A PROSPECTIVE OBSERVATIONAL STUDY TO EVALUATE THE PRESCRIPTION PATTERN OF PIPERACILLIN/ TAZOBACTAM IN UTI AND IT’S RECURRENCE RATE IN PATIENTS WITH OR WITHOUT DIABETES MELLITUS

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ABSTRACT
Background: Many antibiotics have been developed for UTI but showed resistance and recurrence rate, here we looks for the prescription pattern of Piperacillin Tazobactam. Objective: To evaluate the prescription pattern of piperacillin/ tazobactam in uti and its recurrence rate in patients with or without diabetes mellitus. Design, setting and participants: 60 patients having UTI with Piperacillin Tazobactam were identified and followed for two months and a total of 6 month study. Outcome measurement and statistical analysis: Relationship with outcome analysed using simple statistical method. Results and Limitations: This was a short term study. We identified that most of the patients were postmenopausal women and most PI were empirical therapy and DM is the major cause of recurrence, 18%were the recurrence rate. AKI and sepsis were the most common complications. Quality of life were improved (Since P value is less than 0.01, it is highly significant at 1% level of significance.). Conclusion: DM patients is having higher rate of recurrence. This study also suggests that educational interventions regarding strict control and monitoring of the chronic disease condition help in avoiding recurrence of UTIs. Patient summary: The behaviour of UTI varies considerably. In this paper we look into different recurrence rate in patients.

KEYWORDS: UTI, Prescription, Piperacillin/Tazobactam, Recurrence.

1. INTRODUCTION
1.1 URINARY TRACT INFECTION
A Urinary Tract Infection is defined as the presence of microorganisms in urine that cannot be accounted for by contamination. The organisms have the potential to invade the tissues of urinary tract and adjacent tissues. They usually occur in the bladder or urethra, but more serious infections involve the kidney. UTI are one of the most common bacterial infections in the general population, with an estimated overall incidence rate of 18 per 1000 person per year.[1]

In addition, UTIs are a major cause of hospital admissions and are associated with significant morbidity and mortality as well as a high economic burden. A complicated UTI (cUTI) is an infection associated with structural or functional abnormalities of the genitourinary tract or the presence of an underlying disease, which increases the risks of acquiring an infection or of failing therapy. The microbiology of cUTIs is characterized by a greater variety of organisms and an increase therapy. The microbiology of cUTIs is characterized by a greater variety of organisms and an increased require more diagnostic testing, broad-spectrum empiric antimicrobial therapy, and a longer duration of treatment.[2]

The management of a patient with a UTI includes initial evaluation, selection of an antibacterial agent and duration of therapy, and follow-up evaluation. The initial selection of an antimicrobial agent for the treatment of UTI is based primarily on the severity of the presenting signs and symptoms, the site of infection, and whether the infection is determined to be uncomplicated or complicated. Other considerations include antibiotic susceptibility, side-effect potential, cost, and the comparative inconvenience of different therapies.[1]

Classification of Urinary Tract Infection

- Based on anatomical site
  - Upper UTI: Pyelonephritis-acute and chronic
  - Lower UTI: Cystitis
Urethritis
Prostatitis
Epididymitis

✓ Based on complication
Complicated
Uncomplicated

✓ Based on infection occurring
Primary
Recurrent

✓ Based on symptom
Symptomatic
Asymptomatic

1.1.1 EPIDEMIOLOGY
The prevalence of UTIs varies with age and gender. In new-borns and infants up to 6 months of age, the prevalence of abacteriuria is approximately 1% and is more common in boys. Most of these infections are associated with structural or functional abnormalities of the urinary tract and also have been correlated with noncircumcision. Between the ages of 1 and 6 years, UTIs occur more frequently in females. The prevalence of abacteriuria in females and male of this age group is 7% and 2%, respectively. Infections occurring in preschool boys usually are associated with congenital abnormalities of the urinary tract. These infections are difficult to recognize because of the age of the patient, but they often are symptomatic. In addition, the majority of renal damage associated with UTI develops at this age. In the elderly, the ratio of bacteriuria in women and men is dramatically altered and is approximately equal in persons older than age 65 years. The overall incidence of UTI increases substantially in this population, with the majority of infections being asymptomatic.

ETIOLOGY
- Bacteria
  Complicated
  E.coli
  Klebsiella. pneumoniae
  Pseudomonas aeroginosa
  Enterobacter.spp
  Uncomplicated
  E.coli
  Klebsiella. pneumoniae
  Pseudomonas aeroginosa
  Enterococcus.spp
- Fungi
  Candida albicans
  Cryptococcus.neoformans
  Aspergillus species
- Virus
  Adenovirus
  Polyomaviruses

Risk factors of UTI

Through grade school and before puberty, the prevalence of UTI is approximately 1%, with 5% of females reported to have significant bacteriuria prior to leaving high school. This percentage increases dramatically to 1% to 4% after puberty in nonpregnant females primarily as a result of sexual activity. Approximately 1 in 5 women will suffer a symptomatic UTI at some point in their lives. Many women have recurrent infections, with a significant proportion of these women having a history of childhood infections. In contrast, the prevalence of bacteriuria in adult men is very low (<0.1%).

In the elderly, the ratio of bacteriuria in women and men is dramatically altered and is approximately equal in persons older than age 65 years. The overall incidence of UTI increases substantially in this population, with the majority of infections being asymptomatic.

PATHOPHYSIOLOGY
For infection to occur, bacteria must gain access to the bladder, attach to and colonize the epithelium of the urinary tract to avoid being washed out with voiding, evade host defence mechanisms, and initiate inflammation. Most UTIs result from faecal organisms that ascend from the perineum to the urethra and the bladder and then adhere to the mucosal surfaces.
Bacterial virulence factors play a significant role in determining whether an organism will invade the urinary tract and the level of infection acquired. Uropathogenic E. coli (UPEC) is present within bowel flora and pathogenic strains of this microorganism can infect the urinary tract by expressing specific virulence factors that permit adherence and colonisation of the lower urinary tract. Adherence of the micro-organism is dependent on 3 important environmental characteristics; firstly the bacteria’s own adhesive characteristics, secondly the receptive features of the urothelium and finally the fluid that is present between both surfaces. Bacteria will migrate proximally and precipitate a host derived inflammatory response after adhering to the mucosal surface.6

Bacterial Invasion of the Urinary Tract By increasing the normal slow shedding of bladder epithelial cells (resulting in bacteria removal), the bladder can clear itself of even large numbers of bacteria. Glycosaminoglycan (GAG), a hydrophilic protein, normally exerts a non-adherent protective effect against various bacteria. The GAG molecule attracts water molecules, forming water barrier that serves as defensive layer between the bladder and the urine. GAG may be impaired by certain agents (cyclamate, saccharin, aspartame, and tryptophan metabolites). The normal bacterial flora of the vagina and urethral area also interfere with adherence of Escherichia coli (the most common microorganisms causing UTI). Urinary immunoglobulin A (IgA) in the urethra may also provide a barrier to bacteria.

SIGNS AND SYMPTOMS
Lower urinary tract infection (infections of the bladder or urethra)
- Bladder (cystitis, or bladder infection): The lining of the urethra and bladder becomes inflamed and irritated.
- Dysuria: pain or burning during urination
- Frequency: more frequent urination (or waking up at night to urinate, sometimes referred to as nocturia); often with only a small amount of urine
- Urinary urgency: the sensation of having to urinate urgently
- Cloudy, bad-smelling, or bloody urine
- Lower abdominal pain or pelvic pressure or pain
- Mild fever (less than 101 F), chills, and “just not feeling well” (malaise)
- Urethra (urethritis): Burning with urination

Upper urinary tract infection (pyelonephritis, or kidney infection)
Symptoms develop rapidly and may or may not include the symptoms for a lower urinary tract infection.
- Fairly high fever (higher than 101 F).
- Shaking chills.
- Nausea.
- Vomiting.
- Flank pain: pain in the back or side, usually on only one side at about waist level.

In new-borns, infants, children, and elderly people, the classic symptoms of a urinary tract infection may not be present. Other symptoms may indicate a urinary tract infection.
- New-borns: fever or hypothermia (low temperature), poor feeding, jaundice.
- Infants: vomiting, diarrhoea, fever, poor feeding, not thriving.
- Children: irritability, eating poorly, unexplained fever that doesn’t go away, loss of bowel control, loose bowels, change in urination pattern.
- Elderly people: fever or hypothermia, poor appetite, lethargy, change in mental status.

Pregnant women are at increased risk for an UTI. Typically, pregnant women do not have unusual or unique symptoms. If a woman is pregnant, her urine should be checked during prenatal visits because an unrecognized infection can cause pregnancy health complications.

COMPLICATIONS
When treated promptly and properly, lower urinary tract infections rarely lead to complications. But left untreated, a urinary tract infection can have serious consequences.

Fig no.2: Pathophysiology of UTI.
Complications of a UTI may include
- Recurrent infections, especially in women who experience two or more UTIs in a six-month period or four or more within a year.
- Permanent kidney damage from an acute or chronic kidney infection (pyelonephritis) due to an untreated UTI.
- Increased risk in pregnant women of delivering low birth weight or premature infants.
- Urethral narrowing (stricture) in men from recurrent urethritis, previously seen with gonococcal urethritis.
- Sepsis, a potentially life-threatening complication of an infection, especially if the infection works its way up your urinary tract to your kidneys.

DIAGNOSIS
- Elderly women may present with only urinary incontinence and no other symptoms.
- Urine dipstick test showing positive nitrates or leukocyte esterase are suggestive of UTI, raising the pre-test probability by 25%.
  - Nitrite: positive due to bacterial reduction of endogenous nitrates to nitrates; classically positive in Gram-negative Enterobacteriaceae family of enteric uropathogens. However, nitrite dipstick may also be clinically useful in detecting Enterococcus and Staphylococcus bacteria.
  - Leukocyte esterase: positive as neutrophil granules contain enzymes with esterase activity; presence of neutrophils in urine due to inflammation and leukocyte migration into the urinary tract.
- Only a positive urine culture is considered truly diagnostic of a UTI, however, urine should only be cultured in the setting of clinical infection or infective symptoms; as previously mentioned, asymptomatic bacteriuria is common and does not require treatment.[9]
- Analysing a urine sample. A urine sample for lab analysis to look for white blood cells, red blood cells or bacteria. To avoid potential contamination of the sample, may be instructed to first wipe your genital area with an antiseptic pad and to collect the urine midstream.
- Growing urinary tract bacteria in a lab. Lab analysis of the urine is sometimes followed by a urine culture. This determines what bacteria are causing your infection and which medications will be most effective.
- Creating images of your urinary tract. If you are having frequent infections that your doctor thinks may be caused by an abnormality in your urinary tract, you may have an ultrasound, a computerized tomography (CT) scan or magnetic resonance imaging (MRI). Your doctor may also use a contrast dye to highlight structures in your urinary tract.

- Using a scope to see inside your bladder. If you have recurrent UTIs, your doctor may perform a cystoscopy, using a long, thin tube with a lens (cystoscope) to see inside your urethra and bladder. The cystoscope is inserted in your urethra and passed through to your bladder.

MANAGEMENT
- Prevention
  - Drink lot of water and urinate frequently
  - Avoid fluids such as alcohol and caffeine
  - Urinate shortly after sex
  - Wipe from front to back after urinating and bowel movement
  - Keep the Genital area clean
  - Avoid bubble bath
  - Wear cotton underwear and loose fitting clothing

- Treatment
  - Non pharmacological Treatment
    - Make Your Urine Acidic With Citrus Fruit. It is difficult for bacteria to thrive in an acidic environment. Citrus fruits contain high amounts of vitamin C, which increases the acidity of your urine, thus, inhibiting the growth of bacteria.
    - Flush Bacteria Out With Cranberry Juice. Cranberry contains a phytochemical known as tannin, which reduces vaginal colonization of E. coli.[8] It is high in vitamin C, and drinking its unsweetened juice flushes out bacteria from your urinary system and reduces recurrent UTIs.[7]
    - Gulp Down Garlic-Infused Water. Garlic is a potent remedy for urinary tract infections. It has antimicrobial, antioxidant, and anti-inflammatory properties and immune-modulatory effects that help in the treatment of cystitis.
    - Soothe Your Infection with Ginger Tea. Ginger has antimicrobial properties that work against a variety of bacterial strains. While chewing on a piece of ginger will also have positive effects, it’s best to consume it as a tea to treat your UTI.
    - Drink Apple Cider Vinegar on an Empty Stomach. Apple cider vinegar has antibacterial properties. It will kill bacteria present in your urinary system to rid you of infection. Mix 2 tablespoons of the vinegar to a glass of water and drink it in the morning on an empty stomach.
  - Use Cucumber Juice Daily.

Cucumber seeds have diuretic properties that will increase frequency of urination.[10]

Pharmacological
The goals of UTI treatments are (a) to eradicate the invading organism(s), (b) to prevent or to treat systemic consequences of infection, and (c) to prevent the recurrence.
Table 1: Commonly Used Antimicrobial Agents in the Treatment of Urinary Tract Infections.

<table>
<thead>
<tr>
<th>Agent</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Oral therapy</strong></td>
<td></td>
</tr>
<tr>
<td>Trimethoprim-sulfamethoxazole</td>
<td>This combination is highly effective against most aerobic enteric bacteria except <em>Pseudomonas aeruginosa</em>. High urinary tract tissue levels and urine levels are achieved, which may be important in complicated infection treatment. Also effective as prophylaxis for recurrent infections.</td>
</tr>
<tr>
<td>Penicillins</td>
<td></td>
</tr>
<tr>
<td>Ampicillin 500 mg</td>
<td>Ampicillin is the standard penicillin that has broad-spectrum activity. Increasing <em>Escherichia coli</em> resistance has limited amoxicillin use in acute cystitis. Drug of choice for enterococci sensitive to penicillin. Amoxicillin-clavulanate is preferred for resistance problems.</td>
</tr>
<tr>
<td>Amoxicillin-clavulanic acid 500mg q8h</td>
<td></td>
</tr>
<tr>
<td>Cephalosporins</td>
<td></td>
</tr>
<tr>
<td>Cephalexin 250-500mg q 12h</td>
<td>There are no major advantages of these agents over other agents in the treatment of UTIs, and they are more expensive. They may be useful in cases of resistance to amoxicillin and trimethoprim-sulfamethoxazole. These agents are not active against enterococci.</td>
</tr>
<tr>
<td>Cefadroxil 1-2g B.D.</td>
<td></td>
</tr>
<tr>
<td>Cefuroxime 125-250 mg q12h</td>
<td></td>
</tr>
<tr>
<td>Cefixime 200 mg B.D</td>
<td></td>
</tr>
<tr>
<td>Cefprozil 500 mg Q 8h</td>
<td></td>
</tr>
<tr>
<td>Cefpodoxime 100mg q 12h</td>
<td></td>
</tr>
<tr>
<td>Tetracyclines</td>
<td>These agents have been effective for initial episodes of urinary tract infections; however, resistance develops rapidly, and their use is limited. These agents also lead to candidal overgrowth. They are useful primarily for chlamydial infections.</td>
</tr>
<tr>
<td>Tetracycline 250-500m qg 6h</td>
<td></td>
</tr>
<tr>
<td>Doxycycline 100mg q 12h</td>
<td></td>
</tr>
<tr>
<td>Minocycline 200mg q 12h</td>
<td></td>
</tr>
<tr>
<td>Fluoroquinolones</td>
<td>The newer quinolones have a greater spectrum of activity, including <em>P. aeruginosa</em>. These agents are effective for pyelonephritis and prostatitis. Avoid in pregnancy and children. Moxifloxacin should not be used owing to inadequate urinary concentrations.</td>
</tr>
<tr>
<td>Ciprofloxacin 250- 500mg B.D.</td>
<td></td>
</tr>
<tr>
<td>Levofoxacin 250mg O.D.</td>
<td></td>
</tr>
<tr>
<td>Nitrofurantoin 100 mg B. D.</td>
<td>This agent is effective as both a therapeutic and prophylactic agent in patients with recurrent UTIs. Main advantage is the lack of resistance even after long courses of therapy. Adverse effects may limit use (GI intolerance, neuropathies, and pulmonary reactions).</td>
</tr>
<tr>
<td>Azithromycin 1g</td>
<td>Single-dose therapy for chlamydial infections.</td>
</tr>
<tr>
<td>Fosfomycin 3g</td>
<td>Single-dose therapy for uncomplicated infections.</td>
</tr>
<tr>
<td><strong>Parenteral therapy</strong></td>
<td></td>
</tr>
<tr>
<td>Aminoglycosides</td>
<td></td>
</tr>
<tr>
<td>Gentamicin 60-80mg q 8 h</td>
<td>Gentamicin and tobramycin are equally effective; gentamicin is less expensive. Tobramycin has better pseudomonal activity, which may be important in serious systemic infections. Amikacin generally is reserved for multiresistant bacteria.</td>
</tr>
<tr>
<td>Tobramycin 1.5mg/kg/dose</td>
<td></td>
</tr>
<tr>
<td>Amikacin5-7.5 mg/kg/dose q 8 h</td>
<td></td>
</tr>
<tr>
<td>Penicillins</td>
<td></td>
</tr>
<tr>
<td>Ampicillin 500 mg</td>
<td>These agents generally are equally effective for susceptible bacteria. The extended-spectrum penicillins are more active against <em>P. aeruginosa</em> and enterococci and often are preferred over cephalosporins. They are very useful in renally impaired patients or when an aminoglycoside is to be avoided.</td>
</tr>
<tr>
<td>Ampicillin-sulbactam 1-2g</td>
<td></td>
</tr>
<tr>
<td>Ticarcillin-clavulanate 1-4g</td>
<td></td>
</tr>
<tr>
<td>Piperacillin-tazobactam 4.5 g q8h</td>
<td></td>
</tr>
<tr>
<td>Cephalosporins, first-, second-, and third-generation 1-2g in B.D.</td>
<td></td>
</tr>
<tr>
<td>Carbapenems/Monobactams</td>
<td>Second- and third-generation cephalosporins have a broad spectrum of activity against gram-negative bacteria but are not active against enterococci and have limited activity against <em>P. aeruginosa</em>. Ceftazidime and cefepime are active against <em>P. aeruginosa</em>. They are useful for nosocomial infections and urosepsis due to susceptible pathogens.</td>
</tr>
<tr>
<td>Imipenem-cilastatin 250-500mg IVq 6 hr</td>
<td>These agents have a broad spectrum of activity, including gram-positive, gram-negative, and anaerobic bacteria.</td>
</tr>
<tr>
<td>Meropenem 500mg q 8 h</td>
<td>Imipenem, meropenem, and doripenem are active against <em>P. aeruginosa</em> and enterococci, but ertapenem is not. All may be associated with candidal superinfections.</td>
</tr>
<tr>
<td>Ertapenem 1g</td>
<td></td>
</tr>
<tr>
<td>Doripenem 500mg</td>
<td></td>
</tr>
<tr>
<td>Aztreonam 1-2g q8h 0r 12 h</td>
<td>A monobactam that is only active against gram-negative bacteria, including some strains of <em>P. aeruginosa</em>. Generally useful for nosocomial infections when aminoglycosides are to be avoided and in penicillin-sensitive patients.</td>
</tr>
<tr>
<td>Fluoroquinolones</td>
<td>These agents have broad-spectrum activity against both gram-negative and gram-positive bacteria. They provide urine and high-tissue concentrations and are actively secreted in reduced renal function</td>
</tr>
<tr>
<td>Ciprofloxacin 200-400mg q 12h</td>
<td></td>
</tr>
<tr>
<td>Levofoxacin 500mg</td>
<td></td>
</tr>
</tbody>
</table>
SPECIAL CONDITIONS

Pregnancy
In patients with bacteriuria, symptomatic or asymptomatic treatment is recommended to avoid possible complication during the pregnancy. The therapy should consist of an agent with a relatively low adverse effect potential administered for 7 days. The administration of amoxicillin, amoxicillin-clavulanate, or cephalexin, is effective in 70% to 80% of patients. Nitrofurantoin has been utilized in pregnancy, however must be used with caution as occurrences of birth defects have been reported.

Fluoroquinolones, Tetracyclines and Sulfonamides should be avoided during pregnancy.

Catheterised Patients
When bacteriuria occurs in asymptomatic, short term catheterized patient, the use of systematic antibiotic therapy should be withheld and the catheter removed as soon as possible. If the patient becomes symptomatic, the catheter should again be removed, and treatment as described for complicated infections should be started.

The use of prophylactic systemic antibiotics in patients with short-term catheterization reduces the incidence of infection over the first 4 to 7 days. In long-term catheterized patients, however, antibiotics only postpone the development of bacteriuria and lead to the emergence of resistant organisms.[11,12]

PIPERACILLIN TAZOBACTAM
Piperacillin Tazobactum is a injectable antibacterial combination products consisting of the semi synthetic antibacterial piperacillin sodium and the β-lactamase inhibitor tazobactam sodium for intravenous administration.

Fig No. 3: Treatment algorithm for UTI.

Fig No. 4: Structure of P/T.

CATEGORY: Extended spectrum Penicillin Antibiotic.
CLASS: β Lactum Antibiotics
MECHANISM: Piperacillin kills bacteria by inhibiting the synthesis of bacterial cell wall. It binds preferentially
to specific penicillin-binding proteins (PBPs) located inside bacterial cell walls. Piperacillin is an extended-spectrum penicillin antibiotic, but it can be destroyed by an enzyme produced by bacteria called beta lactamase. Tazobactam inhibits beta lactamase and prevents the destruction of piperacillin.

INDICATION
- Complicated and uncomplicated skin and skin structure infections (e.g., cellulitis, skin abscesses, ischemic diabetic foot ulcer)
- Urinary tract infections
- Pneumonia
- Intra-abdominal infections, including peritonitis, appendicitis
- For surgical infection prophylaxis† for patients undergoing liver transplantation
- Cystic fibrosis
- Bacteremia and Septicemia

DOSE: Adult dose – 4.5 g IV every 6 hour, 8 hours, 12 hour
- 2.25g IV in 8 hours, 12 hours
- Pediatric dose- 80 mg/kg IV every 8 hours

ADR
More common
- Diarrhoea

Less common
- Bladder pain
- Bloating or swelling of the face, arms, hands, lower legs, or feet
- Blurred vision
- Changes in urination
- Chest pain
- Confusion
- Dizziness, faintness, or lightheadedness when getting up suddenly from a lying or sitting position
- Sweating
- Headache
- Inflammation or swelling at the injection site
- Lower back or side pain
- Nausea or vomiting
- Pain, tenderness, or swelling of the foot or leg
- Pain, warmth, or burning in the fingers, toes, and legs
- Problems with vision or hearing
- Skin Rash

UTI WITH DIABETES MELLITUS
Type 2 diabetes mellitus is a heterogeneous group of disorders characterized by variable degrees of insulin resistance, impaired insulin secretion, and increased glucose production. Patients with type 2 diabetes mellitus are at increased risk of infections, with the urinary tract being the most frequent infection site and the reason for recurrence. Factors that were found to enhance the risk for UTI in diabetics include age, metabolic control, and long term complications, primarily diabetic nephropathy and cystopathy. All types of UTI are more frequent in patients with type 2 DM. Multiple potential mechanisms unique to diabetes may contribute to the increased risk of UTI in diabetic patients. Higher glucose concentrations in urine may promote the growth of pathogenic bacteria. High renal parenchymal glucose levels create a favourable environment for the growth and multiplication of microorganisms, which might be one of the precipitating factors of pyelonephritis and renal complications such as emphysematous pyelonephritis. Treatment of UTI in patients with type 2 diabetes depends on several factors, including: presence of symptoms, if infection is localized in the bladder (lower UTI) or also involves the kidney (upper UTI), presence of urologic abnormalities, severity of systemic symptoms, accompanying metabolic alterations, and renal function. As a general rule, treatment of UTI in diabetic patients is similar to that of UTI in non-diabetic patients. Antibiotic choice should also be guided by local susceptibility patterns of uropathogens. Treatment should also involve correction of metabolic complications caused by the infectious process.
### Table 2: First-line antibiotic treatment of urinary tract infection in patients with type 2 diabetes mellitus

<table>
<thead>
<tr>
<th>Type of urinary tract infection (UTI)</th>
<th>Sex</th>
<th>Antibiotic treatment</th>
<th>Route</th>
<th>Dosage</th>
<th>Duration of treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asymptomatic bacteriuria</td>
<td>Men and women</td>
<td>None</td>
<td>PO</td>
<td>100 mg x 2-3/d</td>
<td>5 days</td>
</tr>
<tr>
<td>Acute cystitis</td>
<td>Women</td>
<td>Nitrofurantoin</td>
<td>PO</td>
<td>3 g</td>
<td>Single dose</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Foxfomycin</td>
<td>PO</td>
<td>960 mg x 2/d</td>
<td>3 days</td>
</tr>
<tr>
<td>Complicated lower UTI (including catheter-associated UTI)</td>
<td>Men and women</td>
<td>Ciprofloxacin</td>
<td>PO</td>
<td>250-500 mg x 2/4</td>
<td>7-14 days</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Ofloxacin</td>
<td>PO</td>
<td>300 mg x 2/d</td>
<td>7-14 days</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TMP-SMX</td>
<td>PO</td>
<td>960 mg x 2/d</td>
<td>7-14 days</td>
</tr>
<tr>
<td>Uncomplicated pyelonephritis</td>
<td>Women</td>
<td>Ciprofloxacin</td>
<td>IV</td>
<td>400 mg x 2/d</td>
<td>7 days</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Ofloxacin</td>
<td>PO</td>
<td>500 mg x 2/d</td>
<td>7 days</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Gentamicin</td>
<td>IV</td>
<td>5 mg/kg x 1/d</td>
<td>7 days</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Cefuroxime</td>
<td>IV</td>
<td>75 mg x 2/d</td>
<td>10-14 days</td>
</tr>
<tr>
<td>Complicated pyelonephritis/urosepsis</td>
<td>Men and women</td>
<td>Ciprofloxacin</td>
<td>IV</td>
<td>400 mg x 2/d</td>
<td>10-14 days</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Ofloxacin</td>
<td>IV</td>
<td>400 mg x 2/d</td>
<td>10-14 days</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Gentamicin</td>
<td>IV</td>
<td>5 mg/kg x 1/d</td>
<td>10-14 days</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Amikacin</td>
<td>IV</td>
<td>15 mg/kg x 1/d</td>
<td>10-14 days</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Piperacillin-tazobactam</td>
<td>IV</td>
<td>4.5 g x 3/d</td>
<td>10-14 days</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Ertapenem</td>
<td>IV</td>
<td>1 g x 1/d</td>
<td>10-14 days</td>
</tr>
</tbody>
</table>

**RECURRANCE**

While most UTI respond readily to treatment, some are followed by recurrences. These may take two forms:
- Re-infection
- Relapse

**Re-infections**

Recurrent episodes of UTI account for a significant portion of all UTIs. Of the patients suffering from recurrent infections, 80% can be considered reinfections, that is, the recurrence of infection by an organism different from the organism isolated from the preceding infection. These patients most commonly are female, and recurrence develops in approximately 20% of females with cystitis. Reinfections can be divided into two groups: those with less than three episodes per year and those who develop more frequent infection. In patients with more frequent symptomatic infections and no apparent precipitating event, long-term prophylactic antimicrobial therapy may be instituted. Prophylactic therapy reduces the frequency of symptomatic infections in elderly men, women, and children.

TMP-SMX (one-half of a single-strength tablet), trimethoprim (100 mg daily), a fluoroquinolone (levofloxacin 500 mg daily) and nitrofurantoin (50 or 100 mg daily) all reduce the rate of reinfection as single-agent therapy. Full-dose therapy with these agents is unnecessary, and single daily doses can be used. Therapy generally is prescribed for a period of 6 months, during which time urine cultures are followed monthly. If symptomatic episodes develop, the patient should receive a full course of therapy with an effective agent and should be restarted on prophylactic therapy.

**Relapses**

The remaining 20% of recurrent UTIs are relapses, that is, persistence of infection with the same organism after therapy for an isolated UTI. The recurrence of symptomatic or asymptomatic bacteriuria after therapy usually indicates that the patient has renal involvement, a structural abnormality of the urinary tract, or chronic bacterial prostatitis. In the absence of structural abnormalities, relapse often is related to renal infection and requires a long duration of treatment. Women who relapse after short-course therapy should receive a 2-week course of therapy. In patients who relapse after 2 weeks of therapy, therapy should be continued for another 2 to 4 weeks. If relapse occurs after 6 weeks of therapy, urologic evaluation should be performed, and any obstructive lesion should be corrected. If this is not possible, therapy for 6 months or longer may be considered. Asymptomatic adults who have no evidence of urinary obstruction should not receive long-term therapy.

In males, relapse usually indicates bacterial prostatitis, the most common cause of persistent bacteriuria. Although many agents have been used for long-term therapy of relapses, TMP-SMX and the fluoroquinolones appear to be highly effective. [21]

**PRESCRIBING PATTERN**

Prescription pattern monitoring studies (PPMS) are drug utilization studies with the main focus on prescribing, dispensing and administering of drugs. They promote appropriate use of monitored drugs and reduction of abuse or misuse of monitored drugs. PPMS also guide and support prescribers, dispensers and the general
public on appropriate use of drugs, collaborate and develop working relationship with other key organizations to achieve a rational use of drugs. Prescription Patterns explain the extent and profile of drug use, trends, quality of drugs, and compliance with regional, state or national guidelines like standard treatment guidelines, usage of drugs from essential medicine list and use of generic drugs. There is increasing importance of PPMS because of a boost in marketing of new drugs, variations in pattern of prescribing and consumption of drugs, growing concern about delayed adverse effects, cost of drugs and volume of prescription.[29]

The aim of PPMS is to facilitate the rational use of drugs in a population. Irrational use of medicines is a major problem worldwide. WHO estimates that more than half of all medicines are prescribed, dispensed or sold inappropriately, and that half of all patients fail to take them correctly. The overuse, underuse or misuse of medicines results in wastage of scarce resources and widespread health hazards. The rational use of medicines (RUM) is defined as “Patients receive medications appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and their community.”[10] This is all monitored by WHO core indicators.

QUALITY OF LIFE

‘Quality of life’ is an abstract and highly subjective concept influenced by personal and cultural values, beliefs, self-concepts, goals, age and life expectancy. Similarly, it is affected by a broad spectrum of human experiences, including diseases, accidents, treatments, interpersonal relationships and social support. It is usually measured using structured questionnaires which can be completed by the patient or the bystander. They contain a variable number of sections (or domains), which gather information focused on particular aspects of health. These usually include physical function, emotional function, social function, role performance, pain, sleep and disease-specific symptoms.[31]

Patients with symptoms of urinary incontinence have negative impact in their quality of life. Health problems, bad sleep, economic impair, sexual dysfunction, interpersonal uncomfortable relationships, decreased self-confidence are causes to social exclusion and psychological problems of these patients. The treatment of urinary incontinence pursues not just the disease objective cure but also the improvement in patients’ quality of life. The King’s Health Questionnaire is used for rapid assessment of urinary incontinence.

KHQ is a patient self-administered self-report and has 3 parts consisting of 21 items. Part 1 contains general health perception and incontinence impact (one item each). Part 2 contains role limitations, physical limitations, social limitations (two items each), personal relationships, emotions (three items each) and sleep/energy (two items), severity measures (four items). Part 3 is considered as a single item and contains ten responses in relation to frequency, nocturia, urgency, urge, stress, intercourse incontinence, nocturnal enuresis, infections, pain, and difficulty in voiding. The responses in KHQ have four point rating system. The eight subscales (“domains”) scored between 0 (best) and 100 (worst). The Symptom Severity scale is scored from 0 (best) to 30 (worst). Decreases in KHQ domain scores indicate an improvement in quality of life. The minimally important difference - the smallest change in score that subjects perceive as beneficial is 3 points for the symptom severity scale and 5 points for all other KHQ domains. It is interesting to note that lower scores indicate patient wellbeing and higher scores mean that the person is severely affected by the disease condition.[12]

2. REVIEW OF LITERATURE

1. Ehsan Elahi, et al., (2017): Conducted a study on ‘Drug Utilization Review of Piperacillin/Tazobactam in a Tertiary Care Hospital’.[33] This study was conducted to estimate the rationality of Piperacillin/Tazobactam utilization in hospital. A cross sectional retrospective study was conducted in a tertiary reference centre with 76 prescriptions were analyzed and reviewed. This cross sectional, retrospective study was aimed to involve all those patients who were admitted to a tertiary care hospital Pakistan, and were prescribed Piperacillin/Tazobactam as an empiric therapy over a period of three months. The medical records for those patients were retrospectively reviewed and analysed. The result of the study was 66.66% of prescriptions follow as per dosing criteria and indications and 33.33% prescriptions were irrational.

2. Panayappan. L, et al., (2017): Conducted a study on the topic ‘Urinary Tract Infection: Prescribing Pattern Of Antibiotics At A Tertiary Care Hospital.’[34] A prospective observational study was carried out in 100 patients by collecting data from medical records of patients and the prescriptions were analyzed. Result of the study was Cephalosporin (35%), Aminoglycosides (22%) and Quinolones were the most commonly prescribed antibiotics in the study and suggests the need for monitoring antibiotic sensitivity pattern. The most common isolated organisms were Escherichia coli (60%), Proteus (20%), Klebsiella (13.33%), and Pseudomonas (6.66%).

3. Ramanath Katta Venkatesh et al (2016) conducted a study on “Urinary Tract Infection Treatment Pattern of Elderly Patients in a Setup in South India: A Tertiary Hospital Prospective Study”[35] the main objective of this study was to analyze the incidence, causative organisms, types of antibiotics used, drug interactions, the antibiotic cost, and its
outcome. This is a cross-sectional study conducted in selected medicine units over a period of 18 months. The enrolled patient’s therapy pattern spotted from the admission to discharge. The mandatory patients provided with pharmaceutical care services. The result of the study was Among 475 observed cases, 106 patients had UTIs (22.31%). The mean number of drug were 7.42 ±2.31 per prescription. Out of 106 prescriptions, 65 prescriptions had drug interactions. The antibiotic cost of the management ranged from $ 0.21-160.8 with a median of $ 26.30 and the common organisms were E. coli (48%), Enterococcus (16%).

4. Dinesh. K. Dhodi, et al., (2014): Conducted a study on ‘A Study to Evaluate Prescribing Pattern of Antibiotics among Patients of UTI with Pre-existing Renal Disorders.’[36] The objective was to determine the incidence, culture-sensitivity status, prescription pattern of antibiotics and response to various antibiotics and other therapeutic considerations in patients of complicated UTI (cUTI). An observational prospective analytical study conducted in 200 UTI patients of which 119 patients were female (60%) & 81 patients were male (41%). The result of the study was Symptomatically, fever was the most common symptom. Among male, diabetes mellitus was most commonly associated with cUTI whereas recurrent UTI were more common among female. Of the 200 patients, culture sensitivity was done in 133 patients Quinolones were the most commonly prescribed first line drug followed by Beta lactamase inhibitors.

5. Maria C. Paul, et al., (2014): Conducted a study on ‘A Study to Evaluate the Effectiveness of Antibiotics in Reducing the Relapse of UTI IN ESBL Positive Cases’.[37] A perspective observational study was conducted on a total of 60 ESBL positive UTI patients were studied and drug therapy details and culture reports of the patients were collected using a standard data collection form and were analysed. The objectives of study is to evaluate the clinical effectiveness of antibiotics in ESBL positive UTI, antibiotic of choice for the successful eradication of ESBL positive UTI to prevent its relapse and the associated risk factors. The result was E.coli was the most commonly isolated organism and Treatment with higher antibiotics mainly Carbapenems and Colistin proved to reduce the relapse rate of UTI than the other classes of antibiotics.

6. Sushma Muraraiah, Kavitha Rajaratna et al(2012); conducted a study on the ‘Prescribing pattern in complicated urinary tract infections at a tertiary care hospital’[38] The objective is to study the prescribing pattern in cUTI in a tertiary care hospital along with the antimicrobial sensitivity of the causative organisms. The details of demographics, past medical history, details of the drugs including dose, duration of therapy, route of administration, urine culture and antimicrobial sensitivity were obtained from the case records of the patients. A total of 84 patients were included in the study, of which 49 were males and 35 were females. The age of the patients ranged from 16 to 82years, with an average of 48.4 years. The prescriptions were analysed for the WHO indicators. Descriptive statistics was used for the analyses of the results. Only 34.5% of the patients had Culture and sensitivity of urine done, of which E.coli was detected in about half of them. E.coli was sensitive to Piperacillin & Tazobactum, followed by Cefoperoxone & Sulbactum. Most commonly used AMAs include Cephalosporins (29%), Quinolones (26%) and Penicillins (23%). Many patients with cUTI were associated with Type 2 Diabetes mellitus. The result of the study was Average number of drugs per prescription was 6.21 ± 3.36 with number of antibiotics per prescription was 2.1 ±0.78 and number of injections per prescription was 1.9±1.37. The prescription were in accordance with EUA guidelines.

7. Kees J Gorter et al(2010), conducted a study on the “Risk of recurrent acute lower urinary tract infections and prescription pattern of antibiotic in women with and without diabetes in primary care”[39]. To investigate diabetes characteristics associated with the risk of recurrent lower UTIs and the antibiotic prescription pattern. In an exploratory retrospective study involving 7063 women aged >30 years, we studied the incidence of recurrent UTI (relapses and reinfection) in women with (n = 340) and without diabetes (n = 6618). Multivariable logistic regression and multilevel multinomial logistic analyses were used to determine the adjusted associations between diabetes characteristics and recurrent UTI [odds ratio (OR); 95% confidence interval (CI)] and diabetes on the pattern of antibiotic prescriptions for UTI, respectively. The result was Relapses and reinfections were reported in 7.1% and 15.9% of women with diabetes versus 2.0% and 4.1% of women without diabetes. There was an independent higher risk of recurrent UTI in women with diabetes compared with women without diabetes. Women taking oral blood glucose-lowering medication or insulin or who had had diabetes for >5 years or who had retinopathy were at risk of recurrent UTI. The pattern of antibiotic prescriptions for UTI was not influenced by diabetes.

8. Caroline Schneeberger, et al., (2008): conducted a study on Differences in the Pattern of Antibiotic Prescription Profile and Recurrence Rate for Possible UTI in Women With or Without Diabetes.[40] The objective is to compare current treatment strategies with respect to recurrence rates in women with diabetes with those without diabetes.
A retrospective study on a. Total of 10,366 women with diabetes (17.5% Premenopausal) (aged 55 years) and 200,258 women without diabetes (68% premenopausal) who received a first course of Trimethoprim, Nitrofurantoin, Fosfomycin or Norfloxacin between January 1999 and January 2006 were included. A recurrence was defined as a second prescription for one of the above-mentioned agents or a first with amoxicillin (clavulanic acid), fluoroquinolones or TMP-SMX between 6 and 30 days after inclusion. Premenopausal women with diabetes more often received a long (26.5 vs. 19.2%; P = 0.001) treatment with norfloxacin (10.7% vs. 6.2%; P = 0.001) but still had a higher recurrence rate (16.1 vs. 12.2%; P = 0.003) compared with those without diabetes. Similarly, postmenopausal women with diabetes more often received a longer (32.8 vs. 28.8%; P = 0.001) treatment with norfloxacin (15.2 vs. 12.7%; P = 0.001) but had a higher recurrence rate (19.1 vs. 16.4%; P = 0.001) compared with those without diabetes. The result of the study was Patients with diabetes more often received longer and more potent initial treatment than patients without diabetes, pre- and postmenopausal women with diabetes more often had recurrences of their UTIs.

9. Thomas, P. Lodise, et al., (2007): Conducted a study on ‘Piperacillin/Tazobactam for Pseudomonas aeruginosa Infection: Clinical Implications of an Extended-Infusion Dosing Strategy’. A cohort study was conducted on 194 patients who received Piperacillin/Tazobactam for a P. aeruginosa infection in which 102 patients received extended infusions of Piperacillin/Tazobactam and 92 were received intermittent infusions of Piperacillin/Tazobactam. Data on demographic characteristics, disease severity and microbiology were collected and outcomes were compared based on APACHE II score. The result of the study was The Extended-infusion Piperacillin/Tazobactam therapy is a suitable alternative to intermittent-infusion therapy with improved outcomes.

10. Naber KG et al (2002): Conducted a study on “Piperacillin 2 g/tazobactam 0.5 g is as effective as imipenem 0.5 g/cilastatin 0.5 g for the treatment of acute uncomplicated pyelonephritis and complicated urinary tract infections.” The trial was a multinational, randomized, double blind trial that compared piperacillin/tazobactam (2 g/0.5 g/q8h) and imipenem/cilastatin (0.5 g/0.5 g/q8h) as monotherapy in patients with acute pyelonephritis or complicated urinary tract infections. In total, 237 patients were randomised to receive either piperacillin/tazobactam (n=161) or imipenem/cilastatin (n=166). At the early follow-up (=test-of-cure-visit) 5-9 days after antibiotic therapy, clinical success was noted in 122/147 (83.0%) piperacillin/tazobactam recipients compared with 123/154 (79.9%) imipenem/cilastatin recipients, thus proving that both treatments were equally effective. The result of the study was On a descriptive level, an advantage of piperacillin/tazobactam was demonstrated. Microbiological success at the early follow-up was 78/135 (57.8%) for piperacillin/tazobactam and 70/144 (48.6%) for imipenem/cilastatin. These results were confirmed by equivalent success rates on the last therapy day. Both drugs were generally well tolerated.

3. OBJECTIVES AND METHODOLOGY

3.1 AIM

The aim of the study is to evaluate the prescription pattern of Piperacillin/ Tazobactam in UTI and its recurrence rate in patients with or without diabetes mellitus.

OBJECTIVES

1. To assess the prescription pattern of Piperacillin/ Tazobactam in UTI patients with or without DM.
2. To assess the incidence and complication associated UTI with or without DM.
3. To assess the recurrence rate of possible UTI with or without DM.
4. To estimate the quality of life in patients.

3.2 METHODOLOGY

Study Design
Prospective observational study with two month follow up

Study Population
All UTI patients reported to Department of General Medicine, Pushpagiri Medical College Hospital, Thiruvalla.

Study Site
Tertiary care setting: Department of General Medicine; Pushpagiri Medical College Hospital, Thiruvalla.

Study Period
6 months

Sample Size
\[ n = \frac{4PQ}{d^2} \]

Where,

\[ N = \text{Sample size} \]
\[ P = \text{Prevalence} \]
\[ Q = 1 - P \]
\[ d = \text{allowable error} \]

INCLUSION CRITERIA

- IP UTI patients in General Medicine department
- Both female and male patients UTI with or without DM.
- Those who give consent voluntarily to participate in the study.
- Patients receiving Piperacillin Tazobactam Antibiotic.
EXCLUSION CRITERIA
- Patients who are not willing to give consent.
- Patients with indwelling catheters.
- Pregnant and lactating mothers.

BRIEF PROCEDURE OF THE STUDY
A prospective, observational study was conducted in Department of General Medicine at Pushpagiri Medical College Hospital on the topic TO EVALUATE THE PRESCRIPTION PATTERN OF PIPERACILLIN/TAZOBACTAM IN UTI AND IT’S RECURRANCE RATE IN PATIENTS WITH OR WITHOUT DIABETES MELLITUS. The entire study was carried out after getting approval from Institutional Ethics Committee. The selection of patients was based upon the inclusion and exclusion criteria. All patients were provided with a brief introduction regarding the study and the confidentiality of the data. A written Informed Consent was obtained from the patient or care-giver.

Patients who have been on Piperacillin/Tazobactam for a possible UTI with or without DM was identified and demographic details of the patients were collected and recorded. A standardised data collection form was prepared and necessary data were collected including details of demographic data, past medical history, details of the current drugs including dose, duration of therapy, route of administration, urine culture and antimicrobial sensitivity. The information regarding signs and symptoms, etiology and complications, biochemical profile was noted.

During follow up after two month patients parameters were revaluated, outcome assessed. Prescribing pattern of drugs was collected from their medical records and evaluated the rationality of prescribing practices using WHO prescribing indicators. All information significant to the study were collected from the case records and discussions conducted with IP and bystanders during ward rounds, with the support of physician.

The complications associated with UTI were determined from direct patient interview and case records. The incidence rate were calculated using formula

WHO prescribing indicators
1. Number of drugs per prescription
2. Number of antibiotics per prescription
3. Number of drugs prescribed by generic name
4. Number of injections per prescription

The recurrence of UTI was assessed by following up patient and asking them about drug use and other risk factors during therapy.

Quality of life was evaluated by using KING’S HEALTH QUESTIONNAIRE.

4. OBSERVATIONS AND RESULTS

Demographic Details

CLASSIFICATION OF RESPONDENTS

<table>
<thead>
<tr>
<th>Age</th>
<th>Frequency</th>
<th>Percent%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Below 40</td>
<td>9</td>
<td>15.0</td>
</tr>
<tr>
<td>40 - 60</td>
<td>20</td>
<td>33.3</td>
</tr>
<tr>
<td>Above 60</td>
<td>31</td>
<td>51.7</td>
</tr>
<tr>
<td>Total</td>
<td>60</td>
<td>100.0</td>
</tr>
</tbody>
</table>

From the above table and graph it reveals that, majority of the patients belongs to category, above 60 followed by 40-60 category and last below 40 category age group.

<table>
<thead>
<tr>
<th>Sex</th>
<th>Frequency</th>
<th>Percent%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female</td>
<td>34</td>
<td>56.7</td>
</tr>
<tr>
<td>Male</td>
<td>26</td>
<td>43.3</td>
</tr>
<tr>
<td>Total</td>
<td>60</td>
<td>100.0</td>
</tr>
</tbody>
</table>

From the above table and graph it reveals that, majority of the patients belongs to category, above 60 followed by 40-60 category and last below 40 category age group.

Figure no. 5: distribution of sample according to age.

Figure no. 6: distribution of sample according to gender.
From the above table 4 and graph 6, it is clear that the most of the female patient is having UTI than male patients.

Table no. 5: Distribution of Sample According to Martial Status.

<table>
<thead>
<tr>
<th>Martial Status</th>
<th>Frequency</th>
<th>Percent %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unmarried</td>
<td>5</td>
<td>8.3</td>
</tr>
<tr>
<td>Married</td>
<td>55</td>
<td>91.7</td>
</tr>
<tr>
<td>Total</td>
<td>60</td>
<td>100.0</td>
</tr>
</tbody>
</table>

A total of 91.7% were married and remaining 8.3% were unmarried in this study.

Table No. 7: Distribution of Sample According To Menstrual Status.

<table>
<thead>
<tr>
<th>Menstrual Status</th>
<th>Frequency</th>
<th>Percent %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not applicable</td>
<td>26</td>
<td>43.3</td>
</tr>
<tr>
<td>Menopause</td>
<td>23</td>
<td>38.3</td>
</tr>
<tr>
<td>Pre menopause</td>
<td>11</td>
<td>18.3</td>
</tr>
<tr>
<td>Total</td>
<td>60</td>
<td>100.0</td>
</tr>
</tbody>
</table>

In this study, among women majority of them were post-menopausal women having UTI

Table No. 6: Distribution of Sample According To Social Status.

<table>
<thead>
<tr>
<th>Social Status</th>
<th>Frequency</th>
<th>Percent %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nil</td>
<td>42</td>
<td>70.0</td>
</tr>
<tr>
<td>Alcohol</td>
<td>10</td>
<td>16.7</td>
</tr>
<tr>
<td>Smoker</td>
<td>8</td>
<td>13.3</td>
</tr>
<tr>
<td>Total</td>
<td>60</td>
<td>100.0</td>
</tr>
</tbody>
</table>

70% people in the study had no social history and remaining were alcoholics and smokers.

PRESCRIBING PATTERN

Total No. of prescription analysed = 60
Total no. of drugs = 355
1. Number of drugs per prescription = 5.91+/- 1.79
2. Number of antibiotics per prescription = 1.27+/- 0.45
3. Number of drugs prescribed by generic name = 1.03+/- 0.99
4. Number of injections per prescription = 2.45+/- 0.57

Table no. 8: Distribution of Sample According To Dose

<table>
<thead>
<tr>
<th>DOSE</th>
<th>Frequency</th>
<th>Percent %</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.5 g</td>
<td>39</td>
<td>65.0</td>
</tr>
<tr>
<td>2.25 g</td>
<td>21</td>
<td>35.0</td>
</tr>
<tr>
<td>Total</td>
<td>60</td>
<td>100.0</td>
</tr>
</tbody>
</table>
From the above graph and table majority of the patients were prescribed with a dose of 4.5g.

**Table No. 9: Distribution of Sample According To Frequency of Drug Administration.**

<table>
<thead>
<tr>
<th>Frequency of P/T</th>
<th>Frequency</th>
<th>Percent %</th>
</tr>
</thead>
<tbody>
<tr>
<td>8 hour</td>
<td>50</td>
<td>83.3</td>
</tr>
<tr>
<td>6 hour</td>
<td>4</td>
<td>6.7</td>
</tr>
<tr>
<td>12 hour</td>
<td>6</td>
<td>10.0</td>
</tr>
<tr>
<td>Total</td>
<td>60</td>
<td>100.0</td>
</tr>
</tbody>
</table>

Most of the patients were administered P/T at a frequency of 8 hour interval.

**Table No.10: Distribution of Sample According To Organism Affected.**

<table>
<thead>
<tr>
<th>ORGANISM</th>
<th>Frequency</th>
<th>Percent %</th>
</tr>
</thead>
<tbody>
<tr>
<td>No growth</td>
<td>11</td>
<td>18.3</td>
</tr>
<tr>
<td><em>E. coli</em></td>
<td>39</td>
<td>65.0</td>
</tr>
<tr>
<td><em>Pseudomonas.aeruginosa</em></td>
<td>2</td>
<td>3.3</td>
</tr>
<tr>
<td><em>Klebsiella.pneumoniae</em></td>
<td>6</td>
<td>10.0</td>
</tr>
<tr>
<td><em>Yeast</em></td>
<td>1</td>
<td>1.7</td>
</tr>
<tr>
<td><em>Enterococcus.faecalis</em></td>
<td>1</td>
<td>1.7</td>
</tr>
<tr>
<td>Total</td>
<td>60</td>
<td>100.0</td>
</tr>
</tbody>
</table>

In this study we observed that major causative organism of UTI were *E. coli* and second one is *Klebsiella. Pneumonia* and 18% were not affected with any organism.

**Table No. 11: Distribution Of Sample According Number Of Days Prescribed With P/T.**

<table>
<thead>
<tr>
<th>DAYS</th>
<th>Frequency</th>
<th>Percent %</th>
</tr>
</thead>
<tbody>
<tr>
<td>3d</td>
<td>12</td>
<td>20.0</td>
</tr>
<tr>
<td>5d</td>
<td>29</td>
<td>48.3</td>
</tr>
<tr>
<td>7d</td>
<td>16</td>
<td>26.7</td>
</tr>
<tr>
<td>9d</td>
<td>3</td>
<td>5.0</td>
</tr>
<tr>
<td>Total</td>
<td>60</td>
<td>100.0</td>
</tr>
</tbody>
</table>

In this study majority of the patient has taken P/T in 5 days to complete the course.

**Table No. 12: Distribution of Sample According To Prescription.**

<table>
<thead>
<tr>
<th>Type</th>
<th>Frequency</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Empirical</td>
<td>44</td>
<td>73.3</td>
</tr>
<tr>
<td>Definitive</td>
<td>16</td>
<td>26.7</td>
</tr>
<tr>
<td>Total</td>
<td>60</td>
<td>100</td>
</tr>
</tbody>
</table>
Most of the P/T were given as empirical treatment.

Fever is the most common symptom occurred in patient, abdominal pain, dysuria.

<table>
<thead>
<tr>
<th>diabetes Mellitus</th>
<th>Frequency</th>
<th>Percent %</th>
</tr>
</thead>
<tbody>
<tr>
<td>No DM</td>
<td>23</td>
<td>38.3</td>
</tr>
<tr>
<td>DM only</td>
<td>37</td>
<td>61.6</td>
</tr>
<tr>
<td>Total</td>
<td>60</td>
<td>100.0</td>
</tr>
</tbody>
</table>

Hypertension is the most common disorder occurred in this study population, followed by dyslipidemia.

<table>
<thead>
<tr>
<th>Clinical condition</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>HYPERTENSION</td>
<td>25</td>
</tr>
<tr>
<td>HEART DISEASE</td>
<td>9</td>
</tr>
<tr>
<td>HYPOTHYROIDISM</td>
<td>4</td>
</tr>
<tr>
<td>HYPOPITUITIRISM</td>
<td>1</td>
</tr>
<tr>
<td>PSYCHIATRIC ILLNESS</td>
<td>1</td>
</tr>
<tr>
<td>ANAEMIA</td>
<td>4</td>
</tr>
<tr>
<td>DYSLIPIDEMIA</td>
<td>11</td>
</tr>
<tr>
<td>RENAL CALCULI</td>
<td>4</td>
</tr>
<tr>
<td>COPD</td>
<td>3</td>
</tr>
<tr>
<td>ASTHMA</td>
<td>4</td>
</tr>
<tr>
<td>SCROTAL DERMATITIS</td>
<td>1</td>
</tr>
<tr>
<td>CANCER</td>
<td>2</td>
</tr>
<tr>
<td>HEPATITIS</td>
<td>1</td>
</tr>
<tr>
<td>BPH</td>
<td>4</td>
</tr>
<tr>
<td>SEIZURE</td>
<td>2</td>
</tr>
</tbody>
</table>

Hypertension is the most common disorder occurred in this study population, followed by dyslipidemia.
<table>
<thead>
<tr>
<th>Category</th>
<th>Drugs</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiovascular System</td>
<td>Nifedipine, Amlodipine, Carvedilol, Enalapril, Prazosin, Clinidipine, Metoprolol, Atrvastatin, Rosuvastatin, Ivabradine, Olmesartan, Aspirin, Clopidogrel, Losartan, Frusemide, Cilostazol</td>
<td>1, 14, 1, 3, 5, 2, 12, 2, 1, 1, 6, 6, 4, 5, 2</td>
</tr>
<tr>
<td>Respiratory System</td>
<td>Nifedipine, Amlodipine, Carvedilol, Enalapril, Prazosin, Clinidipine, Metoprolol, Atrvastatin, Rosuvastatin, Ivabradine, Olmesartan, Aspirin, Clopidogrel, Losartan, Frusemide, Cilostazol</td>
<td>1, 14, 1, 3, 5, 2, 12, 2, 1, 1, 6, 6, 4, 5, 2</td>
</tr>
<tr>
<td>Hypoglycemic Agent</td>
<td>Nifedipine, Amlodipine, Carvedilol, Enalapril, Prazosin, Clinidipine, Metoprolol, Atrvastatin, Rosuvastatin, Ivabradine, Olmesartan, Aspirin, Clopidogrel, Losartan, Frusemide, Cilostazol</td>
<td>1, 14, 1, 3, 5, 2, 12, 2, 1, 1, 6, 6, 4, 5, 2</td>
</tr>
<tr>
<td>Topical Agent</td>
<td>Nifedipine, Amlodipine, Carvedilol, Enalapril, Prazosin, Clinidipine, Metoprolol, Atrvastatin, Rosuvastatin, Ivabradine, Olmesartan, Aspirin, Clopidogrel, Losartan, Frusemide, Cilostazol</td>
<td>1, 14, 1, 3, 5, 2, 12, 2, 1, 1, 6, 6, 4, 5, 2</td>
</tr>
<tr>
<td>CNS</td>
<td>Nifedipine, Amlodipine, Carvedilol, Enalapril, Prazosin, Clinidipine, Metoprolol, Atrvastatin, Rosuvastatin, Ivabradine, Olmesartan, Aspirin, Clopidogrel, Losartan, Frusemide, Cilostazol</td>
<td>1, 14, 1, 3, 5, 2, 12, 2, 1, 1, 6, 6, 4, 5, 2</td>
</tr>
<tr>
<td>Anti psychotic/depressant</td>
<td>Nifedipine, Amlodipine, Carvedilol, Enalapril, Prazosin, Clinidipine, Metoprolol, Atrvastatin, Rosuvastatin, Ivabradine, Olmesartan, Aspirin, Clopidogrel, Losartan, Frusemide, Cilostazol</td>
<td>1, 14, 1, 3, 5, 2, 12, 2, 1, 1, 6, 6, 4, 5, 2</td>
</tr>
<tr>
<td>Other Antibiotics</td>
<td>Nifedipine, Amlodipine, Carvedilol, Enalapril, Prazosin, Clinidipine, Metoprolol, Atrvastatin, Rosuvastatin, Ivabradine, Olmesartan, Aspirin, Clopidogrel, Losartan, Frusemide, Cilostazol</td>
<td>1, 14, 1, 3, 5, 2, 12, 2, 1, 1, 6, 6, 4, 5, 2</td>
</tr>
</tbody>
</table>

Most commonly prescribed drugs were pantoprazole and cardiovascular drugs.
Majority of patients (66.7%) were not developed complications.

In this study only 18.8% developed recurrence of UTI.

In this study population, type of recurrence occurred is relapse.

Most of the recurrent UTI patient were females.

In this study recurrence of UTI were treated with other antibiotics and were catheterised.
Table No 19: Distribution of Sample According To Quality of Life.

a. General Health Perception

<table>
<thead>
<tr>
<th>General health perception</th>
<th>Mean</th>
<th>Std. Deviation</th>
<th>Mean difference</th>
<th>95% Confidence interval</th>
<th>Paired t value</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Before</td>
<td>37.08</td>
<td>14.91</td>
<td>22.5</td>
<td>19.42 - 25.58</td>
<td>14.628</td>
<td>0.001</td>
</tr>
<tr>
<td>Follow up</td>
<td>14.58</td>
<td>14.03</td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tbody>
</table>

Since P value is less than 0.01, it is highly significant at 1% level of significance.

b) Incontinence impact

<table>
<thead>
<tr>
<th>Incontinence impact</th>
<th>Mean</th>
<th>Std. Deviation</th>
<th>Mean difference</th>
<th>95% Confidence interval</th>
<th>Paired t value</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Before</td>
<td>41.21</td>
<td>21.21</td>
<td>27.34</td>
<td>22.28-32.39</td>
<td>10.815</td>
<td>0.001</td>
</tr>
<tr>
<td>Follow up</td>
<td>13.88</td>
<td>16.56</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Since P value is less than 0.01, it is highly significant at 1% level of significance.

c) Role limitation

<table>
<thead>
<tr>
<th>Role limitation</th>
<th>Mean</th>
<th>Std. Deviation</th>
<th>Mean difference</th>
<th>95% Confidence interval</th>
<th>Paired t value</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Before</td>
<td>29.94</td>
<td>18.63</td>
<td>18.58</td>
<td>15.11-22.04</td>
<td>10.731</td>
<td>0.001</td>
</tr>
<tr>
<td>Follow up</td>
<td>11.37</td>
<td>14.21</td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tbody>
</table>
c) Role limitation

Since P value is less than 0.01, it is highly significant at 1% level of significance.

d) Physical limitation

<table>
<thead>
<tr>
<th>Physical limitation</th>
<th>Mean</th>
<th>Std. Deviation</th>
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<th>95% Confidence interval</th>
<th>Paired t value</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Before</td>
<td>30.49</td>
<td>17.68</td>
<td>20.79</td>
<td>17.37-24.21</td>
<td>12.163</td>
<td>0.001</td>
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<tr>
<td>Follow up</td>
<td>9.7</td>
<td>12.74</td>
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</tr>
</tbody>
</table>

Since P value is less than 0.01, it is highly significant at 1% level of significance.

e) Social limitation

<table>
<thead>
<tr>
<th>Social limitation</th>
<th>Mean</th>
<th>Std. Deviation</th>
<th>Mean difference</th>
<th>95% Confidence interval</th>
<th>Paired t value</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Before</td>
<td>22.36</td>
<td>20.14</td>
<td>14.50</td>
<td>10.95-18.06</td>
<td>8.168</td>
<td>0.001</td>
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<tr>
<td>Follow up</td>
<td>7.85</td>
<td>12.14</td>
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<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

e) Social limitation
Since P value is less than 0.01, it is highly significant at 1% level of significance.

f) Emotions

<table>
<thead>
<tr>
<th>Emotions</th>
<th>Mean</th>
<th>Std. Deviation</th>
<th>Mean difference</th>
<th>95% Confidence interval</th>
<th>Paired t value</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Before</td>
<td>24.69</td>
<td>12.53</td>
<td>17.94</td>
<td>14.76-21.12</td>
<td>11.285</td>
<td>0.001</td>
</tr>
<tr>
<td>Follow up</td>
<td>6.75</td>
<td>9.59</td>
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</table>

Since P value is less than 0.01, it is highly significant at 1% level of significance.

g) Sleep

<table>
<thead>
<tr>
<th>Sleep</th>
<th>Mean</th>
<th>Std. Deviation</th>
<th>Mean difference</th>
<th>95% Confidence interval</th>
<th>Paired t value</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Before</td>
<td>25.57</td>
<td>16.24</td>
<td>18.81</td>
<td>15.43-22.19</td>
<td>11.151</td>
<td>0.001</td>
</tr>
<tr>
<td>Follow up</td>
<td>6.76</td>
<td>10.30</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

Since P value is less than 0.01, it is highly significant at 1% level of significance.

h) Severity

<table>
<thead>
<tr>
<th>Severity</th>
<th>Mean</th>
<th>Std. Deviation</th>
<th>Mean difference</th>
<th>95% Confidence interval</th>
<th>Paired t value</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Before</td>
<td>10.94</td>
<td>10.27</td>
<td>5.23</td>
<td>2.66-7.79</td>
<td>4.075</td>
<td>0.001</td>
</tr>
<tr>
<td>Follow up</td>
<td>5.71</td>
<td>7.88</td>
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<td></td>
</tr>
</tbody>
</table>

Since P value is less than 0.01, it is highly significant at 1% level of significance.
Since P value is less than 0.01, it is highly significant at 1% level of significance

**DISCUSSION**

This study was done to evaluate the prescription pattern of Piperacillin/ Tazobactam in UTI and its recurrence rate in patients with or without diabetes mellitus. The incidence and complications associated with UTI were also studied. The quality of life in these patients were also analysed. This study was carried out in Pushpagiri Medical College Hospital, Thiruvalla. Patients were selected according to the inclusion and exclusion criteria and the data was collected from the General Medicine department. The patient demographic details were collected and recorded. UTI symptoms were assessed using IUPUI UTI QUESTIONNAIRE. Patients were then followed after one month to assess the recurrence of UTI. The KHQ was used to assess the quality of life in patients. The collected data was organised, tabulated and analysed using statistical methods and described with tables and graphs.

**AGE**

The majority of the patients belongs to the above 60 category, followed by 40-60 category, and least by below 40. 51.7% belongs to above 60 age group. This shows that age is a risk factor of having increased UTI incidences.

**Gender**

Females are mostly affected by UTI than males. Most of the recurrent UTI cases were also observed in females. UTI with DM is also increased to be in females than males.

**Social History**

Out of the total patients, majority of them have no habit. But some are having either drinking or smoking or both. Whereas none have other substance. Influences of these two drugs are more effective in patients who have no habits than the other drinking and smoking patients.

**Martial Status**

Among the study population 91.7% were married and only 8.7% were unmarried.

**Menstrual Status**

Among 56.7% women population majority of them were post-menopausal women having UTI. It is also observed that UTI with DM is also increasingly seeing in post-menopausal women. Recurrence rates were also higher in post-menopausal women.

**Prescribing Pattern**

65% of the study population were prescribed with a dose of 4.5 g IV with a frequency of administration of 8 hour interval. Other dose prescribed is about 2.25 g IV. Some patients administered the injection at an interval of 6 hour and 12 hour. Majority of the patients 48.3% were completed the course with in 5 days and 26.7% within 7 days.

73.6% of study population were prescribed P/T as empirical therapy and only 26.4% as definitive treatment. Most of the antibiotic treatment started before the culture report. Major causative organism found in this study is *E.coli*, 65% and 18.3% have not observed any growth followed by *Klebsiella pneumonia* and *Pseudomonas aeroginosa*, yeast infection and *Enterococcus faecalis*. Fever (50%) and abdominal pain (31.6%) were the common symptoms seen in patients, followed by dysuria and increased frequency of micturition. A total of 60 prescriptions were analysed using WHO core indicator and a total of 355 drugs were seen. It is observed that Pantoprazole is the major drug given concurrently with P/T to avoid gastric side effects. Hypertension is the common clinical condition observed in the study population. Many other clinical conditions and drugs were prescribed according to patient condition.

61.6% of population is observed with clinical condition of DM as a risk of developing UTI and most of them were females and postmenopausal women.

**INCIDENCE**

Incidence of UTI patients with DM is 37 cases (61.6%) and without DM is 23 (38.4%).

**COMPLICATIONS**

Majority of the population does not develop any risk, but some develop AKI and sepsis, some have both.

**RECURRENCE**

18% of population developed recurrence and among the recurrence relapse occurred the most with *E. coli* and in that most of them were post-menopausal women with DM. Females were most affected with recurrence. During RC, treatment were done with other antibiotics especially Nitrofurantoin and many patients were catheterised, and some had only treated with P/T during RC. Only one patient had undergone haemodialysis during recurrence due to urosepsis.

**QUALITY OF LIFE**

KHQ was used to analyse quality of life in UTI patient before and after taking P/T. In this scale general health perception, incontinence impact, role limitation, physical limitation, social limitation, emotions, sleep and severity were analysed and in all these scales P value is less than 0.01, it is highly significant at 1% level of significance. So that most of the patient quality of life improved after intake of P/T.

**SUMMARY**

A prospective observational study was conducted in the department of GM, Pushpagiri Medical College Hospital, Thiruvalla and Pushpagiri College of Pharmacy, Thiruvalla to find out the to evaluate the prescription pattern of piperacillin/ tazobactam in UTI and its
recurrence rate in patients with or without diabetes mellitus. The sample size were 60 patients. Patients demographic details were collected, patient’s symptoms were assessed using IUPUI UTI questionnaire and antibiotic prescription chart were analysed. Patient followed up for one month to analyse the recurrence rate and its treatment. Quality of life was analysed using KHQ questionnaire. Collected data was organised, tabulated and analysed using statistical methods and described with tables and graphs.

- All the UTI patients who are taking P/T were having uncomplicated UTI.
- The majority of the patients belongs to the above 60 category. Age showed an increased risk of UTI.
- Majority of the UTI patients were females.
- Among study group above 90% were married.
- In the study population most of them have no social habits.
- According to menstrual status in women many of them were post-menopausal women 67.6%.
- Prescription analysis by WHO core indicators
- Majority of the patients 65% were prescribed a dose of 4.5g IV with a frequency of 8 hour.
- P/T mainly prescribed as empirical treatment 73.6% population under study.
- E.coli is the most commonly isolated micro-organism among patients.
- Most of the antibiotics were given before culture has been send.
- Common symptoms associated with UTI found to be fever and abdominal pain.
- 67.6% patient under study have DM associated UTI.
- Other clinical condition most commonly seen with UTI were Hypertension.
- Pantoprazole were the most commonly prescribed drug with P/T and then by vitamin supplements.
- AKI and sepsis were the complications developed and majority of the study group have no complications.
- 18.4% of study population developed RC and of relapse RC and most commonly isolated organism in recurrence is E.coli.
- Nitrofurantoin is mainly prescribed in recurrence treatment and somewhere catheterised, rarely P/T is given during recurrence.
- Quality of life were improved after taking P/T.

CONCLUSION
UTI patients are increasing in the current scenario this study is an attempt to evaluate the prescription pattern of P/T in UTI and its recurrence rate in patients with or without DM. The current study was conducted in General Medicine department of Pushpagiri Medical College Hospital, Thiruvalla. Sixty UTI patients who has been on P/T were selected for the study and their prescription were analysed according to WHO INDICATORS. All the UTI patients are having uncomplicated UTI. The complications and risk were assessed, recurrence rate was obtained by follow up of the patient. The results concluded that the incidence of UTI was seen to be more in females than males. E.coli sensitive to Piperacillin/Tazobactum, was the most common organism isolated from the urine culture. Out of total patients each age category have UTI majority of the patients belongs to above 60, followed by 40-60 category, below 40 category. AKI and Sepsis are the most common complications associated with UTI. Recurrences are found to be occurred in female than males and in DM patients than without DM. Treatment of UTI in DM and non – DM are same and only difference is that concurrent drugs and uropathogens must be considered for the treatment.

According to WHO/INRUD indicators, the average drug per prescription was high. As there is tendency towards polypharmacy in our hospital, educational interventions towards improving prescribing practices are required. Although the prescription of AMAs were appropriate, intravenous administration of the same could be reduced in order to prevent spreading of infections and use of scarce technical staff. Prescribing by generic name needs to improve in our hospital to prevent medication errors and further adverse effects due to it.

This study clearly suggests that pharmaceutical care services are vibrant in elderly for the prevention and/or minimization of antibiotic resistance proper usage and rational promotion of drugs even though it was conducted only in selected medicine departments of the hospital. This study also suggests that educational interventions regarding strict control and monitoring of the chronic disease condition help in avoiding recurrence of UTIs. The continuous monitoring and reporting of prescribing pattern of antibiotics will surely help the physicians for effective treatment.

ACKNOWLEDGEMENT
Our dissertation work would be incomplete, if we do not express my sincere thanks to all the people who have helped us to complete our work. Although words are not enough to express our immeasurable gratitude, we would like to try to acknowledge their invaluable efforts. First and foremost we would like to thank God Almighty for blessing us with the opportunity and perseverance necessary to complete this work and for always showering his abundant grace upon us.

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We owe a debt of heartfelt thanks to our esteemed co-guide, Dr. R. N. Sharma Professor, Department of General Medicine, Pushpagiri Medical College Hospital, Thiruvalla. It is his vision that led me to initiate and move ahead with this work and we consider it a great honour to have had the opportunity work under such an eminent physician and to share our humble thoughts and ideas with him, and receive immensely useful criticism in return. We are also thankful to Dr. Athulya. G. for her valuable support during our project. We much obliged to Prof. Dr. Lincy Joseph, Head of the chemistry department, Pushpagiri College of Pharmacy for her constant encouragement during the course of my post-graduation study and for her inspiration & enthusiastic support. We take this opportunity to acknowledge our deep and sincere thanks to Mrs. Manju Rani, Assistant professors, Department of Pharmacy Practice, Pushpagiri College of pharmacy, without their critical advice, encouragement and deep-rooted knowledge, this work would not have been a reality. The statistical work for this thesis is the result of the kind-heartedness of an individual, Mr. Girish Babu, who worked hard to understand our requirements and made the results available on time.

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With warm regards,
Elena Cheruvil
Praise Sebastian.

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42. Naber KG, Savov O, Salmen HC Piperacillin 2 g/tazobactam 0.5 g is as effective as imipenem 0.5 g/cilastatin 0.5 g for the treatment of acute uncomplicated pyelonephritis and complicated urinary tract infections, International Journal of Antimicrobial Agents. Feb, 2002; 19(2): 95-103.
PATIENT / INFORMED CONSENT FORM

I, _________________________________________ exercising my free power of choice hereby give my consent to be included in the study "A PROSPECTIVE OBSERVATIONAL STUDY TO EVALUATE THE PRESCRIPTION PATTERN OF PIPERACILLIN/TAZOBACTUM IN UTI AND IT’S RECURRENCE RATE IN PATIENTS WITH OR WITHOUT DIABETES MELLITUS" conducted by Elena Cheruvil and Praise Sebastian of 5th Yr Pharm D, Pushpagiri College of Pharmacy, Thiruvalla.
I whole heartedly without any compulsion agree to give the following details: Age, illness and treatment. I am willing to allow the laboratory staff to provide the residual blood collected for laboratory investigations for the purpose of the study. I am also willing to attend and answer the questionnaire on the following condition that:

1. No harm will occur to me by participating in the study.
2. There won’t be any additional financial burden to my family by enrolling in this study.
3. I am aware of my right to opt out of the study at any given time which by no means will affect my treatment in the future.
4. Data collected from the study would be kept under strict confidentiality, and would not reveal any personal details.

Student:                                         Patient:
Sign:                                            Sign:
Date:

DATA COLLECTION PROFORMA

SERIAL NO.:                                      DATE:

NAME:                                            O.P/LP no.:
AGE:                                             DOA:
SEX:                                             DEPT:
WEIGHT:                                          CONSULTANT:
DOA:                                             DOD:
CONTACT NO.:                                     CONTACT NO.:

MARITAL STATUS                                   UNMARRIED [ ]
MARRIED [ ]  

PATIENT / INFORMED CONSENT FORM

I, _________________________________________ exercising my free power of choice hereby give my consent to be included in the study "A PROSPECTIVE OBSERVATIONAL STUDY TO EVALUATE THE PRESCRIPTION PATTERN OF PIPERACILLIN/TAZOBACTUM IN UTI AND IT’S RECURRENCE RATE IN PATIENTS WITH OR WITHOUT DIABETES MELLITUS" conducted by Elena Cheruvil and Praise Sebastian of 5th Yr Pharm D, Pushpagiri College of Pharmacy, Thiruvalla.
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3. I am aware of my right to opt out of the study at any given time which by no means will affect my treatment in the future.
4. Data collected from the study would be kept under strict confidentiality, and would not reveal any personal details.

Student:                                         Patient:
Sign:                                            Sign:
Date:
OCCUPATIONAL STATUS
EMPLOYED □  UNEMPLOYED □

ECONOMIC STATUS
BPL □  APL □

PRESENT COMPLAINTS:

PAST MEDICAL HISTORY:

PAST MEDICATION HISTORY:

FAMILY HISTORY:

SOCIAL HISTORY:

ALLERGIES:

GENERAL EXAMINATION:

PHYSICAL EXAMINATION:

LAB FINDINGS

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<td></td>
</tr>
<tr>
<td>FBS</td>
<td>70-110mg/dl</td>
<td></td>
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</tr>
<tr>
<td>RBS</td>
<td>&lt;140mg/dl</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HbA1C</td>
<td>&lt;6%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LFT</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AST</td>
<td>&lt;31U</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ALT</td>
<td>&lt;40U</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bilirubin Total</td>
<td>0.3-1mg/dl</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bilirubin Direct</td>
<td>0.1-0.3mg/dl</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Albumin</td>
<td>3.5-5mg/dl</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LIPID PROFILE</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total Cholesterol</td>
<td>&lt;200mg/dl</td>
<td></td>
<td></td>
</tr>
<tr>
<td>TG</td>
<td>60-150mg/dl</td>
<td></td>
<td></td>
</tr>
<tr>
<td>OTHER</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>C-RP</td>
<td>&lt;33mg/dl</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pro-calcitonin</td>
<td>0.15-2ng/dl</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

URINE ANALYSIS:

Reaction: Protein: RBC: Sugar:
WBC:
CULTURE:

DIAGNOSIS:

USG:

OTHER

DRUG CHART

<table>
<thead>
<tr>
<th>BRAND NAME</th>
<th>GENERIC NAME</th>
<th>DOSE</th>
<th>ROA</th>
<th>FREQUENCY</th>
<th>DAYS</th>
</tr>
</thead>
<tbody>
<tr>
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</table>

DISCHARGE STATUS
Fair ☐ Relieved ☐ Better ☐ Same ☐ Worse ☐

FOLLOW UP

Rent Questionnaire

IUPUI Health Services URINARY TRACT INFECTION QUESTIONNAIRE 12/14/2004 Rev. 9/20/2008

Name: ___________________________ Today’s Date: ____________________

Allergies: __________________________ Date of Birth: __________________

Temp: _______ B/P: _________ P: _____ Wt: __________ Height: __________

Please answer questions 1 through 8:

1. Please circle the symptoms you are experiencing. (& explain if space)
   Frequency: How many times an hour do you urinate? __________
   Dysuria: (Burning or pain on urination)
   Hematuria: (Blood in urine)
   Urgency: (sudden need to urinate)
   Nocturia: (awakening during sleep to urinate)
   Incontinence: (loss of control)
   Back pain: if yes, right side, left side or both? __________________
   Fever: if yes, highest temp _______ for how many days? ___

2. How long (days) have you had these symptoms?___________

3. Have you had a previous urinary tract infection(UTI)? Yes No
   If yes, more than 2 per year? Yes No

4. Have you ever had an infection of the kidney? Yes No
   Please list medication taken for past UTI:______________________________

5. Have you taken any medication for current symptoms? Yes No
   List all prescription, over the counter medication, or herbs that you
   have taken in the last 2 days:________________________________________
   ________________________________________________________________
   ________________________________________________________________

6. Females only: when did your last menstrual cycle begin? __________

7. Do you drink caffeinated beverages? (soft drinks/coffee/tea) Yes No
   If yes, how many ounces per day? ______________________________

8. Are you sexually active? Yes No
   If yes, when did you last have sex? ______________________________
### Antibiotic Prescription Chart

<table>
<thead>
<tr>
<th>Patient</th>
<th>Weight</th>
<th>Allergies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Label</td>
<td>eGFR</td>
<td></td>
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</tbody>
</table>

#### Infection Episode 1

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th></th>
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</thead>
<tbody>
<tr>
<td>Pneumonia</td>
<td></td>
<td></td>
</tr>
<tr>
<td>UTI</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Meningitis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Line Infection</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cellulitis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intra-abdominal</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Source**

- Community acquired
- Hospital acquired

**Indication**

- $P$ = prophylactic
- $E$ = empirical
- $D$ = definitive

#### SEND APPROPRIATE CULTURES BEFORE PRESCRIBING ANTIBIOTICS

<table>
<thead>
<tr>
<th>Cultures</th>
<th>Sent before antibiotics</th>
<th>Sent after antibiotics</th>
<th>Not sent</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Indication**

- $P$ = prophylactic
- $E$ = empirical
- $D$ = definitive

<table>
<thead>
<tr>
<th>Start Date</th>
<th>Duration</th>
<th>Frequency</th>
<th>Route</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Doctor’s signature and name**

- Contact
- Pharmacy
## BRITISH SOCIETY OF UROGynaecology

**King's Health Questionnaires (KHQ)**

### Q1. General Health Perception: How would you describe your health at present?
- Very good
- Good
- Fair
- Poor
- Very poor

### Q2. Incontinence Impact: How much do you think your bladder problem affects your life?
- Not at all
- A little
- Moderately
- A lot

### Q3. Role Limitations: Does your bladder problem affect:
- A. Your household tasks e.g., cleaning, shopping etc.? Not at all
  - A little
  - Moderately
  - A lot
- B. Your job or normal daily activities outside the home? Not at all
  - A little
  - Moderately
  - A lot

### Q4. Physical Limitations: Does your bladder problem affect:
- A. Your physical activities (e.g., going for walk, run, sports, gym etc.)? Not at all
  - A little
  - Moderately
  - A lot
- B. Your affect travel? Not at all
  - A little
  - Moderately
  - A lot

### Q5. Social Limitations: Does your bladder problem limit:
- A. Your social life? Not at all
  - A little
  - Moderately
  - A lot
- B. Your limit your ability to see / visit friends? Not at all
  - A little
  - Moderately
  - A lot

### Q6. Personal Relationships: Does your bladder problem affect:
- A. Your relationship with your partner? Not at all
  - A little
  - Moderately
  - A lot
- B. Your sex life? Not at all
  - A little
  - Moderately
  - A lot
- C. Your family life? Not at all
  - A little
  - Moderately
  - A lot

### Q7. Emotions: Does your bladder problem make:
- A. You feel depressed? Not at all
  - A little
  - Moderately
  - Very much
- B. You feel anxious and nervous? Not at all
  - A little
  - Moderately
  - Very much
- C. You feel bad about yourself? Not at all
  - A little
  - Moderately
  - Very much

### Q8. Sleep / Energy: Does your bladder problem affect:
- A. Affect your sleep? Not at all
  - A little
  - Moderately
  - A lot
- B. Make you feel worn out and tired? Not at all
  - A little
  - Moderately
  - A lot

### Q9. Severity Measures:
- Wear pads to keep dry? Never
- Sometimes
- Often
- All the time
- Be careful how much fluid you drink? Never
- Sometimes
- Often
- All the time
- Change your underclothes because they get wet? Never
- Sometimes
- Often
- All the time
- Worry in case you smell? Never
- Sometimes
- Often
- All the time

### Q10. Symptom Severity Scale:
- Frequency of urination: None
  - Mild
  - Moderate
  - Severe
- Nocturia: None
  - Mild
  - Moderate
  - Severe
- Urgency: None
  - Mild
  - Moderate
  - Severe
- Urgo Incontinence: None
  - Mild
  - Moderate
  - Severe
- Stress Incontinence: None
  - Mild
  - Moderate
  - Severe
- Nocturnal Enuresis: None
  - Mild
  - Moderate
  - Severe
- Interurrense Incontinence: None
  - Mild
  - Moderate
  - Severe
- Urinary tract infection: None
  - Mild
  - Moderate
  - Severe
- Bladder pain: None
  - Mild
  - Moderate
  - Severe
- Postvoid dribble: None
  - Mild
  - Moderate
  - Severe

### Calculation of Scores:
- Q1 Overall Score = ((Actual Score - 1)/4) x 10
- Q2 Overall Score = ((Actual Score - 1)/3) x 10
- Q3 Overall Score = ((Actual Total Score – 2)/6) x 10
- Q4 Overall Score = ((Actual Total Score – 2)/6) x 10
- Q5 Overall Score = (Sum of scores to 5A, 5B, 6C) x 10
- Q6 Overall Score = (Sum of scores to 5A, 5B, 6C) x 10
- Region C response is "Not Applicable"
- Region C response is other than "Not Applicable"
- If Q6 C response is "Not Applicable"
- Calculation of scores should be treated as missing value
- Q7 Overall Score = (Sum of scores to 7A, 7B, 7C) x 10
- Q8 Overall Score = (Actual Total Score – 2)/6) x 10
- Q9 Overall Score = (Actual Total Score – 4)/12 X 10

### PART 1 SCORE = (Q1. OVERALL SCORE) + (Q2. OVERALL SCORE)

### PART 2 SCORE = OVERALL SCORE OF Q3 TO Q9

### PART 3 SCORE = OVERALL SCORE OF Q10
RECURRENT UTI PATIENT QUESTIONNAIRE

1. When did you first start getting urine infections?
☐ Less than six months ago
☐ 6-12 months ago
☐ 1 - 2 years ago
☐ 2 - 5 years ago
☐ More than 5 years ago
☐ since childhood (age of first infection)

2. How many infections have you had in the last:
☐ 6 months
☐ 12 months

3. Do you think that anything in particular ‘triggers’ your urinary infections? If so, please describe below:
________________________________________________________________________________________

4. What symptoms do you get with a urine infection? (Tick all that apply)
☐ Burning and/or stinging when passing urine
☐ Burning and/or stinging after passing urine
☐ Passing urine frequently
☐ Rushing to the toilet
☐ Pains in abdomen/stomach
☐ Pains in flank/side
☐ Pains in back
☐ Fever
☐ Not listed above (please describe below)
________________________________________________________________________________________

5. How soon after antibiotics finish does the infection return?
☐ Less than a week
☐ More than a week

6. Are your urine infections usually brought on by sexual intercourse?
YES / NO

7. Have you ever passed air in your urine? YES / NO

8. Have you ever passed blood in your urine? YES / NO

9. Do you have problems with constipation? YES / NO UTI Patient Questionnaire

10. Do you still have periods? YES / NO If ‘NO’ how long ago did they stop? …………………

11. Do you use HRT (hormone replacement)? YES / NO

12. If you have any urinary symptoms when you don’t have an infection, please tick the relevant boxes below:
☐ Passing urine frequently
☐ Rushing to the toilet
☐ Abdominal pain
☐ Straining to pass water
☐ Poor flow of urine or slow stream
☐ Feeling of incomplete bladder emptying
☐ Burning or stinging
☐ Leakage of urine
☐ Fever

13. Do you use feminine hygiene products e.g. perfumed sprays or Vagisil? YES/NO

14. Do you smoke? YES / NO

15. Do you have or have you had any of the following?
☐ Diabetes
☐ Kidney stones
☐ Operations on kidney/bladder
☐ Multiple sclerosis/other neurological disease
☐ Urinary catheter
☐ Long-term steroids
☐ are you pregnant?
☐ Urinary