e-ISSN: 0975-1556, p-ISSN:2820-2643

Available online on www.ijpcr.com

International Journal of Pharmaceutical and Clinical Research 2024; 16(1); 1810-1814

Original Research Article

Comparison between Emset and EMSET+Dexamethasone Preop. for Prevention of Nausea and Vomiting in ENT Surgeries

K.S. Bhatia[1], Babita[2], Chashamjot Kaur Bawa[3], Pankaj Bansal[4]

[1]Associate Professor, Department of Anaesthesiology, Mullana Medical College, Ambala, Haryana, India.
[2]Associate Professor, Department of Anaesthesiology, Mullana Medical College, Ambala, Haryana, India.
[3]Assistant Professor, Department of Anaesthesiology, Mullana Medical College, Ambala, Haryana, India.
[4]Resident, Department of Anaesthesiology, Mullana Medical College, Ambala, Haryana, India.

Received: 25-11-2023 / Revised: 23-12-2023 / Accepted: 18-01-2024
Corresponding Author: Dr. Chashamjot Kaur Bawa
Conflict of interest: Nil

Abstract:

Background: Postoperative nausea and vomiting (PONV), a typical side effect of ENT operations, can unexpectedly postpone hospital discharge. The present study was done to compare the effectiveness of ondansetron and combination of ondansetron and dexamethasone in preventing nausea and vomiting during ENT surgeries because of this issue.

Methods: The present randomised, prospective, comparative study was done in the Anaesthesia Department of MMIMSR, Mullana on 60 Adult patients posted for routine surgery and planned for general anaesthesia during the period of the study. Group 1 received Ondasetrone4mg and group 2 received Ondasetrone and Dexamethasone. The outcomes were analyzed using SPSS version 25.0

Results: The mean age of patients in both groups was between 30 to 40 years. Male patients were higher in number as compared to females. With increase in postoperative hours first the episodes of PONV increased in both groups and later on after passage of 24 hours the episodes of PONV decreased. There was less number of episode in group 2 as compared to group 1. There was no significant difference in the degree of post-operative pain, total consumption of PCA fentanyl, and rescue analgesic used within 24 h after surgery. Side effects seen were headache, drowsiness, dizziness, heartburn and diarrhea.

Conclusion: When preventing post-operative nausea and vomiting in patients following ENT surgery, a combination of ondanserton and dexamethasone is more effective than ondansetron used alone.

Keywords - Dexamethasone, ENT Surgery, Ondansetron, Postoperative Nausea Vomiting.

Introduction

Postoperative nausea and vomiting (PONV) is the term used to describe the undefined incidence of nausea and vomiting in patients following surgery, from the post-anesthesia care unit (PACU) to the early hours following the patient's ward transfer, without any apparent cause, such as hypotension.[1] The incidence of postoperative nausea and vomiting has been documented to range from 20% to 30% across diverse surgical procedures and anaesthesia techniques, and it is the second most often reported symptom.[2]

PONV has a complicated and multifaceted aetiology that includes aspects connected to the patients' health and surgeries. Management of PONV requires a thorough understanding of these factors, as well as the physiology (cranial nerves VIII, IX, X, and gastrointestinal reflex) and neuropharmacology of multiple emetic receptors (dopaminergic, muscarinic, cholinergic, opioid, histamine, and serotonin).[3]

There are at least three types of vomiting; ether and other anaesthetics are linked to the first type, which is reflexive in nature and associated with pain or ovarian surgery, while opioids are responsible for the third type.

According to early research, the incidence of PONV after opioid premedication and extended ether anaesthesia could reach 75%–80%.[4] Many medications have been used to treat PONV over the years. Numerous methods, such as the infusion of olive oil and insulin [5] and the addition of atropine to morphine treatment, have been found to be successful.[6]

Prolonged nausea and vomiting can lead to electrolyte imbalance, dehydration, and postponed discharge. Increased bleeding beneath skin flaps, venous hypertension, and tension on suture lines are some of the effects it may have. It puts the

patient at higher danger of aspirating vomitus into their lungs.[7]

A serotonin 5-HT3 receptor antagonist, ondansetron is mostly used as an antiemetic after chemotherapy. It is believed to have an impact on both central and peripheral nerves. Ondanestron inhibits serotonin receptors in the chemoreceptor trigger zone and decreases vagus nerve activity, which deactivates the vomiting centre in the medulla oblongata. But it's pricey, and it has some risky side effects including headaches and elevated blood pressure, which can cause major problems, particularly in individuals who are already prone to hypertension.[8-10]

Dexamethasone is a cheap medication with no major adverse effects that is often used in individuals undergoing surgery on their noses, throats, or ears. Administering dexamethasone orally or via a parenteral method for an extended duration may result in side effects typical of systemic glucocorticoids.[11-13]. It has been recommended that the use dexamethasone as a prophylactic agent against PONV should be combined with other drugs.

Nonetheless, postoperative nausea and vomiting continue to be a serious concern, and research is ongoing to determine the most effective course of action for both prevention and therapy. We compared the effectiveness of ondansetron and combination of ondansetron and dexamethasone in preventing nausea and vomiting during ENT surgeries because of this issue.

Material & Methods

The present randomised, prospective, comparative study was done in the Anaesthesia Department of MMIMSR, Mullana on Adult patients posted for routine surgery and planned for general anaesthesia during the period of the study. Ethical permission was taken from ethical review board before the commencement of study. Patients were asked to sign the informed consent form after explaining them about the complete procedure of study.

Taking the previous studies as reference, the minimum required sample size with 95% power of study and 5% level of significance is 9 patients in each study group. To reduce margin of error, total sample size taken is 60 (30 patients per group).

They will be randomly allocated into two groups of 30 each.

- GROUP I: These received Ondasetrone 4mg i.v. before the surgery .
- GROUP II: These received Ondasetrone 4mg and Dexamethasone 4mgi.v. before the surgery.

For randomization sealed envelope system (In this system, randomly generated treatment allocations are prepared within sealed opaque envelopes. Once the patient gives consent to enter a trial, an envelope was opened and the patient was then be offered the allocated treatment regimen).

The patients were selected on the basis of following inclusion and exclusion criteria-

Inclusion Criteria

1. ASA grade I and II.
2. Age between 18-60 years of either sex.
3. Mallampati grade 1 and 2.
4. Patients planned to undergo elective ENT surgeries undergoing general anaesthesia with controlled ventilation.
5. Patient giving informed, written and valid consent.

Exclusion Criteria

1. Patient refusal for the procedure
2. Patients with significant coagulopathies
3. Patient with pregnancy
4. Persons with history of notable systemic disorders (CVS, Respiratory or Central nervous system).
5. Persons with renal /and or liver disease.
6. Patients having chronic alcoholism or drug abuse.
7. Respiratory Tract Infection.
8. Mallampati grade III and IV.
9. Emergency surgeries.

All patients who match the inclusion criteria were assessed by a pre-anaesthetic team. A thorough pre-anaesthetic evaluation was done prior to surgery and all the necessary routine specific investigations were done. All patients were kept for fasting 8 hours prior to surgery and were given Tab Alprazolam 0.25 mg and Tab Rantidine 150 mg orally at night and in the morning of procedure with 1-2 sips of water.

On arrival in the operation theatre, an intravenous line was started using 18G cannula and patients were preloaded with 500 ml of Ringer's lactate in 10 minutes and thereafter at 7ml/kg/hr and following parameters were monitored: H.R., Blood Pressure, ECG and SpO_2 .

All patients were given intravenously -Inj Midazolam 0.03mg/kg ; Glycopyrrolate 0.2 mg/kg and fentanyl 2 micrograms per kg. Patients were randomized to receive dexamethasone or dexamethasone with Ondasetrone i.v. prior to the surgery .

Following preoxygenation for three minutes, InjPropofol (2-2.5mg/kg) I/V titrated to loss of response to verbal commands was given for induction. The ability to ventilate the patient was checked. Neuromuscular blockade was carried out

with InjVecuronium0.1mg/kg I/V and endotracheal intubation done with appropriate size endotracheal tube. Adequacy of ventilation was confirmed by the auscultation, chest movements and $EtCO_2$ waveform. Anaesthesia was maintained with nitrous oxide, oxygen and isoflurane. At the conclusion of surgery, patients were reversed using Injglycopyrrolate0.01mg/kg IV and Inj neostigmine 0.05mg/kg IV and O2 was administerd postoperatively

Parameters observed were: Incidence of nausea and vomiting was recorded at post op 0,0.5,2,6,12,24 hrs. of surgery ; Number of vomiting episode was also recorded; Duration after which first rescue antiemetic was given . Any Adverse effects like headache, dizziness, allergic reactions, itching, hypotension was noted.

All the parameters were recorded in the proforma and statistically analysed at the end of the study. Categorical variables were presented in number and percentage (%) and continuous variables were presented as mean ± SD and median. Quantitative variables was compared using Unpaired t-test / Mann-Whitney Test (when the data sets were not normally distributed.) between the two groups. Qualitative variable was compared using Chi-Square test / Fisher's exact test. A p value of <0.05 was considered statistically significant. The data was entered in MS EXCEL spreadsheet and analysis was done using Statistical Package for Social Sciences (SPSS) latest version.

Results

The mean age of patients in both groups was between 30 to 40 years. Male patients were higher in number as compared to female (17/13; 16/14). Number of patients in ASA I category were higher. Average height, weight, anaesthesia time and history of motion sickness was also calculated as shown in table 1.

Table 1: Subject and anaesthetic characteristics. Values are number, mean (SD), or number (%). PONV, postoperative nausea and vomiting

Variable	Group 1 (n=30)	Group 2 (n=30)
Mean Age	33.029±4.6	34.302±5.8
Male /Female	17/13	16/14
Weight (kg)	57.2±7.2	58.4±6.5
Height (cm)	159.02±20.3	158.07±19.5
ASA I/II	18/12	19/11
Anaesthesia time (min)	120.65±13.4	121.54±14.8
History of motion sickness or PONV	12 (40%)	14 (46.6%)

The number and percentage of nausea and vomiting at various postoperative intervals in both groups was calculated and it was found with increase in postoperative hours first the episodes of PONV increased in both groups and later on after passage of 24 hours the episodes of PONV decreased. There was less number of episode in group 2 as compared to group 1 but the results were non-significant with p value greater than 0.05 as shown in table 2.

Table 2: The number and percentage of nausea and vomiting at various postoperative intervals in both group

Group	0 hours	0.5 hours	2 hours	6 hours	12 hours	24 hours
Group 1	6 (20)	8 (26.6)	10 (33.3)	14 (46.6)	10 (33.3)	4 (13.3)
Group 2	5 (16.6)	7 (23.3)	9 (30)	11 (36.6)	8 (26.6)	2 (6.6)
P value	0.153	0.231	0.189	0.134	0.056	0.064

There was no significant difference in the degree of post-operative pain, total consumption of PCA fentanyl, and rescue analgesic used within 24 h after surgery as shown in table 3.

Table 3: The severity of pain, cumulative fentanyl consumption, and rescue analgesic use. Values are mean (SD) or number (percentage)

Variable		Group 1	Group 2	P value
Pain score	0-2 h	3.6±1.2	3.5±1.1	0.189
	2-24 h	2.3±1.0	2.2±0.6	0.124
Fentanyl consumption		190±22.8	195±23.1	0.059
Rescue analgesic use		3 (10)	2 (6.6)	0.063

The incidence of side effects in both groups was seen in both groups like headache, drowsiness, dizziness, heartburn and diarrhoea. The results were found to be non-significant as shown in table 4.

Table 4: Number of patients with side effects in both groups

Side effects	Group 1	Group 2	P value
Headache	18 (60)	17 (56.6)	0.145
Drowsiness	15 (50)	13 (43.3)	0.124
Dizziness	16 (53.3)	12 (40)	0.235
Heartburn	12 (40)	10 (33.3)	0.189
Diarrhoea	11 (36.6)	7 (23.3)	0.178

Discussion

The current study assessed the impact of giving ondansetron and dexamethasone together prior to inducing anaesthesia on postoperative nausea and vomiting in ENT procedures. There has been significant reported incidence of postoperative nausea and vomiting following surgical procedures. [14]

The intricate innervation of this region by the cervical nerves II and III as well as the cranial nerves V, VII, VIII, and X may be the cause of the high prevalence of nausea and vomiting that follows. [15,16] Postoperative nausea, dizziness, and vomiting can also be caused by the cranial surgical field's closeness to the semilunar ducts and vestibular system, as well as heat and vibration transmission at the surgical field's excision due to stimulation of the ampulla. As a result, these patients experience post-operative nausea and vomiting more frequently. [17]

In the present study, the incidence rates of PONV in the both groups just after the operation was 20% and 16.6%. The incidence rate and intensity of PONV in the dexamethasone with ondansetron groups were lower than that in the ondansetron group. In the final stages of the study, incidence rate and intensity of PONV in the dexamethasone+ ondansetron group was less than that in the ondansetron group.

There have only been a few trials comparing the effects of ondansetron and dexamethasone on PONV, and the results are inconsistent. In order to avoid postoperative PONV in laparoscopic cholecystectomy, Erhan et al. conducted a comparative study on the effects of ondansetron (4 mg IV), granisteron (3 mg IV), and dexamethasone (8 mg IV) given prior to induction of anaesthesia. They demonstrated that all three medications considerably decreased the incidence rate of PONV when compared to a placebo in a comparable way. [18] According to Lopez-Olaondo et al., dexamethasone and ondansetron were equally successful in lowering chemotherapy-induced nausea and vomiting. [19] Gupta also came to the conclusion that ondansetron and intravenous dexamethasone had comparable effects on preventing PONV. [20]

Furthermore, Munoz et al. demonstrated that ondansetron and dexamethasone had comparable preventative benefits against PONV. [21] Nonetheless, a different study [22] demonstrated that ondansetron outperformed dexamethasone. Dexamethasone was marginally more successful than ondansetron in avoiding post-tonsillectomy post-op neuropathy, according to another trial. [23] Additionally, a study of 60 patients having a laparoscopic cholecystectomy revealed that the dexamethasone group had a considerably lower incidence rate of PONV (20% versus 43.3%). [24] A variety of factors, including variations in sample sizes, patient characteristics, surgical procedures and anaesthetic methods, the definition and investigation of PONV, and—above all—the dosage and timing of antiemetic drug administration, could account for the discrepancies in the results of the aforementioned studies.

The incidence and severity of pain was less in Group II than in Group I. This probably reflects the strong anti-inflammatory action of dexamethasone, which has been shown to decrease postoperative pain. This is comparable to the study conducted by Elhakim et al. [25]

Both medications are well tolerated when taking into account the adverse effect profiles of the two groups. The three main adverse effects were headache, drowsiness and dizziness. These adverse consequences weren't significant.

Conclusion

Among the most upsetting consequences of anaesthesia and surgery is PONV, which is more common following ENT procedures. In an attempt to find more potent antiemetic medications without the potential for sedative or extrapyramidal side effects, a relatively new family of medications known as 5HT antagonists has just been developed, with ondansetron serving as a prototype. Despite being strong antiemetics, 5HT antagonists have not been able to adequately control PONV in a single medication. As a result, some research have examined the effectiveness of combining ondansetron and dexamethasone, based on the theory that employing a mix of antiemetics that operate on various receptors can further lower the frequency of PONV.

The results of this study indicate that ondansetron with dexamethasone is a more effective combination to prevent PONV than ondansetron alone. Both combination and monotherapy have excellent safety profiles and are well-tolerated by patients. In terms of avoiding PONV, the combo therapy offers greater patient response.

References

1. Miller RD, Eriksson LI, Fleisher LA, Wiener Kronish JP, Young WL. Miller's Anesthesia. 6th ed. USA: Churchill Livingstone. 2009: 2317-33.
2. Jabalameli M, Rouholamin S, Gourtanian F. A comparison of the effects of fentanyl and remifentanil on nausea, vomiting, and pain after cesarean section. Iran J Med Sci. 2011; 36:183-7.
3. Kovac AL. Prevention and treatment of postoperative nausea and vomiting. Drugs. 2000; 59:213–43.

4. Lerman J. Surgical and patient factors involved in post operative nausea and vomiting. Br J Anaesth. 1992; 69:24–32.
5. Islam S, Jain PN. Postoperative nausea and vomiting (PONV): A review article. Indian J Anaesth. 2004; 48:253–8.
6. Rowbotham DJ. Current management of postoperative nausea and vomiting. Br J Anaesth. 1992; 69:46–59.
7. Watcha MF, White PF. White. Postoperative nausea and vomiting – its etiology, treatment and prevention. Anesthesiology. 1992; 77:162–84.
8. Vartik AV, Anil PA, Verma AP. A clinical comparative study of ondansetron, Palonsetron, Ramosetron, and Metoclopramide for prevention of postoperative nausea and vomiting in patients undergoing Laprascopic and ENT surgery under general anaesthesia. International Journal of Advanced and Integrated Medical Sciences. 2017;2(2):65-69.
9. V Rajeev, N Bhardwaj, Y.K. Batra, L.K Dhaliwal. Comparison of ondansetron and dexamethasone in prevention of PONV in diagnostic laparoscopy. Can J Anesth 1999; 46:1,40-44.
10. Abhijeet RM, Uma S, Kumar D, Saraswat N, Kumar A. Nausea and vomiting after ENT surgeries: A comparison between ondansetron, metoclopramide and small dose of propofol. Indian J Otolaryngol Head Neck Surg. 00202010;62(1):29-31.
11. FazalW, Raza M, Mohammad J, Waqar un N. Efficacy of ondansetron alone and ondansetron plu dexamethasone in preventin nausea and vomiting after middle ear surgery. J Ayub Med Coll Abbottabad 2014;26(1).
12. Sinclair DR, Chung F, Mezei G. Can postoperative nausea and vomiting be predicted? Anesthesiology. 1999; 91:109-18.
13. Saini S, Mehta P, Bansal T,T axak S. A study to compare dexamethasone and ondansetron for preventing postoperative nausea and vomiting in children undergoing tonsillectomy. Cumhuriyet Medical Journal.2015;37(3): 213-9.
14. van den Berg AA. A comparison of ondansetron and prochlorperazine for the prevention of nausea and vomiting after tympanoplasty. Can J Anaesth. 1996; 43:939-45.
15. Honkavaara P. Effect of transdermal hyoscine on nausea and vomiting during and after middle ear surgery under local anaesthesia. Br J Anaesth. 1996; 76:49-53.
16. Liu YH, Li MJ, Wang PC, Ho ST, Chang CF, Ho CM, et al. Use of dexamethasone on the prophylaxis of nausea and vomiting after tympanomastoid surgery. Laryngoscope. 2001;111 :1271-4.
17. Erhan Y, Erhan E, Aydede H, Yumus O, Yentur A. Ondansetron, granisetron, and dexamethasone compared for the prevention of postoperative nausea and vomiting in patients undergoing laparoscopic cholecystectomy: A randomized placebo-controlled study. SurgEndosc. 2008; 22:1487-92.
18. López-Olaondo L, Carrascosa F, PueyoFJ, Monedero P, Busto N, Sáez A. Combination of ondansetron and dexamethasone in the prophylaxis of postoperative nausea and vomiting. Br J Anaesth. 1996; 76:835-40.
19. Gupta A. Evidence-based medicine in day surgery. Curr Opin Anaesthesiol. 2007; 20:520– 5.
20. Muñoz HR, Ibacache ME, Mertz VF. [Controlled trial of dexamethasone compared with droperidol and ondansetron for the treatment of postoperative nausea and vomiting]. Rev Med Chil. 2006; 134:697-702.
21. Schnaider TB, Vieira AM, Brandão AC. Comparative study of anti-emetics and their association, in the prevention of postoperative nausea and vomiting in patients undergoing gynecologic surgeries. Rev Bras Anestesiol. 2008;58: 614-22.
22. Bolton CM, Myles PS, Nolan T, Sterne JA. Prophylaxis of postoperative vomiting in children undergoing tonsillectomy: a systematic review and meta-analysis. Br J Anaesth. 2006; 97:593-604.
23. Ionescu D, Mitre C, Leuke L, Bertianu C, Paskarenko G, Puia C, et al. [Procedures for preventing postoperative nausea and vomiting after laparoscopic cholecystectomy: dexamethasone and ondansetron]. Anesteziol Reanimatol. 2007; 2:50-2.
24. Cruz NI, Portilla P, Vela RE. Timing of ondansetron administration to prevent postoperative nausea and vomiting. P R Health Sci J. 2008; 27:43-7.
25. Elhakim M, Nafie M, Mahmoud K, Atef A. Dexamethasone 8 mg in combination with ondansetron 4 mg appears to be the optimal dose for the prevention of nausea and vomiting after laparoscopic cholecystectomy. Can J Anesth. 2002; 49:922–6.