Research Paper E-ISSN NO : 2455-295X | VOLUME : 3 | ISSUE : 1 | JAN 2017

COMPARISON OF PROPHYLACTIC EFFECTS OF INTRAVENOUS METOCLOPRAMIDE AND ONDANSETRON ON POSTOPERATIVE NAUSEA AND VOMITING (PONV) AFTER MAXILLOFACIAL SURGERY.

SAEED NEZAFATI [1] | DR.ABBASALI DEHGHANI [2] | DR.DAWOOD AGHAMOHAMMADI* [3] | DR.HOSSEIN DABBAGH [4]

[1] Associate Professor Of Oral And Maxilla Facial Surgery, Dental And Periodontal Research Center , Tabriz University Of Medical Sciences.

[2] Assistant Professor Of Anesthesiology And Intensive Care Medicine, Department Of Anesthesiology, Imam Reza Hospital, Tabriz University Of Medical Science.

[3] Department Of Anesthesiology, Imam Reza Hospital, Tabriz University Of Medical Science. **(* Corresponding Author)**

[4] Oral And Maxillofacial Surgeon (Private Practice). Tabriz University Of Medical Sciences.

ABSTRACT

Background and aims

Postoperative nausea and vomiting (PONV) remains a significant problem in patients undergoing maxillofacial surgery. PONV is dangerous because it can result in aspiration and patient suffocation especially in patients undergoing intermaxillary fixation (IMF) after the surgery and the mouth is closed. The aim of the present study was to compare the prophylactic effects of intravenous ondansetron and metoclopramide in controlling the PONV in maxillofacial surgery.

Materials and methods

A total of 175 patients with the age range of 18–50 years were randomly allocated into 5 groups. Groups one and two received ondansetron 0.15 mg/kg intravenously in a double-blind manner 30 minutes before surgery or 30 minutes before recovery. Groups three and four received metoclopramide 0.5 mg/kg intravenously in a double-blind manner 30 minutes before surgery or 30 minutes before recovery. In Group 5 (control), metoclopramide was administered postoperatively according to the patient's need. An independent surgeon recorded the postoperative results.

Results

The incidence of nausea and vomiting was highest in the control group (C=33.01%) and lowest when ondansetron was given 30 minutes before the end of anaesthesia (Oa=4.71%) (P=0.001). Regarding the absence of nausea and vomiting 24 hours after surgery, the peak incidence for PONV was recorded 30 minutes after full consciousness for all the groups. The incidence of PONV was significantly lower when ondansetron was given before recovery (2.38% for the group one in comparison to 7.61% of the group 2) (p=0.045).

Conclusion

It can be concluded that ondansetron is significantly more efficacious than metochlopramide in preventing PONV. The best administration time is 30 minutes before recovery.

Keywords:

Introduction

One of the most common complications after surgical procedures is postoperative nausea and vomiting (PONV). Despite the recent advances in anesthetic techniques and introduction of new antiemetic drugs, one-third of the patients undergoing surgery have nausea and vomiting postoperatively which sometimes exert much more dissatisfaction than the postoperative pain. PONV is associated with various problems, including pain in the surgical site, wound dehiscence, hematoma formation, esophageal ruptures, bilateral pneumothorax and aspiration which can potentially be dangerous and result in increased patient discomfort and dissatisfaction and in increased costs related to length of hospital stay. 1, 2 Thousands of studies about PONV have been published and majority of them support prophylactic use of different agents. Several antiemetic regimens have been proposed including only one drug or a combination of several drugs to prevent PONV.3

PONV is a significant problem for maxillofacial patients especially those with intermaxillary fixation and closed mouth. Most of the studies believe that selective prophylaxis in patients who are judged to have PONA might be highly effective with satisfactory results.4There are many factors that contribute to PONV by activation of the vomiting center. Vomiting results from activation and release of some neurotransmitters, including dopamine, histamine, acetylcholine and serotonin. These neurotransmitters stimulate chemical receptors, transmitting afferent impulses to vomiting center of the brain in the medulla. The potential capacities of 5-hydroxy tryptamine (serotonin) receptor antagonists have been proved through different studies and ondansetrone was the first drug in this group

to be commercially produced and successfully used to decrease the incidence of PONV.5 Metoclopramide is routinely used due to its prokinetic and antiemetic effects. It stimulates the upper gastrointestinal tract without exerting any effects on gastric, biliary and pancreatic secretions. It exerts stimulatory effects on the parasympathetic system and inhibits the dopamine receptors in the vomiting center of chemoreceptor trigger zone (CTZ). In addition, it might inhibit serotonin receptors too.6 The effects of metoclopramide and ondansetron have been compared in management of PONV. Taheri et al showed that ondansetron was at least twice more effective than metoclopramide in decreasing PONV incidence.7 There was no control group in that study to attribute the results of the study to each of the drugs used and the drugs had only been administered before the end of general anesthesia. Therefore, the preferred time of the drug administration was not evaluated. Although the advantages of ondansetrone in prevention of PONV have been proved in previous studies, this study was designed to compare the prophylactic effects of intravenous ondansetron and metoclopramide after maxillofacial surgery and evaluate the appropriate timing of use for these drugs.

Materials and Methods

A total of 175 patients, with the age range of 18–50 years, requiring orthognathic surgery or mandibular fracture repair under general anesthesia were included in this double-blind case-control clinical trial. All the patients had been referred to the Department of Oral and Maxillofacial Surgery, Tabriz University of Medical Sciences. The patients were randomly allocated into 5 therapeutic groups (n=35). All the patients underwent a similar general anesthetic procedure using propofol (1.5–2.5 mg/kg) to induce anesthesia with 1.5–4.5 mg/kg an hour to maintain anesthesia. Intravenous acetaminophen (Apotel) was used to control Postoperative pain. If the pain did not respond to this treatment, the patient was received an appropriate opiod analgesic (meperidine ,1 mg/kg) and excluded from the study. Patients were followed for 24 hours after surgery. All the patients with systemic diseases aggravating nausea and vomiting, brain trauma and clinical conditions indicating presence of factors for being placed in a high risk group, were excluded from the study. Duration of surgery more than 3 hours and the use of nausea and vomiting-inducing drugs such as opioid analgesics resulted in the exclusion of patients from the study. A consent form was signed and the patients were randomly allocated into 5 therapeutic groups (n=35) of Ob, Oa, Ma, Mb and C as follows:

Ob: A single dose of 0.15 mg/kg of ondansetron 30 minutes before surgery;

Oa: A single dose of 0.15 mg/kg of ondansetron 30 minutes before the end of the surgical procedure;

Mb: A single dose of 0.5 mg/kg of metoclopramide 30 minutes before surgery;

Ma: A single dose of 0.5 mg/kg of metoclopramide 30 minutes before the end of the surgical procedure;

C (control): No prophylaxis; metoclopramide was administered in a routine manner of PRN and before the end of the surgery.

In the postoperative follow-up, the signs and symptoms of PONV were recorded in special forms by a postgraduate student of oral and maxillofacial surgery, who was not aware of the type of therapy and the distribution of the patients in groups under study at the following six intervals:

1. At entry into the ward (full consciousness) (I)
2. 30 minutes after full consciousness (II)
3. One hour after full consciousness (III)
4. 30 minutes after expiry of the NPO period (almost 6 hours after regaining full consciousness) (IV)
5. Eight hours after regaining full consciousness (V)
6. Twenty-four hours postoperatively (VI)

Data was analyzed for descriptive statistics (frequency/percentage and means ± SD), mean differences in independent groups, chi-squared test, Fisher's exact test, ANOVA and non-parametric Mann-Whitney U test using SPSS 16. Statistical significance was defined at $P<0.05$.

Results

A total of 150 patients with an age range of 18–50 years were randomly included in the study. Demographic data were similar in all the groups (Table 1). Statistical analysis did not reveal any significant differences in gender and the means of age between the groups (P=0.26, P=0.81 respectvely).

The incidence of nausea and vomiting was highest in control group (C=33.01%) and lowest when ondansetron was given 30 minutes before the end of anaesthesia (Oa=4.71%). This difference was statistically significant (P=0.001). Regarding the absence of PONV 24 hours after surgery, the incidence of PONV was the heighest 30 minutes after full consciousness (39.62%) and the lowest 8 hours after full consciousness (4.71%) ($p < 0.001$).

The incidence of PONV in metoclopramide group (47.1) and ondansetrone group (19.81) was statistically significant (p=0.008). Comparing PONV in groups one and two showed that this proportion was 4.71% when ondansetron was given before recovery (Oa) and 15.09% when ondansetron was given 30 minutes before surgery (Ob). This difference was statistically significant (P=0.045).

Discussion

Emesis is one of the most common complications which followed general anaesthesia and maxillofacial surgery and sometimes is more distressing than postoperative pain. 1There are some well-established risk factors that are involved in an increased incidence of PONV such as age, gender, the reason for surgery, non- smoking status, use of volatile anesthesia and opioids.2, 4 In the present study all the groups were matched for the confounding variables such as age range, gender, reason for surgery, smoking and anesthesia protocol and differences were not statistically significant(P=0.81; P=0.26; P=0.72, P=0.27, respectively).

Different studies have evaluated the effect of various drugs on decreasing the rate of post-operative emesis.8 Ondansetrone has an established role in decreasing PONV. However, despite the use of different doses, the optimal time for reducing nausea and vomiting when it is used as a prophylactic agent has not been clearly defined. Diemunsch et al9 (1997) reported that ondansetron is more effective (42% vs 60%)and better tolerated than metoclopramide (P<0.001). The study of Launios in 1998 supported the efficacy of ondansetrone and showed that it is more cost effective than metoclopramide. Krubbuaban10 (2008) compared the prophylactic effects of the same doses (4 mg) of ondansetron and metoclopramide and received better results with the former. Sandha et al administered 4 mg ondansetron at the end of general anesthesia and compared the results with 10 mg of metoclopramide in laparoscopic cholecystectomy11. They found that administration of ondansetron at the end of general anesthesia is much more effective than that of metoclopramide (20% vs 45%; P=0.05). The results of the present study are consistent with the above researches and confirmed the superior properties of ondanseron against metoclopramide in controlling PONV. Taheri et al8 (2010) tried to extend the results of the previous studies to maxillofasial area by administration of ondansetron and metoclopramide to two groups of patients undergoing maxillofacial surgery 30 minutes before the end of general anesthesia. They reported that ondansetron is almost twice more effective than metoclopramide in decreasing the incidence of PONV. The study did not have a control group to be able to attribute the results to the drugs administered. Also, the drugs were administered before the end of general anesthesia and their prophylactic effects before the initiation of the surgical procedure were not evaluated. In the present study, the effects the administration of the two drugs before the induction of general anesthesia and 30 minutes before the end of procedure were compared with a control group. The best results were achieved when ondansetrone was given 30 minutes before the end of anesthesia. This is consistent with the results of Taheri's study (p< 0.001). On the other hand, There was no significant difference between the effects of these drugs when they were given before the surgery (p= 0.36). We also could not get better results by adminsteration of ondansetron before the induction of general anesthesia and this drug has significantly better effects when administered before the end of surgery (p=0.045). Early and rapid metabilization of the drug could be a probable reason for this result. Moreover, the highest incidence rate of nausea and vomiting which observed after full consciousness might be attributed to the fact that during this interval the effect of anesthetic agents have not worn away and the patient's reflexes are restored to normal. In the subsequent intervals (1-, 6- and 8-hour intervals after full consciousness) no significant differences were observed between the groups. This might be attributed to a decrease or at least plateau in the activity of mechanisms responsible for nausea and vomiting.

The results of the present study showed that the administration of a single dose of ondansetron (0.15 mg/kg) 30 minutes before the end of the surgical procedure has the best significant clinical effects. It can be concluded that ondansetrone is more effective than metoclopramide in prevention of PONV.

Table 1:

	Oa *	Ob *	Ma *	Mb *	C *	P *
Age	27.68±10.10	27.60±7.98	26.85±9.54	27.74±9.83	29.51±8.94	0.81
Gender (M/F)	27/8	27/8	33/2	27/8	29/6	0.26

Table 2:

Time / Group	Oa *	Ob *	Ma *	Mb *	C *	Total
At entry into the ward	0	2	3	7	6	18
Half an hour after full consciousness	1	6	7	10	18	42
One hour after full consciousness	1	3	7	3	6	20
Half an hour after expiry of the NPO period	1	5	9	1	5	21
Eight hours after regaining full consciousness	2	0	3	0	0	5
Twenty-four hours postoperatively.	0	0	0	0	0	0
Total	5	16	29	21	35	106

Legends:

Table 1: Demographic data of age and gender in different groups.

(Oa: A single dose of 0.15 mg/kg of ondansetron 30 minutes before the end of anesthesia; Ob: A single dose of 0.15 mg/kg of ondansetron 30 minutes before surgery; Ma: A single dose of 0.5 mg/kg of metoclopramide 30 minutes before the end of the surgical procedure; Mb: A single dose of 0.5 mg/kg of metoclopramide 30 minutes before surgery; C: control group; p: p value)

Table 2: postoperative nausea and vomiting at the six intervals.

(Oa: A single dose of 0.15 mg/kg of ondansetron 30 minutes before the end of anesthesia; Ob: A single dose of 0.15 mg/kg of ondansetron 30 minutes before surgery; Ma: A single dose of 0.5 mg/kg of metoclopramide 30 minutes before the end of the surgical procedure; Mb: A single dose of 0.5 mg/kg of metoclopramide 30 minutes before surgery; C: control group; p: p value)

REFERENCES

1. McCracken G, Houston P, Lefebvre G. Guideline for the management of postoperative nausea and vomiting. Journal of obstetrics and gynaecology Canada: JOGC= Journal d'obstetrique et gynecologie du Canada: JOGC 2008;30:600-7, 8-16.

2. Rüsch D, Eberhart L, Biedler A, Dethling J, Apfel CC. Prospective application of a simplified risk score to prevent postoperative nausea and vomiting. Canadian Journal of Anesthesia 2005;52:478-84.

3. Tramèr MR. Strategies for postoperative nausea and vomiting. Best Practice & Research Clinical Anaesthesiology 2004;18:693-701.

4. Biedler A, Wermelt J, Kunitz O, Müller A, Wilhelm W, Dethling J, et al. A risk adapted approach reduces the overall institutional incidence of postoperative nausea and vomiting. Canadian Journal of Anesthesia 2004;51:13-9.

5. Carlisle J, Stevenson CA. Drugs for preventing postoperative nausea and vomiting. The Cochrane Library 2006.

6. Henzi I, Walder B, Tramer M. Metoclopramide in the prevention of postoperative nausea and vomiting: a quantitative systematic review of randomized, placebo-controlled studies. British Journal of Anaesthesia 1999;83:761-71.

7. Talesh KT, Motamedi MHK, Kahnamouii S. Comparison of ondansetron and metoclopramide antiemetic prophylaxis in maxillofacial surgery patients. Oral Surgery, Oral Medicine, Oral Pathology, Oral Radiology, and Endodontology 2011;111:275-7.

8. Kim EJ, Ko JS, Kim CS, Lee SM, Choi DH. Combination of antiemetics for the prevention of postoperative nausea and vomiting in high-risk patients. Journal of Korean medical science 2007;22:878-82.

9. Diemunsch P, Conseiller C, Clyti N, Mamet J. Ondansetron compared with metoclopramide in the treatment of established postoperative nausea and vomiting. The French Ondansetron Study Group. British journal of anaesthesia 1997;79:322-6.

10. Krobbuaban B, Pitakpol S, Diregpoke S. Ondansetron vs. metoclopramide for the prevention of nausea and vomiting after gynecologic surgery. Medical journal of the Medical Association of Thailand 2008;91:669.

11. Sandhu T, Tanvatcharaphan P, Cheunjongkolkul V. Ondansetron versus metoclopramide in prophylaxis of nausea and vomiting for laparoscopic cholecystectomy: a prospective double-blind randomized study. Asian Journal of Surgery 2008;31:50-4.