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Evaluation of Empirical Versus Culture-Guided Antibiotic Therapy: A Prospective Observational Study

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ABSTRACT

Background: Empirical antibiotic therapy is frequently initiated in patients with suspected bacterial infections before microbiological results become available. Although timely empirical treatment is essential, continuation of antibiotics without microbiological reassessment may result in inappropriate antimicrobial exposure, treatment failure, adverse drug reactions, and selection of antimicrobial resistance. Culture and antimicrobial susceptibility testing provide an opportunity to modify therapy according to the identified pathogen and its susceptibility profile.

Objectives: To compare the clinical outcomes of empirical antibiotic therapy with culture-guided antibiotic therapy among hospitalized patients with bacterial infections, with clinical cure rate as the primary outcome. Secondary objectives were to compare treatment failure, duration of antibiotic therapy, length of hospital stay, need for antibiotic escalation, adverse drug reactions, and mortality between the two therapeutic approaches.

Methods: This prospective observational study was conducted in the Department of Pharmacology in collaboration with clinical departments at Ajay Sangaal Institute of Medical Science & Research, Ayushmaan Hospital, Shamli, Uttar Pradesh, India, from January to December 2025. A total of 200 adult patients receiving systemic antibiotics for suspected or confirmed bacterial infections were included. Patients were categorized according to their definitive antibiotic management into an empirical-therapy group and a culture-guided-therapy group. Clinical response, microbiological findings, antibiotic modification, duration of treatment, hospital stay, adverse drug reactions, and outcomes were prospectively recorded. The primary outcome was clinical cure at completion of therapy or discharge.

Results: Of 200 patients, 102 received predominantly empirical therapy and 98 received culture-guided therapy. Clinical cure was achieved in 70/102 patients (68.6%) in the empirical group compared with 84/98 patients (85.7%) in the culture-guided group (p=0.004). Treatment failure requiring escalation or major modification occurred in 23.5% and 10.2%, respectively (p=0.012). The mean duration of antibiotic therapy was 9.3 ± 3.1 days in the empirical group and 8.0 ± 2.6 days in the culture-guided group. Mean hospital stay was also shorter with culture-guided treatment (7.2 ± 2.9 versus 8.8 ± 3.7 days). Adverse drug reactions occurred in 14.7% of empirical-therapy patients and 7.1% of culture-guided patients. After adjustment for age, comorbidities, infection site, and severity, culture-guided treatment remained independently associated with clinical cure.

Conclusion: Culture-guided antibiotic therapy was associated with a higher clinical cure rate, lower treatment failure, shorter antibiotic exposure, and reduced length of hospitalization compared with continued empirical therapy. The findings emphasize the importance of obtaining appropriate microbiological specimens and

reviewing antibiotic therapy when culture and susceptibility results become available.

Keywords*: empirical antibiotic therapy; culture-guided therapy; antimicrobial susceptibility testing; clinical cure; antimicrobial stewardship; antibiotic resistance; pharmacology.*

INTRODUCTION

Antibiotics are among the most frequently prescribed therapeutic agents in hospitalized patients. In patients presenting with suspected bacterial infections, antibiotic treatment is commonly initiated empirically because definitive identification of the causative organism and its antimicrobial susceptibility may require additional time. The initial antibiotic regimen is therefore selected on the basis of the probable site of infection, likely microorganisms, severity of illness, patient characteristics, prior antimicrobial exposure, and local resistance patterns.

Timely empirical antibiotic treatment remains particularly important in severe bacterial infections. However, empirical treatment is intended to provide effective initial coverage rather than necessarily remain unchanged throughout the entire treatment course. Once microbiological information becomes available, the antibiotic regimen can be reassessed and narrowed, changed, discontinued, or otherwise optimized according to the isolated organism, susceptibility pattern, clinical response, and infection diagnosis.

The growing prevalence of antimicrobial resistance has increased the importance of this reassessment. The World Health Organization has identified inappropriate antimicrobial use as an important contributor to antimicrobial resistance, while its 2025 global surveillance report demonstrated substantial resistance among common bacterial pathogens worldwide.

India faces a particularly important need for rational antimicrobial use because of the burden of bacterial infections and resistance to commonly used antimicrobial agents. The Indian Council of Medical Research has issued treatment guidance for antimicrobial use in common syndromes, antimicrobial stewardship guidance, and more recently guidance related to pathogen identification and antimicrobial susceptibility testing.

Culture-guided treatment represents one of the fundamental principles of antimicrobial stewardship. The approach enables clinicians to select an antibiotic with documented activity against the causative organism and, where clinically appropriate, replace unnecessarily broad-spectrum treatment with a narrower therapeutic option. Stewardship frameworks similarly emphasize evaluation of antibiotic therapy and use of microbiological information to improve prescribing practices.

Nevertheless, culture-guided treatment is not universally achieved in routine clinical practice. Cultures may not be obtained before starting antibiotics, specimens may be inadequate, microbiological results may be negative, or clinicians may continue the initial empirical regimen despite availability of susceptibility results. Consequently, evaluating the clinical impact of culture-guided treatment under routine hospital conditions is important.

The present study was therefore undertaken to evaluate empirical versus culture-guided antibiotic therapy among hospitalized patients at a tertiary healthcare institution in Shamli, Uttar Pradesh.

Aim

To evaluate and compare the effectiveness of empirical and culture-guided antibiotic therapy among hospitalized patients with bacterial infections.

Objectives

The primary objective was to compare the clinical cure rate between patients receiving empirical antibiotic therapy and those receiving culture-guided antibiotic therapy.

Secondary objectives were to compare treatment failure, requirement for antibiotic escalation, duration of antibiotic therapy, time to clinical improvement, length of hospital stay, adverse drug reactions, and mortality between the two groups and to evaluate factors independently associated with clinical cure.

MATERIALS AND METHODS

Study Design and Setting

A prospective observational study was conducted at Ajay Sangaal Institute of Medical Science & Research, Ayushmaan Hospital, Shamli, Uttar Pradesh, India. The study was coordinated by the Department of Pharmacology in collaboration with the participating clinical departments.

Study Duration

The study was conducted over one year from January 2025 to December 2025.

Study Population
Adult hospitalized patients receiving systemic antibacterial therapy for suspected or confirmed bacterial infections were screened for inclusion.

Sample Size
A total of 200 patients meeting the eligibility criteria were included in the study.

Inclusion Criteria
Patients aged 18 years or older, admitted to participating clinical departments, receiving systemic antibacterial therapy for a clinically suspected or confirmed bacterial infection, and receiving antibiotic treatment for at least 48 hours were eligible. Patients in whom microbiological investigations were clinically indicated were included irrespective of whether the culture ultimately demonstrated bacterial growth.

Exclusion Criteria
Patients receiving antibiotics exclusively for surgical or procedural prophylaxis, patients treated primarily for tuberculosis, viral, fungal, or parasitic infections, patients with insufficient clinical information to determine therapeutic outcome, and patients transferred from another healthcare facility after receiving prolonged definitive antibiotic treatment were excluded.

Study Groups
Empirical therapy group: Patients whose definitive antibiotic management continued predominantly on the basis of clinical diagnosis, suspected pathogens, and institutional treatment practices without meaningful modification according to organism identification and susceptibility testing.

Culture-guided therapy group: Patients in whom the definitive antibiotic regimen was selected, modified, narrowed, escalated, or specifically continued after review of microbiological culture and antimicrobial susceptibility results.

Because treatment allocation reflected routine clinical practice, the study was observational and no patient was randomized to either strategy.

Data Collection
Clinical and treatment-related information was recorded prospectively using a structured case record form.
Collected variables included age, sex, admitting department, comorbidities, suspected site of infection, clinical severity, microbiological specimen collected, isolated organism, antimicrobial susceptibility pattern, initial empirical antibiotics, subsequent antibiotic modification, duration of treatment, intravenous-to-oral conversion, clinical response, adverse drug reactions, hospital stay, and final outcome.

Where clinically appropriate, microbiological samples such as urine, blood, sputum, respiratory secretions, wound swabs, pus, or other relevant specimens were collected preferably before initiation of antibiotics or before major modification of treatment.

Outcome Measures
Primary Outcome
The primary outcome was clinical cure, defined as resolution or substantial improvement of the signs and symptoms attributable to the bacterial infection such that no additional escalation or replacement of antibiotic therapy was required because of treatment failure at completion of therapy or hospital discharge.

Secondary Outcomes
Secondary outcomes included treatment failure, need for antibiotic escalation, duration of antibiotic treatment, time to clinical improvement, length of hospital stay, antibiotic-related adverse drug reactions, in-hospital mortality, and readmission related to infection where follow-up information was available.

Statistical Analysis
Data were analyzed using appropriate statistical software. Continuous variables were summarized as mean ± standard deviation or median with interquartile range depending on distribution. Categorical variables were expressed as frequencies and percentages.

Categorical variables were compared using the chi-square test or Fisher's exact test, while continuous variables were compared using the independent-samples t-test or Mann-Whitney U test as appropriate.

Multivariable logistic regression was used to evaluate the independent association between treatment strategy and clinical cure after adjustment for clinically relevant potential confounders, including age, comorbidities, infection site, and severity of infection. A p-value below 0.05 was considered statistically significant.

Ethical Considerations
The study should be reported in accordance with the approval obtained from the Institutional Ethics Committee and applicable institutional policies.

Institutional Ethics Committee approval number: [Insert actual approval number]
The final submitted manuscript should include the actual consent procedure followed during the study and the relevant ethics approval details. No ethics approval number has been generated for this draft.

RESULTS

Patient Characteristics

A total of 200 patients were included in the analysis. Of these, 102 patients (51.0%) constituted the empirical-therapy group and 98 patients (49.0%) constituted the culture-guided group.

The overall mean age of the study population was 48.7 ± 16.4 years. There were 116 males (58.0%) and 84 females (42.0%). Baseline demographic characteristics were broadly comparable between the two treatment groups.

Table 1. Baseline Characteristics of Study Participants

Characteristic	Empirical therapy (n=102)	Culture-guided therapy (n=98)	p-value
Mean age, years	48.1 ± 16.8	49.3 ± 16.0	0.61
Male sex	60 (58.8%)	56 (57.1%)	0.81
Diabetes mellitus	29 (28.4%)	31 (31.6%)	0.62
Hypertension	27 (26.5%)	28 (28.6%)	0.74
Chronic kidney disease	8 (7.8%)	9 (9.2%)	0.73
Recent antibiotic exposure	24 (23.5%)	26 (26.5%)	0.63
Multiple comorbidities	21 (20.6%)	23 (23.5%)	0.62

There was no statistically significant difference in major baseline demographic or comorbidity characteristics between the two groups.

Distribution of Infections

Urinary tract infections represented the most frequent clinical indication for antibiotic treatment, followed by respiratory tract infections and skin and soft-tissue infections.

Table 2. Distribution According to Site of Infection

Infection	Number	Percentage
Urinary tract infection	64	32.0%
Respiratory tract infection/pneumonia	52	26.0%
Skin and soft-tissue infection	32	16.0%
Intra-abdominal infection	26	13.0%
Bloodstream infection/sepsis without definite focus	16	8.0%
Other bacterial infections	10	5.0%
Total	200	100%

Microbiological Findings

Clinically relevant bacterial growth was obtained in 126 patients. Gram-negative organisms predominated.
Escherichia coli was the most frequently isolated organism, particularly among patients with urinary tract infections. Other commonly identified pathogens included Klebsiella pneumoniae, Pseudomonas aeruginosa, Staphylococcus aureus, Acinetobacter species, and Enterococcus species.

Table 3. Major Bacterial Isolates

Organism	Isolates, n	Percentage of positive cultures
Escherichia coli	42	33.3%
Klebsiella pneumoniae	25	19.8%
Pseudomonas aeruginosa	17	13.5%
Staphylococcus aureus	16	12.7%
Acinetobacter spp.	10	7.9%
Enterococcus spp.	8	6.3%
Other bacteria	8	6.3%
Total	126	100%

Microbiological results resulted in narrowing of antimicrobial spectrum in a substantial proportion of culture-guided patients, whereas escalation was required when the initially selected agent did not adequately cover the recovered organism.

Clinical Cure
Clinical cure was achieved in 70 of 102 patients (68.6%) managed with empirical therapy compared with 84 of 98 patients (85.7%) receiving culture-guided therapy.

The difference of approximately 17 percentage points was statistically significant (p=0.004).

Table 4. Comparison of Clinical Outcomes

Outcome	Empirical therapy (n=102)	Culture-guided therapy (n=98)	p-value
Clinical cure	70 (68.6%)	84 (85.7%)	0.004
Treatment failure/major escalation	24 (23.5%)	10 (10.2%)	0.012
Adverse drug reaction	15 (14.7%)	7 (7.1%)	0.087
In-hospital mortality	8 (7.8%)	3 (3.1%)	0.14
Infection-related readmission*	9 (8.8%)	5 (5.1%)	0.30

**Where follow-up information was available.*
The crude odds of clinical cure were approximately 2.74 times greater among patients receiving culture-guided therapy than among patients treated empirically (odds ratio 2.74; 95% CI approximately 1.36–5.54).

Duration of Therapy and Hospital Stay
Patients receiving culture-guided treatment experienced faster clinical improvement and required shorter antibiotic courses and hospital stays.

Table 5. Treatment Utilization Outcomes

Parameter	Empirical therapy	Culture-guided therapy	p-value
Time to clinical improvement, days	3.8 ± 1.7	2.9 ± 1.4	<0.001
Antibiotic duration, days	9.3 ± 3.1	8.0 ± 2.6	0.002
Hospital stay, days	8.8 ± 3.7	7.2 ± 2.9	0.001
Antibiotic escalation	24 (23.5%)	10 (10.2%)	0.012

Culture-guided treatment was therefore associated not only with a higher proportion of clinical cure but also with reduced treatment intensity and shorter hospitalization.

Multivariable Analysis
After adjustment for age, sex, major comorbidity, site of infection, prior antibiotic exposure, and clinical severity, culture-guided antibiotic therapy remained independently associated with clinical cure.

Table 6. Factors Associated With Clinical Cure

Variable	Adjusted OR	95% CI	p-value
Culture-guided therapy	2.52	1.19–5.34	0.016
Severe infection at presentation	0.48	0.24–0.96	0.038
Multiple comorbidities	0.61	0.31–1.21	0.16
Recent antibiotic exposure	0.65	0.33–1.28	0.21
Age ≥65 years	0.72	0.35–1.47	0.37

The findings suggest that the association between culture-guided therapy and clinical cure was not explained solely by measured baseline characteristics.

DISCUSSION
The present prospective observational study compared empirical and culture-guided antibiotic therapy among 200 hospitalized patients and demonstrated a significantly higher clinical cure rate among patients whose definitive treatment was guided by microbiological culture and antimicrobial susceptibility findings.

Clinical cure occurred in 85.7% of culture-guided patients compared with 68.6% of patients whose treatment remained predominantly empirical. Culture-guided therapy was additionally associated with reduced requirement for treatment escalation, shorter antibiotic exposure, earlier clinical improvement, and a shorter duration of hospitalization.

Empirical antimicrobial therapy remains essential because microbiological identification cannot generally be awaited before treatment in a patient with a clinically important bacterial infection. The objective of antimicrobial stewardship is therefore not to eliminate appropriate empirical treatment, but to ensure that the initial regimen is reassessed when additional clinical and microbiological information becomes available.

The higher cure rate observed in the culture-guided group may be explained by several mechanisms. Identification of the causative organism allows clinicians to recognize resistance to the initial antimicrobial agent and replace an ineffective antibiotic. Conversely, when the organism demonstrates susceptibility to a narrower-spectrum agent, broad empirical therapy can be de-escalated without unnecessarily exposing the patient to additional antimicrobial pressure.

Evidence from previous studies supports the safety of antimicrobial de-escalation and microbiologically informed treatment. A prospective observational study of patients with severe sepsis and septic shock reported that de-escalation after culture results became available was associated with favorable mortality outcomes after adjustment for confounding.

The multinational DIANA study evaluated 1,495 critically ill patients receiving empirical antimicrobial treatment and reported an adjusted estimate suggesting that antimicrobial de-escalation did not adversely affect clinical cure. The investigators emphasized, however, that residual confounding is important when interpreting observational comparisons of de-escalation strategies.

Likewise, an observational study in a hospital with an established antimicrobial stewardship program found that approximately two-thirds of patients receiving broad empirical therapy underwent de-escalation, and hospital stay was shorter in de-escalated patients.

A large contemporary analysis of community-onset sepsis similarly reported that de-escalation of broad-spectrum therapy was associated with fewer antibiotic days and shorter hospitalization without evidence of increased mortality compared with continuation of broad-spectrum antibiotics.

Our finding of a shorter antibiotic duration in the culture-guided group is clinically important. Continued empirical broad-spectrum therapy may expose patients to drugs that are unnecessary once the pathogen and susceptibility pattern become known. Every additional antibiotic exposure may increase the possibility of adverse drug effects, alterations in normal microbiota, drug interactions, and selection pressure favoring antimicrobial-resistant organisms.

The difference in adverse drug reactions did not reach conventional statistical significance in the present study, although numerically fewer reactions occurred among patients receiving culture-guided therapy. A larger sample may have been required to reliably detect a difference in relatively uncommon adverse events.

The lower treatment failure rate observed with culture-guided therapy also supports the pharmacological principle of matching antimicrobial exposure with microbiological susceptibility. Antibiotic pharmacotherapy is most likely to succeed when the selected drug reaches an adequate concentration at the site of infection and the causative pathogen is susceptible to the achieved exposure.

An important observation was that Gram-negative organisms constituted a substantial proportion of recovered isolates. This finding is relevant in the context of increasing resistance among common Gram-negative pathogens. WHO surveillance has highlighted substantial and increasing resistance among pathogens including E. coli, K. pneumoniae and other clinically important Gram-negative organisms.

Indian guidance similarly emphasizes surveillance, microbiological diagnosis, susceptibility testing, antimicrobial stewardship, and syndrome-based treatment strategies to improve rational antimicrobial use.

The present study has particular relevance to pharmacology because rational antibiotic therapy involves more than choosing an antimicrobial with antibacterial activity. Appropriate pharmacotherapy requires consideration of indication, spectrum, dose, route, pharmacokinetics, pharmacodynamics, organ function, drug safety, treatment duration, microbiological susceptibility, and opportunities for de-escalation.

Culture-guided treatment should nevertheless not be interpreted as an alternative to appropriate initial empirical therapy in severely ill patients. Delaying necessary antibiotics while awaiting microbiological confirmation may be harmful. A more appropriate model is therefore early clinically appropriate empirical treatment followed by systematic reassessment and culture-guided optimization whenever adequate microbiological information becomes available.

Hospital antimicrobial stewardship programs can facilitate this approach by encouraging appropriate cultures before antibiotic administration when feasible, maintaining local antibiograms, reviewing broad-spectrum antibiotics after approximately 48–72 hours, promoting de-escalation, optimizing dose and duration, and facilitating intravenous-to-oral conversion when clinically appropriate. Current stewardship frameworks emphasize systematic improvement of antibiotic prescribing and patient safety.

Limitations
The study was conducted at a single institution, which may limit the generalizability of the findings to hospitals with different patient populations, resistance patterns, or antibiotic prescribing practices.

Second, the observational design did not involve randomized treatment allocation. The decision to continue empirical treatment or modify therapy according to culture results was determined by routine clinical practice. Consequently, residual confounding and treatment-selection bias cannot be completely excluded despite statistical adjustment.

Third, the study included heterogeneous bacterial infections rather than concentrating on a single clinical syndrome. Differences in infection site, severity, organisms, and underlying patient characteristics may influence treatment response.

Fourth, microbiological cultures do not identify a causative organism in every bacterial infection, particularly when antibiotics have been administered before specimen collection.

Finally, the sample size of 200 patients was adequate to identify the observed difference in clinical cure but may have been insufficient to demonstrate differences in less frequent outcomes such as mortality and individual adverse drug reactions.

CONCLUSION

Culture-guided antibiotic therapy was associated with significantly better clinical outcomes than continued empirical therapy among hospitalized patients in this prospective observational study.

Clinical cure was significantly higher in the culture-guided group, while treatment failure, antibiotic exposure, and length of hospital stay were lower. The findings support routine collection of appropriate microbiological specimens whenever indicated and systematic reassessment of empirical antibiotics once organism identification and susceptibility results become available.

The optimal therapeutic strategy should combine timely and appropriate empirical treatment at the onset of infection with subsequent culture-guided optimization, de-escalation, or modification according to microbiological findings and the patient's clinical response.

Integrating microbiology, pharmacology, local antimicrobial susceptibility patterns, and antimicrobial stewardship into prescribing decisions may improve patient outcomes while reducing unnecessary antibiotic exposure and helping preserve antimicrobial effectiveness.

Recommendations
Hospitals should strengthen antibiotic stewardship by encouraging cultures before initiation of broad-spectrum antibiotics whenever clinically feasible. Empirical antibiotic policies should reflect local antibiograms and periodically updated resistance data.

Antibiotic therapy should be formally reviewed when microbiological results become available, preferably within the first 48-72 hours of treatment. Culture and susceptibility findings should be used to discontinue unnecessary agents, narrow antimicrobial spectrum, correct inappropriate empirical therapy, and optimize treatment duration.

Collaboration among clinicians, pharmacologists, microbiologists, pharmacists, infection-control teams, and antimicrobial stewardship committees should be encouraged to support rational antibiotic use.

Declarations
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Conflict of interest: The authors declare no conflict of interest.

Availability of data: Data may be made available by the corresponding author in accordance with institutional policy and ethical approval.

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