



Original Article

Assessment of the Efficacy of Procalcitonin, C-Reactive Protein, and Albumin Levels-guided Antibiotics Use in Sepsis

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Abstract. Background: Efficient management of sepsis requires precise antibiotic therapy. This study examines the efficacy of guiding such therapy using Procalcitonin (PCT), C-Reactive Protein (CRP), and albumin levels.

Methods: A total of 127 adult sepsis patients were assigned to either standard care or a biomarker-guided group where antibiotic use was adjusted based on biomarker levels.

Results: The biomarker-guided approach significantly reduced the duration of antibiotic therapy (9.0 vs. 10.5 days, $P=0.04$) and expedited antibiotic de-escalation. Hospital costs were lower in the biomarker-guided group (20,000 vs. 24,000 CNY, $P=0.04$), though reductions in secondary infections did not reach statistical significance. There was no significant difference in 28-day mortality rates.

Conclusion: Biomarker-guided antibiotic therapy can enhance the efficiency of treatment in sepsis, reducing both duration and cost without impacting patient safety. These findings suggest the potential benefits of incorporating biomarkers into standard sepsis management protocols.

Keywords: Procalcitonin; C-reactive protein; albumin; Antibiotic stewardship; Sepsis management.

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Introduction. Sepsis is a dysregulated host response to infection that triggers life-threatening organ dysfunction. It affects an estimated 50 million people each year, with neonates and children shouldering a disproportionate share of the burden.^{1,2} Progression to septic shock — marked by profound circulatory and cellular abnormalities — carries mortality rates approaching one-third of cases.³ Survivors frequently experience enduring complications, including chronic illness and impaired quality of life.^{4,5} Consequently, advances in early detection and treatment — especially the incorporation of biomarker-guided strategies and coordinated, interdisciplinary care — are critical to improving

outcomes and reducing the substantial societal costs associated with sepsis.^{4,5}

Biomarkers such as procalcitonin (PCT), C-reactive protein (CRP), and albumin have become pivotal in sepsis care, refining diagnosis, guiding therapy, and sharpening prognostic stratification.^{6,7} PCT rises swiftly in bacterial infections and closely parallels disease severity,⁸ whereas CRP — though less specific — offers high sensitivity for systemic inflammation.^{9,10} Comparative studies consistently show PCT to be the more specific marker and CRP the more sensitive one.¹⁰ Persistently elevated PCT or CRP levels, particularly in concert with leukocytosis, signal an increased risk of

mortality.^{11,12} Hypo-albuminemia further reflects capillary leak and poor nutritional reserves, adding complementary prognostic value. Integrating these biomarkers, therefore, enhances both the diagnostic precision and outcome prediction essential to effective sepsis management.

Growing evidence supports the integration of procalcitonin (PCT), C-reactive protein (CRP), and albumin into antibiotic-stewardship protocols, especially for respiratory infections and the critically ill. PCT has emerged as a pivotal biomarker, reliably guiding when to start and, crucially, when to stop antibiotics — thereby reducing unnecessary exposure and improving outcomes in sepsis and acute respiratory infections.^{13,14} PCT-based algorithms can safely shorten treatment courses and lessen drug-related adverse effects.¹⁴ CRP point-of-care testing similarly enhances decision-making in primary care: low levels help rule out serious infection and justify withholding antibiotics.^{15,16} While both markers add value, PCT provides greater specificity but is less widely available and more expensive.¹⁶ Albumin level, reflecting capillary leak and nutritional status, offers complementary prognostic insight. Embedding these biomarkers within stewardship programmes can therefore optimise patient care and curb antibiotic overuse.

This study will test whether tailoring antibiotics to biomarker levels — procalcitonin (PCT), C-reactive protein (CRP), and albumin — improves both clinical and economic outcomes in sepsis. Primary endpoints are total antibiotic-days, time to de-escalation, and the incidence of secondary infections. Secondary analyses will assess cost-effectiveness, including total hospital expenditure and 30-day readmission rates. By linking patient-centred outcomes with resource utilisation, the trial aims to show whether biomarker-guided therapy can simultaneously enhance care quality and curb unnecessary antibiotic use.

Participants and Methods. This study was conducted in Wujing Community Health Center, affiliated with Shanghai University of Traditional Chinese Medicine, to compare the efficacy of biomarker-guided antibiotic therapy against standard care in adult sepsis patients. The study was approved by the institutional review boards of Wujing Community Health Center, affiliated to Shanghai University of Traditional Chinese Medicine. All eligible patients underwent a rapid capacity assessment using the Aid-to-Capacity Evaluation. If the patient was deemed capable, written informed consent was obtained directly. If capacity was lacking, the attending physician sought written consent from the legally authorized representative (LAR). When neither the patient nor an LAR was available within 6 h of meeting inclusion criteria and delaying biomarker sampling would have compromised care, enrolment

proceeded under the Institutional Review Board–approved emergency waiver of consent; written consent was subsequently obtained from the patient or LAR within 72 h. Participants (or their LARs) retained the right to withdraw at any time, and data were expunged should consent not be granted retrospectively.

Inclusion criteria for the participants included: 1) 18 years or older; 2) diagnosed with sepsis according to the Sepsis-3 criteria within the past 24 hours; 3) admitted to the hospital through emergency departments or directly to intensive care units. Exclusion criteria were: 1) age under 18; 2) pregnancy; 3) documented anaphylaxis or severe IgE-mediated hypersensitivity to all first-line antibiotics, precluding their safe use. 4), presence of terminal illness where the life expectancy is less than one month or withdrawal from aggressive treatment is planned.

Patients were randomly assigned to the control group and the biomarker group, using a computer-generated sequence with stratification by site to ensure balanced allocation across different hospitals.

Sample-size calculation and recruitment period. Power analysis (G*Power 3.1) indicated that, assuming a mean antibiotic duration of 11 days (SD 3) in standard care, 63 patients per group would provide 80% power (two-sided α 0.05) to detect a 1.5-day absolute reduction. Allowing for a 2% attrition rate, a target of 127 patients was set. Consecutive eligible adults were screened from January 1, 2023, to March 31, 2024; recruitment stopped automatically when the target was attained and all participants had completed a 28-day follow-up. No interim efficacy or futility analyses were conducted.

Interventions. Empiric therapy followed the Wujing Community Health Center 2023 Sepsis Guideline: piperacillin–tazobactam or cefoperazone–sulbactam (community-onset); meropenem or imipenem–cilastatin (health-care-associated or MDR risk); addition of vancomycin or linezolid when MRSA was suspected. The specific agent, dose, and de-escalation target were chosen by the attending physician in consultation with the stewardship team. The intervention under study was limited to timing decisions based on PCT/CRP/albumin trajectories; no investigational antibiotic was administered.

Biomarker-Guided Therapy Group: Antibiotic therapy adjustments were based on predefined thresholds of PCT, CRP, and Albumin as outlined in **Table 1**. Decisions to escalate, de-escalate, or discontinue antibiotics were made in conjunction with clinical assessment, including signs of infection improvement or deterioration.

Control Group: Participants received antibiotics based on the current best practice guidelines without biomarker integration. Therapy adjustments were made

Table 1. Integrated Biomarker-Guided Treatment Protocol with Specific Thresholds.

Biomarker	Threshold/Condition	Recommendation
PCT	< 0.1 ng/mL	Consider stopping antibiotics if CRP is also decreasing and albumin is stable/improving, unless clinical signs suggest otherwise.
	0.1 to < 0.25 ng/mL	Continue antibiotics; reassess all biomarkers in 24 hrs. Stop antibiotics if PCT decreases, CRP trends down >25%, and albumin stabilizes or improves.
	0.25 to < 0.5 ng/mL	Continue antibiotics; reassess all biomarkers in 24-48 hrs. Consider de-escalation once PCT < 0.1 ng/mL, CRP decreases by >50%, and albumin shows improvement.
	≥ 0.5 ng/mL	Continue antibiotics; monitor biomarkers closely. De-escalate/stop antibiotics if PCT decreases > 90%, CRP falls by >50%, and Albumin increases.
CRP	Decrease > 25% over 24 hrs	Suggestive of an effective antibiotic response. Reassess combined with PCT and Albumin for decisions on continuation or stopping antibiotics.
	Decrease > 50% from peak	Strong indicator of treatment effectiveness. Combine with PCT and Albumin for decision-making on de-escalation.
	Increase or decrease of less than 25% decrease over 24 hrs	Indicates potential non-responsive or complicated infection. Further assessment needed; consider imaging or additional cultures.
Albumin	< 3 g/dL at admission	Indicates severe illness; monitor closely and provide supportive care. Improvement suggests recovery; consider in antibiotic decision-making.
	Improvement (increase by > 0.5 g/dL from baseline)	Positive recovery sign; integrate with PCT and CRP for decisions on de-escalating or continuing therapy.

Note: a) All decisions require simultaneous assessment of PCT, CRP and albumin plus bedside clinical evaluation.

b) PCT is the primary safety biomarker; if PCT suggests "continue", antibiotics are not discontinued even if CRP is favorable.

c) In discordant situations, the algorithm defaults to "continue" and mandates reevaluation within 24 h.

d), Albumin trend is used only to support a stop/de-escalate decision once PCT and CRP thresholds are satisfied.

on clinical judgment without specific biomarker targets.

Clinical decision algorithm: At each daily stewardship round, the attending physician reviewed PCT, CRP, and albumin together and applied the following hierarchy: (1) primary trigger = PCT; (2) secondary modifier = CRP trend; (3) supportive modifier = albumin trend. Antibiotic treatment was discontinued when all of these apply: PCT < 0.10 ng/mL AND CRP has fallen by ≥ 50% from its peak AND albumin has stabilized or risen (≥ baseline). Continue current therapy when PCT is 0.10–0.49 ng/mL or PCT is falling but either CRP has fallen < 50% or albumin remains < baseline; reassess in 24 h. Escalate or broaden cover when PCT ≥ 0.50 ng/mL or PCT has risen by > 25% from the previous value, irrespective of CRP/albumin, unless a non-infectious cause is evident. If PCT and CRP were discordant, the physician prioritized the less favorable marker to maximize safety. Albumin changes were never used in isolation to stop antibiotics.

Microbiological work-up and antibiotic strategy. Blood cultures (two sets from separate venipunctures) plus site-specific cultures (sputum, urine, abdominal fluid) were obtained before the first antibiotic dose wherever feasible. Empiric therapy followed local sepsis guidelines. If a pathogen and susceptibility profile became available within 72 h, therapy was narrowed to the most appropriate agent; this was classified as culture-targeted. Cases in which no pathogen grew, or therapy remained broad-spectrum despite a pathogen, were categorized as empiric-only.

Outcome Measures. Primary Outcomes: 1) duration of antibiotic therapy, defined as the number of days from initiation to cessation of antibiotic treatment. 2), 28-day all-cause mortality. 3), Hospital length of stay from admission to discharge.

Secondary Outcomes: 1) 30-day hospital readmission rates. 2) Incidence of secondary infections during the hospital stay. 3) Economic evaluation, including direct hospital costs associated with treatment.

Data Collection. Timing of Measurements: 1) Biomarkers were measured at admission (baseline), and then at predefined intervals of 24, 48, and 72 hours, and subsequently based on clinical indications. 2) Clinical assessments were conducted daily by attending healthcare professionals.

Statistical Analysis. The results of numerical data were presented as mean ± standard deviation (SD), while the categorical data were presented as numbers and percentages. Continuous variables were compared using Student's t-test or Mann-Whitney U test, depending on data distribution. Categorical variables were analyzed using the chi-square test or Fisher's exact test as appropriate. Time-to-event outcomes were analyzed using the Kaplan-Meier method and compared using the log-rank test.

Results

Participant Baseline Characteristics. A total of 127 patients were enrolled, with 64 assigned to standard care

Table 2. Participant Baseline Characteristics.

Characteristic	Control Group (n = 64)	Biomarker-Guided Group (n = 63)	P value
Age, years (mean ± SD)	45.0 ± 12.0	44.5 ± 11.5	0.73
Gender, n (%)			
Male	33 (51.6%)	34 (54.0%)	0.80
Female	31 (48.4%)	29 (46.0%)	—
Source of Sepsis, n (%)			0.99
Pulmonary	24 (37.5%)	23 (36.5%)	—
Abdominal	15 (23.4%)	16 (25.4%)	—
Urinary	13 (20.3%)	13 (20.6%)	—
Other	12 (18.8%)	11 (17.5%)	—
Comorbidities, n (%)			0.90
Hypertension	15 (23.4%)	14 (22.2%)	—
Diabetes mellitus	8 (12.5%)	7 (11.1%)	—
Chronic kidney disease	6 (9.4%)	5 (7.9%)	—
Chronic obstructive pulmonary disease	4 (6.3%)	6 (9.5%)	—
Severity of Sepsis			
APACHE II score (mean ± SD)	16 ± 5	17 ± 4	0.52
SOFA score (mean ± SD)	8 ± 4	7 ± 3	0.61
Septic shock, n (%)	28 (43.8%)	26 (41.3%)	0.76
Procalcitonin, ng/mL (mean ± SD)	13.7 ± 6.0	13.5 ± 6.2	0.85
C-reactive protein, mg/L (mean ± SD)	146 ± 42	149 ± 45	0.66
Albumin, g/dL (mean ± SD)	2.7 ± 0.5	2.7 ± 0.4	0.94

Abbreviations: SD = standard deviation; APACHE II = Acute Physiology and Chronic Health Evaluation II; SOFA = Sequential [Sepsis-related] Organ Failure Assessment; CRP = C-reactive protein; PCT = procalcitonin.

and 63 to biomarker-guided therapy (**Table 2**). Baseline demographics and clinical characteristics — including age, sex, infection source, and comorbidity profile — were comparable between the two groups, with no statistically significant differences. Mean age was comparable between groups (45.0 ± 12.0 years in the control arm vs 44.5 ± 11.5 years in the biomarker-guided arm; $P = 0.73$). Sex distribution was similarly balanced, with men representing 51.6% of the control group and 54.0% of the biomarker-guided group ($P = 0.80$). The primary sources of sepsis — pulmonary, abdominal, urinary, and others—were also evenly distributed between the groups ($P = 0.99$). The prevalence of major comorbidities — including hypertension, diabetes mellitus, chronic kidney disease, and chronic obstructive pulmonary disease — did not differ significantly between groups ($P = 0.90$). The severity of sepsis, assessed by APACHE II and SOFA scores, and the incidence of septic shock were comparable.

Impact of Biomarker-Guided Antibiotic Therapy on Treatment Outcomes in Sepsis Patients. Antibiotic stewardship improved markedly under biomarker guidance. Mean treatment duration fell to 9.0 ± 2.7 days versus 10.5 ± 3.2 days with standard care ($P = 0.04$; **Table 3**). Median course length likewise declined—from 9 days (IQR 7–11) in the control arm to 8 days (IQR 6–10) in the biomarker-guided arm ($P = 0.03$). Median time to antibiotic de-escalation dropped to 4 days (IQR 3–5) in the biomarker-guided group versus 5 days (IQR 4–7) with standard care ($P = 0.05$). Median time to complete cessation likewise shortened from 9 days (IQR 7–11) to 8 days (IQR 6–9) ($P = 0.04$). However, there was no significant difference in 28-day mortality rates between the groups, with 19.0% in the biomarker-guided group versus 23.4% in the control group ($P = 0.42$). The median hospital length of stay was slightly shorter in the biomarker-guided group, 12 days (range 9–17), compared to 14 days (range 10–19) for the control group ($P = 0.05$).

Table 3. Primary Outcomes.

	Control Group (n = 64)	Biomarker-Guided Group (n = 63)	P value
Duration of Antibiotic Therapy			
Mean ± SD (days)	10.5 ± 3.2	9.0 ± 2.7	0.04
Median (days)	9 (7–11)	8 (6–10)	0.03
Time to Antibiotic De-escalation , Median (days)	5 (4–7)	4 (3–5)	0.05
Time to Complete Cessation , Median (days)	9 (7–11)	8 (6–9)	0.04
28-Day mortality , n (%)	15 (23.4%)	12 (19.0%)	0.42
Hospital Length of Stay , Median (days)	14 (10–19)	12 (9–17)	0.05

Table 4. Secondary Outcomes.

	Control Group (n = 64)	Biomarker-Guided Group (n = 63)	P value
30-Day Readmission , n (%)	13 (20.3%)	11 (17.5%)	0.40
Secondary Infection Rate , n (%)	10 (15.6%)	6 (9.5%)	0.15
Total Hospital Costs , CNY (mean ± SD)	24,000 ± 5,000	20,000 ± 3,000	0.04

Abbreviations: SD = standard deviation; CNY = Chinese Yuan.

Microbiological findings and antibiotic strategy. Blood cultures were positive in 24/64 control patients (37.5%) and 23/63 biomarker-guided patients (36.5%) ($P = 0.92$). Conversion from empiric to culture-targeted therapy within 72 h occurred in 18 (28.1%) vs 17 (27.0%) patients, respectively ($P = 0.93$). Adjusting the primary outcome for culture status and antibiotic strategy left the treatment effect essentially unchanged ($\beta = -1.4$ days, 95% CI -2.3 to -0.5, $P = 0.003$; **Supplementary Table S1**).

Economic and Clinical Efficiency of Biomarker-Guided Therapy in Sepsis Management. In evaluating secondary outcomes for sepsis management between a control group and a biomarker-guided group, there were important distinctions in hospital costs and infection rate (**Table 4**).

The 30-day readmission rates were similar between groups, with 20.3% in the control group and 17.5% in the biomarker-guided group ($P = 0.40$). Secondary infection rates were slight lower in the biomarker-guided group at 9.5% compared to 15.6% in the control group ($P = 0.15$). Notably, there was a significant reduction in total hospital costs for the biomarker-guided group ($P = 0.04$).

Discussion. This study confirms that biomarker-guided antibiotic therapy — using procalcitonin, C-reactive protein, and albumin thresholds — shortens treatment duration without sacrificing clinical efficacy. By tailoring antimicrobial decisions to individual inflammatory profiles, we add persuasive evidence for a personalized approach to sepsis care. As health systems pivot toward precision medicine, integrating biomarker guidance could curb unnecessary antibiotic exposure,

mitigate resistance, and ultimately ease the global burden of sepsis.

The antibiotic savings we observed mirror and reinforce the broader stewardship literature. Stopping therapy when PCT falls below prespecified thresholds can trim exposure by up to 25% without increasing mortality.¹⁷ The ADAPT-Sepsis trial likewise showed that PCT-guided protocols shortened courses in hospitalized patients while maintaining safety.¹⁸ Subsequent studies in sepsis and lower-respiratory-tract infections have confirmed that PCT algorithms safely reduce antimicrobial use, improving patient safety and cutting costs.¹³ A recent systematic review reached the same conclusion, reporting significant reductions in antibiotic days with no compromise in outcomes.¹⁴ CRP point-of-care testing has also proved valuable in primary care, reliably distinguishing bacterial from viral infections and steering prescribers toward more judicious antibiotic use.¹⁵

Consistent with growing evidence favoring personalized antimicrobial strategies,¹⁴ the biomarker-guided cohort required a shorter mean antibiotic course. Curtailing exposure not only optimizes individual outcomes but also helps prevent secondary infections and slows the emergence of antimicrobial resistance (AMR).¹⁶ Integrating biomarkers into sepsis protocols thus dovetails with global efforts toward judicious antibiotic use. This alignment is increasingly critical as multidrug-resistant pathogens proliferate, making innovative, biomarker-guided stewardship essential for safeguarding the efficacy of existing treatments.¹⁹

Although our cohort achieved shorter hospital stays and reduced antibiotic exposure, we did not detect a statistically significant decline in secondary infections.

This finding diverges from reports that credit biomarker-guided protocols with lowering secondary-infection rates through more precise antimicrobial targeting.²⁰ Several factors may explain the discrepancy. First, methodological variations—such as a smaller sample size and a single-center design—limit statistical power and external validity. Second, patient heterogeneity (e.g., differing baseline risk for nosocomial infection) can dilute effect estimates. Finally, our use of fixed biomarker cut-offs may blunt responsiveness; studies that employ dynamic, patient-specific thresholds have documented superior outcomes over static algorithms.²¹ Future work should therefore adopt adaptive thresholds and enroll larger, multicenter populations to clarify the true impact of biomarker guidance on secondary infections.

Biomarker-guided therapy improves both clinical outcomes and economic efficiency. By curbing unnecessary antibiotic exposure, it lowers the risk of secondary infections and drug-related adverse events. In our cohort, this approach shortened antibiotic courses and reduced length of stay—findings that echo prior meta-analyses.²² Real-time biomarker trends also let clinicians tailor treatment duration precisely, a strategy shown to enhance antimicrobial stewardship and cut direct hospital costs.²³

Despite the encouraging findings, this study has important limitations. Foremost, the sample size of 127 patients — adequate for an exploratory analysis — restricts statistical power for secondary endpoints such as secondary-infection rates and longer-term outcomes. Although the trial was adequately powered for its primary endpoint, the sample size was insufficient to robustly analyze secondary outcomes such as infection relapse and long-term morbidity. The study's mostly homogeneous sample — adult patients treated within a single healthcare system — limits the applicability of our findings to other groups, such as pediatric or elderly populations and those in low-resource settings. Systematic reviews consistently highlight the need for larger, more diverse cohorts to validate biomarker

thresholds across different demographic and clinical contexts.²⁴ Future research should therefore prioritize multicenter trials that enroll heterogeneous patient populations and incorporate longer follow-up. Region-specific calibration of biomarker cut-offs, along with continued innovation in affordable point-of-care diagnostics, will be vital to make biomarker-guided protocols broadly feasible and clinically relevant worldwide.

Conclusions. This study highlights the clear advantages of biomarker-guided antibiotic therapy for sepsis. By incorporating real-time procalcitonin, C-reactive protein, and albumin measurements, we show that antibiotics can be tailored more precisely—shortening treatment courses, lowering hospital costs, and preserving patient safety. These gains, achieved without compromising clinical outcomes, point to a practical route for curbing antibiotic overuse and resistance. Our findings, therefore, strengthen the case for integrating biomarker-based algorithms into routine sepsis care and lay a solid foundation for future work — especially studies that probe long-term outcomes and refine biomarker thresholds for diverse patient populations.

Ethical Approval. The study was approved by the institutional review boards of Wujing Community Health Center, affiliated to Shanghai University of Traditional Chinese Medicine. Written informed consent was obtained from all participants, in accordance with the Declaration of Helsinki.

Data availability. Data sets generated during the current study are available from the corresponding author on reasonable request.

Author Contribution Statement. The authors confirm contribution to the paper as follows: study conception and design: Y.S.; data collection: J.C.; analysis and interpretation of results: J.C.; draft manuscript preparation: J.C., Y.S. All authors reviewed the results and approved the final version of the manuscript.

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