

COMPARISON OF POST-OPERATIVE NAUSEA AND VOMITING (PONV) AMONG PATIENTS UNDERGOING TYMpanoplasty UNDER LOCAL ANAESTHESIA.

Anaesthesiology

**Dr. Rahul Shrirang
Jadhav**

Associate Professor Dept. Of Anaesthesiology RCSM GMC Kolhapur.

**Dr. Ajinkya Shivaji
Kale**

Assistant Professor, Dept. Of Anaesthesiology, RCSM GMC Kolhapur.

**Dr. Swapna Shivaji
Kadam**

Assistant Professor, Dept. Of Anaesthesiology, RCSM GMC Kolhapur.

**Dr. Ananya H.
Qza***

Junior Resident, Dept. Of Anaesthesiology, RCSM GMC Kolhapur. *Corresponding Author

ABSTRACT

Background: The most important side effect of Ondansetron medicine is hypersensitivity reactions. Dexamethasone, is cheap and has no serious side effects. Dexamethasone is less widely used for control of post-operative nausea and vomiting (PONV) by anaesthetists in gastrointestinal patients, perhaps because of a lack of proven efficacy in these patients. **Aims:** To compare the PONV among patients undergoing tympanoplasty under local anaesthesia. **Methodology:** A Randomized control study was conducted in patients undergoing tympanoplasty. 60 subjects were randomly divided into two groups- Group O (n=30): received intravenous Ondansetron 4mg & Group D (n=30): received intravenous dexamethasone 8mg. Patients data was collected about age, gender, ASA, duration of anesthesia, duration of the operation, blood pressure before and after the operation, respiratory rate before and after the operation, saturation of peripheral oxygen (SPO2) before and after the operation. All instances of nausea and vomiting was recorded carefully every few hours for 24 hours until the discharge of patient from ward. Side effects were observed and registered. **Results:** The episodes of nausea highest in Group D at 0 to 2 hours, 2 to 6 hours and 6 to 24 hours; the retching and nausea was similar in both group D and group O. The Dexamethasone group has been having statistically significant higher number of nausea, retching and vomiting compared to Ondansetron group at 0 to 2 hours and 2 to 6 hours; however, it there was no statistical difference at 6 to 24 hours. The nausea severity score showed higher score in dexamethasone group, with 66.67% in Group D and 53.3% in Group O at 0 to 2 hours having severe scores of 1 to 3; 66.67% in Group D and 50% in Group O at 2 to 6 hours having severe scores of 1 to 3 & 33.3% in Group D and 23.3% in Group O at 6 to 24 hours having severe scores from 1 to 3. However, these were not statistically significant. The need for antiemetic rescue showed that group D needed more rescue than group O at 0 to 2 hours, however, at 2 to 6 hours Group O had few more rescues needed than Group D. At 6 to 24 hours there were no need for any rescue in Group O compared to 3 in group D. These differences were not statistically significant in both groups. In total Group O had 11 rescue injection (36.7%) and Group D had 18 rescue injection (60%). **Conclusion:** Ondansetron was better in preventing PONV than Dexamethasone in the early stages post-surgery, however, it was similar when seen in the up to 24 hours post-surgery.

KEYWORDS

Dexamethasone; Ondansetron; Post-operative nausea and vomiting

INTRODUCTION

Postoperative nausea and vomiting (PONV) is a common complication after surgery which might result in patient discomfort, electrolyte imbalance, wound dehiscence and pulmonary aspiration.¹ Incidence of PONV was reported between 30-80% depending on the type of surgery and associated risk factors.^{3,4} The incidence of PONV in middle ear surgeries ranges from 60% to 80%, in the absence of any antiemetic treatment.^{5,6} Based on Apfel simplified scoring system, PONV prophylaxis is administered to patients with medium and high risks. Combination of drugs from different classes with different mechanism of action are administered for optimized efficacy in adults with moderate risk for PONV. Multimodal approach with combination of pharmacological and nonpharmacological prophylaxis along with interventions that reduce baseline risk is employed in patients with high PONV risk.¹⁰

The recently introduced 5- hydroxytryptamine receptor antagonists (5HT3RA) have no such adverse effects and are more effective in the preventing PONV. Ondansetron is the oldest 5HT3RA with a half-life period of 3 to 5 hours which is very short. Dexamethasone has been used as an antiemetic for patients receiving chemotherapy with limited adverse effects. It is the first medicine introduced in this group. Ondansetron is a serotonin 5-HT3 receptor antagonist used mainly as an antiemetic following chemotherapy. However, it is expensive and has some dangerous side effects such as headaches and high blood pressure that can lead to serious complications, especially in susceptible and hypertensive patients.¹⁵ The most important side effect of this medicine is hypersensitivity reactions. Other side effects include headaches, light headedness, dizziness, obstruction of the intravenous line, temporary increase in liver transaminase levels, feeling of heat in the epigastrium, and constipation.¹⁶

Dexamethasone, which is used frequently in the patients undergoing ear, throat and nose surgical operations, is cheap and has no serious

side effects.¹⁰ It is extensively used in all types of surgery to reduce PONV.¹⁷ In practice, dexamethasone is less widely used for control of PONV by anaesthetists in gastrointestinal patients, perhaps because of a lack of proven efficacy in these patients. However, its use is advocated in some enhanced recovery programs (ERAS) to improve recovery after colorectal surgery.¹⁵

Concerning the high incidence of PONV after middle ear surgery, and as there are very few previous studies to assess and compare the preventive effect of ondansetron and dexamethasone on PONV, present study aimed to compare the efficiency of ondansetron versus dexamethasone in prevention of post tympanoplasty nausea and vomiting. The present study is aimed to assess the occurrence of PONV and compare the efficacy of intravenous ondansetron and dexamethasone as prophylactic antiemetics.

MATERIALS AND METHODS:

The present Randomized control study was conducted between Jan 2024 to May 2024 at Department of Anesthesiology, Rajarshree Chhatrapati Shahu Maharaj Medical College and CPR Hospital. 60 patients of both sexes undergoing tympanoplasty in our hospital were randomly divided in to two groups, **Group O (n=30):** received intravenous Ondansetron 0.08 to 0.1 mg/kg and **Group D (n=30):** received intravenous Dexamethasone 0.1 to 0.2 mg/kg.

Patients aged 18 to 60 years, both sexes, ASA grade I and II, undergoing tympanoplasty surgery under local anesthesia were included for study. Patients with history of nausea or vomiting in last 24 hours, gastro-esophageal reflux disorder, taking antiemetic drug in previous 24 hours, undergoing concomitant mastoid surgery and pregnant patients were excluded.

After approval of institutional ethical committee 60 patients undergoing tympanoplasty under local anaesthesia was assigned to

one of two prophylactic treatment groups (to receive ondansetron or dexamethasone) according to random number table as mentioned above. A written consent was obtained from all the patients. Standard pre-operative, intra-operative and post-operative protocols were followed. Using a pre-formed questionnaire, patients data was collected about age, gender, ASA, duration of anesthesia, duration of the operation, blood pressure before and after the operation, respiratory rate before and after the operation, saturation of peripheral oxygen (SPO₂) before and after the operation. All instances of nausea and vomiting was recorded carefully every few hours for 24 hours. Side effect like headache, dizziness, dry mouth, restlessness palpitation was observed and registered.

The necessary post-operative details about presence and the intensity of nausea or vomiting was taken. Episodes of PONV was noted at 0-2, 2-8 and 16-24 hours after the operation. At the end of each interval the investigator will register for any incidence of nausea or retching or vomiting. The result was scored as per the Bellville scoring scale (lack of nausea and vomiting=0, nausea=1, nausea with belching=2, and vomiting=3). Patient who experiences any episode of nausea, retching and vomiting was managed by inj. Metoclopramide 10mg IV/slow as rescue treatment.

All the data was noted down in a pre-designed study proforma. Qualitative data was represented as percentage. Association between qualitative variables was assessed by Chi-Square test. Quantitative data was represented using Mean $\pm$ SD and Median & IQR (Interquartile range). Analysis of Quantitative data between the two groups was done using unpaired t-test. A p-value < 0.05 was taken as level of significance. Results was graphically represented where deemed necessary. SPSS Version 26.0 was used for most analysis and Microsoft Excel 2010 for graphical representation.

RESULTS:

In our study there were two groups who were randomly assigned to the Ondansetron group (Group O) and Dexamethasone groups (Group D). In both the groups there were 30 patients each included randomly. Total 60 patients were present in the study. The local anaesthetic used was 2% lignocaine and Adrenaline. The antiemetic used were Injection Dexamethasone 0.1 to 0.2 mg/kg in half of the participants (30 nos.) and Injection Ondansetron 0.08 to 0.1 mg/kg in the other half (30 nos.).

Table 1. Age And Gender Wise Distribution Among The Two Groups:

Age and Gender		Group O	Group D
Age groups (years)	< 20	1 (3.3%)	4 (13.3%)
	21 to 30	9 (30.0%)	7 (23.3%)
	31 to 40	10 (33.3%)	12 (40.0%)
	41 to 50	5 (16.7%)	3 (10.0%)
	51 to 60	5 (16.7%)	4 (13.3%)
Gender	Male	14 (46.7%)	11 (36.7%)
	Female	16 (53.3%)	19 (63.3%)
Total		30 (100%)	30 (100%)

The mean age of the study population is 35.58 ± 12.1 years, in that Group O were having higher mean age of 37.23 ± 11.9 years when compared to 33.93 ± 12.3 years for Group D. The majority of the patients in the both groups were between the age 41 to 50 years, with 33.3% and 40% in Group O and Group D respectively. The lowest were in the age group 21 to 30 years.

Gender distribution showed that females were higher in both groups, with 53.3% and 63.3% in Group O and Group D respectively. Males in both groups were lower than females with 46.7% and 36.7% % in Group O and Group D respectively.

Table 2: Diagnosis Of The Patients From Two Groups:

Diagnosis	Group O	Group D
Bilateral CSOM	4 (13.3%)	5 (16.7%)
Left CSOM	12 (40.0%)	12 (40.0%)
Left inactive mucosal CSOM	5 (16.7%)	0 (0%)
Right CSOM	6 (20.0%)	7 (23.3%)
Right inactive mucosal CSOM	2 (6.7%)	2 (6.7%)
Right mucosal CSOM	1 (3.3%)	0 (0%)
Bilateral inactive CSOM	0 (0%)	1 (3.3%)
Left inactive CSOM	0 (0%)	1 (3.3%)
Left mucosal CSOM	0 (0%)	2 (6.7%)

The left CSOM are the most common diagnosis in both groups, followed by Right CSOM as the next commonest cause.

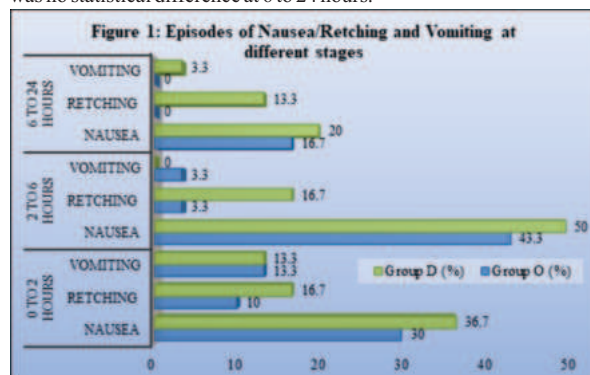
Table 3: Haemodynamic Parameters Among The Two Groups Before And After Procedure:

Haemodynamic parameters		Group O (Mean $\pm$ S.D.)	Group D (Mean $\pm$ S.D.)
Before procedure	Heart rate (beats/min)	79.37 $\pm$ 9.77	78.47 $\pm$ 11.37
	SBP (mm of Hg)	125.60 $\pm$ 10.08	127.47 $\pm$ 8.96
	DBP (mm of Hg)	83.40 $\pm$ 8.07	83.00 $\pm$ 6.72
	SPO ₂ (%)	98.70 $\pm$ 0.47	98.50 $\pm$ 0.509
After procedure	Heart rate (beats/min)	78.77 $\pm$ 7.40	78.57 $\pm$ 11.35
	SBP (mm of Hg)	125.93 $\pm$ 8.97	126.00 $\pm$ 7.74
	DBP (mm of Hg)	84.60 $\pm$ 5.99	83.87 $\pm$ 5.99
	SPO ₂ (%)	98.67 $\pm$ 0.48	98.50 $\pm$ 0.51

The haemodynamic parameters among the two groups before and after the procedure was with their physiological limit.

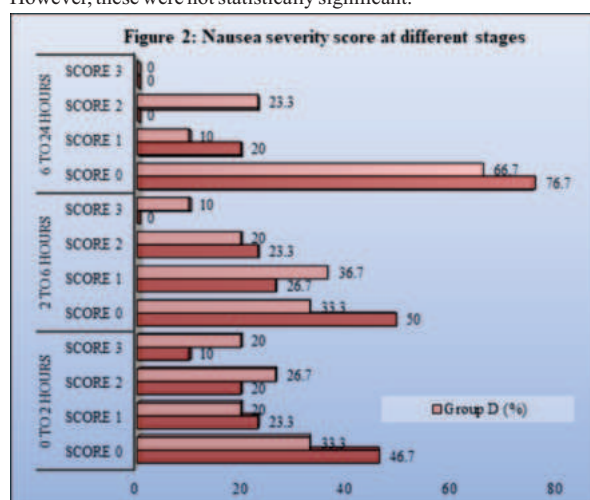
Episodes of Nausea/Retching And Vomiting At Different Stages:

The episodes of nausea highest in Group D at 0 to 2 hours, 2 to 6 hours and 6 to 24 hours; the retching and nausea was similar in both group D and group O. The Dexamethasone group had statistically significant higher number of nausea, retching and vomiting compared to Ondansetron group at 0 to 2 hours and 2 to 6 hours; however, it there was no statistical difference at 6 to 24 hours.



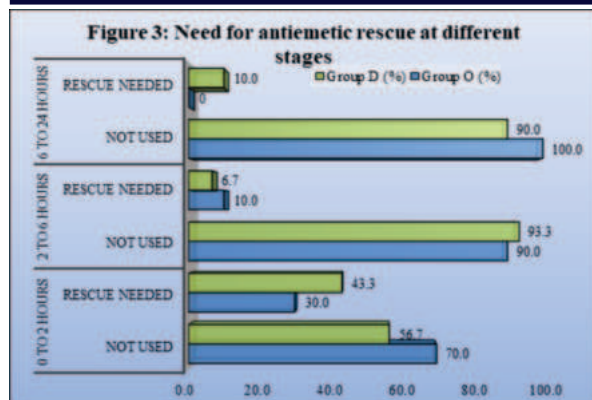
Nausea Severity Score At Different Stages

The nausea severity score showed higher score in dexamethasone group, with 66.67% in Group D and 53.3% in Group O at 0 to 2 hours having severe scores of 1 to 3; 66.67% in Group D and 50% in Group O at 2 to 6 hours having severe scores of 1 to 3 & 33.3% in Group D and 23.3% in Group O at 6 to 24 hours having severe scores from 1 to 3. However, these were not statistically significant.



Need For Antiemetic Rescue At Different Stages:

The need for antiemetic rescue showed that group D needed more rescue than group O at 0 to 2 hours, however, at 2 to 6 hours Group O had few more rescues needed than Group D. At 6 to 24 hours there were no need for any rescue in Group O compared to 3 in group D. These differences were not statistically significant in both groups. In total Group O had 11 rescue injection (36.7%) and Group D had 18 rescue injection (60%).



DISCUSSION:

In this study there were two groups who were randomly assigned to the Ondansetron group (Group O) and Dexamethasone groups (Group D). In both the groups there were 30 patients each included randomly. Total 60 patients were present in the study. The local anesthetic used was 2% lignocaine + Adrenaline. The antiemetic used were Injection Dexamethasone 0.1 to 0.2 mg/kg in half of the participants (30 nos.) and Injection Ondansetron 0.08 to 0.1 mg/kg in the other half (30 nos.). Postoperative nausea and vomiting is a common complication after tympanoplasty and may be even more distressing than postoperative pain. In our study the episodes of nausea & vomiting were highest in Dexamethasone group at 0 to 2 hours, 2 to 6 hours and 6 to 24 hours, when compared to Ondansetron group which had low episodes of nausea and retching, which was statistically significant; with 56.7% having nausea and vomiting in Ondansetron group and 63.3% in Dexamethasone group (p value <0.001). The nausea severity score showed higher score in dexamethasone group, however, these were not statistically significant. In the reviewed study by Anisha Puri et.al.⁵¹ They showed that the post-operative nausea was 60% in patients among Ondansetron and 26.6% in patients of palonosetron. 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 Ondansetron and 3.33% in palonosetron. 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). Hence palonosetron is a better and longer acting anti emetic than ondansetron. Mahmoud Eidi Khosro Kolahdouzan et al¹⁵ showed that there was no significant difference among PONV in the three groups in the first two hours after the surgery. However, in 2-8, 8-16 and 16-24 hours after the surgery the PONV in ondansetron and dexamethasone groups were significantly lower than that in the control group. The study showed that Ondansetron and dexamethasone were more effective than placebo in controlling PONV after tympanoplasty surgeries. Moreover, dexamethasone was more effective than ondansetron in preventing PONV. Sindhuri Kolluru ,et.al⁵² observed that ondansetron is as effective as dexamethasone in controlling postoperative nausea and vomiting. Ondansetron is as effective as dexamethasone in preventing PONV in laparoscopic cholecystectomy. Both ondansetron and dexamethasone have minimal side effects. and Use of rescue antiemetic is same with ondansetron as well as dexamethasone.

Sandhya M S et al.⁵⁶ showed that all there is no statistically significant difference between Ondansetron and Dexamethasone in preventing postoperative nausea and vomiting either in the early or late postoperative period. But clinically significant difference was noted between these two groups .ie, when 83.3% had no nausea and vomiting in the Dexamethasone group 93.3% had no nausea and vomiting in Ondansetron group. But in the late postoperative period, Dexamethasone had a better effect, ie, while 86.7% had no vomiting in Ondansetron group, 93.3% were free of vomiting episodes in Dexamethasone group. Patient satisfaction score was also comparable. This study concluded that in the prevention of postoperative nausea and vomiting, Ondansetron is clinically better than Dexamethasone in early postoperative period. Dexamethasone is more effective in late postoperative period. Maitra S et al.⁵⁴ Study was a meta-analysis of randomized trials that compared ondansetron and dexamethasone for PONV prophylaxis after laparoscopic surgeries. Data of 592 patients from 7 RCTs have been included in this meta-analysis. Incidence of postoperative nausea at 4–6 h is significantly lower when dexamethasone was used instead of ondansetron (p=0.04; OR 0.49,

95% CI 0.24–0.98, M-H fixed). Incidence of nausea is similar at 24 hours (p=0.08, OR 0.71, 95% CI 0.48, 1.05; M-H fixed); vomiting is also similar at 4–6 h (p=0.43, OR 1.27, 95% CI 0.70–2.27; M-H fixed) and also at 24 h (p=0.46, OR 0.92, 95% CI 0.73, 1.16; M-H fixed). Study concluded that Dexamethasone is superior to ondansetron in preventing postoperative nausea after 4–6 h of laparoscopic surgeries. Suman Chattopadhyay et.al.⁵⁵ showed a complete response was achieved in 62% of the patients receiving Ondansetron, 64.7% of the patient receiving Dexamethasone and in 84.6% of patients receiving Ondansetron plus Dexamethasone (P<0.05). No difference in adverse events was observed in between group. This study concluded that combination of Ondansetron plus Dexamethasone is better than each drug alone as an antiemetic prophylaxis against PONV following laparoscopic cholecystectomy.

In our study the need for antiemetic rescue showed that group D needed more rescue than group O at 0 to 2 hours, however, at 2 to 6 hours Group O needed few more rescues than Group D. At 6 to 24 hours there were no need for any rescue in Group O compared to 3 in group D. These differences were not statistically significant in both groups. In total Group O had 11 rescue injection (36.7%) and Group D had 18 rescue injection (60%). Similarly, the study by Anisha Puri et.al.⁵¹ 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. This study concluded that the Incidence of PONV is less in patients who received IV Palonosetron in comparison with those who had received IV Ondansetron in patients of tympanoplasty. Jash D et al.⁵³ showed the need for rescue drug (Inj. metoclopramide 10 mg I.V.) was similar in both groups. Study concluded that Ondansetron is as effective as Dexamethasone in reducing the incidence of nausea and vomiting in post-operative period of laparoscopic cholecystectomy and has minimal side effects.

In our study the nausea severity score showed higher score in dexamethasone group, with 66.67% in Group D and 53.3% in Group O at 0 to 2 hours having severe scores of 1 to 3; 66.67% in Group D and 50% in Group O at 2 to 6 hours having severe scores of 1 to 3 & 33.3% in Group D and 23.3% in Group O at 6 to 24 hours having severe scores from 1 to 3. However, these were not statistically significant. Similarly, Jash D et al.⁵³ showed that the incidence of nausea is higher in Ondansetron and Dexamethasone in the first hour though it is not statistically significant. Within 3-6 hours, patients receiving Dexamethasone had higher incidence of nausea, but it is not statistically significant. Incidence of retching is higher in both groups in the first hour. It is not statistically significant. Vomiting was more in the first 3 hours in both groups. It was not statistically significant.

Incidence of PONV after laparoscopic cholecystectomy may be as high as 63% when no antiemetic prophylaxis is used.⁵⁷ Dexamethasone and ondansetron are the two most commonly used drugs in clinical practice for PONV prophylaxis. Individual clinical studies have found that dexamethasone is an effective antiemetic prophylaxis at a dose of 5–8 mg and recommended dose of ondansetron is 4 mg for prophylaxis.⁵⁸ Alghanem et al.⁵⁹ reported that ondansetron is less effective in preventing nausea in the 0–4 h period after surgery. However, their result did not reach statistical significance probably because of small sample size. On the contrary Gautam et al.,⁶⁰ found that dexamethasone is less effective in preventing early vomiting. However, we have not found such finding in our analysis. Longer onset of action of dexamethasone may result in relative less effectiveness in preventing early PONV. Subramaniam et al.⁶¹ found that ondansetron is more effective in preventing early PONV and dexamethasone is more effective in preventing late PONV after strabismus surgery. Use of single dose dexamethasone is free from significant side effects including delayed wound healing.⁶² Moreover, it may decrease postoperative pain after laparoscopic cholecystectomy.⁶³ Use of PONV prophylaxis is routine in clinical practice due to high incidence of PONV in patients who did not receive any prophylaxis.

Some of the reviewed studies showed that dexamethasone is better than Ondansetron in preventing PONV, however, there are also contrary studies which showed that Ondansetron was better than dexamethasone in some studies. There were in fact studies showed a mixed picture were both were equally effective and both were equally non-effective. In our study it showed Ondansetron was better in preventing PONV than Dexamethasone in the early stages post-surgery, however, it was similar when seen in the up to 24 hours post-surgery.

CONCLUSION:

The nausea severity score shows higher score in dexamethasone group at but not statistically significant. Group D needs more rescue than group O at 0 to 2 hours, however, at 2 to 6 hours Group O needs few more rescues than Group D. At 6 to 24 hours there are no need for any rescue in Group O compared to 3 in group D. These differences are not statistically significant. Ondansetron is better in preventing PONV than Dexamethasone in the early stages post-surgery, however, it was similar when seen in the up to 24 hours post-surgery.

REFERENCES: