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Original Article

Assessment of Efficacy of Azithromycin And Ciprofloxacin For Cholera in Paediatric Subjects: A Comparative Study

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ABSTRACT

Background: One of the common cause for occurrence of diarrhoea in children and paediatric patients is Rotavirus. The disease affects infants and children aged three months and by age 3-4 years; virtually all children have had the disease. Previous infection offers protection from subsequent illnesses. However, re-infections are frequent but subsequent illnesses tend to be less severe than the first infection. Hence, we planned the present study to assess the efficacy of single dose of azithromycin to ciprofloxacin in treating cholera in paediatric subjects.

Materials and Methods: The present study included assessment of efficacy of single dose of azithromycin to ciprofloxacin in treating cholera in paediatric subjects. For the present study, we included paediatric subjects within the age groups of 3 to 10 years and with clinical manifestation of severe dehydration. Out of these cases, only those subjects were included, who demonstrated presence of Vibrio cholerae in stool samples. A total of 30 paediatric samples were included in the present study. All the subjects were divided randomly into two study groups. One group included subjects who received single dose of oral azithromycin (20 mg/kg) while the other group included subjects who received a single dose of ciprofloxacin (20 mg/kg). All the results were compiled and analysed by SPSS software.

Results: Mean age of the subjects in the ciprofloxacin group and in the azithromycin group was 54.2 and 56.8 years respectively. Mean duration of diarrhoea in the subjects of ciprofloxacin group and azithromycin group was 16.1 hours and 17.5 hours respectively.

Conclusion: Azithromycin should be considered as first line of treatment for cholera in paediatric subjects.

KEYWORDS: Azithromycin, Diarrhoea, Paediatric.

INTRODUCTION

Rotavirus is the most common cause of diarrhoea in infants and young children in both developed and developing countries. On a global scale, rotavirus is responsible for nearly 140 million cases of diarrhoea each year in children aged six months to two years.[1-3] It is also one of the major contributors to deaths of infants and young children in developing countries, claiming 500, 000-600, 000 lives each year, and up to 85% of these deaths occur in low-income countries. Diarrhoea due to rotavirus in children is recognized as the leading cause of hospitalizations worldwide.[4-6]

The disease affects infants and children aged three months and by age 3-4 years; virtually all children have had the disease. Previous infection offers protection from subsequent illnesses. However, re-infections are frequent but subsequent illnesses tend to be less severe than the first infection.[7-9]

Hence, we planned the present study to assess the efficacy of single dose of azithromycin to ciprofloxacin in treating cholera in paediatric subjects.

MATERIALS & METHODS

The present study was conducted in the Department of Paediatrics, Rajshree Medical Research Institute & Hospital, Bareilly, Uttar Pradesh (India) and included assessment of efficacy of single dose of azithromycin

and ciprofloxacin in treating cholera in paediatric subjects. Ethical approval was taken from institutional ethical committee and written consent was obtained from all the patient's guardians after explaining in detail the entire research protocol. For the present study, we included paediatric subjects within the age groups of 3 to 10 years and with clinical manifestation of severe dehydration. Out of these cases, only those subjects were included, who demonstrated presence of Vibrio cholerae in stool samples. A total of 30 paediatric samples were included in the present study. All the subjects were divided randomly into two study groups. One group included subjects who received single dose of oral azithromycin (20 mg/kg) while the other group included subjects who received a single dose of ciprofloxacin (20 mg/kg). After giving the primary dose, examination of the patients was done ten minutes after the drug administration. Stool samples were checked for the presence or absence of bacteria the stool specimens of the subjects after the administration of antibiotic. Resolution of diarrhoea within three days was categorized as clinical success of the drug. All the results were compiled and analysed by SPSS software. Chi-square test and student t test was used for assessment of level of significance. P-value of less than 0.05 was taken as significant.

Table 1: Comparison of baseline characteristics of subjects in the present study

Parameter	Ciprofloxacin group	Azithromycin group
Mean age (months)	54.2	56.8
Mean weight (Kg)	16.1	17.9
Height (cm)	99.7	101.2
Duration of diarrhoea (hours)	16.1	17.5
Frequency of vomiting	8.9	8.8

Graph 1: Descriptive values for demographic and clinical detail of the subjects

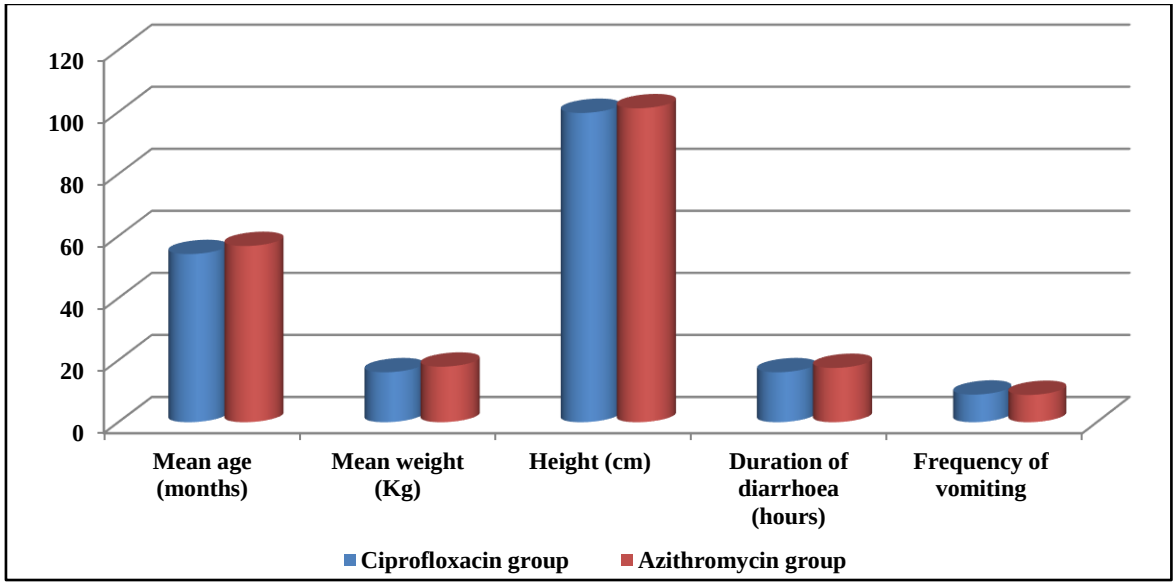

Table 2: Comparison of outcome of subjects in both the study groups

Parameter	Ciprofloxacin group (N)	Azithromycin group (N)	P- value
Clinical success	10	14	0.02*
Bacteriological success	13	15	0.25

*: Significant

RESULTS

A total of 30 subjects were included in the present study. All the subjects were divided randomly into two study groups with fifteen subjects in each group. Mean age of the subjects in the ciprofloxacin group and in the azithromycin group was 54.2 and 56.8 years respectively. Mean duration of diarrhoea in the subjects of ciprofloxacin group and azithromycin group was 16.1 hours and 17.5 hours respectively (Table 1, Graph 1).

On comparing the outcome in both the study groups, we observed that clinical success was seen in 10 and 14 cases ciprofloxacin group and azithromycin group respectively (Table 2). Significant results were obtained while comparing the clinical success in both the study groups (P- value < 0.05) while on comparing the bacteriological success; we obtained non- significant results (P- value > 0.05).

DISCUSSION

In the present study, we observed that better clinical results were displayed by Azithromycin group; however, in terms of microbiological evaluation, both antibiotics exhibited almost similar efficacy (Table 2). Alam S et al[10] assessed the prevalence of antibiotic associated diarrhea (AAD) and Clostridium difficile infection (CDI) in children and reviewed evidence available for use of probiotics in the prevention of AAD. They did a PubMed, Medline and Cochrane libary search for literature available in last 25 years. Prevalence of antibiotic associated diarrhea (AAD) is around 11% Children younger than 2 years and type of antibiotics are the two risk factors identified for AAD. For the pediatric population, CDI reportedly decreased in a tertiary care hospital in India, though number of suspected samples tested increased. The incidence of community acquired CDI is increasing in the pediatric population also. Detection of toxin A and B by enzyme linked immunosorbent assay (ELISA) and detection of toxin B by tissue culture form the mainstay in the diagnosis of C. difficile. Most of the AAD would respond to only discontinuation or change of the antibiotic. Oral metronidazole or oral vancomycin are drugs of choice for CDI. Probiotics reduce the risk of AAD in children and for every 7-10 patients one less would develop AAD. Prevalence of AAD is low and majority will respond to discontinuation of antibiotic. CDI is uncommon in children. Probiotics will prevent AAD in only 1 in 7 children on antibiotics. They need cost effectiveness studies to decide the issue of needing a probiotic antibiotic combination to prevent AAD.

Johnston BC et al [11] assess the efficacy of probiotics (of any specified strain or dose) for the prevention of antibiotic-associated diarrhoea in children and to assess adverse events associated with the use of probiotics when coadministered with antibiotics to children. They also contacted experts and searched registries and meeting abstracts for additional relevant articles. Randomized controlled trials that compared probiotic treatment with placebo or no treatment, involving pediatric subjects less than 19 years of age were included. Two reviewers independently applied eligibility criteria and assessed the studies for methodological quality. Data were independently extracted by 2 reviewers and analyzed via the standard Cochrane methodology. Six studies were included (total n = 707 patients). The combined results, analyzed with a per-protocol method that reported on the incidence of diarrhea during antibiotic treatment, showed significant benefit for the use of probiotics over placebo (relative risk [RR] 0.43, 95% confidence interval [CI] 0.25–0.75, I2 = 70.1%). In contrast, results from intention-to-treat analysis were nonsignificant overall (RR 1.01, 95% CI 0.64–1.61). Subgroup analysis on 4 studies that provided at least 5 billion single- strain colony- forming units (CFUs) daily (range 5.5–40 × 109 Lactobacillus GG, L. sporogens or Saccharomyces boulardii) showed strong evidence with narrow CIs for the preventative effects of probiotics for antibiotic-associated diarrhoea (RR 0.36, 95% CI 0.25–0.53, I2 = 3.5%). No serious adverse events were reported. The potential protective effects of probiotics to prevent antibiotic-associated diarrhoea in children do not withstand intention-to-treat analysis. Before routine use is recommended, further studies (with limited losses of subjects to follow-up) are merited. Trials should involve those probiotic strains and doses with the most promising evidence. Koletzko S et al[12] selectively searched the literature based on national and international guidelines The therapeutic goal is to replace the fluid and electrolyte losses resulting from diarrhea and vomiting. The administration of a hypotonic oral rehydration solution (ORS) is indicated to treat impending dehydration (infants aged up to 6 months with diarrhea and/or more than 8 watery stools in the last 24 hours and/or more than 4 episodes of vomiting in the last 24 hours), or when mild or moderate dehydration is already present. Oral rehydration with ORS given in frequent, small amounts over 3–4 hours is successful in more than 90% of cases. Regular feeding can be begun immediately afterward. Laboratory testing of blood or stool is usually unnecessary. Children who can be rehydrated orally or through a nasogastric tube should not be given intravenous fluids.

CONCLUSION

From the above results, the authors concluded that azithromycin should be considered as first line of treatment for treating treating cholera in paediatric subjects.

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