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## RESEARCH ARTICLE

# A STUDY OF CLINICO-PATHOLOGICAL PROFILE AND OUTCOME IN PATIENTS ADMITTED WITH SEPSIS USING SEQUENTIAL ORGAN FAILURE ASSESSMENT AND QUICK SEQUENTIAL ORGAN FAILURE ASSESSMENT SCORING SYSTEM AT A TERTIARY CARE CENTRE

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### ABSTRACT

**Objectives:** Organ failure worsens outcome in sepsis. The Sequential Organ Failure Assessment (SOFA) score numerically quantifies the number and severity of failed organs. We examined the utility of the SOFA score for assessing outcome of patients with severe sepsis with evidence of hypoperfusion at the time of emergency department (ED) presentation. **Design:** Prospective observational study. **Interventions:** SOFA scores were calculated at ED recognition (T0) and 72 hours after intensive care unit admission (T72). The primary outcome was in-hospital mortality. The area under the receiver operating characteristic curve was used to evaluate the predictive ability of SOFA scores at each time point. The relationship between  $\Delta$  SOFA (change in SOFA from T0 to T72) was examined for linearity. **Results:** In the present study, we evaluated distribution of patients according to outcome. It was found that majority of the patients (68%) were discharged from the hospital. 32% of patients were expired during the study. We also compared qSOFA score parameters between admission and 48 hours. At admission, RR was found higher in expired patients (29.63) compared to discharged patients (26.43). At 48 hours, same trend was seen. At admission, SBP was found higher in discharged patients (120.74) compared to expired patients (113.75). At 48 hours, same trend in SBP was noted. GCS was noted higher in discharged patients (11.78) compared to expired patients (9.78) at admission. Same trend at 48 hours was noted in GCS also. **Conclusion:** During the study, SOFA score increased at 48 hours compared to admission. This difference was statistically significant. qSOFA score decreased at 48 hours compared to admission. This difference was statistically significant.

## INTRODUCTION

Patients are frequently admitted to ICU (intensive care units) because of sepsis significant morbidity and death occur in intensive care unit patients with severe sepsis or shock. Sepsis has a mortality rate of 30-40%.<sup>1</sup> Despite breakthroughs in sepsis treatment during the last two decades, mortality remains stable. When the body's reaction to an infection becomes out of control, it causes sepsis, a life-threatening event that can be fatal. For the time being, we're using the Sepsis-3 criteria as follows: Suspected (or documented) infection, and an abrupt rise in the number of SOFA points attributable to sepsis. Septic shock, a severe form of sepsis in which anomalies in the circulatory, cellular, and metabolic systems increase the patient's mortality risk significantly.

Septic shock and severe sepsis (acute organ dysfunction as a result of a proven or suspected infection) are both caused by sepsis, which is a systemic, harmful host response to infection (severe sepsis and hypotension not responsive to fluid resuscitation). Sepsis has a complicated pathophysiology. Infection sets off a pro- and anti-inflammatory response, both of which aid in infection control and tissue damage, both of which contribute to organ failure as a result. Both the host (comorbidities and immunosuppression) and pathogen features influence patient response to sepsis (virulence and organism load). Inflammation of the endothelium causes coagulation problems such as intravascular coagulation, fibrinolysis, microvascular thrombi, and reduced oxygenation of tissue. As a result of vasodilation and hypotension, tissues are deprived of blood circulation, resulting in organ failure. This study was conducted in the year of 2016.

SOFA is a easy and objective score that can be used to determine the number and gravity of organ dysfunction in six different organ systems. On a scale of one to six, the lower the number, the greater the number of organs that are functioning normally. On a scale of 0 (normal) to 4, each organ receives a letter grade (the most abnormal). There is a new diagnostic technique called the Quick Sequential Organ Failure Assessment introduced by the Sepsis III criteria, which permits rapid risk assessment of sepsis patients requiring longer ICU admission and in-hospital death. Patients with high qSOFA scores should have their SOFA scores examined further. Surviving Sepsis advocates using qSOFA exclusively to predict prognosis. Whether or if this will be integrated into current sepsis recommendations is yet to be seen.<sup>2</sup> The present study aimed to study clinicopathological profile and outcome in patients admitted with sepsis using 'SOFA and qSOFA scoring system at a tertiary care centre.

### Aims and Objectives

**Aim:** To study clinicopathological profile and outcome in patients admitted with sepsis using SOFA and qSOFA scoring system at a tertiary care centre

### Objectives

- To study the clinical profile of sepsis cases by monitoring the clinical parameters & latest scoring systems for critically ill patients (SOFA\* & qSOFA\*).
- To identify and compare SOFA & qSOFA at baseline and after intervention at 48 hours.

### Background

**History:** Hippocrates (460-370 BCE) originated the term sepsis, which is a Greek word.



Fig. 1. Ignaz Semmelweis

Sepsis was originally studied in contemporary times by Ignaz Semmelweis (1818-1865), a medical doctor from Austria-Hungary.<sup>3</sup> The mortality of women in childbed due to puerperal fever was a regular complication during his time as an obstetrician at the Vienna General Hospital. He discovered that his department had the highest death rate, at roughly 18 percent. Pregnant women were frequently examined immediately after a postmortem, as Semmelweis observed. Hand washing or the use of medical gloves were not common hygienic practices back then. "Decomposed animal materials that entered the circulatory system," according to

Semmelweis<sup>4</sup>, caused childbed fever. Hand cleaning with chlorinated lime solution before gynaecological procedures cut mortality to 2.55 percent thanks to him. Nevertheless, his co-workers turned a blind eye to his hygiene efforts, and they tormented him until he fled the city. After around 15 years of research, he published his findings in 1863 under the title "Aetiology, terminal, and prophylaxis of puerperal fever".<sup>5</sup> Later, Semmelweis succumbed to an infection in his wound. It was very unfortunate that he succumbed to the condition he was researching. "Except on some occasions, majority of the times patient appears to die from the body's response to infection rather than from it," said William Osler, considered the father of modern American medicine in his treatise *The Evolution of Modern Medicine*.<sup>6</sup>

**Organ Dysfunction or organ Failure:** Various scoring methods have been used to measure abnormalities based on clinical findings, test data, or treatment interventions to determine the gravity of organ malfunction. Inconsistency in reporting has resulted from the use of several grading systems. The Sequential Organ Failure Assessment (SOFA) is the most often used score right now.

**Septic Shock:** Different definitions for septic shock are being used now. Additional information are offered in an associated essay by. A systematic evaluation of the functionality of currently used definitions indicates significant variability in reported mortality.

**New Terms and Definitions<sup>7</sup>:** A dysregulated host response to infection causes sepsis, which is life-threatening organ failure. The infection causes a 2 point increase in the total SOFA score, which indicates organ dysfunction.

**Pathophysiology:** Multiple physiologic and inflammatory factors interact to generate shock in sepsis, making the pathophysiology multifaceted and difficult to understand. In the majority of septic shock patients, arterial vasodilation causes hypotension. An extremely small percentage of people who have gone into septic shock and are hypovolemic due to inflammation or fluid loss are also suffering from a hemodynamic pattern characterised by severe vasoconstriction and low blood flow shock.

MODS – Multi Organ Dysfunction Syndrome. MODS is a condition characterised by aberrant function or failure in several organs or organ systems that necessitates medical intervention to maintain homeostasis. The organ systems begin to fail one by one in a susceptible person with accompanying co-morbidities, leading to a convoluted disease process and death.

**Management/Treatment:** Below guidelines are derived from the Surviving Sepsis Campaign Guidelines.<sup>28, 29</sup>

**Source Control:** Immediately administer broad-spectrum antibiotics to all patients after diagnosis. All potential pathogens should be active in the initial empiric anti-infective therapy, as should adequate penetration of the source tissue. Patients with cellulitis, abscesses, infected devices, or purulent wounds may need to have infected/necrotic tissue removed if that is the cause of their septic shock.

**Management of Shock<sup>8</sup>:** In the first six hours after a diagnosis, measures are most effective.

- Around 8 to 12 millimetres of mercury (mmHg) for the CVP
- Restore a MAP of at least 65 millimetres of mercury
- Improve venous saturation in the superior vena cava by 70 percent or 65 percent

### Enhancing Host Response

- The use of corticosteroids is suggested in patients with vasoactive-refractory shock and/or low basal cortisol levels (less than 150 ug/L when unstimulated).
- Adding vasopressin to the mix is recommended in patients with vasoactive-resistant shock.

**Prognosis:** In spite of medical improvements, septic shock still carries a high death rate of more than 40%. There are numerous factors that influence mortality, such as the organism type and antibiotic sensitivity, as well as the number of organs affected and the age of the patient. The mortality rate increases in direct proportion to the number of risk variables that match SIRS.

**Sofa Scoring System:** Individual and group organ failure in critical care units can be quantified using the SOFA score, which was developed by Europe's European Society for Intensive Care & Emergency Medicine back in 1994 for this purpose.

**Clinical Studies:** Early goal-directed therapy prior to admission to the critical care unit has been studied by Rivers E et al (2001). Prior to being sent to the critical care unit, patients who presented to an urban emergency room with severe sepsis or septic shock were randomly assigned to receive either EGDT or routine therapy (as a control). Patients' treatment assignments were concealed from the clinicians who took over their care.

## MATERIAL AND METHODS

**Study type:** Prospective observational study

**Study centre:** Sri Aurobindo Institute of Medical Sciences and PGI, Indore

**Study duration:** 18 Months (After approval from ethics committee)

### Inclusion criteria

1. All patients (Males & Females) above 18 years of age admitted to the ICU suspected to have SEPSIS
2. With sofa score more than 2

### Exclusion criteria

1. Those patients who do not give consent
2. Age less than 18 years
3. Have need for immediate surgery.
4. Patient's who have already received treatment for more than 48 hours in other center.

Sample size: Data of 100 patients of SEPSIS patients was collected for a period of one and half year.

### Investigations Performed

- CBC
- Peripheral smear
- RBS
- Sr. Electrolytes
- Urea, Creatinine
- Urine R/M
- SGOT, SGPT, S. BILIRUBIN, PT/INR
- ABG
- Blood cultures, urine and other cultures (WHEN REQUIRED)
- Imaging studies: CXR, USG

Other investigations: CT scan, MRI wherever clinically indicated.

**Statistical analysis:** All the data analysis were performed using IBM SPSS ver. 20 software. Frequency distribution and cross tabulation was performed to prepare the tables. Quantitative data is expressed as mean and standard deviation whereas categorical data is expressed as percentage. Paired sample t test was used to compare the means. Chi Square test was used to compare the categorical data. ROC analysis for Sofa and qSOFA score also performed to obtain the area under the curve. P value of <0.05 is considered as significant.

## RESULTS

**Table 1. Distribution of patients according to age**

Age (years)	Frequency	Percentage
21-30	6	6
31-40	10	10
41-50	15	15
51-60	38	38
61-70	27	27
>70	4	4
Total	100	100

In the present study, we evaluated the distribution of patients according to age. Majority of the patients (38%) having age group between 51-60 years followed by 61-70 years (27%). Least number (4%) of the patients were found in age > 70 years.

**Table 2. Distribution of patients according to comorbidities**

Comorbidities	Frequency	Percentage
Cyanotic heart disease	1	1
DM	62	62
BA	3	3
CLD	1	1
COPD	5	5
CVA	1	1
IHD	9	9
Hypothyroidism	2	2
RA	1	1
HTN	45	45
CKD	3	3
Pulmonary TB	2	2
ILD	2	2
Sickle cell anaemia	1	1

In the present study, we evaluated the distribution of patients according to comorbidities. Majority of the patients were having DM (62%) followed by HTN (45%) and IHD (9%). Less

number of patients were having Cyanotic heart disease (1), CLD (1), CVA (1), RA (1), and sickle cell anemia (1).

**Table 3. Distribution of patients according to Outcome**

Outcome	Frequency	Percentage
Discharged	68	68
Expired	32	32
Grand Total	100	100

In the present study, we evaluated distribution of patients according to outcome. It was found that majority of the patients (68%) were discharged from the hospital. 32% of patients were expired during the study.

**Table 4. Comparing SOFA and qSOFA score between admission and 48 hours**

Parameters	Admission	48 hours	P value
SOFA	5.78±2.82	6.08±4.57	0.022
qSOFA	2.03±0.66	1.66±0.97	0.031

We compared SOFA and qSOFA score between admission and 48 hours time interval. SOFA score increased from 5.78 to 6.08 at 48 hours compared to admission. This difference was statistically significant ( $p=0.022$ ). qSOFA score decreased from 2.03 to 1.66 at 48 hours compared to admission. This difference was statistically significant ( $p=0.031$ ).

**Table 5. Comparing SOFA score between admission and 48 hours**

SOFA score	Outcome		Total	P value
	Discharged	Expired		
Admission	5.25	6.91	5.78	<0.001
48 hours	3.81	10.91	6.08	
P value	<0.001	<0.001		

We also compared SOFA score between admission and at 48 hours and its association with outcome. At admission, it was found that patients who were expired (6.91) were having higher SOFA score compared to discharged (5.25). At 48 hours, same trend was seen in which higher SOFA score was noted in expired patients (10.91) compared to discharged patients (3.81). This difference was statistically significant ( $p<0.001$ ). In discharged patients, lower SOFA score was seen at 48 hours (3.81) compared to admission (5.25). In expired patients, higher SOFA score was seen at 48 hours (10.91) compared to admission (6.91). This difference was statistically significant ( $p<0.001$ ).

**Table 6. Compare requirement of ventilator**

Ventilator required	No of patients	Percentage	P value
Yes	32	32	<0.001
No	68	68	

We compared requirement of ventilator among patients. Majority of the patients (68%) did not require ventilator.

## DISCUSSION

Despite its prevalence, sepsis is a one of the common cause of illness and mortality all across the world. However, how to detect sepsis has long been a conundrum for medical professionals and scholars alike. The sole real cause of sepsis, notwithstanding everything we've said, is infection. Although 20% to 40% of patients having sepsis do not have positive

culture findings, this means that a significant portion of these individuals have an infection that cannot be detected with present technology, or does not have an infection at all. In the past three decades, numerous expert committees and task forces have met to develop a consensus definition of sepsis. Sepsis-3, the latest definition of sepsis, was developed recently by a task team using the Sequential Organ Failure Assessment (qSOFA).

The SOFA score, developed by the European Society of Intensive Care Medicine (ESICM) Working Group on Sepsis-Related Problems, can represent both individual and multiple organ failure. The effectiveness of the SOFA score has already been examined in large cohorts of critically sick patients. Due to its ease of use and ability to incorporate easily available clinical and laboratory data, the SOFA score has a number of benefits in the emergency department.<sup>9</sup>

We looked at the patients age distribution in the current study. 38% of patients were in the ages of 51 and 60, with the remaining 16% being between the ages of 61 and 70. (27 percent). Only 4% of the patients were more than age of 70 years. A study by Baig et al. found that patients having severe sepsis were on average 59.6 years old, whereas those in septic shock were on average 60 years old. Most septic shock patients had urinary tract infections, whereas severely septic patients had stomach infections. More than 60% of patients who had septic shock required intensive care unit admission, whereas 88% of those with severe sepsis required admission to an intermediate care unit. We looked at how patients' comorbidities were distributed in this study. The most common comorbidity among the patients was diabetes mellitus (62%), followed by hypertension (45%), and idiopathic heart disease (IHD) (9). Cyanotic heart disease, CLD, CVA, RA, and sickle cell anaemia were all found in fewer patients<sup>1</sup> We also looked at how patients were distributed based on their medical history. Most of the patients (47 percent) smoked and drank cigarettes and alcohol (30 percent). Only a small percentage of patients smoked cigarettes (3 percent). We looked at how patients were distributed based on how they fared in the research. Most of the patients were discharged from the hospital, with 68% of them being deemed to be in good health. Thirty-two percent of the patients passed away during the research.

Between admission and 48 hours, we compared SOFA score parameters. GCS (9.81) was lower in expired patients than in released patients when patients were admitted (11.81). GCS in released patients was found to be higher (13.22 points) than in expired patients after 48 hours (6.47). When compared to expired patients, the majority of discharged patients (55) had MAP levels more than 70mmHg at admission (22). Most released patients (61 of them) had MAP levels greater than 70 at 48 hours, whereas expired patients had MAP levels less than 50. (9). Patients who had passed away had a higher creatinine level (2.40) than those who had been discharged after 48 hours (1.41). The bilirubin levels in discharged and expired patients did not differ significantly at the time of admission. In one study, Kovach et al. looked at hospital mortality in a retrospective data set of 3749 surgical and medical ICU patients with suspected infections, while Zhang et al. looked at 5109 cardiac surgical patients retrospectively, with both studies resulting in AUCROC > 0.8 for the prediction of mortality using SOFA and qSOFA ratings. In contrast to our strategy, Kovach's analysis<sup>71</sup> included patients who were adjusted for a baseline risk factor for death, which improved

