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The Comparison of the Efficacy of Probiotic (Bacillus Clausii)with Yoghurt in the Management of Acute Watery Diarrhoea

Romisa Rehman, Asad Maqbool Ahmad, Asma Razzaq, Hakeem Ullah, Zarlish Rehman*, Roshaan Rehman**

Combined Military Hospital, Peshawar/National University of Medical Sciences (NUMS) Pakistan, *Khyber Teaching Hospital, Peshawar Pakistan, **Kabir Medical College, Peshawar Pakistan

ABSTRACT

Objective: To compare the efficacy of Probiotics with the yoghurt in the management of children with acute diarrhoea in terms of frequency and consistency of stools.

Study Design: Quasi-experimental study.

Place and Duration of Study: Department of Paediatric Medicine, Combined Military Hospital, Peshawar Pakistan, from Jun to Dec 2020.

Methodology: Patients were allotted into three Groups A, B, or C. Group-A received a Probiotic (Bacillus Clausii), Group-B received plain yoghurt, and Group-C did not receive yoghurt or Probiotic. The outcome was an improvement in stool consistency at 72 hours. Stool consistency was assessed via Bristol stool chart along with frequency. Data were collected 72 hours after initiation of treatment.

Result: The total number of patients enrolled was 159(53 in each Group). Among these, 85(53.5%) were males, and 74(46.5%) were females. There was a statistically significant association in terms of consistency (p=0.001) and term of frequency (p<0.001) in the Probiotic and Yoghurt-Group.

Conclusion: The outcome in terms of consistency is almost equal in the Probiotic and Yoghurt-Group. However, Probiotic is superior to yoghurt in terms of frequency.

Keywords: Bacillus clausii, Diarrhea, Probiotic, Yoghurt.

How to Cite This Article: *Rehman R, Ahmad AM, Razzaq A, Ullah H, Rehman Z, Rehman R. The Comparison of the Efficacy of Probiotic (Bacillus Clausii) with Yoghurt in the Management of Acute Watery Diarrhoea. Pak Armed Forces Med J 2022; 72(6): 2059-2062. DOI: https://doi.org/10.51253/pafmj.v72i6.7601*

INTRODUCTION

Despite improvements in access to health care and protocols of treatment, diarrhoea is the second leading cause of child mortality globally amongst children younger than five years, causing about 1.5 to 2 million deaths annually.[1] Child mortality due to diarrheal illness has declined considerably from the year 2000; nevertheless it resulted in 8% of total childhood deaths in 2017.[2] There are numerous causes of diarrhoea, including, irritation of gastric mucosa, allergies, food malabsorption, or infection. It can be caused by unhygienic food, drinking water, or person-to-person transmission due to poor sanitation.[3] Most of these deaths occur in low-middle income families due to inadequate provision of clean water, sanitation issues and lack of nutritional adequacy in children. [4,5]

Probiotics have been defined as a live microbial feed supplement beneficial to health.[6,7] They repopulate the normal gut commensal organisms, which are valuable for the human body as they help in the treatment of acute infectious diarrhoea, constipation, colonic disorders, side-effects of pelvic radiotherapy, food allergy including milk hypersensitivity and also have a role in the prevention of colonic carcinoma, treat vancomycin-resistant Enterococcus and Clostridium difficile associated diarrhoea.[8] Probiotics are easily accessible, easy to administer, comparatively inexpensive and less likely to induce resistance as they have complex mechanisms of action.[9] According to the World Gastroenterology Organization (WGO) Guidelines 2013, many strains have been identified that help in diarrheal illness. However, no single strain is superior to the other.[10]

Whilst many studies have been done on the effect of Probiotics on the duration of diarrhoea, this does not hold for its effect on the consistency and frequency of diarrhoea. Therefore, the rationale of this study is to compare the effectiveness of yoghurt with Probiotics in managing acute watery diarrhoea.

METHODOLOGY

This quasi-experimental study was carried out at the Department of Paediatric Medicine, Combined Military Hospital, Peshawar Pakistan, from June to December 2020, after obtaining approval from the Ethical Review Committee (ped-4987). Informed consent was taken at the time of enrollment. The sample size was calculated using the software G-Power after

Correspondence: Dr Romisa Rehman, Registrar Paeds, Combined Military Hospital, Peshawar, Pakistan

Received: 02 Nov 2021; revision received: 01 Jan 2022; accepted: 06 Jan 2022

conducting a pilot study to determine the exact size. The values of alpha were set as 0.05, the power of the test as 80% and the effect size as 0.25. A total sample size of 159 was calculated (53 in each Group).

Inclusion Criteria: Children of either gender with an age range of 6 months to 8 years, presenting in the Outpatient Department with acute diarrhoea without the signs of severe dehydration, were included in the study.

Exclusion Criteria: Children having serious co-morbid conditions, critically sick patients, malnourishment, chronic or persistent diarrhoea and patients with blood in stool were excluded from the study.

Patients were allotted into three Groups, A, B or C, via a non-probability consecutive sampling technique. Group-A received a Probiotic-Bacillus Clausii available by Enterogermina - 2 million spores, i.e. 10ml twice daily orally. Group-B received plain yoghurt 20ml twice daily, and Group-C did not receive yoghurt or Probiotics.

A structured questionnaire which included a Bristol chart for reference was filled out daily according to the history provided by the mother of the child. All patients were provided low osmolar oral rehydration solution after each loose stool or as required and were given zinc supplementation at 20mg once daily for 15 days. The response was checked after 72 hours of treatment. The variables studied during the patient's stay included stool frequency and consistency graded according to the Bristol stool chart (BSS).[11] Treatment success in frequency was defined as a stool frequency of 2 or less, and that of consistency was stool BSS grade 5 or less. The study included children aged six months to 8 years with the passage of stool greater or equal to three times in 24 hours or passage of stool in softer consistency (Bristol 5,6,7) or both (Table-I).

Table–I: Bristol Stool Chart

Type	Description
Type 1	Separate hard lumps, like nuts. Difficult to pass
Type 2	Sausage-shaped, but lumpy
Type 3	Like a sausage but with cracks on its surface
Type 4	Like a sausage or snake, smooth and soft
Type 5	Soft blobs with clear cut edges
Type 6	Fluffy pieces with ragged edges, a mushy stool
Type 7	Watery, no solid pieces, entirely liquid

Data were analyzed using Statistical Package for the social sciences (SPSS) version 26. Frequency and percentages were calculated for qualitative variables. The chi-square test was used to examine differences among the groups. The *p*-value of ≤0.05 was considered statistically significant.

RESULTS

The total number of patients enrolled was 159(53 in each Group). Among these, 85(53.5%) were male, and 74(46.5%) were female. Change in consistency and frequency was noted on day-4 of admission, i.e. after 72 hours of treatment.

In terms of consistency, in Group-A (Probiotic), 43(36.8%) had resolution of symptoms. In Group-B (yoghurt), 45(38.5%) had a cure. In Group-C, who received no Probiotic or yoghurt, 29(24.8%) had normalization of stool, and 24(57.1%) did not. This was statistically significant result (*p*-value=0.001)

Regarding frequency, in Group-A, 43(57.3%) had a resolution of symptoms as compared to 10(11.9%) children who did not. In Group-B, 21(28.0%) normalization of stool frequency, whereas 32(38.1%) did not, and in Group-C, 11(14.7%) had cured, whereas 42 (50.0%) did not. This was statistically significant result (*p*-value of<0.001), shown in Table-II.

Table-II: Association of Outcome of each Group (n=159)

Groups	Cure in terms of Consistency			Cured in terms of Frequency		
	Yes n (%)	No n (%)	*p*-value	Yes n (%)	No n (%)	*p*-value
A (Probiotic) (n=53)	43 (36.8%)	10 (23.8%)	0.001	43 (57.3%)	10 (11.9%)	<0.001
B (Yogurt) (n=53)	45 (38.5%)	8 (19.0%)		21 (28.0%)	32 (38.1%)	
C (none) (n=53)	29 (24.8%)	24 (57.1%)		11 (14.7%)	42 (50.0%)	

DISCUSSION

In our study, Probiotics improved consistency and frequency, and yoghurt benefited in consistency only. The Probiotic used in the study is Bacillus Clausii which is widely available in the market. It is relatively resistant to both physical and chemical conditions (such as heat and gastric pH) and is highly resistant to most antibiotics; therefore, its efficacy is not affected by concomitant antibiotics.[12] The results of this study pointed towards a clear benefit to those receiving Probiotics versus those not. There was some benefit in terms of consistency in children who were given plain yoghurt; however, those who did not receive anything had no benefit, neither in consistency nor frequency.

A phase II clinical study done in India by Sudha *et al*. assessed Probiotic B. clausii on four parameters:

duration, frequency, abdominal pain and consistency. All these were improved on the 10th day of administration without causing adverse effects. The frequency of defecation decreased from 6.96±1.05 to 1.78±0.50 (p<0.0001) times per day & stool consistency improved from 3.93±0.38 (watery) to 1.22±0.42 (soft) (p<0.0001).[13]

According to previous studies, Probiotic yoghurt is superior to plain yogurt.[14-16]. However, our study demonstrates that adding plain yoghurt with standard treatment modalities is an added advantage. A previous study done on eighty children aged 6-24 months had a significant difference in terms of weight (p=0.017), duration of hospitalization (p=0.035) and frequency of diarrhoea (p=0.049) in children using plain yoghurt alongside regular anti-diarrheal treatment.[17] Along with acute watery diarrhoea yoghurt also has beneficial effects in diarrhoea due to carbohydrate malabsorption and antibiotic-associated diarrhea.[18,19]

A previous study showed a notable diminution in stool frequency in the Probiotic-Group from 8.18±3.64 to 6.43±03 (p= 0.016) when compared with the yoghurt 7.93±3.97 to 7.14±3.90 (p= 0.139).[20]

Yoghurt has a benefit and is somewhat comparable to Probiotics, at least in terms of consistency. Yoghurt is an easily available and cost-effective way to prevent major morbidity associated with diarrhoea, i.e. dehydration. In addition, improving consistency decreases overall fluid loss.

ACKNOWLEDGEMENT

We would also like to thank the staff and our colleagues at Combined Military Hospital, Peshawar Pakistan for their expertise and assistance throughout the study.

STUDY LIMITATIONS

The limitation of our study is that the sample size was small and hence cannot adequately depict the response of the entire population. The addition of Probiotics or yoghurt was done to the standard treatment regime (including ORS and zinc); hence these serve as confounding factors, although to reduce this bias, the same treatment regime was followed for all three groups.

CONCLUSION

According to our study, there is a clear benefit in children who received Probiotics. The outcome in terms of consistency is almost equal in the Probiotic and Yoghurt-Group. However, Probiotic is superior to yoghurt in terms of frequency Children who received Probiotic or yoghurt have an overall better control of frequency and consistency when compared with controls where none was used.

Conflict of Interest: None.

Author's Contribution

Following authors have made substantial contributions to the manuscript as under:

RR & AMA: Conception, study design, drafting the manuscript, approval of the final version to be published.

AR & HU: Data acquisition, data analysis, data interpretation, critical review, approval of the final version to be published.

ZR & RR: Critical review, drafting the manuscript, approval of the final version to be published.

Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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