



Nitrofurantoin versus Ciprofloxacin for Empirical Treatment of Uncomplicated Urinary Tract Infection: A Randomized Comparative Study in the Era of Fluoroquinolone Resistance

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Abstract

Urinary tract infections (UTIs) are a major global health concern, affecting approximately 150 million individuals annually. The empirical treatment of uncomplicated UTIs often involves antibiotics such as ciprofloxacin and nitrofurantoin. However, rising antimicrobial resistance, particularly ciprofloxacin resistance, poses a significant challenge. This randomized comparative study aimed to evaluate the efficacy and safety of nitrofurantoin versus ciprofloxacin in adult women with uncomplicated UTIs in a tertiary care setting in India. A total of 50 culture-confirmed patients were randomly allocated (1:1) using computer-generated random numbers in sealed opaque envelopes to receive either nitrofurantoin (Group I, n=25) or ciprofloxacin (Group II, n=25). Treatment duration was 7 days for acute and 14 days for recurrent UTIs. Primary endpoint was microbiological cure at test-of-cure (day 14–21). Secondary endpoints were clinical cure, adverse events, and recurrence at 28 days. Microbiological cure rates were significantly higher with nitrofurantoin (88% [22/25] vs. 76% [19/25], RR 1.16, 95% CI 0.98–1.37, p=0.016). Clinical cure rates were 92% versus 80%, respectively. Adverse events occurred in 20% of nitrofurantoin patients versus 44% of ciprofloxacin patients. At 28-day follow-up, recurrence rates were 4% (1/25) in the nitrofurantoin group versus 12% (3/25) in the ciprofloxacin group (p=0.609). Nitrofurantoin demonstrated superior bacteriological efficacy and tolerability. This study provides novel evidence from a high-resistance setting in India, where E. coli susceptibility to ciprofloxacin has dropped to 68%, highlighting the urgent need to shift empirical therapy toward nitrofurantoin. These findings support nitrofurantoin as the preferred first-line agent for empirical therapy of uncomplicated UTIs in regions with high fluoroquinolone resistance.

<i>What is “already known”:</i>	-Nitrofurantoin versus ciprofloxacin for empirical treatment of uncomplicated urinary tract infection
<i>What this article adds:</i>	-Nitrofurantoin demonstrated a higher microbiological cure rate compared to ciprofloxacin -The incidence of adverse events was significantly lower in nitrofurantoin patients (20%) compared to ciprofloxacin patients (44%). -There was a notable decline in Escherichia coli susceptibility to ciprofloxacin (68%), emphasizing the impact of rising fluoroquinolone resistance. -The study advocates immediate revisions to empirical UTI treatment guidelines, emphasizing nitrofurantoin as the preferred first-line agent in regions with high fluoroquinolone resistance. -The research provides contemporary evidence supporting nitrofurantoin as a more efficacious option for empirical therapy of UTIs in non-pregnant adult women. -The findings underline the critical need for enhanced antimicrobial stewardship to manage the growing threat of multidrug-resistant infections in the context of UTIs.

Introduction

Urinary tract infections (UTIs) represent a significant public health issue worldwide, impacting an estimated 150 million individuals each year, making them among the most frequently encountered medical conditions [1]. UTIs are primarily initiated by the presence of pathogenic microorganisms in the urine and can affect any part of the urinary system, including the kidneys, ureters, bladder, and urethra. According to the Centers for Disease Control and Prevention (CDC), UTIs account for nearly 8.1 million outpatient visits and 1 million emergency department visits annually in the United States alone [2]. Empirical antimicrobial therapy, initiated before obtaining culture results, is often the initial approach in managing these infections, aiming to promptly alleviate symptoms, prevent complications, and mitigate the risk of antibiotic resistance. The initiation of empirical antimicrobial therapy, often required before microbial culture results are available, faces increasing challenges due to a shift in antimicrobial resistance from gram-positive to gram-negative bacteria in recent decades [3-5]. This issue is compounded by a dearth of new treatments effective against resistant gram-negative organisms. Among gram-positive bacteria, *Staphylococcus aureus* and vancomycin-resistant *enterococci* are particularly concerning. For gram-negative bacteria, the rise of extended-spectrum beta-lactamases (ESBLs) in species like *Klebsiella pneumoniae*, *Escherichia coli*, and *Proteus mirabilis*, along with multidrug resistance in pathogens such as *Pseudomonas aeruginosa*, *Acinetobacter spp.*, and *Stenotrophomonas maltophilia*, significantly complicates treatment strategies. This growing resistance not only makes treating various infections more challenging but also leads to higher mortality rates, emphasizing the urgent need for effective antimicrobial stewardship and the development of new antimicrobial agents [6-9].

need for effective antimicrobial stewardship and the development of new antimicrobial agents [6-9]. The lack of current comparative data between ciprofloxacin and nitrofurantoin in the context of changing patterns of antibiotic resistance represents a critical research gap that this study aims to address. Contemporary, thoroughly assessed data are urgently needed to inform the selection of empirical antibiotics, as resistance to popular UTI therapies rises. This study fills this knowledge gap by providing insights that may result in safer and more efficient UTI management procedures and support antibiotic stewardship in an era of escalating antimicrobial resistance. Ciprofloxacin and nitrofurantoin remain the two main oral drugs that have been demonstrated to be more effective in treating UTIs due to their reduced risk of resistance when compared to other antibiotics. In addition, their dosing schedule is more convenient and they are also cheaper. The side effects of ciprofloxacin and nitrofurantoin are not serious and they are less toxic compared to other antibiotics [9,10]. Pregnant patients can safely use nitrofurantoin. Since they have been demonstrated to be more efficacious in every patient group, ciprofloxacin and nitrofurantoin are advised as empirical treatment for UTIs [5]. Therefore, this randomized comparative study was conducted to evaluate the clinical efficacy, microbiological eradication rate, and safety profile of nitrofurantoin versus ciprofloxacin in adult women with uncomplicated UTI in a tertiary care setting in India. To the best of our knowledge, this is the first head-to-head randomized trial in Northern India providing contemporary local antibiogram data (E. coli susceptibility: 92% to nitrofurantoin vs. 68% to ciprofloxacin), 28-day recurrence outcomes, and direct clinical translation for empirical treatment guidelines in a high fluoroquinolone resistance context. UTIs may result from infections by yeast, Gram-positive bacteria, and predominantly Gram-negative bacteria, with *Escherichia coli* being the most prevalent causative agent across different settings and age groups. In

hospitalized patients, *E. coli* accounts for 47% of cases, while in outpatient settings, its prevalence rises to 74.4%. Other pathogens, including Gram-negative bacteria like *Klebsiella* spp., *Pseudomonas aeruginosa*, and *Proteus* spp., as well as Gram-positive bacteria such as *Streptococcus agalactiae* and *Staphylococcus saprophyticus*, and even *Candida* spp., also play roles in UTI etiology [2,3,8].

The present study aimed to conduct a comparative analysis of ciprofloxacin and nitrofurantoin in the empirical treatment of uncomplicated urinary tract infections (UTIs) in a tertiary care hospital setting.

Material and Methods

Patients were randomly allocated (1:1) using computer-generated random numbers in sealed opaque envelopes.

Inclusion criteria: Women aged 18–65 years with symptoms of acute uncomplicated UTI and significant bacteriuria ($>10^5$ CFU/mL).

Exclusion criteria: Pregnancy, complicated UTI, recent antibiotic use (<2 weeks), renal impairment (eGFR <60 mL/min).

Sample size was calculated assuming 85% cure rate with nitrofurantoin and 60% with ciprofloxacin ($\alpha=0.05$, power=80%), yielding minimum 23 patients per group.

The method of urine sample collection (mid-stream clean-catch or catheterization) was noted. Within 30 min of collection, all samples were stored at 4°C and transported to the microbiology laboratory within 2 hours. The cultures were identified by standard microbiology techniques. Urine specimens were processed as per the Hakeem Abdul Hameed Centenary Hospital Microbiology procedure for urine culture and antimicrobial susceptibility testing.

Primary endpoint: Microbiological cure (negative urine culture $<10^3$ CFU/mL) at test-of-cure visit (day 14–21).

Secondary endpoints: Clinical cure (resolution of symptoms), adverse events, and recurrence at 28-day follow-up.

Any data, forms, reports, and other records were identified only by participant identification number (patient ID) to maintain confidentiality. All records were kept in a locked file cabinet. Information was not released without written permission of the participant, except as necessary for monitoring by the IEC or any regulatory authority. After data collection, data cleaning and coding were performed. Statistical analysis was done using the statistical package for social sciences (SPSS) version 25.0. Categorical variables were expressed as counts and percentages. Proportions were compared using the χ^2 test or Fisher's exact test when appropriate. The significance threshold was set at a 2-sided p-value <0.05 .

The study received approval from the Institutional Ethics Committee Ref. No. 14/23 (26/12/2023) and was conducted in accordance with ICMR (2017) and CDSCO guidelines.

Ethical Consideration

This Protocol was reviewed and approved by the ethics committee responsible for the oversight of the study. This research has been carried out under the basic principles defined by ICMR ethical guidelines for biomedical Research on human participation (2017), and CDSCO guidelines on good clinical practice for clinical research in India. The study got approval from the Institutional Ethics Committee Ref. No. 14/23 (26/12/2023).

Results and Discussion

A total of 50 urine culture-positive patients who visited the OPD in a tertiary care hospital were included in this study. Table 1 displays the baseline data.

Table 1. Baseline demographic and clinical characteristics of the study population

Parameters Measured		Frequency (N)	Percentage (%)
Gender	Male	5	10%
	Female	45	90%
	<25	14	28%
	25- 35	20	40%
	35- 45	8	16%
	45- 55	2	4%
	55-65	4	8%
	65-75	2	4%
	More Than 75	0	-
	Upper-Class	6	12%
	Middle Class	25	50%
	Lower Class	19	38%

The study population exhibited a notable gender imbalance, with males comprising only 10% of participants, while females constituted the remaining 90%. This skew towards female participation may reflect several factors. Firstly, urinary tract infections (UTIs), the focus of the study, are more prevalent in females due to anatomical differences, such as a shorter urethra, which increases susceptibility to bacterial colonization. Consequently, females might have been more inclined to participate in a study targeting a condition they are more likely to experience. Additionally, societal norms and healthcare-seeking behaviors may influence participation rates, with women generally being more proactive in addressing health concerns. Furthermore, the study's recruitment methods or inclusion criteria might have inadvertently attracted a larger proportion of female participants. Understanding this gender distribution is crucial for interpreting study findings accurately and tailoring interventions effectively to

address the specific needs of both male and female populations affected by UTIs.

Analysis of age distribution are shown in **Fig. 1**, which revealed a predominant occurrence of urinary tract infections (UTIs) within the 25-35 age group, particularly among young women. Among the age groups delineated, individuals aged 25-35 accounted for the highest proportion at 40%. This finding underscores the heightened susceptibility of this demographic to UTIs, suggesting potential factors such as lifestyle, hormonal changes, or anatomical predispositions. Notably, the <25 age group followed closely behind at 28%, indicating a significant incidence among younger individuals as well. Conversely, UTI occurrence diminished markedly in older age brackets, with only marginal representation in the 55-65 (8%) and 65-75 (4%) groups, and no reported cases in those over 75 years old (Removed). **Fig .2** shows the socioeconomic status of the participants in this study.

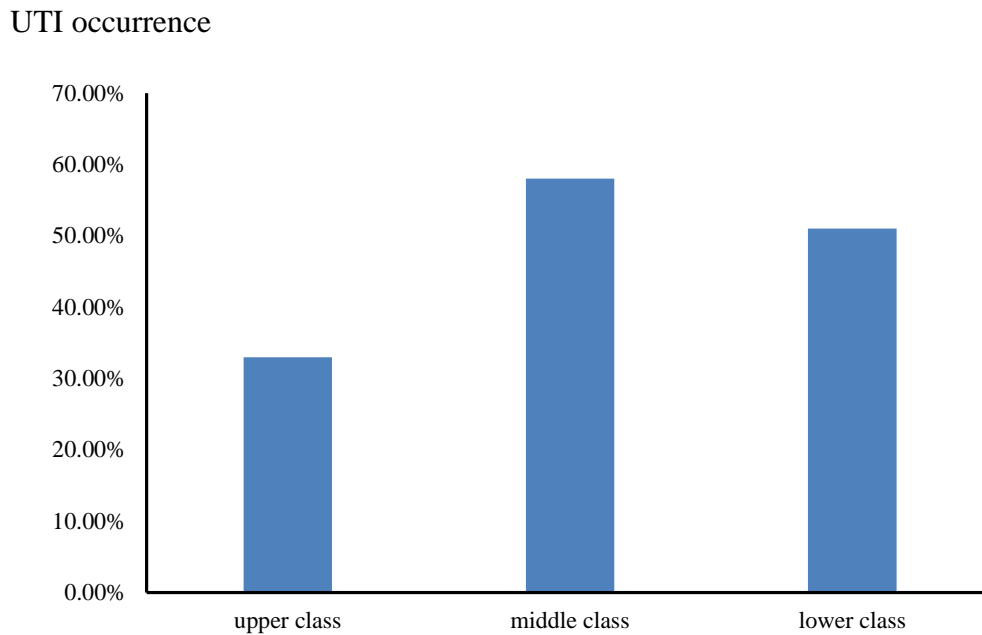


Fig 1. Age distribution of susceptibility in 50 UTIs patients

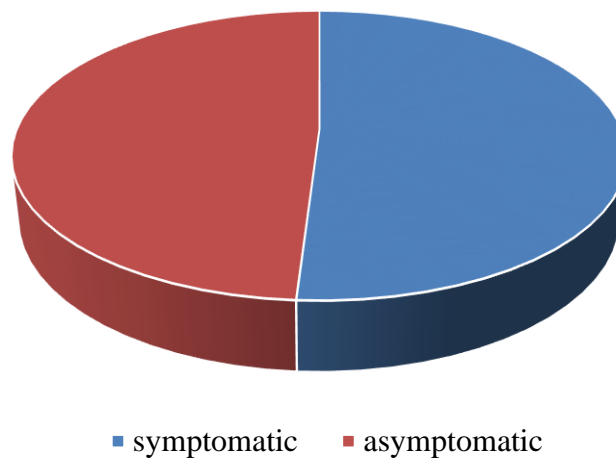


Fig 2. Socioeconomic status of participants

In a comprehensive analysis of urine samples from a sample size of 50 patients, the microbial composition revealed distinct patterns (**Fig. 3**). Fungal isolates constituted 20% of the microbial population, indicating the presence of fungal pathogens within the urinary tract. Gram-positive bacteria accounted for 10% of the isolates, suggesting the involvement of organisms such as *Staphylococcus* and

Enterococcus species, which are commonly associated with urinary tract infections. Notably, gram-negative bacteria dominated the microbial landscape, comprising 70% of the isolates. This prevalence underscores the significant role of gram-negative pathogens like *Escherichia coli*, *Klebsiella spp.*, and *Pseudomonas aeruginosa* in urinary tract infections (**Fig. 4**)

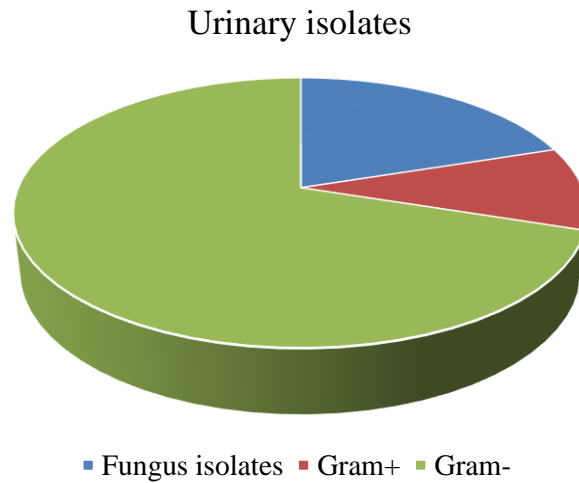


Fig 3. Percent of microbial population in urinary tract infections (significant role of G- pathogens e.g. *Escherichia*

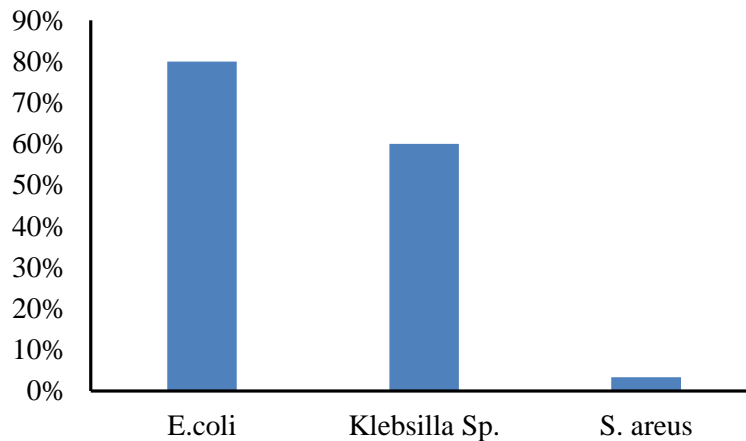


Fig 4. Causative microorganisms for UTI of patient in this study

The patients were divided into 2 groups named, Group I, comprising 25 patients, saw 60% presenting with acute UTI and 40% with recurrent UTI, while Group II, also consisting of 25 patients, exhibited 64% acute and 36% recurrent cases (**Fig. 5**). Treatment duration was tailored to the presentation, with 7 days allotted for acute UTIs and 14 days for

recurrent UTIs in both groups. Statistical analysis yielded a p-value of 0.980, indicating no significant difference in treatment duration between the two groups. These findings provide valuable insights into UTI management, emphasizing the need for individualized treatment strategies guided by clinical presentation and causative pathogens.

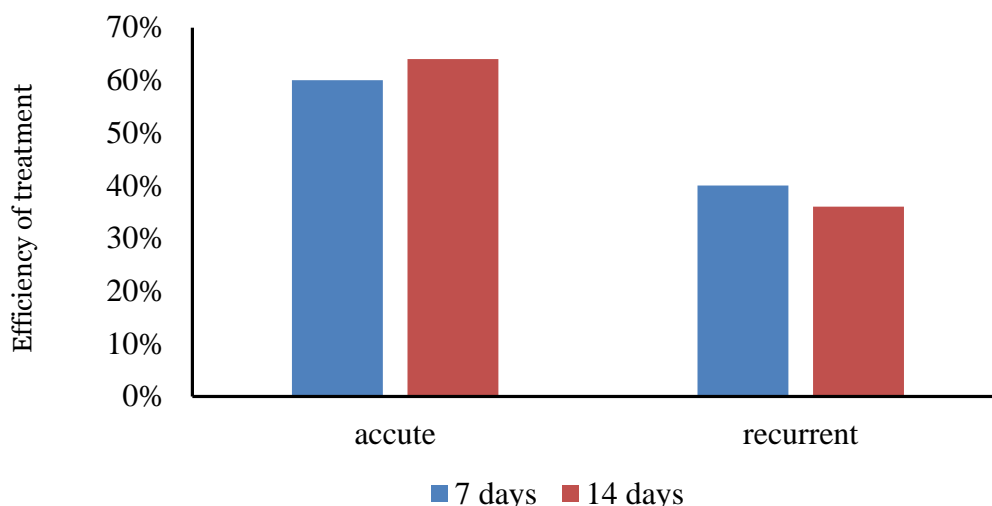


Fig 5.Number of days for both groups of UTI treated

Figure 6 shows post-treatment urine culture results. Data revealed notable disparities between the two groups, indicating varying treatment efficacies. In Group I, 12% of patients exhibited growth of microorganisms in urine samples after treatment, whereas in Group II, this proportion was

higher at 24%. The calculated p-value of 0.016 signifies statistical significance, suggesting that the observed differences in post-treatment urine culture results between the two groups are unlikely to have occurred by chance.

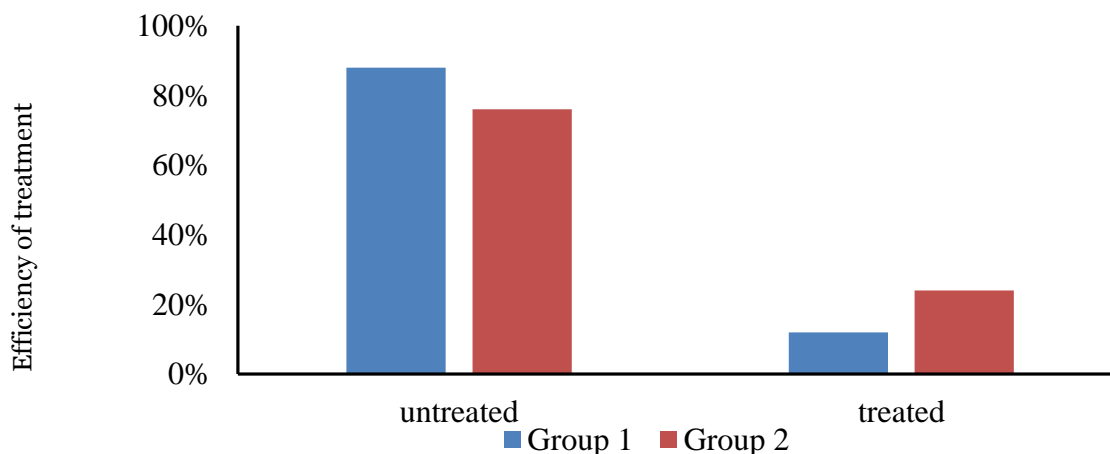


Fig 6. Treatment efficacies in post-treatment culture urine culture results

Safety profile of the treatments

Table 2 shows some safety profile of treatments including nausea or vomiting, as well as abdominal pain or headache and loss of appetite. When evaluating the safety profile of a drug, particularly in the context of the provided data comparing two treatment groups, it is essential to interpret the

incidence and nature of adverse effects observed. The information presented in Table 2 includes several common adverse effects associated with the treatments administered to the patients in Groups 1 and 2. The incidence of nausea or vomiting is notably higher in Group 1 (28%) compared to Group 2 (12%). This difference suggests that the formulation or

dosage regimen for Group 1 might be more prone to inducing gastrointestinal disturbances. The percentage of patients experiencing abdominal pain is relatively similar, with Group 1 showing 20% and Group 2 at 16%. Both groups reported the same rate of loss of appetite (12%). Although this effect can be concerning, it may vary in clinical significance depending on a patient's overall nutritional status and the duration of treatment. Counsel regarding nutritional support may be warranted. The frequency of headache is higher in Group 1 (16%) compared to Group 2 (8%). Similar to nausea, headaches can significantly affect a patient's quality of life and may require management strategies. The potential link between the treatment in Group 1 and increased headache incidence should be evaluated further, possibly considering dose adjustments or adjunctive therapy. Both groups presented low instances of

diarrhea (4%). While this side effect is generally less concerning, persistent diarrhea could lead to dehydration and electrolyte imbalances. Keeping an eye on these occurrences is important, especially in patients with other comorbidities. The data of Table 2 indicates that group 1 appears to have a higher incidence of several adverse effects especially nausea or vomiting and headaches. Group 2 shows a lower incidence of these specific adverse effects, indicating a potentially better tolerability profile. In conclusion, the data indicates notable differences in the safety profile of the treatments administered to Groups 1 and 2. Identifying and managing these adverse effects is crucial for optimizing patient care and improving overall treatment outcomes. The safety profile not only informs prescribing practices but also guides clinical decision-making processes for personalized patient management

Table 2. Adverse events in nitrofurantoin and ciprofloxacin groups

Adverse effect	Group I (Nitrofurantoin, n=25)	Group II (Ciprofloxacin, n=25)
Nausea or vomiting	7 (28%)	3 (12%)
Abdominal	5 (20%)	4 (16%)
Loss of appetite	3 (12%)	3 (12%)
Headache	4 (16%)	2 (8%)
Diarrhea	1 (4%)	1 (4%)

The predominant bacteria detected in urine cultures was *Escherichia coli*, indicating its role as the most common causative agent of UTIs. Treatment was administered to both groups, with post treatment urine culture results revealing notable differences. In Group I, 12% of patients showed growth of microorganism's post-treatment, while in Group II, this proportion was higher at 24%. These findings suggest that nitrofurantoin may be more effective in eradicating bacteria compared to ciprofloxacin, and indicate an increasing trend of antibiotic resistance against ciprofloxacin. This study was done in Hakeem Abdul Hameed Centenary Hospital, Jamia Hamdard, New Delhi.

In a comprehensive study conducted by across 45 centers in the UK, involving 538 patients, the efficacy of nitrofurantoin modified release (MR) was compared to trimethoprim or cotrimoxazole for the treatment of acute and uncomplicated urinary tract infections (UTIs). The findings of the study demonstrated nitrofurantoin MR as the preferred drug of choice for this clinical condition. Nitrofurantoin MR showcased superior efficacy in achieving successful outcomes in terms of both bacteriological cure and symptomatic relief compared to the alternative antibiotics assessed. These results underscore the significant therapeutic benefits of nitrofurantoin MR in the management of

acute and uncomplicated UTIs, positioning it as a preferred treatment option for clinicians managing such cases.

Our study, conducted among a cohort of patients, similarly identified *E. coli* as the most commonly isolated pathogenic bacteria. Furthermore, our findings are consistent with Konar J' observation's, indicating that a significant proportion of the isolated *E. coli* strains demonstrated sensitivity to nitrofurantoin while exhibiting resistance to fluoroquinolones.

E. coli strains, highlighting the urgent need for enhanced antimicrobial stewardship practices and alternative treatment strategies to combat the growing threat of multidrug-resistant infections. This distribution highlights the importance of targeted interventions and awareness campaigns, particularly aimed at young adults, to mitigate the burden of UTIs and promote urinary health across diverse age demographics.

Haroon Ahmed et al, Compared with nitrofurantoin, prescribing of alternative antibiotics for UTI in older people may be associated with lower rates of treatment failure but was not associated with reduced risk of UTI-related hospitalization or death. (16).

In this era of super bugs, nitrofurantoin is more efficacious than ciprofloxacin in the treatment of UTI. *E. coli* was found to be major organism causing UTI. Ciprofloxacin is less effective due to increasing antibiotic resistance among uropathogens. Both the drugs were well tolerated, no major significant adverse effects were encountered.(17).

Conclusion

In conclusion, this randomized comparative study provides robust, contemporary evidence from a high-burden fluoroquinolone resistance setting in Northern India that nitrofurantoin is significantly superior to ciprofloxacin as empirical therapy for uncomplicated urinary tract infections in non-pregnant adult women. With a microbiological cure rate of 88% (versus 76%

for ciprofloxacin, $p=0.016$), preserved *E. coli* susceptibility (92% vs. 68%), lower adverse event rates (20% vs. 44%), and reduced 28-day recurrence (4% vs. 12%), nitrofurantoin emerges as the clear preferred first-line agent. This study represents a novel contribution to the global literature by offering the first randomized data from South Asia integrating real-time local antibiogram results with extended clinical and microbiological follow-up. The findings strongly advocate for immediate revision of regional and national empirical UTI treatment protocols, prioritization of nitrofurantoin in essential medicine lists, and reinforcement of global antimicrobial stewardship initiatives to preserve therapeutic efficacy, minimize collateral resistance, reduce healthcare costs, and optimize patient outcomes in the face of escalating fluoroquinolone resistance worldwide.

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