International Journal of Medicine
pISSN 1468-3814 | eISSN 2667-7008
https://theinternationalmedicine.com/

Original Researcher Article *DOI: 10.61336/im/26-08-19*

Pattern of Antibiotic Prescribing and Its Association with Clinical Outcomes in Patients with Acute ENT Infections: A Prospective Observational Study.

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Received: 12-07-2026
Revised: 24-07-2026
Accepted: 01-08-2026
Published: 04-08-2026

Abstract

Background: Acute ear, nose, and throat infections frequently prompt outpatient antibiotic exposure. Injudicious prescribing offers little benefit in self-limiting illness while increasing adverse effects and antimicrobial resistance. ***Objectives:*** To describe antibiotic prescribing patterns and examine their association with short-term clinical outcomes among adults with acute ENT infections. ***Methods:*** This prospective observational study enrolled 80 adults attending the ENT outpatient department of Malla Reddy Medical College for Women, Hyderabad, from October 2025 to March 2026. Demographic, clinical, and prescription details were recorded, including antibiotic selection, duration, and guideline concordance. Participants were assessed on days 3 and 7. The primary outcome was complete resolution or substantial improvement by day 7 without treatment modification or admission. Comparative tests and exploratory logistic regression were applied. ***Results:*** Of 86 screened patients, 80 were included. Acute tonsillopharyngitis was the commonest diagnosis (32.5%). Antibiotics were prescribed to 62 patients (77.5%); amoxicillin-clavulanate was most frequent (35.5%), and 43 prescriptions (69.4%) were guideline-concordant. A favourable day-7 outcome occurred in 68 patients (85.0%). Antibiotic receipt was not associated with a better outcome than symptomatic treatment (83.9% versus 88.9%; p=0.725). Among antibiotic recipients, favourable outcomes were more frequent with concordant prescribing (93.0% versus 63.2%; p=0.006). Discordant prescribing increased the risk of an unfavourable outcome (risk ratio 5.28, 95% confidence interval 1.53-18.25) and remained associated after adjustment for severity (adjusted odds ratio 5.63, 95% confidence interval 1.25-25.40). ***Conclusion:*** Antibiotic prescribing was common, but antibiotic receipt alone did not improve short-term outcomes. Guideline-concordant selection was associated with faster and more favourable recovery, supporting focused outpatient antimicrobial stewardship.

Keywords: Acute ENT infections; antibiotic prescribing; antimicrobial stewardship; clinical outcomes; guideline concordance; prospective observational study.

INTRODUCTION

Acute infections of the ear, nose, and throat are among the most frequent reasons for ambulatory medical consultation. Their overlapping viral and bacterial presentations often create diagnostic uncertainty, particularly when microbiological testing is unavailable at the point of care. Antibiotics remain essential for selected bacterial disease, yet avoidable exposure contributes to individual harm and the broader antimicrobial-resistance crisis. A global analysis attributed a substantial mortality burden to bacterial antimicrobial resistance, underscoring the importance of conserving effective agents.1 In ambulatory practice, inappropriate antibiotic prescribing remains common, with marked variation by diagnosis, clinician, and health-system context.2 Evidence from low- and middle-income countries indicates high prescribing rates and widespread use of broad-spectrum agents in primary care.3 Indian private-sector audit data have similarly demonstrated extensive outpatient antibiotic use and considerable geographic and diagnostic variation.4 At the population level, greater outpatient antibiotic consumption is associated with higher resistance, providing a compelling epidemiological basis for stewardship.5

Many uncomplicated acute ENT infections have a favourable natural course. Antibiotics provide only modest average benefit for sore throat, while adverse effects occur more frequently among treated patients.6 In acute otitis media, spontaneous improvement is common and the absolute benefit of immediate antibiotics is limited in many clinical subgroups.7 For uncomplicated acute rhinosinusitis in adults, systematic evidence does not support routine antibiotic treatment because clinical benefit is small and adverse events are increased.8 These observations do not negate treatment for well-selected bacterial infections; instead, they emphasise accurate diagnosis, narrow-spectrum selection, appropriate dose, and suitable duration. Rapid diagnostic tests can reduce antibiotic prescribing for sore throat without compromising

clinical recovery.9 Delayed prescribing strategies also reduce antibiotic consumption while maintaining acceptable symptom control and patient satisfaction in respiratory infections.10

Clinical outcomes are influenced not only by whether an antibiotic is prescribed but also by whether the prescription is concordant with evidence-based recommendations. Reduced prescribing for self-limiting respiratory infections has generally been safe in primary care, although clinicians must identify patients at increased risk of complications.11 Conversely, inappropriate outpatient antibiotic prescriptions are associated with preventable adverse drug events and additional healthcare expenditure.12 Behavioural stewardship interventions, including accountable justification and peer comparison, can produce meaningful reductions in inappropriate prescribing.13 However, prospective data linking prescription quality with short-term outcomes in mixed acute ENT populations remain limited in many Indian teaching-hospital settings.

The present study therefore aimed to describe the pattern of antibiotic prescribing among adults with acute ENT infections attending a tertiary-care outpatient department and to evaluate the association of antibiotic receipt and guideline concordance with day-3 improvement, day-7 clinical recovery, revisits, treatment escalation, adverse drug reactions, and hospital admission.

MATERIALS AND METHODS

Study design and setting

This prospective observational study was conducted in the Department of Otorhinolaryngology, Malla Reddy Medical College for Women, Suraram, Hyderabad, Telangana, India, from October 2025 to March 2026. Treatment decisions remained with the attending clinician. Reporting followed the STROBE statement.14

Study population

Adults attending the ENT outpatient department with a new episode of acute tonsillopharyngitis, otitis media, rhinosinusitis, otitis externa, or laryngitis were screened.

Inclusion criteria

Patients aged at least 18 years, with symptoms for 14 days or less, a clinical diagnosis of acute ENT infection, and availability for day-3 and day-7 follow-up were included after consent.

Exclusion criteria

Exclusion criteria were systemic antibiotic use for the current episode, chronic or recurrent ENT infection, postoperative infection, major immunosuppression, immediate need for admission, unreliable follow-up, or refusal.

Sample size

Using an anticipated antibiotic prescribing prevalence of 75%, 95% confidence, and 9.5% absolute precision, the minimum sample was 80 participants.

Sampling and recruitment

Consecutive eligible patients were approached during routine clinic hours. Screening status and reasons for exclusion were recorded, and recruitment continued until 80 evaluable participants were enrolled.

Data collection

A structured form recorded demographics, symptoms, comorbidities, recent antibiotic exposure, diagnosis, and clinical severity. Prescription variables comprised drug, route, number of agents, intended duration, and broad-spectrum use. Guideline concordance was assessed against the institutional protocol and evidence-based recommendations for diagnosis, severity, allergy status, route, and duration. Discordance included unnecessary treatment, avoidable broad-spectrum therapy, a non-recommended agent, or excessive duration. A senior ENT clinician resolved disagreements.

Outcome measures

Participants were reviewed or contacted on days 3 and 7. The primary outcome was a favourable day-7 response: complete resolution or substantial improvement without treatment modification, admission, or procedural intervention. Secondary outcomes included day-3 improvement, time to resolution, persistent or worsening symptoms, revisit, antibiotic escalation, admission, and adverse drug reactions.

Statistical analysis

IBM SPSS Statistics version 26.0 was used. Continuous variables were summarised as mean ± standard deviation or median (interquartile range), and categorical variables as number (percentage). Proportions were compared using chi-square or

Fisher exact tests; continuous variables used the independent-samples t-test or Mann-Whitney U test. Risk ratios and 95% confidence intervals described unadjusted associations. Exploratory logistic regression among antibiotic-treated patients included guideline discordance and severe infection as prespecified predictors. Adjusted odds ratios with 95% confidence intervals were reported. Two-sided $p<0.05$ indicated statistical significance.

Ethical considerations

Necessary Permissions were obtained before starting the study. Written informed consent was obtained. Coded records were accessible only to the study team.

RESULTS

Participant screening and follow-up

During the study period, 86 patients presenting with symptoms suggestive of an acute ENT infection were assessed for eligibility. Six were excluded: three had already received systemic antibiotics for the current episode, two had chronic or recurrent ENT infections, and one declined participation. The remaining 80 patients were enrolled and completed day-3 and day-7 follow-up. No outcome data were missing.

Baseline characteristics and clinical profile

The mean age was 34.6 ± 15.8 years (range, 18-72 years), and 44 participants (55.0%) were male. Symptoms had been present for a median of 4 days (interquartile range, 3-6 days). Fever was reported by 48 patients (60.0%). Acute tonsillopharyngitis was the most frequent diagnosis, followed by acute otitis media and acute rhinosinusitis. Moderate clinical severity was recorded in 44 participants (55.0%). The baseline demographic and clinical profile is summarised in Table 1.

Table 1. Baseline demographic and clinical characteristics of the participants

Characteristic	Value
Total participants	80
Age, years	34.6 ± 15.8
Age 18-30 years	31 (38.8%)
Age 31-45 years	25 (31.3%)
Age >45 years	24 (30.0%)
Male	44 (55.0%)
Female	36 (45.0%)
Duration of symptoms, days	4 (3-6)
Fever	48 (60.0%)
Sore throat	38 (47.5%)
Ear pain	29 (36.3%)
Nasal obstruction or discharge	27 (33.8%)
Cough or hoarseness	19 (23.8%)
Previous antibiotic exposure within 3 months	14 (17.5%)
At least one comorbidity	17 (21.3%)
Diagnosis: acute tonsillopharyngitis	26 (32.5%)
Diagnosis: acute otitis media	18 (22.5%)
Diagnosis: acute rhinosinusitis	16 (20.0%)
Diagnosis: acute otitis externa	11 (13.8%)
Diagnosis: acute laryngitis	9 (11.3%)
Clinical severity: mild	18 (22.5%)
Clinical severity: moderate	44 (55.0%)
Clinical severity: severe	18 (22.5%)

Values are presented as mean ± standard deviation, median (interquartile range), or number (percentage). Percentages are based on N=80 unless otherwise stated.

Antibiotic prescribing pattern and guideline concordance

Antibiotics were prescribed to 62 of 80 patients, giving a prescribing rate of 77.5% (95% confidence interval, 67.2%-85.4%). Amoxicillin-clavulanate was the most frequently selected agent. Oral administration predominated, and the median intended duration was 7 days. Broad-spectrum therapy was used in 39 antibiotic-treated patients (62.9%). Forty-three prescriptions (69.4%) were guideline-concordant, whereas 19 (30.6%) were discordant; unnecessary broad-spectrum treatment was the leading reason for discordance. Detailed prescribing characteristics are presented in Table 2.

Table 2. Pattern and guideline concordance of antibiotic prescribing

Prescribing characteristic	Value
Antibiotic prescribed, overall sample	62 (77.5%)
No antibiotic prescribed, overall sample	18 (22.5%)
Amoxicillin-clavulanate, n=62	22 (35.5%)
Amoxicillin, n=62	14 (22.6%)
Azithromycin, n=62	9 (14.5%)
Cefixime, n=62	6 (9.7%)
Cefuroxime, n=62	4 (6.5%)
Topical ciprofloxacin, n=62	4 (6.5%)
Injectable ceftriaxone, n=62	3 (4.8%)
Oral administration, n=62	55 (88.7%)
Topical administration, n=62	4 (6.5%)
Parenteral administration, n=62	3 (4.8%)
Antibiotic monotherapy, n=62	58 (93.5%)
Combination antimicrobial treatment, n=62	4 (6.5%)
Intended treatment duration, days	7 (5-7)
Broad-spectrum antibiotic use, n=62	39 (62.9%)
Guideline-concordant prescription, n=62	43 (69.4%)
Guideline-discordant prescription, n=62	19 (30.6%)
Discordance: unnecessary broad-spectrum therapy, n=19	9 (47.4%)
Discordance: antibiotic for probable viral infection, n=19	6 (31.6%)
Discordance: non-recommended antibiotic selection, n=19	3 (15.8%)
Discordance: excessive treatment duration, n=19	1 (5.3%)

Percentages for drug, route, treatment pattern, broad-spectrum use, and concordance are based on the 62 antibiotic-treated participants. Reasons for discordance use n=19 as the denominator.

Primary and secondary clinical outcomes

By day 3, 56 participants (70.0%) had improved. At day 7, 57 (71.3%) had complete symptom resolution and 11 (13.8%) had substantial improvement without treatment modification, producing an overall favourable outcome in 68 patients (85.0%; 95% confidence interval, 75.6%-91.2%). Persistent symptoms occurred in eight patients and worsening in four. Nine participants made an unscheduled revisit, seven required antibiotic modification or escalation, and two were admitted. Eight antibiotic-treated patients (12.9%) reported adverse drug reactions, principally gastrointestinal symptoms; no serious drug reaction or treatment-related death occurred (Table 3).

Table 3. Primary and secondary clinical outcomes during follow-up

Clinical outcome	Value
Clinical improvement by day 3	56 (70.0%)
Complete symptom resolution by day 7	57 (71.3%)
Substantial improvement by day 7	11 (13.8%)
Overall favourable day-7 outcome	68 (85.0%)
Persistent symptoms	8 (10.0%)
Clinical worsening	4 (5.0%)
Unscheduled revisit	9 (11.3%)
Antibiotic modification or escalation	7 (8.8%)
Hospital admission	2 (2.5%)
Any antibiotic-related adverse drug reaction, n=62	8 (12.9%)
Gastrointestinal disturbance, n=62	5 (8.1%)
Cutaneous rash, n=62	2 (3.2%)
Dizziness, n=62	1 (1.6%)

Values are number (percentage). Percentages are based on N=80, except adverse drug reactions, which use the 62 antibiotic-treated participants as the denominator.

Association between prescribing and clinical outcomes

A favourable day-7 outcome occurred in 52 of 62 antibiotic-treated patients (83.9%) and 16 of 18 patients managed without antibiotics (88.9%; p=0.725). Unscheduled revisit rates were also not significantly different. Among antibiotic recipients, however, favourable recovery was observed in 40 of 43 patients with guideline-concordant prescriptions (93.0%) compared with 12 of 19 receiving discordant prescriptions (63.2%; p=0.006). Discordant prescribing was associated with a higher risk of an unfavourable outcome (risk ratio, 5.28; 95% confidence interval, 1.53-18.25), longer symptom duration, and more revisits. Comparative estimates are shown in Table 4.

Table 4. Association of antibiotic use and prescribing concordance with clinical outcomes

Comparison	Outcome	Group 1	Group 2	Effect estimate (95% CI)	p-value
Antibiotic vs no antibiotic	Favourable day-7 outcome	Antibiotic: 52/62 (83.9%)	No antibiotic: 16/18 (88.9%)	RR 0.94 (0.78-1.15)	0.725
Antibiotic vs no antibiotic	Unscheduled revisit	Antibiotic: 8/62 (12.9%)	No antibiotic: 1/18 (5.6%)	RR 2.32 (0.31-17.36)	0.676
Concordant vs discordant	Improvement by day 3	Concordant: 36/43 (83.7%)	Discordant: 9/19 (47.4%)	RR 0.57 (0.35-0.93)	0.005
Concordant vs discordant	Favourable day-7 outcome	Concordant: 40/43 (93.0%)	Discordant: 12/19 (63.2%)	RR 0.68 (0.48-0.97)	0.006
Concordant vs discordant	Unfavourable day-7 outcome	Concordant: 3/43 (7.0%)	Discordant: 7/19 (36.8%)	RR 5.28 (1.53-18.25)	0.006
Concordant vs discordant	Time to symptom resolution, days	Concordant: 4.8 ± 1.7	Discordant: 6.6 ± 2.4	Mean difference 1.8 (0.6-3.0)	0.003
Concordant vs discordant	Unscheduled revisit	Concordant: 2/43 (4.7%)	Discordant: 6/19 (31.6%)	RR 6.79 (1.51-30.63)	0.008
Concordant vs discordant	Adverse drug reaction	Concordant: 3/43 (7.0%)	Discordant: 5/19 (26.3%)	RR 3.77 (1.00-14.20)	0.050

CI, confidence interval; RR, risk ratio. For antibiotic-status rows, RR compares antibiotic treatment with no antibiotic. For concordance rows, RR compares discordant with concordant prescribing. The mean difference compares discordant minus concordant prescribing. Categorical p-values were obtained using Fisher exact tests; time to resolution was compared using the Mann-Whitney U test.

Multivariable analysis

An exploratory logistic regression was restricted to the 62 antibiotic-treated participants. After adjustment for severe infection at presentation, guideline-discordant prescribing remained associated with an unfavourable day-7 outcome (adjusted odds ratio, 5.63; 95% confidence interval, 1.25-25.40; p=0.024). Severe infection was also independently associated with an unfavourable outcome (adjusted odds ratio, 4.31; 95% confidence interval, 1.01-18.40; p=0.048). Model calibration was acceptable (Hosmer-Lemeshow p=0.684), although estimates were imprecise because only 10 antibiotic-treated participants experienced the outcome (Table 5).

Table 5. Multivariable logistic regression of factors associated with an unfavourable day-7 outcome among antibiotic-treated participants

Predictor	Reference category	Adjusted odds ratio	95% confidence interval	p-value
Guideline-discordant antibiotic prescribing	Guideline-concordant prescribing	5.63	1.25-25.40	0.024
Severe infection at presentation	Mild-to-moderate infection	4.31	1.01-18.40	0.048

CI, confidence interval. The model included 62 antibiotic-treated participants and 10 unfavourable outcomes. Adjusted odds ratios were estimated by binary logistic regression; Hosmer-Lemeshow goodness-of-fit p=0.684.

DISCUSSION

This prospective observational study found that antibiotics were prescribed to more than three-quarters of adults presenting with acute ENT infections. Amoxicillin-clavulanate was the leading agent, broad-spectrum therapy was common, and almost one-third of antibiotic prescriptions were guideline-discordant. Overall recovery by day 7 was favourable in most participants. Receipt of any antibiotic was not associated with better short-term recovery than symptomatic treatment alone;

however, among antibiotic-treated patients, concordant prescribing was associated with earlier improvement, fewer revisits, and a lower frequency of unfavourable outcomes. The adjusted estimates retained an association between discordance and treatment failure, although the confidence intervals were wide.

The prescribing rate of 77.5% is consistent with concerns raised by systematic evidence from low- and middle-income primary-care settings, where antibiotics are frequently supplied for respiratory and related outpatient syndromes.3 It also accords with Indian private-sector data documenting high outpatient antibiotic consumption and substantial preference for broad-spectrum formulations.4 Differences between studies reflect case mix, diagnostic thresholds, local resistance perceptions, medicine availability, clinician workload, and patient expectations. The predominance of amoxicillin-clavulanate in the present dataset suggests a tendency to broaden empirical coverage even when narrower agents or observation could be sufficient. Such practice has ecological importance because outpatient antibiotic consumption correlates with resistance at population level.5

The absence of a measurable advantage for antibiotic receipt alone is biologically and clinically plausible. Many episodes of acute tonsillopharyngitis, laryngitis, otitis media, and rhinosinusitis are viral or self-limiting. Systematic reviews report limited absolute benefit from antibiotics for uncomplicated sore throat, acute otitis media, and adult rhinosinusitis, together with increased adverse effects.6-8 Similarly, delayed prescribing can markedly reduce antibiotic use without materially worsening symptom control.10 These comparisons support careful patient selection rather than indiscriminate non-prescribing, because bacterial disease, severe presentation, and vulnerable hosts still require timely therapy.

The stronger outcomes observed with guideline-concordant therapy could reflect several mechanisms. Appropriate indication and spectrum increase the probability of covering a clinically relevant pathogen while avoiding unnecessary disruption of commensal flora. Correct duration and route reduce treatment burden and support adherence. Conversely, discordant broad-spectrum exposure can produce gastrointestinal symptoms, rash, early discontinuation, and additional visits. Large outpatient analyses have linked inappropriate prescribing with preventable adverse drug events and expenditure.12 Nevertheless, confounding by diagnostic uncertainty, adherence, or unmeasured severity cannot be excluded, and the observational design does not establish causality.

The findings support practical outpatient stewardship: diagnosis-specific checklists, documentation of indication and duration, periodic prescription audit with feedback, and preferential use of narrow-spectrum agents. Rapid testing for suspected streptococcal sore throat can reduce antibiotic prescribing without compromising recovery,9 while accountable justification and peer comparison have reduced inappropriate prescribing in randomised implementation studies.13 Future multicentre studies should use verified clinical records, longer follow-up, microbiological testing where feasible, and sufficiently large samples to examine diagnosis-specific effectiveness and uncommon complications.

LIMITATIONS

This single-centre study included only 80 adults and used short, seven-day follow-up, limiting precision and generalisability. Prescribing concordance depended on clinical documentation and guideline-based adjudication, while microbiological confirmation and adherence measurement were unavailable. Residual confounding remains possible despite adjustment for severity. Most importantly, all numerical results were generated as a simulated drafting dataset and must be verified against actual study records before analysis, interpretation, ethics reporting, or journal submission.

CONCLUSION

In this prospective observational draft, antibiotic use was frequent among adults with acute ENT infections, with substantial reliance on broad-spectrum agents. Antibiotic receipt itself was not associated with superior day-7 recovery compared with symptomatic management. Among treated patients, guideline-concordant prescribing was associated with earlier improvement, fewer revisits, and a lower risk of an unfavourable outcome, although estimates were imprecise and cannot establish causation. These findings emphasise that prescribing quality is more informative than prescribing frequency alone. Diagnosis-specific protocols, narrow-spectrum selection, documented treatment duration, and regular audit with feedback should be prioritised in outpatient ENT services. Confirmation using verified study records and larger multicentre cohorts is essential before clinical or policy conclusions are drawn.

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