Original Article

A prospective, follow up study to assess guidelines compliance in uncomplicated urinary tract infection

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Abstract

Background and Aims: The study was undertaken to assess the empirical antibiotic prescription in uncomplicated urinary tract infection (UTI) cases and compare them with the Indian council of medical research (ICMR) 2017 guidelines on antimicrobial use. The objective of this study was to study the compliance of prescriptions for uncomplicated UTI with respect to the guidelines recommended by ICMR and assess the success rates in terms of mean days taken to achieve symptomatic relief. **Methodology:** This study was conducted on patients (of age >16 years) presenting to the Urology, Medicine and Gynecology OPD with complaints of uncomplicated UTI over two months. Descriptive statistics were used to assess the results. **Results:** A total of 115 UTI patients were enrolled and followed up for symptomatic relief. 67 (58.26%) patients were prescribed antibiotics, the preferred ones were levofloxacin 500 mg O.D. in 24 (35.82%), nitrofurantoin 100 mg B.D. in 21 (31.34%) and levofloxacin 750 mg O.D. in 6 (8.95%) patients for a mean duration of 7.83 ± 2.37, 7.52 ± 2.68 and 4.33 ± 1.03 days respectively. Symptomatic relief was seen in 6 (25%), 15 (71.42%) and 4 (66.67%) cases within 5 ± 0.63 days, 4.2 ± 2.11 days and 4.5 ± 1 days, respectively. **Discussion:** 23 (34.32%) prescriptions based on choice of empirical antibiotic and 17 (25.37%) prescriptions based on both choice of antibiotic and duration of therapy were found to be compliant with the (ICMR) -2017 guidelines. Results show decreased efficacy of co-trimoxazole and ciprofloxacin as empirical therapy for acute uncomplicated UTI.

Keywords: Antibiotic stewardship, empirical antibiotics, prescription audit, uncomplicated UTI

Introduction

Antibiotics are one of the most commonly prescribed drugs in the outpatient department (OPD). Urinary tract infection (UTI) being the second most common community acquired infectious disease is a very common indication to start antibiotics as an empirical therapy. A recently published systematic review and meta-analysis has shown high rates of antimicrobial resistance among the major UTI causing pathogens, especially higher for the frequently used antibiotics.[1]

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Received: 13-05-2020 **Revised:** 14-06-2020
Accepted: 01-07-2020 **Published:** 25-08-2020

Access this article online

Quick Response Code:

Website: www.jfmpc.com

DOI: 10.4103/jfmpc.jfmpc_849_20

However in contrast to the increasing trend of antimicrobial resistance, the development of newer antibiotics since the past few decades has reduced significantly. Since 1998, only 10 new antibiotics have been approved, among these only 2 i.e., daptomycin and linezolid have newer targets of action and their use has been rising continuously. Other than large scale antibiotic use, inappropriate use of broad spectrum antibiotics poses greater risk of development of antimicrobial resistance, which increases hospital stays, therapy durations and thereby the financial burden on patients.[2] As per Centers for Disease Control (CDC), out of all antibiotics prescribed in U.S. 50% of total prescriptions were found unnecessary or ineffective, the statistics are even worse in the developing nations.[3] The situation can be improved by prescription audits and setting up antimicrobial stewardship teams which can help increase

How to cite this article: Manshahia PS, Bisht M, Mittal A, Bhatia M, Handu SS. A prospective, follow up study to assess guidelines compliance in uncomplicated urinary tract infection. J Family Med Prim Care 2020;9:4292-7.

compliance of treatment with the local guidelines. But there are very few publications on infection control in India (1.45% of total publications) and antibiotic stewardship programs are minimal (1.23% of total) as compared to developed nations like US (21.34% and 37.60%, respectively).[2] Also, the majority of surveillance has been done in megacities like Delhi, Mumbai, and Vellore, and is lacking in relatively less developed regions like Uttarakhand.[2,4] So this study conducted in Rishikesh, is an initiative to fill this gap.

Since the beginning of 21st century both OPD visits and IPD admissions for UTI have been rising and so is the use of antibiotics.[5] Thus to minimize indiscriminate use, it is important to analyze current patterns of antibiotic prescription in uncomplicated UTI cases and compare them with the existing guidelines. Recent studies have found out sensitivity rates among pathogens for different antibiotics in different regions of India,[6,7] but somehow the aspect of drug efficacy in actual clinical settings in terms of symptom relief for the patients is yet to be explored. Various international guidelines are available that recommend and guide the use of antibiotics in UTI including the European Association of Urology (EAU Guidelines)[8] and the National Institute for Health and Care Excellence (NICE Guidelines), but it is also important to tailor the treatment regimens according to local antibiotic susceptibility patterns, availability and cost of antibiotics in the area.[9] Recently in 2017, ICMR has issued treatment guidelines for Antimicrobial Use in Common Syndromes to guide the antibiotic use in Indian settings.[10]

Aims and Objectives

The primary objective of this study was to study the compliance of prescriptions for uncomplicated UTI with respect to guidelines recommended by ICMR.[10] The other objectives were to assess the prescribed antibiotic(s) as empirical therapy and evaluate the adequacy of their dose, duration and frequency (if prescribed), and assess the success rates of empirical therapy in terms of symptomatic relief.

Methodology

After obtaining the ethical approval dated 10/05/2019, from the Institutional Ethics Committee, this study was conducted as a project under short-term studentship (STS) by ICMR. Patients presenting in outpatient setting to the Urology, Medicine and Gynecology OPD with complaints of UTI over a period of two months were enrolled. It was an observational, follow up study. After taking written informed consent, 115 patients that met the above mentioned criteria were included. The inclusion criteria of the study were patients of age >16 years, diagnosed as case of uncomplicated UTI based on clinical suspicion of the physician with symptoms suggestive of UTI including burning micturition, increased frequency of urination, urgency, suprapubic pain, blood in urine, cloudy urine, fever with or without chills and malaise. The exclusion criteria were age <16 years, catheter associated UTI, complicated UTI cases due to stones, strictures, neurogenic bladder etc., recurrent UTI, previous history of surgery involving genito-urinary tract and pregnancy. Details pertaining to the empirical treatment (if given), follow-up details, culture and sensitivity results and any changes in the therapy (if made) after results have been obtained were recorded. On the follow-up, efficacy of empirical treatment was determined in terms of symptomatic relief (in days) experienced by the patient after initiation of therapy. Descriptive statistics were used to describe the results of the study.

Observations and Results

During the two month study period, 115 eligible patients that presented to urology, gynecology and medicine OPD with complaints suggestive of UTI were enrolled after taking proper informed consent. Out of total 115 symptomatic patients, diagnosis was confirmed by positive urine culture in 48 (41.73%) patients. Majority of the patients with symptoms and confirmed diagnosis were females, constituting 70 (61%) and 25 (52%) patients, respectively. Mean age ± S.D. of the patients with symptoms and confirmed diagnosis was 44 ± 16.34 years and 47.81 ± 16.38 respectively. Maximum number of cases fell under 30-50 years' age group, i.e., 48.6% of symptomatic patients and 50% of all culture positive cases.

Almost 109 (95%) of the patients presented with burning micturition as their chief complaint. The second most frequent symptom being supra-pubic pain 53 (46.08%), followed by fever in 51 (44.34%) of the patients. Other frequent complaints included increased frequency of urination in 49 (42.6%) and urgency in 31 (26.95%) of patients.

Table 1 shows the details pertaining to the empirical therapy given to the UTI patients. Out of all the patients (n = 115) 67 (58.26%) were prescribed antibiotics empirically. Most common groups being fluoroquinolones, urinary antiseptics and cephalosporins – prescribed in 34 (50.74%), 21 (31.34%) and 8 (11.94%) patients, respectively.

Figure 1 shows the distribution of most frequently prescribed antibiotics used as empirical therapy for patients with symptoms suggestive of UTI.

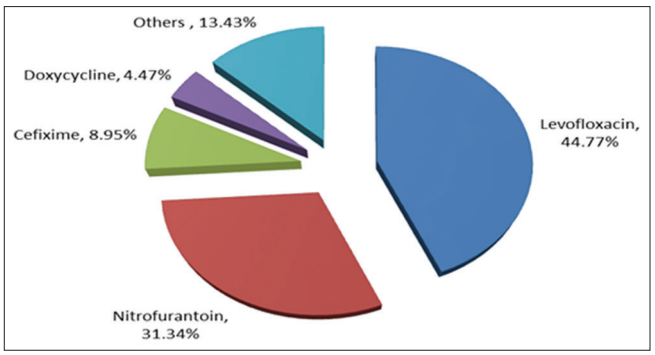

Figure 1: Distribution of most frequently prescribed antibiotic as an empirical therapy for the patients with symptoms suggestive of UTI (n = 67)

Table 1: Empirical therapy given to the patients with symptoms suggestive of UTI (*n*=67)

Antibiotic	Dose	Duration of therapy (days) (Mean±S.D.)	No of Prescriptions (%)	Symptomatic Relief	
				No of patients (%)	Number of days (Mean±S.D.)
Fluoroquinolones -34 (50.74%)					
Levofloxacin	500 mg OD	7.83±2.37	24 (35.82)	6 (25)	5±0.63
	750 mg OD	4.33±1.03	6 (8.95)	4 (66.67)	4.5±1
Ofloxacin	100 mg BD	6	2 (2.98)	2 (100)	5
Ciprofloxacin	500 mg BD	5	1 (1.5)	0 (0)	_
Norfloxacin	400 mg BD	7	1 (1.5)	1 (100)	3
Urinary antiseptics -21 (31.34%)					
Nitrofurantoin	100 mg BD	7.52±2.68	21 (31.34)	15 (71.42)	4.2±2.11
Cephalosporin- 8 (11.94%)					
Cefexime	200 mg BD	8±1.73	3 (4.47)	1 (33.3)	2
Cefexime (+ Doxycycline)	200 mg BD	14	3 (4.47)	2 (66.6)	5
Cefuroxime	500 mg BD	7	2 (2.98)	1 (50)	2
Tetracyclines-3 (4.47%)					
Doxycycline (+ cefexime)	100 mg BD	14	3 (4.47)	2 (66.6)	5
Sulphonamides -1 (1.5%)					
Cotrimoxazole	160/800 mg BD	10	1 (1.5)	0 (0)	_
Aminoglycosides -1 (1.5%)					
Amikacin	500 mg I.V.	single dose	1 (1.5)	1 (100)	1
Others -1 (1.5%)					
Fosfomycin	3 gm	single dose	1 (1.5)	0 (0)	_

Figure 2 shows compliance of antibiotic prescriptions for UTI with the Treatment Guidelines for Antimicrobial Use in Common Syndromes 2017, given by ICMR with respect to the correct choice of antibiotic and correct duration of regimen. 23 (34.32%) antibiotic choices were found compliant. When both choices of antibiotic and its duration were taken into consideration than 17 (25.37%) prescriptions were found compliant as therapy duration exceeded in six (28.57%) of the nitrofurantoin prescriptions.

Out of all 115 urine cultures incubated, 48 (41.73%) showed significant bacterial growth. Males showed higher culture positivity (51.1% out of 45 symptomatic patients) than females (35.7% out of 70 symptomatic patients). Escherichia coli was the major causative organism both in males and females and was isolated from 31 (65%) of all the culture positive urine samples. However, it was associated more frequently with infection in females patients as it was isolated in 17 (68%) samples in females compared to 14 (61%) male samples. Second most common causative organism was Klebsiella: 8 isolates (17%), which was more frequently isolated in male than in female patients i.e., 5 (22%) and 3 (12%) patients, respectively. Gram-positive organisms including CONS (coagulase negative Staphylococcus), MRSA (methicillin resistant Staphylococcus aureus) and enterococcus constituted 4 (8.3%) out of the total isolates.

Table 2 shows the antibiotic susceptibility pattern of isolated microorganisms as percent of isolates sensitive to the particular antibiotic used for empirical therapy. The most preferred antibiotic Levofloxacin was found sensitive only in 35.3% of *Escherichia coli* isolates and rest of the gram-negative organisms

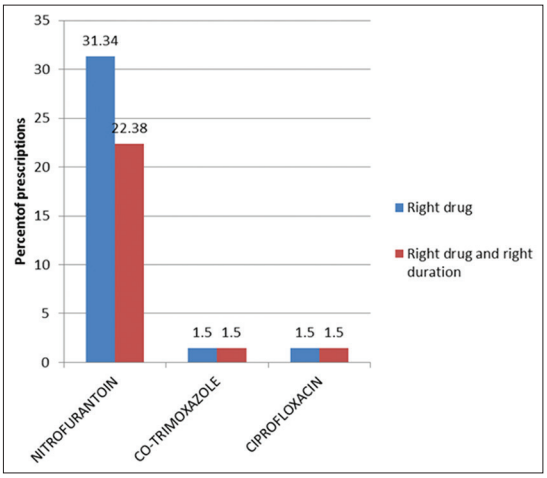

Figure 2: Compliance of the empirical antibiotic prescriptions in UTI with the 2017 ICMR guidelines for antimicrobial use in common syndromes (total prescriptions, N = 67)

were found resistant. Sensitivity of *E. coli* towards nitrofurantoin was 92.8%.

Table 3 shows the analysis of empirical therapy in terms of correct/wrong management. 58 (50.3%) patients were wrongly managed. 30 (26%) patients were over treated, 17 (14.8%) patients were prescribed resistant antibiotics and 11 patients (9.5% of total) i.e., 23% of culture positive patients were undertreated as they were not prescribed any antibiotic. 20 (17.4%) UTI cases were correctly treated with a sensitive antibiotic in the empirical treatment. Males were more often treated with resistant antibiotics 8 (17.7%) than females 9 (12.8%). Also, the

Table 2: Antibiotic susceptibility pattern of the isolated micro-organism as percent of isolates sensitive to the particular antibiotic used for empirical therapy (*n*=48)

Antibiotics	Bacteria						
	Escherichia coli (*n*=31)	Klebsiella spp. (*n*=8)	Pseudomas spp.(*n*=3)	MRSA (*n*=2)	CONS (*n*=1)	Proteus (*n*=1)	Enterococcus (*n*=1)
Fluoroquinolones							
Levofloxacin	11 (35.3%)	0 (0%)	0 (0%)	0 (0%)	-	-	-
Ciprofloxacin	12 (40%)	-	0 (0%)	-	-	-	0 (0%)
Norfloxacin	12 (38.8%)	2 (25%)	-	-	-	1 (100%)	0 (0%)
Nitrofurans							
Nitrofurantoin	26 (92.8%)	3 (37.5%)	-	-	1 (100%)	0 (0%)	1 (100%)
Cephalosporins							
Cefexime	7 (25%)	3 (42.8%)	-	-	-	1 (100%)	-
Cefuroxime	4 (15%)	1 (12.5%)	-	0 (0%)	-	-	-
Tetracyclines							
Doxycycline	20 (77.2%)	5 (83.3%)	-	-	-	1 (100%)	0 (0%)
Folate pathway inhibitors							
Co-trimoxazole	8 (27.5%)	2 (25%)	-	2 (100%)	0 (0%)	0 (0%)	-
Aminoglycosides							
Amikacin	16 (84.2%)	4 (66.6%)	0 (0%)	-	-	1 (100%)	-

Table 3: Analysis of the empirical therapy in terms of correct/wrong management in the patient with symptoms suggestive of UTI (*n*=115)

Management	Number (%)
Correct management	57 (49.6%)
Culture positive and treated with sensitive antibiotic	20 (17.4%)
Culture negative and no antibiotic prescribed	37 (32.2%)
Wrong management	**58 (50.3%)**
Culture negative but antibiotic prescribed	30 (26%)
Culture positive treated with resistant antibiotic	17 (14.8%)
Culture positive but no antibiotic prescribed	11 (9.5%)

prescription of antibiotics in culture negative males 12 (26.6%) was more than culture negative females 18 (25.7%).

Approximately 16 (23.88%) antibiotic prescriptions were modified to a different antibiotic once culture sensitivity results were available. Out of the total levofloxacin prescriptions (30), 6 (20%) prescriptions were changed to nitrofurantoin, 2 (6.6%) treatments modified to co-trimoxazole, other 2 (6.6%) (positive for *Pseudomonas spp.* and *Klebsiella spp.*) changed to piperacillin-tazobactam, 4 (13.3%) continued and the rest 53.3% (16) stopped as no growth was obtained in culture after 24 hours of aerobic incubation. Among the total nitrofurantoin prescriptions, only 2 (9.5%) were modified to other antibiotics ceftazidime and piperacillin-tazobactam in *Pseudomonas spp.* and *Klebsiella spp.* isolates respectively. 13 (61.9%) prescriptions continued due to pathogen sensitivity and 6 (28.5%) were stopped due to negative culture reports.

Discussion

In our study, 61% of the patients were female, which is supported by other studies and the predilection is attributed to shorter length of urethra and its proximity to rectal mucosa.[11] Among the symptomatic patients the prevalence of UTI (culture confirmed cases) was 41.73%, comparable to 32.1% in another study carried out in a tertiary care setting in Bangalore, but on the contrary greater prevalence of UTI in symptomatic males (51% i.e., 23 out of 45) than symptomatic females patients (36% i.e., 25 out of 70) found in the present study is difficult to explain.[7] Major presenting complaints were dysuria (94.78%), supra-pubic pain (46%), fever (44.34%), frequency (42.6%) and urgency (26.95%) of urine, similar to that seen in other studies.[12] However, the frequency of dysuria seen was more in contrast to previous literature (94.78% vs. 42.3%), also patients presenting with both dysuria and fever were relatively higher (41.73% vs. 33.2%).[7]

The most preferred antibiotics prescribed as empirical therapy for uncomplicated UTI were levofloxacin (44.77%) and nitrofurantoin (31.34%). Parenteral antibiotic use in empirical treatment was limited to one prescription of Amikacin i.e., 1.5% of total prescriptions. This trend was entirely different from that seen in a similar study done in 2015 where Ciprofloxacin (27.3%) and Co-trimoxazole (27.3%) were the predominant antibiotics and parenteral antibiotic prescription was high, accounting to 22% of all prescriptions (17/77 patients prescribed).[7] The main reason for change to nitrofurantoin as preferred agent could be recent ICMR guidelines released in 2017. The duration of symptoms persisting after antibiotic therapy was slightly longer, as symptomatic relief achieved by levofloxacin 500 mg (mean 5 ± 0.63 days), Levofloxacin 750 mg (4.5 ± 1 days), litrofurantoin 100 mg (4.2 ± 2.11 days) all exceeded the time duration of 2-4 days as reported in another study.[13] Cefexime (4.47%) and Cefuroxime (2.98%) although less prescribed showed early symptomatic relief in mean duration of 2 days. Thus, this study has been a pioneering study to evaluate the efficacy of the empirical therapies in terms of mean days taken for symptomatic relief, an important aspect which wasn't analyzed in the previous research works done on a similar topic.

E. coli was most frequent cause of UTI both in females (68%) and males (61%), and the result is supported by previous researchers.[9,10,13] The other bacteria frequently isolated were Klebsiella (17%), Pseudomonas (6%) and MRSA (4%). Similar findings have also been shown by the studies conducted in other parts of India and other countries.[2,12]

The 2017 ICMR treatment guidelines for antimicrobial use in common syndromes recommend prescribing any of the three antibiotics as empirical therapy for acute cystitis i.e., Nitrofurantoin (100 mg BD for 7 days), co-trimoxazole (500/125 mg BD for 3-5 days) and Ciprofloxacin (500 mg BD for 3-5 days).[10] The sensitivity patterns of *E. coli* for above three drugs in the present study were 92.8%, 27.5% and 40%; rendering co-trimoxazole and ciprofloxacin less suitable for use as empirical therapy. As compared to the sensitivity patterns given in the antimicrobial resistance surveillance network (AMRSN) data, 2014, in the same guidelines, sensitivity for ciprofloxacin was significantly low in the present study (40% vs. 85% at PGIMER Chandigarh and 90% at AIIMS New Delhi).[10] This reduction in sensitivity of *E. coli* towards ciprofloxacin could be explained by the extensive and widespread use of fluoro-quinolones as empirical therapy for acute uncomplicated UTIs.[11] The sensitivity pattern revealed in the present study were in compliance with the recent 2018 AMRSN data.[14] Levofloxacin was the most preferred antibiotic and was 44.77% of the total prescriptions. However, it was reported sensitive for only 35.3% of *E. coli* cultures and none of the other gram-negative isolates. On the other hand, Nitrofurantoin showed higher sensitivity overall (80%), towards *E. coli* (92.8%) and for gram-positive isolates (100%) (except MRSA), proving its efficacy as an empirical antibiotic for UTI. Similar set of values for antibiotic sensitivity of *E. coli* isolates was reported in a recent study from another country (70% towards Nitrofurantoin and 10% towards ciprofloxacin) highlighting the rising resistance towards fluoroquinolones.[15] Moreover, one-fifth empirical prescriptions of Levofloxacin were later changed to nitrofurantoin once the antibiotic susceptibility results were available whereas only two prescriptions of nitrofurantoin (9.5%) were modified. The latest 2019 ICMR guidelines have also modified the first line empirical therapy for UTI to fosfomycin and nitrofurantoin in compliance with the change in sensitivity pattern of the isolates.[16]

This study showed that 50% of the total study population was wrongly managed, 26% patients were over treated, and 14.8% of the total patients were treated with resistant antibiotics. Both of these proportions were high compared to previous literature (14.3% over treated and 8.7% treated with resistant drugs).[7] One-third of the over treated patients (33.3%) had 6-15 pus cells per high power field (HPF) making 6-15 pus cells/HPF a less conclusive result category for making a decision about empirical antibiotic initiation.

When both choice of antibiotic and duration of treatment of empirical therapy were compared to the 2017 ICMR guidelines,[10] only 25.37% prescriptions were found compliant. A similar prescription audit conducted in UK showed an initial compliance of 75% with the local policy, which was successfully raised to 100% after an intervening teaching session of medical staff, widespread awareness via means of posters and active checking by pharmacists.[17] The data shows that antibiotic stewardship programs, group teaching sessions and awareness of the medical fraternity regarding the changing antibiotic sensitivity trends is essential to curb the threat of emerging antimicrobial resistance among pathogenic bacteria.

This study will help primary care physicians to choose the most appropriate empirical therapy matched with the local antibiotic sensitivity pattern and provide rapid and efficacious symptomatic relief from UTI complaints for the patients, simultaneously decreasing emergence of antimicrobial resistance in the community. These types of studies conducted in the future can help guide the policy makers to formulate the most suitable guidelines for UTI treatment.

Conclusion

This study shows low guideline compliance and reduced sensitivity of common UTI causing pathogens towards both the commonly prescribed antibiotics and the two out of three antibiotics that were the recommended first line agents to be used empirically for acute uncomplicated UTI as per ICMR 2017 guidelines (ciprofloxacin and co-trimoxazole).[10] The results have favored and supported the change of first line antimicrobials to nitrofurantoin and fosfomycin in the latest 2019 ICMR guidelines which were introduced after the study was performed.[16] Nitrofurantoin has proved to be an efficacious antibiotic both in terms of high sensitivity for *E. coli* and faster symptomatic relief. The study highlights the need of setting up antibiotic stewardship teams in hospitals and active checks via periodic prescription audits, surveillance of the changing sensitivity patterns of pathogens towards commonly used antibiotics and spreading awareness among physicians about the latest guidelines for treatment. Drawbacks of the project were short duration of study and small sample size.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

Financial support and sponsorship

Indian council of medical research –short term studentship (ICMR- STS)-2019 project.

Conflicts of interest

There are no conflicts of interest.

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