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ORIGINAL ARTICLE

# Nitrofurantoin or Fosfomycin: The better choice for lower urinary tract infection?

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## ABSTRACT

**Background:** Almost 50%-60% of women have at least one episode of urinary tract infection (UTI) during their lifetime.
**Objective:** To determine and compare the effectiveness of oral Fosfomycin and nitrofurantoin in women of reproductive age with lower UTIs.
**Methods:** A quasi-experimental study was conducted in the urogynaecology department of Shalamar Hospital, Lahore, Pakistan, from 4th September 2024 to 4th March 2025. A total of 392 females presenting with symptoms of lower urinary tract infection were included. Participants received empirical treatment with either nitrofurantoin (Group A) or Fosfomycin (Group B) orally after providing a baseline urine sample for culture and sensitivity testing. The primary outcome was the assessment of clinical resolution at the first follow-up visit on day 7. The second follow-up visit on day 14 was conducted to assess bacterial eradication. Data were analyzed using SPSS version 21.
**Results:** Nitrofurantoin use was associated with higher clinical improvement (82% vs. 71%, p=0.016) and bacteriological resolution (91% vs. 84%, p=0.020) compared with Fosfomycin. Diarrhea was the predominant adverse effect reported more frequently with Fosfomycin use (12.7% vs 6.1%, p=0.02). Nitrofurantoin users achieved faster recovery of symptoms when compared with Fosfomycin e.g., dysuria relief in 2.4 vs 3.1 days (p=0.003), urinary frequency decreased in 3.1 vs 4 days (p=0.005), suprapubic pain settled in 2.9 vs 3.5 days (p=0.04), better post-treatment quality of life in 8.8 vs 8.2 days (p=0.009), and greater willingness to reuse the drug in 89% vs 78% (p=0.008).
**Conclusion:** Nitrofurantoin demonstrated superior clinical and bacteriological efficacy over Fosfomycin, with faster symptom resolution and greater patient satisfaction, supporting its use as the preferred first-line agent for uncomplicated lower UTIs. Fosfomycin remains a viable alternative where adherence is a concern.

**Key Words:** Nitrofurantoin, Fosfomycin, Urinary tract infection, Treatment outcome

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## INTRODUCTION

A urinary tract infection (UTI) includes any infection that involves any section of the urinary tract, from the urethra to the kidneys. Acute uncomplicated cystitis is an infection involving the bladder and urethra, while pyelonephritis is an infection of the renal parenchyma. It is among the most common infections, affecting 50%-60% of women in their lifetime.[1] The bacterium Escherichia coli (E coli) causes 85% of UTIs in the community and 50% in hospital settings. Rising levels of antibiotic resistance among urinary pathogens have become a significant concern.[2] According to a recent report, >70% of E coli is resistant to ceftriaxone and ciprofloxacin in Pakistan.[3] Available data suggest the presence of high resistance to the fluoroquinolones, including ciprofloxacin.[4] Nevertheless, ciprofloxacin remains widely available over the counter in oral form

throughout Pakistan and is frequently prescribed by doctors. This widespread resistance calls into question the continued use of ciprofloxacin as a first-line treatment for UTIs in the country. The rates of resistance to Fosfomycin and nitrofurantoin are comparatively low. Thus, these two are recommended as first-line therapies for the uncomplicated UTIs, resulting in a significant increase in their use.[5]

Despite the widespread use of nitrofurantoin and Fosfomycin as first-line agents for uncomplicated urinary tract infections, data comparing their real-world effectiveness remain limited, particularly in local clinical settings. This study, therefore, aimed to determine and compare the effectiveness of oral Fosfomycin and nitrofurantoin in women of reproductive age presenting with uncomplicated urinary tract infections, thereby identifying the more favorable first-line option for optimal patient outcomes.

## METHODS

A quasi-experimental study was conducted in the urogynaecology department of Shalamar Hospital, Lahore, from 4th September 2024 to 4th March 2025, following approval from the Institutional Review Board (REF # SMDC-IRB/AL/2024-098). In six months, a total of 392 females aged 15–49 years presenting with symptoms suggestive of lower urinary tract infection (LUTI), that is, infection of the urinary bladder and urethra, were enrolled. The sample size was calculated a priori using G*Power version 3.1.9.7. Assuming clinical resolution rates of 90% for nitrofurantoin and 80% for Fosfomycin, a two-sided significance level of 0.05, and 80% power, the required sample size was 196 participants per group (total n=392).[6] Participants were included if they had at least one symptom of LUTI—such as dysuria, urinary urgency, increased frequency, or suprapubic discomfort—and a positive urine test for either nitrites or leukocyte esterase on a reagent strip or ≥ 3 leukocytes per high-power field on urine microscopy.[7] Pregnant or breastfeeding women, patients with signs of upper urinary tract infection (fever, chills, flank pain), recent antibiotic use (within 4 weeks), catheterized patients, immunocompromised individuals, and those with poor kidney function (creatinine clearance <30 mL/min) were excluded.

After obtaining informed consent, baseline (pre-treatment) and day-7 data, coinciding with the clinical evaluation, were recorded on a specialized proforma, and contact numbers were collected for correspondence. Baseline urine samples collected at the time of presentation to the hospital were sent for culture and sensitivity. Body mass index was calculated using weight (kg) divided by height in square meters ($m^2$). The empirical treatment (initiation of Nitrofurantoin or Fosfomycin based on the patient's clinical presentation and probable diagnosis before definitive laboratory or culture results become available) was initiated before the culture report. Patients were assigned consecutively, without randomization, into two treatment groups by alternate allocation (i.e., first patient to Group A, second to Group B). Group A patients (n= 196) were given nitrofurantoin 100 mg twice daily for five days, and patients in Group B (n=196) received 3 gm of oral Fosfomycin as a single dose (Figure 1). Participants were instructed to contact the study investigator if their symptoms did not improve. They were asked to monitor and record their symptoms daily after completing the antibiotic course until their first scheduled follow-up on day 7. Patients were advised to return earlier if symptoms persisted, worsened, or if they experienced any adverse effects. Those requiring a change in antibiotic therapy based on culture results were contacted prior to the first follow-up. The primary outcome was clinical resolution at the first follow-up visit on day 7, and the second follow-up visit on day 14 assessed bacterial eradication in urine samples. Patients were assessed for symptom improvement and any adverse effects of therapy. Urine culture was repeated on day 14 to assess sustained bacteriological cure after completion of antibiotic therapy and to identify persistent or recurrent infection that might not be evident with earlier testing. Repeat urine cultures were considered positive when growth of at least one bacterial species at a concentration of $\geq 10^3$ colony-forming units (CFU)/mL was detected.[8,9] Patient-centered outcomes were assessed using a 0–10 Likert scale for ease of antibiotic use, impact on daily functioning, severity of side effects, and post-treatment quality of life, ensuring reliable measurement of patient experiences and satisfaction.

The primary outcome was the patient's clinical resolution of symptoms at the first follow-up. A patient was considered successfully treated if there was complete relief of all symptoms. Patients whose symptoms persisted at the first follow-up visit or who required a change in antibiotic were classified as

treatment failures. The secondary outcomes measured were bacteriologic resolution at day 14 and adverse drug reactions. Bacteriological success was defined as the complete eradication of the infecting organism, with no recurrence of bacteriuria (≥$10^3$ CFU/mL) during follow-up. Treatment failure was defined as recurrence of the same bacterial strain at a concentration ≥$10^3$ CFU/mL on a urine culture.[10] Following questions were asked: ease of antibiotic use, time taken for symptom relief, impact on daily functioning, severity of side effects, and post-treatment quality of life for other secondary outcomes.

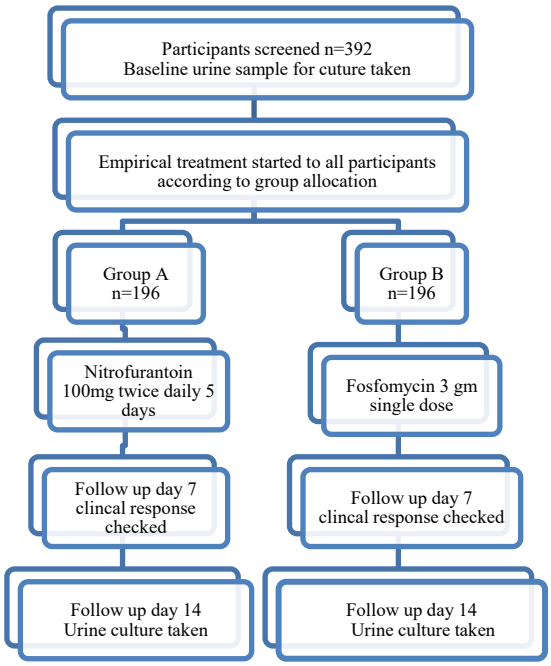


***Figure 1:*** *Overview of Methodology*

### Ethical Approval

The study was conducted in the urogynecology department from 04/09/24 to 04/03/25, following approval from the Institutional Review Board of Shalamar Medical and Dental College, Lahore, Pakistan (IRB#SMDC-IRB/AL/2024-098) on 4th September 2024.

### Statistical Analysis

Data were analyzed using SPSS version 21. Numerical variables were expressed as mean± standard deviation, while categorical data were presented as frequencies and percentages. The chi-square test was used to compare clinical improvement and bacteriological resolution rates between groups. A p-value < 0.05 was considered statistically significant.

## RESULTS

A total of 392 patients were analysed, divided into two groups of 196 each. Average age in group A (Nitrofurantoin) was 40±15.5 years, and in group B was 42.4±13.3 years (p=0.171), with no significant difference. There was no significant difference in mean BMI between participants in the two groups (Group A = 28.4±5.09 kg/m2; Group B = 28.8±5.37 kg/$m^2$), p=0.45. The presenting symptoms of participants are shown in Table 1. The mean duration of symptoms in group A was 9± 8.29 days, and in group B was 8±7.6 days. Baseline urine cultures were positive in 392 out of 400 patients. The most commonly isolated uropathogen was E. coli (77.8%), followed by Enterococcus (10.2%), Klebsiella (7.9%), Staphylococcus (2.5%), and Proteus (1.5%). A total of 06 patients had E. coli UTIs resistant to nitrofurantoin (sensitivity 98.5%, resistance 1.5%), while no resistance was observed to Fosfomycin. Antibiotics were changed for two patients taking nitrofurantoin due to resistance on the culture report, while the remaining four were already on Fosfomycin.

**Table 1: Symptoms of lower urinary tract infection at the time of presentation**

| Variables | Group A (n=196) n (%) | Group B (n=196) n (%) | n=392 |
|---|---|---|---|
| **Increase urinary frequency** | 174 (88.7%) | 167 (85.2%) | 341 (86.9%) |
| **Dysuria** | 184 (93.8%) | 173 (88.2%) | 357 (91%) |
| **Urgency** | 06 (3%) | 09 (4.5%) | 15 (3.8%) |
| **Suprapubic pain** | 33 (16.8%) | 45 (22.9%) | 78 (19.8%) |

*Group A= Nitrofurantoin; Group B =Fosfomycin*

Clinical improvement was significantly greater with nitrofurantoin compared to Fosfomycin (p=0.016), as was bacteriological resolution (p=0.020) (Table 2). Adverse effects, including gastrointestinal symptoms such as nausea, diarrhea, and abdominal discomfort, were reported more frequently in the Fosfomycin group as compared to nitrofurantoin. The most common adverse effect was diarrhea, reported in 25 patients taking Fosfomycin compared with 12 taking nitrofurantoin, a difference that was not statistically significant (p=0.042) (Table 3). Patient-centered outcomes were assessed by evaluating clinical recovery, symptom relief, patient satisfaction, and quality of life. Although Fosfomycin was rated as easier to use, nitrofurantoin was associated with greater patient satisfaction, fewer side effects, and better post-treatment quality of life (Table 4).

**Table 2: Comparison of clinical improvement and bacteriological resolution between the two groups**

| Clinical Improvement | Group A (n=196) | Group B (n=196) | $\chi^2$ | p value |
|---|---|---|---|---|
| Yes | 161 (82%) | 141 (71%) | 5.76 | 0.01* |
| No | 35 (17.8%) | 55 (28%) | | |
| **Microbiological resolution** | | | | |
| Yes | 180 (91%) | 165 (84%) | 5.43 | 0.01 * |
| No | 16 (8.16%) | 31 (15.8%) | | |

*Group A= Nitrofurantoin; Group B =Fosfomycin. Chi-square test was applied. *p<0.05 was taken as statistically significant.*

**Table 3: Frequency of adverse effects reported with Nitrofurantoin and Fosfomycin**

| Adverse Effects | Group A (n=196) | Group B (n=196) | $\chi^2$ | p value |
|---|---|---|---|---|
| **Nausea** | 10 (5%) | 8 (4%) | 0.23 | 0.62 |
| **Abdominal discomfort** | 2 (1%) | 3 (1.5%) | 0.65 | 0.65 |
| **Diarrhea** | 12 (6.1%) | 25 (12.7%) | 5.04 | 0.02* |
| **Headache** | 3 (1.5%) | 5 (2.5%) | 0.51 | 0.47 |

*Group A= Nitrofurantoin; Group B =Fosfomycin. Chi-square test was applied. *p<0.05 was taken as statistically significant.*

**Table 4: Patient-centered outcomes of Nitrofurantoin versus Fosfomycin**

| Symptoms | Measure | Nitrofurantoin (n=196) | Fosfomycin (n=196) | p-value |
|---|---|---|---|---|
| **Dysuria** | Complete relief by Day 7 (%) | 151/184 (82%) | 123/173 (71%) | 0.01*(a) |
| | Time taken for relief in days (mean ± SD) | 2.4 ± 1.1 | 3.1 ± 1.4 | 0.003*(b) |
| **Urinary Frequency** | Complete relief by Day 7 (%) | 142/174 (82%) | 118/167 (71%) | 0.015*(a) |
| | Time taken for relief in days (mean ± SD) | 3.1 ± 1.4 | 4.0 ± 1.8 | 0.005*(b) |
| **Suprapubic Pain** | Complete relief by Day 7 (%) | 27/33 (82%) | 32/45 (71%) | 0.03*(a) |
| | Time taken to relief (days) (mean ± SD) | 2.9 ± 1.2 | 3.5 ± 1.6 | 0.04*(b) |
| **Patient's Satisfaction & Quality of Life** | Ease of antibiotic use (0–10) (mean ± SD) | 7.1 ± 1.8 | 9.2 ± 0.9 | <0.001*(b) |
| | Willingness to reuse medicine (%) | 89% | 78% | 0.008*(a) |
| | Impact on daily functioning (0–10) (mean ± SD) | 8.4 ± 1.2 | 7.6 ± 1.5 | 0.002*(b) |
| | Severity of side effects (0–10) (mean ± SD) | 1.9 ± 0.8 | 3.1 ± 1.2 | <0.001*(b) |
| | Post-treatment QoL score (0–10) (mean ± SD) | 8.8 ± 1.0 | 8.2 ± 1.3 | 0.009*(b) |

*(a)Chi square test and (b)t test was applied. *p<0.05 was taken as statistically significant*

## DISCUSSION

This study evaluated the effectiveness of oral Fosfomycin and nitrofurantoin in women of reproductive age with lower UTI. Nitrofurantoin showed superior clinical and microbiological responses, resulting in more rapid symptom relief, higher treatment success, and better bacterial eradication compared to Fosfomycin. While Fosfomycin was easier to administer as a single-dose therapy, it was associated with a higher incidence of adverse events, particularly gastrointestinal complaints, lower patient satisfaction, and post-treatment quality of life. These findings highlight nitrofurantoin as the preferred empirical therapy for uncomplicated urinary tract infections, with Fosfomycin serving as a useful alternative in cases of poor adherence or intolerance to multi-dose regimens. In this study, Escherichia coli emerged as the predominant uropathogen, accounting for nearly four-fifths of all isolates. This distribution closely aligns with global and regional epidemiological data, in which E. coli consistently accounts for 70–90% of community-acquired UTIs.[10] In the present study antimicrobial susceptibility findings demonstrated exceptionally high sensitivity of E. coli to both nitrofurantoin and Fosfomycin. This is comparable to several recent reports from South Asia and Europe, in which both agents remain >95% susceptible despite widespread resistance to commonly used antibiotics, including fluoroquinolones and cephalosporins.[8,11]

The slightly reduced sensitivity seen with nitrofurantoin in our study may reflect its more frequent empirical use, which parallels observations from other regions where increasing utilization has produced a modest rise in resistance. A key finding of this study was the superior clinical and bacteriological resolution associated with nitrofurantoin. Fosfomycin showed lower clinical recovery compared with nitrofurantoin, and bacteriological eradication at day fourteen also favored nitrofurantoin. These results echo the outcomes of several contemporary trials.[12–14] Growing evidence suggests that single-dose Fosfomycin, while convenient, may be less effective at achieving symptom resolution and bacterial clearance, especially in areas with high bacterial loads or virulent E. coli strains. Some studies have even suggested that single-dose Fosfomycin may be insufficient and may require multi-dose regimens to achieve outcomes comparable to nitrofurantoin.[15,16]

Our focus on clinical response as the primary endpoint was intentional, as symptom relief remains the most patient-centered and clinically meaningful outcome. Nitrofurantoin's higher success rate in this regard reinforces its reliability as first-line therapy, particularly in regions with escalating antimicrobial resistance. The lower treatment success observed with Fosfomycin is consistent with international data showing increasing post-treatment persistence of bacteriuria and recurrence among Fosfomycin-treated patients. [17]

Adverse events were reported more frequently in the Fosfomycin group, with diarrhea as the most common gastrointestinal complaint. Comparable findings have been documented in other studies, in which Fosfomycin was associated with higher rates of diarrhea and gastrointestinal intolerance. [18-21]Although nitrofurantoin is also known to cause mild stomach upset, our study found its side-effect profile to be more favorable, aligning with established safety data.[22] Some trials have reported comparable tolerability profiles for the two drugs, yet our results indicate that, in real-world practice, Fosfomycin may be less well tolerated.[23,24]

In this study, we incorporated patient-centered outcomes as a novel and forward-looking component of our methodology. Traditionally, research in this area has focused predominantly on clinician-reported measures, objective clinical parameters, or anatomical outcomes. While these are essential, they often fail to capture patients' lived experience, the functional impact of disease, and the real-world value of an intervention. By including patient-centered outcomes, such as symptom burden, quality of life, treatment acceptability, and patient satisfaction, our study aligns more closely with contemporary principles of value-based healthcare. This approach allowed us to evaluate the effectiveness of the intervention from the patient's perspective. Despite its ease of administration and single-dose convenience, Fosfomycin did not translate these advantages into superior patient-centered outcomes. Nitrofurantoin was associated with higher patient satisfaction, better post-treatment quality of life and fewer side effects. This suggests that patients value treatment effectiveness and tolerability more than convenience alone.

Overall, the findings of this study support the continued use of nitrofurantoin as the preferred empirical treatment for uncomplicated UTIs in women of reproductive age. Although Fosfomycin remains a valuable option particularly when adherence to multidose regimens is a concern its comparatively lower clinical efficacy and higher rate of adverse events warrant careful consideration. Rational antibiotic prescribing and periodic local surveillance of resistance patterns remain essential to maintaining the effectiveness of these first-line agents.

## CONCLUSION

Nitrofurantoin was more effective than Fosfomycin for the treatment of uncomplicated UTIs in women of childbearing age. A higher proportion of patients treated with nitrofurantoin achieved clinical recovery, indicating superior symptomatic improvement and greater microbiological eradication, as reflected by more effective bacterial clearance on follow-up urine cultures. However, Fosfomycin remains a valuable alternative, particularly for patients with poor adherence or intolerance to multi-dose antibiotic regimens.

### Limitations and future recommendations

The study was a single-center study, which limits the generalizability of the findings to the broader population. Additional multi-center research with extended follow-up durations would help assess recurrence rates and the potential emergence of antibiotic resistance.

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**AUTHORS' CONTRIBUTION:**

**SY:** Conception of the study, data collection, data acquisition, data analysis, manuscript drafting
**NH:** Data collection, data analysis & interpretation, drafting the manuscript, and critical review

All Authors approved the final version to be published and agree to be accountable for all aspects of the work, ensuring that any questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved

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