

Original Article

**ROLE OF ONDANSETRON IN DECREASING VOMITING AND
DURATION OF HOSPITALIZATION IN CHILDREN AGED 6 MONTHS
TO 14 YEARS**

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Abstract

Background: Treatment of vomiting in acute gastroenteritis can increase the rate of successful oral rehydration therapy (ORT) and lower the need for intravenous fluid administration. The aim of this

study was to investigate the role of ondansetron in decreasing vomiting and duration of hospitalization in 6 month to 14 year old children.

Methods: In 2010, a double blind randomized controlled trial was carried out based on 100 children between six months and 14 years old with acute gastroenteritis and vomiting. Each child satisfied the inclusion criteria and agreed to participate in the study after receiving a complete explanation about the study. Participants were randomly divided into two groups to either receive intravenous ondansetron (single dose of 0.15mg/kg) or an intravenous placebo (5% dextrose water). The duration of hospitalization and number of vomiting episodes were compared between the two groups 4 hours after treatment. Data were analyzed using SPSS16 software.

Results: Duration of hospitalization was 38.30±18.62 hours in those receiving ondansetron and 45.10±25.79 hours in the control group. There was no statistically significant difference between the two groups (P=0.352). The number of vomiting episodes was 0.06±0.23 in the ondansetron group and 0.58±0.90 in the control group. This difference is statistically significant (P=0.000). No adverse effects were seen in either group relating to the drug.

Conclusions: This study demonstrated that intravenous ondansetron can effectively reduce the frequency of vomiting associated with acute gastroenteritis. We recommend administration of ondansetron for management of children with acute gastroenteritis but further studies with a larger sample size would be beneficial.

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Keywords: Ondansetron, acute gastroenteritis; vomiting; oral rehydration therapy (ORT)

INTRODUCTION

Annually, acute gastroenteritis causes 150,000 to 170,000 hospitalizations and accounts for about 13% of all hospitalizations among children less than 5 years old in the United States (1). The associated vomiting may cause physicians to stop oral rehydration therapy (ORT) (2). Treatment of vomiting can thus increase the rate of successful ORT and lower the need for intravenous fluid administration (3).

Ondansetron is thought to reduce frequency of vomiting and reduce the need for intravenous fluid and hospitalizations (4). Studies on patients who failed to respond to ORT show ondansetron to be effective in reducing the risk of persistent vomiting and hospital admission (5). Another randomized, double blind, placebo-controlled trial suggested that ondansetron is effective in reducing the frequency of vomiting in patients with gastroenteritis aged 5 months to 8 years old in emergency departments at

both 8 and 24 hours after treatment (6). However, it should be noted that these findings result from randomized control trials in emergency department patients and thus cannot be accurately generalized to the outpatient setting (4). Also, some recent reviews have suggested that evidence for the effectiveness of ondansetron in reducing the number of episodes of vomiting is limited and that ondansetron may increase the incidence of diarrhea due to fluid and toxin retention (7). Despite a number of clinical trials showing the effectiveness of ondansetron in decreasing vomiting (8), in reducing the rate of fluid administration and hospital admission (9) and in preventing emesis (10), other studies did not find any significant difference in the need for hospitalization or return to emergency department visits in comparison with placebo or no intervention groups (11).

The aim of this study was to investigate the duration of hospitalization and frequency of vomiting in children with acute

gastroenteritis attending the emergency department in the pediatric hospital of Bandarabbas.

MATERIALS AND METHODS

This study is a pediatrics residency thesis and is approved by the thesis committee of the faculty of medicine in Hormozgan University of Medical Sciences (HUMS). The study was conducted in the only pediatric hospital of Bandarabbas, which is the capital city of Hormozgan Province in southern Iran.

In 2010, a double-blind randomized controlled trial was conducted based on 100 children aged six months to 14 years who had agreed to participate in the study after receiving a complete explanation about the study. The participants were randomly divided into two groups to either receive intravenous ondansetron (single dose of 0.15mg/kg) or an intravenous placebo (5% dextrose water).

Inclusion criteria were children of age six months to 14 years who attended the emergency department with acute gastroenteritis and vomiting (having had symptoms for less than 48 hours) and in whom vomiting did not stop after 4 hours of

The experimental diet and the analyses are illustrated in table 1 and 2. AD and TD of all formulations was determined in a rat bioassay. AD and TD in casein-diet rats 108 children were invited to participate in the study, of which 100 (92.59%) were included. Of those children who participated in the study, 60 (60%) were male and 40 (40%) were female. The mean age of participants was 20.66 ± 17.91 months. The mean number of vomiting episodes was

oral or intravenous fluid therapy. Exclusion criteria were previous history of hypersensitivity to ondansetron, bloody vomiting, previous history of abdominal surgery, toxicity due to drugs or chemical substances and other diseases such as meningitis, sepsis, pancreatitis and testis torsion.

Data on sex, weight, age, nutrition by breast or formula milk, history of associated diseases, past medical history and history of hypersensitivity to ondansetron were recorded in a checklist.

Dehydration was classified according to World Health Organization standards. Patients were evaluated 4 hours before and 4 hours after treatment. Nurses randomly divided the patients into either the control or intervention group. The number of vomiting episodes and duration of hospitalization were recorded.

With the aim of comparing hospitalization duration between groups, data were analyzed with SPSS16 to obtain descriptive statistics (mean, standard deviation and frequency) and to carry out chi-square and independent samples T-tests.

RESULTS

3.15 ± 1.49 per child at the beginning of the study.

27 (27%) children had mild dehydration, 71 (71%) had moderate dehydration and 2 (2%) had severe dehydration. Eighty two (82%) had received breast milk nutrition and 18 (18%) had received formula nutrition. 72 (72%) were living in cities and 28 (28%) were living in rural areas. Table 1 summarizes the distribution of these

variables between the ondansetron and control groups.

Duration of hospitalization was 38.30 ± 18.62 hours in those receiving ondansetron and 45.10 ± 25.79 hours in the control group. There was no statistically significant difference between the two groups ($P=0.352$). The number of vomiting episodes was 0.06 ± 0.23 in the ondansetron group and 0.58 ± 0.90 in the control group,

yielding a statistically significant difference in mean number of episodes ($P=0.000$). No adverse effects were seen in either group relating to use of the drug.

Table 2 compares the number of vomiting episodes between the two groups and the table 3 compares the number of vomiting episodes and duration of hospitalization between two groups when subdivided according to demographic variables.

Table 1. Comparison of dehydration, nutrition, place of residence and type of diarrhea between ondansetron and control groups

		Ondansetron	Control	Total
Dehydration	Mild	14 (28%)	13 (26%)	27 (27%)
	Moderate	35 (70%)	36 (72%)	71 (71%)
	Severe	1 (2%)	1 (2%)	2 (2%)
Nutrition	Milk	42 (84%)	40 (80%)	82 (82%)
	Formula	8 (16%)	10 (20%)	18 (18%)
Place of residence	Urban	33 (66%)	39 (78%)	72 (72%)
	Rural	17 (34%)	11 (22%)	28 (28%)
Type of diarrhea	Watery diarrhea	41 (82%)	41 (82%)	82 (82%)
	Loose stool	9 (18%)	9 (18%)	18 (18%)

Table 2. Comparison of the number of vomiting episodes between two groups

		Ondansetron	Control	Total	P Value
Number of vomiting episodes	0	7 (94%)	32 (64%)	79 (79%)	0.002
	1	3 (6%)	10 (20%)	13 (13%)	
	2	0 (0%)	5 (10%)	5 (5%)	
	3	0 (0%)	3 (6%)	3 (3%)	
Total		50 (100%)	50 (100%)	100 (100%)	

Table 3. Comparison of duration of hospitalization and mean vomiting episodes 4 hours after treatment according to demographic factors between two groups

			Duration of hospitalization (hours)			Mean vomiting episodes			
			Number	Mean	SD	P value	Mean	SD	P Value
Sex	Male	Ondansetron	34	39.32	18.86	0.399	0.058	0.23	0.001
		Control	26	43.92	23.04		0.576	0.80	
	Female	Ondansetron	16	36.12	18.51	0.218	0.062	0.25	0.053
		Control	24	46.37	28.93		0.583	1.01	
Age	<1 years	Ondansetron	22	36.90	19.35	0.279	0.090	0.29	0.014
		Control	23	44.21	24.83		0.521	0.73	
	1-2 years	Ondansetron	20	37.95	16.25	0.266	0.50	0.22	0.013
		Control	19	46.63	30.07		0.684	1.05	
	>2 years	Ondansetron	8	43	23.56	0.928	0	0	0.207
		Control	8	43	19.60		0.5	1.06	
Nutrition	Milk	Ondansetron	42	38.83	18.62	0.072	0.047	0.21	0
		Control	40	48.07	26.74		0.6	0.9	
	Formula	Ondansetron	8	35.50	19.61	0.799	0.125	0.35	0.317

DISCUSSION

This study demonstrated that intravenous ondansetron can effectively reduce the frequency of vomiting associated with acute gastroenteritis. Freedman et al. reported similar results, and showed that a single dose of ondansetron can reduce vomiting in acute gastroenteritis patients (12) to the extent that the majority of patients in their study ceased vomiting after treatment with ondansetron. In the present study 47 (94%) children reported no further episode of vomiting following the dose of ondansetron

and the other 3 children reported only 3 further episodes of vomiting.

However, Strok et al. found no significant difference in the number of vomiting episodes in the ondansetron, dexametasone or normal saline groups (13). In a meta-analysis in 2006, despite an increase in the chance of relief from vomiting following the use of ondansetron, routine use of ondansetron was not recommended for acute gastroenteritis (14).

Alhashimi et al. reported a small number of clinical trials suggesting ondansetron was effective in decreasing the number of vomiting episodes in comparison to the

placebo (7). These trials also found no significant difference in the duration of hospitalization.

CONCLUSION

Our results show a significant difference in the number of vomiting episodes after treatment with ondansetron in comparison with the placebo, in acute gastroenteritis in children between 6 months and 14 years old. We therefore recommend administration of ondansetron for management of children with acute gastroenteritis, but further studies with a larger sample size would be beneficial. Other factors, such as emergency visit numbers and tolerance of oral rehydration therapy, should be considered in future studies.

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