

Comparison of Efficacy and Acceptability of Ondansetron Oral Solution *versus* Oral Dissolving Films in the Management of Vomiting in Children

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ABSTRACT

Introduction: Oral administration of antiemetic is a very convenient route preferred by children and parents. The most common oral form used in pediatrics is liquid formulation. Orally disintegrating soluble films appear promising for use in pediatric population. Hence this study was conducted to compare the efficacy and acceptability of ondansetron oral solution and oral dissolving films in management of vomiting in children. **Methodology:** A prospective observational study was conducted among children attending OP & Emergency department with vomiting due to Acute Gastroenteritis in the age group 1-6 years. For the purpose of the study children were divided in to two groups, one group will receive the oral ondansetron syrup and other group will receive the oral dissolving films of ondansetron. Children were observed in OP for 1 hour and monitored for vomiting. Child's acceptability was observed and parents' comfortability was recorded. Institute ethical committee clearance was obtained before the start of the study. Written informed consent was obtained from all the participants before including them in the study.

Results: Out of the 200 children immediate vomiting following the administration of drug was observed in 19 % of the study participants. 81 % of the participants accepted the drug and 81% of parents felt it was easy to administer the drug. The readily acceptance of the drug was higher among the film group (92 %) compared to the syrup group (70 %). Similarly, the readily acceptance of the future doses was higher among the film group (94 %) compared to the syrup group (78 %). 94 % of the parents in the film group felt it was easy to administer film while only 68 % of the parents felt it was easy to administer in the syrup group. All the associations were found to be statistically significant.

Conclusion: In conclusion, ondansetron film was found to be a successful antiemetic in children with acute gastro enteritis. This study also shows that the ondansetron oral film has good acceptability among both children and parents compared to the ondansetron oral syrup.

Keywords: Oral dissolving FILM, Oral syrup, anti-emetics, AGE, Ondansetron

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INTRODUCTION

Acute Gastro Enteritis (AGE) is the largest cause of vomiting in children under the age of three, and it is a common reason for children and adolescents to visit emergency rooms. Every year, around 2 million children under the age of five die as a result of gastroenteritis.

Whilst AAP does not suggest antiemetic therapy for AGE, it is distressing for children and parents if vomiting is not controlled. Anti-emetic medications like as Ondansetron, Domperidone, and Prochlorperazone are commonly utilised in OP and ER settings. Among these, Ondansetron is licensed for the treatment of nausea and vomiting and has a lower risk of side effects. Ondansetron hydrochloride, a 5-HT₃ antagonist that inhibits serotonin receptors, works well for nausea and vomiting [1, 2].

Oral dissolving films are oral strips consisting of hydrophilic polymers that include active ingredients as well as excipients. When these films come into contact with saliva, they quickly breakdown and release the medication [3, 4]. ODFs have some advantages over tablets, such as less risk of suffocation or choking

[5] easier manufacture, and a lower production cost [6] as well as greater flexibility and patentability [7] The benefits of ODFs include fast dissolution without the need for water, rapid absorption from the highly vascularized oral mucosa, and bypassing first pass metabolism, making them an appropriate approach for administering ondansetron to emesis patients.

Oral administration of antiemetic is a very convenient route preferred by children and parents. The most common oral form used in pediatrics is liquid formulation. Orally disintegrating soluble films appear promising for use in pediatric population. However, it is not widely studied whether oral solutions or oral dissolving films are better tolerated in children with vomiting. Hence this study was conducted to compare the efficacy and acceptability of ondansetron oral solution and oral dissolving films in management of vomiting in children.

METHODOLOGY

A prospective observational study was conducted among children attending OP & Emergency department with vomiting due to Acute Gastroenteritis in the age group 1-6 years between April 2021 and September 2021. For the purpose of the study children were divided in to two groups, one group will receive the oral ondansetron syrup and other group will receive the oral dissolving films of ondansetron. 100 children attending the hospital on Monday, Wednesday and Friday received ondansetron oral solution. While 100 children attending the hospital on Tuesday, Thursday and Saturday received ondansetron oral dissolving films. All children were given weight-appropriate dose. Both forms were used from same brand. Children were observed in OP for 1 hour

and monitored for vomiting. Child's acceptability was observed and parents' comfortability was recorded. Next day parents were contacted and enquired about number of vomiting episodes recorded in the last 24 hours. The collected data were entered in MS excel and analyzed using SPSS Software version 21.0. Descriptive statistics were presented in the form of frequency and percentage and chi square test and fisher's exact test were applied to find out the strength of association between the factors.

Inclusion Criteria: Children diagnosed as acute gastroenteritis with no and some dehydration in the age group of 1 to 6 years attending OPD and Emergency department were included in the study.

Exclusion criteria: Children with severe dehydration, with chronic medical conditions and vomiting due to other causes (e.g.: sepsis, GI obstruction, drug induced) were excluded from the study.

Ethical consideration: Institute ethical committee clearance was obtained before the start of the study. Written informed consent was obtained from all the participants before including them in the study.

RESULTS

This study was conducted among 200 children attending the hospital for the complaint of vomiting out of which 100 children were administered with film and 100 with oral syrup. Out of the 200 children immediate vomiting following the administration of drug was observed in 19 % of the study participants. 81 % of the participants accepted the drug and 81% of parents felt it was easy to administer the drug. Out of the 200 children included in the study 10 children required admission & intravenous

Table 1: Mode of administration and Details of the associated factors (n=200).

Variable		Frequency (n)	Percentage (%)
Type of administration	Film	100	50
	Syrup	100	50
Immediate vomiting within 30 min after drug admin	Yes	38	19
	No	162	81
Child's acceptability	Accepts the drug	81	81
	Accepts after persuasion and distraction	19	19
Child's acceptance of further doses	Accepts readily	172	86
	Accepts with difficulty	28	14
Parent's comfort	Easy to administer	162	81
	Difficult to administer	38	19
No. of vomit episodes in last 24 hrs	0	144	72
	1	40	20
	2	14	7
	3	2	1
Whether required admission & IVF	Yes	10	5
	No	190	95
Associated diarrhoea	Yes	102	51
	No	98	49
Fever	Yes	22	11
	No	178	89
Hydration status	No dehydration	188	94
	Some dehydration	12	6
Total		200	100

Table 2: Association between the mode of administration of drug and other variables (n=200).

		Mode of administration		Total n (%)	P - value
		Film n (%)	Syrup n (%)		
Immediate vomiting within 30 min after drug admin	No	88 (88)	74 (74)	162 (81)	
	Yes	12 (12)	26 (26)	38 (19)	0.018*
No. of vomit episodes in last 24 hrs	0	82 (82)	62 (62)	144 (72)	0.008#
	1	14 (14)	26 (26)	40 (20)	
	2	4 (4)	10 (10)	14 (7)	
	3	0 (0)	2 (2)	2 (1)	
Child's acceptability	Accepts the drug	92 (92)	70 (70)	162 (81)	<0.00*
	Accepts after persuasion and distraction	8 (8)	30 (30)	38 (19)	
Child's acceptance of further doses	Accepts readily	94 (94)	78 (78)	172 (86)	0.002*
	Accepts with difficulty	6 (6)	22 (22)	28 (14)	
Parent's comfort	Easy to administer	94 (94)	68 (68)	162 (81)	<0.00*
	Difficult to administer	6 (6)	32 (32)	38 (19)	
Total		100 (100)	100 (100)	200 (200)	

*chi-square test applied # Fishers exact test applied

fluids and 51% were associated with diarrhea and 11 % were associated with fever, 6 % had some dehydration while the rest did not have any signs of dehydration Table1.

Among the children who were administered with syrup 26 % of them had immediate vomiting within 30 mins of administration and it was 12 % among the children who were administered with film. The number of vomiting episodes in 24 hours was higher among the children group who were administered with syrup compared to the children who were administered with film. The readily acceptance of the drug was higher among the film group (92 %) compared to the syrup group (70 %). Similarly, the readily acceptance of the future doses was higher among the film group (94 %) compared to the syrup group (78 %). 94 % of the parents in the film group felt it was easy to administer film while only 68 % of the parents felt it was easy to administer in the syrup group. All the associations were found to be statistically significant Table 2.

DISCUSSION

A prospective observational study was conducted among 200 children to compare the efficacy and acceptability of ondansetron oral solution and oral dissolving films in management of vomiting in children. We found a statistically significant association between the mode of administration and the factors involved. Out of the 200 children immediate vomiting following the administration of drug was observed in 19 % of the study participants. Among the children who were administered with syrup 26 % of them had immediate vomiting within 30 mins of administration and it was 12 % among the children who were administered with film, we expected such difference in the results between the groups as film does not require to be swallowed or requires water for the same, we expected a difference of at least 10 % between the groups but we got nearly 15

% difference between the groups. Similar results were found by a study done by Thomson GC. et al, [8] where the vomiting immediately after the administration of drug by oral film was less compared to the syrup group.

Overall, comparing vomiting rates to previous literature is difficult because this study focused on vomiting within 30 minutes of the dose in an attempt to quantify emesis associated with medication administration, whereas previous studies looked at vomiting over a much longer time period, presumably to determine the efficacy of the drug itself. Cubeddu et al. observed vomiting within 4 hours of therapy with a proportion of 0.33 and an overall proportion of 0.42 over the entire follow-up period [9, 10]. Freedman et al. observed patients through an oral rehydration period in the emergency department and found that the ondansetron group had a vomiting proportion of 0.13 [11]. Likewise, Ramsook et al. Patients were monitored for 8 and 24 hours, and the proportion of vomiting with ondansetron was 0.21 and 0.11, respectively [12].

The proportion of patients discharged without IV fluids or admission is 98% in the film group versus 92% in the syrup group. The proportion of patients discharged home without requiring IV fluid administration in our study (0.91 for ondansetron ODF and 0.94 for ondansetron OS) is consistent with those reported by Freedman et al, Ramsook et al, Roslund et al. demonstrated a lower proportion of patients discharged home without requiring IV fluids of 0.81 for patients with confirmed gastroenteritis [13].

Among the children who were administered with syrup 26 % of them had immediate vomiting within 30 mins of administration and it was 12 % among the children who were administered with film. The numbers of vomiting episodes in 24 hours were higher among the children group who were administered with syrup compared to the children who were administered with film. The readily acceptance of the drug was higher among the

film group (92 %) compared to the syrup group (70 %). Similarly, the readily acceptance of the future doses was higher among the film group (94 %) compared to the syrup group (78 %). 94 % of the parents in the film group felt it was easy to administer film while only 68 % of the parents felt it was easy to administer in the syrup group. All the associations were found to be statistically significant. The acceptability of both children and parents were higher for the oral ondansetron film since the mode of administration is easy in oral film as it does not require to be swallowed or requires water. Similar findings were found in a study done by Cohen et al found the ondansetron ODF acceptable by all the children and none of the subjects rejected or spit out the study medication [14].

CONCLUSION

In conclusion, ondansetron film was found to be a successful antiemetic in children with acute gastro enteritis. This study also shows that the ondansetron oral film has good acceptability among both children and parents compared to the ondansetron oral syrup. This preparation of ondansetron may be a useful alternative in preventing nausea and vomiting in children who lack IV access and are unable to take oral medications.

CONFLICT OF INTEREST

None declared

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