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Original Research Article

A PROSPECTIVE OBSERVATIONAL STUDY OF ANTIBIOTIC PRESCRIBING PATTERNS AND THERAPY MODIFICATIONS IN THE MEDICAL OUTPATIENT DEPARTMENT

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ABSTRACT

Background: Irrational antibiotic prescribing in outpatient departments contributes significantly to antimicrobial resistance (AMR), treatment failure, and increased healthcare burden. Monitoring prescribing patterns and resistance-associated therapy modifications is essential to promote rational antibiotic use and strengthen antimicrobial stewardship practices. **Materials and Methods:** A prospective observational study was conducted among 323 patients attending the Medical Outpatient Department of a tertiary care teaching hospital over 6 months. Patients receiving antibiotic prescriptions were included. Data regarding demographic characteristics, clinical indications, antibiotic classes prescribed, therapy modifications, AMR-related modifications, and adverse drug reactions (ADRs) were collected using a structured proforma and analyzed descriptively. **Results:** Females constituted 61.3% of patients, while 56.3% belonged to the age group ≥40 years. Respiratory tract infections were the most common indication for antibiotic use (24.1%), followed by urinary tract infections (16.1%). Penicillins (29.7%) and nitroimidazoles (26.0%) were the most frequently prescribed antibiotic classes. Antibiotic therapy modification was observed in 25.4% of patients, with drug substitution being the commonest modification type (41.5%). Non-response to therapy accounted for 43.9% of modifications. AMR-associated modifications occurred in 6.8% of patients, while ADRs were reported in 4.3%. Most therapy modifications occurred within ≤3 days (58.5%). **Conclusion:** Respiratory tract infections and penicillins predominated in outpatient antibiotic prescribing. Frequent therapy modifications associated with treatment non-response highlight the need for rational prescribing, culture-guided therapy, and strengthened antimicrobial stewardship strategies to minimize antimicrobial resistance.

INTRODUCTION

Antibiotics are among most commonly prescribed medications in outpatient departments and play a crucial role in treatment of infectious diseases. Appropriate antibiotic therapy reduces morbidity, prevents complications, and improves patient outcomes. However, irrational and excessive use of antibiotics has become a major global public health concern due to the rapid emergence of antimicrobial resistance (AMR). Nearly 50% of antibiotics are prescribed or used inappropriately worldwide.[1] The growing burden of AMR has significantly affected the effectiveness of commonly used antibiotics, leading to prolonged illness, treatment failure, increased healthcare costs, and higher mortality rates.[2]

Outpatient departments (OPDs) contribute substantially to overall antibiotic consumption because infections such as respiratory tract infections, urinary tract infections, gastrointestinal infections, and skin infections are frequently managed empirically at the outpatient level. Respiratory tract infections alone account for a large proportion of antibiotic prescriptions globally, despite many of these infections being viral in origin. Studies have reported that a high percentage (often 40–70% or more) of patients presenting with respiratory infections receive antibiotics, often without microbiological confirmation.[3,4] Empirical

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prescribing is commonly practiced due to limited availability of rapid diagnostic tools and the need for early symptom management. However, inappropriate empirical therapy may lead to therapeutic failure and promote the development of resistant organisms.[5]

Antimicrobial resistance has emerged as a major challenge in routine outpatient practice over the past decade. In 2019, antimicrobial resistance was directly responsible for approximately 1.27 million deaths globally (with 4.95 million associated deaths).[2] Increasing resistance has been reported against commonly prescribed antibiotics such as penicillins, fluoroquinolones, cephalosporins, and macrolides, with resistance rates in urinary and respiratory infections often exceeding 20–50% in many settings.[6] Such modifications (including drug substitution, dose adjustment, escalation, de-escalation, or discontinuation) are usually guided by clinical non-response, culture sensitivity reports, adverse drug reactions, or emerging evidence of resistance.

Monitoring antibiotic prescribing patterns and therapy modifications is essential for promoting rational drug use and strengthening antimicrobial stewardship programs. Evaluating the frequency, nature, and timing of prescription modifications can help identify inappropriate prescribing practices and resistance-associated treatment failures.[7] Despite the increasing concern regarding AMR, limited data are available regarding outpatient antibiotic prescribing patterns and resistance-associated therapy modifications in tertiary care teaching hospitals, particularly in Medical OPDs, especially in resource-limited settings.[8,9,10]

Therefore, the present prospective observational study was undertaken to evaluate antibiotic prescribing patterns and assess the extent and nature of prescription modifications in the Medical Outpatient Department. The study also aimed to identify the frequency and types of therapy modifications and assess the time interval between the initial prescription and subsequent modification of antibiotic therapy.

MATERIALS AND METHODS

This was a prospective observational study conducted in the Medical Outpatient Department (OPD) of Sree Mookambika Institute of Medical Sciences & Hospital over a period for 6 months from Jan 2025 to June 2025. The study included patients attending the Medical OPD who received antibiotic prescriptions during the study period. The study involved minimal risk to participants, and informed consent was obtained from all participants prior to enrollment. Confidentiality of patient information was maintained throughout the study period.

Sample Size Calculation

The minimum required sample size was calculated using the formula:

$$n = \frac{Z^2 \cdot p \cdot (1-p)}{d^2}$$

Where:

- (n) = sample size
- (Z) = 1.96 for 95% confidence interval
- (p) = expected proportion of antibiotic therapy modifications (30%)
- (d) = margin of error (5%)

Assuming an expected prevalence of 30% for antibiotic therapy modifications based on findings from similar studies, with a precision of 5% and 95% confidence interval, the calculated sample size was approximately 323 participants.[11]

Inclusion and Exclusion Criteria

Patients attending the Medical OPD who received one or more antibiotic prescriptions during the study period and were willing to provide informed consent were included in the study. Patients with incomplete medical records, those not receiving antibiotic therapy, and individuals unwilling to participate were excluded from the study.

Methods

Data were collected using a structured data collection proforma that included demographic characteristics such as age and sex, clinical indications for antibiotic prescription, antibiotic classes prescribed, frequency and type of antibiotic therapy modifications, reasons for therapy modification, antimicrobial resistance (AMR)-related modifications, time to therapy modification, and occurrence of adverse drug reactions (ADRs).

Clinical indications for antibiotic prescribing included respiratory tract infections, urinary tract infections, gastrointestinal infections, skin and soft tissue infections, pelvic inflammatory disease, febrile illness, and other infectious conditions. Antibiotic classes prescribed were categorized into penicillins, nitroimidazoles, fluoroquinolones, cephalosporins, macrolides, tetracyclines, and others.

Antibiotic therapy modifications were assessed based on changes in prescribed antibiotic regimens during follow-up and were categorized as drug substitution, dose adjustment, escalation, de-escalation, or discontinuation of therapy. Reasons for modification included non-response to therapy, culture-guided changes, adverse drug reactions, and empirical modifications. AMR-related modifications and adverse drug reactions were documented from patient records and clinical evaluation during follow-up visits.

Statistical Analysis

Descriptive methods were used to summarize the data. Qualitative variables such as age group, sex, clinical indications, antibiotic classes prescribed, therapy modifications, AMR-related modifications and adverse drug reactions were expressed as frequency and percentage.

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RESULTS

Females constituted 61.3% and males 38.7%. Most patients belonged to age group ≥40 years (56.3%), 21–40 years (30.3%). Respiratory tract infections were the most common indication for antibiotic use (24.1%), while urinary tract infections (16.1%) and gastrointestinal infections (12.7%). [Table 1]

Table 1: Demographic Characteristics and Clinical Indications

Variable	Category	n (%)
Sex	Male	125 (38.7%)
	Female	198 (61.3%)
Age (years)	≤20	43 (13.3%)
	21–40	98 (30.3%)
	≥40	182 (56.3%)
Clinical Indications	Respiratory tract infection	78 (24.1%)
	Urinary tract infection	52 (16.1%)
	Gastrointestinal infection	41 (12.7%)
	Skin & soft tissue infection	36 (11.1%)
	Febrile illness	30 (9.3%)
	Pelvic inflammatory disease	22 (6.8%)
	Others	64 (19.8%)

Penicillins were most frequently prescribed antibiotics (29.7%). Nitroimidazoles (26.0%). Fluoroquinolones (16.1%) and cephalosporins (12.7%) were also commonly prescribed. [Table 2]

Table 2: Distribution of Antibiotic Classes Prescribed

Antibiotic Class	n (%)
Penicillins	96 (29.7%)
Nitroimidazoles	84 (26.0%)
Fluoroquinolones	52 (16.1%)
Cephalosporins	41 (12.7%)
Macrolides	28 (8.7%)
Tetracyclines	22 (6.8%)

Antibiotic therapy modification was observed in 25.4% of patients. Drug change was the most common modification type (41.5%), followed by dose adjustment (22.0%). Non-response to therapy was the leading reason for modification (43.9%). while culture-guided changes accounted for 26.8%. [Table 3]

Table 3: Frequency and Types of Antibiotic Therapy Modification

Variable	Category	n (%)
Antibiotic Modification	Yes	82 (25.4%)
	No	241 (74.6%)
Modification Type	Drug change	34 (41.5%)
	Dose adjust	18 (22.0%)
	Escalation	14 (17.1%)
	De-escalation	10 (12.2%)
	Stop	6 (7.3%)
Reasons for Modification	Non-response	36 (43.9%)
	Culture	22 (26.8%)
	ADR	12 (14.6%)
	Empirical	12 (14.6%)

AMR modification was identified in 6.8% of patients. Among patients who required antibiotic therapy modification (n=82), most modifications occurred within ≤3 days (58.5%). ADR were reported in 4.3% of patients. [Table 4]

Table 4: Antimicrobial Resistance Modification, Duration of modification, and ADR

Variable	Category	n (%)
Antimicrobial Resistance Modification	Yes	22 (6.8%)
	No	301 (93.2%)
Duration of modification	≤3 days	48 (58.5%)
	4–5 days	24 (29.3%)
	>5 days	10 (12.2%)
ADR	Present	14 (4.3%)
	Absent	309 (95.7%)

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DISCUSSION

Antibiotic prescribing in outpatient settings plays a major role in antimicrobial resistance and therapy-related complications. This prospective observational study evaluated antibiotic prescribing patterns and resistance-associated therapy modifications in the Medical OPD. Penicillins and nitroimidazoles were the most commonly prescribed antibiotics, while therapy modifications were frequently associated with treatment non-response, emphasizing the importance of rational prescribing and early monitoring strategies.

In our study, female patients and older adults constituted the majority of the study population. Respiratory tract infections emerged as the most common clinical indication for antibiotic prescribing, followed by urinary and gastrointestinal infections, reflecting the common infectious conditions encountered in the Medical OPD. Similarly, Priyadharsini et al. reported that antibiotics were prescribed in 17.5% of encounters, with penicillins and quinolones being the predominant antibiotic groups prescribed.[12] Similarly, Mononen et al. reported that women were slightly more to receive antibacterial prescriptions than men (adjusted probability 1.09; 95% CI: 1.08–1.11). While antibacterial prescribing increased with age, reaching 15.1% among patients aged ≥65 years.[13] Furthermore, Kasse et al. reported a pooled antimicrobial prescribing rate of 66% (95% CI: 0.57–0.73) for outpatients with respiratory tract infections across 36 included studies.[14] These findings suggest that female sex, older age, and respiratory tract infections are commonly observed demographic and clinical patterns associated with outpatient antibiotic prescribing in outpatient settings across diverse healthcare systems.

Our findings demonstrated that penicillins and nitroimidazoles were the most frequently prescribed antibiotic classes. The prescribing trend indicates a preference for broad-spectrum agents commonly used in routine outpatient infectious disease management. Similarly, Priyadharsini et al. observed that penicillins and quinolones were the predominant antibiotic groups prescribed in outpatient departments. Amoxicillin emerging as most commonly prescribed antibiotic.[12] Similarly, Zhang et al. reported that amoxicillin accounted for 28.1% of antibiotic prescriptions, followed by first-generation cephalosporins at 26.0%, with respiratory indications driving 47.3% of all prescriptions.[15] Furthermore, Mahmood et al. reported that penicillins accounted for approximately 50–60% of all antibiotic prescriptions in outpatient and emergency settings, with amoxicillin-clavulanate being the most commonly prescribed penicillin for respiratory tract infections.[16] These findings are consistent with prescribing trends reported in multiple outpatient studies, reflecting their established safety profile, broad-spectrum activity, and consistency with standard treatment guidelines for common community-acquired infections.

The present study observed that a considerable proportion of patients required modification of antibiotic therapy. Drug substitution was the predominant form of modification, and treatment non-response was the leading reason for altering therapy. Similarly, Yamaki et al. reported that 72% of patients with gram-negative bacterial infections had antibiotic regimen modifications, with lack of patient response (14%), additional history reviewed (9%), and clinical decompensation (7%) being the most common reasons for modification.[17] Further, Dunne et al. defined treatment failure in outpatient urinary tract infections as receipt of a subsequent antibiotic prescription or UTI-related hospitalization within 28 days, and reported that 34.3% of patients receiving inappropriate empiric therapy required further treatment compared with 18.9% receiving susceptible therapy.[18] Furthermore, Neill et al. reported substantial variation in antibiotic treatment failure definitions, with prescription changes, escalation of care, and changes in clinical condition identified as the three principal components used to define treatment failure outcomes.[19] These findings suggest that a substantial proportion of outpatient antibiotic prescriptions require modification, with therapeutic non-response as the dominant reason, highlighting the critical need for structured follow-up and outcome monitoring in the medical OPD.

In this study, AMR modifications were observed in a smaller subset of patients. Most therapy modifications occurred early after initiation of treatment, while adverse drug reactions were reported infrequently, suggesting an overall acceptable safety profile of prescribed antibiotics. Similarly, Habboush et al. reported nearly 28% of outpatient antibiotic prescriptions were unnecessary and 29.5% involved broad-spectrum Watch-category antibiotics associated with a higher risk of promoting resistance. highlighting the ongoing contribution of outpatient antibiotic prescribing to antimicrobial resistance concerns.[20] Similarly, Dunne et al. reported that resistance rates among Enterobacterales isolates causing outpatient urinary tract infections exceeded 20% for quinolones, β-lactams, and trimethoprim-sulfamethoxazole, with 1% of isolates resistant to all commonly available oral antibiotic classes.[18] Furthermore, Agrawal et al. reported that antimicrobial-associated ADRs constituted 54.33% of reported ICSRs, with skin and subcutaneous tissue reactions being most common (52.56%), followed by gastrointestinal disorders (11.19%).[21] These findings collectively suggest that while AMR-attributable modifications and adverse drug reactions remain relatively infrequent in outpatient settings, their early identification through culture-guided review and active pharmacovigilance is essential to prevent resistance progression and ensure patient safety in routine antibiotic prescribing.

Overall, the study showed that respiratory tract infections and penicillins predominated in outpatient

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antibiotic prescribing, while therapy modifications were mainly driven by treatment non-response. The findings emphasize the need for rational prescribing, culture-guided therapy, and strengthened antimicrobial stewardship practices.

Limitations

This study was conducted in a single tertiary care hospital Medical OPD, limiting generalizability to other healthcare settings. Microbiological confirmation was not available for all patients, and follow-up duration was limited. The observational design could not establish causality. Potential prescribing bias and reliance on clinical records may also have influenced the findings.

CONCLUSION

This study highlights substantial antibiotic utilization in the Medical OPD, particularly for respiratory tract infections, with penicillins being the most commonly prescribed agents. A notable proportion of patients required therapy modification, mainly due to inadequate clinical response. These findings underscore the importance of antimicrobial stewardship, regular prescription review, and culture-guided treatment strategies to promote rational antibiotic use and minimize antimicrobial resistance.

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