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Clinical Out Come with Single Dose Ondansetron versus Domperidone in Paediatric Gastroenteritis – Our Experience

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Abstract
Background: *Acute gastroenteritis (AGE) is a diarrheal disease of rapid onset, with or without accompanying symptoms and signs, such as nausea, vomiting, fever, or abdominal pain. The WHO recommends ORS as the treatment of choice for children with mild to moderate gastroenteritis in both developed and developing countries. Vomiting limits the success of oral rehydration in children with gastroenteritis. Ondansetron has been proven safe and effective in chemotherapy induced and post operative vomiting. It is a selective serotonin 5HT-3 receptor blocker and inhibits the initiation of the vomiting reflex in the periphery. We have evaluated single dose of ondansetron versus domperidone on clinical outcome in paediatric gastroenteritis.*
Methods: *It is an open-label randomized study was undertaken at department of Pediatrics, Narayana Medical College, Nellore for a period of six months. A total 84 children, age group between 3- 10 years of age were selected for the study. The patients were randomly assigned to receive Ondonsetron or Domperidone and were stratified according to the dose of medication. The bedside nurse or care giver is instructed to administer the medication. Vomiting episodes were tabulated in 24 hrs starting from the time of drug administration until cessation of vomiting. The primary outcomes recorded were the need and duration for oral / intravenous rehydration and hospitalization. Data was presented as Mean, SD, Range, actual numbers and Percentages. Statistical analysis was carried by using paired t test.*
Results: *Out of 84 children in each group whose data were analyzed, 42 patients received ondansetron and remaining 42 received domperidone along with oral-rehydration therapy. As compared with children who received domperidone, children who received ondansetron were less likely to vomit (12 percent vs. 37 percent; relative risk, 0.44; 80 percent confidence interval with $P<0.001$)*
Conclusion: *In children with acute gastroenteritis with vomiting, a single dose of ondansetron reduces vomiting and well tolerated with oral rehydration therapy compared to domperidone*
Keywords: *Acute Gastro Enteritis (AGE), Vomiting, Oral Rehydration Solution (ORS), Ondansetron, Domperidone,*

INTRODUCTION

Acute gastroenteritis (AGE) is a diarrheal disease of rapid onset, with or without accompanying symptoms and signs, such as nausea, vomiting, fever, or abdominal pain. [1-2] World Health Organization (WHO) and UNICEF data in developing countries shows there are about two billion cases of diarrheal disease worldwide every year and 1.9 million children younger than 5 years of age perish from diarrhea each year. This amounts to 18 percentage of all the deaths of children under the age of five.[3] The severity of the acute gastroenteritis varies widely depending on the volume of fluid loss the child experiences through vomiting and diarrhea. Preventing the development of dehydration and rehydration therapy is the mainstay of emergency department treatment. A range of therapies have been proposed to achieve these aims in children with acute AGE by alleviating vomiting and diarrhea.[4] The WHO recommended ORS as the treatment of choice for children with mild to moderate gastroenteritis in both developed and developing countries.[5] Vomiting confines the achievement of oral rehydration in children with AGE.[6] The American Academy of Pediatrics for the treatment of gastroenteritis expressed concerns about frequency of adverse effects such as sedation and extra pyramidal reactions, seen with conventional antiemetics.[7-8] Ondansetron has been proven safe and effective in chemotherapy induced and post operative vomiting. It is a selective serotonin 5HT-3 receptor blocker and inhibits the initiation of the vomiting reflex in the periphery. The Cubeddu (1997) was the first man to demonstrate the antiemetic effects of ondansetron in AGE.[9] Even though a number of investigators like Ramsook et al [10] Reeves et al [11] Freedman et al [12] Stork et al [13] Roslund et al [14] Yilmaz et al [15] have evaluated its effectiveness in pediatric gastroenteritis, there is lack of Indian studies. To this purpose we have evaluated single dose Ondansetron versus Domperidone on Clinical Outcome in Paediatric Gastroenteritis.

METHODS

It is an open-label randomized study was undertaken at department of Pediatrics, Narayana Medical College, Nellore for a period of six months. A total 84 children, age group between 3-10 years of age were selected for the study. Institutional ethics committee has approved and informed consent was obtained from the parents. Patients with mild to moderate dehydration were included and patients with severe dehydration, history of abdominal surgery, hypersensitivity to Ondonsetron, and Domperidone were excluded from the study. A baseline dehydration score of 6 - 21 was assigned to all enrolled paediatric patients.

The patients were randomly assigned to receive Ondonsetron or Domperidone and were stratified according to the dose of medication. The bedside nurse or care giver is instructed to administer the medication. An one hour period of intense oral rehydration was initiated 15 minutes after administration of the medication, and then continued until the final decision was taken. The Standardized follow - up care performed for 3 - 7 days after patient enrollment. Vomiting episodes were tabulated in 24 hrs starting from the time of drug administration until cessation of vomiting.

The primary outcomes recorded were the need and duration for oral / intravenous rehydration and hospitalization. A vomiting episode was defined as any episode of forceful expulsion of stomach contents. Secondary outcome included number of vomiting episodes after drug administration including the duration and frequency of diarrhea and, frequency of return visits to the hospital.

STATISTICAL ANALYSIS

Data was presented as Mean, SD, Range, actual numbers and Percentages. The enrollment of 84 children was undertaken to provide the study with a statistical power of 80 percent confidence interval with 5 percent error. Statistical analysis was carried by using paired t test.

RESULTS

Out of 84 children in each group whose data were analyzed, 42 patients received ondansetron and remaining 42 received domperidone along with oral-rehydration therapy. As compared with children who received domperidone, children who received ondansetron were less likely to vomit (12 percent vs. 37 percent; relative risk, 0.44; 80 percent confidence interval with P<0.001)

Table-1 - ONDANSETRON

Total No.	Age range	Wt.range (kgs)	Male children	Female children	ORT-Group		I.V therapy Group	
42	3 yrs - 10yr	15 -31	24	18	15(M)	12(F)	9(M)	6(F)
Dehydration Score		Mild			2(F)	2(M)	0(M)	0(F)
		Moderate			13(M)	10(F)	8(M)	7(F)
DOMPERIDONE								
Total No.	Age range	Wt.range (Kgs)	Male children	Female children	ORT-Group		I.V therapy Group	
42	3 yrs - 10yr	15-31	24	18	16(M)	11(F)	8(M)	7(F)
Dehydration Score		Mild			3(F)	2(M)	0(M)	0(F)
		Moderate			8(M)	14(F)	8(M)	7(F)

Table 2 – Follow Up	Ondansetron group(n=42)		Domperidone group (n=42)	
	ORT (n - 27)	I.V (n - 15)	ORT (n - 27)	I.V (n - 15)
Follow Up On Day 3				
Completed follow-up	27/27 (0%)	15/15 (0%)	26/27 (4%)	15/15 (0%)
Return visit to the hospital	1/27(96%)	4/15(73%)	7/27(74%)	4/15(73%)
Repetition of IV rehydration	0/27 (0%)	2/15 (86%)	2/27 (92%)	9/15 (40%)
Continued hospitalization	0/27(0%)	0/15(0%)	6/27(77%)	3/15(80%)
Follow Up On Day 7				
Completed follow-up	24/27 (4%)	15/15 (0%)	22/27 (18%)	15/15 (0%)
Return visit to the hospital	0/27 (100%)	1/15(93%)	1/27 (96%)	6/15(60%)
Repetition of IV rehydration	0/27 (100%)	0/15 (100%)	1/27 (96%)	0/15 (100%)
Continued hospitalization	0/27(100%)	3/15(80%)	1/27(96%)	8/15(46%)

DISCUSSION

Ondansetron is a specific 5-hydroxytryptamine-3 antagonist that blocks receptors in the gastrointestinal tract and the central nervous system. It initially was found to be effective in the treatment of vomiting in patients receiving chemotherapy and radiation therapy. Schnadower et al study also proved that Ondansetron and probiotics may improve patient outcomes in pediatric AGE. Appropriate strategies are needed to optimally integrate oral ondansetron into clinical practice to maximize its potential benefits. (16)

In our study on observation was that a single dose of Ondansetron can improve the success of oral rehydration in dehydrated children with gastroenteritis. The oral dose was well tolerated, in ORH & IV rehydration groups. As compared with children who received Domperidone, children who received Ondansetron had few episodes of vomiting, greater oral intake of fluids and shorter stay in the hospital.

Further it has been observed that a single dose of oral Ondansetron reduced vomiting and the need for intravenous fluids without any clinically significant adverse effects. Less No. of patients in

Ondansetron group than in the Domperidone group required intravenous fluids for rehydration. Significant reduction in No. of days of hospital stay & revisit were noted in OND group than DOM group. Scientific evidence supports the use of ondansetron for children with AGE and vomiting.[17] In fact, it is the only antiemetic medication for which multiple randomized, controlled trials support its benefit.[18-19] In one trial, oral ondansetron stopped vomiting within the first 4 h for 67% of patients and in the first 24 h for 58% of patients. [20]

CONCLUSION

In children with acute gastroenteritis with vomiting, a single dose of ondansetron reduces vomiting and well tolerated with oral rehydration therapy compared to domperidone.

CONFLICT OF INTEREST: NONE

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