Original Research Article

A Hospital Based Prospective Study to Match the Impact of Palonosetron-Dexamethasone and Ondansetron-Dexamethasone Combination with PONV in Patients of Middle Ear Surgery

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Abstract

Background: Post-operative nausea and vomiting (PONV)usually may be such an unpleasant experience that patients often rate it worse than postoperative pain. Concerning the high incidence of PONV after middle ear surgery, and as there is no previous study to assess and compare the preventive effect of palonosetron-dexamethasone and ondansetron plus dexamethasone on PONV. The current study to match the impact of palonosetron-dexamethasone and ondansetron-dexamethasone combination with PONV in patients of middle ear surgery. **Material & Methods:** This is a prospective study done on 50 ASA I and II patients undergoing middle ear surgery under general anesthesia at SK Government Medical college, Sikar, Rajasthan, India during 5 months period. Patients were randomly selected for two equal groups of 25 each. Group O - Ondansetron 8 mg + dexamethasone 8 mg intravenously before induction of anesthesia and Group P - Palonosetron 0.075 mg + dexamethasone 8 mg intravenously before induction of anesthesia. The primary outcome was the incidence and severity of nausea and vomiting experienced by each patient after surgery. This was recorded at the following three assessment periods: 0-2, 2-6, and 6-24 hours after surgery. **Results:** The incidence of nausea was 44% in group O and 16% in group P 24 hours postoperatively ($p<0.05$*). The incidence and severity of vomiting were not statistically significant between groups O and P during the study period. The incidence of vomiting was 28% in group O and 20% in group P 24 hours postoperatively ($p>0.05$). The overall incidence of PONV (0-24 hours postoperatively) was 36% in group O and 8% in group P ($p<0.05$*). **Conclusion:** We concluded that palonosetron-dexamethasone is simpler within the prevention of PONV with superior antiemetic efficaciousness within the initial 24 hours compared to ondansetron-dexamethasone.

Keywords: Middle Ear Surgery, Palonosetron, Dexamethasone, Ondansetron, Nausea, Vomiting.

Introduction

Post-operative nausea and vomiting (PONV) incidence due to multiple factors such as a length of surgery, the type of medicine used & techniques used throughout general anesthesia, age of patients, gender and habit of smoking[1,2]. The PONV remains a seamless drawback with an average incidence was reported between 30 to 80% depending on the surgical procedure and associated risk factors[3,4].

PONV usually may be such an unpleasant experience that patients often rate it worse than postoperative pain[5]. The prevalence of PONV in middle ear surgeries ranges from 60% to 80%, in the absence of any antiemetic treatment[6]. Higher prevalence of PONV considerably interferes with smooth emergence from anesthesia and markedly increases patient discomfort in the postoperative period.

Ondansetron was the initial 5-HT3 receptor antagonist used clinically and its antiemetic efficacy is well established. It has a moderately short half-life of 3-5 hours[7].

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Palonosetron is a second-generation 5-HT3 receptor antagonist having larger receptor binding affinity with a half-life of 40 h and is more effective than granisetron 1 mg and ondansetron 4 mg in preventing PONV. Dexamethasone reported to be effective and safe for prevention of PONV following different surgeries including breast surgery and laparoscopic cholecystectomy[8-10]. None of the offered antiemetics is entirely effective in all patients, perhaps because there is no single stimulus for PONV. Concerning the high incidence of PONV after middle ear surgery, and as there is no previous study to assess and compare the preventive effect of palonosetron-dexamethasone and ondansetron plus dexamethasone on PONV. The current study to match the impact of palonosetron-dexamethasone and ondansetron-dexamethasone combination with PONV in patients of middle ear surgery.

Materials & methods

This is a prospective study done on 50 ASA I and II patients undergoing middle ear surgery under general anesthesia at SK Government Medical college, Sikar, Rajasthan, India during five months period.

Exclusion Criteria

1. Patients with allergy to study drug,
2. history of addiction or use of other antiemetic drugs,
3. Systemic disease such as motion sickness, nervous system disorders, cardiovascular,

4. Pregnant and lactating women

Methods

Patients were randomly selected for two equal groups of 25 each.

Group O - Ondansetron 8 mg + dexamethasone 8 mg intravenously before induction of anesthesia.

Group P - Palonosetron 0.075 mg + dexamethasone 8 mg intravenously before induction of anesthesia.

All the study drugs were taken in identical 5 mL syringes and diluted up to 5 mL with normal saline. The study drugs were administered slowly over 30 seconds just before the induction of anesthesia. Patients, anesthesiologists involved in intraoperative care, and investigator collecting data in the post-operative ward.

Patients were premedicated with inj. Glycopyrrolate (0.004mg/kg), inj. Midazolam (0.03mg/kg), inj. Fentanyl (1.5-2µg/kg). After preoxygenation for five minutes anesthesia was induced with inj. Propofol 2mg/kg & inj. Scoline 2mg/kg was given after bag & mask ventilation was confirmed. Patients' trachea was intubated with appropriate size of tube. Intraoperative muscle relaxation was maintained with inj. Atrocurium 0.5mg/kg loading dose & 0.1 mg/kg maintenance dose. MV was provided with oxygen: air mixture. Anesthesia was maintained with iv inj. Propofol 50-200µg/kg/min., infusion dose N2O & sevoflurane was avoided. Reversal of anesthesia was done by inj. Neostigmine 0.05mg/kg & inj. Glycopyrrolate 0.01mg/kg.

The primary outcome was the incidence and severity of nausea and vomiting experienced by each patient after surgery. This was recorded at the following three assessment periods: 0-2, 2-6, and 6-24 hours after surgery. Nausea was assessed using a Apfel scale includes four variables and assigns one point for each. High risk (3 to 4 points) 60-80%, moderate risk (2 points) 40% and low risk (0-1 points) 10-20%. In addition, we used the vomiting count to quantify vomiting intensity, scored as the number of vomits (0–2, or 3 if three or more vomits). If the episodes of vomiting were more than two, it was considered as severe, two was moderate and less than two was mild. We thus added both scores together to obtain the simplified PONV impact scale score.

Statistical Analysis

Patient characteristics data were analyzed with the Student t-test for continuous variables and Chi-Square test for categorical variables. A p-value of < 0.05 is considered statistically significant.

Results

Our study showed that demographics were similar in study groups (Table 1).

Table 1: Demographic profile of patients

Demographic data	Group O (N=25)	Group P (N=25)	P-value
Mean age (yrs)	36.48±11.23	37.62±12.13	>0.05
Male/female	15/10	14/11	1.00
Mean weight (Kg)	52.67±8.22	54.44±7.92	>0.05
Type of surgery (Tympanoplasty/ Mastoidectomy)	18/7	20/5	>0.05
Duration of Surgery (Min.)	73.58±17.22	78.14±19.11	>0.05
Intraoperative fentanyl	91.44±12.40	94.23±13.55	>0.05

The incidence of nausea was statistically significant between groups O and P at the time interval 2-6 hours only (p <0.05*). The severity of nausea was statistically significant between the two groups during the whole study period. The incidence of nausea was 44% in group O and 16% in group P 24 hours postoperatively (p<0.05*). The incidence and severity of vomiting were not statistically significant between groups O and P during the study period. The incidence of vomiting was 28% in group O and 20% in group P 24 hours postoperatively (p>0.05). The overall incidence of PONV (0-24 hours postoperatively) was 36% in group O and 8% in group P (p<0.05*)(Table 2 & 3).

Table 2: Incidence and severity of nausea& vomiting

Time interval	0-2 hr.			2-6 hr.			6-24 hr.		
	Group O	Group P	P-value	Group O	Group P	P-value	Group O	Group P	P-value
Nausea									
No	22	23	>0.05	19	24	<0.05*	23	24	1.00
Yes	3	2		6	1		2	1	
Vomiting									
No	23	23	1.00	22	23	>0.05	23	23	1.00
Yes	2	2		3	2		2	2	

Table 3: Incidence of postoperative nausea and vomiting 0-24 h

Incidence	Group O (N=25)	Group P (N=25)	P-value
Nausea incidence			
No	14	21	<0.05*
Yes	11	4	
Vomiting incidence			
No	18	20	>0.05
Yes	7	5	
PONV incidence			
No	16	23	<0.05*
Yes	9	2	

The patient's satisfaction score was higher in group P than in group O (p<0.05*). There is no significant difference regarding the incidence of adverse effects between the groups.

Discussion

Postoperative Nausea and Vomiting (PONV) may be a difficult experience in general anesthesia, with an incidence ranging between 20-80% among different surgeries. Palonosetron is a highly effective 5-HT3 antagonists and has favourable side effect profile in comparison to others drugs used in the past for prevention and treatment of PONV[11]. Dexamethasone is reported to be an effective antiemetic having central antiemetic action through an activation of the glucocorticoid receptors in the bilateral nuclei tractus solitarii in the medulla[12]. Dexamethasone 8 mg is effective and safe for the prevention of PONV following different medical and surgical conditions[13,14]. Multimodal approach to PONV has been advocated in recent guidelines and medical literature[15]. With a better understanding of pathophysiology of PONV involving different sets of receptors, combination therapy with antiemetics acting through different pathways appear to be the logical choice.

Desai et al[16]. confirmed the prevalence of dexamethasone and ondansetron combination than ramosetron alone for the prevention of

PONV after middle ear surgeries. A combination of granisetron and dexamethasone was more efficient than each drug alone for the prevention of PONV after middle ear surgery as observed by Fujii et al[17]. Chatterjee and colleagues[18] also reported the same results in investigations of the influence of palonosetron and dexamethasone on PONV. They found the lower incidence of PONV in combination therapy than using each drug individually. The incidence declined from 56% to 23% by the use of this combination.

In our study, we used ondansetron 8 mg or palonosetron 0.075 mg with a combination of dexamethasone 8 mg because various authors suggested that these are the most effective doses of a drug. Kovac et al[19]. also suggested that palonosetron in a dose of 0.075 mg was the most effective dose for the prevention of PONV after comparing three different doses of palonosetron. Sekhavat et al[20]. confirmed that prophylactic 8 mg dexamethasone is effectively reducing PONV. Single-dose ondansetron 8 mg was found to be efficient in reducing PONV compared to 4 mg in patients undergoing laparoscopic cholecystectomy[21].

In our study, the incidence of PONV was 36% in the ondansetron-dexamethasone group and 8% in the palonosetron-dexamethasone group. The decrease incidence of PONV in our study may be caused by of the addition of dexamethasone to both groups and avoidance of sevoflurane during maintenance of anesthesia. Dexamethasone aggravates the effect of other antiemetics by various mechanisms like prostaglandin antagonism, release of endorphins and bradykinin reduction. Sharma S et al[22]. compared palonosetron (1 mcg/kg) with ondansetron (0.1 mg/kg) for the prevention of PONV in middle ear surgery and observed that the incidence of PONV was 66% in ondansetron group and 30% in palonosetron group in the first 24 hours. The patient's satisfaction was higher in group P than in group O because of palonosetron drug control PONV up to 24 hours. Both palonosetron and ondansetron are known to have non-serious adverse effects like headache, constipation, dizziness, and prolongation of QTc interval.

Conclusion

We concluded that palonosetron-dexamethasone is simpler within the prevention of PONV with superior antiemetic efficaciousness within the initial 24 hours compared to ondansetron-dexamethasone with remittent incidence of nausea, remittent demand of rescue antiemetics and higher patient satisfaction. Therefore, we recommend a combination of palonosetron-dexamethasone for prophylaxis for PONV in middle ear surgeries.

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