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To Study the Comparison of Ondansetron and Granisetron with Dexamethasone as Adjuvant for Prevention of Post Operative Nausea and Vomiting in Middle Ear Surgery

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Abstract

Aims: To determine the efficacy and safety of prophylactic ondansetron and granisetron with adjuvant dexamethasone in the prevention of PONV in patients of middle ear surgery.

- To assess the requirement of doses of rescue antiemetic in the postoperative period.
- To note the side effect of both the drugs if any

Settings and Design: Prospective, randomized, single blind study.

Methods and Material: After institutional review board approval and informed written consent from patients, total 100 patients were randomly assign in two groups of each 50. Group O received intravenously inj. dexamethasone 8mg two minute before induction and inj. ondansetron 4 mg diluted in 5cc NS, half hour before extubation. Group G received intravenously inj. dexamethasone 8 mg two minute before induction and inj. granisetron 1mg diluted in 5cc NS, half hour before extubation. Premedication was given to all patients. General anesthesia was given to all the patients. At the end of surgery, trachea was extubated when patient had spontaneous breathing and follow verbal command. After extubation, all the patients were shifted to post-anesthesia recovery room [PACU] and observed for post operative nausea and vomiting for 24 hours at interval of 0–2 hours, 2–6 hours, 6–12 hours,12–18 hours and 18–24 hours. Episodes of post operative nausea and vomiting were identified by spontaneous complaints by the patients.

Statistical analysis used: Data were analysed by using unpaired t -test, Chi-square test.

Results: Both the groups were comparable with regard to demographic data and hemodynamic parameters. The incidence of mean PONV score at different time interval was high in group O compare to group G but, the p value was more than 0.05 which was statistically not significant. The requirement of rescue antiemetic was more in group O (16%) compare to group G (6%) but, the p value was more than 0.05 which was statistically not significant. Complete response in 24 hours was more in group G (82%) compare to group O (72%) but, the p value was more than 0.05 which was statistically not significant. The incidence of PONV in 24 hours was high in group O (28%) compare to group G (18%) but, the p value was more than 0.05 which was statistically not significant. Incidence of side effects were comparable in both the groups (p value >0.05). So, in our study both the groups were comparable in prevention of PONV in middle ear surgery under general anesthesia.

Conclusion: Both ondansetron and Granisetron with dexamethasone as adjuvant were equally effective and safe for prevention of post operative nausea and vomiting [PONV] in middle ear surgery. Requirement of rescue antiemetic was comparable in both the groups. Minimal side effects were observed in both the groups. So, combination of dexamethasone 8 mg with either Granisetron 1 mg or ondansetron 4 mg was equally effective and safe in prevention of post operative nausea and vomiting in middle ear surgery under general anesthesia.

Keywords: Ondansetron; Granisetron; Dexamethasone; PONV score.

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Introduction

Post operative nausea, retching and vomiting are the known postoperative complications and it occur after regional, general and local anesthesia. A chance of PONV was higher especially with middle ear surgery, laparoscopic surgery, gynecological surgery and emergency laprotomy etc. Among all, the incidence of PONV is as high as 62– 80% when no prophylactic antiemetic is given.[15]

Post operative nausea and vomiting [PONV] can cause patient discomfort, alter the attitude of the patient, electrolyte disturbance, and may lead to delay in resumption of normal activities after elective surgery, increase pain at operative site, bleeding, dehydration and aspiration pneumonia in over sedated patient, delayed wound healing. The deleterious effect of PONV are not only limited to the patient health but can also produce a negative impact on hospital resource and the patient due to delay in recovery and prolonged hospitalization.[27]

Vestibular apparatus generates impulses when body is rotated or equilibrium is disturbed or when ototoxic drugs act. These impulses reach the vomiting centre mainly relayed from the cerebellum and utilize muscarinic as well as H1 receptor and 5 HT receptor.[28] The vestibular system can stimulate PONV as a result of surgery involving the middle ear. Sudden movement of the patient's head after awakening leads to middle ear vestibular disturbance, and increased incidence of PONV which is the main cause for PONV in middle ear surgery.[29]

Though several traditional antiemetic agent viz. metoclopromide, procloperazone, droperidol, antihistaminic, phenothiazine derivatives, anticholinergic and dopamine receptor antagonist are available in anaesthesthetic armamentarium, they were used in past but today they are not in much use for the prophylaxis and therapy because of their relative ineffectiveness and higher incidence of serious side effect like sedation, dysphoria, extra pyramidal symptoms, dry mouth, restlessness and tachycardia.[27]

Newer antiemetic agent like ondansetron and granisetron, a selective competitive antagonist of 5-hydroxytryptamine-3 [5HT] receptor, are used to treat PONV but still sometime not satisfied with this drug alone so, dexamethasone, a glucocorticoid; can be used as adjunct to antiemetics. Dexamethasone used as a component of combined prophylaxis for control of PONV in patients undergoing middle ear surgery because of potentiating effects of antiemetic agent, partial analgesic effect and anti-inflammatory action at surgical site.[3]

The FDA and SAMBA guidelines recommended 1 mg as the dose of granisetron for prevention of PONV.[2] Elhakim M et al concluded that dexamethasone 8mg represented the minimal effective dose for combination with ondansetron 4mg for prophylaxis of PONV.[3] So, with this background, the present study was undertaken to compare the antiemetic effects of optimal dose of ondansetron and granisetron with adjuvant dexamethasone to prevent PONV in patient of middle ear surgery.

Material and Methods

After getting approval from Institutional Review Board (IRB(HEC) 815/2018) and informed written consent from patients, this prospective, randomized, double blind study was carried out in the Department of Anaesthesiology, Govt. Medical College and Sir. T. Hospital, Bhavnagar, Gujarat. Trial was registered under Clinical Trial Registry India (CTRI registration No.CTRI/2019/05/025854.

Total 100 patients of either gender posted for middle ear surgery under general anaesthesia were enrolled in this study according to following criteria:

Inclusion Criteria:

- informed written consent
- Age : 18–50 years
- Gender: Male/female
- ASA : I and II
- Surgery: middle ear surgery

Exclusion Criteria

- Patient refusal
- History of drug allergy.
- Patient suffering from any major medical illness like uncontrolled diabetes mellitus, hypertension.
- Patient suffering from psychotic disorder and patient on antiepileptic drugs.

100 Patient were divided into two equal group of 50 patient in each. the patient were allocated to respective group by computer generated random number sequence.

Group O:

Patient in this group was received iv inj.

dexamethasone 8mg two minute before induction and inj. ondansetron 4 mg diluted in 5cc NS, half hour before extubation.

Group G:

Patient in this group was received iv inj. dexamethasone 8 mg two minute before induction and inj granisetron 1mg diluted in 5cc NS, half hour before extubation.

After through pre anesthetic check up, following patients were included and excluded from the study.

Procedure

Written informed consent was taken in local language. After shifting the patient to the pre anaesthetic care room, 20G intravenous canula was inserted in non dominant hand; ECG, non invasive blood pressure and SpO_2 was recorded by using multipara monitor. Inj.Dns was started and patient is shifted to operation room.

Premedication was given which include Inj. Dexamethasone 8mg, Inj.Glycopyrolate .004mg/kg, Inj.Midazolam 0.02mg/kg intravenously.

Multipara monitor was attached and ECG, pulse oximeter, non invasive blood pressure and end-tidal CO_2 were recorded in given time interval. General anesthesia will be induced by using intravenous Inj. Fentanyl 1 µg/kg, Inj. Propofol 1.5–2 mg/kg and Inj. Succinyl choline 2mg/kg.

Tracheal intubation was done using appropriate size cuffed portex endotracheal tube. Anaesthesia was maintained using oxygen, nitrous oxide, intermittent positive pressure ventilation, intermittent dose of Inj.Vecuronium and inhalational sevoflurane.

Mechanical ventilation was maintained with an 8 ml/kg tidal volume and frequency was adjusted to maintain $ETCO_2$ around 40 mmHg.

Half an hour before extubation inj granisetron 1mg diluted in 5 cc or inj ondansetron 4 mg diluted in 5cc was given to the patient in group ''O'' and group ''G'' respectively.

AT the end of the surgery, sevoflurane was turned off in both the groups, and mechanical ventilation was converted to manual ventilation with 100% oxygen at 8 liter/ min.

The patient was not to be disturbed, except by continual verbal requests to open their eyes. All other stimuli were prevented.

After thorough oropharyngeal suction, anesthesia was reversed using Inj. Glycopyrolate 0.008 mg/kg and Inj. Neostigmine 0.05 mg/kg after confirming return of neuromuscular function.

Trachea was extubated when patient had spontaneous breathing and follow verbal command. After extubation, all the patients were shifted to post anaesthesia [PACU] recovery room and observed for post operative nausea and vomiting and other complications.

The incidence of postoperative nausea and vomiting were recorded within 24 hr after surgery at interval of 0–2 hours, 2–6 hours, 6–12 hours, 12–18 hours and 18–24 hours. Episodes of post operative nausea and vomiting were identified by spontaneous complaints by the patients.

Score Table:

Score table to assess post operative nausea and vomiting[3,38]

0	No Sympotoms
1	Nausea Only
2	Nausea With Retching
3	Vomiting

Complete response was defined as the absence of nausea, retching or vomiting and no need for rescue antiemetics (inj Metoclopromide) during 24 hours observation period.

Rescue antiemetic was given in the form of inj Metoclopromide 10 mg iv slowly for vomiting or persistent nausea.

Side effects

Patient were observed for side effect like this:

- Headache
- dizziness
- drowsiness
- gastritis

Statistical analysis

The data entry was done in Microsoft Excel 2010 and the data analysis was done in Graph Pad InStat. Mean and percentages were calculated and p-value was established to find a statistical difference between the variables. The significance level was set at $p<0.05$. t test and Mann-whitney test were also applied for the analysis and qualitative data was analysed using chi-square test.

Observation and Results

Both the groups were comparable with regard to demographic data and hemodynamic parameters. The incidence of mean PONV score at different time interval was high in group O compare to group G but, the p value was more than 0.05 which was statistically not significant. The requirement of rescue antiemetic was more in group O (16%) compare to group G (6%) but, the p value was more than 0.05 which was statistically not significant. Complete response in 24 hours was more in group G (82%) compare to group O (72%) but, the p value was more than 0.05 which was statistically not significant. The incidence of PONV in 24 hours was high in group O (28%) compare to group G (18%) but, the p value was more than 0.05 which was statistically not significant. Incidence of side effects were comparable in both the groups (p value >0.05). So, in our study both the groups were comparable in prevention of PONV in middle ear surgery under general anesthesia.

Table 1: Patient characteristic's.

Patients Characteristic's	Group-O Mean±Sd	Group-G Mean±Sd	P Value
Age(Years)	33.22± 11.02	34.54± 11.11	0.288
Gender(M/F)	32/18	30/20	>0.05
Weight(Kg)	55.8± 8.33	58.48± 7.18	0.096
Height	160.30± 4.26	160.28 ± 3.58	0.426

Patients characteristic's in terms of age, gender, weight and height were comparable among both the groups.(p>0.05).

Graph 1 : Patient characteristics.

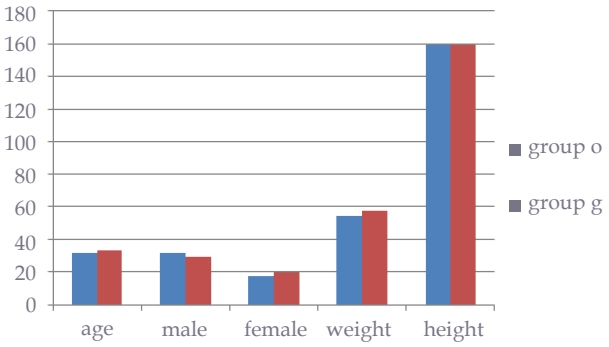
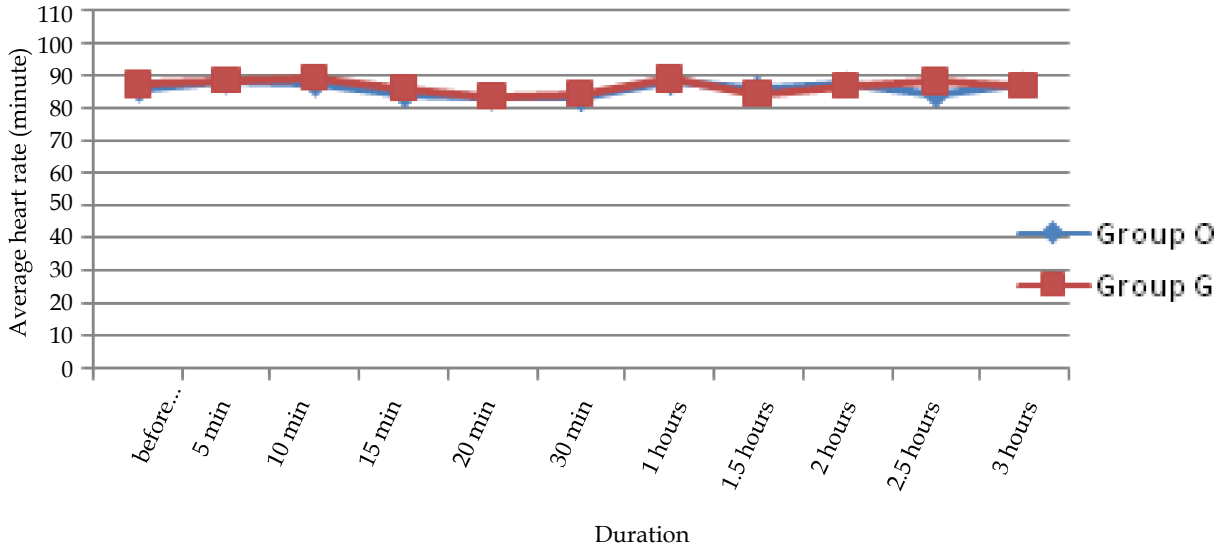


Table 2: Change in heart rate.

Time	Group O (N=50) Mean±Sd	Group G(N=50) Mean±Sd	P Value
Before Induction	86 ± 9.23	87.54 ± 50	0.724
After Induction			
5 Min	88.5± 10.02	88.64 ± 8.1	0.1409
10Min	88.1 ± 11.34	89.30 ± 9.05	0.1168
15 Min	84.82 ± 10.82	86.18± 9.63	0.4167
20 Min	83.76. ± 10.37	83.72 ± 8.56	0.1828
30 Min	83.46 ± 8.84	84.58± 8.41	0..7297
1Hours	88.28 ± 10.29	89.02± 8.92	0.3214
1.5Hours	86.46 ± 10.23	84.74 ± 9.01	0.3766
2 Hours	88.0± 10.19	87.38 ± 9.71	0.7392
2.5 Hours	84.70 ± 9.06	88.38 ± 9.10	0.9732
3 Hours	88.10 ± 8.43	86.9 ± 10.11	0.2067

Graph 2: Changes In Heart Rate.

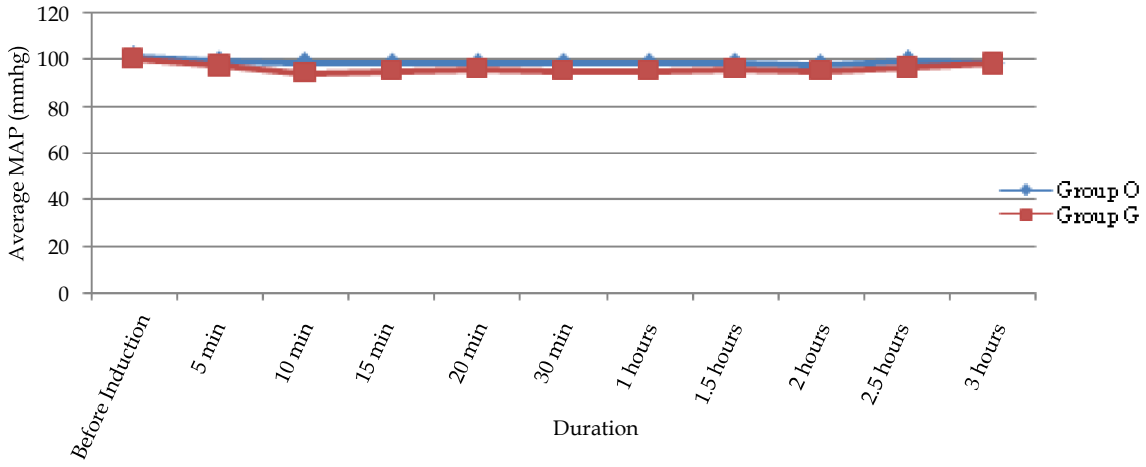


No significant difference was observed in the heart rate of two groups at different time interval (P value >0.05).

Table: 3: Comparison of Mean arterial pressure between two groups.

Time	Group O (N=50) Mean±Sd	Group G (N=50) Mean±Sd	P Value
Before Induction	100.78 ± 6.26	100.32± 7.02	0.505
After Induction			
5 Min	99.33 ± 5.09	97.33 ± 6.13	0.339
10Min	98.20 ± 5.20	94.46 ± 5.8	0.079
15 Min	98.8 ± 5.51	94.93 ± 6.68	0.101
20 Min	98.6 ± 5.07	95.74 ± 5.12	0.164
30 Min	98.73 ± 4.94	94.93 ± 7.6	0.116
1 Hour	98.86 ± 5.60	95.13 ± 7.08	0.120
1.5Hour	98.8 ± 5.11	95.73 ± 8.14	0.227
2 Hour	97.3 ± 4.7	95.2± 7.3	0.350
2.5 Hours	99 ± 5.24	96.2 ± 6.46	0.202
3 Hours	98.6 ± 5.18	96.06 ± 6.9	0.253

Graph 3: Changes In Mean Arterial Pressure.

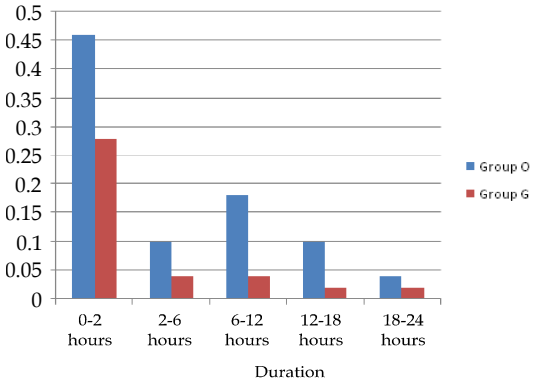


No significant difference was observed in the mean arterial pressure of two groups at different time interval (P value >0.05)

Table 4: Comparison of PONV SCORE between 2 groups.

Time after extubation	Group- O Mean±SD	Group-G Mean±SD	P value
0–2 hours	0.46 ± .90	0.28 ± 0.72	0.373
2–6 hours	0.10 ± 0.36	0.04 ± 0.19	0.713
6–12 hours	0.18 ± .56	0.04 ± 0.197	0.711
12–18 hours	0.10 ± 0.36	0 .02± 0.141	0.581
18–24 hours	0.04± 0.19	0.02± 0.141	0.857

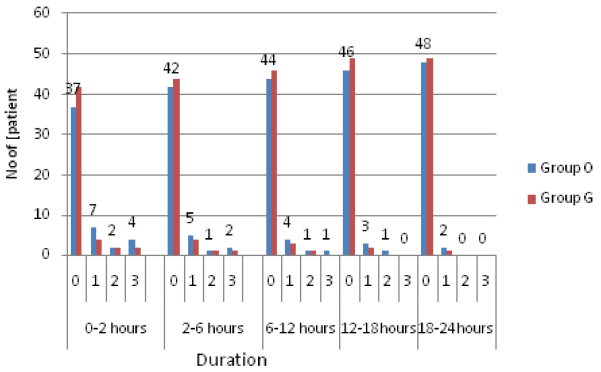
Graph 4: Comparison of PONV SCORE.



The Table 4 showed that mean PONV SCORE from 0 min to 24 hrs in study group.
PONV score was not significant in these two groups in 24 hours (p value >0.05).

Table 5: Ponv Score Wise Distribution.

Time	PONV score	Group O (N=50) No. of patient	Group G (N=50) No. of patient
0–2 hours	0	37	42
	1	7	4
	2	2	2
	3	4	2
2–6 hours	0	42	44
	1	5	4
	2	1	1
	3	2	1
6–12 hours	0	44	46
	1	4	3
	2	1	1
	3	1	0
12–18 hours	0	46	49
	1	3	2
	2	1	0
	3	0	0
18–24 hours	0	48	49
	1	2	1
	2	0	0
	3	0	0



Graph 5: PONV Score Wise Distribution.

Table 5: showed that

Complete response for 0–2 hours was 74% (37 patients) in group O and 84% (42 patients) in group G so, p value was more than 0.05 which was statistically not significant . (P value 0.3261, C.I. 0.5023–1.14).

Complete response for 2–6 hours was 84% (42 patients) in group O and 88% (44 patients) in group G so, p value was more than 0.05 which was statistically not significant. (P value 0.7732, C.I. 0.5170–1.413).

Complete response for 6–12 hours was 88 % (44 patients) in group O and 92% (46 patients) in group G so, p value was more than 0.05 which was statistically not significant. (P value 0.738, C.I. 0.4708–1.14).

Complete response for 12–18 hours was 92% (46 patients) in group O and 98% (49 patients) in group G so, p value was more than 0.05 which was statistically not significant. (P value 0.358, C.I. 0.3726–0.983).

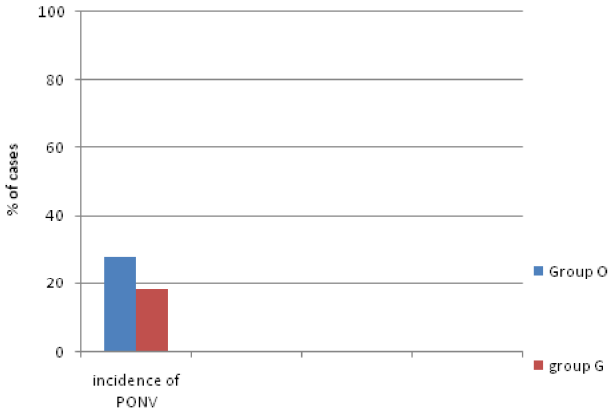
Complete response for 18–24 hours was 96% (48 patients) in group O and 98% (49 patients) in group G so, p value was more than 0.05 which was statistically not significant. (P value 0.557, C.I. 0.3252–1.694).

Complete response for 24 hours was 72% (36 patients) in group O and 82% (41 patients) in group G but, p value was more than 0.05 which was statistically not significant. (P value 0.3419, C.I. 0.5121–1.152).

Table 6: Incidence of PONV.

Incidence of PONV	Group O	Group G	P value
	28%	18%	0.341

Graph 6: Incidence of vomiting.

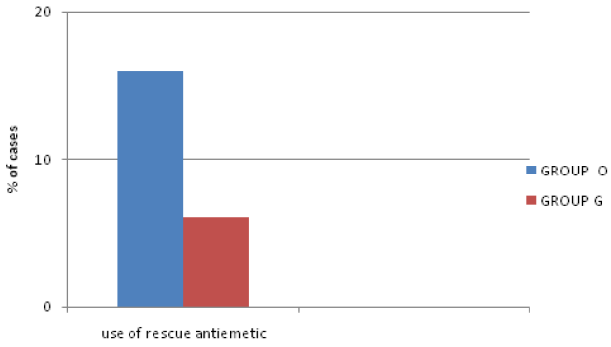


In 24 hours, overall incidence of PONV in group O was 28% (14 patients) and in group G was 18% (9 patients) but, p value was more than 0.05 which was statistically not significant.(p value–0.341, C.I..868–1.95).

Table 7: Use of rescue antiemetic.

Group O	Group G	P Value
8/50 (16%)	3/50 (6%)	0.2011 (C.I.=1.009–2.35)

Graph 7: Use of rescue antiemetic.



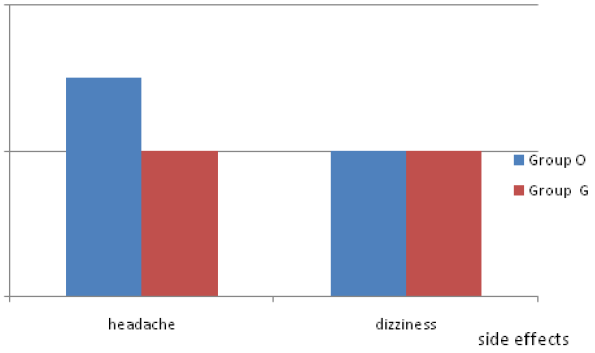
Rescue antiemetic (inj. Metoclopromide 10 mg iv slowly) was used 6% patients in group G while 16% patients in group O. Thus, incidence was higher in group O compare to group G but, the p value was more than 0.05 which was statistically not significant. (p value 0.2011, C.I–1.009–2.35).

Table 8: Comparison of Side effects.

In the present study side effects of drug like headache and dizziness were observed.

Side effects	GROUP O	GROUP G	P value
headache	6%	4%	0.738
dizziness	4%	4%	1.00

Graph 8: Comparison of Side effects.



Incidence of headache was 4% in group G and 6% in group O, but p value was more than 0.05 which was statistically not significant. (P value 0.738 with C.I. 0.709 to 2.124).

Incidence of dizziness was 4% in both the group but, p value was more than 0.05 which was statistically not significant. (P value 1.00 with C.I. 0.547 to 1.828).

Discussion

Post operative nausea and vomiting are one of the most common complications after anesthesia and surgery with a relative high incidence (60–80%) after middle ear surgery.[7] These high incidence justify the use of prophylactic antiemetic for prevention of PONV after middle ear surgery.

PONV can contribute to the development of medical problems and patients with PONV consume more resources and require additional health care professional time compared with patients in whom these complications are avoided.[1]

Several traditional antiemetic agents like antihistamines (hydroxyzine), Butyrophenones (droperidol), and dopamine receptor antagonist (metoclopromide) were used in past, but these drugs have undesirable side effects such as sedation, hypotension, dry mouth, dysphoria, restlessness and extra pyramidal symptoms.[15]

Newly introduced, the 5HT3 receptor antagonists are highly specific and selective for nausea and vomiting. Member of this group exert their effects by binding to the serotonin 5HT3 receptor in the chemoreceptor trigger zone and at vagal afferents in the gastrointestinal tracts.[11]

A potential new entry into the antiemetic pharmacopia in the year 1991 is ondansetron; of the class of selective 5 hydroxytryptamine subtype 3 (5HT3) receptor antagonists which lack effects on cholinergic adrenergic, dopaminergic or histaminergic receptors.[1]

The antiemetic property of ondansetron may be mediated peripherally, centrally or both. Ondansetron has little effect on lower esophageal sphincter pressure, esophageal or gastric motility, or small bowel transit time. By 5HT3 selectivity, the undesirable side effects of using antagonists of dopaminergic, cholinergic or histaminergic receptors as antiemetic agents, such as dysphoria, sedation and extrapyramidal symptoms, are avoided.[14]

The use of ondansetron has now become extended to the management of PONV routinely. Extensive trails using oral and intravenous ondansetron in various types of patients posted for various surgeries have confirmed the efficacy of the drug with a less side effect profile.[14]

Granisetron is recently introduced, 5-hydroxy tryptamine receptor antagonist, with stronger 5HT3 binding. It is more potent and longer acting antiemetic agent compared to ondansetron against emesis associated with chemotherapy and have been found to be very effective for preventing PONV. Granisetron has fewer incidences of side effects.[14] Granisetron is highly selective in its ability to bind the 5HT3 receptor 1000:1 to other receptor such as (5HT1A, 5HT1B, 5HT1C, 5HT1, 5HT2) or alpha 1 and alpha 2 adrenergic, dopamine D2, histamine H1, benzodiazepines, beta adrenergic and opoid receptors while the selectivity for ondansetron is only 250–400:1.[8]

Dexamethasone was first reported to be an effective agent in patient undergoing cancer[14] Granisetron is highly selective in its ability to bind the 5HT3 receptor 1000:1 to other receptor such as (5HT1A, 5HT1B, 5HT1C, 5HT1, 5HT2) or alpha 1 and alpha 2 adrenergic, dopamine D2, histamine H1, benzodiazepines, beta adrenergic, and opoid receptors, while the selectivity for ondansetron is only 250–400:1. chemotherapy in 1981.[12] Since, then randomized, placebo controlled studies have shown that the role of dexamethasone for the prevention of post operative nausea and vomiting compared to placebo shows that dexamethasone treatment, reduces early and late PONV.[13]

Combination therapy using antiemetics acting at different neuroreceptor sites is more effective than using individual component alone. This is particularly true when dexamethasone is combined with a serotonin receptor antagonist such as granisetron or ondansetron. The mechanism of antiemetic action of corticosteroid is unknown, but may be related to inhibition of prostaglandin synthesis, decrease in 5HT3 level in the cns and by an anti-inflammatory action at operative site.[9]

With regard to timing, the 5-HT3 receptor antagonists are most effective when administered

at the end of surgery where as dexamethasone seems to be most effective when given before the induction of anesthesia.[10]

The combination of dexamethasone and ondansetron was better than ondansetron alone.[8] Also, dexamethasone and granisetron was better than granisetron alone.[11]

With this background, present study was carried out in the dept. of Anaesthesiology, Government medical college & Sir T General Hospital, Bhavnagar to study the comparison of Ondansetron and Granisetron with Dexamethasone as adjuvant for prevention of post operative nausea and vomiting [PONV] in middle ear surgery.

The result of our study shows that demographic data (age, weight, sex, and height) and hemodynamic parameter (mean pulse rate, mean blood pressure) were comparable in both the groups. ($p > 0.05$).

The FDA and SAMBA guidelines recommended 1mg as the dose of granisetron for prevention of PONV.[2] Elhakim M et al concluded that dexamethasone 8 mg represented the minimal effective dose for combination with ondansetron 4 mg for prophylaxis of PONV.[3] Hence, our dose selection is justified.

During first 2 hours, after extubation, 37 patients (74%) did not developed PONV in group O while in group G, 42 patients (84 %) did not developed PONV. So, complete response for 0–2 hours was 74% in group O and 84% in group G but, p value was more than 0.05 which was statistically not significant. Mean PONV score in group O was (0.46 ± .90) and in group G was (0.28 ± 0.72), PONV score was high in group O, but p value was more than 0.05 which was statistically not significant. So, results of both the group were comparable in our study. (Table 4, 5).

Gan et al.[4] reported a similar study to ours using different dosages for abdominal hysterectomy. They also found that both combinations were equally effective in preventing PONV in the first two hours postoperatively. Thus, our result was in consonance with this study.

During 2–6 hours, after extubation, 42 patients (84%) did not developed PONV in group O while in group G, 44 patients (88%) did not developed PONV. So, complete response for 2–6 hours was 84% in group O and 88% in group G but, p value was more than 0.05 which was statistically not significant. Mean PONV score in group O was (0.10 ± 0.36) and in group G was (0.04 ± 0.19), PONV score was high in group O but, p value was more than 0.05 which was statistically not significant. (Table 4, 5)

During 6–12 hours, after extubation, 44 patients (88%) did not developed PONV in group O while in group G, 46 patients (92%) did not developed PONV. So, complete response for 6–12 hours was 88 % in group O and 92% in group G but, p value was more than 0.05 which was statistically not significant. Mean PONV score in group O was (0.18 ± .56) and in group G was (0.04 ± 0.197), PONV score was high in group O but, p value was more than 0.05 which was statistically not significant. (Table 4, 5)

Nethra H. et.[2] was also suggested that there is no statistical difference in between both groups in 12 hrs post operatively. Thus, our result was in consonance with this study.

During 12–18 hours, after extubation, 46 patients (92%) did not developed PONV in group O while in group G, 49 patients (98%) did not developed PONV. So, complete response for 12–18 hours was 92% in group O and 98% in group G but, p value was more than 0.05 which was statistically not significant. Mean PONV score in group O was (0.10 ± 0.36) and in group G was (0.02± 0.141), PONV score was high in group O but, p value was more than 0.05 which was statistically not significant. (Table 4 ,5).

During 18–24 hours, after extubation, 48 patients (96%) did not developed PONV in group O while in group G, 49 patients (98%) did not developed PONV. So, complete response for 18–24 hours was 96% in group O and 98 % in group G but, p value was more than 0.05 which was statistically not significant. Mean PONV score in group O was (0.04± 0.19) and in group G was (0.02± 0.141), PONV score was high in group O but, p value was more than 0.05 which was statistically not significant. (Table 4, 5).

Complete response was found 82% patients (41 patients) in group G and 72% patients (36 patients) in group O during 24 hours, but the p value was more than 0.05. So, it was statistically not significant. Thus, our result showed that both the groups were equally effective in prevention of PONV in middle ear surgery.

In our study during 24 hours, in group G 18% patients (9 patients) developed PONV, while 28% patients (14 patients) developed PONV in group O. So, the incidence of PONV was lesser in group G compared to group O but, the p value was more than 0.05 which was statistically not significant. (Graph 9).

Rescue antiemetic (inj. Metoclopromide 10 mg iv slowly) was used 6% patients in group G while

16% patients in group O, thus incidence was higher in group O compare to group G but, the p value was more than 0.05 which was statistically not significant. (Graph 10).

Our study showed that 6% patients complained of headache in group O and 4% in group G. So, p value was more than 0.05 which was statistically not significant. 4% patients, developed dizziness in both the groups, which was comparable in both the groups. So, side effects in both the groups were comparable. (Graph 11).

Dabbous A et al[2] also found that the combination of dexamethasone 8mg with either granisetron 1 mg or ondansetron 4 mg following induction of anesthesia in patients undergoing laparoscopic surgery showed no statistically significant difference in antiemetic efficacy with minimal side effects.[5] Thus, our result was in consonance with this study.

Similar results was also found by Nethra H. et[2] that granisetron 1 mg and ondansetron 4 mg in combination with dexamethasone 8 mg are equally effective and safe in decreasing the incidence of post operative nausea and vomiting in laparoscopic cholecystectomies under general anaesthesia. Thus, our result was in consonance with this study.

Similar study by Rakesh bendre et al.[1] showed that there was no statistically significant difference between the two combinations concerning rescue antiemetic required or side effects. It also showed that there is no statistical difference in two groups in late post operative period in terms of PONV and in early post operative period in terms of retching and vomiting. Thus, our result was in consonance with this study.

Gan et al[4] was also found similar result with both the groups during 0–2 hrs. Thus, our result was in consonance with this study.

Our study shows that administration of either combination granisetron with dexamethasone or ondansetron with dexamethasone were equally effective in prevention of PONV with minimal side effects in middle ear surgery under general anesthesia.

In our study, we observed that the incidence of PONV and requirement of rescue antiemetic drugs were higher in group O compare to group G. It was because of high receptor specificity and potency of Granisetron[26] but, the p value was more than 0.05. So, we concluded that both the groups were equally effective and safe in prevention of PONV with minimal side effects in middle ear surgery under general anesthesia.

Conclusion

We conclude the study of comparison of "Ondansetron and Granisetron with Dexamethasone as adjuvant for prevention of post operative nausea and vomiting [PONV] in middle ear surgery" as follows:

I. Both ondansetron and Granisetron with dexamethasone as adjuvant were equally effective and safe for prevention of post operative nausea and vomiting [PONV] in middle ear surgery.

II. Requirement of rescue antiemetic was comparable in both the groups.

III. Minimal side effects were observed in both the groups.

Thus, combination of dexamethasone 8 mg with either Granisetron 1 mg or ondansetron 4 mg is equally effective and safe in prevention of post operative nausea and vomiting in middle ear surgery under general anesthesia.

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