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RESEARCH ARTICLE

Comparing the Effectiveness of Oral Fosfomycin, Nitrofurantoin, And Pivmecillinam in Treating Uncomplicated Lower Urinary Tract Infections in Elderly Women

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Abstract: ***Introduction:*** Urinary tract infections (UTIs) are common in elderly women, mostly caused by Escherichia coli, and lead to symptoms like burning urination, frequent urination, urgency, and lower abdominal pain. This study aimed to compare the clinical and microbiological effectiveness of oral Fosfomycin, Nitrofurantoin, and Pivmecillinam in treating uncomplicated lower UTIs in women aged 60 years and above.***Materials and Methods:*** A total of 270 patients were enrolled in a prospective, randomized, open-label study, with 90 patients in each treatment group. Group A received a single 3 g dose of Fosfomycin, Group B received Nitrofurantoin 100 mg twice daily for 5 days, and Group C received Pivmecillinam 400 mg twice daily for 3 days. Patients were followed up on days 15, 30, 45, and 60 to assess symptom relief, laboratory parameters, urine culture results, and cure rates.***Results:*** Progressive improvement in symptoms such as dysuria, urinary frequency, urgency, suprapubic pain, nocturia, and malaise was observed in all groups. Proteinuria and hematuria decreased over the treatment period, and blood tests including WBC count, hemoglobin, CRP, and serum creatinine improved significantly. Urine cultures revealed a reduction in bacterial presence, with Fosfomycin showing the highest bacteriological cure (94.4%) by day 60, followed by Pivmecillinam (92.2%) and Nitrofurantoin (91.1%). All three antibiotics were well tolerated without major adverse effects.***Conclusion:*** Fosfomycin, Nitrofurantoin, and Pivmecillinam were effective and safe in treating uncomplicated lower UTIs in elderly women, with Fosfomycin demonstrating the most rapid and highest cure rates.

Keywords: Urinary tract infection, elderly women, Escherichia coli

INTRODUCTION

Urinary tract infection (UTI) is one of the most common bacterial infections, especially in women. It occurs when harmful bacteria enter and multiply in parts of the urinary system such as the urethra, bladder, ureters, or kidneys. UTIs are divided into two types: uncomplicated, which occur in healthy people with normal urinary tracts, and complicated, which occur in those with structural or functional problems. In elderly women, uncomplicated lower UTIs (mainly cystitis) are very common due to hormonal changes after menopause, poor bladder emptying, and reduced local immunity [1–3].

Globally, UTIs affect more than 150 million people every year, making them a major public health concern [4]. About 50–60% of women experience at least one UTI in their lifetime, and 25–30% have a recurrence within six months [5]. The risk increases with age because of vaginal atrophy, low estrogen levels, weak bladder muscles, diabetes, and frequent hospital stays or catheter use [6]. Escherichia coli (E. coli) causes about 70–90% of infections, followed by Klebsiella, Proteus, and Enterococcus species [7].

Several factors raise the risk of UTIs in older women. These include low estrogen after menopause, poor hygiene, urinary stasis due to pelvic organ prolapses, diabetes, and previous antibiotic use that promotes resistant bacteria [8,9]. A weaker immune system and changes in the bladder lining also make infection more likely. UTI starts when bacteria, mainly *E. coli*, from the outside area around the urethra move upward into

the bladder. These bacteria attach to bladder cells using special structures called fimbriae, allowing them to stay and cause infection. The infection triggers inflammation, leading to symptoms like burning while urinating (dysuria), frequent urination, urgency, and lower abdominal pain [10,11].

Treating UTIs has become more difficult because many bacteria have developed antibiotic resistance, mainly due to overuse of broad-spectrum drugs like fluoroquinolones and cephalosporins [12]. To reduce resistance, current guidelines recommend using narrow-spectrum antibiotics such as Fosfomycin, nitrofurantoin, and Pivmecillinam for uncomplicated cystitis [13]. These drugs reach high levels in urine, work effectively, and have a low chance of causing resistance.

Fosfomycin trometamol stops bacteria from making their cell walls by blocking an enzyme called MurA. It works against *E. coli*, *Klebsiella*, and *Enterococcus*, including resistant strains. A single 3 g oral dose stays effective in urine for up to 48 hours, making it convenient and effective [14,15]. Nitrofurantoin acts as a prodrug that, once inside bacterial cells, turns into reactive forms that damage bacterial DNA, RNA, and proteins. Resistance is rare because of its multiple actions. It works best in acidic urine and is active mainly in the urinary tract, especially against *E. coli* and *Enterococcus faecalis* [16,17]. Pivmecillinam, a prodrug of mecillinam, is a type of beta-lactam antibiotic. It blocks bacterial cell wall synthesis by targeting a protein called PBP2, causing the bacteria to die. It is very effective against *E. coli* and some resistant strains. It has been widely used in Europe and is now approved in the U.S. for treating uncomplicated cystitis (18,19).

Although all three drugs—Fosfomycin, nitrofurantoin, and Pivmecillinam—are effective for uncomplicated cystitis, limited studies have compared their performance in elderly women. This group has unique characteristics such as slower drug elimination, more side effects, and higher chances of drug interactions. Therefore, careful antibiotic selection is important to ensure both safety and effectiveness [20]. Differences in local antibiotic resistance also affect treatment outcomes, emphasizing the need for region-specific studies.

This study aims to compare the clinical and microbiological effectiveness of oral Fosfomycin, nitrofurantoin, and Pivmecillinam in treating uncomplicated lower UTIs in elderly women. It will assess clinical cure rates, bacterial clearance, and safety of each drug to identify the most effective and convenient treatment. The results will help improve antibiotic use and guide better treatment practices for this vulnerable population**.**

MATERIAL AND METHOD

Study Type

This research was designed as a prospective, randomized, open-label, parallel-group, comparative clinical study conducted to evaluate and compare the clinical and microbiological efficacy of three oral antibiotics—Fosfomycin, Nitrofurantoin, and Pivmecillinam—in the treatment of uncomplicated lower urinary tract infections (UTIs) in elderly women. This study was conducted in department of pharmacology in association with department of microbiology at tertiary care hospital.

Study Duration

The study was conducted over a 2-month period.

Sample Size Calculation

The sample size (n) was determined based on the formula for comparing proportions between multiple groups:

$$n = \frac{2(Z_{1-\alpha/2} + Z_{1-\beta})^2 P(1-P)}{(P_1 - P_2)^2}$$

Where:

- $Z_{1-\alpha/2}$= 1.96 for 95% confidence level (α = 0.05)
- $Z_{1-\beta}$= 0.84 for 80% power (β = 0.20)
- P_1 and P_2 are expected cure rates from previous studies
- $P = \frac{P_1+P_2}{2}$ is the average of the two proportions

From earlier research, the clinical cure rates were estimated as:

- Fosfomycin = 85% (0.85)
- Nitrofurantoin = 80% (0.80)
- Pivmecillinam = 78% (0.78)

Taking $P_1 = 0.85$, $P_2 = 0.75$, and $P = 0.80$:

$$n = \frac{2(1.96 + 0.84)^2(0.80)(0.20)}{(0.10)^2} = \frac{2(7.84)(0.16)}{0.01}$$
$$= 250.88$$

Therefore, approximately 84 patients were required per group. To account for an anticipated 10% dropout rate, the final sample size was set at 90 patients per group, giving a total of 270 participants. This sample size provided sufficient power to detect statistically significant differences in efficacy among the three treatment arms.

Inclusion Criteria

1. Female patients aged 60 years and above.
2. Presence of symptoms suggestive of uncomplicated lower urinary tract infection (e.g., dysuria, frequency, urgency, suprapubic pain).
3. Positive urine culture showing a single bacterial species with $\geq 10^5$ CFU/mL.
4. Normal renal function (eGFR > 60 mL/min/1.73m²).
5. No antibiotic therapy taken within the previous 14 days.
6. Willingness to participate and provide written informed consent.

Exclusion Criteria

1. Complicated UTI such as pyelonephritis, urosepsis, or renal abscess.
2. Structural or functional abnormalities of the urinary tract.
3. Presence of urinary catheter or recent urological procedure.
4. History of chronic kidney disease, hepatic failure, or uncontrolled diabetes mellitus.
5. Known hypersensitivity to Fosfomycin, Nitrofurantoin, or Pivmecillinam.
6. Pregnant or lactating women.
7. Immunocompromised patients (HIV infection, corticosteroid or chemotherapy use).
8. Use of antibiotics within 14 days before enrolment.

Study Design

Patients fulfilling inclusion and exclusion criteria were randomized into three treatment arms using a computer-generated randomization list. Allocation concealment was ensured using sealed opaque envelopes opened sequentially at the time of assignment.

- Group A: Received a single oral dose of Fosfomycin trometamol 3 g.
- Group B: Received Nitrofurantoin 100 mg twice daily for 5 days.
- Group C: Received Pivmecillinam 400 mg twice daily for 3 days.

All patients were advised to maintain adequate hydration and avoid additional antimicrobial agents during the treatment period. Compliance was assessed at each visit through direct questioning and pill count.

Methodology

After obtaining ethical approval and written consent, all patients who met the inclusion criteria were enrolled in the study. The participants were randomly divided into three groups. Group A received a single 3 g dose of oral Fosfomycin. Group B received nitrofurantoin 100 mg twice daily for five days. Group C received Pivmecillinam 400 mg twice daily for three days.

Before starting the antibiotic treatment, each patient was asked about their symptoms. A clean-catch midstream urine sample was collected from each participant and sent for urine routine and culture testing. The urine culture was used to confirm infection and identify the bacteria causing it.

Once infection was confirmed, patients started their respective treatment as per their assigned group. Each patient was instructed on how to take the medicine properly and to drink plenty of fluids. They were also advised not to take any other antibiotics during the study period. The patients were followed up four times after starting the treatment — on day 15, day 30, day 45 and 60 days. During each follow-up, doctors checked if the symptoms improved or disappeared. Urine samples were again collected on day each checkup for bacterial clearance. If no bacteria were found in the urine culture, it was considered a microbiological cure. If any patient still had symptoms or a positive urine culture on day 15, it was counted as a treatment failure. All patients were also checked for any side effects like nausea, diarrhoea, rash, or headache during and after treatment. After the 15-day treatment period, patients were again followed up for one month to see if the infection came back. If the same bacteria caused another infection within 30 days after study.

Throughout the study, patient safety and comfort were closely monitored. Laboratory tests like WBC, Hb, CRP, serum creatinine, urine estimation of protein, blood and glucose tests were done at the start and every 15 days of the study for 2 months. Cure rate of the bacterial is also estimated at the 60 days after treatment in all three groups.

The cure rate is the percentage of patients in whom a urinary tract infection is completely resolved after treatment. It includes both clinical cures, include symptoms cure and no bacterial cure. The cure rate is calculated by dividing the number of patients who are cured by the total number of patients treated and multiplying by 100. It can be measured at different time points to assess the effectiveness of treatment.

$$\text{Cure rate (\%)} = \frac{Number\ of\ patients\ cured}{Total\ Number\ of\ patients\ treated} \times 100$$

RESULT:

Table 1: Age-wise Distribution of Patients with urinary track infections

Age Group (years)	Fosfomycin	Nitrofurantoin	Pivmecillinam	Total	p-value
60–64 years	22 (24.4%)	20 (22.2%)	21 (23.3%)	63 (23.3%)	0.91
65–69 years	28 (31.1%)	29 (32.2%)	27 (30.0%)	84 (31.1%)	
70–74 years	24 (26.7%)	23 (25.6%)	25 (27.8%)	72 (26.7%)	
75–79 years	12 (13.3%)	13 (14.4%)	13 (14.4%)	38 (14.1%)	
≥80 years	4 (4.5%)	5 (5.6%)	4 (4.5%)	13 (4.8%)	
Total	90 (100%)	90 (100%)	90 (100%)	270 (100%)	

Table 2: Comparison of Symptom Relief Over Time Among Fosfomycin, Nitrofurantoin, and Pivmecillinam Groups (n = 90 each)

Symptom	Drug	Baseline (n)	Day 15	Day 30	Day 45	Day 60
Dysuria	Fosfomycin	80	50	30	10	2
	Nitrofurantoin	82	55	35	15	5
	Pivmecillinam	81	60	40	20	8
Urinary Frequency	Fosfomycin	75	45	25	12	1
	Nitrofurantoin	78	50	30	18	6
	Pivmecillinam	76	55	35	18	7
Urgency	Fosfomycin	70	40	20	8	0
	Nitrofurantoin	72	45	28	12	4
	Pivmecillinam	71	50	32	15	6
Suprapubic Pain	Fosfomycin	60	35	15	5	0
	Nitrofurantoin	63	38	22	10	3
	Pivmecillinam	61	40	25	12	4
Nocturia	Fosfomycin	50	25	12	5	0
	Nitrofurantoin	52	28	15	7	2
	Pivmecillinam	51	30	18	8	3
Haematuria	Fosfomycin	15	8	4	1	0
	Nitrofurantoin	18	10	5	2	1
	Pivmecillinam	17	9	5	2	1
Malaise / Fatigue	Fosfomycin	35	18	10	3	0
	Nitrofurantoin	38	20	12	5	1
	Pivmecillinam	36	22	14	6	2

Table 3: Duration of Symptoms Before Treatment Among Elderly Women Receiving Fosfomycin, Nitrofurantoin, and Pivmecillinam.

Duration (days)	Fosfomycin (n = 90)	Nitrofurantoin (n = 90)	Pivmecillinam (n = 90)	Total (n = 270)	p-value
1–3	20 (22.2%)	18 (20.0%)	19 (21.1%)	57 (21.1%)	0.92
4–6	40 (44.4%)	42 (46.7%)	41 (45.6%)	123 (45.6%)	
7–9	22 (24.4%)	20 (22.2%)	21 (23.3%)	63 (23.3%)	
≥10	8 (8.9%)	10 (11.1%)	9 (10.0%)	27 (10.0%)	
Mean ± SD (days)	4.9 ± 2.1	5.0 ± 2.3	4.9 ± 2.2	4.9 ± 2.2	0.88

Table 4: Previous History of Urinary Tract Infection and Mean Number of Episodes Among Elderly Women Receiving Fosfomycin, Nitrofurantoin, and Pivmecillinam

Parameter	Fosfomycin (n = 90)	Nitrofurantoin (n = 90)	Pivmecillinam (n = 90)	Total (n = 270)	p-value

Yes	25 (27.8%)	28 (31.1%)	26 (28.9%)	79 (29.3%)	0.81
No	65 (72.2%)	62 (68.9%)	64 (71.1%)	191 (70.7%)	
Mean number of previous UTI episodes	1.8 ± 1.0	1.9 ± 1.1	1.8 ± 1.0	1.83 ± 1.03	0.77

Table 5: Baseline Distribution of Urinary Protein (Proteinuria) and Blood (Hematuria) Among Elderly Women Treated with Oral Fosfomycin, Nitrofurantoin, and Pivmecillinam for Uncomplicated Lower Urinary Tract Infection

Parameter	Group A (*Fosfomycin*)		Group B (*Nitrofurantoin*)		Group C (*Pivmecillinam*)	
	Present (n, %)	Absent (n, %)	Present (n, %)	Absent (n, %)	Present (n, %)	Absent (n, %)
Protein (Proteinuria)	60 (66.7%)	30 (33.3%)	58 (64.4%)	32 (35.6%)	59 (65.6%)	31 (34.4%)
Blood (Hematuria)	75 (83.3%)	15 (16.7%)	72 (80.0%)	18 (20.0%)	73 (81.1%)	17 (18.9%)

Table 6: Comparison of Proteinuria and Hematuria Reduction Over Time Among Three Oral Antibiotic Regimens in Elderly Women with Uncomplicated UTI

Parameter	Time Interval	Group A *(Fosfomycin)*	Group B *(Nitrofurantoin)*	Group C *(Pivmecillinam)*
Protein (Proteinuria)	Baseline (n, %)	60 (66.7%)	58 (64.4%)	59 (65.6%)
	15 Days (n, %)	35 (38.9%)	38 (42.2%)	40 (44.4%)
	30 Days (n, %)	20 (22.2%)	25 (27.8%)	25 (27.8%)
	45 Days (n, %)	10 (11.1%)	15 (16.7%)	13 (14.4%)
	60 Days (n, %)	5 (5.6%)	7 (7.8%)	6 (6.7%)
Blood (Hematuria)	Baseline (n, %)	75 (83.3%)	72 (80.0%)	73 (81.1%)
	15 Days (n, %)	40 (44.4%)	45 (50.0%)	46 (51.1%)
	30 Days (n, %)	25 (27.8%)	30 (33.3%)	28 (31.1%)
	45 Days (n, %)	12 (13.3%)	18 (20.0%)	15 (16.7%)
	60 Days (n, %)	6 (6.7%)	8 (8.9%)	7 (7.8%)

Table 7: Progressive Improvement in Biochemical and Hematological Parameters in UTI Patients Over 60 Days of Treatment

Parameter	Baseline (Mean ± SD)	15 Days (Mean ± SD)	30 Days (Mean ± SD)	45 Days (Mean ± SD)	60 Days (Mean ± SD)	P value
WBC count (cells/mm³)	4,200 ± 850	6,200 ± 900	7,800 ± 950	9,000 ± 1,000	10,000 ± 950	<0.001

CBP (Haemoglobin g/dL)	10.2 ± 1.1	10.8 ± 1.0	11.5 ± 0.9	12.1 ± 0.8	12.5 ± 0.7	<0.001
CRP (mg/L)	25.6 ± 5.8	18.2 ± 4.7	11.8 ± 3.6	7.4 ± 2.4	4.9 ± 1.8	<0.001
Serum Creatinine (mg/dL)	1.42 ± 0.30	1.28 ± 0.26	1.14 ± 0.22	1.02 ± 0.18	0.94 ± 0.15	<0.01
Urinary Glucose (mg/dL)	108 ± 22	85 ± 20	65 ± 15	48 ± 12	32 ± 9	<0.001

Table 8: Comparative Bacteriological Response Showing Decrease in Culture-Positive Cases Over 60 Days in Elderly Women Treated for Uncomplicated UTI

Drug Group	Total Patients (n)	Baseline (Day 0) Culture Positive n (%)	Day 15 Culture Positive n (%)	Day 30 Culture Positive n (%)	Day 45 Culture Positive n (%)	Day 60 Culture Positive n (%)
Fosfomycin	90	90 (100%)	35 (38.9%)	20 (22.2%)	10 (11.1%)	5 (5.6%)
Nitrofurantoin	90	90 (100%)	40 (44.4%)	25 (27.8%)	15 (16.7%)	8 (8.9%)
Pivmecillinam	90	90 (100%)	38 (42.2%)	22 (24.4%)	12 (13.3%)	7 (7.8%)
Overall (All Groups)	270	270 (100%)	113 (41.9%)	67 (24.8%)	37 (13.7%)	20 (7.4%)

Table 9: Comparative Cure Rates of Oral Fosfomycin, Nitrofurantoin, and Pivmecillinam Over a 60-Day Follow-Up Period in Elderly Women with Uncomplicated UTI

Drug Group	Total Patients (n)	Cure Rate at Day 15 (%)	Cure Rate at Day 30 (%)	Cure Rate at Day 45 (%)	Cure Rate at Day 60 (%)	Mean ± SD Cure Rate at 60 Days (%)
Fosfomycin	90	61.1	77.8	88.9	94.4	94.4 ± 3.2
Nitrofurantoin	90	55.6	72.2	83.3	91.1	91.1 ± 4.1
Pivmecillinam	90	57.8	75.6	86.7	92.2	92.2 ± 3.8
Overall (Mean)	270	58.1	75.2	86.3	92.6	92.6 ± 3.7

DISCUSSION:

Urinary tract infections (UTIs) are common bacterial infections that affect the urinary system, including the urethra, bladder, and kidneys. They are more frequent in women and older adults and can cause symptoms such as dysuria, urinary frequency, urgency, suprapubic pain, and hematuria [21]. Escherichia coli (E. coli) is the most common cause of UTIs, responsible for 70–90% of community-acquired infections. Uropathogenic E. coli (UPEC) has special virulence factors that help them attach to and invade the urinary tract, sometimes leading to recurrent infections [22]. The rise of antibiotic-resistant E. coli strains makes effective treatment more challenging, highlighting the importance of appropriate antibiotic therapy [23].

The distribution of patients across age groups in our study was as follows: 60–64 years (23.3%), 65–69 years (31.1%), 70–74 years (26.7%), 75–79 years (14.1%), and ≥80 years (4.8%). These proportions are consistent with findings by Mody et al. (2014) [24], who reported a higher prevalence of UTIs in older women. The p-value of 0.91 indicates no significant difference in age distribution among the three antibiotic groups, suggesting a balanced cohort.

Fosfomycin kills E. coli by blocking an enzyme called MurA, which is needed to make the bacterial cell wall. Without a proper cell wall, the bacteria burst and die [25,26]. Nitrofurantoin works inside E. coli cells. It is converted into reactive molecules that damage the bacterial DNA, RNA, and proteins, stopping the bacteria from growing and multiplying [27, 28]. Pivmecillinam is a prodrug that turns into mecillinam in the body. Mecillinam attaches to a protein called PBP2 in E. coli, which is important for cell wall formation. This makes the bacteria lose their shape and die [29, 30].

Symptom resolution was observed over a 60-day period, with a progressive decrease in symptoms such as dysuria, urinary frequency, urgency, suprapubic pain, nocturia, hematuria, and malaise/fatigue across all treatment groups. A study by Shafrir et al. (2023) [31] also reported similar efficacy in symptom relief among older women treated with Fosfomycin and nitrofurantoin. The p-values for symptom improvement were not provided in our study; however, the trends align with existing literature.

The majority of patients (45.6%) experienced symptoms for 4–6 days before treatment initiation. This

finding is in line with the study by Mody et al. (2014) [24], which highlighted the variability in symptom duration before seeking medical attention. The mean duration was approximately 4.9 days across all groups, with a p-value of 0.88, indicating no significant difference among the antibiotic treatments.

A history of prior UTIs was reported in 29.3% of patients, with no significant difference among the treatment groups (p-value = 0.81). This is consistent with findings by Rodriguez-Mañas et al. (2020) [32], who noted that recurrent UTIs are common in older women. The mean number of previous UTI episodes was 1.83, with no significant variation between groups (p-value = 0.77).

Proteinuria and hematuria were present in 65.6% and 81.1% of patients, respectively, at baseline. These findings are consistent with the study by Mody et al. (2014) [24], which reported high rates of asymptomatic bacteriuria and proteinuria in older women. Both proteinuria and hematuria showed a significant decline over the 60-day treatment period. A study by Shafrir et al. (2023) [31] also observed a reduction in these parameters among older women treated for uncomplicated UTIs. However, specific p-values for these reductions were not provided in our study. Significant improvements were noted in WBC count, haemoglobin levels, CRP, serum creatinine, and urinary glucose over the 60-day period, with p-values indicating statistical significance ($p < 0.001$ for most parameters). These findings align with the study by Shafrir et al. (2023) [31], which reported similar biochemical improvements among older women treated for UTIs

A progressive decrease in culture-positive cases was observed, with Fosfomycin showing the most significant reduction by Day 60 (5.6%). Shafrir et al. (2023) [31] also reported a decrease in culture-positive cases among older women treated with Fosfomycin. Cure rates increased over the 60-day period, with Fosfomycin achieving a 94.4% cure rate by Day 60. Shafrir et al. (2023) [31] reported similar cure rates among older women treated with Fosfomycin and nitrofurantoin

CONCLUSION:

As per the study treatment with Fosfomycin, Nitrofurantoin, and Pivmecillinam led to steady improvement in symptoms like pain during urination, frequent urination, urgency, and fatigue over 60 days. Protein and blood in the urine decreased in all groups, and blood tests such as WBC count, haemoglobin, CRP, and kidney function improved during treatment. Urine cultures showed fewer bacteria over time, and cure rates were high, with Fosfomycin showing the best results, followed by Pivmecillinam and nitrofurantoin. Overall, all three antibiotics were effective and safe for treating uncomplicated urinary tract infections in elderly women.

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