

A study of ondansetron alone and ondansetron plus dexamethasone for prevention of nausea and vomiting after post-tympanoplasty under local anesthesia

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Abstract

Introduction: Nausea and vomiting are common complications of anesthesia and surgery. Patients undergoing tympanoplasty are exposed to a higher risk of postoperative nausea vomiting (PONV). These complications may alter the results of reconstruction and anatomical alignments. Numerous antiemetics have been studied to prevent and treat PONV in patients undergoing tympanoplasty. The aim of this study was to compare the effect of intravenous ondansetron and ondansetron with dexamethasone on post-tympanoplasty PONV. **Methods:** In a double-blind randomized controlled clinical trial, 300 patients were divided into two groups including one receiving ondansetron, one receiving ondansetron plus dexamethasone. All patients were subjected to tympanoplasty. The patients in the first group received ondansetron (4 mg IV), second group received ondansetron (4mg) with dexamethasone (8 mg) prior to infiltration of local anesthesia. Using Belliville's scoring system, the incidence of PONV and its severity during the 24-hour period after surgery were measured and compared. **Results:** There was no significant difference among PONV in the two 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 with dexamethasone groups were significantly lower than ondansetron group. **Conclusion:** Ondansetron with dexamethasone were more effective than ondansetron in controlling PONV after tympanoplasty surgeries. Moreover, ondansetron with dexamethasone was more effective than ondansetron in preventing PONV.

Keywords: Postoperative, Ondansetron, Dexamethasone, vomiting, tympanoplasty.

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INTRODUCTION

Postoperative nausea and vomiting (PONV) is defined as nausea and vomiting occurring within 24 hours after tympanoplasty. It is one of the most frequently occurring side effects affecting one third of cases (24-30%). Nowadays it is a major concern for the patients and

physicians in the postoperative period. It results in patient dissatisfaction, delayed discharge from hospital, unexpected hospitalization, and administration of various treatment modalities.¹ Ondansetron is a serotonin 5-HT₃ receptor antagonist used mainly as an antiemetic following chemotherapy. Its effects are thought to be on both peripheral and central nerves. Ondansetron reduces the activity of the vagus nerve, which deactivates the vomiting center in the medulla oblongata, and blocks serotonin receptors in the chemoreceptor trigger zone. Dexamethasone, which is used frequently in the patients undergoing ear, throat and nose surgical operations, is cheap and has no serious side effects. Persistent vomiting is costly in terms of both financial burden and potential medical sequel. It seems that PONV has multiple causes and is influenced by a number of factors including anesthetics, surgery and individual risk factors like

smoking, anxiety and age. After the age of 50 years, the incidence of PONV decreases to about 13% in every 10 years.² Recently dexamethasone has been found to have a prophylactic effect on postoperative nausea and vomiting in adults undergoing middle ear surgery. Ondansetron is a carbazole derivative that is structurally related to serotonin and possesses specific 5 HT3 subtype receptor antagonist properties, without altering dopamine, histamine, adrenergic or cholinergic receptor activity. There are numerous studies on the efficiency of ondansetron for prevention of PONV.³ The antiemetic effects of glucocorticoids (dexamethasone and methylprednisolone) are known; however, their mechanism is not fully understood. Although dexamethasone has been traditionally useful in preventing and treating nausea in the patients undergoing chemotherapy, it is widely used in preventing PONV. It has been shown that given intravenously one dose (8-10 mg) of this drug is effective in preventing PONV. It has been recommended that the use dexamethasone as a prophylactic agent against PONV should be combined with other drugs.⁴ Postoperative nausea and vomiting, however, remains a significant problem and the issue of the best prevention or treatment method is still under consideration. This problem prompted us to compare the efficacy of ondansetron and ondansetron with dexamethasone in the prevention of post-tympanoplasty nausea and vomiting. This study aimed at comparing the incidence and frequency of PONV and the need of additional rescue antiemetic in ondansetron group and ondansetron plus dexamethasone group in early and late postoperative period.

MATERIALS AND METHODS

After obtaining approval from the institutional review board and informed consent of subjects, the study was prospectively carried out in 80 patients, ASA (American Society of Anesthesiologists) physical status I or II aged between 20 to 60 years, who underwent local anesthesia for tympanoplasty. Patients with gastrointestinal disease, a history of motion sickness, or a previous episode of PONV, and those who had received any opioid, steroid, or antiemetic medication within 24 h before surgery, and those who were pregnant or menstruating were excluded. The study is a double-blind randomized controlled clinical trial performed at Bharati Vidyapeeth medical college and hospital Sangli over a period of one year. Eighty patients divided into two groups. Each group contains 40 patients.

Group I: Received Inj ondansetron 4mg iv

Group II: Received Inj ondansetron 4mg iv with inj dexamethasone 8 mg iv

Surgeon administered LA using 2% Lignocaine with adrenaline (1:2, 00,000).Using a questionnaire, all instances of nausea and vomiting were recorded carefully every few hours for 24 hours until the patient was discharged to the ward. The intensity of vomiting was evaluated through the Bellville scoring scale (lack of nausea and vomiting=0, nausea=1, nausea with belching=2, and vomiting=3). Data were collected on the type of the surgical operation, age, ASA, duration of the operation, blood pressure before and after the operation, pulse rats before the operation, saturation of peripheral oxygen (SPO₂) before the operation, duration of recovery, presence and the intensity of nausea or vomiting at 0-2, 2-8, 16-24 hours after the operation. Data, presented as Mean±SD or frequency and percentage, were analyzed using.

RESULTS

Table 1: Baseline patient characteristic

	Group O(n=40)	Group O+D(n=40)
Age in year	37+/-17	38+/-12
Weight in kg	55+/-4	58+/-7
Height in cm	167+/-5	162+/-7
Baseline mean arterial blood pressure in (mmhg)	84+/-7	88+/-4
Baseline heart rate(min)	78+/-6	80+/-5
Spo ₂ at room air	99+/-1	98+/-2

Values are expressed as mean +- SD, number or number (%) of patients

Table 2: Comparison of emetic symptoms that occurred during intraoperative period (duration of surgery>30min)

	Group O (n=40)	Group O+D (n=40)
No symptoms	38(95%)	39(97.5%)
Incidence of nausea	1(2.5%)	1(2.5%)
Incidence of retching	1(2.5%)	0
Incidence of vomiting	0	0

Values are expressed as number or number (%) of patients

Table 3: There was no significant difference among PONV in the two groups in the first two hours after the surgery

Group	0-2 hr after operation	2-8 hours after operation	8-16 hours after operation	16-24 hours after operation
O (n=40)	2(5%)	2(5.26%)	2(5.55%)	3(5.44%)
O+D (n=40)	1(2.5%)	-	1(2.56%)	1(2.63%)

The number and percentage of nausea and vomiting at various postoperative intervals in groups receiving ondansetron (group O), Ondansetron with

dexamethasone (group O+D) However, in 2-8, 8-16 and 16-24 hours after the surgery the PONV were significantly lower in group O+D than that in the O group. Moreover, PONV at 8-16 and 16-24 hours after the surgery was significantly lower in O+D group compared to that of O group. Shows the intensity of nausea and vomiting according to Bellville scoring scale. During 0-2 hours after the operation there were only few cases of nausea, which were not significantly different among both groups. During 2-8 and 8-16 hours post operation, there were cases of nausea and nausea with belching, but no vomiting. The incidence of nausea and nausea with belching was significantly higher in group O than group O+D. During 16-24 hours nausea, but nausea with belching or vomiting, occurred in all groups. The incidence of nausea was significantly lower in O group than O+D groups. Intensity of nausea and vomiting according to Bellville scoring scale (lack of nausea and vomiting=0, nausea=1, nausea with belching=2, and vomiting=3) at various postoperative intervals in groups receiving ondanesetron (group O), ondanesetron with dexamethasone (group O+D).

Table 4

	Group O	Group O+D
0-2 hr after the operation		
Lack of nausea and vomiting (0)	38(95%)	39(97.5%)
Nausea (1)	1(2.5%)	1(2.5%)
Nausea with bleching (2)	1(2.5%)	0
Vomiting (3)	0	0
2-8 hr after operation		
Lack of nausea and vomiting (0)	38	39
Nausea (1)	1(3.33%)	-
Nausea with bleching (2)	-	-
Vomiting (3)	1(3.33%)	-
8-16 hours After the operation		
Lack of nausea and vomiting (0)	36	39
Nausea (1)	-	-
Nausea with bleching (2)	1(2.77%)	1(2.56%)
Vomiting (3)	2(5.55%)	-
16-24 hours After the operation		
Lack of nausea and vomiting (0)	33	38
Nausea (1)	-	-
Nausea with bleching (2)	1(3.03%)	-
Vomiting (3)	2(6.06%)	1(2.63%)

DISCUSSION

In the present study, the effects of administration of ondanesetron (4mg IV) and ondanesetron (4mg IV) plus dexamethasone (8mg IV) given before injected local infiltration in tympanoplasty and was evaluated postoperative nausea and vomiting in tympanoplasty under local anaesthesia. The incidence rate of postoperative nausea and vomiting after tympanoplasty surgical operation has been reported to be significant.⁵

surgery is associated with a high risk for PONV, because the operation may stimulate the vestibular labyrinth, which is innervated by the vestibular portion of cranial nerve VIII (vestibular-cochlear), which in turn activates the chemoreceptor trigger zone (CTZ) in the area postrema. Stimulation of the parasympathetic nerves of pinna during surgical manipulations may induce PONV.^{6,7} The etiology of PONV after middle-ear surgery is complex and depends on several factors, which include patient characteristics, type of surgery, anesthetic drug and technique and postoperative pain.^{8,9} Moreover, proximity of cranial surgical field to the semilunar ducts and vestibular system, and heat and vibration transmission at excision of the surgical field through stimulation of the ampulla can lead to postoperative nausea, dizziness, and vomiting. Therefore, post-operative nausea and vomiting are more common and these patients in these patients.¹⁰ Results of our study with regards to incidence of nausea and its score are similar to other studies.^{11,12,13} These studies also found that the nausea score was significantly less in patients receiving combination of ondanesetron plus dexamethasone than in patients receiving ondanesetron alone as an antiemetic drugs.¹⁴ Previous studies have shown that compared to distilled water, intravenous dexamethasone significantly reduced the rate and intensity of the PONV.^{15,16} Lopez-Olaondo *et al.* reported that dexamethasone was as effective as ondanesetron in reducing nausea and vomiting induced by chemotherapy.¹⁷ The present study showed that ondanesetron plus dexamethasone was more effective than ondanesetron alone in preventing PONV; therefore, it may be more suitable to be administered in such a situation. The present study showed that neither dexamethasone nor ondanesetron was associated with no significant side effects. The safety of these drugs has already been confirmed.^{18,19} Although ondanesetron plus dexamethasone was more effective than ondanesetron alone in reducing PONV.

CONCLUSION

ondanesetron with combination of dexamethasone has better prophylactic antiemetic effect than ondanesetron alone to prevent PONV after tympanoplasty surgery under local anesthesia. It suggests that dexamethasone may be used as component of combine prophylaxis for a control of PONV in patient undergoing tympanoplasty under local anesthesia.

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