



# A Prospective Observational Comparative study Between qSOFA and SIRS Scores for Early Prediction of Sepsis Outcome in an Emergency Medicine Department , Kozhencherry, South Central Kerala,India

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## ABSTRACT

### Background

Sepsis remains a significant challenge in emergency medicine, with early identification crucial for improved outcomes. The introduction of the quick Sequential Organ Failure Assessment (qSOFA) score has sparked debate about its efficacy compared to the traditional Systemic Inflammatory Response Syndrome (SIRS) criteria in predicting sepsis outcomes.

### Objective

To compare the performance of qSOFA and SIRS scores in early prediction of sepsis outcomes in an Emergency Medicine Department.

### Methods

A prospective observational study was conducted on 63 patients aged 18-80 years presenting with suspected sepsis at Muthoot Health Care, Kozhencherry. Patients were assessed using both qSOFA and SIRS criteria. Exclusion criteria included pregnancy, terminal illness, and severe comorbidities. Participants were followed up to determine final diagnosis and outcomes. Data analysis compared the effectiveness of qSOFA and SIRS in predicting sepsis outcomes.

### Results

The majority of participants (59.9%) were over 50 years old, with a slight male predominance (54%). qSOFA scores of 0-1 were observed in 55.6% of patients, while 60.3% had SIRS scores of 3-4. The mean qSOFA and SIRS scores were 1.59 and 2.75, respectively. A significant correlation was found between qSOFA scores and outcomes ( $p=0.007$ ). The in-hospital mortality rate was 30.2%.

### Conclusion

While qSOFA demonstrated a slight advantage in predicting in-hospital mortality, SIRS showed higher sensitivity in sepsis diagnosis. The study suggests that a combined approach using both scoring systems may provide a more comprehensive assessment of patients with suspected sepsis in the emergency department setting. Further large-scale, multicenter studies are recommended to validate these findings across diverse populations.

**Keywords:** Adherence; Hypertension; Socio-demographic; Lifestyle

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## INTRODUCTION

More than two decades ago, sepsis was defined as the combination of infection and Systemic Inflammatory Response Syndrome (SIRS) (1). However, subsequent research revealed that sepsis is not an exclusively proinflammatory condition; rather, it may involve early antiinflammatory responses (2). Moreover, SIRS criteria were found to be too sensitive and insufficiently specific to identify infected patients at risk for a complicated course (3),(4). In the light of such developments, the Third International Consensus Definitions for Sepsis and Septic Shock (Sepsis-3) Task Force recently redefined sepsis (5). Sepsis is accordingly viewed as a "lifethreatening organ dysfunction caused by a dysregulated host response to infection" (5).

Organ dysfunction was characterized by the acute increase of at least two points in the Sequential (Sepsis-related) Organ Failure Assessment (SOFA) score (5). Given that SOFA requires laboratory testing and is rarely performed outside the intensive care unit (ICU), for patients in a non-ICU setting, the Sepsis-3 Task Force introduced a simpler algorithm, named quick SOFA (qSOFA) (5). The qSOFA has merits according to its proponents. It is simple (consisting of three clinical elements, namely hypotension, tachypnea and altered consciousness), it can be easily and repeatedly assessed, it was generated through a data-driven approach, and in a large retrospective study it was more accurate than SIRS score for predicting death and ICU transfer of patients with suspected sepsis outside the ICU (6),(7),(8). However, thoughtful criticisms have also been articulated. It has been stressed that the increased specificity of qSOFA over SIRS score for predicting poor prognosis may come at the expense of lower sensitivity, which may lead to delays in initiation of treatment (9). Others pointed that it was not endorsed by key scientific societies or they were skeptical about its misapplication as a clinical decision tool (10),(11). The Sepsis-3 Task Force itself has strongly encouraged independent validation in multiple health care settings to confirm its robustness and suggested that qSOFA should also be evaluated for outcomes other than mortality and ICU stay (5)(6). Having the above considerations into mind, we endeavoured to evaluate the discriminatory capacity of qSOFA versus SIRS criteria for predicting in-hospital mortality and ICU-

free days in patients with suspected infection. In addition, we sought to assess the comparative accuracy of qSOFA and SIRS criteria for predicting other important clinical outcomes, such as ventilator-free days and organ dysfunction-free days. The current use of 2 or more SIRS criteria to identify sepsis was unanimously considered by task force to be unhelpful. SIRS criteria include Two or more of temperature  $>38^{\circ}\text{C}$  or  $<36^{\circ}\text{C}$ , heart rate  $>90/\text{min}$ , respiratory rate  $>20/\text{min}$  or  $\text{paco}_2 <32\text{mmHg}$ , white blood cell count  $>12000/\text{mm}^3$  or  $<<4000/\text{mm}^3$  or  $>10\%$  immature bands. In a prospective study of the epidemiology of patients demonstrating systemic inflammatory response syndrome (infectious and non infectious) mortality rates were 3% in patients with no SIRS (14), 6% in those meeting two criteria, 10% in three criteria and 17% in those meeting all criteria. In fact SSC-3 proposed a conceptual change in the definition and diagnosis of sepsis. The SIRS criteria do not necessarily indicate a dysregulated, life threatening response. SIRS criteria are present in many hospitalized patients including those who never develop infection and never incur adverse outcomes hence they propose a new but simple study tool called qSOFA to predict outcome of sepsis in ED and other similar environments like ward settings. Adult patients with suspected infection can be rapidly identified as being more likely to have poor outcomes typical of sepsis if they have at least two of the following clinical criteria that together constitute a new bedside clinical score termed quickSOFA (qSOFA) which include respiratory rate  $\geq 22/\text{min}$  or greater, altered mentation, or systolic blood pressure of 100 mmHg or less. The qSOFA Score was introduced by the Sepsis-3 group in February 2016 as a simplified version of the SOFA Score as an initial way to identify patients at high risk for poor outcome with an infection. If hospital admissions could be prioritized based on scoring systems, the use of financial, medical and human resources can be optimized and will allow the best usage in the hospital. The study suggests that qSOFA criteria be used to prompt clinicians more vigilant in sepsis patients. They could further investigate for organ dysfunction, to initiate or escalate therapy as appropriate and to consider to referral to critical care or to increase the frequency of monitoring, if such actions have not already been



undertaken and thereby try tackle sepsis related morbidity and mortality. Objective of the study was to compare between qSOFA and SIRS score in early prediction of outcome of sepsis in Emergency medicine department.

## METHODOLOGY

### Study Design

This study was a prospective, comparative design conducted at Muthoot Health Care Pvt Ltd, Kozhencherry, Kerala, India. The hospital, established in 1988, is an ISO 9001:2008 certified multispecialty tertiary care facility with 407 beds and NABH accreditation. Ethical approval was obtained from the Institutional Ethics Committee (IEC No: EC/765/Inst/KL/2015), and written informed consent was acquired from all participants in both English and Malayalam.

### Inclusion Criteria:

- Patients aged between 18 and 80 years.
- All patients presenting to the emergency department with suspected sepsis who are admitted to the Intensive Care Unit (ICU).

### Exclusion Criteria:

- Patients younger than 18 years or older than 80 years.
- Pregnant women.
- Terminally ill patients.
- Patients with severe comorbidities that may confound the results.

### SIRS and qSOFA Criteria

The study utilized both the Systemic Inflammatory Response Syndrome (SIRS) criteria and the quick Sequential Organ Failure Assessment (qSOFA) criteria for identifying sepsis. The criteria are as follows:

- **SIRS Criteria:**
  - Body temperature  $>38^{\circ}\text{C}$  or  $<36^{\circ}\text{C}$ .
  - Heart rate  $>90$  beats per minute.
  - Respiratory rate  $>20$  breaths per minute or arterial  $\text{CO}_2 <32$  mmHg.

## RESULTS

Out of 63 participants Majority of the study participants were above 50 years of age (59, 9.7%). Three participants were between 30 and 50 years of age and one participant was less than 30 years of age. Males constituted 54 % of the study population and females were 46%.Majority of the participants belonged to a qSOFA score of 0-1 (35, 55.6%) and

- White blood cell count  $>12,000/\mu\text{L}$  or  $<4,000/\mu\text{L}$  or  $>10\%$  immature neutrophils.
- **qSOFA Criteria:**
  - Altered mental status (Glasgow Coma Scale  $<15$ ).
  - Respiratory rate  $\geq 22$  breaths per minute.
  - Systolic blood pressure  $\leq 100$  mmHg.

Patients were examined by a physician who assessed them against these criteria using a specially designed data collection tool developed under the guidance of my supervisor. This tool is user-friendly and facilitates comparison between the two criteria.

### Sample Size Calculation

The sample size ("n") for this study was calculated using Cochran formula taking  $z=1.96$ ,  $p=0.8$  and  $e=0.1$ , putting these values, the calculated sample size was 61.54 rounded to 62. Hence minimum sample size for the study is 62. During the study period 63 observations were found and so we fixed the sample size is 63.

### Statistical Analysis

Data collected will be analyzed using appropriate statistical tests to compare the effectiveness of qSOFA versus SIRS criteria in diagnosing sepsis. The following statistical methods will be employed:

- Descriptive statistics to summarize patient demographics and clinical characteristics.
- Chi-square tests for categorical variables.
- Linear Regression Model for SIRS score and Qsofa score prediction of final outcome
- Receiver Operating Characteristic (ROC) curve analysis to evaluate the diagnostic accuracy of both criteria.
- A p-value of  $<0.05$  will be considered statistically significant.

The collected data will be analyzed at the end of one year to assess outcomes related to sepsis diagnosis and management based on the chosen criteria.

44.4 % belonged to a score of 2-3. Mean qSOFA score was 1.59. Most of the study participants had a SIRS score of 3-4 (38, 60.3%) and 39.7 % had a score of 1-2 and the mean score was 2.75. 69.8 % of the study participants were discharged from the hospital and 30.2 % of them expired.



Table1: Age distribution of the participants

Age group	Frequency	Percentage
<30	1	1.6%
30-50	3	4.8%
>50	59	93.7%
TOTAL	63	100%

In this study population of age more than 50 were 93.7%(59) ,between 30 and 50 were 4.8%(3) and <30 were 1.6%(1).

Table2: Sex distribution of the participants

Sex	Frequency	Percentage
Male	29	46%
Female	34	54%
TOTAL	63	100%

Out of 63 participants selected for our study 34(54%) were females and 29(46%) were males.

Table 3 Association between qSOFA score and Independent variables using Chi square test

Variable	qSOFA score		Chi square value	P value	
	0-1	2-3			
Age	<30	1	0	0.992	0.609
	30-50	2	1		
	>50	32	27		
Gender	Female	14	15	1.153	.283
	Male	21	13		



In the qSOFA score assessment, participants were categorized into low (0-1) and high (2-3) risk groups. The age distribution revealed that predominantly participants over 50 years (32 participants) were

having low qSOFA score (0-1). Statistical analysis showed no significant associations between qSOFA scores and Age ( $P \leq 0.609$ ) and Gender ( $P \leq 0.283$ )

Table 4 Association between SIRS score and Independent variables using Chi square test

Variable	SIRS score		Chi square value	P value	
	1-2	3-4			
Age					
	<30	0	1	0.733	0.693
	30-50	1	2		
	>50	24	35		
Gender	Female	12	17	.065	.799
	Male	13	21		

The SIRS score evaluation (Table 2) categorized participants into low (1-2) and high (3-4) risk groups. High SIRS score (3-4) were seen in predominantly older participants (35 participants over 50 years).

Statistical testing revealed no significant relationships between SIRS scores and Age ( $P \leq 0.693$ ) and Gender ( $P \leq 0.799$ ).

Table 5: Association between Final outcome and Independent variables using Chi square test

Variable	Outcome		Chi square value	P value	
	Discharged	Expired			
Age					
	<30	1	0	0.450	0.799
	30-50	2	1		
	>50	41	18		
Gender	Female	22	7	.925	.336
	Male	22	12		

The final outcome analysis showed in discharged patient, majority were over 50 years (41 participants) and expired patients were primarily older participants (18 participants over 50 years). No

statistically significant associations were observed between outcomes and Age ( $P \leq 0.799$ ) and Gender ( $P \leq 0.336$ )

Table 6: Association between Final outcome and Dependent variables using Chi square test

Score	Score Range	Outcome		Total Patients	Survival Rate	Mortality Rate	Chi square value	P value
		Discharged	Expired					
qSOFA	0-1	27	8	35	77.1%	22.9%	1.993	0.158
	2-3	17	11	28	60.7%	39.3%		
SIRS	1-2	19	6	25	76.0%	24.0%	.746	.388
	3-4	25	13	38	65.8%	34.2%		

Despite observed differences in survival rates across score categories, neither qSOFA nor SIRS scores demonstrated statistically significant predictive power for patient outcomes. Higher score categories

exhibited a trend towards decreased survival, though not statistically significant ( $P \leq 0.158$  and  $P \leq 0.388$ ).

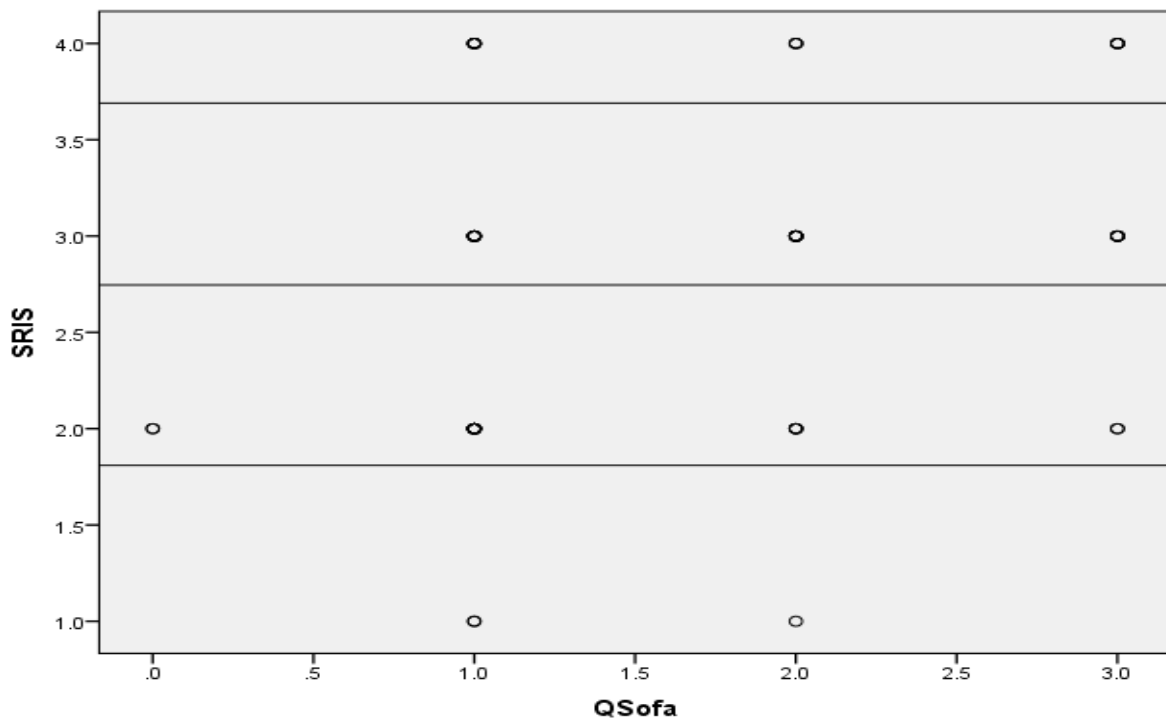


Figure 1: Bland-Altman plot for agreement between of SIRS score and qSOFA score



Bland-Altman analysis was employed to evaluate the concordance between SIRS and qSOFA scoring systems. **Coverage Interval:** 95% of the data points are contained within the designated shaded region .

,this substantial overlap indicates a strong potential correlation between SIRS and qSOFA scores in clinical assessment

Table 7: qSOFA score prediction of final outcome by Linear Regression Model

Model	Unstandardized Coefficients		Standardized Coefficients	t	Sig.
	B	Std. Error			
(Constant)	1.000	.122		8.205	.000
Qsofa	-.190	.068	-.335	-2.778	.007

The table presents a linear regression model using the qSOFA (Quick Sequential Organ Failure Assessment) score to predict the final outcome with Constant (Intercept): 1.000 and qSOFA Coefficient: -0.190. The negative coefficient (-0.190) indicates an

inverse relationship between qSOFA score and the outcome with P value  $\leq 0.007$ . As qSOFA scores increase, the predicted final outcome tends to decrease, with this relationship being statistically meaningful.

Table 8: SIRS score prediction of final outcome by Linear Regression Model

Model	Unstandardized Coefficients		Standardized Coefficients	t	Sig.
	B	Std. Error			
(Constant)	.875	.201		4.362	.000
SIRS	-.064	.070	-.117	-.920	.361

Linear regression model using SIRS (Systemic Inflammatory Response Syndrome) score to predict final outcome with Constant (Intercept): 0.875 and SIRS Coefficient: -0.064. The negative coefficient (-

0.064) suggests a slight inverse relationship with P value  $\leq 0.361$  shows no statistically significant relationship.



Table 9: Combined prediction by Qsofa and SRIS scores of final outcome by Linear Regression Model

Model	Unstandardized Coefficients		Standardized Coefficients	t	Sig.
	B	Std. Error	Beta		
(Constant)	1.027	.201		5.118	.000
Qsofa	-.186	.072	-.329	-2.587	.012
SRIS	-.012	.070	-.021	-.167	.868

This table Combines both qSOFA and SIRS scores in a single predictive model with a Constant (Intercept): 1.027 and qSOFA Coefficient: -0.186 and SIRS Coefficient: -0.012. qSOFA score remains statistically significant (p-value = 0.012) but SIRS

loses its significance in the combined model with P value  $\leq 0.868$ . Thus in a combined model, qSOFA remains a robust predictor, while SIRS becomes statistically irrelevant

## DISCUSSION

This prospective observational study compared the performance of qSOFA and SIRS scores in predicting sepsis outcomes in the Emergency Department (ED) setting. Our findings contribute to the ongoing debate surrounding the utility of these scoring systems in early sepsis identification and prognosis.

and laboratory data, including systemic manifestations, organ dysfunction indicators, and microbiological evidence(12). This multifaceted approach highlights the complexity of sepsis diagnosis and the need for comprehensive assessment tools.

### Sample Characteristics and Methodology

Our study included 63 patients presenting to the ED with suspected sepsis. Patients with positive qSOFA scores were selected as the primary sample population, and both qSOFA and SIRS scores were calculated for all participants. This approach allowed for a direct comparison of the two scoring systems within the same cohort(12)

### Sepsis-3 Criteria and qSOFA

The introduction of the Sepsis-3 criteria, which emphasizes organ dysfunction, led to the development of qSOFA as a rapid bedside tool. qSOFA assesses respiratory rate, systolic blood pressure, and mental status(12). While our study found qSOFA to be slightly superior in mortality prediction, it's important to note that its overall performance was moderate, with an area under the ROC curve of 0.66 in some studies(14).

### Comparative Performance of qSOFA and SIRS

The results of our analysis suggest that qSOFA demonstrates a slight advantage over SIRS in predicting in-hospital mortality. However, SIRS appears to be more sensitive in diagnosing sepsis(12). This finding aligns with previous research, including a meta-analysis by Seymour et al., which found qSOFA to be a better predictor of mortality in non-ICU patients(13).

### Comparison with Other Scoring Systems

Recent research has compared qSOFA and SIRS with other early warning scores. Churpek et al. found that while qSOFA outperformed SIRS in predicting in-hospital mortality, it was less accurate than general early warning scores like the Modified Early Warning Score and the National Early Warning Score(15). Additionally, Wang et al. reported that qSOFA's discriminatory power for mortality was lower than that of the Mortality in Emergency Department Sepsis (MEDS) score(16).

### Diagnostic Challenges in Sepsis

The lack of a definitive gold standard for sepsis diagnosis remains a significant challenge in the field. Current practice relies on a combination of clinical





### Age-Specific Considerations

It's worth noting that the performance of these scoring systems may vary in different age groups. A study focusing on elderly patients ( $\geq 60$  years) found qSOFA to be superior to SIRS, NEWS, and REWS in predicting 28-day mortality and septic shock in the ED(14). This suggests that age-specific validation of these tools may be necessary for optimal clinical application.

### Strengths of qSOFA and SIRS for Mortality Prediction: Simplicity and Speed:

qSOFA is a quick bedside tool that assesses only three clinical criteria (respiratory rate, systolic blood pressure, and mental status), making it easy to use in emergency settings.

**Better Mortality Prediction:** Our study, along with others, found that qSOFA demonstrates a slight advantage over SIRS in predicting in-hospital mortality, particularly in non-ICU settings.

**Specificity:** In the context of sepsis diagnosis, qSOFA appears to have better specificity compared to SIRS. **Higher Sensitivity:** SIRS demonstrates greater sensitivity in diagnosing sepsis compared to qSOFA, which is crucial for early identification and treatment of septic patients. **Established Use:** SIRS criteria have been widely used and understood in clinical practice for many years, making them familiar to healthcare providers.

### Weakness of qSOFA and SIRS for Mortality Prediction:

qSOFA is less sensitive than SIRS for diagnosing sepsis, which may lead to delayed recognition of septic patients. **Moderate Overall Performance:** While better than SIRS, qSOFA's overall performance in mortality prediction is still moderate, with an area under the ROC curve of 0.66 in some studies.

**Age-Dependent Efficacy:** The performance of qSOFA may vary across different age groups, potentially requiring age-specific validation. **Lower Specificity:** SIRS criteria are less specific than qSOFA, potentially leading to over-diagnosis of sepsis.

**Inferior Mortality Prediction:** Our study, consistent with others, found that SIRS is slightly less effective than qSOFA in predicting in-hospital mortality. **Complexity:** SIRS involves more clinical criteria than qSOFA, making it potentially more time-consuming to calculate in emergency situations.

In conclusion, while qSOFA shows promise in predicting mortality, particularly in non-ICU settings, SIRS remains valuable for its higher

sensitivity in sepsis diagnosis. The choice between these scoring systems should consider the specific clinical context and the balance between sensitivity and specificity required for each situation.

**Limitations and Future Directions**  
Our study was limited by its single-center design and relatively small sample size. Future research should focus on larger, multicenter studies to validate these findings across diverse populations. Additionally, investigating the integration of biomarkers or other clinical parameters with qSOFA and SIRS could potentially enhance their predictive accuracy(17).

**Recommendations**

1. **Implement Combined Scoring Approach:** Consider using both qSOFA and SIRS in the ED to leverage their respective strengths in mortality prediction and sepsis diagnosis.

### Recommendations

2. **Age-Specific Validation:** Conduct further studies to validate the performance of qSOFA and SIRS in different age groups, particularly in elderly populations.

### Recommendations

3. **Integrate with Electronic Health Records:** Develop automated systems to calculate these scores within electronic health records to facilitate rapid and consistent assessment.

4. **Explore Biomarker Integration:** Investigate the potential of combining qSOFA or SIRS with biomarkers like procalcitonin or C-reactive protein to improve predictive accuracy.

5. **Standardize Reporting of Social Determinants:** Include standardized reporting of social determinants of health in future sepsis studies to better understand their impact on outcomes(18).

6. **Develop Composite Scores:** Research the potential of creating composite scores that incorporate elements of qSOFA, SIRS, and other relevant clinical parameters for improved sepsis prognostication.

7. **Education and Training:** Implement comprehensive training programs for ED staff on the appropriate use and interpretation of these scoring systems.

8. **Longitudinal Follow-up:** Design studies with longer follow-up periods to assess the long-term predictive value of these scoring systems beyond in-hospital mortality.

**CONCLUSION**

This prospective observational study comparing qSOFA and SIRS scores in predicting sepsis outcomes in the Emergency Department yielded valuable insights. While qSOFA demonstrated a slight advantage in predicting in-hospital mortality, SIRS exhibited higher sensitivity in sepsis diagnosis. The study revealed that higher qSOFA scores were significantly associated with poorer outcomes ( $P \leq 0.007$ ), whereas SIRS scores showed no statistically significant relationship with final outcomes. The findings suggest that a combined approach utilizing both scoring systems may provide a more comprehensive assessment of patients with suspected sepsis. The qSOFA's simplicity and specificity complement SIRS's higher sensitivity, potentially offering a balanced tool for clinicians. However, the study's limitations, including its single-center design and relatively small sample

size, necessitate further large-scale, multicenter research to validate these findings across diverse populations. Future studies should also explore the integration of biomarkers or other clinical parameters with qSOFA and SIRS to enhance predictive accuracy. In conclusion, while both scoring systems have their strengths, their combined use, alongside clinical judgment, may offer the most effective approach for early sepsis identification and outcome prediction in the emergency department setting.

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