Prognostic accuracy of qSOFA in predicting 28-day mortality among infected patients in an emergency department: a prospective validation study

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ABSTRACT

Background Few prospective studies have evaluated the quick Sequential (Sepsis-Related) Organ Failure Assessment (qSOFA) criteria in emergency department (ED) settings. The aim of this study was to determine the prognostic accuracy of qSOFA compared with systemic inflammatory response syndrome (SIRS) in predicting the 28-day mortality of infected patients admitted to an ED.

Methods A prospective observational cohort study of all adult (≥18 years) infected patients admitted to the ED of Slagelse Hospital, Denmark, was conducted from 1 October 2017 to 31 March 2018. Patients were enrolled consecutively and data related to SIRS and qSOFA criteria were obtained from electronic triage record. Information regarding mortality was obtained from the Danish Civil Registration System. The original cut-off values of ≥2 was used to determine the prognostic accuracy of SIRS and qSOFA criteria for predicting 28-day mortality and was assessed by analyses of sensitivity, specificity, positive predictive value, negative predictive value, likelihood ratios and area under the receiver operating characteristic curve (AUROC) with 95% confidence intervals (CI).

Results A total of 2112 patients were included in this study. A total of 175 (8.3%) patients met at least two qSOFA criteria, while 1012 (47.9%) met at least two SIRS criteria on admission. A qSOFA criteria of at least two for predicting 28-day mortality had a sensitivity of 19.5% (95% CI 13.6% to 26.5%) and a specificity of 92.6% (95% CI 91.4% to 93.7%). A SIRS criteria of at least two for predicting 28-day mortality had a sensitivity of 52.8% (95% CI 44.8% to 60.8%) and a specificity of 52.5% (95% CI 50.2% to 54.7%). The AUROC values for qSOFA and SIRS were 0.63 (95% CI 0.59 to 0.67) and 0.52 (95% CI 0.48 to 0.57), respectively.

Conclusion Both SIRS and qSOFA had poor sensitivity for 28-day mortality. qSOFA improved the specificity at the expense of the sensitivity resulting in slightly higher prognostic accuracy overall.

BACKGROUND

Sepsis is a clinical emergency and often progresses to life-threatening conditions and is associated with a high mortality rate 11%–45%. Since 1992, sepsis was defined as the combination of an infection and the systemic inflammatory response syndrome (SIRS) (figure 1). However, the criteria for SIRS are not specific, requires laboratory testing and manifest in conditions other than infection.

In 2016, the sepsis-3 task force redefined sepsis definition from an inflammatory response to a clinical condition among infected patients manifesting with organ dysfunction (Sequential Organ Failure Assessment (SOFA) score). To assist the bedside clinician in promptly identifying septic patients likely to have adverse outcomes, a modified SOFA scoring system, the quick SOFA (qSOFA) (figure 1), was introduced. Like SOFA, the qSOFA criteria emphasise organ dysfunction and consist of three clinical signs without the need for blood tests.

qSOFA has been endorsed by numerous scientific societies worldwide. However, there are controversies concerning its lower sensitivity as compared with the SIRS criteria in predicting
Inclusion and exclusion criteria

All adult patients in the ED were screened on the following working-day after admission for an infection and included in the study. The exclusion criteria were: foreigners without a Danish civil personal registration (CPR) number, missing data or registration error, treatment with antibiotics for <48 hours after admission, transfer to other hospitals within 24 hours, prophylactic antibiotic treatment (eg, in relation to surgery) and readmission and previously included during the study period (figure 2).

ED patients with infection

All patients were triaged immediately by nurses after admission and registered in the electronic triage record, with information regarding chief complaints and a short clinical assessment including HR, RR, oxygen saturation, body temperature (TP), systolic BP (SBP) and consciousness level determined using the GCS or the Alert-Voice-Pain-Unresponsive (AVPU) scale. In accordance with the sepsis treatment protocol, the nurse notified an ED physician of patients with suspected or documented infection on admission who met at least two qSOFA or SIRS criteria (figure 1) and these patients were examined by a physician within 10 min of triage. Simultaneously, the following standard treatment protocol was initiated: oxygen administration, ABG analysis, treatment with intravenous fluids and intravenous antibiotics. An ECG, blood samples for laboratory analyses and blood cultures were routinely obtained. Other examinations (eg, X-ray, ultrasound, CT and gynaecological examinations) were performed as required. The above treatment protocol was based on national sepsis treatment guidelines and the recommendations from The International Surviving Sepsis Campaign. There were no changes in treatment guidelines during the study period.

After the initial treatment and if the patients required hospitalisation for >48 hours, they were transferred to a medical ward. Deteriorating or critically ill patients despite adequate treatment in the ED were transferred to the ICU.

Data sources

The authors (SMOB, RHS) obtained information regarding antibiotic treatment, data from triage records and electronic patient records. Data concerning the SIRS and qSOFA criteria were obtained from triage records. When GCS or AVPU data were missing, mental state was evaluated by use of the information from the initial clinical examination of the patient and registered in the medical records. If the patient was described as fully awake and oriented to time, place and own data, we considered the GCS to be 15. Changes in consciousness level or orientation were registered as GCS14. An AVPU other than A was converted to GCS ≤14.

Demographic data, presence of comorbidities as well as clinical and laboratory information were obtained from the electronic medical records. Data regarding deaths were obtained from the Danish Civil Registration System (CRS), an administrative registry with individual-level information on vital status of all Danish citizens. The unique 10-digit CPR number allows accurate individual-level linkage of Danish registries.

We performed a 3-day pilot study prior to the initiation of the study to ensure the collection of all data defined in the protocol.

Finally, the collected data were entered in an electronic database. The data collection and data entry process was randomly controlled by the authors.
Estimation of sample size
The sample size was based on an estimated difference in the area under the receiver operating characteristic curve (AUROC) for SIRS of 0.65 and an AUROC of 0.8. Statistical significance was set at 0.05% with a power of 80%. Based on a previous study of mortality\(^\text{15}\) in our department, we calculated a ratio of survivors to non-survivors of 6.7, resulting in an estimated minimum sample size of 308 (40 positive cases and 268 negative cases).

Statistical analysis
The primary outcome was 28-day mortality. Baseline characteristics including the distribution of numbers of patients fulfilling the qSOFA scores and the SIRS criteria were analysed according to the survival status. Categorical variables are reported as counts and percentages with 95% confidence intervals (CI). Assuming non-normality continuous data are presented as medians with IQRs. Significant differences between proportions or medians among different groups were estimated using exact differences with 95% CI. We determined the number/percentage of the cohort that were positive for either 1 or ≥2 elements for SIRS and qSOFA, and the number that were positive for both. Unadjusted risk of 28-day mortality according to qSOFA and SIRS criteria was assessed by estimating the OR for qSOFA and SIRS at cut-off points 1 and ≥2 with zero as reference. Sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), positive and negative likelihood ratio with 95% CI were used to estimate the prognostic accuracy of the qSOFA score and the SIRS criteria with the proposed cut-off points of ≥2.\(^6\) These analyses were repeated with ≥1 as cut-off points (online supplementary appendix 1). The overall AUROC was used to assess prognostic accuracy. All analyses were performed using STATA V 15.1.

RESULTS
Patients
A total of 3176 patients received antibiotic treatment during the study period (figure 2). Nine hundred ninety-two (31.2%) patients did not fulfil the inclusion criteria. Seventy-two patients were excluded due to missing data or foreign resident status, leaving 2112 patients with a median age of 73.1 years (IQR 60.3–82.7) for further analyses.

A total of 175 (8.3%) patients met at least two qSOFA score, while 1012 (47.9%) patients met at least two SIRS criteria. Notably, 142 (6.7%) patients met at least two criteria of both scores.

Baseline characteristics
Table 1 shows the baseline characteristics. Non-survivors were older; their comorbidity burden was increased, and they had higher values of creatinine, bilirubin and lactate on admission. Furthermore, lower SBP, GCS<15 and lower TP were more common among non-survivors. The proportion of non-survivors meeting at least two qSOFA criteria on admission were significantly greater compared with survivors (19.5% vs 7.4%; 95% CI for difference 5.8% to 18.3%). However, the proportion of patients meeting at least two SIRS criteria on admission did not differ among non-survivors and survivors (52.8% vs 47.5%; 95% CI for difference ~2.8% to 13.4%).

Outcome
Overall 28-day mortality among all infected patients was 7.4% (95% CI 6.4% to 8.7%). As shown in table 2, 28-day mortality was significantly increased among patients meeting at least two qSOFA criteria on admission compared with those meeting at least two SIRS criteria (17.7% vs 8.3%; 95% CI on difference

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Figure 2 Study flow chart. qSOFA, quick Sequential Organ Failure Assessment; ICU, intensive care unit; SIRS, systemic inflammatory response syndrome.
Table 1  Baseline characteristics

|                               | All patients | Non-survivors* | Survivors |
|-------------------------------|--------------|----------------|-----------|
|                               | n=2112       | n=159          | n=1953    |
| Female sex, no. (%)           | 1107 (52.4)  | 78 (49.1)      | 1029 (52.7)|
| Age, median, (IQR), years     | 73.1 (60.3–82.7) | 79.8 (71.8–87.6) | 72.7 (58.5–82.1)|
| Charlson Comorbidity Index, no. (%) | 662 (31.3)  | 15 (9.4)       | 647 (33.1) |
| 1–2                           | 993 (47.0)   | 80 (50.3)      | 913 (46.8) |
| 3+                            | 457 (21.6)   | 64 (40.3)      | 393 (20.1) |
| Vital signs on admission, median (IQR) |            |                |           |
| Systolic BP, mm Hg            | 131 (116–148)| 126.5 (109–145)| 132 (116–149)|
| RR, breaths/min               | 19 (16–22)   | 20 (17–24)     | 19 (16–22) |
| HR, beats/min                 | 90 (77–103)  | 91 (78–107)    | 90 (77–103) |
| Temperature, °C               | 37.2 (36.7–38.1)| 37.0 (36.5–37.7)| 37.3 (36.7–38.1)|
| Peripheral oxygen saturation, % | 96 (94–98)  | 96 (93–98)     | 96 (94–98) |
| GCS<15 on admission, no. (%)† | 286 (13.5)   | 9 (30.8)       | 237 (12.1) |
| qSOFA, no. (95% CI)           |              |                |           |
| 0                             | 1211 (57.3; 55.2 to 59.5) | 57 (35.9; 28.4 to 43.8) | 1154 (59.1; 56.9 to 61.3) |
| ≥1                            | 901 (42.7; 40.5 to 44.8) | 102 (64.2; 56.2 to 71.2) | 799 (40.9; 38.7 to 43.1) |
| ≥2                            | 175 (8.3; 7.1 to 9.5)  | 31 (19.5; 13.6 to 26.5) | 144 (7.6; 6.3 to 8.6) |
| SIRS§, no. (95% CI)           |              |                |           |
| 0                             | 497 (23.5; 21.7 to 25.4) | 31 (19.5; 13.6 to 26.5) | 466 (23.9; 22.0 to 25.8) |
| ≥1                            | 1615 (76.5; 74.6 to 78.3) | 128 (80.5; 73.5 to 86.4) | 1487 (76.1; 74.2 to 78.0) |
| ≥2§                           | 1012 (47.9; 45.8 to 50.1) | 84 (52.8; 44.8 to 60.8) | 928 (47.5; 45.3 to 49.8) |
| Laboratory results, median (IQR) |            |                |           |
| White blood cell count (×10^9/L) | 11.1 (8.4–14.7) | 11.9 (8.7–17.0) | 11.0 (8.4–14.6) |
| Creatinine (µmol/L)           | 82 (63–113)  | 97 (64–161)    | 83 (63–110) |
| Platelet count (×10^9/L)       | 242 (188–315)| 247 (189–330)  | 241 (188–314) |
| Bilirubin (µmol/L)             | 9 (6–13)     | 10 (7–16)      | 9 (6–13)   |
| Lactate (mmol/L)$¶$            | 1.2 (0.8–1.9)| 1.5 (0.9–3.0)  | 1.2 (0.8–1.8)|
| Sites of infections, no. (%)   |              |                |           |
| Lungs                         | 1111 (52.6)  | 100 (62.9)     | 1011 (51.8)|
| Abdomen                       | 225 (10.7)   | 12 (7.6)       | 213 (10.9)|
| Genitourinary                 | 542 (25.7)   | 44 (27.7)      | 498 (25.5)|
| Others                        | 340 (16.1)   | 15 (9.4)       | 325 (16.6)|

*Death within 28 days from admission.
†GCS<15 includes patients with AVPU classification other than Alert.
‡Total qSOFA score.
§Total number of SIRS criteria.
¶Lactate values were available for 778 patients (not a routine laboratory analysis among infected patients).

APVU, Alert-Voice-Pain-Unresponsive; qSOFA, quick Sequential Organ Failure Assessment; SIRS, systemic inflammatory response syndrome.

Table 2  Mortality according to sepsis criteria

|                               | 28-day mortality | Unadjusted OR (95% CI) |
|-------------------------------|------------------|------------------------|
|                               | Total 2112 | 159; 7.4 (6.4 to 8.7) | Reference |
| qSOFA                         | 0 1211 | 57; 4.7 (3.6 to 6.1) | Reference |
| 1 726 | 71; 9.8 (7.7 to 12.2) | 2.2 (1.5 to 3.2) |
| ≥2 175 | 31; 17.7 (12.4 to 24.2) | 4.4 (2.7 to 7.0) |
| SIRS                           | 0 497 | 31; 6.2 (4.3 to 8.7) | Reference |
| 1 603 | 71; 7.3 (5.4 to 9.7) | 1.2 (0.7 to 1.9) |
| ≥2 1012 | 84; 8.3 (6.7 to 10.2) | 1.4 (0.9 to 2.1) |

qSOFA, quick Sequential Organ Failure Assessment; SIRS, systemic inflammatory response syndrome.

As qSOFA criteria increased from 0 to 3, the unadjusted OR for mortality also significantly increased (table 2). However, unadjusted OR for mortality did not increase significantly with increasing SIRS criteria (table 2).

The 28-day mortality among patients only meeting at least two SIRS criteria was 6.9% (95% CI 5.3% to 8.8%) (table 3). In-hospital mortality among patients meeting at least two qSOFA or SIRS criteria was 9.1% and 4.2% (95% CI for difference 0.5% to 9.3%), respectively. A total of 155 (7.3%; 95% CI 6.3% to 8.5%) patients were admitted to the ICU. The proportion of patients admitted to the ICU differed significantly among those meeting at least two qSOFA or SIRS criteria (16.0% vs 10%; 95% CI for difference 0.3% to 11.8%).

Prognostic accuracy of qSOFA and SIRS

In patients meeting at least two qSOFA criteria, a sensitivity of 19.5% (95% CI 13.6% to 26.5%), specificity of 92.6% (95% CI 3.6% to 15.4%). As qSOFA criteria increased from 0 to 3, the unadjusted OR for mortality also significantly increased (table 2). However, unadjusted OR for mortality did not increase significantly with increasing SIRS criteria (table 2).
91.4% to 93.7%) and PPV and NPV of 17.7% (95% CI 12.4% to 24.2%) and 93.4% (95% CI 92.2% to 94.5%), respectively, were determined (table 4). In patients meeting at least two SIRS criteria, a sensitivity of 52.8% (95% CI 44.8% to 60.8%), specificity of 52.5% (95% CI 50.2% to 54.7%) and PPV and NPV of 8.3% (95% CI 6.7% to 10.2%) and 93.2% (95% CI 91.5% to 94.6%), respectively, were found (table 4). The positive likelihood ratio was higher for qSOFA (2.64; 95% CI 1.86 to 3.76) than SIRS (1.11; 95% CI 0.95 to 1.30) (table 4). The AUROC values for qSOFA and SIRS were 0.63 (95% CI 0.59 to 0.67) and 0.52 (95% CI 0.48 to 0.57), respectively (figure 3 and table 4).

Analyses combining end points of ‘in-hospital mortality or transfer to ICU’ and ‘28-day mortality or transfer to ICU’ did not reveal new information concerning the prognostic accuracy of qSOFA or SIRS (table 4). The sensitivity increased and the specificity decreased considerably in the analyses with qSOFA ≥ 1 and SIRS ≥ 1 as cut-off points (online supplementary appendix 1).

**DISCUSSION**

In this study, we found that the prognostic accuracy of qSOFA for 28-day mortality was slightly better than that of SIRS among infected patients admitted to an ED. Our results also revealed that qSOFA was more specific, but less sensitive, than the SIRS criteria in identifying patients at increased risk of mortality.

Management of sepsis remains controversial as a robust definition of sepsis has not been established. Clinicians typically use consensus criteria to identify this condition. qSOFA and SIRS are not diagnostic tools, and the validity of the criteria to predict mortality compared with other tools have been examined in several studies with varying conclusions.5–8, 11–16–20

*AUROC values for qSOFA or SIRS.
†Patients meeting at least two qSOFA criteria.
‡Patients meeting at least two SIRS criteria.
AUROC, area under the receiver operating characteristic; ICU, intensive care unit; LR−, negative likelihood ratio; LR+, positive likelihood ratio; NPV, negative predictive value; PPV, positive predictive value; qSOFA, quick Sequential Organ Failure Assessment; SE, sensitivity; SIRS, systemic inflammatory response syndrome; SP, specificity.

**Table 3 Twenty-eight-day mortality among patients meeting either qSOFA, SIRS or both criteria**

| qSOFA (≥2) | SIRS (≥2) | Total, N (%) | Mortality; n (%) |
| --- | --- | --- | --- |
| + | + | 142 (6.7) | 24; 16.9 (11.1 to 24.0) |
| – | + | 870 (41.2) | 60; 6.9 (5.3 to 8.8) |
| + | – | 33 (1.6) | 7; 21.2 (9.0 to 38.9) |
| – | – | 1067 (50.5) | 68; 6.4 (5.0 to 8.0) |

+, Patients meeting at least two qSOFA or SIRS criteria; –, patients meeting <2 qSOFA or SIRS criteria.

**Figure 3 The area under the receiver operating characteristic (AUROC) curve. AUROC curve for full qSOFA and SIRS criteria to predict 28-day mortality. qSOFA, quick Sequential Organ Failure Assessment; SIRS, systemic inflammatory response syndrome.**

Freund et al10 conducted a large international multicentre prospective cohort study of 879 infected ED patients, qSOFA was calculated based on the worst values of qSOFA variables during the ED stay. This study reported that qSOFA performed better than SIRS in predicting in-hospital mortality. The AUROC values for in-hospital mortality of qSOFA and SIRS were 0.80 and 0.65, respectively, substantially higher than in our study.10 The sensitivity and specificity of qSOFA for predicting in-hospital mortality were 70% and 79%, respectively.10 A qSOFA score of at least 2 was met among 25% of patients included in that study10 compared with 8.3% in ours, where the score was calculated based on the admission variables. Use of the worst values of qSOFA score during the ED stay possibly biased results to a higher qSOFA score in the study by Freund et al, whereas the current study used the initial presentation to calculate the score.10 Their results could not be extrapolated to the arrival evaluation at the ED and therefore, the authors have recommended a new study of qSOFA based on arrival measurements.10 However, by only measuring qSOFA on admission, we may have missed some patients who met qSOFA criteria later during their ED stay. qSOFA can vary during the ED stay, and the optimal time window for measurement of qSOFA is not known.
In the sepsis-3 task force study by Seymour et al, supporting the use of qSOFA the investigators applied a 72 hours time window (48 hours before to 24 hours after the onset of infection). Therefore, it is suggested that serial measurements of qSOFA could have improved its performance in our study.

Two other prospective ED studies similarly reported low sensitivity, as noted in our study of qSOFA as compared with SIRS.9 11 A Spanish study by González Del Castillo et al of 1071 older patients (≥75 years) reported a sensitivity of 28% and a specificity of 94% for qSOFA for predicting 30-day mortality by use of arrival variables at the ED. A Norwegian study of 1335 patients using qSOFA variables obtained on arrival reported sensitivity and specificity of qSOFA in predicting 30-day mortality was 12% and 96%, respectively.

Three meta-analyses published in 2018 reported similar results with higher sensitivity for SIRS criteria compared with those of qSOFA among patients with infection.21–23 A systematic review and meta-analysis by Fernando et al included 38 retrospective and prospective studies from EDs, ICUs and hospital wards. In their subgroup analyses of ED patients, they found a pooled qSOFA sensitivity of 46.7% and specificity of 81.3% for predicting mortality. The pooled specificity and sensitivity of SIRS were 83.6% and 30.6%, respectively. Fernando et al ascertained that the low sensitivity and moderate specificity of qSOFA for early detection would likely miss many cases and suggested continued use of SIRS for detection of patients with infection who are at risk of clinical deterioration. Another meta-analysis by Jiang et al included eight ED studies and reported a pooled sensitivity of 42% and specificity of 88% for qSOFA in predicting mortality in patients with infection. Pooled AUROC values for qSOFA and SIRS were 0.78 (95% CI 0.74 to 0.81) and 0.70 (95% CI 0.65 to 0.73), respectively. The definition of infection, time of sepsis criteria evaluation and primary outcomes differed in the studies. Differences in study methodology may to some extent explain the reported differences in the validity of sepsis criteria.

Data from our and other studies9 11 16 20 have clearly revealed that qSOFA is more specific, but less sensitive, than SIRS in predicting mortality. A highly sensitive test is required for cases in which missing a potentially serious clinical condition may result in unfavourable clinical consequences. A highly specific test is also needed when false-positive results may harm the patients. A highly sensitive bedside test will detect most of the critically ill patients at an early stage and facilitate prompt treatment, while a highly specific test will assist clinicians in avoiding overdiagnosis, overinvestigation and overtreatment. The higher sensitivity the AUROC analyses revealed that the use of the SIRS test was equivalent to the identification of the patients by flipping a coin. Although the sensitivity of qSOFA was poor, the statistically significant AUROC presents evidence in favour of qSOFA compared with SIRS.

Although qSOFA demonstrates a better prognostic accuracy, our and other21–23 results strongly indicate that qSOFA is not an ideal prognostic tool for the identification of infected patients at high risk of serious outcomes. However, we believe it is premature to discard these criteria as an initial evaluation tool for risk of early clinical deterioration and poor outcomes among patients with infection. Use of the worst variables included in the qSOFA criteria during the entire stay has enhanced the sensitivity of qSOFA in some studies,23 while use of admission variable to measure qSOFA has resulted in low sensitivity, as reported in our and other studies.9 11 23 Importantly, the qSOFA criteria can change rapidly and over a short time frame, indicating that a single measurement of qSOFA criteria on admission may be insufficient. A study involving serial measurements of qSOFA may accurately determine the optimal time window for the measurement of qSOFA criteria throughout the ED stay.

**Strengths and limitations**

This was a prospective study, minimising the risk of bias and missing data observed in many retrospective studies of sepsis. A prospective design ensures that almost all infected patients admitted to the ED were included in the study. All adult patients in the ED were consecutively screened for infection. Therefore, we are confident we included all patients with an infection who met the inclusion criteria. Furthermore, use of the CRS with daily updates on the vital status of patients ensured complete follow-up.

A total of 66 (2.1%) patients of all the infected patients were excluded because of missing values required to calculate either the qSOFA score or the SIRS criteria. However, we believe this small number of excluded patients did not introduce bias into our analyses. Other exclusions were in accordance with the predefined exclusion criteria.

We cannot exclude the possibility of bias from misclassification of the mental status due to missing data on the GCS/AVPU score. However, fewer than 20 patients had missing data on GCS/AVPU and we believe it did not affect overall results.

This was a single-centre study and the representativeness of the study may be limited. The identification and treatment of infectious patients with risk of sepsis in our department was based on national guidelines. Therefore, the present study, at least, is representative of Danish EDs.

**CONCLUSIONS**

The qSOFA score improved specificity at the expense of sensitivity. Both SIRS and qSOFA had low prognostic accuracy in predicting 28-day mortality among patients with infection in an ED setting. However, qSOFA had better prognostic accuracy when compared with SIRS. It is not recommended to use the qSOFA score as the only bedside clinical tool to rule out increased risk of death in ED patients with infection.

**Contributors** FEN conceived the idea and designed the study together with SMOB. Data were analysed by FEN and RHS. SMOB wrote the first draft of the manuscript. All authors interpreted data and revised the manuscript. All authors approved the final version of the manuscript.

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