Original Article

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Role of Probiotics in the Prevention of Recurrent Upper Respiratory Tract Infections in the Pediatric Age Group

Nidda Arshad Waraich[1], Muhammad Omer Tufail[2], Zainab Akmal Abbasi[3], Muhammad Umer Farooq[4]

[1]Postgraduate Resident, Dept of Pediatrics Medicine, CMH Quetta, [2]HOD Dept of Pediatrics Medicine, CMH Quetta
[3]Medical Officer, Pediatric, Pak Medical and Diagnostic Center, Rawalpindi, [4]DADMS/Medical Officer CR Bigd Quetta

Author`s Contribution

[1,2]Substantial contributions to the conception or design of the work; or the acquisition, Drafting the work or revising it critically for important intellectual content [2]Final approval of the study to be published, [3]Active participation in active methodology, [4]analysis, or interpretation of data for the work,

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Address of Correspondent
Dr Nidda Arshad Waraich
CMH Quetta
niddaarshad22@gmail.com

ABSTRACT

Objectives: To determine the role of probiotics in prevention of recurrent upper respiratory tract infection in children.

Methodology: This quasi-experimental study was conducted at Pediatrics department of Combined Military Hospital, Quetta, Pakistan from October 2024 to April 2025 after taking parental informed consent and ethical approval from institution. A total of 64 children with recurrent upper respiratory tract infection were included, selected through non-probability consecutive sampling technique, who were divided into Group-P (probiotic) and Group-S (no probiotics) containing 32 children each. Children were followed up after three months to assess for recurrence. Analysis of data was performed through Statistical Package for Social Sciences (SPSS) software version 22.

Results: Median age was 5.00 (3.00) years. There were 45 (70.30%) male and 19 (29.70%) female patients. Median number of episodes of URTI in three months at the end of study in Group-P was 1.00 (2.00) while in Group-S it was 2.00 (3.00), (p = 0.136). Frequency of recurrence of URTI in Group-P (n = 32) at three months follow up was 9 (28.13%) while in Group-S (n = 32), it was 17 (53.13%), (p = 0.042).

Conclusion: Probiotics can effectively prevent recurrent upper respiratory tract infection in children.

Keywords: Probiotics, Recurrence, Upper respiratory tract infections.

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Introduction

Globally, amongst the most frequent causes of pediatric hospital visits and admissions are the upper respiratory tract infections (URTI) which encompass pharyngitis, tonsillitis, otitis media, sinusitis, and the common cold. Although, they can be self-limiting, yet can cause a variety of complications and add to the medical expenses causing major financial burden. [1, 2] Globally, the incidence rate of this highly common pediatric morbidity has been reported to exceed 166 thousand children per hundred thousand pediatric population. [3] In Pakistan, although the exact incidence is not known, but according to a study, URTIs make up approximately 20.83% of the cases of pediatric respiratory infections. [4]

Viruses are the main cause of this pediatric pathology related to the respiratory tract, however, isolated as well as co-infection with bacteria is also common. Some of the common organisms that are involved in its etiology are rhinoviruses, respiratory syncytial virus (RSV), influenza viruses, parainfluenza viruses, adenoviruses, coronaviruses, Streptococcus pyogenes, Haemophilus influenzae, Moraxella catarrhalis and Streptococcus pneumoniae.[5, 6] Due to their highly contagious nature, URTIs have a very high tendency to spread rapidly across the household contacts and subsequently the community which increases the chances of recurrence of this condition in the pediatric age group. [7] When it comes to label a child to have recurrent URTI, a study was recently conducted in which its definition was provided and it stated that for a child to be labeled to have recurrent URTI, he/she must have at least four episodes of this condition with each episode to last for the minimal duration of four days and this should occur within a period of six months from the first URTI event of the year. [8]

The management of URTI in children involves supportive therapy and preventive measures. These measures play the most crucial role owing the predominantly viral etiology

of this infectious disease, however, antibiotics are required in cases where infection is mediated by bacterial pathogens. [9] Recently, probiotics have been gaining a lot of popularity in the management of various conditions in general as well as pediatric population, particularly the gastrointestinal disorders. However, their role in the respiratory illnesses, particularly in preventing the recurrence of URTIs in children is still controversial since there are studies that provide unequivocal evidence in favor of their use while others negate any potential benefit of this therapy in this regard. [10] Therefore, to answer this highly important research question that whether probiotics have any role in preventing the recurrence of URTIs in pediatric population, present study was conducted with the aim of determining the role of probiotics in prevention of recurrent upper respiratory tract infection in children. Results from this study may provide better understanding of the benefits of probiotics use in children with the goal of preventing development of recurrent URTIs.

Methodology

This quasi-experimental study was conducted at the Pediatrics department of Combined Military Hospital, Quetta, Pakistan from October-2024 to April-2025 after getting approval from institutional ethical committee (Ref No: CMH QTA-IERB 43/2024). Sample size calculation was performed using WHO sample size calculator. Sample size calculation was performed by using level of significance 5%, power of 90% and anticipated frequency of recurrence of URTI with versus without probiotic use of 31.3% and 70.6%, respectively. [11] This gave a sample size of 64 (32 in each group).

Male and female children aged between six months and twelve years who had a history of recurrent URTI and presented with a new episode of URTI in the outdoor department were included in the study using non-probability consecutive sampling technique. Patient with chronic respiratory tract problems like (cystic fibrosis, ciliary dyskinesia, asthma and bronchitis), immunocompromised due to inborn error of immune system or immunosuppressant medications and those who received influenza vaccine were excluded from the study. Recurrent URTI was defined by presence of either of the following criterion; more than three episodes of pharyngitis/tonsillitis/otitis media or greater than five episodes of infectious rhinitis in last twelve months.

Before inclusion of a child in the study, all the parents were explained regarding the purpose and methodology of the study and informed written consent of the parents was taken. Baseline demographics were age, gender, type of recurrent URTI and number of episodes in three months before enrollment. For presenting URTI, all the children were provided standard supportive therapy with hydration and anti-inflammatory medication as per institutional guidelines. However, probiotics were provided only to the Group-P patients. Group allocation was performed based on the medical registration (MR) number of the patients. Patients with their MR number ending at an even number were allocated in Group-P in which patients were prescribed probiotic sachet containing combination of Lactobacillus rhamnosus and Saccharomyces boulardii (Bactocell ®) once daily for four weeks in addition to the supportive therapy with or without antibiotics (depending upon patient's condition) which was given till complete resolution of symptoms. Patients who had their MR number ending at an odd number were allocated in Group-S in which they were only given supportive therapy with or without antibiotics (depending upon patient's condition) till complete resolution of symptoms.

Patients were followed up till three months from the date of enrollment through telephonic correspondence with the parents to document any episode of URTI and to request them for bringing their child to hospital for diagnostic assessment of URTI. Upon confirmation of its presence, event was documented. For every recurring episode, similar protocol was followed and patients were provided with the supportive therapy. After three months completion, final in-person follow up was held at which history was reviewed to re-confirm the collected data regarding recurring episodes of URTI. In case of occurrence of two or more episodes during the three months period, patient will be labeled to have recurrence of URTI.

Data was analyzed using Statistical Package for Social Sciences (SPSS) version 22. Quantitative variables normality was checked by Shapiro-Wilk test which showed that age, number of episodes in three months before enrollment and number of episodes in three months at the end of study period were not normally distributed and were thus presented as median interquartile range (IQR). Age, number of episodes of URTI in three months before enrollment and number of episodes of URTI at three months at the end of study were compared between groups by using Mann Whittney U-test. Qualitative variables (gender, type of recurrent URTI and recurrence of URTI) was presented as frequency and percentages and were compared between group using Chi-square test. Comparison of median number of episodes of URTI pre-

enrollment and end of study within groups was performed using Wilcoxon matched pair signed rank test. A p-value of ≤ 0.05 was considered as statistically significant.

Results

In this study, 64 patients were included. Median age was 5.00 (3.00) years. Among these patients, children aged 1-5 years were 36 (56.30%), 23 (35.90%) were aged 6-10 years and 5 (7.80%) were aged 11-14 years. There were 45 (70.30%) male and 19 (29.70%) female patients. Most common type of recurrent URTI was infectious rhinitis found in 24 (37.50%) children followed by pharyngitis in 18 (28.10%), tonsillitis in 14 (21.90%) and otitis media in 8 (12.50%) children. There was no significant difference in age, gender and type of URTI between the two groups (p-value > 0.05). Pre-treatment patient characteristics are compared between groups in Table I.

Table I: Comparison of pre-treatment patient characteristics between groups. (n = 64)

Parameter	Group-P (n = 32)	Group-S (n = 32)	p-value
Median age	6.00 (4.00) years	4.00 (2.00) years	0.052
Age group			
1-5 years	13 (40.63%)	23 (71.88%)	
6-10 years	17 (53.12%)	6 (18.75%)	0.016
11-14 years	2 (6.25%)	3 (9.37%)	
Gender			
Male	24 (75.00%)	21 (65.63%)	0.412
Female	8 (25.00%)	11 (34.37%)	
Type of recurrent URTI			
Infectious rhinitis	14 (43.75%)	10 (31.25%)	0.708
Pharyngitis	8 (25.00%)	10 (31.25%)	
Tonsillitis	7 (21.88%)	7 (21.88%)	
Otitis media	3 (9.37%)	5 (15.62%)	

Median number of episodes of URTI in three months before enrollment in Group-P was 7.00 (2.00) while in Group-S it was 7.00 (1.00), (p = 0.456). Median number of episodes of URTI in three months at the end of study in Group-P was 1.00 (2.00) while in Group-S it was 2.00 (3.00), (p = 0.136). This shows that within the group, median number of episodes of URTI reduced significantly in both the groups (p < 0.001) but not between the groups. Within and inter-group comparison of median number of episodes of URTI in three months before enrollment and median number of episodes in three months at the end of study is given in Table II.

Frequency of recurrence of URTI in Group-P (n = 32) at three months follow up was 9 (28.13%) while in Group-S (n = 32), it was 17 (53.13%), (p = 0.042). This comparison of recurrence of URTI between groups at three months follow up is given in Table III.

Association of disease recurrence with age is given in Table IV. Association of disease recurrence with gender is given in Table V. Association of disease recurrence with type of URTI is given in Table VI

Table II: Comparison of median number of episodes of URTI between groups (n = 64)

Median number of episodes of URTI	Group-P (n = 32)	Group-S (n = 32)	p-value*
Pre-enrollment	7.00 (2.00)	7.00 (1.00)	0.456
End of study	1.00 (2.00)	2.00 (3.00)	0.136
p-value†	< 0.001	< 0.001	

** Intergroup comparison*
† Within group comparison

Table III: Comparison of recurrence of URTI at three months follow up between groups (n = 64)

Recurrence of URTI	Group-P (n = 32)	Group-S (n = 32)	p-value
Yes	9 (28.13%)	17 (53.13%)	0.042
No	23 (71.87%)	15 (46.87%)	

Table IV: Association of disease recurrence with age. (n = 64)

	Association with age			
Group-P (n = 32)	1-5 years (n = 13)	6-10 years (n = 17)	11-14 years (n = 2)	p-value
Recurrence	3 (23.08%)	6 (35.29%)	0 (0.00%)	0.502
Group-S (n = 32)	1-5 years (n = 23)	6-10 years (n = 6)	11-14 years (n = 3)	p-value
Recurrence	9 (39.13%)	6 (100%)	2 (66.67%)	0.026

Table V: Association of disease recurrence with gender. (n = 64)

	Association with gender		
Group-P (n = 32)	Male (n = 24)	Female (n = 8)	p-value
Recurrence	8 (33.33%)	1 (12.50%)	0.256
Group-S (n = 32)	Male (n = 21)	Female (n = 11)	
Recurrence	10 (47.62%)	7 (63.63%)	0.388

Table VI: Association of disease recurrence with type of URTI. (n = 64)

	Association with type of URTI				
Group-P (n = 32)	Infectious rhinitis (n = 14)	Pharyngitis (n = 8)	Tonsillitis (n = 7)	Otitis media (n = 3)	p-value
Recurrence	8 (57.14%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0.013
Group-S (n = 32)	Infectious rhinitis (n = 10)	Pharyngitis (n = 10)	Tonsillitis (n = 7)	Otitis media (n = 5)	p-value
Recurrence	7 (70.00%)	5 (50.00%)	2 (28.57%)	3 (60.00%)	0.396

Discussion

With the advancements in the field of pharmaceutical industry and medicine, a novel therapeutic approach has been developed for managing and preventing a number of conditions which is probiotics. [12, 13] Primarily, these are used in the management of diarrheal disease in the pediatric population [14, 15], however, recently evidence has been emerging regarding its use in prevention of URTIs in this age group. Present study was thus focused on determining the role of probiotics in this particular infectious disease process in pediatric population. In present study, average age of the children who were diagnosed with having recurrent URTI was five years with majority children aged between one and five years. This could be because in this age group, immune system is still under the process of maturing and children tend to touch and experience objects in their surroundings. [16]

It was observed that more than 70% of the cases of upper respiratory tract illness were of male gender. Compared to this, a study was conducted by Turyasiima et al. [17] focusing on the clinical characteristics of children who presented with URTI and similar to present study they reported this male predominance regarding the distribution of this condition. In another such study conducted by Khan et al.[18] in Pakistani children, similar male predominance was observed in this regard. The exact reason for this predominance of URTI in male children is not known but the differences in the hormonal, socio-demographic and behavioral factors may have some association with it. [19]

Upon comparative analysis of recurrence of URTI in study groups, i.e., probiotic and no probiotic group, it was observed that although there was no significant benefit of probiotic administration on the median number of episodes of URTI after three months of therapy ($p = 0.136$), however, recurrence rate was significantly reduced by probiotic use ($p = 0.042$) which shows it to be highly useful in prevention of URTI recurrence in children. Compared to this, a study was conducted by Marushko et al. [11] which showed the similar significant reduction in the recurrence rate of this respiratory illness in children ($p = 0.0149$).

Similarly, in another single group study conducted by Espinosa et al. [20], it was found that the number of various type of URTI episodes significantly reduced after the use of probiotics compared to pre-probiotic use. In addition, another study found this usefulness of the use of probiotics in not only preventing the recurrence but also reduce the severity of symptoms of an ongoing URTI in children. [21] The mechanism by which probiotics can mitigate the rate of recurrence of URTI in pediatric population is through the immune modulation and strengthening the mucosal integrity of the respiratory mucosa. Contrarily, Pulmamidi et al. [22] found that probiotics use had no significant preventative role in URTI recurrence among pediatric population ($p = 0.082$).

Conclusion

In conclusion, a clear benefit is evident regarding the role of probiotics to prevent URTI recurrence in children. Therefore, the use of probiotics in children with this recurrence of this common respiratory illness is strongly recommended. There were no limitations of present study.

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