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Comparative Assessment of Antibiotic Utilization in Patients with Renal Impairment and Normal Renal Function

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ABSTRACT:
Antibiotics are essential medicines used for the treatment and prevention of bacterial infections. Rational antibiotic therapy requires appropriate selection of the antimicrobial agent, dose, route, frequency and duration to achieve effective treatment while minimizing adverse effects and antimicrobial resistance. Renal function is an important consideration because many antibiotics are eliminated primarily through the kidneys. In patients with renal impairment, reduced renal clearance may prolong drug half-life and increase antibiotic accumulation, thereby increasing the risk of toxicity.Renal impairment may occur as acute kidney injury (AKI) or chronic kidney disease (CKD). Assessment of renal function using serum creatinine, estimated Glomerular filtration rate (eGFR) and creatinine clearance helps identify patients who may require modification of antibiotic therapy. Renal dose adjustment may involve reducing the dose, extending the dosing interval, or both, depending on the antibiotic and severity of renal impairment. Renal dysfunction can also alter pharmacokinetic processes, including absorption, distribution, metabolism and elimination. Antibiotics such as Aminoglycosides and Vancomycin require careful monitoring because of their renal elimination and potential toxicity. Therefore, appropriate renal assessment, rational antibiotic use and therapeutic drug monitoring when indicated are essential for safe and effective antimicrobial therapy.

Keywords: *Antibiotics, rational use, renal impairment, AKI, CKD, pharmacokinetics, renal dose adjustment, eGFR, creatinine clearance.*

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I. INTRODUCTION:

ANTIBIOTICS:

Antibiotics are antimicrobial agents used to inhibit the growth of or destroy bacteria. The first clinically effective antibiotic, Salvarsan, was introduced in 1910 for the treatment of syphilis. Over the past century, antibiotics have transformed modern medicine by significantly reducing deaths from bacterial infections and contributing to an increase in average human life expectancy. The discovery of penicillin by Alexander Fleming in 1928 marked a major milestone in medical history and initiated the golden era of antibiotic discovery, which reached its peak during the mid-1950s. Penicillin revolutionized the treatment of bacterial diseases and paved the way for the development of numerous other antimicrobial agents. An antibiotic is defined as a chemical substance that either inhibits the growth of bacteria or destroys them, thereby helping to treat bacterial infections effectively.

ROLE OF ANTIBIOTICS IN CLINICAL PRACTICE:

Antibiotics play a vital role in modern clinical practice by preventing and treating bacterial infections. They are widely prescribed for infections involving the respiratory tract, urinary tract, gastrointestinal system, skin and soft tissues, and bloodstream. Appropriate and judicious use of antibiotics is essential not only for achieving successful treatment outcomes but also for minimizing the emergence of antimicrobial resistance.

The major clinical applications of antibiotics include:

- **Treatment of bacterial infections:** Antibiotics are used to manage both mild and severe bacterial diseases, including streptococcal pharyngitis, urinary tract infections, pneumonia, and sepsis.
- **Surgical prophylaxis:** Antibiotics are administered before and, when necessary, after surgical procedures to reduce the risk of postoperative wound infections.

- **Protection of high-risk patients:** Preventive antibiotic therapy is provided to individuals with weakened immune systems, such as patients undergoing chemotherapy, organ transplantation, or other immunosuppressive treatments, to lower their risk of developing bacterial infections.

RATIONAL USE OF ANTIBIOTICS:

- Rational use of antibiotics is important to avoid adverse effects, antibiotic resistance and increased healthcare costs. Antibiotics should only be used for bacterial infections and are not needed for most viral infections.
- In selecting an antibiotic, the aetiological agent, patient factors, pharmacokinetic properties of the drug, and efficacy of therapy should be considered. Antibiotics must achieve effective concentrations at the site of infection.
- Guidelines provide recommendations for common infections, but clinical judgement is also needed. Empiric therapy should be modified based on culture results and the patient's response.

RENAL SYSTEM:

The renal system or urinary system, filters blood to remove waste and extra water. It consists of the kidneys, ureters, a bladder, and a urethra. The overall function of the system filters approximately 200 litres of the fluid a day from renal blood flow which allows for toxins, metabolic waste products, and excess ion to be excreted while keeping essential substance in the blood. The kidney regulates plasma osmolarity by modulating the amount of water, solutes, and electrolytes in the blood.

FUNCTIONS OF KIDNEY IN DRUG ELIMINATION:

- The kidneys play a vital role in eliminating drugs and their metabolites from the body, thereby maintaining safe and effective drug concentrations. The major functions involved in drug elimination include:
- **Glomerular filtration:** Drugs and their metabolites that are not bound to plasma proteins are freely filtered from the bloodstream into the renal tubules through the glomeruli.
- **Tubular secretion:** Certain drugs are actively transported from the blood into the renal tubular fluid, enhancing their elimination from the body.
- **Tubular reabsorption:** Some drugs may be reabsorbed from the renal tubules back into the bloodstream, reducing the amount of drug excreted in the urine.
- **Urinary excretion:** Drugs and their metabolites present in the tubular fluid are ultimately removed from the body through urine.
- **Regulation of urinary pH:** The pH of urine influences the ionization and reabsorption of drugs, thereby affecting their rate of elimination.
- **Maintenance of renal blood flow:** Adequate blood flow to the kidneys is essential for efficient filtration, secretion, and overall drug clearance.
- **Regulation of urine flow**: Variations in urine flow can affect the speed at which drugs and their metabolites are excreted from the body.
- **Elimination of water-soluble metabolites:** The kidneys efficiently remove many water-soluble drug metabolites from the circulation, preventing their accumulation.
- **Prevention of drug accumulation:** Effective renal elimination prevents excessive accumulation of renally excreted drugs.

RENAL ELIMINATION OF ANTIBIOTICS:

- Renal elimination is one of the major routes by which antibiotics are removed from the body. It mainly occurs through glomerular filtration, active tubular secretion, and, to a lesser extent, tubular reabsorption. Many commonly used antibiotics, including aminoglycosides, vancomycin, penicillins, cephalosporins, and fluoroquinolones, are substantially eliminated through the kidneys.
- In patients with normal renal function, these drugs are efficiently cleared, maintaining appropriate plasma concentrations. However, in patients with renal impairment, reduced glomerular filtration and tubular function can decrease antibiotic clearance.
- This may result in prolonged half-life, increased drug accumulation, and a higher risk of adverse drug reactions or toxicity. Therefore, renal function should be assessed using parameters such as serum creatinine and creatinine clearance/eGFR before and during antibiotic therapy.
- Depending on the degree of renal impairment, the antibiotic dose may need to be reduced or the dosing interval extended. Appropriate dose adjustment helps maintain therapeutic effectiveness while minimizing toxicity and supports rational antibiotic utilization in patients with renal impairment.

RENAL IMPAIRMENT:

Renal impairment is a condition in which the kidneys have a reduced ability to perform their normal functions, particularly the filtration of blood and elimination of metabolic waste products. It is commonly associated with a decrease in glomerular filtration rate (GFR) and an increase in serum creatinine levels. Renal impairment may be temporary or progressive and can result from conditions such as diabetes, hypertension, infections, kidney diseases, or nephrotoxic drugs. Reduced kidney function can also affect fluid and electrolyte balance and the elimination of drugs from the body. Therefore, renal impairment is an important consideration in drug selection, dosage adjustment, and antibiotic therapy, especially for drugs that are primarily eliminated through the kidneys.

Renal failure is split into two main types:

- ✓ **Acute kidney injury (AKI)**: which happens fast over hours or days, and
- ✓ **Chronic kidney disease (CKD)**: which builds up slowly over three months or more.

CLASSIFICATION / STAGES BASED ON eGFR:

According to the KDIGO classification, chronic kidney disease (CKD) is categorized into different stages based on eGFR.

STAGES	BASED ON SEVERITY	eGFR ml/min
Stage 1	Normal or high	eGFR ≥90 mL/min/1.73 m².
Stage 2	Mildly decreased	eGFR 60-89mL/min 1.73 m².
Stage 3 A	Mild to moderately decreased	eGFR45–59mL/min/1.73m².
B	Moderatelyto severely decreased	eGFR30–44mL/min/1.73m².
Stage 4	Severely decreased	eGFR15–29mL/min/1.73m².
Stage 5	Kidney failure	eGFR <15 mL/min/1.73 m².

EFFECTS OF RENAL DYSFUNCTION ON PHARMACKOKINETIC PROCESSES:

- ➢ **ABSORPTION:**
  - Renal dysfunction may delay drug absorption from the gastrointestinal tract.
  - Delayed gastric emptying can increase the time required to reach peak plasma concentration.
  - In severe renal dysfunction, oral bioavailability may increase due to reduced first-pass metabolism.
  - Binders may reduce the absorption of certain antibiotics, particularly fluoroquinolones.

- ➢ **DISTRIBUTION:**
  - Renal dysfunction can cause reduced plasma protein binding, especially of acidic drugs.
  - This may increase the unbound (active) fraction of the drug.
  - Volume of distribution (Vd) may increase due to fluid overload, altered protein binding, and changes in tissue binding.

- ➢ **METABOLISM:**
  - Severe renal dysfunction can reduce drug metabolism, even for drugs primarily metabolized by the liver.
  - Accumulation of uremic substances may interfere with hepatic drug-metabolizing enzymes.
  - Reduced metabolism can increase drug exposure and half-life, potentially increasing the risk of adverse effects.
- ➢ **ELIMINATION:**
  - Reduced renal function decreases the renal clearance of drugs, particularly drugs eliminated unchanged in urine.
  - This can cause drug accumulation and prolonged half-life.
  - Therefore, dose or dosing interval adjustment may be required in patients with renal impairment.

ANTIBIOTICS REQUIRING RENAL DOSE ADJUSTMENT:

- Renal impairment can alter the elimination of antibiotics, particularly those that are predominantly cleared through the kidneys. As kidney function decreases, the clearance of certain antimicrobial agents may be reduced, resulting in increased drug exposure and a

potential risk of accumulation. Therefore, antibiotic therapy should be appropriately adjusted according to the patient's renal function**.**

- Renal function is commonly considered using parameters such as estimated glomerular filtration rate (eGFR) or creatinine clearance. Depending on the antimicrobial agent and the degree of renal impairment, dose adjustment may involve reducing the individual dose, extending the dosing interval, or modifying both.
- The purpose of renal dose adjustment is to maintain sufficient antimicrobial exposure for effective treatment while minimizing the possibility of adverse effects. Inadequate dose reduction may result in excessive drug exposure and toxicity, whereas excessive dose reduction can lead to insufficient antimicrobial concentrations and reduced treatment effectiveness.
- Dose requirements may also differ according to the severity of infection, pharmacokinetic properties of the antibiotic, and whether the patient is receiving dialysis. Therefore, renal function should be assessed regularly, and antimicrobial therapy should be reviewed when there are significant changes in kidney function.

II. AIM AND OBJECTIVES:

Aim:

To comparatively assess the pattern, appropriateness, and outcomes of antibiotic utilization in patients with renal impairment and patients with normal renal function, with special emphasis on dose adjustment, prescribing practices, and treatment outcomes.

Objectives:

- To evaluate the pattern of antibiotic utilization in patients with renal impairment and compare it with patients having normal renal function.
- To assess the appropriateness of antibiotic selection, dosage, frequency, and duration according to renal function.
- To determine the proportion of antibiotics requiring renal dose adjustment and evaluate whether appropriate dose modifications were made.
- To compare the incidence of antibiotic-related adverse drug reactions (ADRs) and nephrotoxicity between the two groups.
- To assess the clinical outcomes of antibiotic therapy, including treatment response, length of hospital stay, and mortality, in patients with renal impairment versus those with normal renal function**.**
- To identify factors associated with inappropriate antibiotic utilization in patients with renal impairment**.**

III. MATERIAL AND METHODS:

1.Study Design:
Prospective observational comparative study.
2.Study Site:
Department of General Medicine and associated wards in hospital.
3.Study Duration:
Four months**.**
4.Study Population:
Hospitalized adult patients receiving systemic antibiotics.
5.Sample Size:
Nearly 70 to 80 people on both renal impairment and no renal impairment
Inclusion Criteria:
Group A
Adults diagnosed with early impairment (based on serum creatinine)
Receiving at least one antibiotic
Group B
Adults with normal renal function
Receiving at least one antibiotic

6.Exclusion Criteria

- Patients on dialysis
- End stage renal disease
- Kidney transplant recipients
- Patient with incomplete medical records

7.Source of data:

Data will be collected from:

- Patient medical records
- Physician prescriptions
- Medication administration records
- Laboratory reports
- Hospital electronic medical records

8.Method of data collection:

Patient data collected using a structured data collection form containing:

- Patient information
- Diagnosis
- Renal function
- Antibiotics details
- Patient assessmim

IV. RESULT AND DISCUSSION:

BASED ON GENDER WISE DISTRIBUTION:

A total of 70 patients were included in the study. Among them, 46 (65.70%) were male, whereas 24 (34.30%) were female. Thus, males represented nearly two-thirds of the total study population, demonstrating a higher proportion of male participants compared with females. The male-to-female ratio was approximately 1.92:1.

Table:1

Characteristic	Category	No. of Patients	Percentage
Gender	Male	46	65.7%
	Female	24	34.3%
Total		70	100%

BASED ON AGE WISE DISTRIBUTION:

The age distribution showed that the largest proportion of patients belonged to the 41–60-year age group, comprising 29 patients (41.40%). This was followed by the 61–80-year age group, which included 23 patients (32.90%). A total of 15 patients (21.40%) were between 18 and 40 years of age, while only 3 patients (4.30%) were aged above 80 years.

The 41–60-year age group therefore represented the major age category in the study, whereas patients aged >80 years constituted the smallest proportion.

Table:2

Age Group	No. of Patients	Percentage
18–40 years	15	21.4%
41–60 years	29	41.4%
61–80 years	23	32.9%
>80 years	3	4.3%
Total	**70**	**100%**

RENAL FUNCTION GROUP:

Renal function assessment revealed that 39 patients (55.71%) were categorized as having severe renal impairment, representing the largest group. Early renal impairment was observed in 14 patients (20.00%), whereas 13 patients (18.57%) were classified under renal impairment. Only 4 patients (5.71%) had normal renal function. When the renal impairment categories are considered together, 66 of the 70 patients were classified into one of the reported renal impairment categories, while only four patients had normal renal function

Most of the patient who are all having early-stage renal impairment may develop further renal impairment with the long-term use of antibiotics without known about their toxicity and rational use

Table:3

Final group	No. of patients	Percentage
Severe renal impairment	39	55.71%
Early renal impairment	14	20.00%
Renal impairment	13	18.57%
Normal renal function	4	5.71%
Total	**70**	**100%**

DOSAGE ADJUSTMENT:

A Total 70 patients evaluated, 25 patients (35.71%) required renal dose adjustment, whereas 34 patients (48.57%) did not require dose adjustment. In 11 patients (15.71%), renal dose adjustment was either not applicable or antibiotic-related data were unavailable. Thus, more than one-third of the total study population had antibiotic therapy requiring consideration of renal dose adjustment**.**Vancomycin, meropenem, nitrofurantoin, cefepime, doxycycline these are the drugs were mostly needed renal dosage adjustment in our study

Table:4

Renal Dose Adjustment	No. of patients	Percentage
Yes	25	35.71%
No	34	48.57%
Not applicable / No antibiotic data	11	15.71%
Total	**70**	**100%**

CLASSES OF ANTIBIOTICS:

The antibiotic utilization pattern showed that cephalosporins were the most frequently represented antibiotic class, occurring in 32 patients (45.71%). The second most frequently represented class was β-lactam antibiotics, used in 9 patients (12.86%), followed by glycopeptides, used in 7 patients (10.00%).

Carbapenems, macrolides and nitroimidazoles were each reported in 6 patients, accounting for 8.57% each. β-lactamase inhibitor combinations were reported in 4 patients (5.71%).Aminoglycosides, tetracyclines, fluoroquinolones and penicillins were each represented in 3 patients (4.29%). Sulfonamides, lincosamides, oxazolidinones and aminopenicillins were the least frequently represented classes, with one patient each (1.43%).

Table:5

Antibiotic class	No. of patients (n)	Percentage (%)
Cephalosporins	32	45.71%
Glycopeptides	7	10.00%
β-Lactam antibiotics	9	12.86%
Carbapenems	6	8.57%
Aminoglycosides	3	4.29%
Macrolides	6	8.57%
Tetracyclines	3	4.29%
Nitroimidazoles	6	8.57%
Fluoroquinolones	3	4.29%
Sulfonamides	1	1.43%
Lincosamides	1	1.43%
Oxazolidinones	1	1.43%
Aminopenicillins	1	1.43%
Penicillins	3	4.29%
β-Lactamase inhibitor combinations	4	5.71%

ANTIBIOTIC THERAPY PATTEN:

Among the 58 patients for whom antibiotic therapy pattern was available, 32 patients (55.17%) received monotherapy, whereas 26 patients (44.83%) received combination antibiotic therapy.

Monotherapy therefore represented the more frequently observed treatment pattern, accounting for more than half of the patients with available antibiotic therapy data. Combination therapy was reported in approximately two-fifths of the patients.

Table: 6

Therapy type	No. of patients (n)	Percentage (%)
Monotherapy / Single therapy	32	55.17%
Combination therapy	26	44.83%
Total	58	100%

ANTIBIOTICS PRESCRIBED FROM ESSENTIAL MEDICINE LIST

Among 70 patients, lot of antibiotics prescribed for the bacterial infection and risk of infection caused due to other co morbidities. About 75% of antibiotics prescribed from essential medicine and remaining 25% of antibiotics not from the list of essential medicine.

Table: 7

Essential medicine list	Percentage (%)
Antibiotics from EML	75%
Antibiotics not from EML	25%

V. Discussion:

The present study evaluated antibiotic utilization among hospitalized patients with different levels of renal function, with particular emphasis on renal impairment and the need for dose adjustment. A total of 70 patients were included. The study population was predominantly male (65.70%), while females accounted for 34.30%. The largest proportion of patients belonged to the 41–60-year age group (41.40%), followed by 61–80 years (32.90%).

Renal function assessment showed that severe renal impairment was the most common category, comprising 39 patients (55.71%). Early renal impairment was observed in 14 patients (20.00%), while 13 patients (18.57%) were categorized as having renal impairment. Only 4 patients (5.71%) had normal renal function. This distribution highlights the importance of assessing renal function when selecting and dosing antibiotics, particularly because reduced renal clearance can increase drug accumulation and toxicity.

Regarding renal dose adjustment, 25 patients (35.71%) required adjustment of antibiotic dosage, whereas 34 patients (48.57%) did not require adjustment. For 11 patients (15.71%), dose adjustment was either not applicable or antibiotic-related information was unavailable. The finding that more than one-third of the patients required renal dose adjustment emphasizes the importance of regular assessment of serum creatinine, eGFR or creatinine clearance during antibiotic therapy.

Cephalosporins were the most frequently represented antibiotic class, accounting for 32 patients (45.71%), followed by β-lactam antibiotics (12.86%) and glycopeptides (10.00%). Carbapenems, macrolides and nitroimidazoles each accounted for 8.57%. The utilization of several antibiotic classes in patients with renal impairment demonstrates the need to consider individual pharmacokinetic properties and renal elimination when selecting therapy.

Among the 58 patients for whom antibiotic therapy patterns were available, monotherapy was more common, with 32 patients (55.17%), while 26 patients (44.83%) received combination therapy. This suggests that single-agent therapy was the predominant treatment approach in the available data, although combination therapy was also frequently used.

Among 70 patients, lot of antibiotics prescribed for the bacterial infection and risk of infection caused due to other co morbidities. About 75% of antibiotics prescribed from essential medicine and remaining 25% of antibiotics not from the list of essential medicine.

Drug utilization study shows that combination therapy is mostly given for the patient with severe infections. It shows that about 25% of antibiotics not from essential list of medicine and also most of the antibiotics is prescribed by brand name.

VI. Conclusion:

The study demonstrates that renal function is an important consideration in antibiotic utilization among hospitalized patients. A large proportion of the study population had renal impairment, with severe renal impairment being the most frequently observed category. More than one-third of the patients required renal dose adjustment, highlighting the importance of appropriate renal assessment before and during antibiotic therapy. Cephalosporins were the most frequently represented antibiotic class, and monotherapy was the predominant treatment pattern among patients with available therapy data. The data shows that lots of irrational use of antibiotics, the drugs not based on renal dose adjustment and about 25% antibiotics are not prescribed from essential medicine list. Overall, appropriate renal function assessment and timely dose adjustment are essential to maintain antibiotic effectiveness, minimize drug accumulation and toxicity, and promote rational antibiotic use in patients with renal impairment.

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