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Original Article

Effect of racecadotril as an adjunct to standard therapy and standard therapy alone on the duration of hospital stay in children aged 6–60 months with acute watery diarrhea

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Abstract

Acute watery diarrhea (AWD) is a significant contributor to morbidity as well as mortality among underfive children, predominantly in resource-limited settings. Although rehydration therapy is the cornerstone of management, it has a limited role in reducing the duration and severity of diarrhea. This study compared the duration of hospital stay in children aged 6–60 months with AWD and some or severe dehydration, with or without acute malnutrition, who received racecadotril as an adjunct to standard therapy versus standard therapy alone. This comparative interventional study was conducted in the Pediatric Medicine Department, Mayo Hospital, Lahore. A total of 208 children fulfilling the selection criteria were enrolled and allocated into two groups (104 participants per group) using a random number table. All participants received standard treatment for AWD. Children in Group A received three divided doses of racecadotril (1.5 mg/kg/day) in addition to the standard treatment, whereas children in Group B were administered only the standard treatment. The duration of hospital stay and reduction in loose stool frequency were recorded for all participants. Our results revealed that the median hospital stay duration was significantly shorter in Group A [22.75 hours (IQR = 11.00) versus 61.00 hours (IQR = 24.00) in Group B; $p < 0.001$]. Similarly, the median decrease in the frequency of loose stools during hospitalization was significantly greater in Group A [9.00 (IQR = 2.00) versus 5.00 (IQR = 2.00) in Group B; $p < 0.001$]. Among children with moderate acute malnutrition (MAM), the median hospital stay duration was significantly shorter in Group A [40.00 hours (IQR = 35.00)] than in Group B [65.00 hours (IQR = 29.00)] ($p = 0.003$). Similarly, among children with varying degrees of dehydration (some or severe) classified according to the WHO criteria, the median duration of hospital stay remained significantly lower in Group A ($p < 0.001$) than in Group B ($p = 0.013$). Racecadotril as an adjunct to standard therapy significantly reduced the duration of hospital stay in children aged 6–60 months with AWD, including those with MAM and some or severe dehydration.

Keywords

Acute diarrhea; Child; Dehydration; Hospitalization; Racecadotril

1. Introduction

Three or more episodes of loose stools over 24 hours for less than 14 days are termed acute watery diarrhea (AWD) [1]. In developing countries, it is a frequently occurring condition that causes morbidity as well as mortality in children, particularly those younger than five years [2]. In developed countries, AWD is generally mild; however, with some exceptions, it contributes to hospital admissions and substantial healthcare costs [3,4]. AWD is a global health issue linked to approximately 1.3 million child deaths annually, especially in low-income countries [5]. According to the UNICEF, AWD led to

38,706 deaths among the underfive population in Pakistan, accounting for approximately 20% of the total number of underfive deaths in 2015 [6].

Depletion of fluids and electrolytes (sodium concentration of 55 mEq/L, potassium concentration of 25 mEq/L, and bicarbonate concentration of 15 mEq/L in diarrheal fluid) occurs as a result of AWD. Oral or intravenous rehydration therapy, encouragement for breastfeeding, utilization of probiotics, zinc therapy, and, in selected patients, the administration of antibiotics are recommended for the management of AWD [7]. Notwithstanding the broad use of oral rehydration therapy (ORT) has resulted in substantial decreases in both the morbidity as well as mortality caused by diarrhea, rehydration has minimal effects on the duration and intensity of diarrhea [8]. Racecadotril is a newer addition to the collection of drugs used for the management of AWD in children [9]. Racecadotril exerts its effect through the inhibition of enkephalinase, which increases the antisecretory effect of enkephalin in submucosal enteric neurons. Once absorbed following oral administration, it is transformed into its active metabolite (thiorphan), which prolongs the action of methionine-enkephalin [10]. Racecadotril has an appreciable safety profile and tolerability with no serious adverse effects [5,11].

The administration of racecadotril has also been recommended for the management of AWD, but the recommendation is weak and based on moderate-quality evidence [3,12,13]. However, there is conflicting evidence demonstrating the effectiveness of racecadotril in severe AWD. In 2017, Gharial J et al. studied the effectiveness of racecadotril for the management of severe AWD and reported no remarkable decrease in the frequency of stools, duration of hospital stay or occurrence of diarrhea in the study group [14]. By excluding patients with severe dehydration, Sreenivas S K et al. studied the effectiveness of racecadotril combined with ORT for AWD in children and reported a decrease in the mean frequency of loose stools within 48 hours (34.1%), mean recovery time within 48 hours (79.24%) and mean volume of ORS consumed (30.1%) in the study group [15]. Nevertheless, few studies have compared the average hospital stay duration in children aged 6–60 months with AWD who have some or severe dehydration with or without acute malnutrition and who are treated with racecadotril as an adjunct to standard therapy. AWD is related to considerable hospitalization rates and substantial healthcare costs in our country, which not only increase financial costs to the family but also increase the bed occupancy rate and health care cost in hospitals. Considering these factors, we designed this study to compare the duration of hospital stay in children aged 6–60 months with AWD, some or severe dehydration, and with or without acute malnutrition who received racecadotril as an adjunct to standard therapy versus standard therapy alone; if it is proven efficacious, its use may reduce not only the financial burden on families but also hospital bed occupancy and healthcare costs, particularly during peak diarrheal seasons.

2. Methods

2.1. Study design, duration, and settings

This comparative interventional study was conducted for six months from October 2024 to March 2025 in the Pediatric Medicine Department, Mayo Hospital, Lahore, Pakistan, one of the largest and oldest public healthcare facilities in the country with 2,400 beds, providing general and specialized healthcare services since its inception.

2.2. Ethics considerations

The study received approval from the Board of Studies in Pediatric Medicine (No. Prof/Paeds/BOS/KE/MH/U-1-505-509), Project Evaluation Committee (No. 1159/PEC/RC/KEMU), Institutional Review Board (No. 13725/REG/KEMU/2020) and Advanced Studies &

Research Board (No. 2078/KEMU/2020) of King Edward Medical University, Lahore, Pakistan, which is affiliated with Mayo Hospital, Lahore. Written informed consent was obtained from the parents or caregivers of all the recruited children before enrollment.

2.3. Sample size and sampling technique

Sample size was calculated on the basis of the comparison of two independent groups (racecadotril + standard therapy versus standard therapy alone) using a two-sided t test with α = 0.05 and power = 90%. Expected means and standard deviations were taken from a prior study: racecadotril group mean = 92.40 (SD = 38.99) and placebo group mean = 76.40 (SD = 31.09). Using the pooled variance approach, the pooled variance was σ2 = 1243.40 (pooled SD = 35.26), and the mean difference Δ = 16.0 [16]. The required sample size per group was calculated with the following formula:

$$n = \frac{2\,(Z_{1-\alpha/2} + Z_{1-\beta})^2\,\sigma^2}{\Delta^2} \quad (1)$$

which yielded n ≈ 102.1 per group using G*Power version 3.1. We rounded up to 104 participants per group to allow a small margin for loss to follow-up, resulting in the enrollment of 208 participants (104 per group). Simple random probability sampling was used for participant recruitment.

2.4. Participant selection

Children aged 6–60 months who presented with AWD, defined as the passage of ≥ 3 loose stools/day for < 14 days, and children with some or severe dehydration and either no acute malnutrition or moderate acute malnutrition (MAM) were enrolled, and those with severe acute malnutrition were excluded. Furthermore, children with diarrhea secondary to any local or systemic infection other than gastroenteritis, those with a history of receiving antidiarrheal medications, those who had used probiotics or antibiotics within 24 hours before presentation to the hospital, those with blood in the stools, and those with persistent vomiting were not included in the study.

2.5. Intervention

After enrollment, demographic information, including age, sex, and weight, was recorded for each participant. A detailed clinical history was obtained from parents or caregivers using a predesigned data collection proforma. Clinical examination was performed by the investigator, and the degree of dehydration at registration was assessed clinically according to WHO criteria and categorized as having some degree of dehydration or severe dehydration. Nutritional status was assessed using a WHO weight-for-height Z score chart and categorized as no acute malnutrition or MAM. All the enrolled children received standard treatment for AWD according to the departmental management protocol. Standard treatment included oral or intravenous rehydration therapy as indicated by the degree of dehydration, zinc supplementation, continued feeding, breastfeeding support, and other supportive measures as needed. Body weight was measured at enrollment using a calibrated digital weighing scale and recorded in kilograms (kg).

Children were allocated to two groups, i.e., Group A and Group B, using a random number table. Children in Group A received racecadotril in addition to the standard treatment. Racecadotril was administered at a dosage of 1.5 mg/kg/day in three split doses. For administration, a 10 mg sachet of racecadotril was mixed with 10 mL of plain water, yielding a concentration of 1 mg/mL. The medication was administered for five days or until hospital discharge, whichever occurred earlier. Children in Group B received standard treatment alone and did not receive racecadotril. No placebo was administered to

participants in Group B. All participants were monitored throughout their hospital stay. Patients were discharged when they passed fewer than three stools per day or had two consecutive formed stools, whichever occurred first. The study outcomes included length of hospital stay (hours from admission to discharge) and a decrease in the frequency of loose stools during hospitalization.

2.6. Data analysis

The data were analyzed using SPSS version 26.0. Quantitative variables are summarized using medians, interquartile ranges (IQR), while categorical variables, including sex, degree of dehydration, and nutritional status, are described as frequencies and percentages. The distribution of continuous variables was assessed before analysis; age, weight, length of hospital stay, and reduction in stool frequency were nonnormally distributed. Thus, the Mann–Whitney U test and chi-square test was employed to achieve study objectives. Statistical significance was set at $p < 0.05$.

3. Results

Table 1 delineates that a total of 208 children were enrolled in the study, with 104 participants in each group. The median age was 13 months (IQR = 14.00) in Group A and 16 months (IQR = 20.00) in Group B, with similar distributions across the groups (p = 0.148). Similarly, median weight did not differ significantly between Group A [12 kg (IQR = 5.00)] and Group B [12 kg (IQR = 5.00)] (p = 0.430). The proportions of children with MAM and severe dehydration were also comparable between the two groups ($p > 0.05$), indicating baseline similarity of the study groups.

Table 1. Baseline characteristics of the study participants.

Characteristics		Group A (n = 104)	Group B (n = 104)	Z Statistic/χ^2	*p* Value
		Median (IQR)	Median (IQR)		
Age (months)		13.00 (14.00)	16.00 (20.00)	-1.450	0.148
Weight (in kg)		12.00 (5.00)	12.00 (5.00)	-0.789	0.430
Sex, n (%)	Male	62 (59.62)	57 (54.81)	0.491	0.483
	Female	42 (40.38)	47 (45.19)		
Degree of malnutrition, n (%)	Moderate acute malnutrition	14 (13.46)	20 (19.23)	1.260	0.261
	No acute malnutrition	90 (86.54)	84 (80.77)		
Degree of dehydration, n (%)	Some dehydration	90 (86.54)	96 (92.31)	1.830	0.176
	Severe dehydration	14 (13.46)	8 (7.69)		

The average length of hospital stay was significantly shorter in Group A [22.75 hours (IQR = 11.00)] than in Group B [61.00 hours (IQR = 24.00)] ($p < 0.001$) (Table 2). Similarly, the median decrease in the frequency of loose stools during hospitalization was significantly greater in Group A [9.00 (IQR = 2.00)] than in Group B [5.00 (IQR = 2.00)] ($p < 0.001$).

Table 2. Comparison of study outcomes between the two study groups.

Outcome	Group A	Group B	Z Statistic	*p* Value
	Median (IQR)	Median (IQR)		
Duration of hospital stay (hours)	22.75 (11.00)	61.00 (24.00)	-10.74	< 0.001
Reduction in number of loose stools during hospital stay	9.00 (2.00)	5.00 (2.00)	12.440	< 0.001

Table 3 demonstrates that among the children with MAM, the average duration of hospital stay was significantly shorter in Group A [40.00 hours (IQR = 35.00) versus 65.00 hours (IQR = 29.00) in Group B; $p = 0.003$]. Similarly, among children without acute malnutrition, the median hospital stay was significantly shorter in Group A [22.00 hours (IQR = 10.60)] than in Group B [60.50 hours (IQR = 24.00)] ($p < 0.001$). Among children with some degree of dehydration, the median length of hospital stay was shorter in Group A [22.00 hours (IQR = 10.10) versus 59.50 hours (IQR = 23.50) in Group B, $p < 0.001$]. Similar results were observed among children with severe dehydration, where the median hospital stay was significantly shorter in Group A [41.50 hours (IQR = 41.40)] than in Group B [73.00 hours (IQR = 30.50)] ($p = 0.013$).

Table 3. Comparison of duration of hospital stay by nutritional status and degree of dehydration.

Variables		Duration of Hospital Stay (Hours)		Z Statistic	*p* Value
		Group A	Group B		
		Median (IQR)	Median (IQR)		
Degree of malnutrition	Moderate acute malnutrition	40.00 (35.00)	65.00 (29.00)	-3.011	0.003
	No acute malnutrition	22.00 (10.60)	60.50 (24.00)	-10.240	< 0.001
Degree of dehydration	Some dehydration	22.00 (10.10)	59.50 (23.50)	-10.760	< 0.001
	Severe dehydration	41.50 (41.40)	73.00 (30.50)	-2.490	0.013

4. Discussion

Diarrhea remains among the prominent causes of morbidity as well as mortality among children under 5 years of age, particularly in developing countries. Even though the death toll owing to diarrhea has substantively decreased, it is still responsible for a sizeable proportion of under five deaths. The treatment of choice is oral or intravenous rehydration therapy. Nevertheless, although it is effective in most cases of mild to moderate illness, it does not substantially reduce the frequency, volume, or diarrhea duration [17]. Therefore, adjunctive therapies that can shorten the course of illness, reduce the course of illness and reduce hospitalization remain of clinical interest [18].

Given that local evidence regarding the effectiveness of racecadotril in AWD is limited, this study was conducted to evaluate its role as an adjunct to standard therapy. The findings of the present study suggest that racecadotril may be beneficial for reducing the duration of hospitalization among children with AWD. This finding aligns with those reported by Lehert et al., who conducted a meta-analysis evaluating racecadotril use as an adjunct to oral rehydration solution in children with acute gastroenteritis [19,20]. The authors concluded that racecadotril provided favorable outcomes in reducing diarrheal episodes irrespective of age, rotavirus status, dehydration status, treatment setting, or geographic region. Similarly, Sultana et al reported a significantly shorter duration of hospitalization among children receiving racecadotril than among those receiving placebo [21]. Another study also demonstrated superior outcomes with racecadotril compared with conventional treatment, with a significant reduction in recovery time among both outpatient and hospitalized children [22]. These findings corroborate those of our study, which supports the potential role of racecadotril as an effective adjunctive treatment in children with AWD.

Furthermore, another study reported that the average diarrhea duration was considerably shorter among children treated with racecadotril than among those receiving a placebo [23]. However, not all studies have demonstrated similar benefits. Gharial et al evaluated the efficacy of racecadotril in severe AWD and reported no significant reduction in the stool frequency, duration of diarrhea, or length of hospital stay [14]. Conversely, the findings of our study indicate that racecadotril may still provide clinical ben-

efit even among children who present with dehydration [24]. Differences in our populations, severity of illness, inclusion criteria, treatment protocols, and outcome assessment methods may account for the variation in findings across studies [25].

Our study has several limitations. First, it was conducted at a single tertiary care center, and the target population was limited. In addition, infants younger than six months and children older than five years were excluded. Therefore, our study findings cannot be generalized to the whole pediatric population. Bias could have been introduced because of nonblinding. Therefore, larger multicenter, blinded, randomized clinical trials are needed before the regular use of racecadotril in AWD is recommended. These results may have been affected by recall bias because the stool frequency was reported by parents or caregivers. Assessment of mortality and complication rates was also not included in this study.

5. Conclusions

Racecadotril as an adjunct to standard therapy significantly reduces the length of hospital stay in children aged 6–60 months with AWD, including those with MAM and some or severe dehydration.

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Data availability: The data supporting this study's findings are available from the corresponding author, Hafiza Saima Pracha, upon reasonable request.

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