Post Operative Nausea and Vomiting: A Comparison between Ondansetron and Palonosetron after Tympanoplasty

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***Abstract*- BACKGROUND AND OBJECTIVES**

Post operative nausea and vomiting (PONV) is a troublesome complication after surgery and anaesthesia.The incidence of PONV is around 62-80% after tympanoplasty surgeries when no antiemetic prophylaxis is given. The purpose of this study was to compare ondansetron and palonosetron to prevent of PONV in patients undergoing tympanoplasty.

METHODOLOGY

In this prospective study, 60 patients of ASA grades 1 and 2 between age groups of 20-50years, posted for tympanoplasty under general anaesthesia were randomly divided into two groups of 30 each.. Group O received Inj. ondansetron (4 mg) and Group P received Inj. palonosetron (0.075 mg) intravenously three minutes before anaesthesia.The incidence of nausea, vomiting, requirement of rescue antiemetic and complete response during the first 48 hours were observed.

RESULTS

Post operative nausea was 60% in patients among group O and 26.6% in patients of group P .There was a statistically significant difference in incidence of post operative nausea in first 24 hours(p=0.009). The overall incidence of vomiting once in 24hrs was 23.3% in group Oand 3.33% in group P. (P=0.023) and this difference was statistically significant.The incidence of vomiting more than once in 24hrs was 20% in ondansetron group and 3.3% in palonosetron group and the result was statistically significant (P=0.044) . The incidence of vomiting in 24-48hrs was 16.6% in group Oand 6.6% in group P. (P=0.07) and this difference was statistically not significant.36.6% patients of ondansetron group showed no PONV while this value was 66.6% in group palanosetron.The result was statistically significant(p=0.001). Requirement of rescue antiemetic was 20% in group O and 3.3% in group P, which was also statistically significant(p=0.044). 2 (6.6%) patients in both groups complained of headache.This was not significant statistically.We encountered no other side effect in our study.

CONCLUSION

Incidence of PONV is less in patients who received IV Palonosetron in comparison with those who had received IV Ondansetron in patients of tympanoplasty.Hence palanosetron is a better **and longer acting anti emetic than ondansetron.**

***Index Terms*-** Ondansetron; Palonosetron; General Anaesthesia (GA); Intravenous (IV); Postoperative Nausea and Vomiting (PONV)

I. INTRODUCTION

Post operative nausea and vomiting (PONV) is a major clinical problem after surgery and anaesthesia that prolongs the time of hospital stay[1], increases healthcare expenses and causes patient dissatisfaction.[2] The incidence of PONV after regional anaesthesia is around 19%-22%, whereas after general anaesthesia it is as high as 76%.[3] Tympanoplasty surgeries have a very high incidence of PONV where 80% patients experience PONV if no antiemetic prophylaxis is given.[4]This may cause dangerous implications like dehydration , electrolyte imbalances ,aspiration, bleeding from wound, esophageal rupture and bilateral pneumothorax.[5]Use of PONV prophylaxis is a routine in clinical practice due to increased occurrence of PONV in patients who were not administered any prophylaxis. There are a number of drugs that are used to manage PONV including antihistaminics , butryphenones , anticholinergics, and dopamine antagonist receptor. However, these drugs cause adverse reactions such as sedation, dysphoria, extrapyramidal symptoms, dry mouth,restlessness, and tachycardia[6]. The recently introduced 5- hydroxytryptamine receptor antagonists ($5HT_3RA$) have no such adverse effects and are more effective in the preventing PONV. $5HT_3RA$ come under the classification of ligand-gated ion channels of Cys-loop superfamily and are most common drugs used in the prevention of PONV.[7,8]Ondansetron is the oldest 5HT3RA with a half-life period of 3 to 5 hours which is very short.

Recently a second generation 5-HT3 antagonist palanosetron is becoming popular .It has stronger affinity to bind with the receptor and a greater half-life time compared to other 5-HT3 receptor antagonists .[9] It acts by allosteric binding mechanism which is different from the classical 5-HT3 antagonists. [10]

This study was performed to compare ondansetron 4mg intravenous(I.V.) and palonosetron0.075 mg intravenous(I.V.) in prevention of PONV in patients undergoing tympanplasty.

II. MATERIALS AND METHODS

We conducted this study in M.M.I.M.S.R hospital in Department of Anesthesiology. After the institutional ethical committee approval,60 patients of Grade-I and Grade-II of American Society of Anesthesiologist's (ASA) classification, of either sex in the age group of 18 to 50 years, posted for tympanoplasty under general anaesthesia were studied. We have not included patients of uremia,cardiac problems,head injury,hepatic disorders who experience nausea and vomiting irrespective of surgical and anesthetic technique.Pregnant and lactating patients and patients with history of allergy to any of the 2 medications were excluded.

Pre-Operative Management: A thorough pre-anaesthetic evaluation was done. A detailed history of present problem, past medical or surgical history, drug intake or any allergy history. Vitals were noted. General and systemic examination followed by airway assessment were done. Routine investigations were done. All study patients were given tablet Alprazolam 0.25mg on night before the surgery and were kept nil by mouth for 7 hrs

In the operation theatre an IV access was taken and multipara monitor attached. Patients were allocated randomly to two equal groups of 30 each, Group P (n =30) received inj. palonosetron 0.075mg i.v., Group O(n =30) received inj. ondansetron 4 mg i.v. Both the drugs were diluted to 5ml volume in normal saline. All patients received either injection ondansetron 4mg Iv or injection palanosetron 0.075mg IV 3 minutes before anaesthesia for the elective surgical procedure General anaesthesia was given to all the patients.Premedication injection glycopyrrolate 0.2mg, injection tramadol 1mg/kg, inj. midazolam 0.01mg/kg IV was given. Patients were preoxygenated for 3 minutes was done with 100% oxygen and induced with thiopentone sodium 5 mg/kg and succinylcholine 2 mg/kg to facilitate laryngoscopy and intubation.Endotracheal intubation was done with appropriate sized cuffed endotracheal tube .Propofol was consciously avoided in our study since propofol itself possesses an emesis protective property. was inserted under direct laryngoscopy . After checkin bilateral air entry to be equal,was checked and the tube fixed. The patients were mechanical ventilated. Anaesthesia was maintained with 40:60 ratio oxygen and nitrous oxide N2O , isoflurane (0.2 – 1%) and inj. vecuronium 0.1mg/kg was used as a muscle relaxant as loading dose followed by 0.025 mg /kg of inj. vecuronium. At the end of surgery, when the patients regained spontaneous breathing , reversal was given with injection neostigmine (0.05mg/kg) glycopyrrolate (0.008mg/kg). Oral suctioning was done and patients were extubated when fully awake and adequate muscle power and reflexes were gained clinically. Duration of general anaesthesia and duration of surgery were noted. All patients were shifted to recovery room and were monitored for pulse rate, blood pressure, arterial oxygen saturation .

The incidence of patients with complete absence of nausea and vomiting ,presence of nausea,presence of vomiting, side effects and requirement for rescue antiemetics was observed for 48 hours

The patients with complete absence of nausea and vomiting were not given any rescue antiemetic medication during the observation period.

Vomiting was defined as the forceful oral expulsion of contents of stomach .

Nausea was defined as an unpleasant awareness of the one's sensation to vomit .

Any episode of nausea or vomiting – monitoring for PONV was done for first 24hours postoperatively at intervals of 30mins till first 4 hrs, then at 1 hr interval till next 8hrs and then at 2hrs interval till 24hours and then at 4 hrs interval till 48 hours. Incidence of the emetic episodes were compared in two groups . Patients who experienced even one episode of post operative vomiting with were given injection metoclopramide 10mg intravenous slowly as rescue treatment.

Complete response to antiemetic prophylaxis was considered if no patient experienced nausea and vomiting and did not need a rescue antiemetic during the observation period of 48hrs. Side effects if any like Headache,dizziness, constipation, diarrhoea, fatigue, abdominal pain, insomnia were recorded.

2.1 Statistical Methods

Observation and results were evaluated and compared between the two groups using Graph Pad Prism ® computer software version 6.04. Numerical values were presented as mean & standard deviation (SD) ; unpaired student – t test was done. Categorical variables were presented as percent; chi-square test was done. p value < 0.05 was considered significant.

III. RESULTS

COMPARISON OF DEMOGRAPHICAL PROFILES OF PATIENTS AND OPERATIVE CHARACTERISTICS OF BOTH GROUPS(TABLE I)

S.NO.		GROUP ONDANSETRON(N=30)	GROUP PALONOSETRON(N=30)	P VALUE	SIGNIFICANT/ NON-SIGNIFICANT
1	**AGE (in years)**	43.3	44.4	>0.05	Non -Significant
2	**SEX(M/F)**	18/12	19/11	>0.05	Non-Significant
3	**DURATION OF SURGERY(in minutes)**	93±21.3	95.2±19.8	>0.05	Non -Significant
4	**DURATION OF ANAESTHESIA (in minutes)**	120.8±21.3	119±20.4	>0.05	Non-Significant

There was no statistical difference between two groups in the demographic profile and mean duration of surgery and duration of anaesthesia(p>0.05) ,that helped us to compare the results observed uniformly

COMPARISON OF THE NUMBER OF PATIENTS WITH POSTOPERATIVE NAUSEA AND VOMITING(TABLE II)

S.NO.	EVENT	GROUP ONDANSTERON	GROUP PALONOSTERON	P VALUE	SIGNIFICANT=S NONSIGNIFICANT=NS
1	Incidence of nausea in 24 hours	18	8	0.009	Significant
2	Incidence of vomiting in 24 hours	7	1	0.023	Significant
3	Incidence of vomit more than once in 24 hours	6	1	0.044	Significant
4	Incidence of vomiting in 24-48 hours	5	2	0.07	Non significant

TABLE II

Post operative nausea was 60% in patients among group O and 26.6% in patients of group P .This was a statistically significant difference in incidence of post operative nausea(p=0.009). The overall incidence of vomiting once in 24hrs was 23.3% in group Oand 3.33% in group P. (P=0.023) and this difference was statistically significant.The incidence of vomiting more than once in 24hrs was 20% in ondansetron group and 3.3% in palonosetron group and the result was statistically significant (P=0.044) . The overall incidence of vomiting in 24-48hrs was 16.6% in group Oand 6.6% in group P. (P=0.07) and this difference was statistically not significant.

COMPARISON OF PATIENTS WITH COMPLETE ABSENCE OF POST-OPERATIVE NAUSEA AND VOMITING BETWEEN THE STUDY GROUPS

S.NO.	COMPLETE ABSENCE OF POST OPERATIVE NAUSEA AND VOMITING	GROUP ONDANSETRON(N=30)	GROUP PALONOSTERON	P VALUE SIGNIFICANT/NONSIGNIFICANT
1	YES	11	20	0.001(SIGNIFICANT)
2	NO	19	10	

TABLE III

11 patients of group ondansetron i.e.36.6% patients showed no PONV while this value was 66.6% in group palanosetron.The result was statistically significant(p=0.001).

COMPARISON OF PATIENTS REQUIRING RESCUE ANTI- EMETIC IN BOTH STUDY GROUPS

S.NO.	RESCUE ANTIEMETIC REQUIREMENT	GROUP ONDANSETRON(N=30)	GROUP PALONOSTERON (N=30)	P VALUE SIGNIFICANT/NONSIGNIFICANT 0.044(SIGNIFICANT)
1	YES	6	1	
2	NO	24	29	

TABLE IV

Requirement of rescue antiemetic was 20% in group O and 3.3% in group P, which was also statistically significant

COMPARISON OF ADVERSE REACTIONS IN BOTH STUDY GROUPS

Adverse reaction	Group ONDANSETRON(N=30)	Group PALONOSTERON(N=30)	P VALUE SIGNIFICANT/NON-SIGNIFICANT
Headache	2	2	1.000(Non-significant)
Drowsiness	0	0	
Dizziness	0	0	
Itching	0	0	
Cough	0	0	

TABLE V

2 (6.6%) patients in both groups complained of headache.This was not significant statistically.We encountered no other side effect in our study.

IV. DISCUSSION

Post operative nausea and vomiting(PONV) is one of the biggest issues faced by both surgeon and anaesthesiologist and a major cause of patient dissatisfaction post surgery.[11]It may also lead to apprehension towards future surgery and anaesthesia . Patients are more concerned to avoid PONV than the postoperative pain. [12] PONV may cause deadly consequences like dehydration[13], electrolyte disturbances,bleeding from wound,esophageal rupture .These all factors lead to delayed recovery, hospital readmission and delayed discharge from hospital .

5- hydroxytryptamine(5-HT) receptor antagonists are safe and devoid of side effects caused by antihistaminics, butryphenones ,phenothiazine derivatives,anticholinergics, and dopamine receptor antagonists. The 5-HT3 antagonists inhibit serotonin from binding to 5-HT3 receptors in the gut and the CTZ of area postrema that projects to the vomiting centre of lateral reticular formation of medulla oblongata. [14]

PONV is influenced by many factors likeobesity, prior history of PONV, menstruation, type of surgery,type of anesthesia, and postoperative pain.[15]

The incidence of PONV after tympanoplasty operations is very large.[16] The cause of this may be the complicated nerve supply in this area of middle ear by the cranial nerves V, VII, VIII and X, and cervical nerves II and III.[17,18].Also the semilunar ducts and vestibular system are in close proximity to the cranial surgical field due to which the relay of vibration at surgical field stimulates the ampulla . [19] Hence, PONVis very common in these patients.

The present study was conducted to evaluate the effects of ondansetron (4 mg IV) and palanosetron(0.075 mg IV) on PONV in tympanoplasty surgeries.

In our study, the drugs were given three minutes prior to anesthesia based on previous studies by savant [20]and Bhattacharya and Banerjee[21]

Ondansetron acts by depolarization of vagal afferent nerves via blockade of serotonin induced depolarization. It has a half-life of 3 h.[22]It is a selective 5-HT3 receptor antagonist that acts by opposing emetic signals antagonizing vomiting signals from the stomach or gut and solitary tract nucleus.[23]

One drawback of our study design was the lack of a control group receiving a placebo. Because of ethical reasons as suggested by Aspinall and Goodman since PONV is a very common occurrence.And subjecting patient to PONV symptoms

is unethical when effective treatment[25]is available. Therefore a placebo control group was not included.

Palonosetron is a second generation 5-HT3 receptor antagonist.[24]In our study, we used an intravenous dosage of 4 mg ondansetron based on previous studies by Figueredo and Canosa[26].We selected 0.075 mg intravenous dose of palonosetron as FDA has approved this dose as the minimum effective dose.[27]Kovac AL *et al* (2008)[28] compared palonosetron in dose of 0.025mg, 0.05mg and 0.075mg and found the 0.075mg dose to be statistically superior

There was no statistical difference between two groups in the demographic profile and mean duration of surgery and duration of anaesthesia($p>0.05$) ,that helped us to compare the results observed uniformly. [Table 1]

The duration of surgery and anaesthesia have an influence on PONV since long surgeries will increase the incidence of PONV,hence increasing the requirement of antiemetic. [29,30]

There were no significant haemodynamic changes in either group as seen in earlier studies .[31,32,33].

Post operative nausea was 60% in patients among group O and 26.6% in patients of group P .This was a statistically significant difference in incidence of post operative nausea($p=0.009$) .Hence palonosetron was more efficient than ondansetron in prevention of post operative nausea[Table 2]. The studies conducted by Moon Y E[34] and Nupur Chakravarty [33]showed similar results.

The overall incidence of vomiting once in 24hrs was 23.3% in group Oand 3.33% in group P. ($P=0.023$) and this difference was statistically significant. [Table 2]

The incidence of vomiting more than once in 24hrs was 20% in ondansetron group and 3.3% in palonosetron group and the result was statistically significant ($P=0.044$) . [Table 2] Our results were comparable to the study by Sarbari Swaika[31] Baisakhi Laha[32] andMoon YE[34] .

The overall incidence of vomiting in 24-48hrs was 16.6% in group Oand 6.66% in group P. ($P=0.07$) and this difference was statistically significant. [Table 2] The lesser incidence of vomiting in palanosetron group was because of the longer plasma half life of 40 hrs which increases the duration of action .[35]

Palanosetron possesses clinical, pharmacological and morphological properties which arequite different from other 5-HT $_3$ antagonists. Unlike other antagonists which directly compete with serotonin, palonosetron acts indirectly by binding allosterically to 5-HT_3 receptors [36]. Also it opposes the substance P induced response , decreases interaction with neurokinin-1 receptors by cross-talk, and prevents emesis [37]. These factors are responsible for greater receptor-affinity of palonosetron and its longer half-life .

Patients showing complete absence of PONV and needed no rescue antiemetic during 48 hrs observation period were significantly higher in group P i.e 66.6% while 36.6% in group O ($p=0.001$) [Table 3]. This may be due to longer plasma half-life of palanosetron. Our study had results which were comparable to studies done by Nupur Chakravarty[33] and Shadangi BK [38].

We used metoclopramide as a rescue antiemetic since it is postulated that in patients who experience PONV,to use a rescue antiemetic which has a different mechanism of action than the original antiemetic used for PONV.

Requirement of rescue antiemetic was 20% in group O and 3.3% in group P, which was also statistically significant ($p=0.044$) [Table 4]. This was similar to the results obtained by study by Nupur Chakravarty [33]

Both palonosetron and ondansetron may cause non serious side effects like headache, itching, drowsiness ,cough , prolongation of QTc interval and constipation.No serious adverse effects were seen in either study group. 2 (6.6%) patients in both groups complained of headache, and 1 (3.3%) patient in palanosetron group while 2 (6.6%)patients of ondansetron group complained of dizziness. This difference was not significant statistically.

Hence palonosetron 0.075 mg was found to be better than ondansetron 4 mg[39] in prevention of PONV

V. CONCLUSION

In conclusion palonosetron is a better alternative to ondansetron for prophylaxis of PONV after tympanoplasty surgery due to its lesser incidence of PONV , longer duration of antiemetic effect and minimal side effects.

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