Original Article

Effect of Injection Ondansetron in Gastroenteritis

To Study the Efficacy of Intravenous Ondansetron on Cessation of Vomiting in 1 to 14 Years Old Children with Acute Gastroenteritis to Reduce Length of Hospital Stay

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ABSTRACT

Objective: To determine the efficacy of intravenous ondansetron on stoppage of vomiting in children having acute gastroenteritis to reduce hospital stay.

Study Design: Cross sectional study

Place and Duration of Study: This study was conducted at the Pediatric unit Mardan Medical Complex, Mardan from March 2019 to August 2019.

Materials and Methods: Study suggests intravenous ondansetron for children with acute gastroenteritis having uncontrolled vomiting. 390 patients, aged 1 to 14 years fulfilling the inclusion criteria were included, and randomly grouped. One received intravenous ondansetron, other received placebo. Inclusion criteria were the diagnosis of acute gastroenteritis and the absence of other diseases or allergies to drugs. Ondansetron was given intravenously at a dose of (0.15 mg/kg)(1); normal saline intravenously were given to placebo group. Data were collected and analyzed in SPSS20.

Results: After drug administration 184 out of 196 patients(93.9%)in the ondansetron group completely ceases vomiting(mean :1.0612 /sd 0.24036/ p value <0.001) and were discharge with a hospital stay of less than 4-6 hrs as compared to placebo group where only 9 patients out of 185(4.6%) have stopped vomiting (mean 1.9536 / SD. 21088).

Conclusion: We have concluded that intravenous ondansetron is safe for children to control vomiting acute gastroenteritis. This will result in complete cessation of vomiting that will decrease patients stay in hospital,therefore decreasing the cost of treatment.

Key Words: Acute gastroenteritis, vomiting, ondansetron, hospital stay

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INTRODUCTION

Acute gastroenteritis accounts for significant mortality and morbidity in children in developing countries. vomiting in acute gastroenteritis is a major concern for the clinicians as it results in failure of oral rehydration therapy .resultantly there will be promising increase in use of intravenous rehydration and lengthy stay of patients in hospital.[2,3,4]

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Defined as inflammation of gastrointestinal tract manifesting as increase in stool frequency (three or more watery stools),vomiting ,fever, lasting less than 2 weeks.[5]

It is usually a self limited disease that does not require any treatment.

The treatment modalities focuses on correction of electrolytes and rehydration that is achieved with oral rehydration solution or intravenous rehydration depending upon the hydration status of patients[6,7]. As Vomiting limits success of oral rehydration therapy, antiemetics are commonly prescribed to cope with,[9] nowadays promethazine, prochlorperazine, and metoclopramide are less commonly prescribed as they are associated with serious side effects[10].

Previous studies have shown the efficacy of ondansetron to prevent vomiting in acute gastroenteritis. Ondansetronexerts its antagonistic effect on serotonin 5-HT3) receptor, used primarily for prevention of vomiting associated with chemotherapy and after surgery.[11]

It has been used for vomiting in hyperemesis gravidarum.[12] Bydecreasing episodes ofvomiting[13], patient will easily tolerate oral fluids, this will in turn minimize the need for intravenous fluids[7,14-16].

According to FDA, ondasetron is associated with QT prolongation and other abnormal heart rhythms.[7,8]

Recently ondansetron has been studied that showed a promising result in controlling vomiting in patients having acute gastroenteritis, it also causes an increased incidence of diarrhea.[17]

MATERIALS AND METHODS

It was a cross sectional study conducted at the Pediatric unit Mardan Medical Complex, Mardan from March 2019 to august 2019. The study was approved by ethical committee. After taking written consent from the parents. Patients 1 to 14 years, diagnosed as a case of acute gastroenteritis presented with three or more episodes of vomiting in 24 hours were included. Children who take any medication for vomiting or diarrhea prior to admission, children with renal compromise ,any liver pathology, patients who were severely dehydrated defined by a WHO scale for dehydration[18], previous adverse reaction to ondansetron were excluded from the study[19].

Height and weight of the patients were recorded by the nursing staff. Hydration status was classified by WHO scale for dehydration[18]. Enrolled children were grouped on random basis, one received ondansetron, other received placebo. Blood was taken for baseline investigations. one group of patients were given ondansetron intravenously at a dose 0.15 mg/kg over 2 min, the other group were given placebo (normal saline) intravenously in equal amount to ondansetron. Patients were assessed for cessation of vomiting, secondarily length of hospital stay was documented. Vomiting is defined as a forceful expulsion of stomach contents through mouth. Descriptive statistics for age, gender were documented in the form of mean, standard deviation, percentages. To compare results of both groups cross tabulations, bar charts and chi-square test were used. SPSS 20 was used for the analysis of data. The P-value of <0.05 was considered as statistically significant.

RESULTS

Three hundred and ninety patients were enrolled for the study and were randomly assigned to two groups, one group received intravenous ondansetron and the other group received placebo.

Mean age was 2.8 years (sd:1.25).females were 52.1% whereas males were 47.9%.

There were no significant differences in baseline characteristics including demographics and clinical presentation. After drug administration 184 out of 196 patients(93.9%)in the ondansetron group completely ceases vomiting(mean :1.0612 /sd 0.24036/ p value <0.001) and were discharge with a hospital stay of less than 4-6 hrs as compared to placebo group where only 9 patients out of 185(4.6%) have stopped vomiting (mean 1.9536 / SD .21088).

No adverse effects were noted.

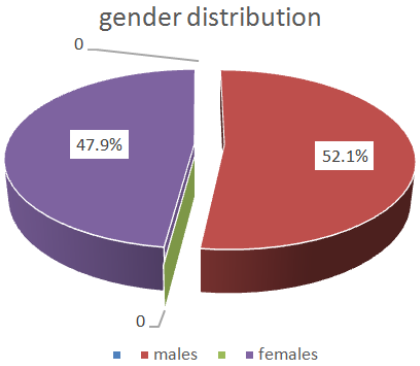

Figure No.1: Gender Distribution

Table No.1: Effect of intravenous ondansetron on cessation of vomiting

	drug	No.of patients	Mean	Std. Deviation	Std. Error Mean
Length of hospital stay	ondansetron	196	1.0612	.24036	.01717
	placebo	194	1.9536	.21088	.01514

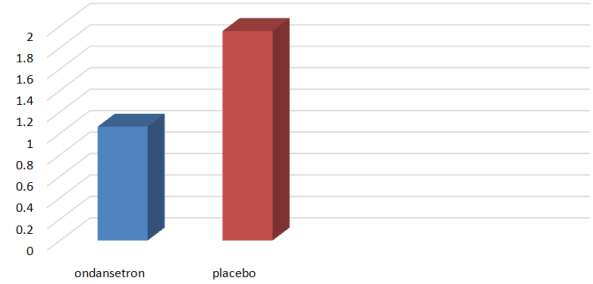

Figure No.2: Mean values for ondansetron and placebo on cessation of vomiting

Following figure shows the effect of intravenous ondansetron on cessation of vomiting .184 out of 196 Patients who have given intravenous ondansetron responded and there was complete cessation of vomiting as compared to the placebo group where only 10 patients have cessation of vomiting.

This figure showing relationship between hospital stay and drug. 184 out of 196 patients given ondansetron have stayed in the hospital for less than 4-6 hours while the patients belonging to placebo group or those who are not given the specified drug only 9 patients have hospital stay less than 4-6 hours ,remaining 185 stayed for longer ,more than 4-6 hours.

This shows that the drug is effective as it decreases the patient's stay at the hospital as a result of decreasing the vomiting episodes.

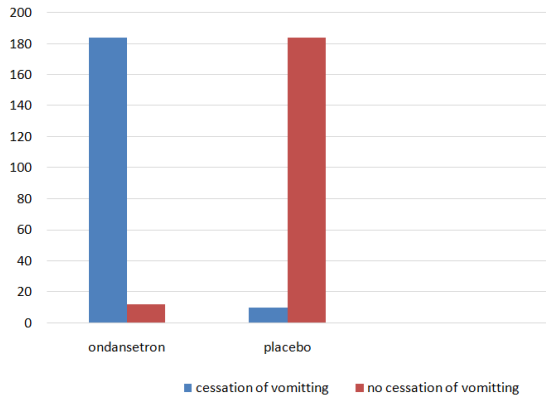

Figure No.3: Vomitting ratio

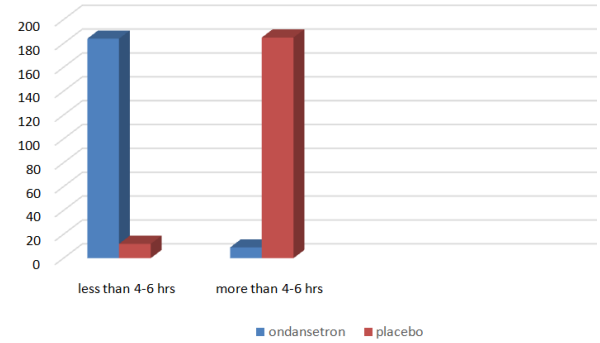

Figure No.4: Effect of drug on hospital stay

According to the given data set figure shows the effect of intravenous ondansetron on different age groups. The group 2 (4-6 years) and group 3 (7-9 years) have less effect of the drug whereas the group 1 (1-3 years), group 4 (10-12 years) and group 5 (13-14 years) showing the effect of ondansetron drug.

This might be because of the sample size as the trial is uncontrolled randomized trial.

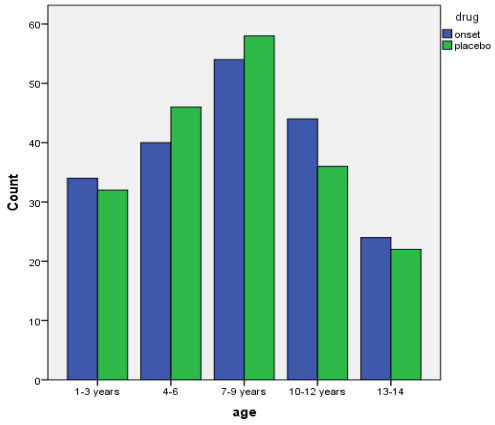

Figure No.5: Relation of age group with drug.

This figure shows the relation of age groups with the drug. Green bars show the placebo group while the blue bars show the ondansetron group.

H0 : No association between hospital stay and drug utilized

H1: There is association between hospital stay and drug

P-Value (.001) was statistically significant for effect intravenous ondansetron on length of hospital stay.

Table No.2: Chi-Square Tests

	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	310.601[a]	1	.000		
Continuity Correction	307.041	1	.000		
Likelihood Ratio	377.480	1	.000		
Linear-by-Linear Association	309.804	1	.000		

P-Value (.012) was statistically significant for effect of intravenous ondansetron on the cessation of vomitting.

Table No.3: Chi-Square Tests

	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	306.998[a]	1	.000		
Continuity Correction[b]	303.460	1	.000		
Likelihood Ratio	371.577	1	.000		
Linear-by-Linear Association	306.211	1	.000		
N of Valid Cases	390				

DISCUSSION

We have found that intravenous ondansetron results in cessation of vomiting and consequently the length of hospital stay in children as compared to placebo.

We have enrolled and investigated 390 patients aged 1-14 years admitted to pediatric unit MTI MMC Mardan diagnosed as acute gastroenteritis having with vomiting. Patients with severe dehydration or allergy to rondansetron were excluded. Also patients with comorbid conditions were excluded as they may have had effects on the results of the study

Intravenous ondansetron given at a dose of 0.15mg/kg results in cessation of vomiting in (93.9%) of participants in comparison to (4.6%) of placebo ,and resultantly the hospital stay in pediatric ward.

P-value (.001) was statistically significant for effect intravenous ondansetron on length of hospital stay and cessation of vomitting.

There is no evidence of cardiovascular events,nor any other adverse effects observed .

Previous studies shows effect of ondansetron on cessation of vomiting that is consistent with our study ,but instead of using oral ondansetron we preferred

intravenous route as younger children are not comfortable to swallow the oral form.[9]

Our study demonstrates clinical benefits of intravenous ondansetron for cessation of vomiting and consequently hospital stay in children with acute gastroenteritis

CONCLUSION

We have concluded that intravenous ondansetron is safe for children to control vomiting acute gastroenteritis. This will result in complete cessation of vomiting that will decrease patients stay in hospital,therefore decreasing the cost of treatment.

Author's Contribution:

Concept & Design of Study:	Nafees Khan
Drafting:	Shah Muhammad Khan Jadoon, Muhammad Fazil, Sehrish Gul
Data Analysis:	Muhammad Qasim Khan, Saqib Saeed
Revisiting Critically:	Nafees Khan
Final Approval of version:	Nafees Khan

Conflict of Interest: The study has no conflict of interest to declare by any author.

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