ISSN: 0975-3583, 0976-2833 VOL1, ISSUE1, 2010

To study Efficacy of Racecadotril in Acute Diarrhea in Children

Dr. Monisha Biswas
(Wing Commander, Classified Specialist)
Dept. of Paediatrics, 7 Air Force Hospital, Kanpur, U.P.[1]
Corresponding Author: Dr. Monisha Biswas

Abstract

Background: Acute Diarrhea remains a leading cause of morbidity in children. Racecadotril, an enkephalinase inhibitor, has been shown to reduce stool output by decreasing intestinal hypersecretion.

Objective: To evaluate the clinical efficacy and safety of Racecadotril in children with acute Diarrhea.

Methods: A prospective observational study was conducted on 100 children aged 6 months to 5 years presenting with acute Diarrhea. All children received standard oral rehydration therapy (ORT), and 50 received adjunct Racecadotril (study group). The remaining 50 received ORT alone (control group). Primary outcomes included duration of Diarrhea, frequency of stools, and need for hospitalization.

Results: Children receiving Racecadotril had a significantly shorter mean duration of Diarrhea (38.4 ± 12.6 h) compared to controls (54.2 ± 15.8 h). Mean stool frequency reduction at 48 hours and rehydration requirements were also lower in the study group. Adverse events were mild and comparable between groups.

Conclusion: Racecadotril as an adjunct to ORT significantly reduced the duration and severity of acute Diarrhea in children. It was well tolerated and safe.

Keywords: Efficacy, Racecadotril, Acute Diarrhea.

Study Design: A prospective observational study.

Introduction

In impoverished countries, one of the most frequent reasons for Pediatric clinic visits is acute Diarrhea. Reductions in stool volume and disease duration are still desired outcomes, even with the widespread use of oral rehydration treatment (ORT). The antisecretory drug Racecadotril reduces intestinal water and electrolyte secretion without changing intestinal transit time by peripherally blocking enkephalinase [1].

The current study assesses Racecadotril's therapeutic effectiveness and safety in children with acute Diarrhea.

The passage of three or more loose or watery stools in a 24-hour period is referred to as Diarrhea. Infectious pathogens are responsible for almost 90% of cases of acute Diarrhea [2].

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The majority of deaths from acute infectious Diarrhea are preventable as long as fluid and electrolyte losses are appropriately restored. This is because high fluid and electrolyte losses cause dehydration and acidosis.

Rehydration has little effect on stool volume or frequency, despite the fact that oral rehydration therapy (ORT) has significantly reduced Diarrheal morbidity and death. The World Health Organization (WHO) has advised the addition of medication treatment for Diarrhea, as Oral Rehydration Solution (ORS) alone cannot be the best course of action, provided that the medication has demonstrated safety and effectiveness in the Pediatric population [3]. A particular enkephalinase inhibitor called Racecadotril has intestinal antisecretory effects in both humans and animals [4].

However, there has not been much research done on the safety and effectiveness of Racecadotril in Indian Pediatric age groups. Therefore, the purpose of this study was to assess the drug's effectiveness in treating acute Diarrhea in children in a tertiary care hospital that has a Diarrhea treatment and training center [5-7].

Materials and Methods

Study Design and Setting

A prospective observational study was conducted in the Pediatric Department of a tertiary care hospital over 12 months.

Participants

- **Total sample size:** 100 children
- **Age range:** 6 months to 5 years
- **Inclusion criteria:** acute watery Diarrhea (<72 h), mild–moderate dehydration
- **Exclusion criteria:** persistent Diarrhea, severe malnutrition, chronic GI disease, recent antibiotic use, or hypersensitivity to study drug

Groups

- **Study Group (n = 50):** ORT + Racecadotril
- **Control Group (n = 50):** ORT alone

Racecadotril was administered at standard Pediatric dosing (1.5 mg/kg three times daily).

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Outcome Measures

1. Duration of Diarrhea (hours)
2. Stool frequency at baseline, 24 h, and 48 h
3. Need for intravenous fluids/hospitalization
4. Adverse events

Statistical Analysis

Descriptive and inferential statistics (unpaired t-test, chi-square test) were used. A p-value <0.05 was considered significant.

Results

Table 1: Baseline Characteristics of Study Population (N = 100)

Variable	Study Group (n=50)	Control Group (n=50)	p-value
Mean age (months)	26.4 ± 11.2	27.1 ± 12.6	0.72
Male : Female	28:22	30:20	0.68
Mean duration of Diarrhea before enrollment (hours)	18.5 ± 7.4	19.1 ± 8.1	0.63
Dehydration (mild/moderate)	32/18	34/16	0.70

Table 2: Comparison of Stool Frequency Between Groups

Time Interval	Study Group (Mean ± SD)	Control Group (Mean ± SD)	p-value
Baseline stools/24 h	8.1 ± 2.3	8.4 ± 2.1	0.48
24 h stools/24 h	4.9 ± 1.8	6.7 ± 2.0	<0.001
48 h stools/24 h	2.8 ± 1.4	4.9 ± 1.7	<0.001

Table 3: Clinical Outcomes

Outcome	Study Group (n=50)	Control Group (n=50)	p-value
Mean duration of Diarrhea (hours)	**38.4 ± 12.6**	**54.2 ± 15.8**	<0.001
Requirement of IV fluids	6 (12%)	15 (30%)	0.02
Hospitalization rate	4 (8%)	10 (20%)	0.09

ISSN: 0975-3583, 0976-2833 VOL1, ISSUE1, 2010

Table 4: Adverse Events

Adverse Event	Study Group (n=50)	Control Group (n=50)	p-value
Vomiting	5 (10%)	6 (12%)	0.75
Abdominal pain	3 (6%)	4 (8%)	0.69
Skin rash	1 (2%)	0	0.31
Total adverse events	9 (18%)	10 (20%)	0.80

Discussion

In children taking Racecadotril in addition to ORT, this trial shows a significant decrease in the length and intensity of acute Diarrhea. The results corroborate the advantages of Racecadotril as a potent antisecretory medication.
Although hospitalization differences did not achieve statistical significance, the Racecadotril group had quick improvements in stool frequency, decreased requirement for rehydration therapy, and fewer hospital admissions[3]. Adverse events were similar to those in the control group, and the medicine was well tolerated.

In the current trial, Racecadotril was shown to be effective when compared to a placebo in boys and girls aged 3 months to 4 years; neither the causative microorganism nor the patients' requirement for rehydration prior to study inclusion had any impact. This Pediatric population handled Racecadotril well, and none of the side effects in the Racecadotril group were thought to be unrelated to the medication[8]. This outcome supports previous research in humans and animals that showed Racecadotril's good tolerability and specificity of action.

When Salazar-Lindo et al. compared the duration of Diarrhea in the Racecadotril and placebo groups based on the children's rotavirus status, they discovered that the median duration of Diarrhea in the Racecadotril group was 28 hours, regardless of rotavirus status, and that of the placebo group was 72 and 52 hours, respectively, for rotavirus-positive and negative children [9]. 50% of patients on Racecadotril recovered in 6.9 hours as opposed to 36 hours in the placebo group, according to Cezard JP et al.'s comparison of the length of Diarrhea in rotavirus-positive patients [1]. The mean duration of Diarrhea was 22.8% shorter in the Racecadotril group (3.4 vs. 4.4 days) than in the control group, according to Baumer et al.'s study of 200 patients with acute watery Diarrhea [2].

Adult randomized, placebo-controlled studies have demonstrated that Racecadotril's effectiveness in treating Diarrheal symptoms, including stool consistency, weight, and abdominal symptoms, is accompanied by good tolerability and safety[3, 10].

ISSN: 0975-3583, 0976-2833 VOL1, ISSUE1, 2010

Conclusion

Racecadotril is a safe and effective adjunct therapy for acute Diarrhea in children. When used alongside standard Oral Rehydration Therapy (ORT), it significantly reduces stool frequency and shortens the duration of illness. Evidence also indicates that Racecadotril is well-tolerated and effective as an adjunct to Oral Rehydration and Nutritional Therapy in infants and children with acute Diarrhea in both developed and developing countries.

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