A Prospective Cohort Study of the Quick Sequential Organ Failure Assessment (qSOFA) Score versus Systemic Inflammatory Response Syndrome (SIRS) Criteria in the Determination and Prognostication of Sepsis in a Philippine Tertiary Hospital

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ABSTRACT

Background. Sepsis is a leading cause of mortality both locally and worldwide. Despite this, early diagnosis of sepsis remains challenging, with a significant number not fulfilling SIRS (Systemic Inflammatory Response Syndrome) criteria. In 2016, the Sepsis-3 guidelines modified its definition to include the qSOFA (Quick Sequential Organ Failure Assessment) score in an attempt to include a significant number of SIRS-negative septic patients.

Methods. To compare the two, 295 adult patients in the emergency room with suspected infection were included in the study and simultaneously determined their qSOFA score and SIRS criteria. Three infection specialists adjudicated the presence of sepsis, and outcomes within the first 48 hours were acquired. Sensitivity, specificity, positive predictive and negative predictive values for qSOFA and SIRS were computed using constructed confusion matrices, and overall predictive accuracy was measured by the Area under the Receiver Operating Characteristic (AUROC) curve.

Results. Of the 295 patients included in the study, 95 (32.2%) were deemed sepsis positive via adjudication. The qSOFA score was a specific (95.5%) but a poorly sensitive (46.3%) test compared to the SIRS criteria (sensitivity 73.7% and specificity 60%). Both qSOFA and the SIRS criteria significantly correlated with sepsis positivity, but the qSOFA score had superior overall predictive accuracy at 70.9% compared to the SIRS criteria. The adjudicators had moderate strength in agreement (Fleiss' kappa = 0.39) and a percentage agreement of 60%.

Conclusion. We concluded that the qSOFA score was a more accurate predictor of sepsis and a reliable predictor of in-hospital mortality, but should not be used as a sepsis screening tool due to the low sensitivity. We recommend that the SIRS criteria be maintained as a screening tool and to use the qSOFA score concurrently for time management.

Key Words: Sepsis, qSOFA, SIRS

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INTRODUCTION

Sepsis continues to be the most frequent cause of death in intensive care units, with a documented mortality of up to 67% worldwide.[1] Sepsis diagnosis requires fulfillment of 2 out of the 4 SIRS criteria.[2] The sepsis definition has

been updated on several occasions, and there is increasing evidence[1,3,4] that the SIRS criteria has poor specificity for sepsis. Among 109,663 clinically septic patients admitted in 172 intensive care units (ICU), 13,278 (12.1%) were SIRS-negative before admission to the ICU.[1] The SIRS criteria was challenged, and as a result, the operational definition of sepsis was revised to include a three-pronged assessment tool called the quick sequential organ failure assessment (qSOFA) score.[5] This includes systolic blood pressure (100 mmHg or less), respiratory rate (22 breaths/min or higher), and a Glasgow Coma Scale (GCS) score 13 or less, where any combination of two variables or more correlated with higher morbidity and mortality.[3,5] Several retrospective studies[2,4,6,7] have been conducted comparing the qSOFA score and SIRS criteria, and researchers have recommended more extensive prospective studies to validate the qSOFA as a diagnostic tool.[4] In this study, we compared the qSOFA scoring system with the traditional SIRS criteria in the prognostication and detection of sepsis by using a prospective cohort design considering how the qSOFA criteria were used in the Sepsis-3 flowchart.[8] We hypothesized that the qSOFA score leads to earlier recognition of sepsis, is more sensitive and specific than the SIRS criteria, and is predictive of morbidity and mortality within the first 48 hours of in-hospital admission.

METHODS

The study was conducted between April 1, 2017, to July 31, 2017, in The Medical City, a tertiary university-affiliated hospital in the Philippines. All adult patients (≥18 years of age) seen at the ED with history and/or physical exam findings suggestive of infection were prospectively identified and included in the study. Patients admitted for elective procedures or with advanced directives were excluded. A sample size of 284 individuals was computed using a confidence interval of 99% and a power of 95 with a prevalence of 25%.[9] The study was approved by the Institutional Review Board (IRB) (IRB registration number GCS MED 2017-005).

The following information was obtained from the medical records: demographic, clinical, laboratory, and microbiologic data for all enrolled patients. Given the 48-hour follow-up protocol from admission, microbiologic culture data was not available during the time of adjudication. SIRS and qSOFA scores were determined using de-identified information. The SIRS criteria included the following clinical parameters: (1) Body temperature > 38˚C or < 36˚C, (2) HR > 90 beats per minute, (3) WBC < 4 or > 12 per mm^3 or > 10% bands, and (4) RR > 20 breaths per minute. Meanwhile, the qSOFA parameters are as follows: (1) SBP ≤ 100 mmHg, (2) RR ≥ 22 breaths per minute, and (3) altered mental status or GCS score of ≤ 13. Sepsis positivity was defined based on the final adjudication of an independent committee of three infectious disease specialists (MFT, CA, and KRH). The authors practiced non-interference and obtained de-identified data from records throughout the study. The adjudicators were blinded to each other's assessment and the clinical outcome of the patient. The healthcare team was blinded with the results of the adjudication and did not influence the current treatment and management strategy that was being provided. Based on clinical and microbiological information presented to the adjudicators, patients were labeled "sepsis-positive" or "sepsis-negative." This classification was correlated with corresponding qSOFA and SIRS scores acquired on admission. Patients were followed for only 48 hours after admission and were classified as discharged, antibiotics de-escalated/escalated, transferred to the critical care unit, or transferred out to a regular nursing unit.

Demographic and clinical information were summarized using descriptive statistics. The qSOFA score and SIRS criteria were both converted into dichotomous variables: SIRS-negative (SIRS score 0 to 1), SIRS-positive (SIRS score ≥2), qSOFA-negative (qSOFA score 0 to 1), qSOFA positive (qSOFA score ≥2). These were independently tested for agreement against final adjudication using the Chi-Square Test of Independence and Cohen's Kappa statistic at a 5% level of significance. Confusion matrices were constructed and were tabulated against sepsis positivity. The area under the receiver operator curve (AUROC), sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) were determined. Prognostic accuracy, defined post hoc as the ability of the SIRS and qSOFA scores to predict clinical outcomes after 48 hours, were computed. Inter-rater variability was computed using Spearman rank correlation analysis at a 5% level of significance. Overall inter-rater agreement was calculated using the Fleiss' Kappa statistic. Fisher's exact test was used to assess the relationship of individual qSOFA scores and SIRS criteria to sepsis positivity at a 5% level of significance.

RESULTS

Of the 295 patients included in the study, 95 patients (32.2%) were sepsis-positive based adjudication. The mean age of the population was 57.4 years (SD of 21.15), with females comprising 53% (Table 1). Of the cohort, 132 had sputum/endotracheal aspirate (ETA), 28 had wound, and 95 had urine Gram's stain initially available.

The most common source of infection was pneumonia (53.2%), followed by gastrointestinal infections (e.g., cholecystitis, cholangitis, intraabdominal infections, 18.3%) and urinary tract infections (12.9%). Thirteen patients (4.4%) died during the first 48 hours of admission, 9 of whom (69.2%) had a qSOFA score of 2. Of the 295 patients, 58 (19.7%) were discharged. Of the 95 sepsis-positive patients, 70 (73.6%) were SIRS-positive (Table 2). Among the 25 SIRS-negative, sepsis-positive patients, 8 (32%) were qSOFA-positive (Table 3). Of the 8 SIRS-negative, qSOFA-positive, sepsis-positive patients (8.4%), three patients (37.5%) were initially admitted to a regular medical unit but subsequently required antibiotic escalation and transfer to

Table 1. Descriptive Statistics, General Profile

Baseline Characteristics	Frequency / Range	Percent / Mean ± SD
Age (in years)	20 - 98	57.4 ± 21.15
Gender		
Female	157	53.2
Male	138	46.8
qSOFA Score	0 - 3	0.7 ± 0.84
0	154	52.2
1	88	29.8
2	44	14.9
3	9	3.1
Negative	242	82.0
Positive	53	18.0
SIRS Score	0 - 4	1.6 ± 1.19
0	69	23.4
1	76	25.8
2	84	28.5
3	47	15.9
4	19	6.4
Negative	145	49.2
Positive	150	50.8
Focus of Infection		
1 – Pulmonary/Pneumonia	157	53.2
2 – Genitourinary	38	12.9
3 – Gastrointestinal	54	18.3
4 – Skin and soft tissue	31	10.5
5 – CNS	11	3.78
6 – Cardiac	2	0.7
7 – Blood	1	0.3
8 – Bone	1	0.3
Clinical Outcome after 48 hours		
1 – Stable	125	42.4
2 – Discharged	58	19.7
3 – De-escalate antibiotics	41	13.9
4 – Escalate antibiotics	38	12.9
5 – Transfer to ICU	13	4.4
6 – Transfer out to room	5	1.7
7 – Expired	13	4.4
8 – Transfer out of ICU	2	0.7
Total	**295**	**100**

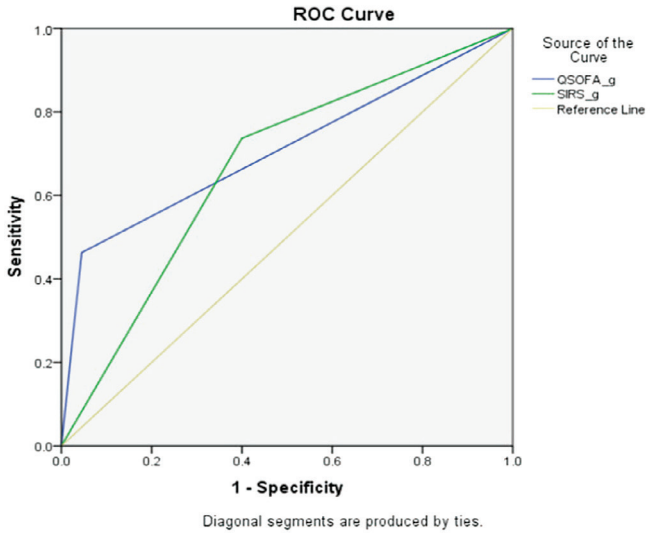

Figure 1. Area under the curve graph for qSOFA and SIRS.

the ICU for closer monitoring due to organ dysfunction. The qSOFA score ≥ 2 had a sensitivity of 46.3% and a specificity of 95.5%, while a SIRS score ≥ 2 had a sensitivity of 73.7% and specificity of 60.0%. The qSOFA and SIRS NPV and PPV were 78.9% and 83.0%, and 82.8% and 46.7%, respectively. The results of the analysis revealed a kappa statistic equal to 0.206 for the qSOFA score and 0.110 for the SIRS criteria.

Using the AUROC (Fig 1), the total variation in final adjudication was 70.9% for the qSOFA score and 66.8% for the SIRS score. The overall predictive accuracy of qSOFA and SIRS were 79.7% and 64.4%, respectively (Table 4). The computed Fleiss' kappa statistic was 0.394 (95% CI: 0.328, 0.460).

Using logistic regression analysis, the risk ratio for sepsis of each qSOFA score and SIRS score were derived. At qSOFA score = 0, the risk ratio was less than 1, while at qSOFA score = 1, the risk ratio was equal to 1.215. However, at qSOFA score = 2, the risk ratio exponentially rose to 12.380 (Table 5). Similarly, at SIRS scores 3 and 4, the risk ratios increased four times (risk ratios 4.443 and 3.986, respectively).

Table 2. Test of Agreement: qSOFA and SIRS on Final Adjudication

Classification Criteria	Final Adjudication			p-Value	Agreement Statistics
	Sepsis Positive	Sepsis Negative	Total		
qSOFA				0.000**	NPV = 78.9%
qSOFA Positive	44	9	53	Kappa = 0.206**	PPV = 83.0%
qSOFA Negative	51	191	242		Sensitivity = 46.3%
Total	95	200	295		Specificity = 95.5%
SIRS				0.000**	NPV = 82.8%
SIRS Positive	70	80	150	Kappa = 0.110**	PPV = 46.7%
SIRS Negative	25	120	145		Sensitivity = 73.7%
Total	95	200	295		Specificity = 60.0%
Total	**295**	**100%**	**100%**		

*ns – not significant * – significant at 5% ** – significant at 1%*

Table 3. SIRS and qSOFA with Final Adjudication

	Sepsis-Positive	Sepsis-Negative
qSOFA +, SIRS -	8	2
qSOFA +, SIRS +	36	7
qSOFA -, SIRS +	34	73
qSOFA -, SIRS -	17	118
Total	**95**	**200**

Table 4. Receiver Operating Characteristic (ROC) Analysis

	Area Under the Curve	Std. Error	P-Value	Overall Accuracy
qSOFA Classification	0.709**	0.036	<0.000	79.7%
SIRS Classification	0.668**	0.033	<0.000	64.4%

*ns – not significant * – significant at 5% ** – significant at 1%*

DISCUSSION

Our data confirmed the findings of several published retrospective studies investigating the validity of the qSOFA score.[5-7,10-14] In a retrospective study, external validation of the SOFA score, SIRS criteria, and qSOFA score were done simultaneously, and they concluded that SOFA score outdid the other two criteria in predicting mortality among critically ill patients with a suspected infection.[10] Tusgul et al. highlighted the low, sub-optimal sensitivity of both the SIRS criteria and qSOFA score in selecting sepsis-positive patients at risk for developing complications when they arrive at the ED.[11] Hwang et al. concluded that the performance of the qSOFA score in identifying patients at high risk of mortality was lowest at the presentation at the ED, but sensitivity gradually increases during a hospital stay, requiring repeat assessment.[12] The pooled sensitivity of the qSOFA score with a larger population in the meta-analysis by Song et al. demonstrated superior specificity in predicting in-hospital mortality, acute organ dysfunction, and ICU admission in patients with suspected sepsis managed outside the ICU.[13] Perhaps this is because the SIRS criteria include more variables and hence more patients, which may or may not be sepsis-positive but showing a healthy inflammatory response to an insult. Meanwhile, the qSOFA score alludes to responses that herald organ dysfunction and will more likely include deteriorating patients.

In our data set, the qSOFA score was able to detect a significant number of SIRS-negative sepsis-positive patients (8.4%). If the SIRS criteria was solely used for screening and identification, these patients would have been misdiagnosed, leading to a delay in antibiotic initiation and potential morbidity and mortality. Of the 200 sepsis-negative patients (based on adjudication), 95.5% were correctly labeled as qSOFA-negative, which would translate to proper triaging and proper stewardship of antibiotics. On the other hand, 40% were improperly labeled as SIRS-positive, which would lead to unnecessary antibiotic resistance and increased hospitalization costs. SIRS positivity does not necessarily translate to the presence of infection. It should be kept in mind that SIRS is a response to an inflammatory state, and a knee-jerk reaction of initiating antibiotics (solely based on SIRS) is discouraged. This would only lead to irrational antibiotic use that leads to the problem of antibiotic resistance and to the increased costs of healthcare for the patient, which could have been allocated elsewhere (Table 5).

Our data showed that the qSOFA score is a good predictor of in-hospital mortality by identifying high-risk patients requiring more aggressive management and a higher level of monitoring even when additional laboratory or diagnostic tests are not available, similar to most studies on qSOFA. Having a qSOFA score of ≥ 2 confers a 12-fold higher risk of sepsis and hence a higher chance of mortality and morbidity.[6] On the other hand, the risk ratio of SIRS score follows the same direction, and as the SIRS score increases, the risk ratio also rises – with the score 3 and 4 having a fourfold risk of being sepsis positive albeit to a lesser extent than that of qSOFA. Finkelstein et al. found the same correlation in their study, which showed that the qSOFA score is a better discriminator than SIRS for predicting mortality and ICU-free days.[14] It is worth mentioning that a formal sequential organ failure assessment (SOFA) score could not be done in this study since patients were seen initially in the ED, and several components needed to complete the score were unavailable.

Table 5. qSOFA and SIRS scores versus Sepsis Positivity and Risk Ratios

	Sepsis Negative	Sepsis Positive	Total	P-Value	Risk Ratio	95% CI on RR
qSOFA Score = 0	134 (87%)	20 (13%)	154 (52%)	<0.001**	0.131	0.074, 0.233
qSOFA Score = 1	57 (65%)	31 (35%)	88 (30%)	0.497ns	1.215	0.717, 2.059
qSOFA Score = 2	9 (20%)	35 (80%)	44 (15%)	<0.001**	12.380	5.630, 27.219
qSOFA Score = 3	0 (0%)	9 (100%)	9 (3%)	<0.001**	–	–
SIRS Score = 0	61 (88%)	8 (12%)	69 (23%)	<0.001**	0.210	0.096, 0.459
SIRS Score = 1	59 (78%)	17 (22%)	76 (26%)	0.035*	0.521	0.284, 0.955
SIRS Score = 2	55 (65%)	29 (35%)	84 (29%)	0.591ns	1.158	0.678, 1.979
SIRS Score = 3	18 (38%)	29 (62%)	47 (16%)	<0.001**	4.443	2.315, 8.428
SIRS Score = 4	7 (37%)	12 (63%)	19 (6%)	0.005**	3.986	1.516, 10.484

*ns – not significant * – significant at 5% ** – significant at 1%*

We treated the final adjudication among three observers as the gold standard for diagnosis of sepsis and septic shock. In other studies, sepsis and septic shock were diagnosed based on final diagnoses based on hospital records.[3,4,7,10,12-14] In our study, we found significant inter-rater variability that we realize as a limitation, and may need to be addressed by future studies.

In light of our study findings, we recommend the re-evaluation of the Sepsis-3 recommendation of the qSOFA as the initial screening tool since the SIRS criteria perform better for this purpose. Our data suggest that the value of the qSOFA score is its utility in predicting mortality and morbidity for patients with suspicion of sepsis.

We agree that the qSOFA score should not replace the SIRS criteria in the diagnosis of sepsis[15]. Preferably, it should be used to help the clinician consider the possibility of sepsis and impending organ failure. Sepsis may still be present despite a low qSOFA score <2, such as in cases where other organ dysfunctions are present and are not included within the qSOFA criteria (i.e., coagulopathies, hyperbilirubinemia, hypoxemia).[15]

Our study findings are in contrast with that of Askim et al., where they compared the prognostic ability to predict sepsis and mortality in the ED between qSOFA, SIRS, and their triage system, the Rapid Emergency Triage and Treatment System (RETTS). Their results showed that the RETTS detected more septic patients and was a better predictor of mortality compared to the qSOFA score. However, we arrived at a similar conclusion that a more sensitive tool (rather than specific) is needed for sepsis diagnosis and detection.[16]

Haydar et al. reviewed 200 medical records of patients who were treated for suspected sepsis in the ED. Their review showed that qSOFA score ≥ 2 was valuable in predicting sepsis-related mortality but had poor performance as a screening tool for sepsis and that the SIRS criteria were superior for this purpose,[17] which resonated with our study results. However, in another study, the qSOFA score performance in predicting 28-day in critically ill patients was poor, especially in the early period after ED presentation.

A combination of diagnostic tools was advocated by an editorial by Kolditz et al. showing that for patients with community-acquired pneumonia (CAP), combining the qSOFA score ≥ 2 with the CRB-65 improved the area under the curve (AUC) of predicting mechanical ventilation and vasopressor support.[18]

We acknowledge the single-center nature of this study, the absence of microbiological culture data, the lack of formal SOFA scoring, and the inter-rater variability between the adjudicators as a limitation. However, this study is the first of its kind and the first attempt to make a head-to-head comparison between the qSOFA and SIRS criteria in the country since the Sepsis-3 was published.

CONCLUSIONS

Locally, the qSOFA score is under-utilized, and sepsis is diagnosed by using the SIRS criteria. We advocate the use of the SIRS criteria as the preferred screening tool for sepsis while simultaneously using the qSOFA score to prognosticate since the former is a more sensitive test while the latter is more specific for organ dysfunction and mortality. A higher qSOFA score should prompt the clinician to be more vigilant in facilitating diagnostic tests to confirm a possible source of infection and to be more decisive in administering earlier interventions such as admission to a critical care unit, initiation of empiric antibiotics, and aggressive hydration in sepsis-positive patients. With the simultaneous use of the qSOFA score, clinicians should have the advantage of being able to identify a SIRS-negative septic patient that may clinically deteriorate. Given the limitations, we advocate that this study be reproduced using a bigger sample size (possibly multi-center) and attempt to lessen inter-rater variability.

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Statement of Authorship

All authors participated in data collection and analysis, and approved the final version submitted.

Author Disclosure

All authors declare no conflicts of interest.

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