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Original Article

A COMPARATIVE EVALUATION ON THE EFFECT OF ZINC-PROBIOTIC AND PROBIOTIC THERAPY IN PAEDIATRIC ACUTE DIARRHOEA AND THE IMPACT OF COUNSELLING OF MOTHERS

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ABSTRACT

Objective: To compare the efficacy of zinc-probiotic combination therapy and probiotic therapy alone in the treatment of acute paediatric diarrhoea and to assess the knowledge, attitude and practice (KAP) of the mothers of affected children and the impact of counselling on diarrhoea management.

Methods: A prospective observational comparative study was conducted from October 2014 to March 2015 in the paediatric department of Cosmopolitan Hospitals Pvt. Ltd., Thiruvananthapuram, Kerala, South India. The study was carried out on 150 patients between the ages of 3 mo to 12 y. The selected patients were divided into 2 groups of 75 members each. Initially, demographic data, details of socioeconomic status, severity, duration and frequency of diarrhoea and the presence of other associated symptoms and KAP of mothers before and after counselling was collected by using specially designed proforma. Group 1 patients received zinc and probiotic and Group 2 received probiotic only by oral administration. All children in both groups received sufficient quantity of oral rehydration solution (ORS). The requirement of other medications and adverse effects were also monitored.

Results: The study revealed that, in group 1, 54.6% of patients were males and in group 2, 58.6% were females. The mean age of affected children was 5.14±3.53. In both groups, the majority of patients were from outpatient (OP) departments. In group 1, majority of patients, 49.3% were resting in upper lower economic class followed by 30.7% were lower middle class. In the case of group 2, 34.6% patients were from lower middle and 28% were from upper middle class. Other medications such as antiemetic and antipyretic were administered to 127and 110 patients respectively. Antisecretory and antibiotic were administered to 31 and 26 patients respectively. Totally 8 patients were affected with adverse drug reactions such as rashes and swelling of lips. In both groups severity of diarrhoea was high before treatment and it was changed after effective treatment with drugs. Comparing with group 2, the duration and severity of diarrhoea and other associated symptoms in group 1 patients were significantly reduced after treatment. Before counseling, the majority of mothers had very poor knowledge about the diarrhoeal disease and its management. Evaluation after counselling showed a significant improvement.

Conclusion: Low socioeconomic life is a risk factor for diarrhoea. A combination of zinc and probiotic therapy is more effective than probiotic therapy alone in the treatment of acute diarrhoea and vomiting in children. The emergence and severity of the diarrhoeal disease can be reduced by effective clinical pharmacist interventions, and a great emphasis is needed in the counselling and education of mothers about this disease and its management.

Keywords: Paediatric diarrhoea, Zinc, Probiotic, KAP, Counselling and education

INTRODUCTION

Diarrhoea is a common problem, affects all age groups. It is defined as the passage of loose and watery stools for 3 or more times in a day [1, 2]. A bacterial infection such as *Campylobacter*, *E. coli*, *Salmonella* and *Shigella* infections, viral infections such as Rotavirus, Cytomegalovirus, Norwalk, Hepatitis and Herpes simplex infections, intestinal parasites infections and food intolerances are some of the important causes of diarrhoea in both children and adults. Administration of antibiotics and antacids containing magnesium may also lead to diarrhoea. Overcrowding, poor sanitation and lack of safe drinking water are some of the important issues closely associated with diarrhoeal disease [1].

Diarrhoea is one of the common causes of childhood morbidity and mortality in developing countries [3, 4]. Diarrhoea kills more children worldwide, comparing with tuberculosis, malaria, and AIDS combined. Dehydration, acidosis, impairment of renal function, secondary infections are some of the important factors closely associated with deaths due to diarrhoea [1]. According to the guidelines of World Health Organization, antibacterial, antiamoebic and antidiarrhoeal agents have a little role in the management of diarrhoea [3]. In developing countries, duration and severity of diarrhoea is more among younger age groups with malnutrition and impaired immune status which may be associated with zinc deficiency. Diarrhoea is more common in children with zinc deficiency and responds quickly to zinc supplementation [5, 6]. In recent years, probiotics have been widely studied in the prevention and treatment of diarrhoea particularly in paediatric population [7, 8]. Probiotics are live microbes administered in sufficient quantity to develop a health benefit on the host. Either single or mixed culture of bacteria of genera Bacillus, Lactobacillus, Bifidobacterium and non-pathogenic yeast such as Saccharomyces boulardii are some examples for commonly used probiotics.

It is used in the prevention and treatment of diarrhoea based on the assumption that they modify the microflora composition of the colon and act against enteric pathogens [7]. Diarrhoeal episodes are mostly treated in homes and mothers are the main caregivers for children below five years old. Hence their knowledge about this disorder gains importance [2, 3]. Though lot of studies has been conducted on diarrhoea and KAP of mothers of young children worldwide, it was identified that in the present study area, none of the studies were carried out in this regard in recent years. With this view, the present study was designed to evaluate the efficacy of zinc-probiotic combination therapy and probiotic therapy alone in the treatment of acute paediatric diarrhoea and to assess the KAP of the mothers of affected children and the impact of counselling provided to them regarding diarrhoea management. The outcome of this study would provide a good platform for further study.

After obtaining necessary consent from hospital authorities, (IHEC 9/21/2015) a prospective observational comparative study was conducted in the paediatric department of Cosmopolitan Hospitals Pvt. Ltd., a 550 bedded multispecialty hospital located in Thiruvananthapuram, Kerala, South India. It was a six-month study conducted from October 2014 to March 2015. Totally 150 paediatric patients were enrolled for the study.

The inclusion criteria for the enrollment

- Patients aged 3 mo to 12 y
- Patients who had>3 times stools/day for >one d ay and under medical care as inpatient or outpatient
- Mothers of the patients willing to participate in the study

The exclusion criteria were

- Patients received antibiotic, probiotics or any other anti-diarrhoeals in the previous 24h.
- Diarrhoea for more than 48h
- Patients who have blood in their stool
- Patients with other chronic diseases
- Patient with severe undernutrition
- Parents of patients not willing to participate in the study

The selected patients were randomly allocated into 2 groups of 75 members each. A brief introduction about the study was given to the parents of participants and their consent was obtained in the prescribed format.

Baseline data such as name, age, gender, duration of illness, frequency of diarrhoea and vomiting, and the presence of associated symptoms such as abdominal pain, fever, etc and communication details of parents including contact numbers were collected. Details of the socioeconomic status of parents such as education, economic status, and physical assets were also recorded. Kuppuswamy's socioeconomic status scale [9] was used for the data collection. By using standardized scores, the parents of patients were classified into upper, middle and lower classes.

All children in both groups received sufficient quantity of ORS after passing each stool or vomiting or both and whenever the child demanded for it. Group 1 patients received zinc and probiotic and Group 2 received probiotic only by oral administration. Child less than 6 mo old received zinc 10 mg/day and child above 6 mo old received 20 mg/day zinc for 14 d. The probiotic, *Bacillus clausii* was administered two times a day for 5 d. prescribing of other medications was also monitored. The severity of diarrhoea before and after treatment was investigated using Vesikari severity scoring system [10]. Duration and frequency of diarrhoea were monitored during hospitalization and also after discharge. The presence of any toxicity and side effects associated with zinc and probiotic administration such as nausea, vomiting, abdominal pain, and sepsis were monitored. Home monitoring was done by telephone contact with parents and caregivers.

KAP of the mothers of participants was evaluated by using a questionnaire developed and validated by [2]. Data collection was done by direct interview method. Initially demographic data, details regarding knowledge about diarrhoea and its management were collected. Then leaflets containing information about diarrhoea and its management were distributed, and counselling was given to them. Again KAP data was collected from counselled mothers. All the collected data was analyzed by using the statistical package for the social sciences (SPSS) software.

Regarding with demographic data, the results showed that 41 of 75 patients (54.6%) in group-1 were males. Rests 34 (45.3%) were females whereas in group-2, 31 patients (41.3) were males and remaining 44 patients (58.6%) were females. According to age, the total population in both the groups was divided in to 3 categories. The results showed that in group-1, there were no patient in the initial category of 0-12 mo age whereas in group-2, 10 patients (13.3%) were belongs to this age category. Next, 1-5 y age category consists of 31 patients (41.3%) in group-1 and 46 patients (61.3%) in group-2. Finally, 44 patients (58.6%) of group-1 and 19 patients (25.3%) of group-2 were aged between 6-12 y category. Analysis of socioeconomic status of study population revealed that a major proportion, 37 of 75 patients (49.3%) in group-1 were rested in upper lower economic class followed by 23 patients (30.7%) were in lower middle class. 13 patients (17.3%) belonged to upper middle and only 2 patients (2.66%) were from the upper class. In the case of group-2, the majority of patients, 26 (34.6%) were from lower middle class followed by upper middle-class consists of 21 patients (28%). Upper lower and lower class individually constituted 10 patients (13.3%) and only 8 patients (10.6%) were from the upper class. The results are shown in table 1.

Table 1: Socio-economic status of study population

Socio economic status	Group-1		Group-2	
	No. of patients	Percentage (%)	No. of patients	Percentage (%)
Upper	2	2.66	8	10.6
Upper middle	13	17.3	21	28
Lower middle	23	30.7	26	34.6
Upper lower	37	49.3	10	13.3
Lower	0	0	10	13.3

P<0.001

48 patients (64%) in group-1 received treatment as outpatients. Rests 27 patients (36%) were admitted in the hospital. In the case of group-2, 65 participants (86.6%) were outpatients and remaining 10 participants (13.3%) were inpatients. Assessment of other symptoms associated with diarrhoea in both group-1 and 2 revealed that abdominal pain was present in 146 of 150 patients (97.3%). Fever was observed in 107 patients (71.3%). Vomiting was present in 123 patients (82%) and 37 patients (24.6%) were affected with severe dehydration. The seizure was reported in 4 patients (2.6%).

Results of assessment of drugs prescribed to the patients revealed that all the 150 study subjects (100%) received probiotic and ORS. 75 patients (50%) belong to group-1 received zinc also. Other medication such as antisecretory was administered to 31 patients (20.6%) and antibiotic was administered to 26 patients (17.3%). The antiemetic administration was needed to 127 patients (84.6%), and 110 patients (73.3%) received antipyretic administration. The antiepileptic administration was needed to 7 patients (4.6%).

Table 2: Comparison of the stage of diarrhoea in group-1 and 2 patients before and after the treatment

Group-1					Group-2			
Stage	Before the treatment		After the treatment		Before the treatment		After the treatment	
	No. of patients	% of patients	No. of patients	% of patients	No. of patients	% of patients	No. of patients	% of patients
Mild	0	0	61	81.3	0	0	17	22.6
Moderate	4	5.3	14	18.6	28	37.3	58	77.3
Severe	71	94.6	0	0	47	62.6	0	0

P<0.001

Investigation of the severity of diarrhoea before and after the treatment showed that, in group-1, before the treatment, a major proportion, 71 of 75 patients (94.6%) were affected with severe diarrhoea and remaining 4 patients (5.3%) were affected with moderate diarrhoea. But after the treatment, it was found that none of the patients were affected with severe diarrhoea.

A mild diarrhoea was observed in 61 patients (81.3%) and 14 patients (18.6%) were affected with moderate diarrhoea. In the case of group-2, before the treatment, 47 patients (62.6%) were affected with severe diarrhoea and remaining 28 patients (37.3%) were affected with moderate diarrhoea. After the treatment, it was observed that 58 patients (77.3%) were affected moderate diarrhoea and 17 patients (22.6%) were affected with mild diarrhoea. The results are shown in table 2.

From these results, it was clear that the group-1 patients were having a greater response to the treatment. Results of monitoring of adverse drug reactions showed that only a minor proportion of study subjects, 6 of 75 patients (8%) in group-1 and 2 of 75 patients (2.6%) in group-2 were affected with adverse drug reactions such as rashes and swelling of lips mainly associated with antibiotic administration.

KAP of the mothers of all the study subjects were evaluated. The results revealed that 108 of 150 mothers (72%) had the very poor knowledge and 36 mothers (24%) had poor knowledge and only 6 mothers (4%) had a good knowledge before counselling. The results of evaluation after counselling showed that 123 mothers (82%) gained a very good knowledge and 26 mothers (17.3%) possessed a good knowledge and only one candidate (0.66%) had a poor knowledge after counselling. The results are shown in table 3.

Table 3: KAP of mothers of study participants before and after counselling

			After counseling	
KAP	**No. of mothers**	**Percentage (%)**	**No. of mothers**	**Percentage (%)**
Very Poor	108	72	0	0
Poor	36	24	1	0.66
Good	6	4	26	17.3
Very Good	0	0	123	82

All these results clearly indicate a significant relationship between knowledge and socioeconomic status and also the importance of education and counselling of parents of children about diarrhoea and its management. Previous literature reports [2-4] also emphasize the importance and necessity of health education and counselling provided to the mothers of young children. It was also identified that the zinc supplementation had a clinically significant impact in the reduction of duration and severity of diarrhoea in infants and children [5]. The present study revealed that a combination of zinc and probiotic therapy is more effective than probiotic therapy alone in reducing the severity of acute diarrhoea as well as vomiting in children. It was found that low socioeconomic life is a risk factor for diarrhoea. It was also found that counselling is an important tool to educate the parents about diarrhoeal disease and its drugs. Of course, a similar study with larger sample size may give more valuable data, however from this study, it was clear that the emergence and severity of the diarrhoeal disease can be reduced by effective clinical pharmacist interventions, and a great emphasis is needed in the counselling and education of mothers about this disease and its management.

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CONFLICT OF INTERESTS

Declared none

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