Original Article

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FosfomycinTrometamol for Acute Lower UTIs in Pregnancy: An Efficacy Study

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Abstract:

Background: Pregnancy-related urinary tract infections (UTIs) pose serious health risks to both the mother and foetus due to physiological and anatomical changes, including immune adaptations and hormonal fluctuations.

Aims: This study aimed to evaluate the efficacy of Fosfomycintrometamol in treating acute lower urinary tract infections in pregnant women.

Methods: The study employed a convenient sampling technique and was conducted at Sylhet MAG Osmani Medical College from January to December 2022. It was a descriptive observational study involving 60 pregnant patients with confirmed UTIs.

Results: A single oral dose of Fosfomycintrometamol was administered, and clinical and laboratory outcomes were assessed after seven days. The study revealed a significant reduction in urinary pus cell counts (mean 16.73±5.81 to 3.83±2.30, $p<0.001$) and bacterial growth (96.7% reduction, $p<0.001$). The most common uropathogen was *Escherichia coli* (71.7%), followed by *Klebsiellapneumoniae* (25%). Clinical symptoms, including burning micturition, urgency, and dysuria, improved in over 95% of patients. Adverse effects such as nausea, dizziness, and headache were reported but were mild and transient. **Conclusion:** With few adverse effects and excellent patient compliance, the results validate Fosfomycintrometamol as a safe and efficient therapy for lower urinary tract infections during pregnancy.

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Introduction:

UTIs are a serious concern during pregnancy as they can negatively impact the health of both the foetus and the mother.[1] World Health Organization (WHO) estimates indicate that infections during pregnancy cause 10.7% of maternal deaths globally, with around 28% of these instances occurring in the urinary system.[2]

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Due to physiological and anatomical changes that take place during pregnancy, including hormonal shifts and the mechanical pressure from the growing uterus, pregnant women are susceptible to UTIs.[1,3] A key contributor is the rise in progesterone levels, which relaxes smooth muscle tissue throughout the urinary tract, including the bladder and ureters. This facilitates bacterial ascent from the urethra to the bladder or kidneys by lowering the ureteral tone, altering bladder function, and causing urine stasis.[1] Additionally, hormonal changes alter vaginal flora, enhancing the growth of uropathogens, while immunological adaptations, such as reduced cell-mediated immunity, weaken the body's defence against infections.[3]

Globally, the prevalence of symptomatic UTIs in pregnancy ranges from 4% to 47%.[4] In Bangladesh, approximately 4.4% of pregnant women are affected.[5] UTIs are most commonly caused by *Escherichia coli* (82.5%), followed by other bacteria such as *Proteus mirabilis*, *Klebsiellapneumoniae*, *Staphylococcus saprophyticus*, and *Enterococcus faecalis*.[6] Typical symptoms include dysuria, suprapubic discomfort, haematuria, and foul-smelling urine.[7] If untreated, UTIs can progress to the upper urinary tract, causing pyelonephritis, which increases the risk of maternal complications such as chronic renal failure, preterm delivery, low birth weight, and hypertensive disorders of pregnancy.[8] Women with medical comorbidities like diabetes or recurrent UTIs are at higher risk.[9]

Empirical treatment of UTIs in pregnancy aims to balance efficacy with safety for both the mother and foetus. While some antibiotics have been linked to birth defects, Fosfomycintrometamol has emerged as a first-line option. It is a category B drug approved by the FDA, offering bactericidal activity by disrupting bacterial cell wall synthesis.[10,11] This drug is effective against both Gram-positive and Gram-negative bacteria, including *E. coli* biofilms, which are common in acute cystitis.[8,12] A single 3g dose of Fosfomycintrometamol maintains therapeutic urine concentrations for over 36 hours, making it highly effective and well-tolerated, with minimal side effects.[11,13,14]

Despite its widespread use, there is a lack of published data on the safety and efficacy of Fosfomycintrometamol in Sylhet, Bangladesh. This study seeks to evaluate the efficacy of Fosfomycintrometamol for treating lower UTIs during pregnancy.

Methodology:

This descriptive observational study aimed to assess the efficacy of Fosfomycintrometamol in treating lower urinary tract infections (UTIs) during pregnancy, focusing on symptom relief, microscopic changes in urine analysis, and adverse effects. Conducted between January 1, 2022, and December 31, 2022, at the Department of Pharmacology and Therapeutics, Sylhet MAG Osmani Medical College, in collaboration with the Model Family Planning Clinic under the Department of Obstetrics and Gynaecology and the Department of Microbiology, the study included pregnant patients presenting with symptoms such as burning micturition, urgency, and frequency of micturition. Inclusion criteria required participants to be between the 12th and 36th weeks of pregnancy, exhibit pyuria (>10 leukocytes/HPF), have a positive urine culture ($\geq 10^5$ CFU/mL), and demonstrate sensitivity to Fosfomycintrometamol, while exclusion criteria included congenital urogenital anomalies, hydronephrosis, renal stones, pyelonephritis, severe nausea or vomiting, recurrent UTIs, or drug allergies. Participants received a single 3-gram oral dose of Fosfomycintrometamol, taken on an empty stomach after dilution in water. Data were collected through face-to-face interviews using a modified validated questionnaire and the collection of two mid-stream urine samples—one for routine microscopic examination and another for culture and sensitivity testing. Patients were followed up on the 7th day post-treatment to evaluate outcomes, including symptom resolution and laboratory confirmation of infection resolution through repeated urine tests. Data analysis was performed using SPSS (version 25), with paired t-tests and Z-statistics applied to compare laboratory outcomes before and after treatment. Ethical considerations included convenient sampling, obtaining written informed consent, anonymizing participant data, and securing ethical approval from the Sylhet MAG Osmani Medical College Ethical Committee. (Memo No/SOMC/2022/57)

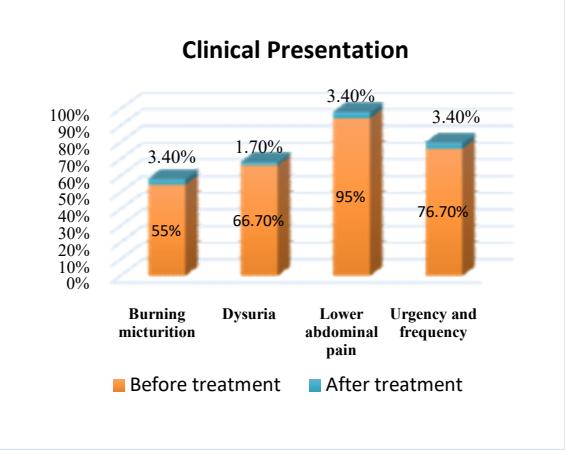
Result:

Table I: Distribution of Patients by Socio-Demographic Characteristics (n=60)

Parameters	Frequency(n=60)	Percentage (%)
Age		
<20 years	8	13.3%
20 – 24 years	27	45%
25 – 29 years	18	30%
≥30 years	7	11.7%
Education		
Illiterate	29	48.3%
Primary level	14	23.3%
SSC	11	18.4%
HSC	6	10%
Monthly income		
Low income	42	70%
Middle income	18	30%
High income	0	0%
Para (mean ± SD)	0.88 ± 0.90	
Gravida (mean ± SD)	1.92 ± 0.94	
Gestational age (weeks) (mean ± SD)	26.22 ± 6.88	

The majority of patients were aged 20–24 (23.70 ± 3.95) years, with a significant portion having low educational attainment, as nearly half (48.3%) were illiterate. Most patients (70%) belonged to the low-income group, while no high-income earners were reported. The mean parity, gravida, and gestational age were 0.88 ± 0.90, 1.92 ± 0.94, and 26.22 ± 6.88 weeks, respectively.

The results indicated significant improvement in clinical symptoms following treatment. Burning micturition decreased from 55% to 3.4%, dysuria dropped from 66.7% to 1.7%, lower abdominal pain reduced from 95% to 3.4%, and urgency and frequency declined from 76.7% to 3.4%.



(variables in several answers)

Figure 1: Clinical presentation of patients before and after treatment with Fosfomycintrometamol

Table II: Urinary findings of patients before and after treatment with Fosfomycintrometamol (n=60)

Urinary pus cell counts before and after treatment	
Before treatment(mean ± SD)	16.73 ± 5.81
After treatment(mean ± SD)	3.83 ± 2.30
Percentile reduction	77.11%
Test value	15.991
p-value*	<0.001
Bacterial growth in urine culture before and after treatment	
Before treatment	60 (100%)
After treatment	2 (3.3%)
Percentile reduction	96.7%
p-value**	<0.001
Urinary pus cell counts after 7 days of treatment	
<10 pus cell/HPF	58 (96.7%)
>10 pus cell/HPF	2 (3.3%)
Percentile reduction	96.7%
p-value**	<0.001

*Paired t-test, **Z-test

The urinary findings showed significant improvement after treatment with Fosfomycintrometamol. Urinary pus cell counts decreased from a mean of 16.73 ± 5.81 to 3.83 ± 2.30, reflecting a 77.11% reduction ($p < 0.001$). Bacterial growth in urine culture dropped from 100% of patients to 3.3%, with a 96.7% reduction ($p < 0.001$). After seven days of treatment, 96.7% of patients had <10 pus cells/HPF, while only 3.3% had >10 pus cells/HPF, showing a 96.7% improvement ($p < 0.001$). The clinical cure rate of 96.7% can be inferred from the percentage of patients achieving less than 10 pus cells/HPF after treatment, supported by significant bacterial reduction in urine culture findings.

The findings revealed that E. coli was the most common organism (71.7%), followed by Klebsiella (25%) and Pseudomonas (3.3%). No cases of Staphylococcus aureus were detected.

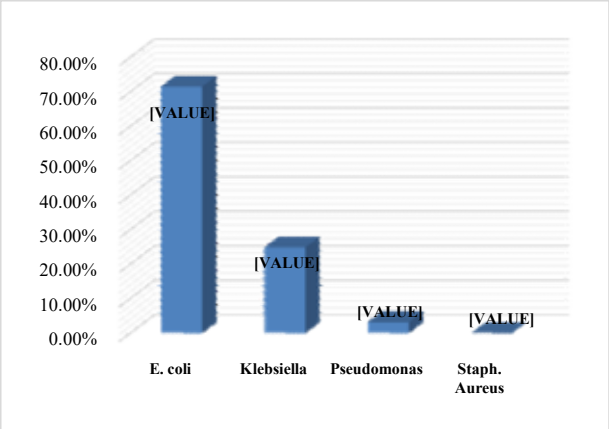


Figure 2: Distribution of Organism cultured from urine sample(n=60)

The observed adverse effects included nausea and vomiting in 28 participants (46.7%), dizziness in 18 participants (30.0%), and headache in 12 participants (20.0%). No cases of diarrhoea were reported.

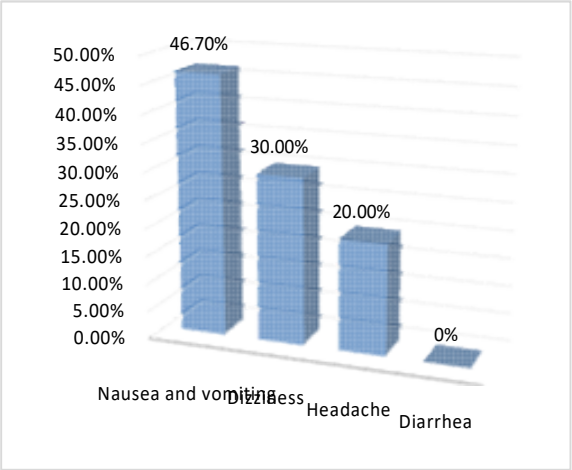


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Figure 3: Adverse effects of Fosfomycintrometamol

Discussion:

Pregnancy-related alterations in the anatomy and physiology of the genitourinary system make urinary tract infections (UTIs) a common occurrence during pregnancy.[15] UTIs may present as asymptomatic bacteriuria, systemic pyelonephritis, or symptomatic cystitis with associated symptoms such as dysuria, urgency, frequency, and suprapubic discomfort.[15,16]To prevent poor obstetric outcomes, the appropriate, safe, and effective use of antibiotics is crucial. However, repeated courses of antibiotics and recurrent lower urinary tract infections have led to high levels of bacterial resistance among pregnant women.[17]

Fosfomycintrometamol is considered a first-line therapy (category B) for uncomplicated UTIs in pregnancy due to its high efficacy, low bacterial resistance, and favourable safety profile.[17,18]It is often administered as a single-dose treatment, with minimal adverse effects and lower rates of resistance compared to other antibiotics.[17-19]

This descriptive observational study was conducted at the Department of Pharmacology and Therapeutics, in collaboration with the Model Family Planning Clinic under the Department of Obstetrics and Gynaecology and Department of Microbiologyat Sylhet MAG Osmani Medical College, Sylhet, from January to December 2022. The study assessed the effectiveness of Fosfomycintrometamol in treating lower urinary tract infections during pregnancy. Of the 64 pregnant patients initially enrolled in the study, 60 completed it, as four patients missed the 7th-day follow-up visit.

The mean age of patients in this study was 23.70±3.95 years, consistent with findings from Ozel et al. (2011) and Radwan (2021), who reported mean ages of 24.26±4.6 years and 24.48±5.35 years, respectively. However, slightly higher mean ages were observed in studies by Patel (2018) (25.4±2.8 years), El-Mehy et al. (2021) (27.09±7.3 years), Dawood et al. (2017) (28.5±3.4 years), and Hakeem (2022) (29.41±4.71 years).[15-20,21]The study population comprised a substantial proportion of individuals with low educational levels, with nearly half (48.3%) having no formal education. The majority of participants (70%) belonged to low-income groups, with no high-income earners identified.The mean parity among patients treated with Fosfomycintrometamolwas 0.88±0.90, which was lower than those reported by Dawood et al. (2017) (1.7±0.7), El-Mehy et al. (2021) (1.40±0.81), and Hakeem (2022) (1.92±1.06).[15,17,18] Similarly, the mean gravida in this study was 1.92±0.94, aligning with Patel (2018) (1.7±0.4) but higher than Dawood et al. (2017) (1.2±0.3).[15,21]The mean gestational age of patients in this study was 26.22±6.88 weeks. In

comparison, Ozel et al. (2011) and El-Mehy et al. (2021) reported slightly lower gestational ages of 25.24±4.8 weeks and 23.91±4.1 weeks, respectively. Conversely, Dawood et al. (2017) studied patients with a higher mean gestational age of 33.40±1.70 weeks.[15,16,18,]

In this study, all patients were symptomatic and had positive urine culture reports at baseline. E. coli was the most frequently isolated organism (71.7%), followed by Klebsiella (25%), Pseudomonas (3.3%), while no cases of Staphylococcus aureus were detected. Similarly, Ozel et al. (2011) reported E. coli (90.7%) and Klebsiella (9.3%) as the predominant isolates, while Huttner et al. (2015) found E. coli in 61% and Klebsiella in 7.2% of urine samples, along with other organisms not observed in this study. In contrast, Hakeem (2022) documented E. coli in 46.9% of cases, Staphylococcus aureus in 32.7%, and Klebsiellapneumoniae in 10.25%.[16,17,22]

A patient was considered clinically cured when complaints of dysuria (burning micturition), increased frequency, urgency, and lower abdominal pain were completely resolved. The treatment resulted in a significant improvement in clinical symptoms. The prevalence of burning micturition decreased from 55% to 3.4%, dysuria reduced from 66.7% to 1.7%, lower abdominal pain dropped from 95% to 3.4%, and urgency and frequency declined from 76.7% to 3.4%. The clinical cure rate observed in this study was 96.7%. These findings align with Patel (2018), who reported a 98.3% clinical cure rate in patients treated with Fosfomycintrometamol. Similarly, Dawood et al. (2017) documented a 100% subjective clinical cure rate.[15,21]

The treatment with FosfomycinTrometamol led to a significant reduction in urinary pus cell counts. Before treatment, the mean count was 16.73 ± 5.81, which decreased to 3.83 ± 2.30 after treatment, reflecting a 77.11% reduction. The paired t-test value was 15.991, with a highly significant p-value of <0.001, confirming the effectiveness of the treatment in reducing inflammation indicators. This finding aligns with Sashidhar Reddy B. (2021), who reported that the mean pus cell count decreased from 7.90 ± 1.30 to 3.20 ± 0.95 after treatment.[23]

A remarkable improvement was observed in bacterial growth within the urine culture. Before treatment, all 60 patients (100%) had positive bacterial growth, which dropped to only 2 patients (3.3%) post-treatment, resulting in a 96.7% reduction. The Z-test analysis yielded a statistically significant p-value of <0.001, indicating the antibiotic's effectiveness in eradicating the infection. This finding is consistent with Ozel et al. (2011), who reported a slightly lower bacteriological cure rate of 94.5%.[16]

After seven days of treatment, 96.7% of patients (58 out of 60) showed fewer than 10 pus cells per high-power field (HPF), while only 3.3% (2 patients) had more than 10 pus cells per HPF. This represented a 96.7% reduction. The Z-test confirmed the significance of this improvement with a p-value of <0.001, underscoring the treatment's efficacy in resolving urinary tract infections and restoring normal urinary findings. El-Mehy et al. (2021) showed a similar way of reduction in their study and reported a similar percentage reduction of pus cell count; 97.1% reduction.[18]

The most common adverse effect was nausea and vomiting (46.7%), followed by dizziness (30.0%) and headache (20%). El-Mehy et al. (2021) also observed nausea/vomiting as the most frequent adverse effect (70.4%). Ozel et al. (2011) reported nausea as the sole adverse effect, while Dawood et al. (2017) noted diarrhoea, nausea/vomiting, and dizziness. Similarly, Radwan (2021) reported that 6.5% of patients experienced diarrhoea, and another 6.5% reported nausea and vomiting.[15,16,18,20]

ShrikantDeshpande (2024) emphasized that Fosfomycintrometamol is generally well-tolerated, with most adverse effects being mild and transient. Common side effects include gastrointestinal symptoms such as nausea, diarrhoea, and abdominal pain. Serious adverse reactions are rare, and other minor adverse events include dizziness, back pain, vaginitis, dysmenorrhea, dyspepsia, pharyngitis, rhinitis, skin rash, non-localized pain, and asthenia.[13,24,25]

Conclusion:

UTIs are a common concern during pregnancy. This study demonstrated the efficacy of Fosfomycintrometamol as a treatment option, showing significant clinical and laboratory

improvements with minimal adverse effects. These findings support its use as a safe and effective therapy for lower urinary tract infections during pregnancy.

Limitations:

The present study had several limitations:
This was a single-centre study.
The sample size was limited due to time constraints.
The study did not evaluate disease relapse; follow-up was conducted only once.

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