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## Comparison of Hemodynamic Changes in Administration of Ondansetron and Metoclopramide to Preventing Post Operative Nausea and Vomiting after Strabism Surgery

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(Received 3 July 2010; Accepted 19 Sep 2010)

### Abstract

**Background:** The aim of the present study was to compare the hemodynamic changes of intravenous ondansetron and metoclopramide for prevention of post-operative nausea and vomiting in patients undergoing strabism surgery under general anesthesia.

**Methods:** This is a randomized double blind clinical trial performed on 96 patients with average age of 6-12y/o, ASA (American Society of Anesthesiologists) physical status I and II candidates for strabism surgery with general anesthesia between the years 2009 till July 2010. After the hospital's Ethic Committee approval, the study was conducted in Tabriz University of Medical Sciences, Tabriz, IRAN. The patients were randomized into two groups, ondansetron (n=48) and metoclopramide (n=48). In this study ondansetron 50mg/kg and metoclopramide 150mg/kg administered intravenously five minutes before induction of general anesthesia after routine monitoring. Systolic and diastolic blood pressure and heart rate were measured as hemodynamic variables in both groups. In recovery room Aldrete scoring system employed as the patients' discharge criteria. Incidence and severity of post-operative nausea and vomiting documented in recovery room and in different times in surgical ward by using a specified scoring system and getting information from patients and their caregivers.

**Results:** There were not significant differences between two groups in demographics, hemodynamic parameters and anesthesia length. There was not also significant difference about the incidence and severity of nausea and vomiting between two groups.

**Conclusion:** It is concluded that preoperative administration of both ondansetron and metoclopramide can decrease frequency and also intensity of post-operative nausea and vomiting without having significant difference and prominent complication.

*J Cardiovasc Thorac Res* 2010; Vol.2 (3): 29-33

**Keywords:** Ondansetron –Metoclopramide –Strabism surgery

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## Introduction

The most common and distressing symptom, which follows anesthesia and surgery is emesis. The consequences of post-operative nausea and vomiting (PONV) are physical, surgical and anesthetic complications for patients as well as financial implications for the hospitals and institutions. Sometimes nausea and vomiting may be more distressing especially after some surgeries such as strabism.<sup>1</sup> Strabismus surgery is the most common pediatric eye surgery and it occurs in 2-5% of the general population.<sup>2</sup> Patients having strabismus surgery, who are not given prophylaxis, are frequently exposed to increased risk (48-85%) of post-operative nausea and vomiting.<sup>3</sup> Metoclopramide the drug employed in the present study has been used for decades to prevent or treat PONV. Its antiemetic properties are primarily mediated through its anti dopaminergic action and it also probably has prokinetic properties.<sup>4,5</sup> In this study ondansetron the first serotonin antagonist is also used. Which is a serotonin 5-HT<sub>3</sub> receptor antagonist used mainly to treat nausea and vomiting. Its effects are thought to be on both peripheral and central nerves. One part of its action is to reduce the activity of the vagus nerve which is a nerve that activates vomiting center in the medulla oblongata and the other is blockage of serotonin receptors in the chemoreceptor trigger zone. It is reported that this drug is considerably more effective with fewer side effects (no extra pyramidal symptoms or sedation) compared with all previous antiemetics. It is noticeable that ondansetron quickly established a reputation as the most effective antiemetic for prevention of PONV.<sup>6,7</sup> The purpose of this study was to compare efficacy of ondansetron and metoclopramide in preventing post operative nausea and vomiting after strabismus surgery.

## Methods

This is a randomized double blind clinical trial performed in Tabriz University of medical sciences (Tabriz, Iran) after obtaining the hospital's Ethic

Committee approval and written informed parental consent. The study conducted over a period of one year from January 2009 to July 2010 at Nikocari ophthalmologic hospital. The patients categorized into two groups using online computerized software. In this study each group consisted of 48 patients, 6-12 years of age, ASA (American Society of Anesthesiologists) physical status I and II undergoing strabismus surgery. The patients received either metoclopramide 150µg.kg or ondansetron 50µg.kg by intravenous route slowly 5 minutes before induction of general anesthesia in a double blind fashion from coded ampoules (syringes). Characteristics of the patients kept concealed during and after surgery. In this study the patients did not receive any premedication and did not consume milk or solid foods at least 6 hours before induction of anesthesia. Inclusion criteria consisted of ASA I and II patients who were candidates for strabismus repair. The reason for not selecting patients younger than 6 years of age was their inability to state nausea and its severity. Exclusion criteria included the patients who received antiemetics during previous 24 hours. The patients suffering from liver, renal, gastrointestinal disorders and motion sickness were also excluded. It is noticeable that in the present study all of the patients were evaluated in pre-anesthetic clinic in pre-operative period. When the patients admitted to the operating room, after establishing an intravenous line and standard monitoring which documented patients' cardiac parameters and SPO<sub>2</sub> every 3 minutes, general anesthesia with unique technique and drugs induced. Drugs administered included midazolam (0.1mg/kg), thiopental of Na (3-5mg/kg) and atracurium (0.4mg/kg). Anesthesia maintained with 50% N<sub>2</sub>O in Oxygen and 1-1.5MAC of isoflurane. Extubation criteria (deep technique) was similar in both groups. By using Aldrete scoring system the patients discharged from recovery room, of course documenting PONV by specific scoring systems done with the help of one of the investigators not aware of the drug used in the operating room, as follows (Zero for not having nausea - 1, for mild nausea- 2, for moderate nausea and 3 for severe nausea). Vomiting evaluated as considering zero for the patients not experiencing vomiting, 1 for the little vomiting, 2 for vomiting

gastric contents and 3 for vomiting food particles. It is noticeable that in this study results reported in percent. After 0-2, 2-6 and 6-24 hours patients and their family corporated for reporting PONV in surgical ward. Investigator again blinded for the type of intervention also supervised the research. Use of rescue antiemetics in post-operative period was one of the other points that should be noticed. In this study data collection has done using the questionnaire. The collected qualitative data was analyzed by chi-square test and quantitative ones analyzed by student's t-test using SPSS software V.14.0. In this study  $p \leq 0.05$  was considered significant.

### Results

The results of this study revealed that both groups ondansetron group (O) and metoclopramide (M) were homogeneous in demographics data and there was no significant difference between two groups (Figures 1, 2).

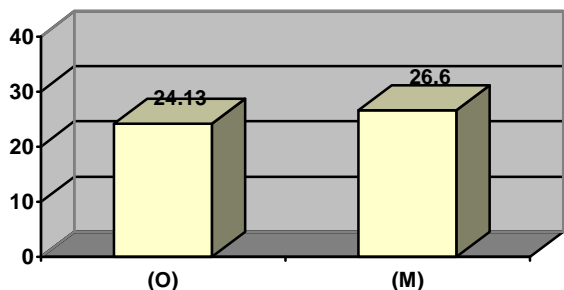


Fig 1- weight of the patients in kg

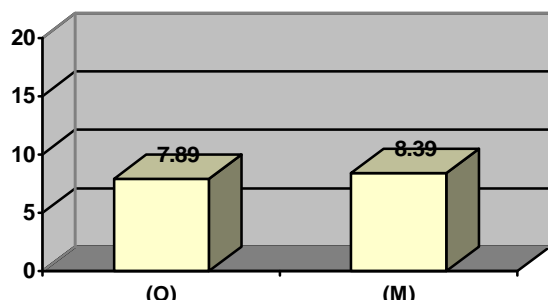


Fig 2- Age of the patients in years

From the point of physical status classification 90% of the patients were in ASA class I and only 10% were in class II. Form the point of changes in hemodynamic parameters including systolic blood pressure, diastolic blood pressure, pulse rate, saturation pressure of oxygen, no significant changes reported to be present between two groups after induction and during maintenance of anesthesia. P values were 0.33, 0.73, 0.64 and 0.15 respectively (Figures -3-4).

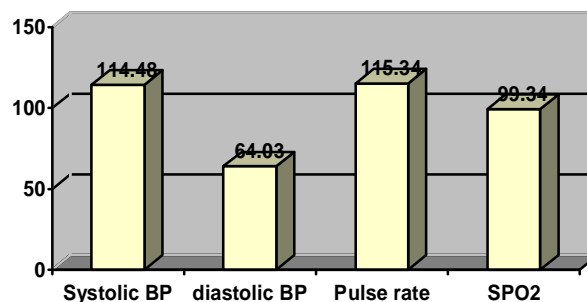


Fig 3- Mean of hemodynamic changes in ondansetron group

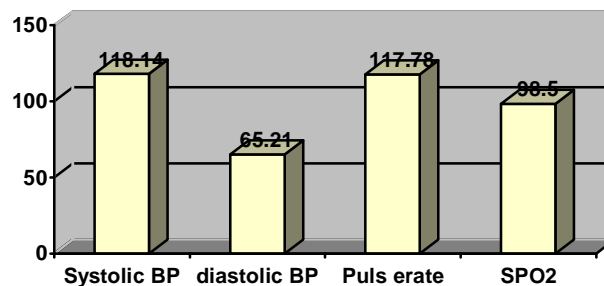
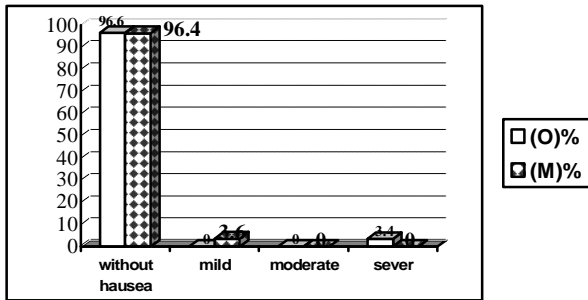


Fig 4 - Mean of hemodynamic changes in metoclopramide group

Estimation the duration of anesthesia was another factor which reported to be 37 and 35 minutes in ondansetron and metoclopramide groups respectively ( $p=0.56$ ). During post anesthesia care unit (PACU) stay, the presence of nausea must be evaluated. It is noticeable that there was not statistically reportable significant differences between two groups ( $p=0.43$ ). Vomiting was another factor that must be determined in PACU. There was not also significant differences about this factor between two groups ( $P=0.67$ ). After discharge from PACU the incidence of PONV must be reported 0-2, 2-6 and 6-24 hrs afterwards. During 0-2 hours stay in surgical ward, in ondansetron group 96.6%



of the patients didn't experience nausea, this measure was 96.4% about metoclopramide group. Incidence of mild nausea in metoclopramide group reported to be 3.6% greater than ondansetron group and sever nausea reported to be 3.4% greater in ondansetron group than metoclopramide during the mentioned period (p=0.36) (Figure.5).



**Fig 5-** Comparison the incidence of nausea in percent 0-2 hours afterwards in both groups

It is noticeable that in both groups nausea was not reported to be present 2-6 and 6-24hrs later. Vomiting was another factor should be evaluated as nausea. The results didn't show statistically significant differences between two groups in different periodically mentioned time intervals (p=0.43, p=0.19, p=0.16). Table-1 shows a comparative evaluation of vomiting sequela in ondansetron and metoclopramide groups. In this study there was not much differences between two groups from the point of rescue antiemetic drugs administration. It was 5 times in metoclopramide versus 3 times in ondansetron group using 1/2 Amp metoclopramide administered only once. Drug adverse effects such as dizziness, agitation, dry mouth, extrapyramidal symptoms, headache, restlessness, flushing, diarrhea or any other abnormal symptoms didn't reported.

**Table 1-** Comparative evaluation of vomiting sequelae in ondansetron and metoclopramide groups.

time	Classification and severity of vomiting	Ondansetron group	Metoclopramide group
0-2hrs	1. no vomiting	89.7%	75%
	2. little bit vomiting	6.9%	10.7%
	3. Vomiting with gastric contents	3.4%	10.7%
	4. Vomiting with food particles	0%	3.6%
(P=0.43)			
2-6hrs	1. no vomiting	96.6%	78.6%
	2. little bit vomiting	0%	7.1%
	3. Vomiting with gastric contents	3.4%	10.7%
	4. Vomiting with food particles	0%	3.6%
(P=0.19)			
6-24hrs	1. no vomiting	93.1%	89.3%
	2. little bit vomiting	0%	10.7%
	3. Vomiting with gastric contents	3.4%	0%
	4. Vomiting with food particles	3.4%	0%
(P=0.16)			

### Discussion

Treatment of poor alignment of the visual axis with amblyopia (strabismus) in children 1 to 6 years of age usually consists of surgery on the extraocular muscles. Three problems associated with strabismus are of particular interest for the anesthetist: the possible increased risk of malignant hyperthermia, the high incidence of post-operative nausea and vomiting (PONV) and the likelihood of an Oculo-Cardiac-Reflex (OCR). The incidence of nausea and vomiting after outpatient strabismus surgery varies from 48% to 85%. Van den Berg reported that after strabismus surgery 10% of the patients had early PONV and as many as 75% had a delayed incidence of PONV caused by the ocular-emetic reflex. Many regimens have been used in an attempt to control nausea and vomiting in these patients without prolonging recovery time. Intravenous administration of lidocaine (1.5mg/kg) before tracheal intubation reduces the incidence of PONV to 16% from 20%. Weir and colleagues have shown a significant decrease in the incidence and frequency (41%) of vomiting in the first 24 hours after strabismus surgery with the use of a propofol infusion and N2O technique. This incidence was



further reduced (24%) when opioids were avoided. Splinter and Rhine reduced the incidence of vomiting after strabismus surgery in children to 9% by using a combined low dose ondansetron (50µg/kg) regimen.<sup>3</sup> Many other studies were also planned to prevent PONV for example Polati and colleagues compared efficacy and safety of ondansetron and metoclopramide, and they found that ondansetron 4mg was more effective than metoclopramide 10mg.<sup>8</sup> Efficacy of ondansetron in comparison to metoclopramide has also be shown by Karen B. Domino.<sup>9</sup> Sadhasivam S. investigated prophylactic and effective dose of ondansetron in preventing of PONV following pediatric strabismus surgery which reported to be 75 and 150µg/kg.<sup>10</sup> Nasreen laiq and colleagues showed that in children undergoing strabismus repair ondansetron was an effective drug in preventing PONV.<sup>11</sup> According to the results of previously mentioned studies results of the present study in which ondansetron 50µg/kg and metoclopramide 150µg/kg were employed showed that ondansetron solely and in combination with metoclopramide could reduce the incidence of PONV after strabismus repair. In this study none of these drugs caused hemodynamic changes and none of them resulted in feeling of dizziness, agitation, dry mouth, extrapyramidal symptoms and headache. Rescue antiemetic drugs injected 5 times in metoclopramide group versus 3 times in ondansetron group using 1/2 Amp metoclopramide administered only once. In conclusion the researchers of this study have demonstrated that both of these drugs could be used safely before induction of general anesthesia for prophylaxis of PONV in strabismus repair. Acknowledgement: The present article is the result of a research was approved to be executed by the Deputy of Research of Tabriz Medical Sciences University. Tabriz, IRAN. It is the researchers' duty to appreciate for their so much support, attention and regard.

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