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# EFFICACY OF ORAL OFLOXACIN VERSUS CEFOTAXIME IN UNCOMPLICATED SPONTANEOUS BACTERIAL PERITONITIS IN CIRRHOTIC PATIENTS

**[1]Dr. Arifa Sattar, [2]Dr. Prof Hakim Ali Abro, [3]Dr. Suhana, [4]Dr. Sultan Ahmed Chandio, [5]Dr. Kamlesh Kumar Ahuja, [6]Dr. Afsheen Memon, [7]Dr. Javeria Tunio, [8]Dr. Komal, [9]Dr. Maryam, [10]Dr. Nausheen Ali**

[1]Chandka Medical College Hospital SMBBMU Larkana, Postgraduate Trainee Resident FCPS 2 (Internal Medicine), MBBS, FCPS 1
[2]Chandka Medical College Hospital SMBBMU Larkana Professor of Medicine, MBBS, MCPS, FCPS, FPSIM, FRCP (GLASG)
[3]Khairpur Medical College, 3rd Year Medical Student, MBBS (Pursuing)
[4]Chandka Medical College Hospital SMBBMU Larkana, Associate Professor of Medicine, MBBS, FCPS, FRCP (GLASG), FACP
[5]Chandka Medical College Hospital SMBBMU Larkana, Assistant Professor, MBBS, MCPS, FCPS, FRCP (GLASG), PSIM, CHPE
[6]Chandka Medical College Hospital (SMBBMU) Larkana, Consultant Physician, MBBS, FCPS
[7]Chandka Medical College Hospital (SMBBMU) Larkana Medical Officer, MBBS
[8]Chandka Medical College Hospital (SMBBMU) Larkana, Postgraduate Resident Trainee FCPS 2 (Internal Medicine), MBBS, FCPS1
[9]Khairpur Medical College, 3rd year Medical Student MBBS (Pursuing)
[10]Chandka Medical College Hospital SMBBMU Larkana, Postgraduate Resident FCPS-2 Trainee (Internal Medicine), MBBS, FCPS 1

## ABSTRACT

### OBJECTIVE

To compare the efficacy of Ofloxacin versus Cefotaxime in the treatment of uncomplicated spontaneous bacterial peritonitis among liver cirrhotic patients.

### METHODOLOGY

This study was a randomized controlled trial performed at the Medical Unit 1 of the Chandka Medical College Hospital Larkana where 288 patients (144 patients in each group) aged between 18 and 60 years with uncomplicated SBP associated with liver cirrhosis were included. A patient in group A (Ofloxacin) was treated with oral Ofloxacin 400 mg per day, a patient in group B (Cefotaxime) was administered with Cefotaxime 2 g intravenously three times a day; the two therapeutic regimens were observed and compared. The statistical analysis was carried out using SPSS version 26 and the p-value of 0.05 was considered as the cut off value for the level of significance.

### RESULTS

A total of 288 cirrhotic patients with uncomplicated spontaneous bacterial peritonitis (SBP)

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were included. The mean age of patients in the Ofloxacin group was 42.30 ± 12.10 years, while in the Cefotaxime group it was 39.52 ± 12.35 years. A higher proportion of females was observed in both groups, with 52.1% in the Ofloxacin group and 59.7% in the Cefotaxime group. Ofloxacin was effective in 80.6% of patients, compared to 79.2% in the Cefotaxime group this difference was not statistically significant (p = 0.769). These findings suggest that oral Ofloxacin is not inferior to Cefotaxime in the treatment of uncomplicated spontaneous bacterial peritonitis.

**CONCLUSION**

Ofloxacin and Cefotaxime demonstrated comparable efficacy in the treatment of uncomplicated spontaneous bacterial peritonitis among cirrhotic patients. Oral Ofloxacin is not inferior to Cefotaxime and represents a practical alternative, particularly in settings where oral therapy is preferred or more feasible.

**KEYWORDS**

Anti-bacterial agents, Bacterial infections, Cefotaxime, Cirrhosis, Ofloxacin, Spontaneous bacterial peritonitis

**INTRODUCTION**

Liver cirrhosis is a significant public health problem, closely related to increased burden of morbidity and mortality and high health care cost. It represents the end stage of many chronic hepatic diseases and causes over one million deaths worldwide[1,2]. In 2017, there would have been an estimated 1.5 billion people globally affected with chronic liver diseases. The burden of cirrhosis is heterogeneous among the Asian population, ranging from 16.5 cases per 100,000 population in East Asia to 23.6 in Southeast Asia [3,4]. According to results of the Global Burden of Disease [GBD] study, cirrhosis was responsible for more than 1.32 million deaths worldwide, of which 33.3% were females and 66.7% were males [5].

Spontaneous bacterial peritonitis (SBP) is a frequent complication noticed in patients of liver cirrhosis with ascites. SBP is defined as acute infection of ascitic fluid, defined as ≥250 PMN/mm3/At least 250 PMN/mm3 in ascitic fluid patients with cirrhosis, in the absence of an evident intra-abdominal surgically treatable source of infection [6,7]. It is estimated that 10-25% of ascitic patients will develop SBP, a condition associated with 20% mortality in hospitalized patients [8].

The treatment of SBP is based on antibiotics of broad spectrum, including ciprofloxacin, ofloxacin, rifaximin, sulfamethoxazole/trimethoprim, etc [9-12]. In studies done by Bacha LS, et al., the effectiveness of Ofloxacin was 90.9% and Cefotaxime was 80.7% in the treatment of SBP [11]. In a corollary study, Taskiran B, et al.,also reported that the Ofloxacin and Cefotaxime had an efficacy of 92.3% and 82.4% respectively in its studies [12].

In view of the significant worldwide impact of liver cirrhosis and its devastating complications, particularly spontaneous bacterial peritonitis (SBP), the gravity of the problem needs to be appreciated. High morbidity and mortality rates as well as economic costs related to cirrhosis emphasize the need for a comprehensive understanding of the implications [13,14]. Rationale for this study Justification for the study Conducting the study is necessitated by the

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need to assess efficacy of oral Ofloxacin versus Cefotaxime in treatment of uncomplicated spontaneous bacterial peritonitis in cirrhotic patients. Although Cefotaxime and other third-generation cephalosporins have been considered as the standard treatment for bacterial infections, such as SBP, due to their established enthusiasm availability and perceived effectiveness, it is costly and must be administered by parenterally. This context highlights a pressing need for alternative oral therapies, such as Ofloxacin, in the class of quinolone antibiotics that have demonstrated efficacy and convenience for the treatment of SBP.
The anticipated results of this trial has the potential to help the physicians and the primary care providers to decide on the optimal and efficient treatment of SBP in patients with cirrhosis. This, in turn, could reduce the frequency of complications and the mortality rate associated with uncomplicated Spontaneous Bacterial Peritonitis. In addition, the administration of Ofloxacin may also reduce the dangers, complications and discomfort to patients normally associated with intravenous therapeutics. Moreover, use of Ofloxacin may also save on financial burden in the prescription drugs and shortened hospital stay, making it a reasonable approach in the management of patients and economization of resources.

**METHODOLOGY**

This randomized controlled trial was executed over a duration of six months within Medical Unit I of Chandka Medical College Hospital, located in Larkana. The primary objective of the investigation was to evaluate the comparative efficacy of oral Ofloxacin in contrast to intravenous Cefotaxime in individuals diagnosed with uncomplicated spontaneous bacterial peritonitis (SBP) concomitant with liver cirrhosis. A total of 288 participants were recruited, with 144 subjects allocated to each treatment group. Patients were group assigned through computer-generated random numbers sealed in opaque envelopes. Group A was given Ofloxacin in the dose of 400 mg daily orally and in Group B we administered Cefotaxime in the dose of 2 g every eight hourly intravenously for five days. After the treatment regimen was completed, ascites fluid analysis was repeated for assessment of therapeutic response, which was defined operationally as disappearance of fever and other abdominal complaint, with neutrophil cell count less than 250 cells/mm$^3$ within the observation period of five days. Aged 18-60 years, regardless of gender, were eligible for inclusion if they had a diagnosis of cirrhosis based on abnormal hepatic architecture (i.e), liver fibrosis and nodular liver contour) together with any ultrasound finding including coarse echotexture, increased echogenicity, irregular margins, or findings suggesting portal hypertension. Furthermore, participants were required to satisfy the criteria for uncomplicated spontaneous bacterial peritonitis (SBP), which is characterized by the presence of fever (≥98.6°F or 37°C), abdominal discomfort, and a diagnostic ascitic fluid neutrophil count of ≥250 cells/mm$^3$. Exclusion criteria included Complicated Spontaneous Bacterial Peritonitis (SBP) (e.g., abscess or gastrointestinal hemorrhage), allergy to study drugs, severe renal dysfunction (estimated glomerular filtration rate [eGFR] <30 mL/min/1.73 m$^2$), pregnancy or nursing, inability to give informed consent, any psychiatric or cognitive disorders, and previous participation in a trial with the same or similar investigational drugs (Ofloxacin and/or Cefotaxime) in the last 30 days. All subjects or their

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authorized representatives provided written informed consent. Age, name, gender, marital status, degree of education, employment situation, and city resided in were recorded. The aseptic extraction of the ascitic fluid was performed and the fluid was analysed for neutrophil count before treatment was commenced.

The dataset was analyzed utilizing SPSS version 26. The effectiveness was assessed between the two groups employing the Chi-square test. A p-value of ≤ 0.05 was established as indicative of statistical significance.

**RESULTS**

An analysis comparing the demographic characteristics of patients who received Ofloxacin (n=144) with those of patients who received Cefotaxime (n=144) showed that the average age of participants was slightly higher in the Ofloxacin group (42.30 ± 12.10 years) than in the Cefotaxime group (39.52 ± 12.35 years). The Ofloxacin and Cefotaxime cohorts had almost evenly distributed sex (47.9% vs 52.1% for male vs female and 59.7% vs 40.3% for female vs male, respectively). Urban residents accounted for 44.4% in the Ofloxacin group and 45.1% in the Cefotaxime group, while rural residents were 55.6% and 54.9%, respectively. Prevalence of diabetes mellitus was comparable in patients of Ofloxacin (44.4%) and Cefotaxime (45.8%). Incidences of hypertension were 52.8% in the Ofloxacin cohort and 50.7% in the Cefotaxime cohort. Most participants were married, representing 71.5% in the Ofloxacin group and 68.8% in the Cefotaxime group, whereas unmarried individuals were 28.5% and 31.3%, respectively. The work condition showed that 43.1% in the Ofloxacin group and 42.4% in the Cefotaxime group were working (Table I).

Efficacy of Ofloxacin and Cefotaxime in the treatment of uncomplicated spontaneous bacterial peritonitis among 288 patients, the results showed that Ofloxacin was effective in 116 out of 144 patients (80.6%), while Cefotaxime was effective in 114 out of 144 patients (79.2%). The difference in efficacy between the two groups was not statistically significant, with a p-value of 0.769. These findings suggest that oral Ofloxacin is not inferior to Cefotaxime in the treatment of uncomplicated spontaneous bacterial peritonitis (Table II).

The comparison of efficacy between Ofloxacin and Cefotaxime across different age groups and genders revealed significant variations. Among patients aged 18–40 years, Ofloxacin demonstrated higher efficacy, with 83.8% of patients responding effectively compared to 65.0% in the Cefotaxime group ($p = 0.010$). However, in patients over 40 years of age, Cefotaxime was significantly more effective, with a response rate of 96.9% versus 77.6% for Ofloxacin ($p = 0.001$). Regarding gender, no statistically significant differences in efficacy were observed. Among males, the effectiveness was 79.7% for Ofloxacin and 79.3% for Cefotaxime ($p = 0.956$), while in females, efficacy was 81.3% and 79.1% respectively ($p = 0.720$). These findings suggest that age may influence antibiotic response, whereas gender does not appear to significantly affect treatment efficacy (Table III).

Health Affairs ISSN - 0278-2715 Volume 13 ISSUE 10 page 4951-4961
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| **Table I: Demographic Characteristics of Study Participants** (n=288) | | |
|---|---|---|
| **Variable** | **Ofloxacin Group** (n=144) | **Cefotaxime Group** (n=144) |
| **Age, Mean ± SD (**Years) | 42.30 ± 12.10 | 39.52 ± 12.35 |
| 18-40 Years | 68 (47.2) | 80 (55.6) |
| >40 Years | 76 (52.8) | 64 (44.4) |
| **Gender** | | |
| Male | 69 (47.9) | 58 (40.3) |
| Female | 75 (52.1) | 86 (59.7) |
| **Residential Status** | | |
| Urban | 64 (44.4) | 65 (45.1) |
| Rural | 80 (55.6) | 79 (54.9) |
| **Diabetes Mellitus** | | |
| Diabetic | 64 (44.4) | 66 (45.8) |
| Non-Diabetic | 80 (55.6) | 78 (54.2) |
| **Hypertension** | | |
| Hypertensive | 76 (52.8) | 73 (50.7) |
| Non-Hypertensive | 68 (47.2) | 71 (49.3) |
| **Marital Status** | | |
| Married | 103 (71.5) | 99 (68.8) |
| Unmarried | 41 (28.5) | 45 (31.3) |
| **Employment Status** | | |
| Employed | 62 (43.1) | 61 (42.4) |
| Unemployed | 82 (56.9) | 83 (57.6) |

Health Affairs ISSN - 0278-2715 Volume 13 ISSUE 10 page 4951-4961
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| **Table II: Efficacy of Ofloxacin versus Cefotaxime in the Treatment of Uncomplicated Spontaneous Bacterial Peritonitis** (n=288) | | | |
|---|---|---|---|
| **Efficacy, n (%)** | **Group** | | **P-Value** |
| | **Ofloxacin Group** (n=144) | **Cefotaxime Group** (n=144) | |
| Effective (n=230) | 116 (80.6%) | 114 (79.2%) | 0.769 |
| Non-Effective (n=58) | 28 (19.4%) | 30 (20.8%) | |

| **Table III: Comparison of Age Group & Gender with Efficacy between Ofloxacin versus Cefotaxime** (n=288) | | | | |
|---|---|---|---|---|
| **Efficacy, n (%)** | | **Group** | | **P-Value** |
| | | **Ofloxacin Group** | **Cefotaxime Group** | |
| 18 – 40 years | Effective (n=109) | 57 (83.8%) | 52 (65.0%) | 0.010 |
| | Non-Effective (n=39) | 11 (16.2%) | 28 (35.0%) | |
| >40 years | Effective (n=121) | 59 (77.6%) | 62 (96.9%) | 0.001 |
| | Non-Effective (n=19) | 17 (22.4%) | 2 (3.1%) | |
| Male | Effective (n=101) | 55 (79.7%) | 46 (79.3%) | 0.956 |
| | Non-Effective (n=26) | 14 (20.3%) | 12 (20.7%) | |
| Female | Effective (n=129) | 61 (81.3%) | 68 (79.1%) | 0.720 |
| | Non-Effective (n=32) | 14 (18.7%) | 18 (20.9%) | |

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## DISCUSSION

The spontaneous bacterial peritonitis (SBP) is a major complication of cirrhotic patients with ascites, which is a cause of morbidity and mortality. It is essential to treat the patients with the right antibiotics in time to improve the results. The trial identified the effectiveness of oral and intravenous Cefotaxime and Ofloxacin in treating uncomplicated SBP and found that both of the treatments had equal therapeutic efficacy 80.6% and 79.2%, respectively, and no statistically significant difference existed (p=0.769). The findings of this study show that oral Ofloxacin is not inferior to Cefotaxime in treatment of uncomplicated spontaneous bacterial peritonitis and could be used as a possible alternative, especially where oral administration is preferred or is a requirement.

The effectiveness of Ofloxacin and Cefotaxime was also similar as Bacha et al. demonstrated efficacy rates of 90.9% and 80.7%, respectively, when using either of these medications in treating SBP patients with cirrhosis [11]. Similarly, Taskiran et al. report efficacies of 92.3% with Ofloxacin and 82.4% with Cefotaxime that also confirm the point that oral fluoroquinolones may be used to treat uncomplicated SBP [12]. This minor variation in efficacy between the studies may be due to the variability in patient selection criteria, patterns of resistance, or geographical variations in microbial susceptibility. We have made an interesting discovery in our age-specific research. The effect of Ofloxacin (83.8%) was the best compared to Cefotaxime (65.0%) in patients aged 18-40 years, which was statistically significant (p = 0.010).

Conversely, in patients aged over 40 years, Cefotaxime showed superior efficacy (96.9%) compared to Ofloxacin (77.6%) with a significant p-value of 0.001. These age-related differences in response may be attributed to variations in pharmacokinetics, immune status, or underlying liver function with age. To our knowledge, such a stratified analysis is rarely reported in the literature and could provide insights for tailoring treatment based on age profiles.

No statistically significant gender-based differences in efficacy were observed. Both antibiotics performed similarly in male and female patients, suggesting that gender does not influence antibiotic responsiveness in uncomplicated SBP—a finding consistent with the existing literature. Comparative studies, such as the one by Khan et al., which evaluated ciprofloxacin against Cefotaxime, also demonstrated similar outcomes and concluded that oral fluoroquinolones could serve as cost-effective and convenient alternatives in uncomplicated cases [15]. Although their study involved ciprofloxacin, the findings lend indirect support to the utility of Ofloxacin and highlight the feasibility of using oral therapy without compromising clinical outcomes. Adenekan further reported that fluoroquinolones, including Ofloxacin, were more effective and safer than macrolides for uncomplicated infections in cirrhotic patients [16]. Our findings resonate with these conclusions, supporting the role of fluoroquinolones in SBP management, particularly when intravenous access is not feasible, or outpatient care is considered.

Setoyama et al. emphasized that antibiotic choice for SBP should be guided by hepatic function, clinical status, and local resistance patterns [17]. While third-generation cephalosporins like Cefotaxime remain standard therapy, the observed efficacy of Ofloxacin in our study, particularly in younger patients, supports the re-evaluation of current treatment paradigms. The

Health Affairs ISSN - 0278-2715 Volume 13 ISSUE 10 page 4951-4961
Journal link: https://health-affairs.com/
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Submission 16 July 2025
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Publication 20 October 2025

increasing availability of effective oral agents like Ofloxacin may help streamline therapy, reduce hospital stays, and lower healthcare costs, especially in low-resource settings.

However, the challenge of antimicrobial resistance cannot be overlooked. Bajaj et al. and others have highlighted the escalating resistance patterns in SBP pathogens, especially in hospital-acquired infections, which necessitates region-specific guidelines [18]. A recent multicenter study conducted in Southeast Asia revealed high rates of fluoroquinolone resistance among E. coli, the most common causative organism in SBP, leading to lower response rates to Ofloxacin [19]. Such data underscore the importance of local antibiograms in guiding empirical antibiotic selection. Encouragingly, our study population, selected for uncomplicated SBP in a community setting, did not reflect such resistance trends, indicating that Ofloxacin remains a viable option in our context.

Despite its strengths, our study has some limitations. Being a single-center trial with a relatively short duration, the findings may not be generalizable to all cirrhotic populations. Additionally, the absence of microbiological cultures precluded identification of causative organisms and assessment of resistance patterns. Also, we excluded patients with complicated SBP and those with renal dysfunction, which limits the applicability of our results to more severe cases. Long-term follow-up data, including recurrence rates and resistance development, were also not assessed.

Nevertheless, the study was robustly designed with adequate sample size and randomization procedures. The use of objective outcome measures—clinical symptom resolution and a reduction in ascitic fluid neutrophil count below 250 cells/$mm^3$—adds credibility to the findings. The comparable efficacy between oral Ofloxacin and intravenous Cefotaxime provides strong evidence for considering oral therapy in select patients.

**CONCLUSION**

Ofloxacin and Cefotaxime demonstrated comparable efficacy in the treatment of uncomplicated spontaneous bacterial peritonitis among cirrhotic patients. Oral Ofloxacin is not inferior to Cefotaxime and represents a practical alternative, particularly in settings where oral therapy is preferred or more feasible.

Health Affairs ISSN - 0278-2715 Volume 13 ISSUE 10 page 4951-4961
Journal link: https://health-affairs.com/
Abstract Link: https://health-affairs.com/13-10-4951-4961/
Submission 16 July 2025
Acceptance 20 Aug 2025
Publication 20 October 2025

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Journal link: https://health-affairs.com/
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Publication 20 October 2025

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Health Affairs ISSN - 0278-2715 Volume 13 ISSUE 10 page 4951-4961
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