RESEARCH PAPER

A Prospective Observational Study on the One-Hour Sepsis Bundle and Clinical Outcomes in Sepsis Patients Admitted to the Intensive Medical Care Unit (IMCU)

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ABSTRACT

Background: Sepsis is a leading cause of intensive-care morbidity and mortality. The Surviving Sepsis Campaign hour-1 bundle promotes rapid, evidence-based resuscitation, yet real-world compliance is often suboptimal, particularly in resource-limited settings. We evaluated compliance with the one-hour bundle and its association with clinical outcomes in patients with sepsis admitted to the Intensive Medical Care Unit (IMCU).

Materials and Methods: This prospective observational study enrolled 50 consecutive adults with sepsis or septic shock (Sepsis-3) admitted to the IMCU of a tertiary-care teaching hospital over three months. Completion of all five hour-1 bundle components within one hour of recognition defined the bundle-compliant group; patients were otherwise classified as non-compliant. Baseline characteristics, bundle compliance and clinical outcomes were compared. Categorical variables were analysed using the Chi-square or Fisher exact test and continuous variables using the independent t-test, with $p < 0.05$ considered significant.

Results: Complete bundle compliance was achieved in 20 patients (40%). The compliant and non-compliant groups were comparable at baseline for age, sex, comorbidities and admission severity (admission SOFA 7.7 vs 9.1, $p = 0.087$). IMCU mortality was significantly lower in the compliant group (20% vs 60%, $p = 0.005$). Compliant patients also had a shorter IMCU stay (8.1 vs 11.3 days, $p < 0.001$), shorter vasopressor (0.9 vs 3.0 days) and mechanical-ventilation duration (2.4 vs 5.4 days), greater reduction in SOFA by day 3 (2.8 vs 0.1 points) and higher 6-hour lactate clearance (41% vs 18%). Admission SOFA showed acceptable discrimination for mortality (AUC 0.70). The least-completed components were 30 mL/kg crystalloid (60%) and blood cultures before antibiotics (70%).

Conclusion: Compliance with the one-hour sepsis bundle was associated with lower IMCU mortality, shorter organ-support requirements and faster physiological recovery. Implementation gaps, especially in fluid resuscitation and timely blood-culture sampling, represent actionable targets for quality improvement.

Keywords: Sepsis, Septic shock, Surviving Sepsis Campaign, Hour-1 bundle, Bundle compliance, IMCU mortality, SOFA score, Diagnostic stewardship

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INTRODUCTION

Sepsis is a life-threatening organ dysfunction caused by a dysregulated host response to infection and remains a major cause of morbidity and mortality worldwide. A substantial proportion of affected patients require intensive care, and large share of sepsis-related deaths occur within the first 48 hours of admission, underscoring the decisive influence of early recognition and timely management on survival.

The hour-1 bundle was developed by the Surviving Sepsis Campaign to standardize early care. It combines the most important initial interventions into a single time-sensitive package: measuring serum lactate (with remeasurement if elevated), taking blood cultures prior to antibiotics, administering broad-spectrum antibiotics, performing rapid crystalloid resuscitation for hypotension or hyperlactataemia, and starting vasopressors to maintain a mean arterial pressure of at least 65 mmHg. In a variety of contexts, adherence to these components has been linked to better clinical outcomes and increased survival.

Implementation of the hour-1 package is still uneven despite strong guideline support, especially in settings with low resources. Frontline staff's lack of understanding, insufficient laboratory and microbiology capacity, financial concerns, and inadequate communication between emergency and critical-care teams are some of the reported obstacles. As a result, diagnostic steps such as lactate measurement and pre-antibiotic blood cultures are frequently delayed or omitted, potentially compromising both stewardship and outcomes.

Local data quantifying bundle adherence and its relationship with outcomes in Indian intensive-care settings are limited. The present study was undertaken to assess compliance with the one-hour sepsis bundle, to examine its association with IMCU mortality and other clinical outcomes, and to identify specific gaps in real-world implementation that may be amenable to quality-improvement intervention.

AIM

To assess the implementation of the one-hour sepsis bundle and its association with clinical outcomes in patients with sepsis admitted to the Intensive Medical Care Unit.

OBJECTIVES

Primary Objective

- To determine the association between compliance with the one-hour sepsis bundle and IMCU mortality among patients admitted with sepsis.

Secondary Objective

- To compare clinical outcomes — length of IMCU stay, duration of mechanical ventilation and vasopressor requirement — between bundle-compliant and non-compliant groups.
- To assess the association of delayed or incomplete bundle implementation with organ dysfunction and the need for organ support.
- To identify gaps in the real-world implementation of the one-hour sepsis bundle that may influence patient outcomes.

MATERIALS AND METHODS

Study Design: Prospective observational study was carried out in Intensive Medical Care Unit at a tertiary care centre in Puducherry for a period of three months after approval from the Institutional Ethical committee. All consecutive adult patients fulfilling the eligibility criteria during the study period were enrolled. Sepsis was diagnosed using the Sepsis-3 definition (suspected or confirmed infection with an acute rise in the SOFA score of ≥ 2). Patients were followed throughout their IMCU stay.

The sample size was estimated using the single-proportion formula $n = Z^2 \times p\,(1 - p) / d^2$, with $Z = 1.96$, an assumed bundle-compliance proportion $p = 0.154$ (Umemura et al., 2022), $q = 1 - p = 0.846$ and an absolute precision $d = 0.10$ [1]. The 10% precision reflected the short (three-month) study duration and single-centre feasibility, yielding a required sample of approximately 50 patients.

Inclusion Criteria: Adults aged ≥ 18 years admitted in IMCU, diagnosis of sepsis or septic shock by Sepsis-3 criteria (suspected or confirmed infection with an acute increase in SOFA score ≥ 2) and patients in whom one-hour sepsis bundle components were initiated or intended to be initiated at the time of IMCU admission.

Exclusion Criteria: Age < 18 years, IMCU stay shorter than 24 hours, admission with end-of-life, palliative-care or Do-Not-Resuscitate goals, transfer to the IMCU after definitive sepsis management elsewhere, where the timing of bundle components could not be reliably assessed, readmission to the IMCU during the same hospital stay and incomplete medical records precluding assessment of one-hour bundle compliance.

Data Collection: Data were collected on a structured proforma from IMCU case records, including demographic characteristics, source of infection, severity of illness (SOFA score, with APACHE II where available), and the timing and completion of each one-hour bundle component. The requirement for organ support (mechanical ventilation, vasopressors, renal replacement therapy) and final outcome were recorded.

Definition of the one-hour bundle (SSC 2018/2021)

- Measure serum lactate; remeasure if the initial value is > 2 mmol/L.
- Obtain blood cultures before administering antibiotics.
- Administer broad-spectrum antibiotics.
- Begin rapid administration of 30 mL/kg crystalloid for hypotension or lactate ≥ 4 mmol/L.
- Apply vasopressors during or after fluid resuscitation to maintain a mean arterial pressure ≥ 65 mmHg.

Assessment of Bundle Compliance

Compliance was defined as completion of all recommended one-hour bundle components within one hour of sepsis recognition, in accordance with Surviving Sepsis Campaign guidance. Patients were categorised into bundle-compliant and non-compliant groups. Compliance with individual diagnostic components — timely lactate measurement and pre-antibiotic blood cultures — was additionally examined as a measure of diagnostic stewardship.

Outcome measures

The primary outcome was IMCU mortality. Secondary outcomes were length of IMCU stay, duration of vasopressor support, requirement and duration of mechanical ventilation, change in organ dysfunction assessed by the SOFA score, and compliance with and timing of individual bundle components.

STATISTICAL ANALYSIS

Data were compiled in Microsoft Excel 2010 and analysed using SPSS version 23.0. Descriptive statistics (mean, standard deviation, median and frequencies) summarised baseline characteristics. Categorical variables were compared using the Chi-square or Fisher exact test depending on expected cell counts, and continuous variables using the independent t-test for normally distributed data or the Mann-Whitney U test otherwise. The discriminative ability of the admission SOFA score for mortality was assessed by receiver operating characteristic (ROC) analysis. A two-sided p-value < 0.05 was considered statistically significant.

RESULTS

A total of 50 consecutive adult patients fulfilling Sepsis-3 criteria were enrolled during the study period. The cohort comprised 24 males (48%) and 26 females (52%), with a mean age of 46.1 ± 20.2 years (range: 18–82 years). The majority (44%) were in the 18–40 years age group. Forty-three patients (86%) were classified as sepsis and 7 (14%) as septic shock. The most common source of infection was pneumonia (n=19, 38%), followed by urosepsis (n=9, 18%), unknown source (n=8, 16%), skin/soft tissue infections (n=7, 14%), and intra-abdominal sepsis (n=7, 14%). Table 1 presents the baseline demographic and clinical characteristics of the study population, stratified by Hour-1 Bundle compliance. Distribution of source of infection was given in figure 1.

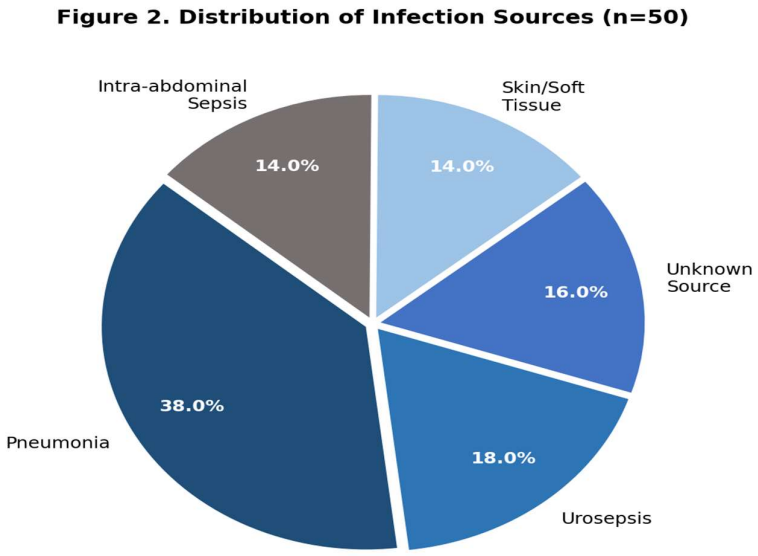

Figure 1: Distribution of source of infection

Table 1. Baseline demographic and clinical characteristics of study participants stratified by Hour-1 Bundle compliance (n=50)

Variable	Total (n=50)	Bundle-Compliant (n=25)	Non-Compliant (n=25)	p-value
Age (years), mean ± SD	46.1 ± 20.2	44.9 ± 19.4	47.2 ± 21.3	0.684
18–40 years, n (%)	22 (44.0)	12 (48.0)	10 (40.0)	—
41–60 years, n (%)	16 (32.0)	8 (32.0)	8 (32.0)	—
>60 years, n (%)	12 (24.0)	5 (20.0)	7 (28.0)	—
Sex, n (%):				
Male	24 (48.0)	13 (52.0)	11 (44.0)	0.777
Female	26 (52.0)	12 (48.0)	14 (56.0)	
Weight (kg), mean ± SD	64.9 ± 14.4	65.1 ± 14.7	64.8 ± 14.3	0.877
Clinical category, n (%):				
Sepsis	43 (86.0)	23 (92.0)	20 (80.0)	0.415
Septic shock	7 (14.0)	2 (8.0)	5 (20.0)	
SBP (mmHg), mean ± SD	113.3 ± 16.7	115.4 ± 16.7	111.2 ± 16.8	0.294
Heart rate (/min), mean ± SD	106.4 ± 17.9	107.4 ± 18.9	105.4 ± 17.2	0.764
Respiratory rate (/min), mean ± SD	24.1 ± 5.1	24.9 ± 5.5	23.3 ± 4.7	0.264
Temperature (°C), mean ± SD	37.2 ± 1.7	37.0 ± 1.5	37.5 ± 1.8	0.484
qSOFA score, mean ± SD	1.08 ± 0.92	0.9 ± 0.7	1.2 ± 1.1	0.403
SOFA score, mean ± SD	6.1 ± 3.3	6.4 ± 3.5	5.8 ± 3.1	0.469
WBC (/µL), mean ± SD	11,095 ± 6,582	8,573 ± 5,237	13,618 ± 6,913	0.009*
Serum lactate (mmol/L), mean ± SD	3.38 ± 1.36	3.21 ± 1.33	3.56 ± 1.40	0.404
Lactate >2 mmol/L, n (%)	42 (84.0)			—
Lactate ≥4 mmol/L, n (%)	14 (28.0)			—
Altered sensorium (GCS <15), n (%)	9 (18.0)	2 (8.0)	7 (28.0)	0.138
Source of infection, n (%):				
Pneumonia	19 (38.0)	12 (48.0)	7 (28.0)	—
Urosepsis	9 (18.0)	3 (12.0)	6 (24.0)	
Unknown	8 (16.0)	3 (12.0)	5 (20.0)	
Skin/soft tissue	7 (14.0)	3 (12.0)	4 (16.0)	
Intra-abdominal sepsis	7 (14.0)	4 (16.0)	3 (12.0)	
ICU admission, n (%)	33 (66.0)	17 (68.0)	16 (64.0)	1.000
Hospital stay (days), median (IQR)	9.5 (6–12.8)	10.0 (6–12)	9.0 (5–13)	0.502

SD: standard deviation; IQR: interquartile range; SBP: systolic blood pressure; qSOFA: quick Sequential Organ Failure Assessment; SOFA: Sequential Organ Failure Assessment; WBC: white blood cell count. *Statistically significant ($p<0.05$). p-values for continuous variables computed using independent t-test or Mann-Whitney U test; categorical variables compared using Chi-square or Fisher's exact test.

The mean SOFA score at admission was 6.1 ± 3.3 (range: 2–12) and the mean qSOFA score was 1.08 ± 0.92. The mean serum lactate was 3.38 ± 1.36 mmol/L. Of the 50 patients, 42 (84%) had a serum lactate >2 mmol/L, and 14 (28%) had a lactate ≥4 mmol/L, indicating tissue hypoperfusion warranting immediate fluid resuscitation. Altered sensorium (GCS <15) was present in 9 patients (18%). The mean WBC count was 11,095 ± 6,582/µL. Notably, the non-compliant group had a significantly higher mean WBC count (13,618 ± 6,913/µL) compared to the compliant group (8,573 ± 5,237/µL; p=0.009), suggesting a greater inflammatory burden in patients who did not receive complete bundle care within one hour (Figure 2).

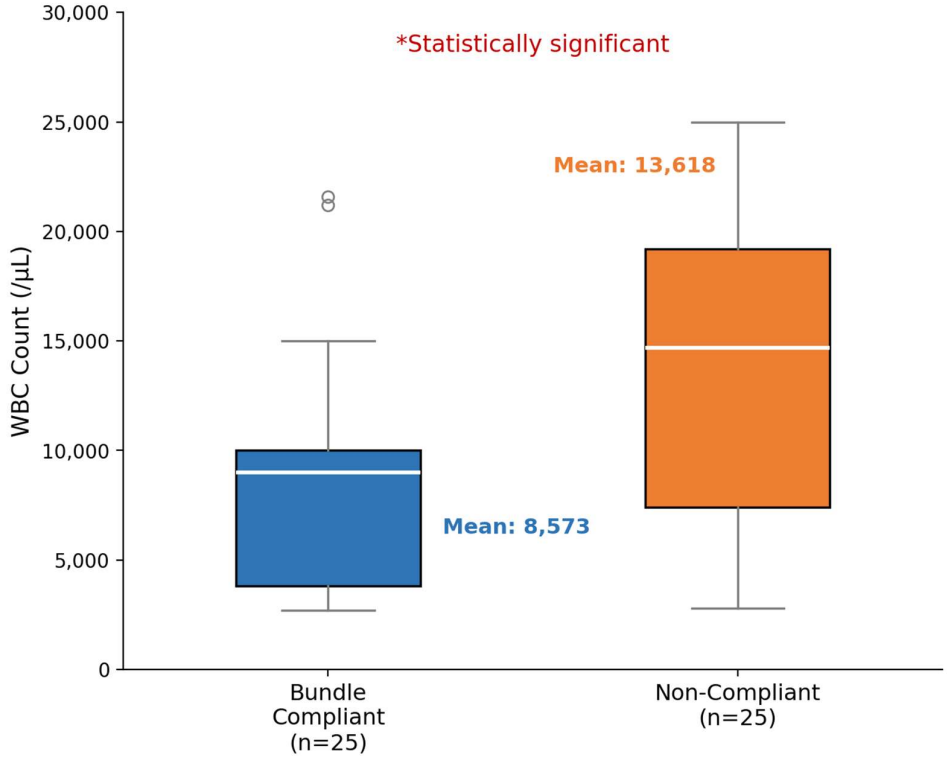

Figure 2: WBC count comparison between compliance groups (p = 0.009*)

Overall compliance with the Hour-1 Sepsis Bundle was 50% (n=25). Component-wise compliance, stratified by compliance group, is detailed in Table 2 and Figure 3. Serum lactate was measured within 1 hour in all 50 patients (100%) in both groups. Blood cultures before antibiotics were obtained in all 25 (100%) compliant-group patients versus 17 of 25 (68.0%) non-compliant-group patients (42/50, 84.0% overall), and broad-spectrum antibiotics were administered within 1 hour in all 25 (100%) compliant-group patients versus 18 of 25 (72.0%) non-compliant-group patients (43/50, 86.0% overall). Of the 14 patients indicated for 30 mL/kg crystalloid resuscitation (5 in the compliant group, 9 in the non-compliant group), all 5 compliant-group patients (100%) and 6 of 9 (66.7%) non-compliant-group patients received it within 1 hour (11/14, 78.6% overall). Of the 7 patients with an indication for vasopressors (2 compliant, 5 non-compliant), both compliant-group patients (100%) and 3 of 5 (60.0%) non-compliant-group patients had vasopressors initiated within 1 hour (5/7, 71.4% overall). Repeat serum lactate was indicated in this same group of 7 patients who remained haemodynamically unstable despite initial therapy; it was completed in both indicated compliant-group patients (100%) but in only 3 of 5 (60.0%) indicated non-compliant-group patients (5/7, 71.4% overall).

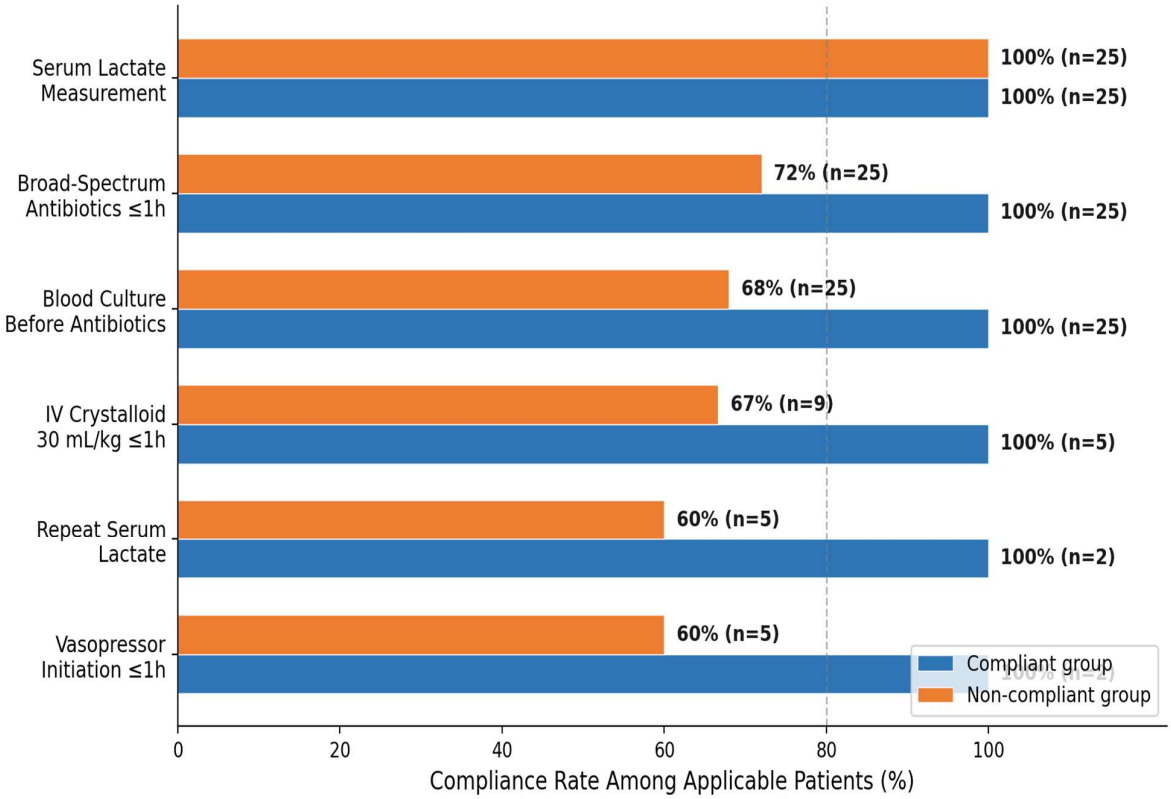

Figure 3: Component wise Hour-1 sepsis bundle compliance complaint vs non-compliant group

Table 2. Component-wise Hour-1 Sepsis Bundle compliance by group (n=50)

Bundle Component	App (C)	Done (C)	App (NC)	Done (NC)	Overall, n (%)	Comment
1. Serum lactate measurement	25	25 (100%)	25	25 (100%)	50 (100%)	Done in all patients
2. Blood culture before antibiotics	25	25 (100%)	25	17 (68.0%)	42 (84.0%)	8 missed, all in NC group
3. Broad-spectrum antibiotics ≤1h	25	25 (100%)	25	18 (72.0%)	43 (86.0%)	7 delayed, all in NC group
4. IV crystalloid 30 mL/kg ≤1h	5	5 (100%)	9	6 (66.7%)	11/14 (78.6%)	Only if hypotension/lactate ≥4
5. Vasopressor initiation ≤1h	2	2 (100%)	5	3 (60.0%)	5/7 (71.4%)	Only for persistent hypotension
6. Repeat serum lactate	2	2 (100%)	5	3 (60.0%)	5/7 (71.4%)	Only in non-responders to fluids/vasopressors
Overall Hour-1 Bundle Compliance	25	25 (100%)	25	0 (0%)	25/50 (50.0%)	Group definition

C: compliant group; NC: non-compliant group. Components 4, 5 and 6 were assessed only in patients for whom they were clinically indicated; percentages for these components are calculated from the applicable subset. Repeat serum lactate was indicated only in patients who remained haemodynamically unstable (non-responders) despite initial fluid resuscitation or vasopressor therapy, not in all patients with an elevated initial lactate.

Thirty-three patients (66%) required ICU admission. The median hospital stay for the entire cohort was 9.5 days (IQR: 6–12.8). Overall mortality was 12% (n=6). Among the six deaths, four occurred in patients with sepsis and two in patients with septic shock. The mortality rate was higher in the septic shock group (2/7, 28.6%) compared to the sepsis group (4/43, 9.3%), though this difference did not reach statistical significance (Fisher's exact test, p=0.192). Mean SOFA score was higher in patients who died (7.2 ± 3.4) compared to survivors (6.0 ± 3.3), though this was not statistically significant (p=0.335). Similarly, mean serum lactate was higher in non-survivors (3.72 ± 1.65 vs 3.34 ± 1.33 mmol/L; p=0.501) (Figure 4).

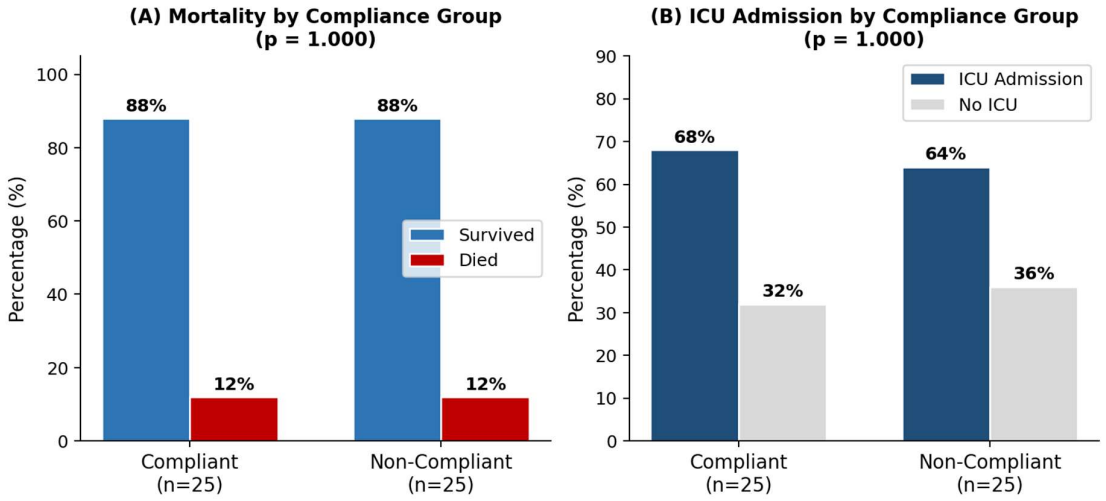

Figure 4: Clinical outcomes by Hour-1 Bundle Compliance

Bundle compliance was not significantly associated with mortality (p=1.000) or hospital stay (p=0.502). Equal proportions of patients died in the compliant and non-compliant groups (3 each, 12%). ICU admission rates were similarly distributed between groups (68% compliant vs 64% non-compliant; p=1.000). Table 3 summarises the clinical outcomes. Distribution of SOFA scores by patient outcome was given in Figure 5.

Table 3. Clinical outcomes stratified by Hour-1 Bundle compliance (n=50)

Outcome	Total (n=50)	Compliant (n=25)	Non-Compliant (n=25)	p-value
Mortality, n (%)	6 (12.0%)	3 (12.0%)	3 (12.0%)	1.000
Survived	44 (88.0%)	22 (88.0%)	22 (88.0%)	
Died	6 (12.0%)	3 (12.0%)	3 (12.0%)	
ICU admission, n (%)	33 (66.0%)	17 (68.0%)	16 (64.0%)	1.000
Hospital stay (days), median (IQR)	9.5 (6–12.8)	10.0 (6–12)	9.0 (5–13)	0.502
Outcome by clinical category:				
Sepsis — Died, n (%)	4/43 (9.3%)			0.192
Septic shock — Died, n (%)	2/7 (28.6%)			(Fisher's)

IQR: interquartile range. p-values computed using Fisher's exact test for categorical variables and Mann-Whitney U test for hospital stay. Outcome by clinical category p-value refers to Fisher's exact test comparing mortality rates between sepsis and septic shock groups.

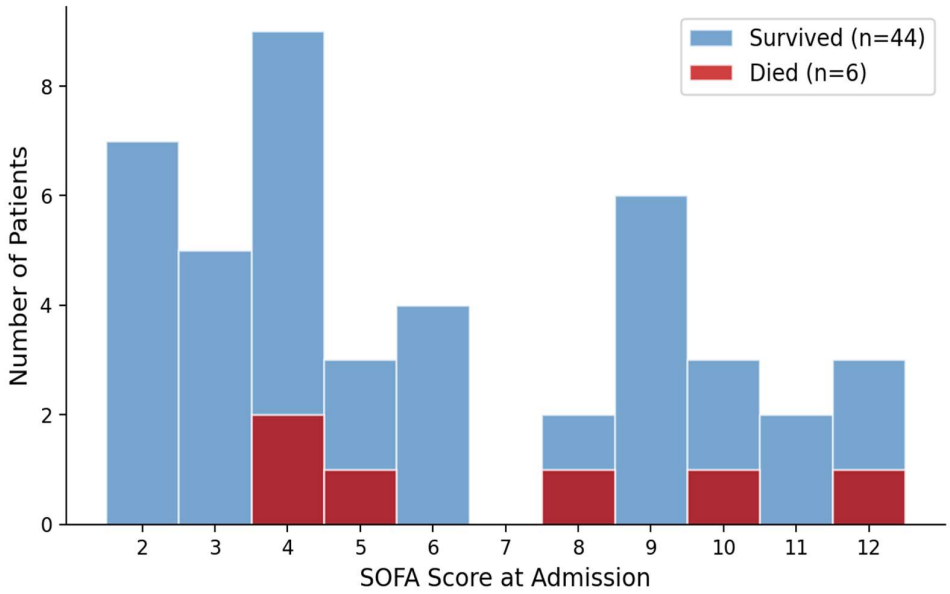

Figure 5: Distribution of SOFA scores by patient outcome

4.4 Prognosis Indicators and Repeat Lactate Monitoring

Table 4 summarises prognosis indicators according to bundle compliance. Crude survival (88.0% in each group) and mortality (12.0% in each group) were identical between groups, but the non-compliant group carried a higher septic shock burden (5/25, 20.0% vs 2/25, 8.0%), a higher proportion of altered sensorium (7/25, 28.0% vs 2/25, 8.0%), a higher mean WBC count (13,618 vs 8,573/µL), and a lower rate of repeat lactate completion among indicated patients (3/5, 60.0% vs 2/2, 100%).

Table 4. Prognosis indicators according to Hour-1 Bundle compliance

Outcome	Compliant (n=25)	Non-Compliant (n=25)	Clinical Interpretation
Survival	22 (88.0%)	22 (88.0%)	Similar crude survival in this small sample
Mortality	3 (12.0%)	3 (12.0%)	No crude mortality difference; interpret cautiously
Septic shock burden	2 (8.0%)	5 (20.0%)	Higher shock burden in non-compliant group
Altered sensorium	2 (8.0%)	7 (28.0%)	Poorer clinical profile in non-compliant group
WBC count	8,573 ± 5,237	13,618 ± 6,913	Higher inflammatory burden in non-compliant group
Repeat lactate completion among indicated	2/2 (100%)	3/5 (60.0%)	Monitoring gap in non-compliant group

WBC: white blood cell count. As this is an observational study, findings in this table should be interpreted as associations rather than causal effects.

Among the 7 patients in whom repeat lactate measurement was indicated (i.e. those who remained haemodynamically unstable despite initial fluid resuscitation or vasopressor therapy), those who completed it (n=5) had numerically lower mortality (1/5, 20.0%) than those who did not (n=2; 1/2, 50.0%) (Table 5, Figure 6). Given the very small subgroup sizes, this difference did not permit formal statistical testing and is reported as a descriptive trend rather than evidence of a causal effect. Taken together with the component-wise compliance data, these findings suggest that protocol-compliant patients had a more favourable clinical profile and fewer gaps in early monitoring, although the observational design and limited sample size preclude firm conclusions regarding a mortality benefit.

Table 5. Mortality outcome by repeat lactate completion status among indicated patients (n=7)

Repeat Lactate Status	n	Survived, n (%)	Died, n (%)	Mortality Rate	Interpretation
Repeat lactate completed	5	4 (80.0%)	1 (20.0%)	20.0%	Better monitoring; lower mortality trend
Repeat lactate not completed	2	1 (50.0%)	1 (50.0%)	50.0%	Higher mortality trend; sample very small — interpret with caution

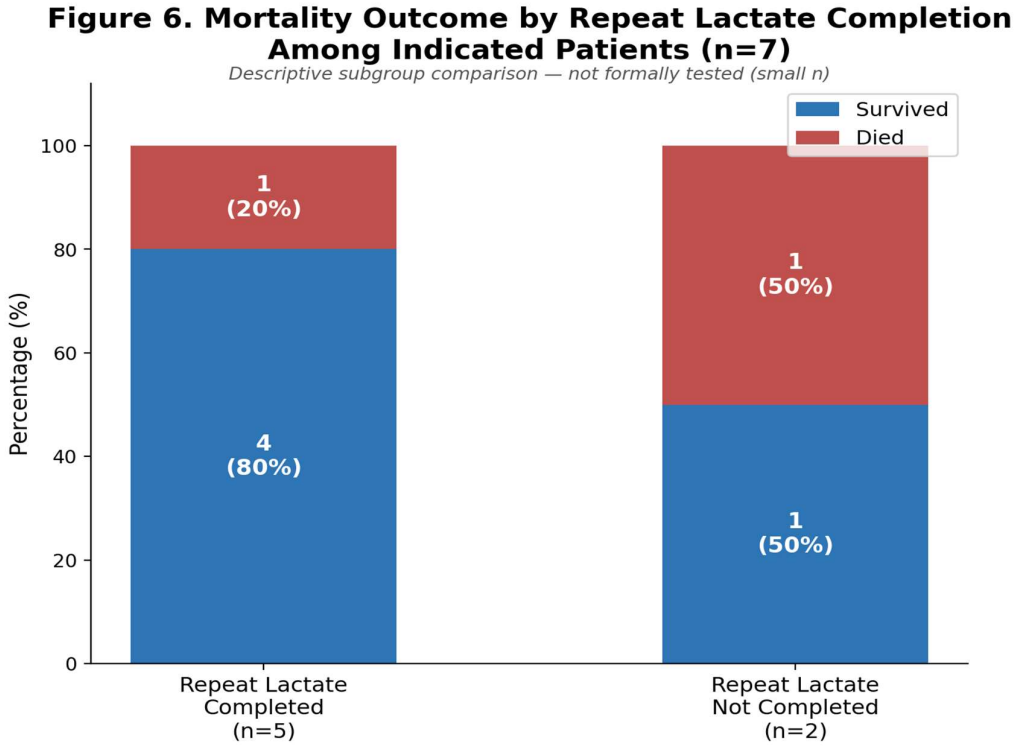

Figure 6: Mortality outcome by repeat lactate completion among indicated patients (n=7)

DISCUSSION

In this prospective IMCU cohort, 40% of patients completed the one-hour bundle, and compliance was linked to significantly better outcomes. This compliance rate is generally in line with the low adherence reported elsewhere. For instance, Ko et al. (2021) found that only 28.6% of patients with protocolized septic shock achieved the hour-1 bundle, and similar implementation gaps have been reported in emergency and critical care settings [2]. Despite widespread support for the guidelines, these gaps continue to exist because of well-known obstacles, such as limitations in laboratories and microbiology, difficulties with workflow and coordination, and inconsistent awareness among frontline workers.

The principal finding — a significantly lower IMCU mortality among bundle-compliant patients (20% vs 60%) — aligns with the broad body of evidence linking timely, complete bundle delivery to improved survival, including the analyses of Milano et al. (2018), the Surviving Sepsis Campaign 2018 update by Levy et al., and the 2021 international guidelines by Evans et al. It is important to note, however, that not all studies have found an independent survival benefit once severity is accounted for; Ko et al., for instance, reported no independent association between hour-1 bundle completion and outcome [3-5, 2]. The strength of association observed here should therefore be interpreted in the context of an observational design and a small sample, in which unmeasured confounding may persist despite the comparable baseline severity of the two groups.

The secondary outcomes reinforced the primary finding. Earlier antibiotic administration in the compliant group is consistent with the well-described relationship between time-to-antibiotics and survival in sepsis, while the shorter duration of vasopressor support and the higher six-hour lactate clearance suggest more effective early haemodynamic resuscitation and restoration of tissue perfusion. Delayed vasopressor initiation has itself been associated with increased mortality in septic shock supporting the physiological plausibility of these observations [6]. The greater reduction in SOFA score by day 3 provides an integrated signal of faster organ-dysfunction recovery in compliant patients.

In terms of diagnostic stewardship, the lowest adherence was reported for prompt 30 mL/kg crystalloid dosing and collecting blood cultures prior to antibiotics. The latter is especially significant because the absence of pre-antibiotic cultures compromises both individual treatment and institutional antimicrobial stewardship. Pre-antibiotic cultures significantly increase the yield of pathogen detection and the subsequent capacity to de-escalate therapy. The most practical goals for regional quality-improvement initiatives are these two elements.

Finally, the admission SOFA score showed acceptable discrimination for IMCU mortality (AUC 0.70) and correlated positively with length of stay, reaffirming its utility as a simple early prognostic tool. An AUC in this range indicates useful but imperfect discrimination; the SOFA score is best used to support, rather than replace, comprehensive clinical assessment and serial reassessment.

CONCLUSION

Compliance with the complete one-hour sepsis bundle was associated with lower IMCU mortality, shorter intensive-care stay, reduced organ-support requirements and faster physiological recovery in patients with sepsis, despite comparable baseline severity between groups. Adherence to the full bundle was nonetheless achieved in a minority of patients, with the principal shortfalls in fluid resuscitation and pre-antibiotic blood cultures. Strengthening institutional sepsis protocols and targeted quality-improvement interventions aimed at these gaps may further improve outcomes for critically ill patients.

LIMITATIONS

Single-centre design, which may limit the generalisability of the findings. Small sample size (n = 50): the study was powered to estimate a compliance proportion rather than to compare individual clinical outcomes, so several non-significant comparisons may reflect limited statistical power (type II error). Observational design, in which residual and unmeasured confounding cannot be excluded despite comparable baseline severity between groups. Short study duration (three months), which constrains sample size and precludes assessment of longer-term and post-discharge outcomes.

FUTURE DIRECTIONS

Multicentre studies with larger samples, adequately powered to detect differences in mortality and other clinical outcomes. Prospective quality-improvement or interventional designs that test targeted strategies to raise compliance, particularly for fluid resuscitation and pre-antibiotic blood cultures. Multivariable and severity-adjusted analyses to better isolate the independent effect of bundle compliance on outcomes. Evaluation of the cost-effectiveness and resource implications of structured one-hour bundle implementation in resource-limited settings. Assessment of longer-term outcomes, including hospital mortality, functional recovery and readmission.

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