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qSOFA or SIRS - The Better Predictor of Bacterial Sepsis in the Emergency Room

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1. Introduction

Sepsis is a major cause of Emergency Medicine Department admissions. It is associated with high morbidity and mortality.[1, 2]Early identification is of prime importance in the management of the same. Prompt and effective decision making is critical as early diagnosis of sepsis not only decreases the mortality rate, but it is also guides emergency medicine physicians to perform further therapy steps (ie, resuscitation with fluids, administration of antibiotics) simultaneously. Routine laboratory tests lack both sensitivity and specificity in correctly identifying which patients should receive antibiotics, and most confirmatory laboratory test results are not available for 24 hours in low and medium income countries. In most cases, the ED physicians have to decide on immediate treatment without even a confirmatory laboratory diagnosis is available. The February 2016. The Sepsis-3 consensus definitions were developed by a task force appointed by the European Society of Intensive Care Medicine and the Society of Critical Care Medicine (SCCM/ESICM) and has defined sepsis as a life-threatening organ dysfunction caused by a dysregulated host response to infection. The task force proposed a new criteria called the quick Sepsis-related Organ Failure Assessment (qSOFA) to identify patients in sepsis outside the ICU and to help clinicians to improve their diagnostic accuracy and prognostic prediction and also to guide treatment accordingly. This criteria is a quick rapid bed side clinical assessment that does not need the help of laboratory parameters like the novel SIRS criteria to identify a probable septic patient. SIRS is the clinical syndrome that results from a dysregulated inflammatory response to an infectious or a non-infectiousinsult. The use of systemic inflammatory response syndrome (SIRS) criteria to identify those with sepsis is falling out of favour since it is considered that SIRS criteria are present in many patients who has no infection, and their ability to predict death is poor when compared with other scoring systems(eg,SOFA score).There are various markers published for diagnosis of Sepsis. Among them Procalcitonin (PCT) is a peptide precursor of the hormone calcitonin and is produced by numerous cell types and organs after proinflammatory stimulation, especially when there is bacterial invasion.[17]Elevated PCT levels indicate bacterial infection when accompanied by a systemic inflammatory reaction..

We conducted the present prospective study to validate the efficacy of qSOFA in comparison with SIRS criteria to diagnose bacterial sepsis using procalcitonin as a marker for the same among patients who presented to the emergency room. Also the association of qSOFA with 28 day mortality is also established in our study population.

2. Methods

The study is a Prospective Cross Sectional Validation study was carried out over a span of 1.5 years during the period of February 2017 to August 2018 in patients admitted to the Emergency Room at a tertiary care centre under the Department of Emergency Medicine. Since there were no similar studies in the existing literature, this study was done among 200 consecutive patients who came to the department of Emergency Medicine department. The study was approved by the ethics committee and institutional review board

2.1 Selection and Description of Participants

200 subjects visiting the Emergency Room in AIMS, Kochi, were enrolled in the study after informed consent. Inclusion criteria were, any patient among the general population over the age of 18 who fulfilled either the SIRS criteria or the qSOFA criteria with a SOFA score of two or more. Patients of age less than 18yearsand those over the age of 18 who fulfilled either the SIRS criteria or the qSOFA criteria but having a SOFA score of less than 2 ,pregnant individuals were excluded in this study. After exclusion, the sample size was 128.

2.2 Technical Information

The main objective of this study was to validate the efficiency of qSOFA in comparison with SIRS criteria to diagnose bacterial sepsis using Procalcitonin as a marker of sepsis. Another objective was to find the association of qSOFA with mortality at 28 days.

2.3 Data collection

All patients presenting to the Emergency room are screened with the qSOFA and the SIRS criteria to identify patients who are probably in sepsis. After a brief history and clinical examination patients suspected to have sepsis are identified and the probable sources of the same is recognised and sepsis bundles are initiated .Procalcitonin is sent for all patients who fulfil the qSOFA or the SIRS criteria or both. SOFA score is also calculated to define sepsis The number of Procalcitonin positive cases is compared with the positivity of either the qSOFA or SIRS and a comparison is drawn between them in terms of efficacy. Comparison

between qSOFA+ SIRS with SOFA is also done. Finally the association of qSOFA and 28 day mortality is also found.

A SOFA Score (Sequential Organ Failure Asessment) calculated ranges from a minimum of 0 to a maximum of 24.As a score of 15 or more has a high mortality rate (90%) ,we divided our study group into two,one that has a SOFA score ≥15 and <15.The association of qSOFA and SIRS criteria with SOFA ≥ 15 is also found. An association of SOFA score ≥ 15 with 28 day mortality has also been evaluated. Finally by incorporating the SIRS criteria with the qSOFA criteria, the association of this with Procalcitonin,28 day mortality and SOFA score ≥ 15 is also found.

3. Study Tools

SIRS
Temperature >38.3^{0}C or< 36^{0}C
Heart Rate >90bpm
Respiratory Rate >20bpm
White blood cell count - >12000 / < 4000
If 2 or more of the above criteria is positive then it is a Positive SIRS criteria.

qSOFA
Systolic Blood pressure (Manual)-≤ 100mmHg
Altered Mental Status GCS ≤15
Respiratory Rate > 22 per minute
If 2 or more of the above criteria is positive then it is a PositiveqSOFA criteria.

SOFA Score[12]

Respiratory system

PaO_2/FiO_2 (mmHg)	SOFA score
≥ 400	0
< 400	1
< 300	2
< 200 and mechanically ventilated	3
< 100 and mechanically ventilated	4

Nervous system

Glasgow coma scale	SOFA score
15	0
13–14	1
10–12	2
6–9	3
< 6	4

Cardiovascular system

Mean arterial pressure OR administration of vasopressors required	SOFA score
MAP ≥ 70 mm/Hg	0
MAP < 70 mm/Hg	1
Dopamine ≤ 5 µg/kg/min or Dobutamine (any dose)	2
dopamine > 5 µg/kg/min OR Epinephrine ≤ 0.1 µg/kg/min OR Norepinephrine ≤ 0.1 µg/kg/min	3
Dopamine > 15 µg/kg/min OR Epinephrine > 0.1 µg/kg/min OR Norepinephrine > 0.1 µg/kg/min	4

Liver

Bilirubin (mg/dl)	SOFA score
< 1.2	0
1.2–1.9	1
2.0–5.9	2
6.0–11.9	3
> 12.0	4

Coagulation

Platelets×10^3/µl	SOFA score
≥ 150	0
< 150	1
< 100	2
< 50	3
< 20	4

Kidneys

Creatinine (mg/dl)] (or urine output)	SOFA score
< 1.2	0
1.2–1.9	1
2.0–3.4	2
3.5–4.9 [(or < 500 ml/day)	3
> 5.0 (or < 200 ml/day)	4

A maximum SOFA score of 24 and a minimum of 0.
In this study we have divided the study population as those having a score ≥ 15 and those <15 .

Statistics
Statistical analysis was performed using IBM SPSS version 20.0 software. Categorical variables are expressed using frequency and percentage. Numerical variables are presented using mean and standard deviation. The diagnostic measures such as sensitivity, specificity and accuracy was used to study whether qsofa or sirs is the better predictor of bacterial sepsis. To study the association of mortality with qSOFA and SIRS, McNemar's test was used.

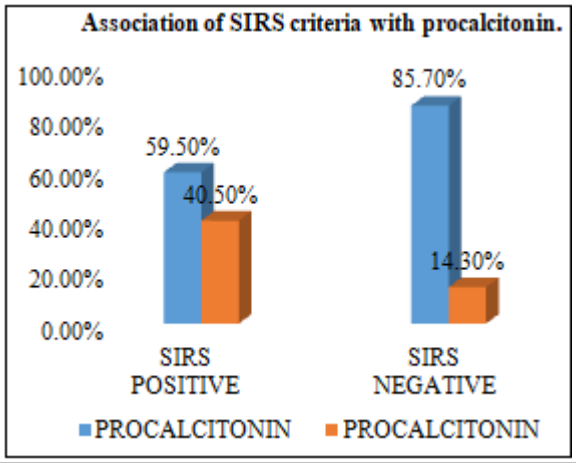
4. Results

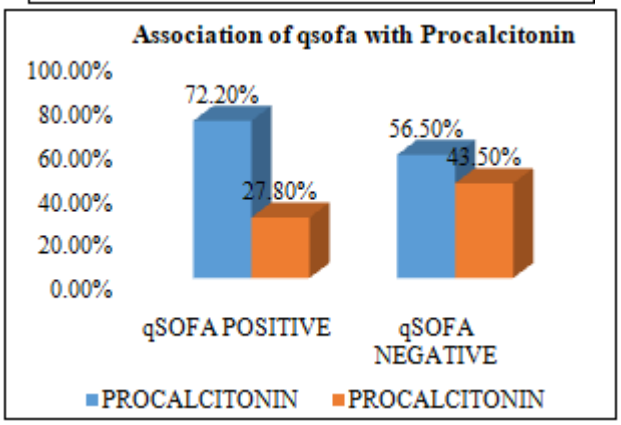
A total of 128 consecutive patients who fulfilled the inclusion criteria were included in the study.Out of them 76% were among the age group between 51 – 75 years, with a mean age of 57.57±16.054. 74.2% were Males and 25.8% were females in this study. Out of the 121 SIRS positive cases, 59.5% of them had Procalcitonin>1ng /dL, and this was statistically significant (p value <0.001). This test had a sensitivity of 92.3%, specificity of 2% and an Accuracy of 57%. Out of the total 36 cases who were positive for the qSOFA criteria, 72.2% of patients had Procalcitonin>1ng/dL, and this was statistically significant (p value =0.102) when compared to qSOFA negative cases. This test had a sensitivity of 33.3%, specificity of 80% and an accuracy of 51.5%.

Out of 121 cases who were SIRS positive, 24.8 % had expired by the end of 28 days, which shows no statistical significance when compared with SIRS negative patients (p value =0.002). 63.9 % of patients with a positive qSOFA criteria had expired by the end of 28 days, which showed statistical significance when compared to the qSOFA negative group (p value <0.001). Also when compared to those who had qSOFA negative, mortality at 28 days was

10.7 times more for patients who were positive for the qSOFA criteria.

The SOFA score helps predict morbidity rather than mortality, but in individuals with a score more than 15, the mortality rate was 90%[12].In our study we divided the study group into 2 categories, those who had a score more than or equal to 15 and those with a score of less than 15. Out of 36 cases who were positive for the qSOFA criteria , 69.4 % of patients had a SOFA score ≥ 15 which was statistically significant when compared with patients who were qSOFA negative (p value =0.002).This test had a sensitivity of 92.59%,specificity of 89.11% and Accuracy of 89.6%. Out of 121 cases who were positive for the SIRS criteria , 19.8 % of patients had a SOFA score ≥ 15 which was statistically significant when compared with patients who were qSOFA negative (p value <0.001). This test had a sensitivity of 88.89%, specificity of 3.96% and Accuracy of 21.88%. 66.7% of the study population who had a SOFA score more than ≥ 15 expired by the end of 28 days. This was statistically significant when compared to those who had a SOFA score <15 (p value <0.001).





5. Discussion

This study was carried out to find out whether the qSOFA criteria or the SIRS criteria is a better predictor of bacterial sepsis in the Emergency room with procalcitonin as a marker for the same. Identifying septic patients in the Emergency room, who require prompt initiation of treatment including antibiotics and fluid resuscitation, requires a diagnostic tool that is quick and easy to apply among all age groups and disease conditions .Introduction of the qSOFA in the Sepsis 3 guidelines was identify patients in sepsis outside the ICU and to help clinicians to improve their diagnostic accuracy ,prognostic prediction and also to guide treatment accordingly. This tool does not comprise of lab investigations (which is needed for the SOFA score, SIRS) and consists of only 3 clinical parameters which can be checked on the bed side namely systolic blood pressure of ≤100 mmHg, respiratory rate of ≥22/minute, and Altered mentation (Glasgow Coma Scale score of <15)[3]. The value of qSOFA in low-and middle-income countries) has been addressed in one analysis of 6218 hospitalized patients derived from eight cohort studies and one randomized trial [14]which concluded that higher qSOFAscores were associated with a greater risk of death but as predictive validity varied significantly among cohorts there were limitations in interpreting the outcomes. The use of systemic inflammatory response syndrome (SIRS) criteria to identify those with sepsis is falling out of favour since it is considered that SIRS criteria are present in many patients who do not develop infection (eg- autoimmune disorders, pancreatitis, vasculitis, thromboembolism, burns, or surgery), and their ability to predict death is poor when compared with other scores such as the SOFA score [3,15,16].

Procalcitonin is one of the most useful acute phase reactants in medicine today.and has shown to correlate with the severity of sepsis and also the morbidity of the disease.[6,7,8] Many studies have stressed on the fact that procalcitonin is a better marker to identify bacterial sepsis .Becker et al in their study has also shown that serum procalcitonin levels rises early and becomes detectable as early as 3-4hrs[9]. The Surviving Sepsis Campaign Guidelines recommend "that administration of IV antimicrobials be initiated as soon as possible after recognition and within 1 hour for both sepsis and septic shock". Also studies have shown that the early administration of appropriate antibiotic therapy (ie, antibiotics to which the pathogen is sensitive) has a beneficial impact on bacterial sepsis [11,12].In another study of 4211 patients published by Alexander et al in 2015, found procalcitonin as a good predictor of identifying patients at risk for mortality.[10]Hence the association of qSOFA and SIRS with procalcitonin was found in our study.

Out of 128 patients in our study population 76% were among the age group between 51 – 75 years, with a mean age of 57.57±16.054. 74.2% were Males and 25.8% were females.

In this study qSOFA criteria was found to be inferior to SIRS criteria in diagnosing bacterial sepsis (Accuracy of 57% and 51.4% respectively).While SIRS had a sensitivity of 92.3% ,qSOFA has a senstitivity of only 33.3%. Hence we concluded that SIRS criteria is a better predictor of sepsis in the Emergency room.

While 24.8% of patients who were positive for the SIRS criteria had expired by the end of 28 days, 63.9% of patients who were positive for the qSOFA criteria had expired by the end of 28 days. Also, when compared to those who had a negative qSOFA criteria, mortality at 28 days was 10.7 times more for those patients who were positive for the qSOFA criteria. In this study qSOFA had a better specificity for the diagnosis of sepsis when compared to the group who

were positive for the SIRS criteria (80% and 2% respectively).

The SOFA score helps predict morbidity rather than mortality, but in individuals with a score more than 15,the mortality rate was 90%.[13]69.4 % of patients who were positive for the qSOFA criteria had a SOFA score ≥ 15 which was statistically significant when compared with patients who were qSOFA negative (p value =0.002).This association showed a sensitivity of 92.59%,specificity of 89.11% and and an accuracy of 89.6%. Thus, it seems that the qSOFA criteria helps in identifying a population of critically ill patients from sepsis.

Thusthe management of the same in the emergency room can be a two-step approach :first with a sensitive screening tool for the diagnosis (SIRS) and second a better predictor of outcome for resource allocation and mortality (qSOFA).

Strengths and Limitations: Patient population was confined to local geographical area, procalcitonin can be positive in other conditions like invasive fungal infections, acute attacks of plasmodium falciparum malaria, medullary carcinoma of the thyroid , first days after a major trauma or major surgical interventions and pediatric age group was not involved in the study.

6. Conclusion

Sepsis is a major cause of Emergency Medicine department admissions which is associated with high morbidity and mortality. Early identification and effective decision making including antibiotic therapy and fluid resuscitation is of prime importance in the management of sepsis . In our study despite the criticisms faced by the SIRS criteria ,the same remains to be a better predictor of sepsis in the Emergency room. (accuracy of 57% and 51.5% respectively). Patients who were positive for the qSOFA criteria had a higher chance of mortality than others.

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