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EFFICACY OF LEVOFLOXACIN VERSUS CIPROFLOXACIN IN THE TREATMENT OF CHILDHOOD TYPHOID FEVER

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Abstract

Objective: *"To compare the outcome of levofloxacin versus ciprofloxacin in the treatment of childhood typhoid fever"*

Study design: *Randomized controlled trial*

Study place and duration: Department of Pediatric Medicine, Avicenna hospital, Lahore for 3 months (March 2025 till May 2025)

Methodology: *Sample size of 360 children with typhoid fever were enrolled and randomly divided in two groups. In group A, children were given oral 200 mg levofloxacin tablet. In group B, children were given oral 900–1,000 mg ciprofloxacin tablet. All children were followed-up pediatric wards for 7 days. If fever was resolved within 5 days, then efficacy was labeled. Total time required to resolve fever was also noted. All this information was recorded on Proforma and analysed in SPSS version 25.*

Results: *In this trial, the mean age of children was observed to be 7.71 ± 2.81 years in levofloxacin group while 7.90 ± 2.60 years in ciprofloxacin group. In levofloxacin group, there were 99 (55%) male children and 81 (45%) female children. In ciprofloxacin group, there were 90 (50%) male children and 90 (50%) females children. In levofloxacin group, clinical efficacy was achieved in 176 (97.8%) children. In Ciprofloxacin group, clinical efficacy was achieved in 144 (80.0%) children (p-value <0.0001). The mean time to resolve the fever in levofloxacin group was 3.83 ± 1.10 days while with ciprofloxacin group was 4.64 ± 1.70 days (p-value <0.0001).*

Conclusion: *Thus, levofloxacin is a better drug of choice for children presenting with typhoid fever.*

INTRODUCTION

Typhoid fever, another name for enteric fever, is a prevalent infectious illness in low- and middle-income nations. It is the most frequent bacterial cause of fever in migrants and returning tourists from these regions. According to estimates from the 2017 Global Burden of Disease Study, 136 000 people die each year, primarily in poor and middle-income countries, and around 14 million people are afflicted.[1, 2] Early tests are inconclusive, and symptoms might overlap with other causes of fever, making diagnosis challenging. Concern over antibiotic resistance is rising. In the areas of early diagnosis and treatment, timely referral of patients with serious illnesses, and prevention,

including immunization, general practitioners play a crucial role.[3, 4] The extended fever clearance time of the present single-drug regimens places a significant burden on patients and health systems, and it may also be a factor in the development of antibiotic resistance and the chronic carriage of the infections.[5]

The broad-spectrum antibiotic family known as fluoroquinolones directly inhibits the creation of bacterial DNA. These fluoroquinolones are now reasonably priced for usage in many places with limited resources.[6] The current WHO recommendation is that typhoid fever can be treated with third-generation cephalosporins (cefotaxime, ceftriaxone), macrolides (azithromycin), and fluoroquinolones (ciprofloxacin, ofloxacin).[7] Following the failure of traditional medications due to outbreaks of multidrug-resistant Salmonella enterica serotype Typhi in the Indian subcontinent in the late 1980s, ciprofloxacin was introduced as the first-line treatment for enteric fever. Nonetheless, decreased ciprofloxacin susceptibility, which has been extensively documented since 1994, has presented a therapeutic challenge.[8] Levofloxacin works well against both gram-positive and gram-negative bacteria and has a wide range of antibacterial action. Given its superior demonstrated clinical performance and decreased risk of adverse gastrointestinal effects in this kind of illness, it could be a preferable option than ciprofloxacin. [9, 10]

The purpose of the study was to assess the effectiveness of ciprofloxacin and levofloxacin in treating typhoid fever in children. Literature showed that ciprofloxacin is more appropriate and effective in resolving typhoid fever than levofloxacin. But limited work has been done before as no evidence exist in local literature. Therefore, we conducted this trial to obtain the evidence and current extent of knowledge about more appropriate regiment for typhoid fever in pediatric population. This would help in the improvement of our knowledge and to update guidelines in future for better treatment protocol.

METHODOLOGY

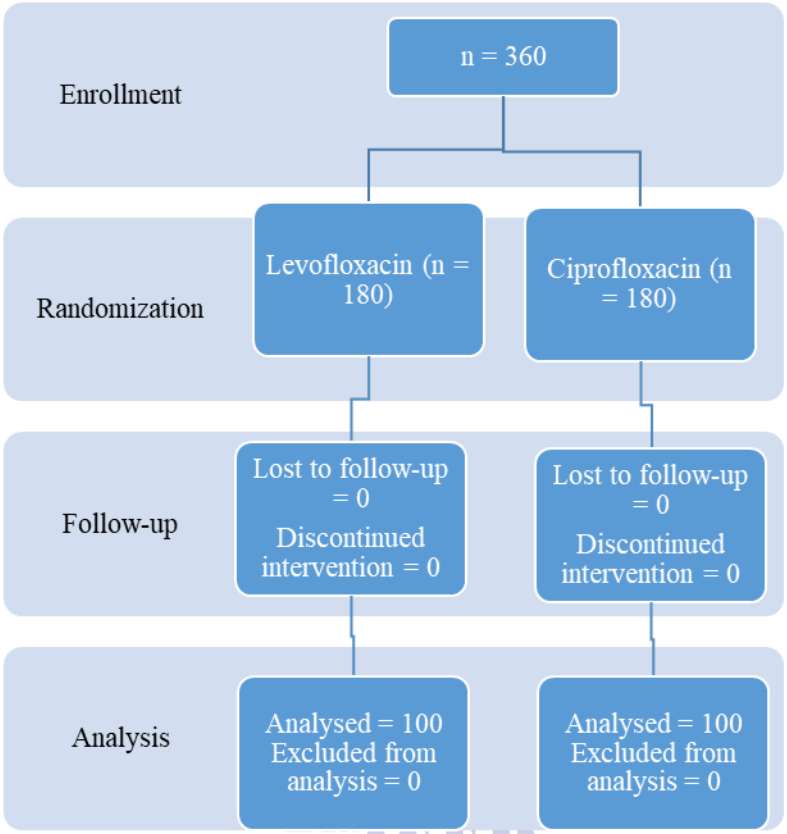
After approval from Ethical Review Committee of the hospital this Randomized controlled trial was conducted at the Department of Pediatric Medicine, Avicenna hospital, Lahore for 3 months (March 2025 till May 2025). Sample size of 360 cases; 180 in each group is calculated with 5% significance level, 80% power of study and percentage of efficacy i.e. 79.8% with levofloxacin and 89.3% with ciprofloxacin.[11] All the children were enrolled by applying Non-Probability, consecutive sampling technique after filtering the children for following criteria:

Inclusion: Children of age 1-12 years, both genders, presenting with typhoid fever were enrolled. typhoid fever was defined as presence of fever >100°F of >3 days and Salmonella typhi in blood, confirmed on blood culture.

Exclusion: Recurrent typhoid within 3 months, intestinal perforation, evidence of progressive or complicated disease, inability to swallow oral medication, hypersensitivity to trial drugs, already taken fluoroquinolone, third generation cephalosporin or macrolide in last week were excluded from the trial.

All the children were enrolled in the trial from Pediatrics emergency. Informed consent was obtained from parents. Demographics (name, age of child, sex of the child, duration of fever, weight, season, socioeconomic status and residence) were noted. Then children were admitted and randomly divided in two groups by using lottery method. In group A, children were given oral 200 mg levofloxacin tablet. In group B, children were given oral 900–1,000 mg ciprofloxacin tablet. All children were followed-up pediatric wards for 7 days. If fever was resolved within 5 days (body temperature falls <99°F and remain stable for at least 5 days), then efficacy was labeled. Total time required to resolve fever i.e. body temperature <99°F in all children was also noted. All this information was recorded on Proforma.

Figure-1: Patient Flow Diagram (n= 360)



Data was entered & analysed by using SPSS version 25. Normality was checked by Shapiro-Wilk test. Both groups were compared for efficacy by using chi-square test and mean time to resolve fever by using independent samples t-test. P-value ≤0.05 was taken as significant.

RESULTS

In this trial, the mean age of children was observed to be 7.71 ± 2.81 years in levofloxacin group while 7.90 ± 2.60 years in ciprofloxacin group. In levofloxacin group, there were 99 (55%) male children and 81 (45%) female children. In ciprofloxacin group, there were 90 (50%) male children and 90 (50%) females children. The mean weight of children was 28.66 ± 10.20 kg in levofloxacin group while 30.19 ± 10.11 kg in Ciprofloxacin group. The mean duration of fever was also similar showing unbiased distribution of children in both groups. In levofloxacin group, out of 180 children, 11 (6.1%) were coming from rural areas, 127 (70.6%) were living in urban areas and 42 (23.3%) were living in semi-urban areas. In ciprofloxacin group, out of 180 children, 19 (10.6%) were coming from rural areas, 115 (63.9%) were living in urban areas and 46 (25.6%) were living in semi-urban areas. In levofloxacin group, 31 (17.2%) were from low socioeconomic class, 35 (19.4%) belonged to middle class families and 114 (63.3%) belonged to high socioeconomic class. In ciprofloxacin group, 33 (18.3%) were from low socioeconomic class, 42 (23.3%) belonged to middle class families and 105 (58.3%) belonged to high socioeconomic class. In levofloxacin group, about 69 (38.3%) children presented with typhoid during summer season, 53 (29.4%) presented during winter, 34 (18.9%) presented during spring season while 24 (13.3%) presented during autumn season. In ciprofloxacin group, about 62 (34.4%) children presented with typhoid during summer season, 59 (32.8%) presented during winter, 38 (21.1%) presented during spring

season while 21 (11.7%) presented during autumn season. Table-I

Out of 360 children, clinical efficacy was achieved in 320 (89%) children. Figure-2

In levofloxacin group, clinical efficacy was achieved in 176 (97.8%) children. In Ciprofloxacin group, clinical efficacy was achieved in 144 (80.0%) children. The difference was highly significant and levofloxacin group better efficacy as compared to Ciprofloxacin group (p-value <0.0001). The mean time to resolve the fever in levofloxacin group was 3.83 ± 1.10 days while with ciprofloxacin group was 4.64 ± 1.70 days. The difference was highly significant and levofloxacin group early resolution of fever as compared to Ciprofloxacin group (p-value <0.0001). Table-II

Data was stratified according to different characteristics of children. In children aged 1-5 years, levofloxacin showed 100% clinical efficacy while ciprofloxacin was effective in 71.9% cases (p-value<0.0001). Similarly, in children aged 6-9 years, levofloxacin showed 100% clinical efficacy while ciprofloxacin was effective in 71.9% cases (p-value<0.0001). But in children aged 10-12 years, levofloxacin showed efficacy in 93.5% children while ciprofloxacin was effective in 100% children, although the difference was insignificant (p-clue>0.05). Gender has no impact on clinical efficacy of levofloxacin as camped to ciprofloxacin, as levofloxacin was significantly better in achieving clinical efficacy (97% & 98.8%) than ciprofloxacin (80% & 80%) in both; males and females (p-value<0.0001). In children living in rural areas or semi-urban areas, levofloxacin was 100% effective while in children living in urban areas, levofloxacin was effective in 96.9% children. Ciprofloxacin was effective in 89.5% children living in rural areas, 87% in semi-urban areas while in 75.7% children living in urban areas. The efficacy of levofloxacin was better in children living in different communities. When stratified for season at presentation, it was observed that levofloxacin showed better efficacy in all seasons as compared to ciprofloxacin (p-value <0.05). Table-III

In children aged 1-5 years, levofloxacin showed resolution of fever within mean time of 3.20 ± 1.08 days while ciprofloxacin achieved resolution of fever in 4.78 ± 1.72 days (p-value<0.0001). Similarly, in children aged 6-9 years, levofloxacin showed resolution of fever within mean time of 3.35 ± 1.12 days while ciprofloxacin achieved resolution of fever in 5.01 ± 1.87 days (p-value<0.0001). But in children aged 10-12 years, levofloxacin showed resolution of fever within mean time of 3.55 ± 1.10 days and ciprofloxacin achieved resolution of fever in 3.87 ± 0.99 days (p-value>0.05). Gender has no impact on resolution of fever and levofloxacin showed significantly shorter time to resolve fever as camped to ciprofloxacin (p-value<0.0001). In children living in rural areas, semi-urban or urban areas, levofloxacin resolve fever within 3-4 days as compared to ciprofloxacin that took >4 days to resolve the fever. When stratified for season at presentation, it was observed that levofloxacin showed early resolution of fever in all seasons and season did not affect the efficacy of levofloxacin to resolve fever as compared to ciprofloxacin (p-value <0.05). Table-IV

Table-I: Baseline characteristics of children included in the trial (n = 360)

	Group	
	Levofloxacin	Ciprofloxacin
n	180	180
Age (years)	7.71 ± 2.81	7.90 ± 2.60
Gender		
Male / Female	99 (55%) / 81 (45%)	90 (50%) / 90 (50%)
Weight (kg)	28.66 ± 10.20	30.19 ± 10.11
Duration of fever (days)	6.57 ± 2.49	6.31 ± 2.27
Area of residence		

Rural / Urban / Semi-urban	11 (6.1%) / 127 (70.6%) / 42 (23.3%)	19 (10.6%) / 115 (63.9%) / 46 (25.6%)
Socioeconomic status		
Low / Middle / High	31 (17.2%) / 35 (19.4%) / 114 (63.3%)	33 (18.3%) / 42 (23.3%) / 105 (58.3%)
Season at the time of presentation		
Summer	69 (38.3%)	62 (34.4%)
Winter	53 (29.4%)	59 (32.8%)
Spring	34 (18.9%)	38 (21.1%)
Autumn	24 (13.3%)	21 (11.7%)

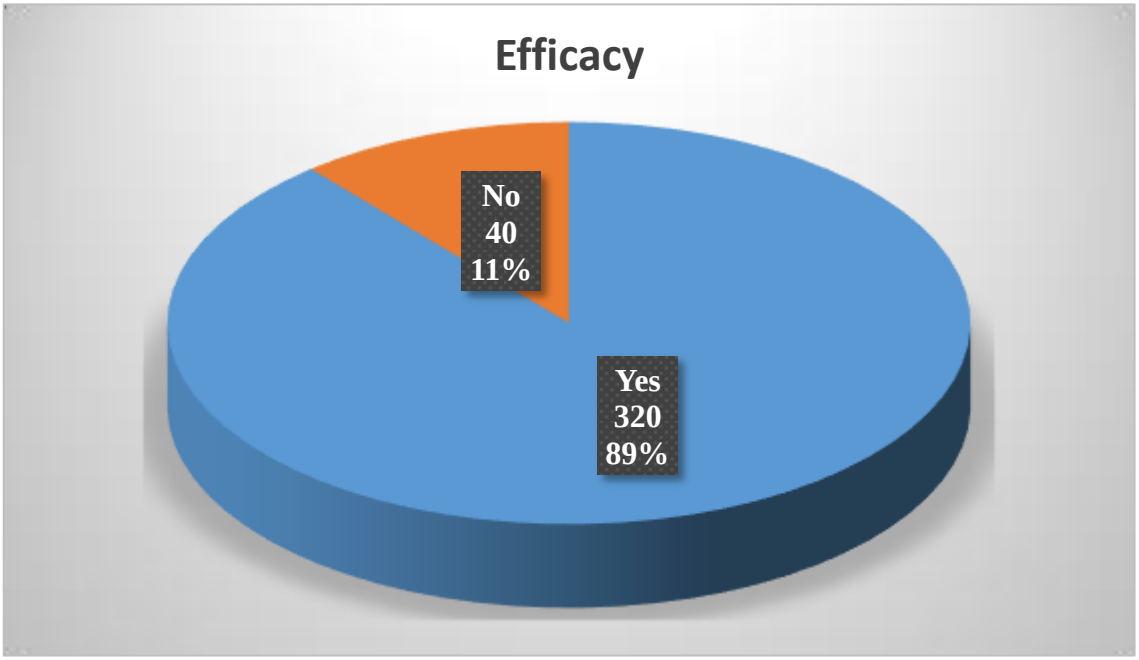


Figure-2: Efficacy achieved in whole group (n = 360)

Table-II: Clinical efficacy and time to resolve fever in both trial groups (n = 360)

	Group		P-value
	Levofloxacin n = 180	Ciprofloxacin n = 180	
Clinical efficacy achieved in	176 (97.8%)	144 (80.0%)	<0.0001
Mean time required to resolve fever	3.83 ± 1.10	4.64 ± 1.70	<0.0001

Table-III: Clinical efficacy achieved in both trial groups when stratified for different characteristics of children

	Group		p-value
	Levofloxacin	Ciprofloxacin	
Age 1-5 years	41 (100%)	23 (71.9%)	<0.0001
Age 6-9 years	77 (100%)	69 (71.9%)	<0.0001

Age 10-12 years	58 (93.5%)	52 (100%)	0.124
Male	96 (97.0%)	72 (80.0%)	<0.0001
Female	80 (98.8%)	72 (80.0%)	<0.0001
Living in rural areas	11 (100%)	17 (89.5%)	0.265
Living in urban areas	123 (96.9%)	87 (75.7%)	<0.0001
Living in semi-urban areas	42 (100%)	40 (87.0%)	0.015
Patient presentation during			
Summer	68 (98.6%)	48 (77.4%)	<0.0001
Winter	51 (96.2%)	47 (79.7%)	0.008
Spring	33 (97.1%)	31 (81.6%)	0.037
Autumn	24 (100%)	18 (85.7%)	0.055

Table-IV: Comparison time to resolve fever in both trial groups when stratified for different characteristics of children

	Group		p-value
	Levofloxacin	Ciprofloxacin	
Age 1-5 years	3.20 ± 1.08	4.78 ± 1.72	<0.0001
Age 6-9 years	3.35 ± 1.12	5.01 ± 1.87	<0.0001
Age 10-12 years	3.55 ± 1.10	3.87 ± 0.99	0.111
Male	3.43 ± 1.08	4.66 ± 1.78	<0.0001
Female	3.32 ± 1.14	4.62 ± 1.63	<0.0001
Living in rural areas	3.36 ± 1.36	4.16 ± 1.50	0.160
Living in urban areas	3.40 ± 1.08	4.90 ± 1.75	<0.0001
Living in semi-urban areas	3.33 ± 1.14	4.20 ± 1.54	0.004
Patient presentation during			

Summer	3.25 ± 1.08	4.73 ± 1.79	<0.0001
Winter	3.53 ± 1.10	4.54 ± 1.77	0.001
Spring	3.24 ± 1.07	4.89 ± 1.71	<0.0001
Autumn	3.67 ± 1.20	4.19 ± 1.08	0.134

DISCUSSION

In this trial, clinical efficacy was achieved in 320 (89%) children, out of which clinical efficacy was achieved in 176 (97.8%) children with levofloxacin and in 144 (80.0%) children with Ciprofloxacin (p-value <0.0001). The mean time to resolve the fever was 3.83 ± 1.10 days with levofloxacin group while 4.64 ± 1.70 days with ciprofloxacin (p-value <0.0001).

Hadisaputro et al., conducted a trial in Indonesia on 137 children with typhoid fever and observed that efficacy (good to moderate response) was achieved 98% with levofloxacin and 96% with ciprofloxacin (p>0.05), while mean duration to resolve fever completely was 3.47 vs. 4.08 days (p<0.05). The authors came to the conclusion that because levofloxacin offered a simpler method of medication administration, it may be a superior choice for the antibiotic of choice in complex typhoid fever treatment. [12]

But in another trial, Klausner et al., discovered that the eradication rates for ciprofloxacin and levofloxacin at the conclusion of treatment were 77.5% and 79.8%, respectively. Eradication rates for levofloxacin and ciprofloxacin-treated individuals in the microbiologically evaluable cases were 88.3% and 86.7%, respectively (95% CI, -7.4% to 4.2%). Although the difference was calculated to be insignificant (p-value>0.05).[11] Nelwan et al., reported that mean duration to resolve fever completely was short with levofloxacin i.e. 3.0 ± 0.96 days as compared to ciprofloxacin i.e. 5.0 ± 3.60 days (p<0.005). The levofloxacin achieved clinical efficacy in 100% cases as compared to ciprofloxacin (77.8% cases, p-value <0.05).[13]

Chhetri et al., discovered that whereas 8% of S. Typhi isolates were resistant to ciprofloxacin and 3% to levofloxacin, fluoroquinolone-resistant S. Paratyphi A was not detected.[14] Adhikari et al., found that 5% isolates of S. Typhi and 9% isolates of S. Paratyphi A were resistant to ciprofloxacin.[15] Additionally, research carried out in central Nepal have found ciprofloxacin therapeutic failure and resistant Salmonella.[16] This could be because fluoroquinolones are often prescribed as the first line of treatment for enteric fever, especially in children, regardless of sensitivity patterns and without a careful evaluation of the quality of the available data.[17, 18]

Frequent bacterial infections in many low- and middle-income nations include typhoid and paratyphoid (enteric fever). Due to widespread resistance to older, first-line antibiotics, the World Health Organization presently advises therapy with ceftriaxone, ciprofloxacin, or azithromycin. Resistance patterns change over time and varies depending on the region. In South Asia, ciprofloxacin usage is frequently prohibited due to fluoroquinolone resistance. In Pakistan, highly resistant forms of enteric fever have surfaced.[19] According to Hussain et al., Ciprofloxacin had 11.8% sensitivity against Salmonella typhi and Salmonella paratyphi A-C.[20] Chhetri observed only 1 multi-drug resistant S. Typhi against levofloxacin. Even if it demonstrates the importance of levofloxacin in treating enteric fever, bacteria that are resistant to several drugs require greater fluoroquinolone concentrations for therapy. [14] In Pakistan, the reported rate of multi-drug resisitance of salmonella typhi against fluoroquinolones is 37.5%.[21]

CONCLUSION

Thus, levofloxacin is a better drug of choice for children presenting with typhoid fever. Now in future, we will prescribe levofloxacin for resolution o typhoid fever in pediatric population, instead of other less effective drugs. This would help in the improvement of our knowledge and to update guidelines in future for better treatment protocol.

CONFLICT OF INTEREST

None.

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