in prophylaxis of PONV (Helmer, 1993). For effective control of PONV the knowledge of identification of high risk patients is necessary. Apfel and colleagues have developed a risk scoring system predictive for PONV (Apfel, 1999 and Apfel, 2014). Among ENT surgeries middle ear surgery (due to activation of vestibular afferent and auricular branch of vagus) and tonsillectomy (due to activation of glossopharyngeal afferent to brainstem) are associated with high incidence of PONV. The incidence of PONV can be as high as 70% during the first 24 hr after tonsillectomy (Apfel, 1999).

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## MATERIALS AND METHODS

The study was under taken at VSS Medical College Hospital Burla, a tertiary referal center in western Odisha. Patients of ASA grade I & II of age group 20 to 50 yrs of either sex scheduled for middle ear surgeries and tonsillectomy under general anaesthesia were selected as study cases.

### Exclusion Criteria

Patients belonging to ASA grade III & IV, Obese patients, Pregnant women and lactating mother, Known allergy to test drugs, Any known systemic, metabolic disorder, Patients on chronic steroid therapy or have received antiemetic within 24 hrs of surgery

**Study Type:** A prospective randomised single blinded controlled study. The patients were randomly divided into two groups of 50 patients each.

**Group A-** ondan setron 8 mg I.V
**Group B**- palonosetron 0.75 mg I.V

The drugs diluted to 4 ml with normal saline and is given 5 minutes prior to induction.

### Observation

Clinical observation of all 100 cases were done, and all admitted and under went surgery in the dept of otolaryngology, VSS Medical College, Burla. Observation regarding patients demography, duration of surgery, intra operative and post operative heart rate, blood pressure, incidence of PONV were recorded.

**Table 1. Sex Distribution**

| Gender | Group-O | | Group-P | | P value | Significance |
|---|---|---|---|---|---|---|
| | n | % | n | % | | |
| Male | 26 | 52 | 27 | 54 | >0.05 | NS |
| Female | 24 | 48 | 23 | 46 | >0.05 | NS |

**Table 2. Age distribution**

| Age in years | Group-O | | Group-P | | P value | Significance |
|---|---|---|---|---|---|---|
| | n | % | n | % | | |
| 20-30 | 24 | 48 | 27 | 54 | >0.05 | NS |
| 30-40 | 18 | 36 | 16 | 32 | >0.05 | NS |
| 40-50 | 8 | 16 | 7 | 14 | >0.05 | NS |

**Table 3. Weight Distribution**

| Weight in kg | Group-O | | Group-P | | P value | Significance |
|---|---|---|---|---|---|---|
| | n | % | n | % | | |
| 40-45 | 14 | 28 | 14 | 28 | >0.05 | NS |
| 46-50 | 20 | 40 | 24 | 48 | >0.05 | NS |
| 51 -55 | 14 | 28 | 10 | 20 | >0.05 | NS |
| 56-60 | 2 | 4 | 2 | 4 | >0.05 | NS |

**Table 4. Comparision of demographic profile**

| Variable (Mean ± SD) | Group-O | Group-P | P value | Significance |
|---|---|---|---|---|
| Age(Mean ± SD) yrs | 28.2 ±5,72 | 29.8 ±4.49 | >0.05 | NS |
| weight(Mean ± SD) kg | 50.4 ±3.9 | 49.5 ±4.1 | >0.05 | NS |
| Duration of surgery (Mean ± SD) mins | 93 ±21.3 | 95.2 ±19.8 | >0.05 | NS |
| Duration of anaesthesia (Mean ± SD) mins | 119 ±20.04 | 120.8 ±21.3 NS | >0.05 | NS |

**Table 5. Patients on anaesthesia exposure during surgery of varied duration**

| Duration of surgery (min) | Group-O | | Group-P | | P value | Significance |
|---|---|---|---|---|---|---|
| | N | % | N | % | | |
| 30-60 | 6 | 12 | 6 | 12 | >0.05 | NS |
| 61-90 | 10 | 20 | 12 | 24 | >0.05 | NS |
| 91-120 | 345 | 68 | 32 | 64 | >0.05 | NS |

**Table 6. Incidence of nausea**

| Duration (hour) | Group-O | | Group-P | | P value | Significance |
|---|---|---|---|---|---|---|
| | N | % | N | % | | |
| 0-2 | 15 | 30 | 5 | 10 | <0.05 | S |
| 2-6 | 10 | 20 | 5 | 10 | <0.05 | S |
| 6-12 | 10 | 20 | 4 | 8 | <0.05 | S |
| 12-24 | 9 | 18 | 2 | 4 | <0.05 | S |
| 0-24 | 44 | 88 | 15 | 30 | <0.05 | S |

**Table 7. Incidence of Vomitting**

| Duration (hour) | Group-O | | Group-P | | P value | Significance |
|---|---|---|---|---|---|---|
| | N | % | N | % | | |
| 0-2 | 0 | 0 | 3 | 6 | >0.05 | NS |
| 2-6 | 3 | 6 | 2 | 4 | >0.05 | NS |
| 6-12 | 2 | 4 | 1 | 2 | >0.05 | NS |
| 12-24 | 4 | 8 | 1 | 2 | >0.05 | NS |
| 0-24 | 9 | 18 | 7 | 14 | >0.05 | NS |

**Table 8. Incidence of side effect**

| Adverse Event | Ondansetron | Palonosetron |
|---|---|---|
| Headache | 5 | 5 |
| Dizziness | 6 | 7 |
| Constipation | 2 | 3 |
| Myalgia | 0 | 1 |
| Rescue Medication | 9 | 6 |

## DISCUSSION

PONV is the common complication with incidence ranging from 20 t0 25 % with modern anaesthetic technique. In adition to patients dissatisfaction, PONV may have other adverse consequences such as dehydration, electrolyte imbalance, delayed recovery, extended hospital stay, delayede return to work (Myles, 2000). Catastropic complication like rupture of oesophagus can occur rarely. Etiological factor for PONV include female gender, age, obesity, non smoker, history of motion sickness, duration and type of surgery, intra operative use of opioids and nitrous oxide postoperative factor like pain, dizziness and early ambulation also contributes to PONV. If patients are given prophylactic antiemetic drug only 20 to 25 % benefit towards complete response and this has proved the importance of prophylaxis of PONV. Aproximately 20 drugs show efficacy out of which 5HT3 antagonists are more efficacious in preventing PONV[74]. From our study we found that the over all incidence of nausea in 0 to 24 hr time interval in the palonosetron & ondansetron group are 88 % & 30 % respectively. But difference in incidence of vomitting was not significant (14%against 18% of palonosetron).60% patients in palonosetron group had complete response i.e; no emesis and no resque antiemetic as compared to 26 % in ondansetron group for 0 to 24hr time period. This study has confirmed the findings of previous study by S.K Park etal[16] who showed incidence of PONV was significantly lower in palonosetron group than ondansetron group (42.2% against 66.7%).

Bajwa *et al*, (Bajwa, 2011), found palonosetron a comparatively better drug to prevent PONV in day care surgeries as compared to ondansetron due to its prolonged duration of action.[18] Y.E.Moon *et al* compared the effect of i.v. ondansetron & palonosetron at the end of surgery in high risk patients and found palonosetron group having lower incidence of PONV than ondansetron (42% vs 62%). In the study palonosetron 0.75 mg was more effective at reducing PONV than ondansetron 8 mg. This reflects the high receptor affinity of palonosetron for 5HT3 and longer duration of action. The

incidence of vomiting had very little difference than that of ondansetron. This is because palonosetron has less afinity for other receptors like 5HT1b, 5HT1c, α2 adrenergic, μ opioid and GABA which are involved in the initiation and co-ordination of vomiting reflex. Palonosetron 0 .75 mg i.v. improves the control of nausea and vomiting through the 2nd and 3rd day as it under goes slow elimination phase (half life approximately 40hrs) than ondansetron (half life aproximately 3 to 5 hrs).

**Conclusion**

Palonosetron is superior to the established 1st generation 5HT3 receptor antagonists in respect of pharmacokinetic data such as a high receptor binding affinity and a prolonged mean elimination half life after i.v. administration. Although our study found that the side effects associated with palonosetron were slightly higher than ondansetron & vomiting profile was similar in both the group which were not significant, hence we conclude that Palonosetron 0 .75mg is stastistically superior to ondansetron 8 mg in preventing Nausea component of PONV.

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