International Journal of Environmental Sciences
ISSN: 2229-7359
Vol. 11 No. 4,2025
https://theaspd.com/index.php

Palonosetron Versus Ondansetron For Post-Operative Nausea And Vomiting During Middle Ear Surgery: A Comparative Observational Study

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ABSTRACT

Background: *Post-operative nausea and vomiting (PONV), a common morbidity after anesthesia, particularly in middle ear surgeries, has multifactorial etiology. Palonosetron, a newer 5-HT3 receptor antagonist, has been compared with ondansetron for PONV prophylaxis in this study.*

Aim: *To evaluate the efficacy of palonosetron versus ondansetron in preventing PONV during middle ear surgeries.*

Methodology: *Sixty ASA I and II patients were divided into two groups of 30 each. Group I received ondansetron (8 mg IV), and Group II received palonosetron (0.075 mg IV). Parameters assessed included nausea and vomiting severity, recovery time, and discharge time.*

Results: *Palonosetron showed mild early nausea in 10%, moderate in 6%, while ondansetron had mild in 3%, moderate in 7%. Late nausea was mild in 13%, moderate in 4% for palonosetron, and mild in 3%, moderate in 7% for ondansetron. Early vomiting was mild in 7%, moderate in 3% for palonosetron, and mild in 7%, moderate in 10% for ondansetron. Late vomiting was mild in 7%, moderate in 3% for palonosetron, and mild in 10%, moderate in 7% for ondansetron.*

Palonosetron was more effective in preventing PONV in the late postoperative stage (4–24 h), while ondansetron was better in the early stage (0–3 h).

Conclusion: *Palonosetron is as effective and safe as ondansetron in PONV prevention, with superior efficacy in the late postoperative period.*

Keywords: *Middle ear, nausea, vomiting, early, delayed, ondansetron, palonosetron.*

INTRODUCTION

The middle ear is located in the center of the temporal bone and bears a highly complex anatomy. The recently introduced exclusively endoscopic trans canal approach to the middle ear is minimally invasive technique sparing the bone and mucosa of the mastoid bone. Since the middle ear is accessed through the external auditory canal. This emerging method has several advantages over the traditional approaches to the middle ear such as the panoramic wide-angle views of the anatomy, the possibility of looking around the corner using angled endoscopes. (1)Middle ear anatomy and physiology is highly complex, yet familiarity is important to performmiddle ear surgery and understand surgically relevant ventilation pathways of the ear compartments. The middle ear is divided into five subspaces. The mesotympanum, the retro tympanum posteriorly, the epitympanum superiorly, the protympanum anteriorly and the hypotympanum inferiorly. The eustachian tube plays a crucial role in maintaining middle ear aeration and atmospheric pressure. (2)The most common and distressing symptoms following surgery and anaesthesia are pain,nausea and vomiting. Pain causes suffering and draws first attention. Sometimes nausea and vomiting maybe more distressing especially after minor and ambulatory surgery, delaying the hospital discharge. (3) But postoperative pain management has received much more attention in past two decades than post operative nausea and vomiting. Incidence of post operative nausea and vomiting is still very high in spite of few newer medications in our armament. It is in the range of 20-30%. (4)

Ondansetron is a potent and highly selective serotonin 5HT3 receptor antagonist which has demonstrated important antiemetic activity and good tolerability in the prevention of chemotherapy-induced nausea vomiting. ondansetron is completely and rapidly absorbed from the gastro- intestinal tract after oral administration and does not accumulate with repeated oral administration.

Owing to hepatic first pass metabolism, its bio-availability is only about 60% compared with ondansetron administrated after standard meal and is not influenced by co administration of antacids, a slightly enhanced bio-availability has been observed in patients with cancer. (5)Ondansetron has proven to be appropriate as a single part (or) as an addition to standard antiemetic therapy (i.e., cortico steroids, benzodiazepines, neurotransmitter blockers) in preventing and treating acute chemotherapy-induced emesis (CIE). Initial results of clinical trials in prevention of radio therapy-induced emesis and anesthesia – induced emesis upper positive ondansetron is will tolerate with few adverse effects (e.g., headache, sedation). (6)Palonosetron is a selective serotonin subtype-3 (5-HT3) receptor antagonist with a strong binding affinity. It is used to prevent nausea and vomiting caused by cancer chemotherapy.In addition, it was granted FDA approval in March 2008 for the prevention of PONV during the period up to 24 h after surgery (7,8)Palonosetron was generally well tolerated in clinical trials. Intravenous palonosetron is a valuable option in the prevention of acute- and delayed-phase CINV in adult patients receiving MEC, and of acute-phase CINV in patients receiving HEC. Oral palonosetron is likely to be a useful addition to oral formulations of other 5-HT3 receptor antagonists in preventing CINV in patients receiving MEC. Intravenous palonosetron is a useful alternative to currently recommended agents in PONV prevention. (9).Palonosetron is as safe as and more effective than placebo, ramosetron, granisetron, and ondansetron in preventing delayed PONV. For early PONV, it has higher efficacy over placebo, granisetron and ondansetron. (10)

MATERIALS AND METHODS

This study was done in Sree Balaji Medical College and hospital during the year 2023. The study was conducted on 60 patients with ASA grading I and II of both gender and age group between 18 - 50 years old who were Scheduled for elective middle ear surgery under general anaesthesia.

PRE-OP EVALUATION

Preoperative visit was conducted on the previous day or day before day of surgery. Detailed history and present complaints were noted. General and systemic examination of cardio vascular, respiratory and central nervous system were done. Routine laboratory investigations like hemoglobin level, total count and differential count, routine urine, blood urea nitrogen and serum creatinine, Bleeding and clotting time, ECG were done.

A thorough airway examination has been done which includes of Mallampati classification, mouth opening, neck movement, breath holding time also the denture status.

ETHICAL CONSIDERATION

Ethical clearance was taken from Ethical and Research Committee of Sree Balaji Medical College and Hospital and Written Consent was taken from all patients.

DATA COLLECTION:

PONV was assessed using a standardized scoring system (0 = none; 1 = mild; 2 = moderate; 3 = severe) by trained clinicians blinded to group allocation. Hemodynamic parameters, recovery time, and adverse events were also recorded.

STATISTICAL ANALYSIS:

The data was tabulated in Microsoft Excel worksheet and computer-based analysis was performed using the Statistical Package Social Science Software and Microsoft Excel 2021.

Results on continuous measurements are presented as Mean ± SD (Standard Deviation). All other demographic data and intra-operative vitals were observed using student's 'T – test'. For all analysis, Value of $P < 0.05$ is considered as significant and Value of $P > 0.05$ is considered as non-significant.

INTERVENTIONS:

Both drugs were administered intravenously 10 minutes before the induction of anesthesia. Standardized

anesthesia protocols were followed for all patients, including the use of propofol for induction and sevoflurane for maintenance.

OUTCOME MEASURES:

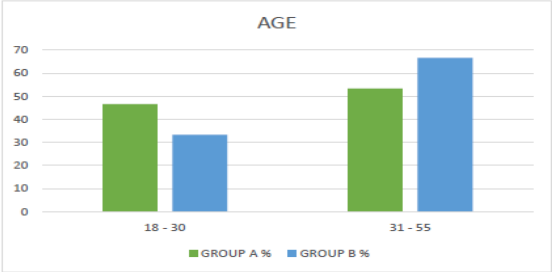
Primary Outcomes: Incidence and severity of PONV at 0–3 hours (early phase) and 4–24 hours (late phase).

Secondary Outcomes: Requirement for rescue antiemetics and adverse events.

Table 5.1: Age Distribution of Study Group

AGE (years)	GROUP A		GROUP B		P VALUE	SIGNIFICANCE
	n	%	n	%		
18 - 30	14	46.66	10	33.33	P = 0.3321	Non-Significant
31 - 55	16	53.33	20	66.66		

Figure 5.1: Age Percentage Graph

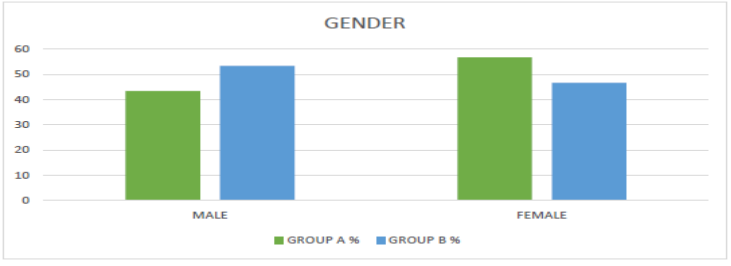


This graph shows the Age Percentage between Group A and Group B

Table 5.2: Gender Distribution of Study Group

GENDER	GROUP A		GROUP B		P VALUE	SIGNIFICANCE
	n	%	n	%		
MALE	13	43.33	16	53.33	P =0.4325	Non-Significant
FEMALE	17	56.66	14	46.66		

Figure 5.2: Gender Percentage Graph



This graph shows the Gender Percentage between Group A and Group B.

International Journal of Environmental Sciences
ISSN: 2229-7359
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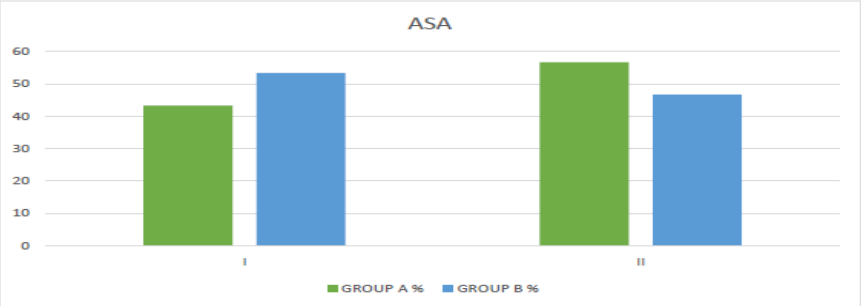
5.3 ASA DISTRIBUTION OF STUDY GROUP

Table 5.3: ASA Distribution of Study Population

ASA	GROUP A		GROUP B		P VALUE	SIGNIFICANCE
	n	%	n	%		
I	13	43.33	16	53.33	P = 1.0000	Non-Significant
II	17	56.66	14	46.66		

Figure 5.3: ASA Percentage Graph



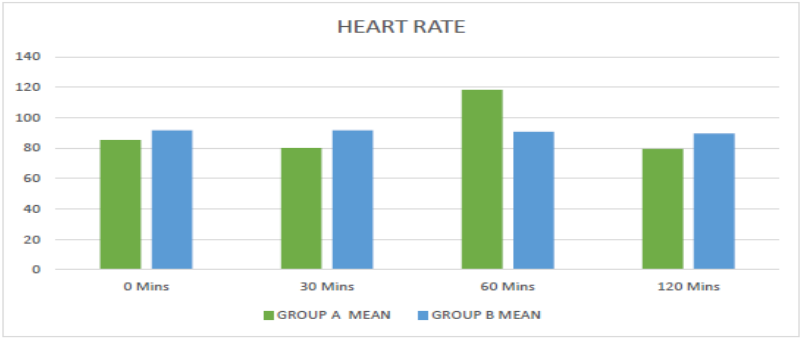
This graph shows the ASA Percentage between group A and Group B

5.4 MEAN HEART RATE

Table 5.4: Mean Heart Rate

HEART RATE	GROUP A	GROUP B	P VALUE	SIGNIFICANCE
	MEAN ± SD	MEAN ± SD		
0 Mins	85.33 ± 8.45	91.63 ± 11.93	P = 0.0242	Not Significant
30 Mins	79.96 ± 14.87	91.5 ± 11.54	P = 0.0014	Significant
60 Mins	118.09 ± 10.86	90.66 ± 12.40	P < 0.0001	Significant
120 Mins	79.43 ± 11.74	89.5 ± 11.20	P = 0.0013	Significant

Figure 5.4: Heart Rate Graph



This Graph shows the Mean Heart Rate between Group A and Group B. At 0 min results were comparable and the results were statistically non-significant. Whereas at 30 min, 60th min and at 120th min, the results were $p < 0.0001$ and they were statistically significant

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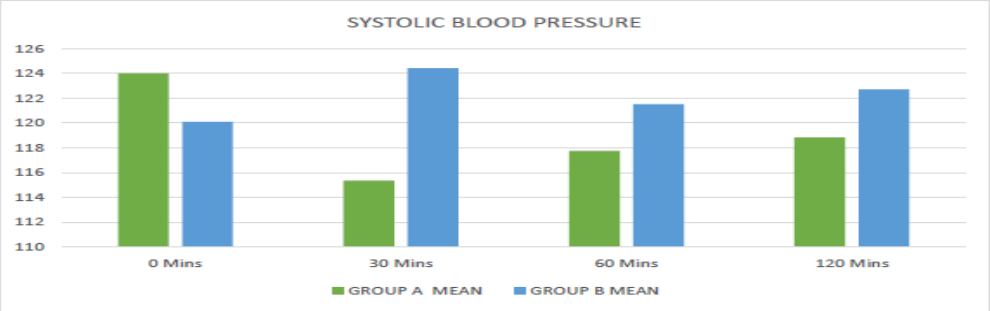
5.5 MEAN SYSTOLIC BLOOD PRESSURE

Table 5.5: Mean Systolic Blood Pressure

SDP	GROUP A	GROUP B	P VALUE	SIGNIFICANCE
	MEAN ± SD	MEAN ± SD		
0 Mins	124 ± 11.7	120.1 ± 10.73	P = 0.1837	Non-Significant
30 Mins	115.36 ± 9.90	124.43 ± 8.98	P = 0.0005	Significant
60 Mins	117.76 ± 11.26	121.53 ± 12.54	P = 0.7095	Non-Significant
120 Mins	118.83 ± 11.98	122.73 ± 9.12	P = 0.1510	Non-Significant

Figure 5.5: Mean Systolic Blood Pressure Graph



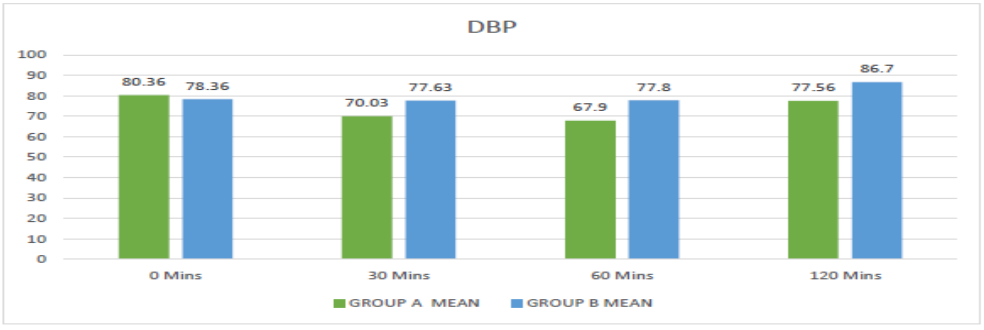
This Graph shows the Mean Systolic Blood Pressure between Group A and Group B. They were comparable and the results were statistically non-significant

5.6 MEAN DIASTOLIC BLOOD PRESSURE

Table 5.6: Mean Diastolic Blood Pressure

DBP	GROUP A	GROUP B	P VALUE	SIGNIFICANCE
	MEAN ± SD	MEAN ± SD		
0 Mins	80.36 ± 10.16	78.36 ± 12.64	P = 0.5171	Non-Significant
30 Mins	70.03 ± 9.85	77.63 ± 7.37	P = 0.0013	Significant
60 Mins	67.9 ± 10.70	77.8 ± 6.33	P = 0.0001	Significant
120 Mins	77.56 ± 5.38	86.7 ± 95.73	P = 0.6036	Non-Significant

Figure 5.6: Mean Diastolic Blood Pressure Graph



This Graph Shows the Mean Diastolic Blood Pressure between Group A and Group B. They were comparable and the results were statistically non-significant

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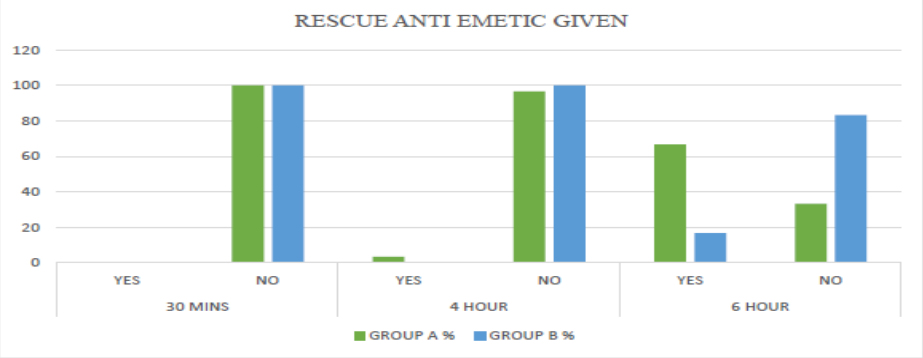
5.8 Rescue Anti-Emetic Given

Table 5.8: Rescue Anti-Emetic Given

RESCUE ANTI EMETIC GIVEN		GROUP A		GROUP B		P VALUE	SIGNIFICANCE
		n	%	n	%		
30 MINS	YES	0	0	0	0	P<0.0001	SIGNIFICANT
	NO	30	100	30	100		
4 HOUR	YES	1	3.33	0	0		
	NO	29	96.66	30	100		
6 HOUR	YES	20	66.66	5	16.66		
	NO	10	33.33	25	83.33		

Figure 5.8: Rescue Anti-Emetic Graph



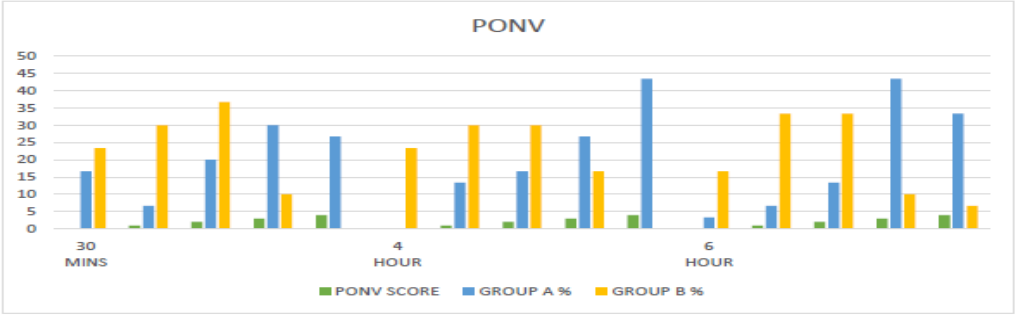
This graph shows Rescue Anti Emetic given at 30 mins, 4 hour and 6 hours. Their p value was <0.0001. The analysis was found to be statistically significant.

5.7 POST-OPERATIVE NAUSEA AND VOMITING SCORE

Table 5.7: Post-Operative Nausea & Vomiting

PONV SCORE		GROUP A		GROUP B		P VALUE	SIGNIFICANCE
		n	%	n	%		
30 MINS	0	5	16.66	7	23.33	P <0.0001	SIGNIFICANT
	1	2	6.66	9	30		
	2	6	20	11	36.66		
	3	9	30	3	10		
	4	8	26.66	0	0		
4 HOUR	0	0	0	7	23.33		
	1	4	13.33	9	30		
	2	5	16.66	9	30		
	3	8	26.66	5	16.66		
	4	13	43.33	0	0		
6 HOUR	0	1	3.33	5	16.66		
	1	2	6.66	10	33.33		
	2	4	13.33	10	33.33		
	3	13	43.33	3	10		
	4	10	33.33	2	6.66		

Figure 5.7 Post-Operative Nausea & Vomiting Graph



This graph shows the Post Operative Nausea and Vomiting score at 30 mins, 4 hour and 6 hours. Their p value was <0.0001. The analysis was found to be statistically significant.

DISCUSSION

Post operative nausea and vomiting (PONV) is very common sequelae of general anaesthesia and is very distressing for the patient. It is leading cause of delayed discharge, of unanticipatedhospital admission after ambulatory surgical procedure, pulmonary aspiration, wound dehiscence and dehydration. 5-HT3 receptor antagonists in 1990s was heralded as the major advance in prophylaxis of PONV as they lack the major adverse effects which were observed commonly with traditionallyused antiemetic drugs. And are routinely used now a days to prevent post operative nausea and vomiting. Currently available 5-HT3 antagonists include ondansetron, granisetron, dolasetron, topisetron and palonosetron. FDA has approved the use of palonosetron for prophylaxis of PONV in 2008 and is now available in India.

Palonosetron is a second-generation 5-HT3 antagonist with unique pharmacodynamic characteristics. Palonosetron is an allosteric 5- HT3 receptor antagonist, allosteric binding creates a conformational change in the serotonin receptor so that serotonin binding is indirectly inhibited. Consequently, palonosetron has higher affinity with 5-HT3 receptors, which ultimately leads to greater potency and longer duration of action in comparison with standard 5-HT3 antagonists (41) Present study was done to compare the efficacy of palonosetron 0.075mg and ondansetron 8mg for prevention of PONV administered 30min prior to the reversal agent in the patients undergoing middle ear surgeries under general anaesthesia The patients were divided into two groups (30 patients each). Group A receiving Palonosetron and Group B receiving Ondansetron.The study groups were comparable between two groups regarding demographic variables such as age, gender, ASA grading. There was no statistical difference. Regarding the Post Operative and Nausea Vomiting, Taninder Singh (5), the overall incidence of post operative nausea (PONV Score 1) in 24hrs was 56.66 % in patients among ondansetron group and 30 % in palonosetron group. The overall incidence of vomiting more than once (PONV Score 3) in 24hrs was 3.3% in ondansetron group and 0 % percentage in palonosetron group.

In our study, the post operative and nausea vomiting the overall incidence in 4th hour was 0 % in patients among palonosetron group and 43.33% in ondansetron group ($p < 0.0001$) Regarding the Rescue Anti Emetic Requirement, Taninder Singh (5), The no need for rescue anti emetic was 80 % in group palonosetron and 96.66% in ondansetron group. The need for rescue anti emetic was 20 % in palonosetron group and 3.3 % in ondansetron group. The need for anti-emetic rescue was 16.66 % in palonosetron and 66.66 % in ondansetron in the 6th hour. ($p < 0.0001$) Regarding the hemodynamic effects, we observed that the HR in both groups were not statistically significant. We have also observed Systolic Blood Pressure in both the groups was not statistically significant difference. There was also no statistical difference regarding Diastolic Blood Pressure. Both palonosetron and ondansetron are known to have nonserious adverse effects like shortduration headache, constipation, dizziness. Few patients in both groups complained of headache, dizziness. This difference was not significant statistically. Apart from this no side effects were observed in patients of both the groups in our study. To conclude palonosetron 0.075mg IV is more effective than ondansetron 8mg IV to prevent post operative nausea and vomiting in patients undergoing middle ear surgeries under general anaesthesia as the overall incidence of post operative nausea, vomiting, number of patients with incomplete response and requirement of rescue antiemetic were less in palonosetron group as compared to ondansetron.

CONCLUSION

Postoperative nausea and vomiting is an undesirable manifestation of the recovery period.Following middle ear surgery, the incidence can be as high as 80%. In our study, palonosetron was found to be superior to ondansetron for PONV prophylaxis after middle ear surgery. It has similar safety profile and longer duration of action than ondansetron. Palonosetron with its single dose regimen can reduce the need for multiple injections in postoperative period as with Ondansetron and can prove to be cost effective in the long run.

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