

**STUDY OF OUTCOME IN PATIENTS ON MECHANICAL VENTILATOR IN A
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ABSTRACT

Background: Critical care medicine is a complex, multidisciplinary specialty, designed to benefit all patients with a variety of critical illnesses. Patients admitted to the ICU need aggressive supportive management as well as detailed investigations to reverse the causal factors. Early initiation of an appropriately effective antimicrobial therapy is essential for a favorable outcome in a patient with sepsis. **Materials and methods:** It was a Prospective Observational Study conducted among 100 cases above the age of 15 who got intubated in a tertiary care Medical ICU in their course of hospital stay during the course of January 2016 to June 2017. **Results:** In the present study we found that the mortality rate was 44% among male and 68% among females, Significantly higher proportion of females after 48 hrs of admission with SOFA score above 6 (96%) had expired when compared to females with SOFA score between 0-6 (27%) (p value = <0.001). **Conclusions:** In the present study, the SOFA score demonstrated fair to good accuracy for predicting in hospital mortality when applied to patients on mechanical ventilators for more than 24 hours.

KEYWORDS: SOFA score, Intensive care unit, Multi-organ dysfunction syndrome, Sepsis, Intubation.**INTRODUCTION**

Critical care medicine is a complex, multidisciplinary specialty, designed to benefit all patients with a variety of critical illnesses. Even in the developed countries, concerns about the high costs of treatment in the ICU are being felt.^[1] Thus, illness severity scoring systems have been devised depending on the therapeutic, anatomical and physiological basis.^[1]

The primary cause; infectious or noninfectious, triggers an uncontrollable inflammatory response. Sepsis with multiorgan dysfunction syndrome (MODS) is a common cause of Intensive Care unit (ICU) mortality and morbidity.^[1] Multiorgan dysfunction syndrome is well established as the final stage of the continuum.^[2] Patients admitted to the ICU need aggressive supportive management as well as detailed investigations to reverse the cause.^[3] Early initiation of an appropriately effective antimicrobial therapy is essential for a favorable outcome in a patient with sepsis.

Using scores like SOFA (Sequential/Sepsis related Organ Failure Assessment) on admission and also in due course may help in predicting outcome.^[4] Prediction models do face many challenges but proper application of these

models helps in decision making at the right time and in decreasing hospital costs. In fact, they have become a necessary tool to describe ICU populations and to explain differences in mortality.^[5] Use of SOFA scores in the ICU as a prediction model in India has been rare. Among the various scoring systems for predicting outcomes in the ICU, SOFA score is easy as the variables measured are easily available and routinely measured in the ICU and can be measured in various cohorts of patients.^[6,7] The aim of the present study was to study the outcome of patients on mechanical ventilator using the sofa score as a prediction model.

MATERIALS AND METHODS

It was a Prospective Observational Study conducted among 100 cases above the age of 15 who got intubated in a tertiary care Medical ICU in their course of hospital stay during the course of January 2016 to June 2017.

Patients who were put on mechanical ventilation (between 15 and 90 years) during their stay in MICU of a tertiary care hospital after an informed written consent given by the patient or immediate relative (first degree) were included in the present study Whereas, patients who were discharged against medical advice, whose investigations

could not be done or brain dead patients were excluded from the study. The detailed clinical history and examination findings were recorded. All the reports of investigations and clinical measurements were recorded and the score was assigned according to the score for individual organ system of the SOFA, and a final SOFA score at the time of admission (0 hr) was recorded. Necessary investigations like Complete blood count, serum electrolytes, renal and liver function tests, urine tests, Arterial Blood Gas Analysis were done in all the patients who were in the inclusion criteria after taking informed consent from the patient or immediate relative (first degree). Association between ICU Outcome and study parameters was assessed by Chi-Square test and Logistic Regression Analysis was carried out to identify most appropriate predictors on Admission and after 48 hrs of admission of ICU stay. (In statistical modeling, regression analysis is a set of statistical processes for estimating the relationships among variables. It includes many techniques for modeling and analyzing several variables, when the focus is on the relationship between a dependent variable and one or more independent variables (or 'predictors'). More specifically, regression analysis helps one understand how the typical value of the dependent variable (or 'criterion variable') changes when any one of the independent variables is varied, while the other independent variables are held fixed.) When P value was < 0.05 the predictor was said to be significantly associated or significant predictor of the ICU Outcome. The Statistical software SPSS 20.0 was used for the analysis of the data and Microsoft word and Excel have been used to generate graphs, tables etc.

RESULTS

The present study was conducted among 100 patients who were put on mechanical ventilation during their stay in MICU of a tertiary care hospital. Majority of study subjects were belonged to >40 years of age group (72%) whereas 28% cases belonged to <40 years of age group. The difference in mortality rates was not found statistically significant among different age groups (Table 1). In the present study we found that the mortality rate was 44% among male and 68% among females, Significantly higher proportion of females after 48 hrs of admission with SOFA score above 6 (96%) had expired when compared to females with SOFA score between 0-6 (27%) (p value = <0.001) (Table 1). In the present study, the overall mortality rate was found higher in patients with SOFA score above 6 at admission (62%) than in patients with SOFA score between 0-6 (45%). After 48 hours there seen a significant association in mortality rate and SOFA score above 6 (96%) (Table 1).

The mortality was found to be statistically significant (70%) when PaO₂/FiO₂ values were < 400mmHg as compared to PaO₂/FiO₂ values > 400mmHg (23%). Very high proportion of patients who survived were predicted to be alive (specificity = 0.9787 i.e. 97.9%) by SOFA score. Similarly very high proportion of patients that expired were predicted to be dead (sensitivity = 0.9434 i.e. 94.3%) by SOFA score. Significantly higher proportion of mortality was found on admission with platelet counts below 1.50 lakhs (65%) when compared to those with platelet counts above 1.50 lakhs (38%) in relation to their final ICU Outcome (p value = 0.01). Findings became more significant after 48 hours (81%) (p value = <0.001) The mortality rates in cases with bilirubin level above 1.2 mg/dl at admission was higher (53%) than in cases with bilirubin level below 1.2 mg/dl (52%) however the findings were not statistically significant when analyzed on admission, but the difference turned to be significant after 48 hours of admission. The mortality was found to be 74% among cases with elevated serum bilirubin levels (p value = <0.001) (Table 1) Significantly higher mortality was observed among cases admitted with hypotension (74%), this proportion worsened to 95% after 48 hours (p value = <0.001) (Table 1). However we could not get significant association between GCS parameters when we compared it between GCS <15 and GCS = 15 both on admission as well as after 48 hours of ICU admission. The Glasgow coma scale scores at admission for males (p value = 0.71) in relation to their final ICU Outcome wasn't statistically significant.

In the present study, the mortality was found to be higher among cases with serum creatinine values > 1.2 mg/dl. The findings became statistically significant after 48 hours (64%) (p value = <0.001) (Table 1).

We analyzed age, gender and all the 6 components of SOFA score on admission as well as after 48 hours of admission as independent parameters with ICU outcome as dependent parameter using logistic regression analysis. The backward logistic regression analysis identified sex (Female), Platelet counts (<1.50 lakhs) and Blood pressure (Hypotension) as significant predictors of ICU outcome (Death) at the time of admission (Table 2).

On basis of these predictors, this model identified 59.6% survivals and 79.2% deaths correctly. Age, Sex and SOFA score after 48 hrs of admission were introduced as independent parameters with ICU outcome as dependent parameter to conduct logistic regression analysis. The backward logistic regression analysis identified Gender (Female), SOFA score above 6 as significant predictors of ICU outcome (Death) after 48 hrs the of admission (3). On basis of these predictors, this model identified 95.7% survivals and 90.6% deaths correctly. (Table 4)

Table 1: Comparison of patient related variables with outcome.

| Variables | | On admission | | P- value | After 48 hours | | P- value |
|------------------------------------|----------------|--------------|----------|----------|----------------|----------|----------|
| | | Survived | Expired | | Survived | Expired | |
| SOFA score | 0-6 | 30 (55%) | 25 (45%) | 0.14 | 45 (90%) | 5 (10%) | <0.001 |
| | >6 | 17 (38%) | 28 (62%) | | 2 (4%) | 48 (96%) | |
| Age wise distribution | < 40 | 16 (57%) | 12 (43%) | 0.29 | 16 (57%) | 12 (43%) | 0.29 |
| | >40 | 31 (43%) | 41 (57%) | | 31 (43%) | 41 (57%) | |
| Genderwise distribution | Males | 35 (56%) | 27 (44%) | 0.01 | 35 (56%) | 27 (44%) | 0.01 |
| | Females | 12 (32%) | 26 (68%) | | 12 (32%) | 26 (68%) | |
| PaO ₂ /FiO ₂ | <400 | 20 (31%) | 45 (69%) | <0.001 | 20 (30%) | 45 (70%) | <0.001 |
| | >400 | 27 (77%) | 8 (23%) | | 27 (77%) | 8 (23%) | |
| Platelet counts | <1.5 Lakh | 19 (35%) | 36 (65%) | 0.01 | 10 (19%) | 41 (81%) | <0.001 |
| | >1.5 lakh | 28 (62%) | 17 (38%) | | 37 (75%) | 12 (25%) | |
| Serum bilirubin levels | <1.2 mg/dl | 20 (48%) | 22 (52%) | 0.92 | 32 (74%) | 11 (26%) | <0.001 |
| | >1.2 mg/dl | 27 (47%) | 31 (53%) | | 15 (26%) | 42 (74%) | |
| Blood pressure | No hypotension | 34 (70%) | 15 (30%) | <0.001 | 45 (88%) | 6 (12%) | <0.001 |
| | Hypotension | 13 (26%) | 38 (74%) | | 2 (5%) | 47 (95%) | |
| GCS | <15 | 41 (48%) | 45 (52%) | 0.96 | 40 (45%) | 48 (55%) | 0.59 |
| | 15 | 6 (43%) | 8 (57%) | | 7 (59%) | 5 (41%) | |
| Serum Creatinine levels | <1.2 | 10 (50%) | 10 (50%) | 0.96 | 21 (78%) | 6 (22%) | <0.001 |
| | >1.2 | 37 (46%) | 43 (54%) | | 26 (36%) | 47 (64%) | |

Table 2: Levels of significance in logistic Regression model predicting mortality on basis of SOFA components.

| Variables | Odds ratio on admission | Significance on admission | Odds ratio after 48 hours | Significance after 48 hours |
|-----------------|-------------------------|---------------------------|---------------------------|-----------------------------|
| Gender | 3.47 | 0.014 | 5.78 | 0.054 |
| Platelet counts | 2.90 | 0.026 | 6.55 | 0.035 |
| Hypotension | 7.09 | <0.001 | 98.63 | <0.001 |
| Constant | 0.14 | <0.001 | 0.017 | <0.001 |

Table 3: Predictive ability of logistic regression model on the basis of SOFA components on admission.

| Observed Patient outcome | | Predicted Patient outcome | | |
|--------------------------|---------------|---------------------------|---------|-----------------|
| | | Survived | Expired | True Percentage |
| On admission | Survived | 28 | 19 | 59.6 |
| | Expired | 11 | 42 | 79.2 |
| | Overall Total | 39 | 61 | 70 |
| After 48 hours | Survived | 45 | 2 | 95.7 |
| | Expired | 5 | 48 | 90.6 |
| | Overall Total | 50 | 50 | 93.0 |

Table 4: Sensitivity and specificity of SOFA score as compared to ICU outcome of the patients.

| SOFA Outcome | Patient outcome | | |
|--------------|-------------------------------------|---------|-------|
| | Survived | Expired | Total |
| Survived | 46 | 3 | 49 |
| Expired | 1 | 50 | 51 |
| Total | 47 | 53 | 100 |
| Specificity | 97.87% (at 95% confidence interval) | | |
| Sensitivity | 94.34% (at 95% confidence interval) | | |

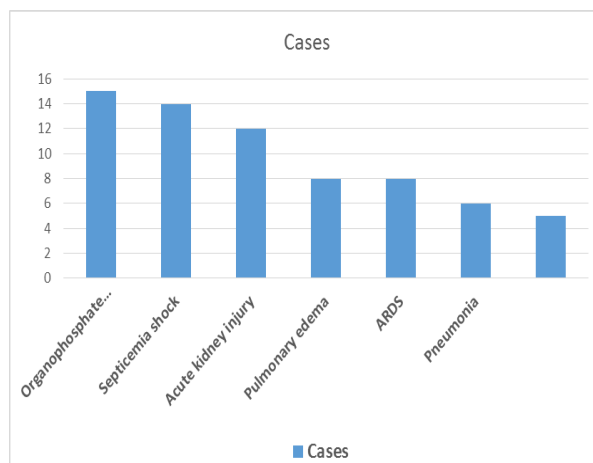


Figure 1: Distribution of study cases according to their diagnosis.

DISCUSSION

The present study was conducted to evaluate predictive ability of SOFA scoring system among mechanically ventilated patients in ICU in a tertiary healthcare institute. Among the various scoring systems for predicting outcomes in ICU, SOFA score is easy as the variables measured are easily available and routinely measured in the ICU and can be measured in various cohorts of patients. In our study the Mean age of Patients among the Survivors was 47.36 years while that of Non survivors was 53.32 years. Age was not Statistically significant criteria associated with the outcome of patients in our study group (p value = 0.29), similar to the study by Acharya et al (2007).^[1] where Mean age of patient among the non survivors was 35.7 yrs while that among the survivors was 32.6 yrs, (p value = 0.429). While Study by Chakor S Vora et al (2015).^[8] observed that as age increased, the risk of death increased. This might be as they had included only patients who needed prolonged ventilation (> 21 days). In our study 47% survived and 53% expired amongst which 62% were males and 38% were females. Out of Males, 56% survived and 44% expired while In Females 32% survived and 68% expired. Sex was significantly associated with the outcome of patients in our study group (P value = 0.01), Opposed by the study by Acharya et al.^[1] where Among the non survivors, 65% were males, while among the survivors only 53.4% were males, and similarly 35% of non survivors were females and 46.6% of non survivors were females (p value = 0.41). The overall mortality in the ICU was 53% and it has been described in large clinical trials that the mortality associated with severe sepsis and septic shock ranges between 13% and 50%. In the present study all 100 patients were intubated and 47 out of those 100 patients (47%) survived and were successfully weaned off the ventilator support and discharged from the hospital. The mean SOFA score at the admission was 6 while Mean SOFA score at 48 hrs of admission was 3. In our study, out of the 100 patients who were on mechanical ventilator their percent wise diagnosis were Acute Coronary Syndrome (15%), Organo-phosphorus poisoning (14%), Sepsis with Severe Septic shock (12%), Acute kidney injury (8%), Pulmonary odema (8%), Acute Respiratory distress syndrome (6%), Infarct (5%), Extensive Pneumonia (5%), as compared to the study by Chakor S Vora et al⁽⁸⁾ wherein 45 patients who required prolonged mechanical ventilation their diagnosis were Acute Inflammatory Demyelinating Polyneuropathy (AIDP) (28.50%) and Cerebro-Vascular Accident (CVA) (17.30%) were the commonest diagnoses followed by tetanus (8.60%) and Acute Respiratory Distress Syndrome (ARDS) (6.50%).

SOFA score parameters

The Respiration parameter (PaO₂/FiO₂) SOFA score taken at admission and after 48 hours was found to be statistically significant, which implies that PaO₂/FiO₂ values less than 400 are associated with higher mortality. Similarly, The Coagulation parameter (Platelet counts)

values less than 1.5 lakh were associated with higher mortality.

The Liver parameter (Bilirubin levels) SOFA score taken at admission was not found significant but after 48 hours, serum bilirubin levels greater than 1.2 mg/dl were found to be significantly associated with increased mortality. Out of the total 62 males 31 (50%) males required inotropic support while out of 38 females, 20 (58%) required inotropic support. While the study done by Abhinandan K S et al (2013)^[9] found 13 out of 18 (72.2%) among non-survivors required inotropic support whereas 15 out of 32(46.9%) among survivors required inotropic support suggesting that there was statistically significant hypotension in non survivors.

The Cardiovascular parameter (Hypotension) SOFA scores taken at the time of admission and 48 hrs for Males (p value = <0.001 [at admission], p value = <0.001 [after 48 hrs of admission]), for Females (p value = 0.02 [at admission], p value = <0.001 [after 48 hrs of admission]) and of the Total patients (p value = <0.001 [at admission], p value = <0.001[after 48 hrs of admission]) was found to be statistically significant at both times. The CNS parameter (Glasgow Coma Scale) SOFA score taken at 0 hrs for males (p value = 0.71), for females (p value = 0.79) and of the total patients (p value = 0.96) Wasn't found statistically significant. At 48 hrs for males (p value = 0.71), of the total patients (p value = 0.59) wasn't statistically significant while for females (p value = 0.04) was found statistically significant. The Kidney parameter (Creatinine levels) SOFA score taken on admission as well as after 48 hours, serum creatinine levels greater than 1.2 mg/dl were found to be associated with increased mortality.

CONCLUSIONS

In the present study, the SOFA score demonstrated fair to good accuracy for predicting in hospital mortality when applied to patients on mechanical ventilators for more than 24 hours. SOFA score after 48 hrs of admission has shown a strong correlation with the outcome and provide the clinician with important information on degree and progression of organ dysfunction in critically ill patients. Outcome prediction is important in intensive care unit management. Although outcome prediction and measurement should not be the only measure of ICU performance, outcome prediction can be usefully applied to monitor the performance of an individual ICU. The SOFA scoring system can help the ICU physicians in admitting patients, monitoring the clinical course, assessment of organ dysfunction, predicting mortality and for transferring patients out from the ICU and thus in proper utilization of ICU resources also in developing countries like ours, where the resources are limited. The model is closely related to outcome and identifies patients who are at increased risk for prolonged ICU stay.

In our study Very high proportion of patients who survived were predicted to be alive (specificity = 0.9787

i.e. 97.9%) by SOFA score. Similarly very high proportion of patients that expired were predicted to be dead (sensitivity = 0.9434 i.e. 94.3%) by SOFA score. Age, Sex and all 6 components of SOFA score at admission and at 48 hrs of admission were introduced as independent parameters with ICU outcome as dependent parameter to conduct logistic regression analysis. The backward logistic regression analysis identified sex (Female), Platelet counts (<1.50 lakhs) and Blood pressure (Hypotension), Liver (Bilirubin levels) as significant predictors of ICU outcome (Death) at the time of admission and at 48 hrs of admission.

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