Antibiotic Use Evaluation in Genitourinary Tract Infections in Female Patients at a Tertiary Care Hospital

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ABSTRACT

BACKGROUND

Genitourinary tract infections are some of the most common infections in females. These problems are a challenge in terms of diagnosis and treatment. The present study was conducted to evaluate the prescribing pattern in three of the most common types of female genitourinary tract infections.

METHODS

A prospective and observational study was conducted on genitourinary tract infections in female patients at the gynaecology outpatient department in a tertiary care university hospital.

RESULTS

Majority of the infected female patients were in 26 - 35 years age group (31.8%) followed by 36 - 45 years age group (25.9%). The common infection noticed was urinary tract infection (42.2%), followed by pelvic inflammatory disease (32.2%) and vaginitis (25.5%) in infected female patients. The types of antibiotics prescribed for urinary tract infection were aminoglycosides, fluoroquinolones, cephalosporins and penicillins. The commonly prescribed antibiotics for pelvic inflammatory disease were tetracyclines, azoles, fluoroquinolones and cephalosporins, and for vaginitis azoles and aminoglycosides. The most commonly prescribed class of antibiotics for urinary tract infection, pelvic inflammatory disease and vaginitis were fluoroquinolones (11.8%), azoles (11.8%) and aminoglycosides (15.7%), respectively. Oral route was the preferred mode of administration (71%), followed by rectal (suppositories, 17.2%) and topical (cream, 11.8%).

CONCLUSIONS

Young married women in this urban Indian community have a high prevalence of genitourinary tract infections but seldom seek treatment. Education and outreach are needed to reduce the stigma, embarrassment and lack of knowledge related to genitourinary tract infections.

KEY WORDS

Drug Utilization Pattern, Prescribing Pattern, Genitourinary Tract Infection, Antibiotic Therapy, Feedback

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BACKGROUND

Genitourinary tract infections are divided into urinary tract infections (upper and lower) including cystitis, pyelonephritis and prostatitis; and sexually transmitted infections (STIs) such as gonorrhoea, chlamydia, syphilis, vaginitis, genital herpes, genital warts, pelvic inflammatory disease, chancroid, hepatitis B and human immunodeficiency virus infection.[1] Diseases of the genitourinary tract are a usual cause of morbidity in both the general residents and in patients with compromised immune complex. Genitourinary tract infections including STIs represent a major public health problem in many developing countries. Genital infections are uncommon in children and increase dramatically in sexually active adults in whom sexually transmitted diseases are the second most prevalent group of communicable illness in North America. The urinary tract and urine are normally sterile. Numerous mechanical and biologic processes ensure that microorganisms do not enter the urinary tract. Women are more susceptible to urinary tract infections because the female urethra is short and the area around the urethral opening is colonized with Staphylococcus saprophyticus (S. saprophyticus).[2] In addition, factors like dilatation of urethra, increased bladder volume and decreased bladder tone, along with decreased urethral tone which contributes to increased urinary stasis and uretero-vesical reflux, predispose women to urinary tract infection. Besides this, as many as 70% of women during pregnancy have presence of glucose in urine, which increases the chances of bacterial growth in the urine.[3]

Urinary tract infections are the second most common infection around the globe. Urinary tract infection is a significant public health problem in forms of morbidity and financial burden with an approximated 150 million cases yearly around the globe, costing the global economy in surplus of 6 billion US dollars.[4] An approximated 50% of women experience at least one episode of urinary tract infection at some point of their lifespan and between 20% and 40% of women can have recurrent event.[5,6] Urinary tract infection is one of the most frequent reasons for consulting general practitioners (GPs) in most of the developed countries. Urinary tract infections mainly affect women as compared to men. Kunin has stated that about 40-50% of adult women report that they had urinary tract infection at some time in their life.[7] One out of two suffer from urinary tract infections at least once in their life, 12% of women with an initial infection and 48% who already had recurrent urinary tract infections will have a further episode within 1 year. In India, there is no accurate incidence of urinary tract infections in women reported.[7] Majority of urinary tract infections are caused by E. coli bacteria, followed by Proteus species, Staphylococcus saprophyticus, Klebsiella species and other *Enterobacteriaceae*.[8]

Similarly, vaginal infections are the most common women's health problem, and have been increasingly linked to a growing array of serious health risks. Vaginal infections, known medically as vaginitis, are the most frequent reason for hospital visit.[9] Women of procreative age are most often affected by bacteria vaginitis.[10] Pelvic inflammatory disease is another genitourinary tract infection and a common cause of morbidity and accounts for 1 in 60 general practitioner consultations by women under the age of 45. Delays of only a few days in receiving appropriate treatment markedly increase the risk of infertility, ectopic pregnancy and chronic pelvic pain.[11]

Bacterial infections warrant antimicrobial therapy. Antibiotics commonly recommended for treatment of urinary tract infections include co-trimoxazole (trimethoprim/ sulfamethoxazole), nitrofurantoin, ciprofloxacin and ampicillin.[12] However, there is a growing concern about bacterial resistance. For a matter of fact many studies have reported increasing rates of resistance in bacteria to the commonly used antibiotics.[13,14,15] Scientific evidence suggests significant relationship between inappropriate use of antibiotics and antimicrobial resistance.[16] Inappropriate antibiotic prescription can lead to antibiotic resistance, increase the duration of hospitalization and mortality.[17,18] Furthermore, antibiotic misuse has led to increased adverse effects, drug resistance and the outburst of multidrug resistant (MDR) organisms.[19,20] In the modern era drug-resistant urinary tract infection has exploded into a major public health concern, each and every attempt must be made to avoid indiscriminate use" of antibiotic in order to prevent resistance. The curtailment of imprudent antibiotic use has been shown to effectively decrease resistance and avoid adverse effects.[21,22]

In majority of genitourinary tract infection cases, the treatment decision is empirical and the pattern of antibiotic resistance in a wide variety of pathogenic organisms may vary over short periods and depend on site of isolation and different environmental conditions.[23] In most of the developing countries including India, where is lacking of local epidemiology data, choice of antimicrobials is dependent upon clinical status and clinicians experience. In this scenario drug utilization evaluation (DUE), a recommendation by WHO, has a vital role to play. Drug utilization evaluation is a method to explore the drug administration problems and to observe if drugs are administrated appropriately.[24] It is a tool to detect the antibiotic utilization flaws and helps in optimization of antibiotic usage pattern that will result in reduction in antibiotic resistance, morbidity, mortality and cost of therapy.[25] Data on the prevalence and prescribing patterns among genitourinary tract infection in northern Indian women are scare. Therefore, this study was aimed to evaluate the prescribing pattern of female genitourinary tract infection and consequently guide the selection of empirical therapy.

METHODS

A prospective and observational drug utilization evaluation study of genitourinary tract infection among female patients at a gynaecology department in a tertiary care university hospital, Jamia Hamdard, New Delhi was conducted. The designed study includes the common genitourinary tract infections namely, urinary tract infections, vaginitis and pelvic inflammatory disease because of their increased prevalence in the world including India. The study was carried out during the time period of February to May, 2009.

Study was conducted on all 204 eligible genitourinary tract infection female patients at a tertiary care university hospital,

who had willingly participated for this study. Subjects were enrolled on the basis of inclusion and exclusion criteria.

Inclusion Criteria

- All genitourinary tract infections female patients visiting outpatient department of gynaecology department in a tertiary care university hospital.
- Female patients aged ≥6 years were included in this study.
- Pregnant and lactating patients were also included.

Exclusion Criteria

Patients suffering from sexually transmitted diseases such as gonorrhoea, chlamydia, syphilis, genital herpes, genital warts, chancroid, hepatitis B and HIV were excluded.

Sources of Data

- Physicians prescribing records.
- Patient's medication profile.
- Patient personal interaction.

Evaluation of Parameters

The following parameters were evaluated

- Frequency of the disease.
- Average age range of patients utilizing antibiotics.
- Types of antibiotics prescribed
- Most commonly used agents of a particular class.
- Comparison of antibiotics prescribing by generic vs. brand name
- Route of administration of drugs.
- Compliance or adherence (Using Weekly Diary Cards). A criterion for non-compliance is <80% of recommended intake of prescribed drugs.

Data Collection

The following data were collected based on the questionnaire

1. Patient profile (age, patient address, marital status, pregnancy status, education, work profile, menstruation cycle and hygiene measure).
2. Types of genitourinary tract infection
3. Drugs prescribed (Types of antibiotics, routes of administration, generic/brand name)

Interviews were conducted by using structured questionnaire (Open question method). Weekly diary cards for daily drug intake to monitor adherence to prescribed dosage regimen was used. The desired information was collected on a pre-designed proforma and transferred into Microsoft Excel sheet.

Ethical Issues

The clinical protocol entitled "drug utilization pattern and adverse drug reactions monitoring of genitourinary tract infection in female patients" was reviewed and approved by Institutional Review Board (IRB), Jamia Hamdard, New Delhi. Written consent was obtained from all the subjects participated in the study in the informed consent form. Written consent was obtained.

RESULTS

Age Distribution

A total of 204 female genitourinary tract infection was evaluated in this study. It was observed that maximum patients, 31.8% were in the age range of 26-35 years, followed by 25.9% patients who were in the age range of 36-45 years and minimum patients, 2.4% were in the age range of 6-15 years (Table 1).

Age (Yrs.)	No. of Patients	Percentage of Patients
6-15	05	2.4%
16-25	28	13.7%
26-35	65	31.8%
36-45	53	25.9%
46-55	32	15.6%
56-65	15	7.3%
66-75	06	2.9%
Total	**204**	**100%**

Table 1. Age Distribution among Female Patients with Genitourinary Tract Infections

Patients' Personal Details

Patients detailed information is provided in Table 2. From a pool of 2004 female genitourinary tract infection patients, a predominant proportion, 156(76.5%) were from rural area and remaining, 48(23.5%) were from urban area. Majority of the patients, 185 (90.7%) were married and 19 (9.3%) were unmarried. Out of married women 55 (29.7%) were pregnant and 130 (70.3%) were non-pregnant. Regarding education status of the study population almost 50% have no schooling at all, followed by less than high school, 22.5% and high school, 20.6% education. A predominant portion of the females were housewives, 72.1%, followed by employed, 19.6% and students, 8.3%. It was noted that out of total female patients, 116 (56.9%) women had regular menses every month whereas 88 (43.1%) women had irregular menses. Regarding hygiene 106 (52%) women used cloth or cotton during menstruation and 98 (48%) women used sanitary pads during menstruation.

Participants	204 Female Patients
Place of residence	Rural Area 156(76.5%) Urban Area 48(23.5%)
Marital status	Married 185 (90.7%) Unmarried 19 (9.3%)
Pregnancy status	Pregnant 55 (29.7%) Non-pregnant 130 (70.3%)
Education	No Schooling 91(44.6%) Less than high school 46(22.5%) High school 42(20.6%) Graduate 25(12.3%)
Work status	Employed 40(19.6%) Student 17(8.3%) Housewives 147(72.1%)
Menstruation cycle	Regular menses 116 (56.9%) Irregular menses 88 (43.1%)
Menstrual hygiene	Cloth or cotton 106 (52%) Sanitary pads 98 (48%)

Table 2. Personal Details of Patients

Prevalence of Genitourinary Tract Infections

Majority of infected female patients suffered from urinary tract infection (29.9% with first attack and 12.3 % with recurrent attacks), followed by pelvic inflammatory disease, 32.3% and vaginitis, 25.5% (Table 3).

Disease Type	No. of Patients	% of Patients
Urinary tract infection (First attack)	61	29.9%
Urinary tract infection (Recurrent attack)	25	12.3%
Pelvic inflammatory disease	66	32.3%
Vaginitis	52	25.5%
Total	**204**	**100%**

Table 3. Prevalence of Genitourinary Tract Infections among Study Patients

Types of Antibiotics Prescribed

During the study period, a total of 408 antibiotics were prescribed to the patients (Table 4). The average number of antibiotics prescribed per prescription was found to be 2. For urinary tract infection ciprofloxacin (n=36, 8.8%) was the most frequently prescribed antibiotic, closely followed by amikacin (n=32, 7.8%). For pelvic inflammatory disease metronidazole (n=48, 11.8%) was the most frequently prescribed antibiotic, followed by ofloxacin (n=24, 5.9%) and cefotetan (n=20, 4.9%). For vaginitis clindamycin (n=64, 15.7%) was the most frequently prescribed antibiotic, followed by metronidazole and clotrimazole (n=16, 3.9% each). The most commonly prescribed class of antibiotics for urinary tract infection, pelvic inflammatory disease and vaginitis were fluoroquinolones (n=50, 12.3%), azoles (n=48, 11.8%) and aminoglycosides (n=64, 15.7%), respectively. Oral routes were the preferred mode of administration (71%), followed by rectal (suppositories, 17.2%) and topical (cream, 11.8%).

Class	Drugs	No. of Prescriptions	%
Aminoglycoside	Amikacin	16	7.8
	Gentamicin	8	4
	Total	24	11.8
Cephalosporin	Cephalexin	9	4.4
	Cefadroxil	9	4.4
	Cefuroxime	6	3
	Total	24	11.8
Fluoroquinolones	Ciprofloxacin	18	8.8
	Norfloxacin	7	3.4
	Total	25	12.2
Penicillin	Amoxicillin+	3	1.5
	Clavulanic acid	10	5
	Total	13	15.1
Antibiotics Prescribed for pelvic Inflammatory Disease			
Fluoroquinolones	Ofloxacin	12	5.9
	Ciprofloxacin	6	2.9
	Total	18	8.8
Cephalosporins	Cefotetan	10	5
	Ceftriaxone	8	4
	Total	18	9
Tetracyclines	Doxycycline	6	2.9
	Total	6	2.9
Azoles	Metronidazole	24	11.8
	Total	24	11.8
Antibiotics Prescribed for Vaginitis			
Aminoglycoside	Clindamycin	32	15.7
	Total	32	15.7
Azoles	Metronidazole	8	4
	Clotrimazole	8	4
	Fluconazole	2	1
	Miconazole	2	1
	Total	20	10

Table 4. Types of Antibiotics Prescribed

Routes of Administration

Majority of the antibiotics were prescribed by oral route, 71%, followed by rectal (suppositories), 17.2% (Table 5).

Route of Administration	No. of Antibiotics	% of Antibiotics
Oral (Tablets)	145	71
Topical (Creams)	24	11.8
Rectal (Suppositories)	35	17.2
Total	**204**	**100**

Table 5. Route of Administration

Generic vs Branded

All the antibiotics were prescribed by their brand names only.

Patients' Adherence

Weekly diary cards were used for daily drug intake to monitor adherence to the prescribed dosage regimen. Criteria for non-compliance were <80% of recommended intake of prescribed drugs. Majority of the patients, 67.6% showed good compliance with the therapy (Table 6).

Patients Adherence	No. of Patients	% of Patients
< 80% (Poor compliance)	66	32.4
≥ 80% (Good compliance)	138	67.6

Table 6. Patients' Adherence to Treatment

DISCUSSION

In general practice, the therapeutic approach for genitourinary tract infections is nearly empirical and the main aim of the physicians is to treat specifically as possible, while covering the most likely pathogens. This clinical study i.e. prescribing pattern of genitourinary tract infection in female patients was carried out for the first time at a gynaecology department in a tertiary care university hospital in northern India. In our study, 204 female patients, on the basis of inclusion and exclusion criteria, were recruited. Demographic characteristics showed that majority of the infected female patients were in the age group between 26-35 years, followed by 36-45 years, which indicates that genitourinary tract infections infection is more prevalent in young married females. A rural-area-based study reported maximum prevalence of reproductive tract infection in the 25-29 years age group, followed by 40-44 years.[26] The authors further reported that the prevalence of reproductive tract infection was significantly higher in women belonging to joint families as compared to prevalence in women belonging to nuclear families. Study conducted by Guay also reported that adult women across age spectrum 15-39 years were most frequently infected with urinary tract infection.[27]

Majority of the infected patients lived in rural area. A predominant percentage of patients were married. Among the married female patients, 29.7% pregnant women suffered from infection. Most of the infected patients never attended school and approximately two-third were housewives. Pant et al reported similar findings in their study.[26] The authors also reported that one-third of the study population was married before the age of 18 years. Almost similar findings were documented by Dimetry et al., in their study.[28] They observed that women aged being 30 years, married, illiterates and having low education level, low socio-economic level and those with unsatisfactory personal hygiene and using underwear clothes other than cotton were most infected. This reflects that lack of education, awareness among uneducated women is the main cause of increased prevalence of infection.

It was noted that out of total patients, 56.9% women had regular menses every month whereas 43.1% women had irregular menses. More than half women used cloth or cotton during menstruation and remaining patients used sanitary pads during menstruation. Pant et al., reported significantly

higher prevalence of reproductive tract infection among women who used unworked clothes during menstruation as compared to women who used either washed clothes or sanitary pads.[26] A study conducted at Mother and Child Health and Family Planning center in Turkey suggested inadequate hygiene practices as the most significant reason for genitourinary infections among women.[29] This reflects that hygiene plays an important role in combating infections. In India, there is an effort to extend reproductive tract infections treatment services through the formal healthcare system to women seeking family planning and other reproductive health services.[30] Urinary tract infections were the predominant disease among the genitourinary tract infection. Out of that 29.9% had first attack of urinary tract infection and 12.3% had recurrent attack. Pelvic inflammatory disease was second common type of infection seen in female patients, followed by vaginitis. Rathore et al., 2007 reported similar findings.[31] They further reported that at least one symptom related to reproductive tract infections were found in 55% women. Out of 263 cases, 43% had cervicitis, 26% had bacterial vaginitis, 14% had fungal infection, 8% had trichomonas vaginitis, 22% had pelvic inflammatory disease and 19% had cervical erosion.

Patients suffering from various genitourinary tract infections were treated by using antibiotics. For urinary tract infection ciprofloxacin and amikacin was the most frequently prescribed antibiotics. Study conducted by Pandy et al., reported ceftriaxone as the most common antibiotic prescribed and amikacin as the most sensitive antibiotic.[32] For pelvic inflammatory disease metronidazole, ofloxacin and cefotetan was the most frequently prescribed antibiotics. A cross-sectional study conducted at Gynaecology & Obstetrics department in a rural hospital of eastern India documented oral doxycycline in combination with metronidazole as the most prescribed therapy, followed by ofloxacin.[33] Another study reported intravenous ofloxacin twice daily followed by an oral regimen of 10-14 days has been reported to provide almost cent percent cure from both chlamydia and gonococcal pelvic inflammatory disease.[34] For vaginitis clindamycin was the most frequently prescribed antibiotic, followed by metronidazole and clotrimazole. In a review conducted by Okun et al., reported in their findings that for women with trichomonas vaginalis, metronidazole reduced the risk of persistent infection but increased the incidence of preterm birth.[35]

The most commonly used class of antibiotic for urinary tract infection were fluoroquinolones (ciprofloxacin), for pelvic inflammatory disease, azoles (metronidazole) and for vaginitis, aminoglycosides (clindamycin). There is slight difference in selection of antibiotics as compared to reported studies this may be because of choice of antibiotics is dependent on patient condition as well as local situation with regard to antibiotic resistance of the pathogenic bacteria.[36] In our study, most antibiotics were prescribed by oral route, followed by antibiotics given for vaginitis in form of creams (topical) and suppositories. It indicates that in case of vaginitis, vaginal creams and suppositories are more efficient. All the antibiotics were prescribed by their brand names only. A study reported findings with almost 90% drugs were prescribed by their respective brand name.[37] However a recent retrospective, record-based study recorded a contradictory finding with 98.1% drugs prescribed in generic form in a tertiary care hospital in inpatients with urinary tract infection.[38] Prescribing by generic name needs to be promoted in our hospital to curb drug duplication, medication error and adverse effects due to medication therapy. Almost two-third of patients showed good adherence with the prescribed treatment. Adherence was found to be slightly better in educated than in uneducated females; it signifies the importance of education in adherence with the therapy. To reduce medication cost and to control the prevalence of antibiotic-resistant bacteria in the community, there is no doubt that physicians must optimize the use of antibiotics. Furthermore, pharmacists can play a pivotal role in order to reach this objective.[39] Limitations of this study were short duration and involved those female patients only who attended the outpatient department. In order to validate these results the time duration and sample size of the study has to be increased and the population should include women from the large community.

CONCLUSIONS

Young married women in this rural Indian community have a high prevalence of genitourinary tract infections but seldom seek treatment. Education and outreach are needed to reduce the stigma, embarrassment and lack of knowledge related to genitourinary tract infections. The most commonly used class of antibiotics for urinary tract infection were fluoroquinolones, 11.8%, for pelvic inflammatory disease azoles, 11.8%, and for vaginitis aminoglycosides, 15.7%. There is a pressing need to prescribe by generic name and also to prescribe from essential drug list should be emphasised upon.

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