RESEARCH PAPER

Combining Pro-calcitonin with Quick Sequential Organ Failure Assessment (qSOFA) Score for Short Term Mortality Prediction in Patients with Sepsis in Emergency Setting

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ABSTRACT

Background and Objectives

To investigate whether Serum Procalcitonin (PCT) can improve the performance of quick sequential organ failure assessment (qSOFA) score in predicting sepsis mortality, we conducted a prospective cohort study, Patients with presumed sepsis presenting to ED or ICU were included based on SIRS criteria.

Methodology

qSOFA and Serum Procalcitonin was measured on admission for all the study subjects They were followed up till discharge or 28 days whichever is longer. Early mortality (7 days) was recorded. P-value and ROC were used to prove a correlation between mortality and qSOFA plus Serum Procalcitonin.

Results

A total of 100 subjects was included in our study. Our study suggests incorporating PCT levels into qSOFA to correct for its low sensitivity. The high sensitivity (71.9%) and high NPV (61%) of qSOFA_+PCT justify the combined score as an initial screening tool. When 3 parameters i.e., qSOFA, Serum Procalcitonin and qSOFA with PCT was compared based on sensitivity, specificity, PPV & NPV, qSOFA plus PCT has got the best diagnostic value.

Conclusion

The incorporation of Serum Procalcitonin to the qSOFA could enhance sensitivity and reclassify patients into risk groups that better reflect their actual short-term mortality risk.

Keywords:

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INTRODUCTION

Sepsis is a life-threatening infection that affects millions of individuals throughout the world. (1)(2) Organ dysfunction, vascular leakage, and hypotension are thought to be the result of an imbalance between the systemic inflammatory response to infection in the

severe types. A timely diagnosis, followed by a determination of the most appropriate antimicrobial medication, is crucial for a positive outcome. Inappropriate antibiotic usage, on the other hand, will increase antibiotic resistance. In the early hospital course, therapeutic advice from microbiological cultures is weak, and new techniques are needed for early diagnosis and severity evaluation of sepsis patients. (3) Early implementation of evidence-based bundle care can significantly improve sepsis outcomes. Unfortunately, detecting sepsis early and accurately is challenging. As previously said, sepsis is a complicated clinical illness with a wide spectrum of symptoms. Even though the systemic inflammatory response syndrome (SIRS) criteria were previously used to define sepsis, it has been found to be ineffective in distinguishing between severe and uncomplicated illnesses. (4) According to the most recent Sepsis-3 definition, sepsis is defined as a life-threatening organ dysfunction caused by a dysregulated host response to infection with life-threatening organ dysfunction defined as a change in the sequential organ failure assessment (SOFA) score of more than 2 points in ICU patients. (5) A simplified score – quick sepsisrelated organ failure assessment (qSOFA) – was established as a screening tool for patients with sepsis in clinical settings outside the ICU where calculating the SOFA score is not routine and complicated. Concerns have been raised since the implementation of qSOFA. None of the features in qSOFA are specifically designed 2 to identify sepsis, and later validation tests revealed unsatisfactory overall discrimination and sensitivity (reported sensitivity 32%) when used with the suggested cut-off. (11) Furthermore, the accuracy of the physician's clinical suspicion of infection is crucial in identifying sepsis. (12) On the other hand, biomarkers for infectious diseases including C-reactive protein (CRP) and Pro-calcitonin (PCT) have been demonstrated to reliably predict infection and death. (6) In Sepsis-2, these two indicators were approved as diagnostic criteria, however, they were not included in the Sepsis-3 classification. (4) Combining biomarker data with the qSOFA score should improve the qSOFA score's capacity to predict sepsis mortality risk. In this study, we wanted to see if adding serum PCT to the qSOFA score would increase its capacity to predict in-hospital mortality in a multicenter group of patients with systemic infection symptoms. (7)

AIMS AND OBJECTIVES

To determine whether Serum Pro-calcitonin can improve the performance of qSOFA score in predicting in-hospital mortality in patients with Sepsis presenting to SDM Emergency Department (who fulfils at least 2 of 4 SIRS criteria upon admission).

METHODOLOGY

Source of data The present study was carried out in the patients presenting to the SDM emergency department with presumed sepsis defined as patients fulfilling at least 2 of the 4 SIRS criteria.

Inclusion criteria

• Presented to the emergency department of SDM
• Age > 18 years
• Patient with presumed sepsis who fulfilled at least 2 of 4 SIRS criteria upon admission with a presumed diagnosis of systemic infection.

Exclusion criteria

Adults with
• Transfer from other hospitals with a diagnosis of sepsis
• History of malignancy
• Pregnant women
• Trauma or recent surgery
• Do not resuscitate orders
• Thyroid condition that has affected Procalcitonin levels in the past
• Patient who denied consent.

Sampling Method: Simple Random Sampling
Sample Size: 100
Study Design: Prospective Cohort study
Study Period: November 2019-October 2020
Method of collection of data:

A printed proforma meeting the objectives of the study was prepared. The cases of the study were selected based on the above-mentioned inclusion and exclusion criteria. The data were collected according to proforma in terms of details of patient, history, clinical examination with necessary investigation values. i.e., Serum Pro-calcitonin, Total Leucocyte Count & CRP in our study, qSOFA variables and SIRS variables was noted for all the patients included in the study. Enrolled patients were followed from Admission to Discharge or 28 days (whichever is longer).

Method:

• After getting informed consent from each patient (or bystanders) enrolled in the study, 5cc of venous blood from the anti-cubital vein was collected one time within 24 hours of admission.
• Pro-calcitonin concentrations were measured by immune-luminometric assay.

RESULTS

Category	Parameter / Feature	Value / Percentage (n=100)
Demographics	Mean Age	*50.81* ± *16.69* years

Category	Parameter / Feature	Value / Percentage (n=100)
	Gender (Male / Female)	*55.0% / 45.0%*
	Mean Duration of Stay	*11.42 ± 9.14* days
Common Presentations	Fever	*68.0%*
	Lower Respiratory Tract Infection (LRTI)	*47.0%*
	Gastrointestinal Symptoms	*35.0%*
	Neurological Manifestations	*33.0%*
Comorbidities	Diabetes Mellitus (DM)	*57.0%*
	Hypertension (HTN)	*37.0%*
	Chronic Kidney Disease (CKD)	*11.0%*
	No Comorbidities (Nil)	*31.0%*

The Mean Age (Years) was 50.81 ± 16.69.
55 (55.0%) of the participants had Gender: Male.
45 (45.0%) of the participants had Gender: Female
The Mean Duration of Stay (Days) was 11.42 ± 9.14.

CLINICAL FEATURES OF PRESENTATION

68 (68.0%) of the participants had Presentation: Fever.
14 (14.0%) of the participants had Presentation: Myalgia.
5 (5.0%) of the participants had Presentation: Rash.
35 (35.0%) of the participants had Presentation: Gi Symptoms.
20 (20.0%) of the participants had Presentation: Urinary Symptoms.
47 (47.0%) of the participants had Presentation: LRTI.
33 (33.0%) of the participants had Presentation: Neurological.

CO-MORBIDITY

57 (57.0%) of the participants had Comorbidities: DM.
37 (37.0%) of the participants had Comorbidities: HTN.
7 (7.0%) of the participants had Comorbidities: IHD.
29 11 (11.0%) of the participants had Comorbidities: CKD.
5 (5.0%) of the participants had Comorbidities: CLD.
4 (4.0%) of the participants had Comorbidities: HIV.
3 (3.0%) of the participants had Comorbidities: PTB.
4 (4.0%) of the participants had Comorbidities: COPD: Yes.
96 (96.0%) of the participants had Comorbidities: COPD: No.
4 (4.0%) of the participants had Comorbidities: Seizure Disorder.
31 (31.0%) of the participants had no comorbidities.

Clinical Examination, Investigations & Interventions

Category	Parameter	Percentage / Value
Vitals & Severity	Systolic BP < *100* mmHg	*86.9%*
	SpO_2 < *90%*	*75.8%*
	GCS Score < *10*	*51.5%*
Biomarkers & Scores	Mean qSOFA Score	*2.52 ± 0.58*
	Mean SIRS Score	*2.93 ± 0.63*
	Mean Serum	*15.79 ± 22.41* ng/Ml

Category	Parameter	Percentage / Value
	Procalcitonin	
	Deranged CRP / Serum Creatinine	*67.0% / 69.0%*
Interventions & Outcomes	Invasive Ventilation Required	*70.0%*
	Inotropic Support Required	*65.0%*
	Renal Replacement Therapy (Dialysis)	*15.0%*
	Overall Mortality	*57.0%* (*37.0%* early, *31.7%* late)

34 (34.0%) of the participants had Pallor.
16 (16.0%) of the participants had Icterus.
24 (24.0%) of the participants had Edema.
5 (5.0%) of the participants had Clubbing.
86 (86.9%) of the participants had Systolic BP:<100mg
50 (51.0%) of the participants had Respiratory Rate: >20CPM.
51 (51.5%) of the participants had GCS: 90%.
39 (39.4%) of the participants had GCS: 10 to 14.
9 (9.1%) of the participants had GCS: 15.
75 (75.8%) of the participants had SpO2: 90%.
The mean S. Procalcitonin (ng/mL) was 15.79 ± 22.41.
12 (12.0%) of the participants had S. Procalcitonin: 30 ng/mL.
57 (57.0%) of the participants had TLC: Leukocytosis.
23 (23.0%) of the participants had TLC: Leucopenia.
67 (67.0%) of the participants had deranged CRP.
31 (31.0%) of the participants had deranged LFT.
69 (69.0%) of the participants had deranged S. Creatinine.
60 (60.0%) of the participants had an abnormal x-ray.
Summary of Outcomes
15 (15.0%) of the participants needed Dialysis.
70 (70.0%) of the participants required Invasive Ventilation.
65 (65.0%) of the participants required Ionotropic Support.
57 (57.0%) of the participants had a Mortality.
37 (37.0%) of the participants had Early Mortality.
20 (31.7%) of the participants had Late Mortality.
Microbiology & Culture Positivity

Culture Site	Positivity Rate	Predominant Organisms & Frequencies
Endotracheal (ET) C/S	*50.9%*	*Acinetobacter (18.5%), Pseudomonas (18.5%)*
Blood C/S	*42.5%*	MRSA (*26.5%*), *E. coli* (*17.6%*)
Urine C/S	*47.3%*	*E. coli* (*57.1%*), *Candida* (*31.4%*)

27 (50.9%) of the participants had positive ET C/S.
34 (42.5%) of the participants had positive Blood C/S.
35 (47.3%) of the participants had positive Urine C/S.
Predictive Performance for Mortality (ROC Curve Analysis)

Predictor Variable	AUROC (95% CI)	P-Value	Sensitivity	Specificity	PPV	NPV	Diagnostic Accuracy
qSOFA Score (≥ *3*)	0.650 (0.553–0.747)	0.003	68%	60%	70%	59%	65%
Serum Procalcitonin (≥ *28.9*)	0.570 (0.456–0.684)	0.233	30%	86%	74%	48%	54%
qSOFA+Procalcitonin (≥ *0.504*)	0.672 (0.564–0.780)	0.003	74%	58%	70%	62%	67%

AUROC: Area under ROC curve; CI: Confidence interval; P: P value; Sn: Sensitivity; Sp: Specificity; PPV: Positive predictive value; NPV: Negative predictive value; DA: Diagnostic Accuracy.

RESULT TRENDS

• Best parameter in terms of AUROC: qSOFA Score+S. Procalcitonin (ng/mL)

• Best parameter in terms of sensitivity: qSOFA Score+S. Procalcitonin (ng/mL)

• Best parameter in terms of specificity: S. Procalcitonin (ng/mL)

• Best parameter in terms of positive predictive value: S. Procalcitonin (ng/mL)

• Best parameter in terms of negative predictive value: qSOFA Score+S. Procalcitonin (ng/mL)

• Best parameter in terms of diagnostic accuracy: qSOFA Score+S. Procalcitonin (ng/mL)

DISCUSSION

Early identification of septic patients after Arrival at the ED can be particularly challenging especially in an overcrowding situation. Delays in diagnosis can affect further management, resource allocation and prognosis. Although the sepsis 3 task force has suggested the qSOFA as a bedside test that would prompt organ dysfunction investigation, it has also stated the need to validate the newly proposed definitions and the utility of this score using a non-US database. Our prospective study using single-centre cohorts showed that a positive qSOFA score at admission is not a sensitive marker in predicting in-hospital mortality. Similar findings were found in other studies that looked at the sensitivity of the admission score for the same outcome.

According to Tusgul et al, qSOFA had a sensitivity of 68 per cent for mortality within 48 hours, Rodriguez et al had a sensitivity of 64.4 per cent within 72 hours, and Hwng et al had a sensitivity of 39 per cent within 28 days, demonstrating the fragility and ineffectiveness of its use for early recognition. Furthermore, our study found that combining PCT and the qSOFA score by simply adding the ordinal scale of PCT to the qSOFA score can significantly enhance its mortality prediction capability in all dimensions of performance indicators.

Clinically, PCT enhanced qSOFA, the score has got the best sensitivity (71.9%) when compared to qSOFA or Serum Procalcitonin alone and can be served as a screening tool to quickly identify patients with sepsis who may benefit from early intervention. Serum Procalcitonin alone showed the best specificity (86.0%) and can subsequently serve as a quick confirmation tool to aid in the decision to pursue more invasive treatment.

The original Sepsis-3 definitions proposed using the simple qSOFA score as the initial screening tool, followed by the comprehensive SOFA score as the confirmation tool for sepsis. In the original work, the sensitivity of a qSOFA score ≥2 was reported to be low at 55%, a high specificity (84%), whereas a change of SOFA score of ≥2 had a higher sensitivity (68%), but lower specificity (67%). Based on ROC curve analysis it was also noticed that qSOFA plus Serum Procalcitonin in predicting mortality showed a maximum area under AUROC again proving its effectiveness compared to qSOFA alone.

However, the sensitivity and specificity characteristics of qSOFA and SOFA are incompatible with their planned therapeutic applications. A screening tool must have a high level of sensitivity, but a confirmation tool must have a high level of specificity. Thus, our study suggests incorporating PCT levels into qSOFA to correct for its low sensitivity. The high sensitivity (71.9%) and high NPV (61%) of qSOFA_+PCT justify the combined score as an initial screening tool.

As shown in results when 3 parameters, qSOFA, Serum Procalcitonin and qSOFA with PCT was compared based on sensitivity, specificity, PPV & NPV, qSOFA plus PCT has got best diagnostic value. A study done by Hua Yu et al shows similar results. A total of 1318 patients with suspected severe infection were included in the study, with a 30-day death rate of 13.5 per cent. The level of PCT in the blood revealed a substantial link between the qSOFA score and 30-day in-hospital mortality. The area under the ROC curve was 0.56 for SIRS criteria, 0.67 for qSOFA score, and 0.73 for qSOFA PCT in predicting 30-day mortality.

In summary, our study suggests using high-sensitivity qSOFA+ PCT as a screening tool and the high-specificity Serum Procalcitonin score as the confirmation tool is the most optimal use of biomarker information and the best clinical decision rule in clinical settings of ICU and ED.

CONCLUSION

Our study confirmed that qSOFA has low sensitivity in predicting sepsis mortality. The incorporation of Serum Procalcitonin to the qSOFA could enhance sensitivity and reclassify patients into risk groups that better reflect their actual short-term mortality risk. Hence our study proposes using qSOFA+ PCT as a screening tool followed by Serum Procalcitonin as a confirmation tool (after excluding patients who are prone to have false high Procalcitonin as in our exclusion criteria) as it showed maximum specificity for the identification of patients with sepsis in settings in ED and ICU.

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