

**Original article:**

## **Evaluation of Efficacy of Two Different Treatment Regimes in Treating Patients with Traveler's Diarrhea: A Comparative Study**

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### **Abstract**

**Background:** Traveler's diarrhea (TD) is a crucial area for research, as it affects millions of tourists each year and creates a large economic burden. Much of the evidence for the clinical description and management of travelers' diarrhea were generated years ago, however, there is new information on geographic and host risk, etiology, and prevention strategies. Hence; present study was conducted to assess the efficacy of five versus Three Days of Ofloxacin Therapy for patients with Traveler's Diarrhea.

**Materials & Methods:** The present study included evaluation of efficacy of five versus Three Days of Ofloxacin Therapy for patients with Traveler's Diarrhea. A total of 50 patients with traveler's Diarrhea were included in the present study and were broadly divided into two study groups as follows: Group 1: Patients who were given three day ofloxacin therapy, Group 2: Patients who were given five day ofloxacin therapy. Patients were given antibiotic therapy according to their respective study groups. Microbiological assessment of the samples from the patients was done to assess the efficacy of antibiotic regimes. All the results were recorded on excel sheet and were analyzed by SPSS software.

**Results:** Number of cases with treatment failure were 2 in group 1 and 3 in group 2. Any significant difference was not observed while comparing the number of treatment failure cases in between two study groups.

**Conclusion:** Both the treatment regimens are equally effective in treating patients with traveler's Diarrhea.

**Key words:** Antibiotic, Ofloxacin, Traveler's Diarrhea.

### **INTRODUCTION**

Traveler's diarrhea (TD) is a crucial area for research, as it affects millions of tourists each year and creates a large economic burden. So-called "traveler's diarrhea" (TD) is characterized by 3 factors: susceptibility to enteric infectious agents, residence in an industrialized country, and travel to a region of the tropical or semitropical world with lower levels of hygiene. Recent research has helped to define TD, identify new causes, show the incidence of important complications, and provide recommendations for prevention and therapy. Travelers' diarrhea affects 20-60% of travelers to low-income regions of the world.<sup>1-3</sup>

By far the most important etiologic agents of traveler's diarrhea are bacterial pathogens, which have been implicated in more than 80% of cases in several studies.<sup>4,5</sup> Much of the evidence for the clinical description and management of travelers' diarrhea was generated years ago, however, there is new information on geographic and host risk, etiology, and prevention strategies.<sup>6,7</sup>

Hence; we planned the present study to assess the efficacy of five versus Three Days of Ofloxacin Therapy for patients with Traveler's Diarrhea.

## MATERIALS & METHODS

The present study was conducted in the Department of General Medicine, Teerthanker Mahaveer Medical College & Research Centre, Moradabad, UttarPradesh, India. It included evaluation of efficacy of five versus Three Days of Ofloxacin Therapy for patients with Traveler's Diarrhea. Written consent was obtained after explaining in detail the entire research protocol. A total of 50 patients with traveler's Diarrhea were included in the present study and were broadly divided into two study groups as follows:

Group 1: Patients who were given three day ofloxacin therapy,

Group 2: Patients who were given five day ofloxacin therapy.

Only those patients were included in the present study that were between 20 to 50 years of age and were diagnosed with suffering from Traveler's diarrhoea based on criteria previously described in the literature.<sup>8, 9</sup> Patients were given antibiotic therapy according to their respective study groups. Follow-up records of all the patients were maintained. Microbiological assessment of the samples from the patients was done to assess the efficacy of antibiotic regimes. All the results were recorded on excel sheet and were analyzed by SPSS software. Chi-square test was used for assessment of level of significance. P- value of less than 0.05 was taken as significant.

## RESULTS

A total of 50 cases of traveler's diarrhea were included in the present study and were broadly divided into two study groups on the basis of type of treatment regimen followed; group 1 and group 2. Mean age of the subjects of group 1 and group 2 was 40.2 years and 39.5 years respectively. There 14 males in group 1 and 15 males in group 2. Number of cases with treatment failure were 2 in group 1 and 3 in group 2. Any significant difference was not observed while comparing the number of treatment failure cases in between two study groups.

**Table 1: Demographic and clinical details of the subjects**

Group	Mean age (years)	Number of cases	Males	Females
1	40.2	25	14	11
2	39.5	25	15	10

**Table 2: Clinical response of the patients of the two study groups**

Parameter	Group 1	Group 2	P- value
Number of cases with treatment failure	2	3	0.81

## DISCUSSION

In the present study, the number of cases with treatment failure were 2 in group 1 and 3 in group 2. Any significant difference was not observed while comparing the number of treatment failure cases in between two study groups. DuPont HL et al, in 232 patients, compared the efficacy of 300 mg of ofloxacin given orally twice daily for 5 or 3 days with placebo for the treatment of acute diarrhea in U.S. students visiting Guadalajara, Mexico. The 3-day regimen of ofloxacin was found to be as effective as the 5-day regimen in producing a clinical and microbiologic cure. Clinical cures for patients who received ofloxacin for 5 days occurred in 59 of 66 (89%) subjects, whereas clinical cure occurred in 77 of 81 (95%) of those who received ofloxacin for 3 days and in 56 of 79 (71%) of those who took placebo (P = 0.0001). When the duration of diarrhea after therapy was

begun was compared in subgroups, a significant ( $P$  less than 0.05) shortening of posttreatment illness occurred in comparison with that in the placebo group for the following groups: for 5 days of ofloxacin, cases of shigellosis (32 versus 98 h); for 3 days of ofloxacin, all cases (28 versus 56 h), cases of enterotoxigenic *Escherichia coli* diarrhea (26 versus 66 h), cases of shigellosis (24 versus 98 h), all cases of illnesses associated with a bacterial enteropathogen (28 versus 69 h), and cases of illnesses in which numerous leukocytes were found in stool by microscopy (22 versus 49 h). Microbiologic eradication rates were 75 of 78 (96%) for patients who received ofloxacin and 37 of 46 (80%) for patients who received placebo ( $P = 0.009$ ). There was no significant difference in the number of adverse events reported by patients in either of the treatment groups.<sup>9</sup>

DuPont HL et al evaluated a poorly absorbed antimicrobial with in vitro activity against all major bacterial enteropathogens in oral therapy for bacterial diarrhea. One hundred ninety-one US students with diarrhea acquired in Mexico received 100 mg of aztreonam or matching placebo three times a day for 5 days. Stools were cultured for bacterial enteropathogens before and after therapy. They studied US students who acquired diarrhea in Mexico (travelers' diarrhea) in view of the high frequency of bacterial agents in this setting. They examined time of clinical recovery, treatment failures, adverse experiences, and microbiologic eradication from stool of the etiologic agent in subjects randomized to receive aztreonam or placebo. Aztreonam reduced the average duration of diarrhea compared with the placebo: for all cases, by 40 hours ( $P$  much less than .01); for those with enterotoxigenic *Escherichia coli* diarrhea, by 50 hours ( $P$  less than .01); for those with shigellosis, by 90 hours ( $P$ , not significant [small sample size]); for all bacterial agents, by 57 hours ( $P$  much less than .01). Clinical failures during the 5 days of therapy were seen in six patients (6%) receiving aztreonam and 25 (27%) receiving placebo ( $P$  less than .01). Pathogen eradication occurred in 95% of those receiving aztreonam and in 70% of those receiving the placebo ( $P$  less than .01). All bacterial enteropathogens were susceptible in vitro to aztreonam. The drug was well tolerated. Oral aztreonam, which is poorly absorbed, was well tolerated and was an effective therapy for bacterial diarrhea in US adults in Mexico.<sup>10</sup> Ericsson CD et al compared the efficacy of ofloxacin versus ofloxacin plus loperamide in the treatment of acute traveler's diarrhea. Adults newly arrived in Mexico from the United States who developed acute diarrhea of less than 2 weeks' duration were randomized to receive orally either: A) ofloxacin, 400 mg once; B) ofloxacin, 200 mg twice a day for six doses; or C) ofloxacin, 400 mg once, plus loperamide, 4 mg once followed by 2 mg after each loose stool, not to exceed 16 mg per day, for 3 days. The duration of illness was the number of hours elapsed from the beginning of therapy to the passage of the last unformed stool. Ofloxacin and loperamide were well tolerated. Combination therapy with single dose ofloxacin plus loperamide was significantly more efficacious in reducing the duration of diarrhea than single dose ofloxacin or ofloxacin given for 3 days ( $p < .00001$ ). The combined use of a single dose of ofloxacin with loperamide is safe and more efficacious in the treatment of traveler's diarrhea than use of ofloxacin alone.<sup>11</sup>

## CONCLUSION

From the above results, the authors concluded that both the treatment regimens are equally effective in treating patients with traveler's Diarrhea. However; future studies are recommended.

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