Evaluation of the Effect of Intravenous Ondansetron versus Placebo before Anesthesia on Vomiting after Endoscopy and Colonoscopy Procedures

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Abstract

Background: Vomiting is a common complication after endoscopic procedures in children. Different medications could be administered to control vomiting after endoscopy. The goal of this study is to evaluate anti-emetic effects of ondansetron in children who undergo endoscopic procedures.

Methods: In this clinical randomized trial, 198 children (103 female/95 male) were randomly assigned into one of the following two studied groups. Case group (G1): Fentanyl 1 µg/kg + propofol 2.5 mg/kg + ondansetron 0.15 mg/kg and control group (G2): Fentanyl 1 µg/kg + propofol 2.5 mg/kg + 2 cc normal saline.

Results: The mean age was 6.3 ± 3.5 years (6.2 ± 3.6 years in G1 vs. 6.4 ± 3.5 years in G2). The most common cause of endoscopy procedure in both groups was hematochezia. Vomiting, recovery time, Paediatric Anesthesia Emergence Delirium (PAED), and Aldrete scores were compared. Rate of vomiting after recovery and Aldrete score were significantly different between the two groups.

Conclusions: Ondansetron is effective in controlling vomiting after colonoscopy and upper gastrointestinal endoscopic procedures. Also, patients in intervention group experienced better recovery time.

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Introduction

Endoscopic procedures are becoming more frequent procedure for gastrointestinal (GI) tract evaluation (1) which are mostly performed outside the operating room to reduce cost and dis-availability (2). Although in some cases general anesthesia is recommended, intravenous sedation is considered as a safe and effective method for endoscopic procedure in children (3). Ketamine is an N-methyl-D-aspartate receptor antagonist. As it has analgesic and anti-hyperalgesic effects, it could be used as sedation medication for endoscopic procedures in children (4). Midazolam is a short-acting benzodiazepine which is used as a sedative agent for endoscopic procedures in children (1). Thiopental is a short-acting barbiturate general anesthetic. In out room endoscopic procedures, it is used for analgesic and anesthetic purposes (5).

Vomiting is a common complication after administration of these medications and endoscopic procedures. Adding antiemetic agents will help reduce the rate of post-procedural vomiting (6). Patients at risk of developing post-operative nausea and vomiting (PONV) have to receive prophylactic doses of antiemetic drugs. One of the best methods for the prevention of PONV is to preemptively or preventively administrate prophylactic antiemetic drugs (7,8). These drugs are, more often than not, expensive and bring about certain adverse effects, hence the fact that the chosen drug must have minimal side effects and the ability to reduce nausea and vomiting (9,10). Ondansetron is a 5-hydroxytryptamine receptor (5-HT) antagonist with confirmed antinausea and antivomiting effects which does not result in sedation, euphoria, restlessness, dryness of mouth, tachycardia, mydriasis, and urine retention, and does not have extrapyramidal side effects (11). It is not commonly used in endoscopic procedures in children. Hence, we designed this study to evaluate the antiemetic effects of ondansetron in children who undergo endoscopic procedures.

Materials and Methods

This randomized clinical trial (RCT) was conducted on patients who referred to Children Medical Center (affiliated hospital of Tehran University of Medical

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Table 1. Demographic characteristics and endoscopy-related factors in two groups

Variables	Ondansetron group	Control group	P-value
Age (years)	6.2 ± 3.6	6.4 ± 3.5	0.732
Sex (%)			
Male	46 (46.9)	49 (49)	0.900
Female	52 (53)	51 (51)	
Procedure (%)			
Upper GI endoscopy	68 (69.3)	29 (29)	
Colonoscopy	30 (31.6)	71 (71)	0.125
Vomiting after procedure (%)	3 (3)	17 (17)	0.001
Recovery time	32.0 ± 6.8	35.7 ± 11.8	0.090
PAED score	18.4 ± 1.2	18.1 ± 1.5	0.100
Aldrete score	9.40 ± 0.06	9.2 ± 0.8	0.020

PAED: Paediatric Anesthesia Emergence Delirium; GI: Gastrointestinal

Sciences) in the first 6 months of 2016. A total of 198 patients (mean age: 6.3 ± 3.5 years), of American Society of Anesthesiologists (ASA) Class I or II, scheduled for elective gynecologic laparoscopy with general anesthesia were enrolled in the study. Exclusion criteria included congenital disorders, allergy to administered medications, infection of the larynx, behavioral disorders, and psychological disorders. Moreover, patients who used hypnotic medications before entry to endoscopic room were excluded from the study. An expert technician, by means of block randomization, allocated cases into two groups: Group 1: fentanyl 1 µg/kg + propofol 2.5 mg/kg + ondansetron 0.15 mg/kg and Group 2: fentanyl 1 µg/kg + propofol 2.5 mg/kg + 2 cc normal saline.

Neither the physician nor the patients were blinded. Cardiopulmonary monitoring was continuous throughout the procedure. All parents were asked to fill informed consent forms before study although the study had been approved by the local Ethics Committee. After endoscopic procedure, patients were admitted in recovery room, and vomiting, Paediatric Anesthesia Emergence Delirium (PAED), and Aldrete scores were recorded by a blind technician.

Data are expressed as mean ± standard deviation, number, proportion, or percentage. Statistical analysis was performed by SPSS software (version 13, SPSS Inc., Chicago, IL, USA). The frequencies of vomiting and nausea and the proportions of ASA class were compared using the chi-square test or Fisher's exact test with Bonferroni correction. One-way analysis of variance was used to compare the age, weight, duration of surgery, and fentanyl consumption among the six groups. $P < 0.050$ was considered statistically significant.

Results

In this RCT, 200 children who were candidates for colonoscopy and upper GI endoscopic procedures were randomly assigned into one of the two studied groups. Two parents of children in ondansetron group withdrew from the study. And, 198 individuals (103 female/95 male) remained in the study, 98 cases in case group (G1) (fentanyl 1 µg/kg + propofol 2.5 mg/kg + ondansetron 0.15 mg/kg) and 100 cases in control group (G2) (fentanyl 1 µg/kg + propofol 2.5 mg/kg + 2 cc normal saline). The mean age was 6.3 ± 3.5 years (6.2 ± 3.6 years in G1 vs. 6.4 ± 3.5 years in G2).

Rate of vomiting after recovery and Aldrete score were significantly different between the two groups ($P < 0.001$) (Table 1). In addition, the two groups had a statistically significant difference in recovery time and Aldrete score variables ($P = 0.090$ and $P = 0.020$, respectively). Regarding other investigated variables including age, sex, type of used procedures, and PAED score, there was no significant difference between cases and controls. Also, we have compared the underlying disease in the two groups to check the uniformity of the conditions and comparability of the results (Table 2).

Table 2. Underlying disease in the two studied groups

Type of disease	Groups		Total
	Cases	Controls	
Achalasia	5	9	14
Chronic abdominal pain	32	26	58
Chronic vomiting and nausea	2	1	3
FTT	1	0	1
GERD	3	1	4
IBD	2	6	8
Hematemesis	13	11	24
Caustic ingestion and foreign bodies	2	2	4
Hematochezia	37	41	78
R/O celiac	1	3	4
Esophageal	1	0	1
Total	98	100	198

GERD: Gastroesophageal reflux disease; IBD: Inflammatory bowel disease; FTT: Failure to thrive

Based on the obtained results of the present study, there was no statistical difference between the two groups.

Discussion

The result of the current study showed that ondansetron is effective in reducing post-endoscopic vomiting (3 vs. 17), and recovery time was significantly lower in ondansetron group compared to control group (32 vs. 35, respectively) (P = 0.090). In a previous study, Denewa et al. added oral ondansetron to the routine management of dehydration and reported lesser number of vomiting in ondansetron group. In Freedman et al's. (6) study, 215 children who referred due to gastroenteritis were randomly assigned to ondansetron and control groups. Their findings showed that vomiting rate was 14% in ondansetron group and 35% in control group (P = 0.010) while the mean duration of hospitalization was significantly lower in ondansetron group (6). Totally 145 children with vomiting during the last year were randomly assigned to ondansetron or placebo groups. The rate of vomiting was 0-2 in ondansetron and 0-7 in placebo groups (7). Stork et al. evaluated 166 children who had vomiting at least three times during 24 hours and assigned them to normal saline, dexamethasone, and ondansetron groups. The results showed that, after administration of the drugs, the rate of vomiting was significantly lower in ondansetron group (P = 0.020).

By means of endoscopic procedures, diagnostic and therapeutic goals for GI evaluation purposes become possible. Medications which are used for sedation before endoscopic procedures have side effects such as nausea, vomiting, and longer hospitalization. Ondansetron is a 5-HT subtype 3 receptor antagonist which has antiemetic effects (8). It is tolerated well and is effective in controlling nausea and vomiting with less adverse effects. Other antiemetic medications such as promethazine, prochlorperazine, and metoclopramide have several adverse effects such as extrapyramidal reactions, lethargy, respiratory depression, and cardiac dysrhythmias.

Our results showed that it is effective in controlling post-endoscopic vomiting. As a conclusion, ondansetron is effective in controlling vomiting after endoscopic procedures.

Conflict of Interests

Authors have no conflict of interests.

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