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Comparison of the efficacy of intravenous B6, intravenous ondansetron, and venous rehydration on prevention of vomiting in children suffering from gastroenteritis causing mild to moderate dehydration referring Hajar Hospital, Shahrekord

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ABSTRACT

Background: This study is to compare efficacy of intravenous (IV) B6, IV ondansetron, and venous rehydration on prevention of vomiting in children suffering from gastroenteritis causing mild to moderate dehydration. Methods: In this study, 105 1- to 5-year-old children assigned to three groups of 35 each were enrolled. Group 1 was administered with IV B6, group 2 with IV ondansetron, and group 3 only venous rehydration and no antiemetic drug was used. The data were gathered observationally through questionnaire and analyzed using chi-square, t test, and ANOVA. Results: Mean age of participants was 1.99 ± 1.33 years (P > 0.05). 44.8% of the participants were girl (P > 0.05). Overall hospitalization duration was from 2 to 12 (mean: 4.39 ± 1.87) days, with no significant difference among three groups (P>0.05). Frequency of vomiting in ondansetron group was significantly lower during the first 4 days of treatment compared to other two groups (P < 0.05). Conclusions: Although no significant difference in hospitalization duration was observed among the groups, the mean duration was different among the groups. The decrease in vomiting severity in ondansetron group exhibited a significant difference from other groups.

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INTRODUCTION

Gastroenteritis is one of the most prevalent reasons for children's referring treatment centers and also the most important cause of vomiting in children. Gastroenteritis is referred to gastrointestinal infections developed by bacterial, viral, and parasitic pathogens. Many of these infections are transmitted through food. The most prevalent manifestations are diarrhea and vomiting, which may be accompanied with systemic manifestations, such as abdominal pain and fever. Gastroenteritis is referred to a variety of infectious reasons for diarrhea [1]. Gastroenteritis prevalence is directly associated with health level and community development. The main gastroenteritis risk factor is environmental contamination and the rate of contact with microorganism. Other risk factors include early ages, immunodeficiency, measles, malnutrition, and lack of exclusive breastfeeding [2]. Lack of micronutrients such as vitamin A and zinc exacerbates gastroenteritis [3]. What are the most manifestations of gastroenteritis depends on its pathogen; in addition, the disease complications are likely to occur. Of these complications, dehydration and electrolyte imbalance could be mentioned. Sometimes, these complications, if left untreated, could be fatal. The majority of these complications could be prevented through managing patient's vomiting [1].

Acute gastroenteritis with 1.5 billion attacks per year is a key reason for mortalities in the world and is estimated to cause the death of 1.5-2.5 million under five-year-old children annually. Although total mortality due to diarrhea is still high, but it has decreased compared to its rate in 1980-1990. For example, estimate of annual mortalities was five million cases in 1982 and three million cases in 1992. The most important cause of decrease in mortalities is oral rehydration solution [3].

The general guidelines for acute gastroenteritis treatment in children include oral rehydration therapy, enteral nutrition, regime selection, zinc complement, and other treatments, such as probiotics.

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The main target in acute gastroenteritis treatment is oral rehydration in which nutrition is done through fluids, but zinc and probiotic products could be conductive, as well [1]. In contrast to adults, children are highly vulnerable to dehydration and the fluids should be compensated as soon as possible, for example within 4-6 hours, if possible. A variety of methods has been offered to improve oral tolerance in these children; for example, some suggest that small volume fluids in short intervals or cold fluids be used and some others prescribe a single dose of ondansetron. As vomiting is a fundamental component of viral gastroenteritis in children, its association with diarrhea causes dehydration-associated complications; therefore, different treatments have been offered for vomiting, some of which, like metoclopramide and antihistamines are accompanied with many complications. Therefore, we decided to examine intravenous (IV) B6 that has few complications and to compare its effect with more efficacious medications like ondansetron and no medicine administration and exclusive fluid therapy.

Methods:

The sample population of this clinical trial study conducted between April 4, 2013 and August 6, 2013 in Shahrekord, Iran included all 1- to 5-year-old children referring Pediatric Emergency of Hajar Hospital complaining of vomiting due to gastroenteritis causing mild to moderate dehydration. In view of previously conducted studies the sample size was decided to be 105. The participants were assigned to three groups of 35 each. At first some explanations on the purpose of the study and how to collaborate were given to parents. Inclusion criteria were occurrence of acute gastroenteritis preferably viral, causing mild to moderate dehydration, being 1-5 years old, and referring Pediatric Emergency of Hajar Hospital, Shahrekord, lack of pharmacologic, antiemetic treatment prior to hospitalization, completion of consent form by the parents, incidence of gastroenteritis with vomiting being dominant manifestation, and unmanageable vomiting failing to tolerate oral rehydration therapy. Exclusion criteria included administration of antiemetic medications within few days prior to investigation, no particular indication of hospitalization except vomiting, the incidence of other diseases that cause vomiting, hepatic, renal, and metabolic diseases, septicemia, tumor, intestinal obstruction, dehydration exacerbation during the study, the participants' declining to participate in the study, discharge prior to complete recovery with personal consent, and repeated vomiting which may have the risk of dehydration and shock.

The initial assessments of dehydration rate were made and necessary tests such as stool test and stool culture were done. At first, appropriate venous fluids were prescribed for all three groups. Then, group 1 was administered with IV B6 1mg/kg twice daily and group 2 with ondansetron venous ampoule 150 µg/kg twice daily. Group 3 underwent treatment with venous rehydration and other supportive practices. The participants' conditions, frequency of vomiting, and dehydration rate prior to and after treatment were registered in a checklist developed for this purpose. The first examination of participants was done within the first 24 hours of hospitalization, they were visited daily, and vomiting frequency and dehydration assessment were continuously checked and registered in the checklist.

Having gathered and registered the data, we entered them into SPSS software and did data analysis using chi-square, parametric ANOVA, and non-parametric Kruskal-Wallis with Post-hoc Dunn's test.

Results:

In this study, aiming to compare the efficacy of 3 therapeutic methods, IV B6, IV ondansetron, and venous rehydration, in prevention of vomiting in the children with acute gastroenteritis causing mild to moderate dehydration referring Pediatric Emergency of Hajar Hospital, Shahrekord in spring and summer 2013, the following results were obtained:

Overall, 105 children 1-5 years old, assigned to 3 (IV B6, IV ondansetron, and exclusive venous rehydration) groups of 35 each were enrolled into this study. 47 (44.8% of the) participants were female and the rest male; chi-square test indicated no significant difference in gender among the 3 groups ($P > 0.05$). The mean age of the participants with range of 1-5 years old was 1.99 ± 1.33. ANOVA showed no difference in age among the children in different groups ($P = 0.498$).

Hospitalization duration was 2-8 (4.23 ± 1.57), 2-12 (4.30 ± 2.12) and 3-10 (4.91 ± 1.8) days for the children in IV B6, IV ondansetron, and venous rehydration groups, respectively, with no significant difference among the 3 groups according to ANOVA ($P = 0.11$).

At admission, only 4 (3.8% of the) participants had mild dehydration and the rest were admitted with moderate dehydration. After management of vomiting, two (1.9% of the) participants had moderate dehydration and the rest had mild, indicating that dehydration was managed very well during treatment.

The results on vomiting frequency in 3 groups during the first five days are summarized in Table 1. Kruskal-Wallis test indicated a difference in vomiting frequency among the 3 groups, as such the group administered with ondansetron had the least vomiting frequency of all 3 groups during the second to 4th days. Dunn's post-hoc test also indicated a significant difference in vomiting frequency between the group administered with ondansetron in second, third, and 4th days and the other two groups. In the 5th days since a large number of

children were discharged and vomiting frequency, in practice, decreased to at most twice a day and the majority of participants had no vomiting, no difference was observed among the 3 groups, although a partial, significant difference was observed.

Table 1: Frequency of vomiting in the 3 groups during study

P-value	Rehydration			Ondansetron			B6			Group
	Median	Max	Min	Median	Max	Min	Median	Max	Min	
0.038	5	≥6	1	5	≥6	4	3	≥6	3	First day
<0.001	2	≥6	1	1	5	0	2	5	1	Second day
0.001	1	4	0	0	2	0	1	3	0	Third day
0.003	0	2	0	0	0	0	0	3	0	4th day
0.075	0	2	0	0	0	0	0	1	0	5th day

Discussion:

One of the most prevalent reasons for children's referring treatment centers and also the most important cause of vomiting in children is gastroenteritis. Gastroenteritis could be developed by bacterial, viral, and parasitic pathogens. The most prevalent manifestations are diarrhea and vomiting which sometimes are accompanied with systemic manifestations, such as abdominal pain and fever. Gastroenteritis prevalence is directly associated with health level and community development. Management of vomiting is very crucial to treatment management of the patients with gastroenteritis because vomiting could lead to complications such as dehydration and electrolyte imbalance which sometimes, if left untreated, could be fatal and the majority of these complications could be prevented through managing vomiting [2].

Dehydration incidence due to acute diarrhea is more likely in infants compared to older children, which is attributable to higher basal metabolism rate, higher surface area to volume ratio, lower fluid reserves, and being dependent on others for supplying essential fluids [4].

The main target in acute gastroenteritis treatment is oral rehydration in which nutrition is done through fluids [1], but zinc and probiotic products could be conductive, as well [1]. Lack of micronutrients such as vitamin A and zinc exacerbates gastroenteritis [5]. A variety of methods has been offered to improve oral tolerance in these children; for example, some suggest that small volume fluids in short intervals or cold fluids be used and some others prescribe a single dose of ondansetron [6]. As vomiting is a fundamental component of viral gastroenteritis in children, its association with diarrhea causes dehydration-associated complications; therefore, different treatments have been offered for vomiting, some of which, like metoclopramide and antihistamines are accompanied with many complications. Therefore, we decided to examine intravenous (IV) B6 that has few complications and compare its effect with more efficacious medications like ondansetron and/or no medicine administration and exclusive fluid therapy.

In the present study, 105 children referring Pediatric Emergency of Hajar Hospital, Shahrekord complaining of vomiting due to gastroenteritis causing mild to moderate dehydration were enrolled.

47 (44.8% of the) participants were female and the rest male; chi-square test indicated no significant difference in gender among the 3 groups ($P > 0.05$). The mean age of the participants with range of 1-5 years old was 1.99 ± 1.33. ANOVA showed no difference in age among the children in different groups ($P = 0.498$).

Mean hospitalization duration was 4.23, 4.30, and 4.91 days for the participants in IV B6, IV ondansetron, and venous rehydration groups, respectively, with no significant difference among the 3 groups according to ANOVA ($P = 0.11$). Obviously, it should be mentioned that hospitalization duration of the patients was predictable in view of previous studies. In this study, although no significant difference in hospitalization duration was observed between the 3 groups, the mean days of duration was different among the 3 groups, indicating the group receiving ondansetron was hospitalized for the fewest days, followed by the groups administered with vitamin B6 and venous rehydration which were hospitalized for longer duration.

At admission, only 4 (3.8% of the) participants had mild dehydration and the rest were admitted with moderate dehydration. After management of vomiting, two (1.9% of the) participants had moderate dehydration and the rest had mild moderate, indicating that dehydration was managed very well during treatment and after vomiting stopping.

The results on vomiting frequency in 3 groups during the first five days were examined using Kruskal-Wallis test, indicating the difference in vomiting frequency among the 3 groups, as such the group administered with ondansetron had the least vomiting frequency of all 3 groups during the second to 4th days, followed by the groups administered with vitamin B6 and only venous rehydration. The present study indicated that ondansetron was more effective in managing vomiting compared to vitamin B6.

The results obtained in the present study indicate that ondansetron is effective in managing nausea and vomiting in the children with acute gastroenteritis, which corresponds to the results obtained in other studies [7,8].

Kovac indicated that ondansetron is effective in controlling post-surgical nausea and vomiting [7]. Fujii confirmed the efficacy of ondansetron on controlling post-surgical nausea and vomiting [8].

In Ghahiry et al. study, the comparison of ondansetron's efficacy with that of plazil and dexamethasone has been made and no significant difference in managing nausea and vomiting was observed between these two medications and ondansetron [9].

Dunn's post-hoc test also indicated a significant difference in vomiting frequency between the group administered with ondansetron in second, third, and 4th days and the other two groups. In the 5th days since a large number of children were discharged and vomiting frequency, in practice, decreased to at most twice a day and the majority of participants had no vomiting, no difference was observed among the 3 groups although a partial, significant difference was observed.

In Ghahiry et al. study ondansetron was compared with metoclopramide in nausea and vomiting management and the obtained results indicated that the trend of variation in nausea during treatment exhibited no significant difference among the 3 groups but frequency of vomiting grew lower in ondansetron group significantly, which is in agreement with the present study results [10]. In the present study no side-effect caused by the used medications was observed. The results of the present study have been consistent with the hypothesis of investigation, indicating that administration of B6 vitamin and ondansetron was more effective on decrease in vomiting compared to only venous rehydration.

Conclusion:

The practical purpose of this study is decrease in hospitalization and treatment costs. Since hospitalization duration exhibited no significant difference among the 3 groups, the decrease in hospitalization and treatment costs could not be realized through vitamin B6 and ondansetron consumption.

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