

Comparison of QSOFA Score and SIRS Criteria for the Prediction of Sepsis Outcome in Patients with a Suspected Bacterial Infection outside the Intensive Care Unit in the North of Iran

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ABSTRACT

Backgrounds: The present study aimed to determine the quick Sepsis-related Organ Failure Assessment (qSOFA) score in comparison with systemic inflammatory response syndrome (SIRS) criteria to predict adverse consequences of a suspected bacterial infection in patients outside the intensive care unit (ICU).

Materials & Methods: This retrospective study was conducted on patients during March 2018 to March 2019. All hospitalized patients with this suspected infection were positive for both SIRS and microbial cultures. Demographic and laboratory variables were recorded for all patients to determine the presence and time of various components of both SIRS criteria and the qSOFA score.

Findings: Out of 128 patients with suspected sepsis, 87 (68%) patients were confirmed to have septicemia based on SIRS criteria. SIRS criteria classified 68% of patients in the sepsis group (87 of 128), of which 39(44.8%) had a positive qSOFA score. The sensitivity and specificity ratios of qSOFA were 44.83 and 80.49%, respectively.

Receiver operating characteristic (ROC) curve analysis results showed that the area under the ROC curve (AUC) of pSOFA scores for predicting sepsis patients was not significantly different. Moreover, regarding the sepsis-related mortality, the area under ROC showed that qSOFA criteria (score ≥ 2) were able to predict mortality in patients with 71% sensitivity and 72% specificity.

Conclusion: This study findings revealed that the qSOFA score was significantly efficient in predicting mortality. However, SIRS criteria were more sensitive than the qSOFA score in predicting the definitive diagnosis of sepsis. Therefore, the qSOFA score seems to be an invaluable tool for predicting outcome in sepsis patients.

Keywords: Sepsis, SIRS, qSOFA, Bacterial infection

CITATION LINKS

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Introduction

Sepsis is a critical condition accounting for 10% of intensive care unit (ICU) cases and 10 to 20 % of in-hospital mortality rates worldwide [1-3]. In the last few decades, the incidence of sepsis and severe sepsis has increased probably due to the fact that they are more easily diagnosed in elderly patients [4-5].

Rapid detection of sepsis could lead to early intervention, which has attracted much attention in the emergency department (ED). To diagnose sepsis based on the former consensus explanations, the criteria of the infection and two or more criteria of systemic inflammatory response syndrome (SIRS) must be met [6-7]. Tachypnea (respiratory rate of over 20 breaths per minute), leukopenia or leukocytosis (leucocyte count of higher than 12,000 cells/ μ L or < 4000/ μ L), tachycardia (heart rate of over 90 beats per minutes), and hypothermia or fever (body temperature of less than 36 °C or higher than 38 °C, respectively) are four SIRS criteria [6]. Nevertheless, SIRS has been criticized for its prognostic value, utility, and inadequate specificity [6].

Currently, an international task force in the third international consensus explanations has redefined this syndrome as septic shock (Sepsis-3) and sepsis [7]. Accordingly, sepsis is considered as a life-threatening organ dysfunction resulted from a dysregulated reaction of host to infection. An acute increase of at least two points in the sequential organ failure assessment (SOFA) score is characterized as organ dysfunction [5].

The use of the quick sepsis-related organ failure assessment (qSOFA) tool has also been redefined in recent Sepsis-3 guidelines. Studies have indicated that the qSOFA score is more accurate in predicting death outside the ICU than the SIRS score [8]. In Sepsis-3, qSOFA criteria screening is recommended to be performed outside the ICU to encourage clinicians to further assess organ dysfunction

and initiate an appropriate therapy [9].

Novel criteria of qSOFA have been represented in Sepsis-3 (qSOFA scores in the range of 0-3; receiving 1 point if meeting the following criteria: altered mental status, respiratory rate > 21 breaths/min, and systolic blood pressure of less than or equal to 100 mmHg) [10].

Longer ICU stay and higher mortality risk are predicted by a qSOFA score of ≥ 2 [11]. The explanation group has described qSOFA as a better predictor of mortality compared to SIRS, suggesting that a qSOFA score of 2 or higher be used rather than a SIRS score of ≥ 2 to identify infected patients at higher risk of death [12]. Both early diagnosis and treatment of sepsis are necessary to decrease mortality and hospital stay length. The novel explanation could improve the treatment of patients with more severe sepsis.

Objectives: The present study aimed to determine the effectiveness of qSOFA compared to SIRS in predicting adverse consequences for suspected sepsis patients outside the ICU.

Materials and Methods

Study design and patient population:

This cross-sectional study was conducted on patients referring to the emergency medicine department of Razi hospital during March 2018 to March 2019. All hospitalized patients with a suspected infection, who were positive for SIRS and microbial cultures (blood, urine, and CSF) or/and received antibiotics within 48 hrs of admission to ED, were enrolled in this study. Patients were considered as sepsis positive if they met two or more of SIRS criteria. Suspected infection was diagnosed using the following data extracted from patients' hospital records: blood pressure, heart rate, body temperature, respiratory rate, and level of consciousness. Patients who did not have demographic and laboratory variables as

Table 1) Baseline characteristics and clinical outcomes of patients.

Variable	Patients with Definitive Sepsis N (%)	Patients without Sepsis N (%)
Male	44 (50.6)	16 (39)
Female	43 (49.4)	25 (61)
SBP	115±21.5	120.4±22.1
DBP	69.6±10.3	70.6±10.01
PR	91.5±14.6	86.7±13.8
RR	18.5±5.01	18.1±4.5
T	38.4±0.5	38.07±0.5
WBC	15621.8±4413.3	13963.4±3138.1
PT	12.3±0.8	12.2±0.41
PTT	29.2±1.8	28.6±1.2
BUN	29.5±10.3	26.5±8.6
CR	2.6±1.07	1.2±0.37
Type of infection*		
Pneumonia	37 (46.8)	13 (48.1)
UTI	21 (26.6)	11 (40.7)
Intra-abdominal infection	7 (8.9)	0
SSTIs	14 (17.7)	3 (11.1)

UTI: urinary tract infection, SSTIs: skin and soft tissue infections, SBP: systolic blood pressure, DBP: diastolic blood pressure, PR: progesterone-receptor, RR: respiratory rate, T: troponin, PT: prothrombin time, PTT: partial thromboplastin time, BUN: blood urea nitrogen; CR: creatinine

* $p=.23$

well as SIRS criteria were excluded from the study^[13]. After final diagnosis, patients were divided into two groups (with and without sepsis). Then qSOFA criteria in these two groups were evaluated, and the number of patients diagnosed with sepsis based on qSOFA and SIRS criteria was compared. In addition, SIRS criteria served as the gold standard in the diagnosis of sepsis.

Data extraction protocol: Demographic information, comorbidities, vital signs, site of infection, clinical variables, and laboratory results were recorded in a data collection form designed for the study. All data were extracted from the electronic medical record system in the first affiliated Razi Hospital to Guilan Medical University. In this regard,

patients' vital signs were used to determine both SIRS criteria and the qSOFA score.

Findings

Characteristics of the study subjects:

During one year of study, out of 128 patients with suspected sepsis, 87 (68%) patients were diagnosed with septicemia based on SIRS criteria. The median age of subjects was 72.8 ± 15.9 years; of whom 50.6% (44 of 87) were male. There was no significant difference between the mean ages of both sexes. Table 1 shows the baseline characteristics and clinical outcomes of patients.

Accordingly, pneumonia (46.8 and 48.1%) and urinary tract infection (26.6 and 40.7%)

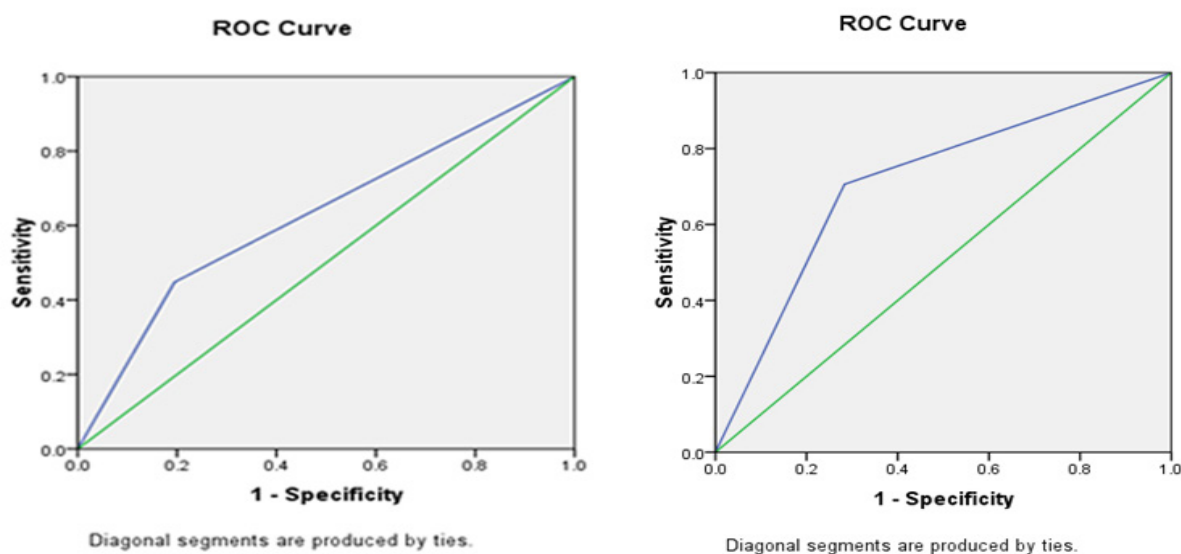


Fig. 1) Prediction of outcome by qSOFA for diagnosis of sepsis and mortality

were the most common infections among sepsis and non-sepsis patients, respectively. However, there was no significant relationship between the site of infection and sepsis ($p=.22$)

Of 87 SIRS positive patients, 39(44.8%) and 48 (55.2%) had positive and negative qSOFA scores, respectively. In this regard, there was a significant correlation between the qSOFA scores and sepsis ($p=.006$).

The sensitivity and specificity ratios of qSOFA were 44.83% (95% CI: 34.15 to 55.87%) and 80.49% (95% CI: 65.13 to 91.18%), respectively. Table 2 summarizes the sensitivity and specificity of the qSOFA index according to comorbidities.

Sensitivity analysis: ROC curve analysis results showed that the area under the ROC curve (AUC) of qSOFA scores for predicting sepsis patients was not significantly different (0.627, $p=.021$) (Figure 1A). Moreover, regarding the sepsis-related mortality, the area under ROC showed that qSOFA criteria (score ≥ 2) were able to predict mortality in patients (AUC, 0.71; $p < .001$) with 71% sensitivity and 72% specificity (Figure 1B). Thirty-four (34 of 87) patients with definitive

sepsis died during hospitalization. Out of 34 expired patients, 24 (70.5%) and 10 (29.4%) were positive and negative for the qSOFA score during hospitalization, respectively.

Accordingly, a significant correlation was observed between mortality in sepsis patients (SIRS criteria) and qSOFA score results ($p \geq .001$). The qSOFA score results for the diagnosis of sepsis patients with comorbidities are shown in Table 2.

There was a statistically significant correlation between sepsis and hypertension ($p=.006$), diabetes ($p=.027$), ischemic heart disease (IHD) ($p=.018$), and results of qSOFA score. In this regard, no significant correlation was found between sepsis and chronic obstructive pulmonary disease (COPD) ($p=.46$), cerebrovascular accident (CVA) ($p=.98$), chronic kidney disease (CKD) ($p=.98$), cancer ($p=.16$), and results of qSOFA score. Moreover, the sensitivity of the qSOFA score in the diagnosis of sepsis was 80, 69.2, 55.3, and 46% in CVA, IHD, hypertension, and diabetes patients with SIRS-positive sepsis, respectively. The specificity and sensitivity of the qSOFA index in the diagnosis of sepsis according to the aforementioned diseases are

Table 2) qSOFA score results for the diagnosis of sepsis patients with comorbidity

qSOFA score	Sensitivity (95% CI)	Specificity (95% CI)	Disease Prevalence	Positive Predictive Value (95% CI)	Negative Predictive Value (95% CI)	Accuracy (95% CI)
Total patients	44.83 (34.15 - 55.87)	80.49 (65.13- 91.18)	67.97% (59.15 to 75.94)	82.98 (71.51- 90.45)	40.74 (35.05- 46.69)	56.25 (47.21- 65)
Patients with hypertension	55.36 (41.47- 68.66)	76.92 (56.35- 91.03)	68.29% (57.08 to 78.13)	83.78 (71.14- 91.55)	44.44 (35.83- 53.41)	62.20 (50.81- 72.68)
Patients with diabetic	46 (31.81- 60.68)	84.21 (60.42- 96.62)	72.46% (60.38 to 82.54)	88.46 (72.23- 95.76)	37.21 (30.05- 44.97)	56.52 (44.04- 68.42)
Patients with IHD	69.23 (52.43- 82.98)	64.71 (38.33- 85.79)	69.64% (55.90 to 81.22)	81.82 (69.58- 89.85)	47.83 (33.75- 62.25)	67.86 (54.04- 79.71)
Patients with CVA	56.34- 94.27	0 (0-70.76)	86.96% (66.41 to 97.22)	84.21 (81.07- 86.91)	0	69.57 (47.08- 86.79)

SOFA: quick SOFA, IHD: ischemic heart disease, CVA: cerebrovascular accident

Table 3) Specificity and sensitivity of the qSOFA index in the diagnosis of sepsis according to the comorbidity

Sepsis and Comorbidity		Negative-qSOFA N (%)	Positive- qSOFA N (%)
Sepsis + hypertension	Yes	25 (55.6)	31 (83.8)
	No	20 (44.4)	6 (16.2)
Sepsis + diabetic	Yes	27 (62.8)	23 (88.5)
	No	16 (37.2)	3 (11.5)
Sepsis + IHD	Yes	12 (52.2)	27 (81.8)
	No	11 (47.8)	6 (18.2)
Sepsis + COPD	Yes	3 (50)	2 (100)
	No	3 (50)	0
Sepsis + CVA	Yes	4 (100)	16 (84.2)
	No	0	3 (15.8)
Sepsis + cirrhosis	Yes	0	1 (100)
	No	0	0
Sepsis + cancer	Yes	10 (90.9)	0
	No	1 (9.1)	1 (100)
Sepsis + CKD	Yes	2 (100)	5 (83.3)
	No	0	1 (16.7)

presented in Table 3.

Discussion

Sepsis is a clinical condition leading to organ dysfunction. It is caused by the host's excessive inflammatory response to infection [14]. There is neither gold standard nor diagnostic criteria to define the diagnosis or prognosis of sepsis. For easier evaluation in the hospital, the qSOFA score has been established to help recognize suspected sepsis patients who appear to have a poor prognosis [15]. Recently, several studies have been conducted to confirm the validity and performance of qSOFA in identifying patients with poor sepsis prognosis and diagnosis compared to SIRS criteria [15-16].

Given the establishment of new criteria and comprehensive use of qSOFA for the diagnosis of sepsis in several studies around the world with different results, this retrospective descriptive study aimed to compare the two criteria of qSOFA and SIRS in identifying sepsis patients in order for timely diagnosis and selection of an appropriate treatment method. The present study results could assist healthcare staff to determine an appropriate pattern to improve the treatment of sepsis patients and reduce false-positive cases.

According to this study results, 68% (87 of 128) of patients were definitely diagnosed with sepsis based on SIRS criteria. Also, the positive predictive value of SIRS criteria for the diagnosis of sepsis was 68%. On the other hand, SIRS criteria classified 68% of patients in the sepsis group, of which 44.8 and 55.2% had positive and negative qSOFA scores, respectively. Therefore, the results showed that 44.8% of confirmed sepsis patients had positive qSOFA scores. This means that, in every two sepsis patients, one does not meet the qSOFA criteria.

In this regard, the sensitivity and specificity ratios of qSOFA were 44.83 and 80.49%,

respectively. Also, there was a significant correlation between the qSOFA score and sepsis ($p=.006$). However, SIRS criteria were more sensitive than the qSOFA score in the diagnosis of sepsis.

In a meta-analysis study, Serafim, et al. found that SIRS criteria were more sensitive than qSOFA criteria in diagnosing sepsis [16]. Among the studies reviewed, only one study comparing the sensitivity of SIRS (84.4%) and qSOFA (97.3%) showed a better specificity for qSOFA in the diagnosis of infection [16].

In another study on 108 severe sepsis patients in the emergency department, a qSOFA score of ≥ 2 was able to identify only 15.4% of patients compared with a SIRS score ≥ 2 identifying 65.4% of patients [17]. The lower sensitivity of qSOFA in the diagnosis of sepsis raises concerns regarding the potential delays in sepsis identification and treatment [16]. In the present study, SIRS criteria were better in the diagnosis of sepsis than qSOFA.

However, according to the literature, the gold standard for the diagnosis of sepsis is not available; therefore, the physician could rely on the intersection of three groups of clinical and laboratory data, including general systemic manifestations, organ dysfunction/failure manifestations, and microbiological documentation [16, 18-19].

Recently, the new definition of sepsis has clearly centered on the organ dysfunction, which is why the Sepsis-3 task force designed a new tool, qSOFA (respiratory rate > 22 /min, systolic blood pressure < 100 mm Hg, altered mentation) [7, 20-21].

This study findings showed a significant relationship between mortality in sepsis patients and qSOFA score results. The ability of qSOFA to predict mortality in SIRS-positive sepsis patients was 61.5%, indicating its significant efficacy in predicting mortality (based on AUC analysis). In addition, the

sensitivity and specificity of qSOFA criteria were 71 and 72% for predicting sepsis-related mortality.

Thus, this study findings may contribute to the accumulation of evidence on the potential clinical usefulness of qSOFA in the prediction of mortality. This finding is in line with the finding of another recently published large retrospective study [22-23]. In a study conducted by Heydar et al. (2017), the sensitivity of SIRS and qSOFA criteria to correctly identify in-hospital mortality was 95.5 and 90.1%, respectively [24]. Moreover, their specificity was 5.6 and 45.7%, respectively [24]. In the present study, a significant correlation was found between sepsis and hypertension ($p=.006$), diabetic ($p=.027$), IHD ($p=.018$), and qSOFA criteria. The results showed different sensitivities and specificities for qSOFA criteria among confirmed sepsis patients with comorbidities.

Among patients with comorbidities, the highest sensitivity of positive qSOFA score in the diagnosis of sepsis was among CVA patients (80%), followed by IHD patients (69.2%), while the highest specificity was among patients with diabetes (84.2%) and hypertension (76.9%).

Conclusions

There was no significant difference in the site of infection between patients with sepsis. This study findings revealed that the qSOFA score was significantly efficient in predicting mortality. These results may help clinicians obtain further insight into the usefulness of qSOFA. However, SIRS criteria are more sensitive than the qSOFA score in predicting the definite diagnosis of sepsis. Therefore, the qSOFA score seems to be an invaluable tool for predicting outcome in sepsis patients in ED.

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