e-ISSN: 0976-822X, p-ISSN:2961-6042

Available online on http://www.ijcpr.com/

International Journal of Current Pharmaceutical Review and Research 2026; 18(2); 542-548

Original Research Article

Cost-Effectiveness Analysis of Empirical Versus Culture-Guided Antibiotic Therapy in a Tertiary Care Hospital

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Received: 01-11-2025 / Revised: 15-12-2025 / Accepted: 21-01-2026

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Conflict of interest: Nil

Abstract

Background: Empirical antibiotic therapy is routinely initiated in hospitalized patients with suspected bacterial infections; however, prolonged broad-spectrum use may increase antimicrobial resistance and healthcare costs. Culture-guided therapy, involving modification of antibiotics based on culture and antimicrobial susceptibility testing (AST), may optimize treatment and improve cost-effectiveness. Aim of the study was to compare the clinical outcomes and cost-effectiveness of empirical versus culture-guided antibiotic therapy in a tertiary care hospital.

Material and Methods: A prospective observational comparative study was conducted in the Department of Pharmacology in collaboration with clinical departments. A total of 75 adult inpatients receiving systemic antibiotics for suspected bacterial infections were included. Patients were categorized into empirical therapy (n=38) and culture-guided therapy (n=37) groups based on antibiotic modification following culture/AST results. Baseline characteristics, microbiological profile, antibiotic utilization, clinical outcomes, and direct medical costs were analyzed. Continuous variables were compared using the Independent t-test, and categorical variables using the Chi-square/Fisher's exact test. Cost-effectiveness was assessed by comparing mean costs and clinical cure rates.

Results: Baseline characteristics were comparable between groups ($p>0.05$). The culture-guided group demonstrated a significantly higher de-escalation rate (56.8% vs 15.8%, $p<0.001$), shorter duration of antibiotic therapy (8.1±2.5 vs 10.4±3.2 days, $p=0.002$), and reduced length of hospital stay (8.9±3.6 vs 11.6±4.3 days, $p=0.004$). Mean antibiotic cost (₹6,320±1,980 vs ₹8,950±2,430; $p<0.001$) and total direct medical cost (₹45,900±11,600 vs ₹58,200±14,300; $p=0.001$) were significantly lower in the culture-guided group. Clinical cure rates were higher in the culture-guided group (83.8% vs 71.1%), though not statistically significant ($p=0.18$).

Conclusion: Culture-guided antibiotic therapy was associated with shorter hospital stay, reduced antibiotic exposure, and significant cost savings without compromising clinical outcomes. It represents a cost-effective and potentially dominant strategy in tertiary care settings.

Keywords: Cost-effectiveness; Empirical antibiotic therapy; Culture-guided therapy; Antimicrobial stewardship; De-escalation; Antimicrobial resistance.

DOI: 10.25258/ijcpr.18.2.85

Introduction

Empirical (initial) antibiotic therapy remains fundamental in tertiary care hospitals because life-threatening infections such as sepsis, severe pneumonia, and intra-abdominal infections require prompt treatment before culture and antimicrobial susceptibility testing (AST) results become available. However, prolonged continuation of broad-spectrum empirical therapy without timely review may promote antimicrobial resistance (AMR), increase adverse drug reactions (ADR), predispose to Clostridioides difficile infection, and escalate healthcare costs. AMR is a major global health threat, contributing to 1.27 million deaths directly in 2019 and nearly 4.95 million associated deaths worldwide, largely driven by inappropriate antibiotic use [1,2]. The WHO AWaRe framework further emphasizes rational empirical prescribing and minimization of Watch and Reserve antibiotics to curb resistance and improve stewardship practices [3].

Culture-guided (definitive) therapy—where antibiotics are optimized based on culture/AST results—supports de-escalation, targeted spectrum selection, and appropriate duration of therapy. International Sepsis Guidelines advocate early empiric therapy followed by daily reassessment for de-escalation once microbiological data are available [4].

Similarly, Infectious Diseases Society of America (IDSA)/ Society for Healthcare Epidemiology of America (SHEA) stewardship guidelines highlight the importance of integrating microbiology reporting with clinical decision-making to improve appropriateness of therapy and reduce unnecessary exposure [5]. Although de-escalation has been shown to be feasible in tertiary settings, it remains underutilized due to delayed reporting, workflow gaps, and prescriber hesitancy [6]. Previous studies suggest that culture-guided strategies can be economically advantageous, though findings vary across clinical contexts. Cost-effectiveness analyses in community-acquired pneumonia and sepsis indicate that culture-based optimization may reduce unnecessary antibiotic exposure and overall costs when implemented effectively [7,8]. Hospital-level blood-culture–guided review systems and rapid diagnostic–linked stewardship programs have demonstrated reductions in antimicrobial consumption, hospital stay, and expenditure [9–11]. Evidence from low- and middle-income countries indicates that maintaining functional microbiology services may itself be cost-effective due to improved timeliness of definitive therapy [12]. In India, systematic reviews of antimicrobial stewardship programs report reductions in antibiotic use and costs but note limited patient-level economic comparisons between empirical and culture-guided therapy [13].

Despite strong stewardship recommendations, many tertiary hospitals—especially in resource-limited settings—continue prolonged empirical broad-spectrum therapy due to delays in culture turnaround, inconsistent de-escalation practices, and limited integration of microbiology results into bedside decisions [4–6,12]. Existing studies often focus on rapid diagnostics or specific syndromes and lack comprehensive incremental cost-effectiveness analyses incorporating local cost drivers and resistance patterns [7–11,13]. Therefore, robust, setting-specific evidence comparing empirical versus culture-guided antibiotic therapy at the patient level remains limited.

The present study aims to evaluate the cost-effectiveness of empirical antibiotic therapy versus culture-guided therapy among hospitalized patients with suspected bacterial infections in a tertiary care hospital, by comparing clinical outcomes (clinical cure, treatment failure, mortality, and length of stay) and direct medical costs, and by estimating incremental cost-effectiveness of culture-guided optimization in line with antimicrobial stewardship principles.

Materials and Methods

Study design and setting: A hospital-based, prospective observational comparative study was conducted in the Department of Pharmacology in collaboration with the Departments of Medicine/Microbiology in a tertiary care teaching hospital. The study compared two real-world antibiotic decision pathways among admitted patients treated for suspected bacterial infection:

i. **Empirical therapy group**—patients who continued on initial empirical antibiotics as per routine practice, and
ii. **Culture-guided therapy group**—patients whose antibiotic regimen was modified (de-escalated/escalated/targeted) after availability of culture and antimicrobial susceptibility testing (AST) results.

The total sample size was 75 patients recruited by consecutive sampling from January 2025 to September 2025 after obtaining Institutional Ethics Committee approval. Written informed consent was taken from all participants. Confidentiality was maintained using coded identifiers.

Sample size and sampling technique: A sample size of 75 was fixed as per feasibility and expected eligible admissions during the study period. Consecutive sampling was used until the required sample size was achieved.

Patients were classified into empirical vs culture-guided groups based on actual clinician practice and documentation of whether antibiotics were changed according to culture/AST within the defined review window (e.g., 48–96 hours after culture sent/when reports became available).

Study population: Adult inpatients admitted to wards/ICU with suspected bacterial infections for whom systemic antibiotics were initiated and where culture sampling was clinically indicated (blood/urine/respiratory/sterile body fluid/wound as appropriate).

Inclusion Criteria

- Age ≥18 years.
- Admitted patients started on systemic antibiotics for suspected bacterial infection (community-acquired or hospital-acquired).

- At least one appropriate clinical specimen sent for culture and AST (blood/urine/sputum/ET aspirate/wound/sterile fluid) before or within 24 hours of initiating antibiotics.
- Availability of minimum required records: antibiotic chart, microbiology reports (culture/AST), and hospital billing/consumption details.
- Provided written informed consent.

Exclusion Criteria (point wise)

- Age <18 years.
- Pregnant or lactating women (if your IEC requires exclusion in pharmacoeconomic audits).
- Patients on long-term antibiotic therapy prior to admission (>48–72 hours) for the same illness episode.
- Known viral/fungal/parasitic infections without suspected bacterial component.
- Patients discharged/expired/transferred before culture/AST results could be acted upon (e.g., within 48 hours), where classification is not possible.
- Culture reports contaminated/indeterminate and no repeat sample sent (optional).
- Refusal to consent.

Methodology

Baseline patient variables

- Age, sex, diagnosis/suspected infection site, comorbidities
- Severity markers (e.g., ICU admission, vasopressors, sepsis criteria if available)

Microbiology variables

- Specimen type(s), culture positivity/organism isolated
- AST pattern and resistance category (e.g., ESBL/MRSA/CRE if reported)
- Time to culture report availability (hours/days)

Antibiotic utilization variables

- Empirical antibiotic(s): name, dose, route, frequency, start date/time
- Change after culture/AST: de-escalation/escalation/targeted switch/stop
- Total duration of therapy, combination therapy, IV-to-oral switch

Outcome variables

- Clinical response/cure at discharge (as per treating unit notes)
- Treatment failure (need for escalation/new antibiotic due to non-response)
- Length of hospital stay (LOS), ICU days (if any)
- In-hospital mortality (if applicable)
- Antibiotic-related adverse drug reactions (documented) and C. difficile (if tested/recorded)

Economic variables

- Direct medical costs per patient: antibiotics + diagnostics + bed-days/ICU days + adverse event management
- Total cost per episode of care

Statistical Analysis: Data were analyzed using SPSS version 24.0. Continuous variables were expressed as mean ± SD or median (IQR) based on normality (Shapiro–Wilk test), and categorical variables as frequency and percentage. Comparisons between empirical and culture-guided groups were performed using the Independent t-test or Mann–Whitney U test for continuous variables and the Chi-square/Fisher's exact test for categorical variables.

A p-value <0.05 was considered statistically significant. Cost-effectiveness was assessed using the Incremental Cost-Effectiveness Ratio (ICER).

Results

Table 1: Baseline Demographic and Clinical Characteristics of Study Participants

Variable	Empirical (n=38)	Culture-Guided (n=37)	p-value
Age (years)	54.6 ± 13.2	56.8 ± 12.5	0.47
Male	23 (60.5%)	22 (59.5%)	0.93
Diabetes Mellitus	17 (44.7%)	16 (43.2%)	0.89
Hypertension	19 (50.0%)	18 (48.6%)	0.90
Chronic Kidney Disease	6 (15.8%)	7 (18.9%)	0.72
ICU admission at baseline	11 (28.9%)	12 (32.4%)	0.74

Table 1 shows the baseline demographic and clinical characteristics of patients in the empirical and culture-guided therapy groups.

The mean age and gender distribution were comparable between groups. The prevalence of major comorbidities, including diabetes mellitus, hypertension, and chronic kidney disease, did not differ significantly. ICU admission rates at baseline were also similar.

All baseline variables showed no statistically significant difference (p > 0.05), indicating that both groups were clinically comparable prior to intervention, thereby allowing valid outcome comparison.

Table 2: Distribution of Infection Types among Study Participants

Infection Site	Empirical (n=38)	Culture-Guided (n=37)	p-value
Lower Respiratory Tract Infection (LRTI)	11 (28.9%)	10 (27.0%)	0.85
Urinary Tract Infection (UTI)	9 (23.7%)	8 (21.6%)	0.82
Sepsis / Bloodstream Infection (BSI)	7 (18.4%)	9 (24.3%)	0.51
Skin and Soft Tissue Infection (SSTI)	6 (15.8%)	5 (13.5%)	0.78
Intra-abdominal Infection	5 (13.2%)	5 (13.5%)	0.97

Table 2 presents the distribution of suspected infection sites in both study groups. Lower respiratory tract infections were the most common indication for antibiotic therapy, followed by urinary tract infections and sepsis/bloodstream infections. The distribution of infection types was comparable between the empirical and culture-guided groups, with no statistically significant differences observed (p > 0.05).

This indicates similar clinical profiles with respect to infection focus across both groups.

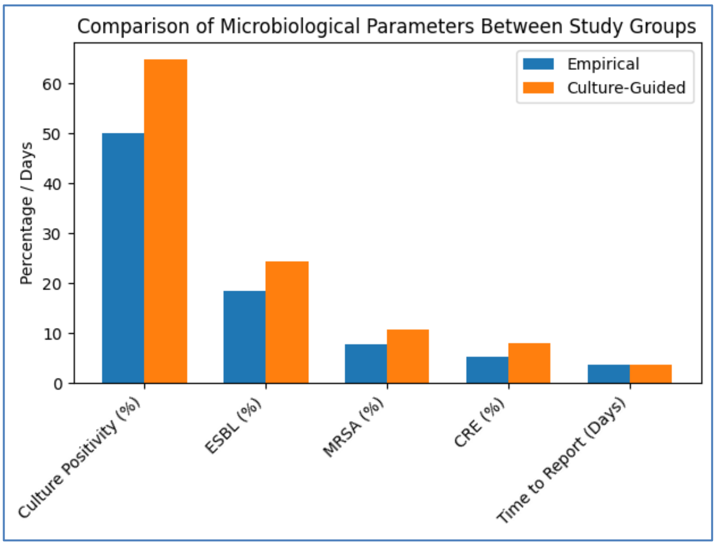

Figure 1: Microbiological Profile of Study Participants

Figure 1 summarizes the microbiological characteristics of patients in both groups. Culture positivity was higher in the culture-guided group (64.9%) compared to the empirical group (50.0%), although the difference was not statistically significant (p = 0.19). The proportion of resistant organisms, including ESBL-producing isolates, MRSA, and CRE, was comparable between groups (p > 0.05). The mean time to availability of culture reports was similar in both groups. Overall, microbiological profiles did not differ significantly, ensuring that outcome comparisons were not influenced by major baseline differences in pathogen distribution or resistance patterns.

Table 3: Comparison of Antibiotic Utilization Patterns

Parameter	Empirical (n=38)	Culture-Guided (n=37)	p-value
De-escalation rate	6 (15.8%)	21 (56.8%)	<0.001*
Escalation rate	10 (26.3%)	8 (21.6%)	0.63
Duration of antibiotics (days), Mean ± SD	10.4 ± 3.2	8.1 ± 2.5	0.002*
IV-to-oral switch	9 (23.7%)	18 (48.6%)	0.02*

Table 3 compares antibiotic utilization between the empirical and culture-guided therapy groups. A significantly higher rate of de-escalation was observed in the culture-guided group (56.8%) compared to the empirical group (15.8%) (p < 0.001).

The total duration of antibiotic therapy was significantly shorter in the culture-guided group (8.1 ± 2.5 days) than in the empirical group (10.4 ± 3.2 days) (p = 0.002). Additionally, IV-to-oral switch was significantly more frequent in the culture-guided group (p = 0.02).

Escalation rates did not differ significantly between groups. These findings demonstrate improved antibiotic optimization and stewardship practices in the culture-guided group.

Table 4: Comparison of Clinical Outcomes between Study Groups

Outcome	Empirical (n=38)	Culture-Guided (n=37)	p-value
Clinical cure	27 (71.1%)	31 (83.8%)	0.18
Treatment failure	9 (23.7%)	4 (10.8%)	0.13
Length of stay (days), Mean ± SD	11.6 ± 4.3	8.9 ± 3.6	0.004*
ICU days, Mean ± SD	4.1 ± 2.8	3.2 ± 2.1	0.18
In-hospital mortality	4 (10.5%)	2 (5.4%)	0.40

Table 4 presents the clinical outcomes observed in both groups. Although the culture-guided group demonstrated a higher clinical cure rate (83.8% vs 71.1%) and lower treatment failure and mortality rates, these differences were not statistically significant ($p > 0.05$). However, the mean length of hospital stay was significantly shorter in the culture-guided group (8.9 ± 3.6 days) compared to the empirical group (11.6 ± 4.3 days) ($p = 0.004$). ICU stay duration was numerically lower but not statistically significant. These findings suggest that culture-guided therapy may improve resource utilization without adversely affecting clinical outcomes.

Table 5: Comparison of Economic Outcomes between Study Groups

Cost Parameter (INR)	Empirical (n=38)	Culture-Guided (n=37)	p-value
Antibiotic cost (Mean ± SD)	8,950 ± 2,430	6,320 ± 1,980	<0.001*
Total hospitalization cost (Mean ± SD)	52,400 ± 12,800	41,300 ± 10,200	0.001*
Total direct medical cost (Mean ± SD)	58,200 ± 14,300	45,900 ± 11,600	0.001*

Table 5 summarizes the economic comparison between the empirical and culture-guided therapy groups. The mean antibiotic cost was significantly lower in the culture-guided group compared to the empirical group ($p < 0.001$). Similarly, both total hospitalization cost and total direct medical cost were significantly reduced in patients managed with culture-guided therapy ($p = 0.001$ for both). These findings demonstrate that culture-guided antibiotic optimization was associated with substantial cost savings, supporting its economic advantage in the tertiary care setting.

Discussion

This study evaluated the clinical and economic impact of culture-guided antibiotic optimization compared with continued empirical therapy among 75 inpatients in a tertiary care hospital. Culture-guided therapy was associated with a significantly higher de-escalation rate (56.8% vs 15.8%, $p<0.001$), shorter duration of antibiotic therapy (8.1±2.5 vs 10.4±3.2 days, $p=0.002$), reduced length of hospital stay (8.9±3.6 vs 11.6±4.3 days, $p=0.004$), and significantly lower antibiotic and total direct medical costs ($p\leq0.001$). Overall, culture-guided therapy emerged as a dominant strategy, being less costly with numerically better clinical outcomes.

The marked increase in de-escalation aligns with contemporary evidence demonstrating that structured antibiotic optimization safely reduces unnecessary broad-spectrum exposure. A target-trial emulation in community-onset sepsis showed that de-escalation was not associated with worse outcomes, supporting its safety in appropriate patients [14]. Furthermore, delayed de-escalation of broad-spectrum therapy has been linked to increase in-hospital mortality, underscoring the importance of timely review once microbiological data become available [15]. Although mortality differences were not statistically significant in our study, the trend toward lower mortality in the culture-guided group is consistent with these findings.

The significant reduction in hospital stay and antibiotic duration observed in the present study mirrors results from hospitalized UTI cohorts and systematic reviews demonstrating that de-escalation reduces antimicrobial exposure and may shorten hospitalization [16,17]. From an economic perspective, our findings are consistent with studies reporting reduced costs associated with stewardship-linked de-escalation pathways [18]. Evidence suggests that the benefit of culture-guided therapy is maximized when microbiology results are actively integrated into clinical workflows through structured stewardship interventions [19].

Optimizing microbiological processes also plays a critical role. Studies evaluating blood culture utilization and rapid stewardship-linked reporting have shown improvements in antibiotic appropriateness and resource utilization [20,21]. Even with conventional culture turnaround times (approximately 3–4 days), our results indicate that systematic review and targeted optimization can yield measurable cost savings [21,22]. Indian tertiary-care stewardship evaluations further support the feasibility and economic value of such interventions in similar healthcare settings [23,24].

The primary implication of this study is that culture-guided therapy reduces direct medical costs mainly through shorter antibiotic exposure and reduced hospital stay—two major modifiable cost drivers. The increased IV-to-oral switch rate further reflects improved antibiotic streamlining. Although differences in clinical cure and mortality were not statistically significant, the absence of adverse outcomes alongside cost reduction supports culture-guided optimization as a value-based approach. Importantly, effective implementation requires not only obtaining cultures but also timely action based on results within structured stewardship systems [19,22].

Limitations

This single-center observational study may be subject to confounding by indication and documentation bias. The analysis focused on direct medical costs and did not account for indirect societal costs or long-term resistance implications. The modest sample size may have limited power to detect differences in mortality and other infrequent outcomes.

Conclusion

Culture-guided antibiotic therapy in this tertiary care cohort was associated with significantly higher de-escalation, shorter antibiotic duration, reduced hospital length of stay, and lower antibiotic and total direct medical costs compared with continued empirical therapy, without evidence of worse clinical outcomes. These findings support strengthening microbiology-linked antimicrobial stewardship processes to ensure timely review and optimization of antibiotics once culture/AST results are available.

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