

## Analysis of Various Treatment Modalities in Diarrhoea: A Comparative Study

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### ABSTRACT

**Background:** Diarrhea may mean many things to different people. A patient's subjective experience of altered bowel habits may not necessarily fit the physician's criteria for diarrhea. Hence; the present study was conducted for analysis of various treatment modalities in diarrhoea patients.

**Materials & Methods:** A total of 50 patients with presence of diarrhea were enrolled and were randomized into two study groups as follows: 100 mg tablets of racecadotril three times daily (half an hour before or one hour after meal), or 2.0 mg tablets of loperamide twice daily. Patients were treated until recovery, defined as the production of 2 consecutive normal stools or no stool production for a period of 12 h. If recovery did not occur in 7 d, this treatment was discontinued. The first dose of the medication was taken under the supervision of a designated study physician or nurse. The overall clinical response as a success or failure was assessed by physicians.

**Results:** Mean age of the patients of the Racecadotril group and Loperamide group was 41.3 years and 43.5 years respectively. Majority proportion of patients were males. Clinical success among patients of Racecadotril group and

Loperamide group was 84 percent and 88 percent of the patients respectively. Non-significant results were obtained while comparing clinical outcome.

**Conclusion:** Racecadotril is equally effective as Loperamide for managing acute diarrhea in adults.


**Key words:** Diarrhea, Treatment, Racecadotril.

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### INTRODUCTION

Diarrhea is an increase in the volume and weight of daily stool. The frequency of bowel movements is usually increased as well. Diarrhea may mean many things to different people. A patient's subjective experience of altered bowel habits may not necessarily fit the physician's criteria for diarrhea. For some patients, the occurrence of a single unformed stool is enough to provoke a visit to the physician for "diarrhea." Thus; it is important for the physician first to determine if the patient has diarrhea and then proceed to characterize it.<sup>1, 2</sup>

Because some enteric pathogens such as *Vibrio cholerae* are not ubiquitous, some pathogens are seasonal and some pathogens are responsible for epidemics, the prevalence of various pathogens responsible for diarrhea is variable. The bacterial pathogens most frequently found are enteropathogenic clones of *E. coli*, *Shigella* spp., *Salmonella enterica* subsp., *Campylobacter* spp. and *Aeromonas* spp. The most frequently identified causative viruses (outside local epidemics) include rotavirus, caliciviruses

(norovirus and sapovirus), astrovirus and enteric adenovirus. Less prevalent viruses include paramyxovirus, morbillivirus, rubivirus and reovirus.<sup>3, 4</sup>

A few other viruses have been associated with acute diarrhea, yet their role remains to be firmly established. These include coronavirus, a definite agent of diarrhea in animals and seldom visualized by electron microscopy and isolated in culture from the stools of patients with diarrhea. Likewise, rotavirus is responsible for acute human gastroenteritis and is responsible for nosocomial cases.<sup>5-7</sup> Hence; the present study was conducted for analysis of various treatment modalities in diarrhoea patients.

### MATERIALS & METHODS

The present study was conducted for analysis of various treatment modalities in diarrhoea patients. Acute diarrhea was defined as the passing of at least 3 watery stools in a minimum of 24 h and for the duration of less than five days.

The study excluded patients with certain conditions, including bloody, purulent, or chronic diarrhea, as well as those with functional intestinal disorders. Additionally, patients who had recently started new medications (within 7 days of diarrhea onset) or received antibiotic treatment (within 15 days of entering the study) were also excluded. Other exclusion criteria included patients with kidney or liver failure, HIV positivity, diabetes, or concurrent progressive infections. These criteria were established to ensure a specific patient population was studied and to minimize potential confounding factors. A total of 50 patients with presence of diarrhea were enrolled and were randomized into two

study groups as follows: 100 mg tablets of racecadotril three times daily (half an hour before or one hour after meal), or 2.0 mg tablets of loperamide twice daily. Patients were treated until recovery, defined as the production of 2 consecutive normal stools or no stool production for a period of 12 h. If recovery did not occur in 7 d, this treatment was discontinued. The first dose of the medication was taken under the supervision of a designated study physician or nurse. The overall clinical response as a success or failure was assessed by physicians. All the results were recorded in Microsoft excel sheet and were subjected to statistical analysis using SPSS software.

**Table 1: Demographic data**

Variable	Racecadotril group	Loperamide group
Mean age (years)	41.3	43.5
Males	15	13
Females	10	12

**Table 2: Clinical outcome**

Result	Racecadotril group		Loperamide group	
	Number	Percentage	Number	Percentage
Clinical success	21	84	22	88
Clinical failure	4	16	3	12
Total	25	100	25	100
p-value	0.235			

**RESULTS**

Mean age of the patients of the Racecadotril group and Loperamide group was 41.3 years and 43.5 years respectively. Majority proportion of patients were males. Clinical success among patients of Racecadotril group and Loperamide group was 84 percent and 88 percent of the patients respectively. Non-significant results were obtained while comparing clinical outcome.

**DISCUSSION**

Diarrhea is defined as the production of stools of abnormally loose consistency, usually associated with excessive frequency of defecation and with excessive stool output. Normal stool output is approximately 100 to 200 g/day. Although diarrhea is a common symptom, most cases are self-limited or successfully treated by patients with over-the-counter medications. Acute diarrhea, defined as diarrhea that has been present for <4 weeks, is a nonspecific response of the intestine to several different conditions, including infections, adverse reactions to drugs, inflammatory bowel disease, and ischemia. The specific drugs and poorly absorbed sugars that can cause acute diarrhea are discussed by Fine et al. Although most cases of diarrhea are a result of infections, specific organisms can be identified in only a minority of patients. Patients seek medical attention for diarrhea when it is severe, prolonged, or if they develop worrisome symptoms, such as fever, prostration, or rectal bleeding.<sup>8-10</sup>

Hence; the present study was conducted for comparing various treatment modalities in treating diarrhea patients.

Salari P et al meta-analyzed clinical trials to show actual benefit of probiotics in treatment of diarrhea. The literature search provided 1228 articles while only 19 articles focusing on the analyses performed on children were eligible to be included in the meta-analysis with a total of 3867 patients enrolled in the study. Studies in adults' diarrhea, HIV patients, diarrhea induced by Clostridium difficile, radiation and chemotherapy were also systematically reviewed. The meta-analysis showed that probiotics decrease the duration of diarrhea and fever significantly in children while their effects on the duration of hospitalization, vomiting and number of stools per day were not significant. The results of systematic review on adults' diarrhea, amoebiasis, clostridium difficile-associated diarrhea, diarrhea in HIV positive patients, radiation-induced diarrhea, and chemotherapy-induced diarrhea did not support efficacy of probiotics in acute diarrhea. Probiotics may reduce duration of diarrhea and fever in children but their exact efficacy in treatment of diarrhea is not obvious yet.<sup>11</sup> Urbancsek H et al determined the efficacy and tolerability of Lactobacillus rhamnosus (Antibiophilus®) in comparison to placebo in a double-blind trial design. Its aim was to determine any clinically relevant difference between Antibiophilus® and placebo in terms of efficacy in patients suffering from mild to moderate diarrhoea

induced by radiation therapy. The study was performed in two radiotherapy units in Hungary; the results are based on the data for 206 recruited patients. Based on statistical analysis, Antibiohilus® patients showed superiority with respect to the number of bowel movements ( $P < 0.10$ ) and faeces consistency ratings by the investigators ( $P < 0.05$ ) at the study end. Statistical analysis of the patients' self-ratings with regard to diarrhoea grade and faeces consistency showed a statistically highly significant treatment-by-time interaction ( $P < 0.001$ ) which was supported by the evidence of tendencies or  $P$  values below the nominal 5% level in the second half of this study. Overall, there was a highly favourable benefit/risk ratio in favour of Antibiohilus®.<sup>12</sup>

## CONCLUSION

Racecadotril is equally effective as Loperamide for managing acute diarrhea in adults.

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