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Evaluation of sequential organ failure assessment (SOFA) score as an indicator of 30 day mortality in patients with sepsis admitted in surgical ICU

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***Abstract*---**Background: The existing study was conducted to find out the adequacy of sequential organ failure assessment (SOFA) score as predictor of mortality in sepsis patients in surgical ICU (SICU). Methods: 119 critically ill patients of age group 16 years and above with sepsis or septic shock admitted in SICU over a period of 18 months. The initial score, maximum score, the mean of first three days score and the mean of scores within the first week were assessed and correlated with mortality. Results: The maximum SOFA score was found to be (12.94 + 2.73), subsequently maximum score in survivors of (10.20 + 1.79) was lower than that in non-survivors (14.80 + 1.35). In the present study mean SOFA score also statistically correlated with mortality ($p<0.01$). Conclusion: It was observed that SOFA score is useful in predicting the mortality and morbidity in patients with sepsis. The early prediction of outcome in sepsis using SOFA score is a useful and economical tool to aid and plan the management strategies in ICU.

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Introduction

Sepsis, a potentially life-threatening condition that occurs when the body's response to an infection damages its own tissues. When the infection fighting process turns on, the organs in the body function poorly and abnormally. Sepsis may progress to septic shock where there is a dramatic hemodynamic instability which can lead to multi organ failure and subsequently death. Sepsis is among the leading causes of death. It is estimated that the global incidence of sepsis cases is 31.5 million cases and that of severe sepsis is 19.4 million cases per year.[1] Although the outcomes have subsequently improved because of various collaborative efforts, but still the mortality remains very high, with an estimated in hospital mortality rates of 17% to 26%.[2] The estimated mortality of patients presenting with septic shock is even higher, that is 46% subsequently.[3] Despite advances over the past two decades, mortality in sepsis remains unchanged.[4,5]

The Sepsis-3 Task force, convened in 2014 by the Society of critical care medicine (SCCM) and the European Society of intensive care medicine (ESICM) introduced new definitions for sepsis and septic shock.[7,8,3] The definitions focus on the understanding that sepsis is a multifaceted patient response to infection and result in organ dysfunction.[7,8] as per the third international consensus definitions for sepsis and septic shock- Sepsis is "Life threatening organ dysfunction caused by a dysregulated host response to infection" with a SOFA Score >2.[9] Septic shock is "a subset of sepsis in which particularly profound circulatory, cellular and metabolic abnormalities are associated with a greater risk of mortality than with sepsis alone", identified clinically by a vasopressor requirement to maintain a MAP > 65 and serum lactate > 2 mmol/L In the absence of hypovolemia. Severe sepsis is no longer part of the definition.[9]

The Sepsis-3 recommendation is to use an organ dysfunction assessment tool to identify patients with sepsis. The sequential organ failure assessment (SOFA) is the most commonly used in ICUs and is effective in quantifying the severity of organ dysfunction, morbidity and estimating mortality risk.[10,11] The higher the SOFA, the greater risk of morbidity and mortality.[12] Various scoring systems such as Acute Physiology and Chronic Health Evaluation (APACHE),[13] Simplified Acute Physiological Score (SAPS),[14] Mortality Prediction Model (MPM)[15] and Sequential Organ Failure Assessment (SOFA)[16] have been validated and are being used in predicting prognosis of patients admitted in ICU and as per sepsis-3 recommendation, organ dysfunction scoring system has been established to identify patients with sepsis.[10,11] The present study was planned to assess the ability of SOFA scoring to predict mortality in our ICU setting.

Methodology

This prospective observational study was conducted in Government Medical College, Srinagar at SMHS Hospital among patients of 16 years of age and above with sepsis or septic shock admitted in SICU over a period of 18 months. The patients excluded from our study were following:

- Patients who died within 24 hours of admission in SICU.
- Pregnant patients.
- Patients in immune compromised states (malignancy, AIDS, Viral hepatitis).
- Patients with head trauma.

After approval from the ethical committee, an informed consent was taken from the relatives of the subjects or subjects themselves prior to recruitment in the study. The patients underwent detailed history, clinical examination and laboratory investigations. The patients with sepsis admitted to SICU or those developing sepsis after SICU admission, who required intensive treatment and monitoring were screened for sepsis at admission or during their stay, as defined by the European Society of Intensive care Medicine and the Society of Critical Care Medicine. Data collection included demographic information (gender and age), history, clinical examination, pre-existing underlying comorbidity and six different scores of body system, necessary for computing severity of illness and classification as sepsis. The privacy of patients was maintained by not publishing their personal information. Vital parameters of patients were recorded at the time of admission and during their stay in SICU which includes Glasgow coma scale (GCS), heart rate (HR), blood pressure (BP), central venous pressure (CVP) and mean arterial pressure (MAP). All the baseline investigations including arterial blood gas (ABG), complete blood count (CBC), kidney function tests (KFT), liver function tests (LFT), electrocardiogram (ECG) and x-ray chest were done. Septic profile; blood, urine and endotracheal tube tip cultures; were assessed if sent. SOFA score consists of six parts scores: Respiratory, cardiovascular, renal, liver, coagulation, and neurological.

The higher SOFA scores indicate the higher probability of mortality rate. This score was determined at the time of admission to the ICU as SOFA (day 0), SOFA 1 (day 1), SOFA 2 (day 2), and SOFA 7 (day 7). Initial SOFA score, maximum SOAF score, mean SOFA score mean of the first three days SOFA score and mean of SOFA scores within the first week was assessed and correlated with mortality in SICU. Vital status of the patients was assessed and correlated with mortality in SICU. Vital status of the patients was assessed over 30 days following discharge by calling patients or their relatives (In cases they were discharged) or visiting the department in cases of remaining hospitalized).

System or organ and measure	Sofa score				
	0	1	2	3	4
Respiratory					
P_a0_2/FIO_2, mmHg	≥400	300-399	200-299	100-199 with respiratory support	<100 with respiratory support
Coagulation					
Platelets,$x10^3/\mu l$	≥150	100-149	50-99	20-49	<20
Liver					
Bilirubin, µmol/(mg/dl)	<20(1.2)	20-32 (1.2-1.9)	33-101 (2.0-5.9)	102-204 (6.0-11.9)	>204 (12.0)
Circulatory					

Mean arterial pressure, mmHg	≥70	<70	Low dose Dopamine Or any dose Dobutamine	Low-medium dose Noradrenaline or adrenaline, medium dose dopamine	High dose Noradrenalin, adrenalin, or dopamine
Central nervous system					
Glasgow Coma Scale score	15	13-14	10-12	6-9	<6
Renal					
Creatanine, µmol/l(mg/dl)	<110 (1.2)	110-170 (1.2-1.9)	171-299(2.0-3.4)	300-440(3.5-4.9)	>440(5.0)
Urine output,ml/day	-	-	-	<500	<200

*Our recommendations apply to patients with an infection and a SOFA score of ≥2.
P_aO_2= partial pressure of oxygen (arterial). FiO_2=fraction of inspired oxygen.

Statistical analysis

The data was entered in a Microsoft Excel spreadsheet. SOFA Score was summarized as mean and standard deviation. Receiver operating characteristic curve (ROC) for initial SOFA Score, day 1 SOFA score, day 2 SOFA score was made with 30 day mortality as the outcome. Sensitivity and specificity of cut off values obtained usingYouden Index were reported. Unpaired t-test was used for difference in SOFA Score among the two 30 day mortality categories.Kaplan-Meier Survival analysis was done to estimate median survival and Cox regression was done to estimate hazard ratios. Analysis was done using Stata. A p-value <0.05 was considered statistically significant.

Results

The primary object of our study was to determine the usefulness of SOFA score for prediction of 30 day mortality and identify the best cut off value to predict the mortality risk among 119 patients with substance we were admitted in ICU over a period of 18 months.Maximum number of non survivors in comparison to survivors were in the age group of (51-70) yrs (Table 1).

Table.1: Age distribution of survivors and non survivors

Age Distribution	Survivors	%	Non-survivors	%
<30	19	15.96	14	11.76
31-50	25	21.00	26	21.84
51-70	3	2.52	25	21.00
>70	1	0.84	6	5.04

Kaplan-Meier Survival estimates, the Incidence rate was calculated as no of deaths divided by time at risk. Patients with age group between (51-70), Incidence rate was 0.1316, with number of deaths 25 out of 28 patients and median survival time was 4 days was statistically significant with p value <0.001 (fig 1).

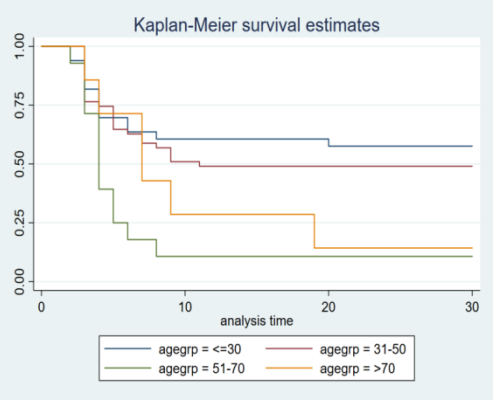

Fig 1

The percentage of non-survivors with comorbidities was 68.08% in comparison to non survivors with no known Comorbidity was 54.16% . Among 111 patients who received inotropes, 36.4 % of them survivors and 63.96 % were non survivors. The patients who received mechanical ventilation, 30.39% were survivor and 69.61% were non survivors. Out of 119 patients in this study, only 40% survived i.e. 48 patients (Table2).

Table.2: Different variables among the study population

variable	Survivors %	Non survivors %
Comorbidities	68.08%	54.16%
Inotropes	36.4%	63.96%
Mechanical ventilation	30.39%	69.61%
Out come	40%	60%

Mean of Initial SOFA (SOFA0) was found to be 12.18±2.60, Mean SOFA score Day1, Day2 and Day7 were (12.20±3.08), (11.83±3.83) and (8.40±4.47) respectively. Mean for highest SOFA was (12.94±2.73). Overall Mean SOFA was found to be 11.73 ± 3.32. Mean number of ICU days was 6.38±4.21 (table 3).

Table.3: Initial SOFA score at different time intervals among the study population

VARIABLE	OBSERVATIONS	MEAN	SD	MIN	MAX
SOFA 0	119	12.18	2.60	6	18
SOFA 1	119	12.20	3.08	5	18
SOFA2	118	11.83	3.83	5	18
SOFA7	44	8.40	4.47	4	16
MAXIMUM SOFA	119	12.94	2.73	6	18

MEAN SOFA	119	11.73	3.32	5.33	18
SOFA MEAN 3DAYS	119	12.01	3.04	5.33	18
SOFA MEAN 7 DAYS	119	11.70	3.34	4.4	18
DEATH DAYS	71	5.04	3.20	2	20
ICU DAYS	119	6.38	4.21	1	23
DISCHARGE DAYS	48	8.41	4.66	3	23

Initial SOFA 0, 1, 2, and 7 among the survivors was (9.95±1.72, 9.14±2.02, 7.83±2.39 and 5.37±1.39) found to be comparatively lower than non survivors (13.70±1.93, 13.70±1.93, 14.26±1.61, 14.57±1.51 and 14.26±1.33) with statistically significant (p<0.001) (table 4).

Table.4: SOFA scores among the study population

SOFA score	Survivors	Non survivors	p- value
SOFA 0	9.95±1.72	13.70±1.93	p<0.001
SOFA 1	9.14±2.02	13.70±1.93	p<0.001
SOFA 2	7.83±2.39	14.26±1.61	p<0.001
SOFA 7	5.37±1.39	14.57±1.51	p<0.001

ROC area for SOFA 0, SOFA 1 and SOFA 2 was found to be of value 0.91, 0.95, 0.98 respectively among the study population (fig2).

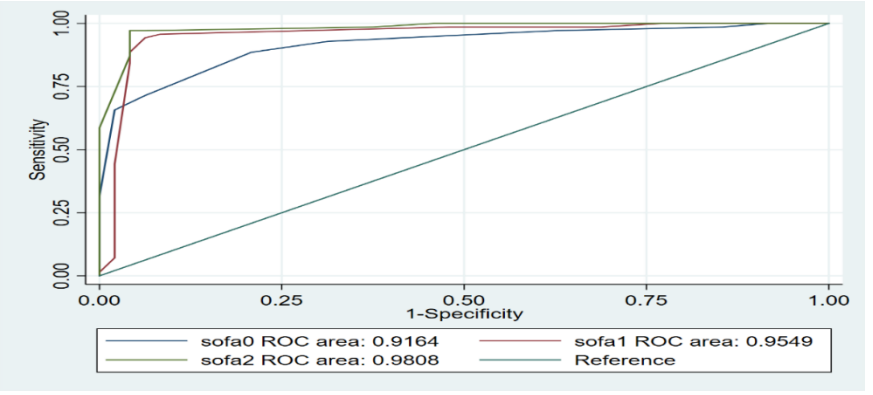

Fig 2

Discussion

Our study was thus conducted to determine the usefulness of SOFA score for prediction of mortality and identify the best cutoff value to predict the mortality risk among 119 sepsis patients admitted in our ICU, over a period of 18 months. In this study out of total 119 patients 40.34% patients survived and 59.66 % succumbed to their illness. The minimum SOFA score of patients in this study is 04 and the Maximum SOFA score is 18. Out of 111 patients receiving inotropic support, 63.96 % were non survivors and 36.04% were survivors. It was found that there was significant correlation between inotropic support and mortality of

patients in our study (p<0.01). Jain A et al17 showed a statistically significant association between inotropic support on day 1 and 3 with mortality (p value < 0.01) and Hewett JN et al18 indicated that cardiovascular scores showed highest correlation with the mortality. Fuchs PA et al19 showed that the Mean arterial pressure and requirement of vasoactive agents was statistically significant with the mortality (p<0.001).

Of 119 patients 102 (85.71%) were mechanically ventilated. Among 102 mechanically ventilated patients 30.39% survived and 59.66% did not survive. In present study need formechanical ventilation had statistically significant association with mortality (p<0.001). Nagyan T et al20 observed that the need for mechanical ventilation clearly predicted mortality outcome, since the patients who were mechanically ventilated showed a higher mortality rate compared to those who did not require ventilator support (p<0.001).

Mean of initial SOFA (SOFA 0) was found to be 12.18+2.60 with min score being 6 and maximum score 18. Initial SOFA among the survivors (9.95+1.72) is comparatively lower in case of non survivors (13.70+1.93). Correlation of initial SOFA with mortality using Two sample t-test with equal variances shows to be statistically significant (p<0.001). Ferreira FL et al16 in his study stated that initial SOFA score up to 9 predicted a mortality rate of less than 33% while initial SOFA score of greater than 11 predicted a mortality rate of 80% (p<0.001). Thapa S et al21 calculated higher sensitivity (96.9%) and specificity (57%) of initial SOFA at the cutoff value of 8.50 (P<0.05) .In a study done by Garbero et al22 in emergency department, sensitivity of SOFA was 93.7% for mortality. In our study Area under curve of initial SOFA is 0.91 with empirical optimal cutoff 11.5 with sensitivity at cutoff is 0.89 and specificity at cutoff is 0.79. Fuchs PA et al19 showed that the SOFA scores (within 24 hrs of admission) show good discrimination (AUC 0.788) for predicting the prognosis of the patients hospitalized in the ICU.

Mean SOFA score (Day1) was 12.20+3.08 with minimum score being 5 and maximum score 18. Day1 SOFA among the survivors (9.95+1.72) is comparatively lower in case of non survivors (13.70+1.93). Correlation of SOFA after 24 hrs admission in ICU (day1) with mortality using Two sample t-test with equal variances shows to be statistically significant (p<0.001). Area under curve of Day 1 SOFA is 0.95 with empirical optimal cutoff of 11.5 with sensitivity at cutoff being 0.94 and specificity at cutoff being 0.94.

Mean SOFA score (Day2) of 118 patients was 11.83+3.83 with minimum score being 5 and maximum score 18. SOFA 2 among the survivors (9.95+1.72) is comparatively lower in case of non survivors (13.70+1.93). Correlation of Day 2 (SOFA within 48 hrs) with mortality using Two sample t-test with equal variances shows to be statistically significant (p<0.001). In our study Area under curve of SOFA 2 is 0.98 with empirical optimal cutoff of 11.5 with sensitivity at cutoff being 0.97 and specificity at cutoff being 0.96. Mazzola P et al23 showed that One-month survival was significantly lower for patients with SOFA-48h score greater than 4 (71% of patients died in this group), with a sevenfold increased risk to die during hospitalization or in the 30 days following discharge.

Among SOFA 0, SOFA 1 and SOFA 2, SOFA at 48 hr of ICU admission (SOFA 2) is better predictor of mortality with higher sensitivity and specificity in comparison of other SOFA scores. Similar results seen by Ferreira FL et al16 ($p<0.001$). Mean SOFA score (Day 7) of 44 patients was 8.40+4.47 with minimum score being 4 and maximum score 16. SOFA 7 among the survivors (5.37+1.39) is comparatively lower in case of non survivors (14.26+1.33). Correlation of Day 7 with mortality using Two sample t-test with equal variances shows to be statistically significant($p<0.01$). Tee YS et al24 in his study showed the SOFA score on day 7 had the largest AUROC (0.858, SE 0.055 and 0.944, SE 0.030, respectively, ($p<.001$). Karakike E et al25 showed that the earliest time point where SOFA score predicted mortality was day 7 (AUROC (95% CI) 0.84 (0.80–0.89); $p<0.001$).

In our study Mean SOFA score, Mean of first 3 days, Mean of first 7 days was 11.73+3.32, 12.01+ 3.04, 11.70+ 3.34 subsequently. In our study mean SOFA score statistically correlated with mortality ($p<0.01$) Similar results by Ferreira FL et al16 concluded that the Mean SOFA score correlation with mortality was statistically significant ($p<0.001$). Anami EH et al26 conducted the study regarding serial evaluation of SOFA scoring in Brazilian teaching hospital which concluded that Mean SOFA reflects organ dysfunction during the ICU stay and can be a useful tool to stratify patients in clinical trials. Basham M et al27 showed that the Mean SOFA scores up to nine correlated with a mortality rate of up to <79%, while scores 10 and above predicted a 100% mortality rate.(p-value of <0.01).

In our study Maximum SOFA was found to be 12.94+2.73 , subsequently maximum score in the survivors (10.20+1.79) was lower than among non survivors (14.80+1.35). Jain A et al17 in her study demonstrated that the maximum score in survivors (3.92±2.17) was significantly lower than among non-survivors (8.9±3.45). Moreno JL et al28 also demonstrated a strong correlation of maximum SOFA score with mortality outcome. Ferreira FL et al16 showed that maximum SOFA score of >11 correlated with mortality rate 80%, so there was statistical correlation of maximum SOFA with mortality ($p<0.001$). Mean length of ICU stay was 6.38+ 4.21 with minimum number of days >24hrs or 1 day and maximum number of days 23. Ferreira FL et al16 Mean length of ICU stay was 6.5 days. In our study mean discharge days 8.41+4.66 and maximum discharge days 23. Tee YS et al24 in his study showed that patients in the non-survival group also had a longer ICU stay (29.2±38.3 vs 8.1±13.1 days, P=0.000) and hospital stay (50±73.6 vs 29.1±26.9 days, P=0.018) than those who survived.

Conclusion

We demonstrated that the SOFA score system is a useful technique in predicting mortality and morbidity in patients suffering from sepsis. Mechanically ventilated patients have more risk of mortality in comparisons to the non-ventilated ones. Patients on higher inotropic support have a higher risk of mortality than those without any inotropic support. Day 2 SOFA (SOFA at 48hrs) is a better predictor of 30day mortality. Using SOFA score may predict the outcome of sepsis patients in the early phase of their admission in SICU which can lead to modification of

management strategies with proper utilization of whatever limited resources we have thus the improvement in the outcome of the patients.

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