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Comparison of Malaria Assessment Scales in Predicting the Outcomes of Malarial Patient

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ABSTRACT

Background: Malaria is a dreadful disease that is caused by Plasmodium parasites Malaria if not treated promptly and appropriately, can rapidly lead to complications that eventually result in death. This study was therefore designed to compare Sequential organ failure assessment score (SOFA) and Malaria severity score(MSS) in predicting the outcome of malaria patients attending a tertiary care centre.
Methods: Total 60 patients suffering from malaria which were admitted in ICU and ward having more than one organ involvement were selected. SOFA and MSS were measured on three days (0, 2, 7 days) to find out whether subsequent day scores can predict mortality/morbidity better or not. Death or recovery are the two outcomes, which were assessed for prediction analysis.
Results: Among the total patients enrolled, recovery occurred in 47 patients & 13 patients died .The mean age of patients who survived was 39.9±15.9 years & those who died was 42.2±16.7 years . An ROC curve was constructed to determine the predictive value and an area under curve of 0.786 ± SE of 0.076, 0.935 ± SE was calculated for MSS & SOFA scores respectively .
Conclusion: In this study outcome of malaria patients was independent of the age and sex. SOFA score proved to be the score with excellent prediction ability when compared with MSS in predicting outcome. Scoring system can be improved by adding co-morbidity status and parasite count for the better prognosis of patients.

Key words: Malaria, Malaria Severity Score, Sequential Organ Failure Assessment.

INTRODUCTION

Malaria is a dreadful disease that is caused by Plasmodium parasites. This parasite is transmitted by the bite of infected Anopheles mosquitoes, called "malaria vectors", and thereby spread among people. The four major types of malaria infecting humans are Plasmodium malariae, Plasmodium ovale , Plasmodium vivax and Plasmodium falciparum ; the latter two pose maximum threat at a global level.(1)

Malaria if not treated promptly and appropriately, can rapidly lead to complications that eventually result in death (2). Due to high morbidity and mortality rates, malaria is a major public health crisis in developing countries. Nearly half of the world's population lives in 87 countries and territories in areas at risk for malaria transmission. In 2020, malaria caused an estimated 241 million clinical episodes and 627,000 deaths out of which an estimated

95% of deaths in occurred in the WHO African Region (3)

India bears 85.2% of the malaria burden in South East Asia contributing to 2% global malaria deaths i.e 52 % malaria deaths outside of sub-Saharan Africa. Of significance, India carries 47% of the global P. vivax malaria burden, making it strategically important for global malaria elimination, particularly in the Southeast Asian region (4)

Malaria infections may lead to vital organ dysfunction and death. Severe malaria, caused mostly due to *P. falciparum* is defined by clinical or laboratory evidence of vital organ dysfunction. The manifestations of which include unarousable coma/ cerebral malaria, acidosis, severe normochromic normocytic anaemia, renal failure, pulmonary oedema/ adult respiratory distress syndrome, hypoglycaemia, hypotension/ shock, haemorrhage/ disseminated intravascular coagulation and convulsions. Other clinical manifestations include haemoglobinuria, extreme weakness, hyperparasitemia and jaundice.

Diverse scoring systems viz. Sequential organ failure assessment score (SOFA), Malaria severity score (MSS) , Malaria Severity Assessment Score (MSA) and Coma Acidosis Malaria (CAM) scores have been used to gauge the prognosis of patients of complicated malaria. Higher scores are indicative of higher mortality rates in patients. Malaria severity score (MSS) which is targeted only for patients having malaria is a "Specific" prognostic scoring system which is disease specific (5). Sequential organ failure assessment score (SOFA) is used for MODS (Multi Organ Dysfunction Syndrome) patients especially with sepsis (6,7). MODS patients are critically ill and are admitted in ICUs. It is "semi generic" or is specifically targeted to organ failure. Evaluation, validation and comparison of these generic, semi-generic and specific prognostic scoring systems are lacking in malaria patients.

The reason - malaria, especially *P. falciparum* and *P. vivax* types, has very severe complications lead to high mortality and morbidity. The presence of pregnancy makes it all the more difficult and critical. Therefore, analysis using scoring systems can help improve patient management to achieve better outcomes. The current study was therefore designed to compare SOFA score and MSS scoring systems in predicting the outcome of malaria patients attending a tertiary care centre.

Objectives: To Evaluate, Validate and Compare SOFA score and MSS in malaria patients.

MATERIAL AND METHODS

Study design: Cross sectional study.

Study site: Department of Medicine, D.Y Patil University School of Medicine, Navi Mumbai, Maharashtra (India)

Study population: Patients attending the Department of Medicine of our study site, diagnosed with malaria.

Sample size: 60

Study selection criteria:

Inclusion criteria

1. Patients willing to give written informed consent.
2. Patients more than 18 years of age including pregnant females Upper age limit being 80 years.
3. Patients with positive peripheral smear for malarial parasite or positive malarial antigen test,
4. Patients infected with *P. Vivax*, *P. Falciparum* individually as well as mix infections of both having multi-organ involvement (more than one organ involvement) and admitted in ICU and ward of Medicine Department .

Exclusion criteria

1. Patients in whom protocol of investigations and assessment was not possible due to some reasons.

Methodology:

This study was conducted during 2015 in the above mentioned study population and study site .The purpose and rationale of the study was explained to the participants & written informed consent was obtained from all the patients prior to enrolling them in the study .Institutional ethics committee approval was taken before initiating the study.

Every patient demographic details including name, age, gender, address, occupation as well as indoor registration number was recorded in a pre-designed case record form (CRF). Malaria was diagnosed on the basis of a peripheral smear examination. Both thick as well as thin smear were performed. Additionally, malarial antigen test was also done; selection of cases was done by any, positive peripheral smear examination or positive malarial antigen test. All investigations required in critically ill patients as well as depending on patient situation were performed. Patients admitted in critical care wards as well as in general wards were examined daily.

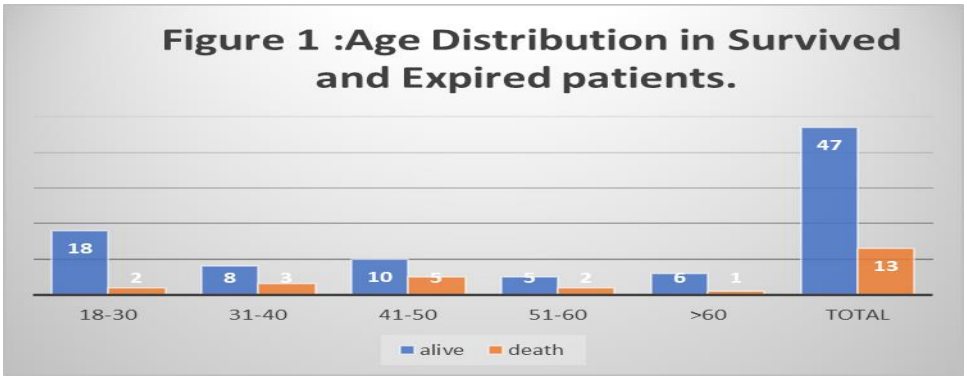
SOFA score and MSS were used to prognosticate patients of malaria. As per classical SOFA score, it should be done daily and trend of severity can be noticed. To compare SOFA score with MSS, we kept original principal of SOFA of serial evaluation and was done thrice in first seven days. MSS is also one time score but to compare it with SOFA, it was also done thrice. These scores were measured on three days (0, 2, 7 days) to find out whether subsequent day scores can predict mortality/morbidity better or not. Death or recovery are the two outcomes, which were assessed for prediction analysis.

Statistical analysis:

Baseline study participant characteristics were described using descriptive statistics. Categorical data were analysed using Chi-square test. Parametric correlation analysis was done using Pearson correlation test while non-parametric correlation analysis was done using Spearman correlation test. A p-value of <0.05 was considered to be significant. The analysis was done using SPSS V18 and MS Office 2010.

RESULTS

Out of the 60 patients enrolled in the study 44 (73.3%) were males and 16(26.7%) were females. Maximum patients (33.3%) belonged to age group category 18-30 years followed 25 % patients in 41- 50 year category . Amongst the total patients enrolled, recovery occurred in 47 patients and 13 patients died. The mean age of patients who survived was 39.9±15.9 years and those who died was 42.2±16.7 years however the difference was statistically insignificant (p> 0.05) using unpaired t test .(Figure 1)



Among the parasites responsible for malaria in our study population, 22 (36.7%) were due to *P. vivax*, 31 (51.7%) due to *P. falciparum* and 7 (11.7%) due to other or a mixture of species. In Group A(alive) , 18 (30%) were infected by *P. vivax*, 24 (40%) by *P. falciparum* and 5 (8.3%) due to other/mix of species. In Group B (patients

that died) 4 (6.7%) were infected by *P. vivax*, 7(21.7%) by *P. falciparum* and 2 (3.3%) due to mix infection. A significant difference ($p<0.05$) was found between the two groups of alive and death, with highest mortality found in patients of *P. falciparum.* (Table 1)

Table 1 Causative malarial species

Causative organism	Alive	Death	Total	P value*
P vivax	18 (30)	04 (6.67)	22 (36.67)	0.004
P falciparum	24 (40)	07 (11.67)	31 (51.67)	
Mix	05 (8.33)	02 (3.33)	07 (11.67)	
Total	47 (78.33)	13 (21.67)	60 (100.0)	
*Using Chi-Square test				

Amongst our study population, co-morbidities were seen in 20 (33%) patients: 15 (25%) from Group A and 5 (8.3%) from Group B however no significant difference found between two groups obtained (.(Table 2) .Out of 20 patients having co-morbidities, 9 (15%) had Diabetes Mellitus, 7 (11.66%) had Hypertension, 2 (3.33%) had both Diabetes Mellitus and Hypertension, 1 (1.66%) had Chronic Kidney Disease and 1 (1.66%) patient had Cirrhosis of liver

Table 2: Presence of co-morbid conditions

Co-morbid conditions	Alive	Death	Total	P value*
Present	15 (25)	05 (8.34)	20 (33)	0.9118
Absent	32 (53.33)	08 (13.33)	40 (67)	
Total	47 (78.33)	13 (21.67)	60 (100.0)	
*Using Chi-Square test				

In current study, the parasite count were: 1-10 parasites per 100 fields in 12 (20%) patients (Group A); 11-100 parasites per 100 fields in 25 (41.7%) patients (Group A: 20 and Group B: 5); 1-10 parasites per field in 19 (31.7%) patients (Group A: 15 and Group B: 4); 4 (6.7%) patients had a count greater than 10 parasites per field (Group B). A significant difference in parasite count was found between the two groups. Moreover mortality as per the parasite count group is 0%, 20%, 21% & 100% respectively. Thus as the parasite count increases, so does the mortality rate.(Table 3)

Table 3 : Parasite count

Parasites	Alive	Death	Total	P value*
+	12 (20.00)	0 (0)	12 (20.00)	0.0005
++	20 (33.33)	05 (8.33)	25 (41.67)	
+++	15 (25)	04 (6.66)	19 (31.67)	
++++	00 (00)	04 (6.66)	04 (6.66)	
Total	47 (78.33)	13 (21.67)	60 (100.0)	
*Using Chi-Square test				

The mean SOFA score on the day of admission was 6.87 ± 2.18 in group A and 12.07 ± 2.49 in group B. The mean score on the 2nd day was 7.38 ± 2.21 in group A and 10.38 ± 2.60 in group B. The mean score on the 7th day was 5.93 ± 4.33 in group A and 11.76 ± 5.50 in group B. Using the unpaired t test, a significant difference in the mean SOFA scores was found between the two groups at all three time points (p value of less than 0.0001, 0.0001 and 0.0002 was calculated for the first, 2nd and 7th day) (Table 4)

Table 4: Validity of SOFA score

SOFA Score	Outcome	Total patients (N)	Mean	SD	SEM	P value*
Day 0	Alive	47	6.87	2.18	0.31	<0.0001
	Death	13	12.07	2.49	0.69	
Day 2	Alive	47	7.38	2.21	0.32	0.0001
	Death	13	10.38	2.60	0.72	
Day 7	Alive	47	5.93	4.33	0.63	0.0002
	Death	13	11.76	5.50	1.52	
*Using unpaired t test						

The mean MSS on the day of admission was 5.38 ± 2.69 in group A and 8.76 ± 3.3 in group B. The mean score on the 2nd day was 6.12 ± 2.18 in group A and 7.15 ± 1.95 in group B. The mean score on the 7th day was 6.7 ± 3.48 in group A and 8.84 ± 4.42 in group B. Using the unpaired t test a significant difference in the mean MSS values was found between the two groups on the day of admission (p-values of 0.0003, 0.1309 and 0.0660 were obtained for the first, 2nd and 7th day respectively)

but on the 2nd and 7th day no significant difference between the two groups was found. (Table 5)

Table 5: Validity of MSS in malaria patients

Malaria Severity Score (MSS)	Outcome	Total patients (N)	Mean	SD	SEM	P value*
Day 0	Alive	47	5.38	2.69	0.39	0.0003
	Death	13	8.76	3.30	0.91	
Day 2	Alive	47	6.12	2.18	0.31	0.1309
	Death	13	7.15	1.95	0.54	
Day 7	Alive	47	6.70	3.48	0.50	0.0660
	Death	13	8.84	4.22	1.17	
*Using unpaired t test						

An receiver operating characteristic (ROC) curve was constructed using the SOFA scores and MSS to determine its predictive value . An area under curve of 0.935 with standard error of 0.037 & .786 with standard error of 0.076 was calculated for SOFA score and MSS respectively. It was concluded that SOFA scores (area was greater than 0.9) have an excellent predictive value whereas MSS (area was between 0.7-0.8) has a fair predictive value.

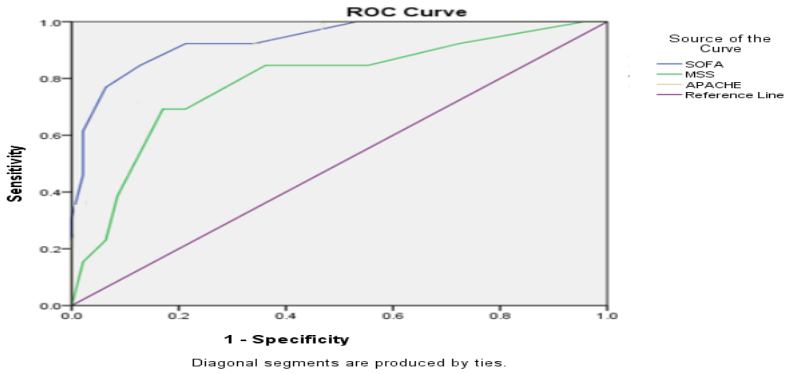


Figure 2: ROC curves of SOFA score and MSS combined

DISCUSSION

This study was conducted to compare SOFA score and MSS for severity assessment and outcome validation in the patients with severe malaria. A total of 60 patients of either sex was enrolled for evaluation. By the end of the study 78.3% patients survived and 21.7% died. A significant difference in the proportion of patients admitted to ward and ICU was found between those who died (21.67%) and those that survived (45%) This suggests that magnitude of change in parameters is equally important in predicting the mortality. In this study ward patients had more than one organ involvement but the magnitude of change in the parameters specific to that organ was not as severe as ICU patients.

In the present study a higher prevalence of P. falciparum was found compared with P. vivax. The results are in agreement with those of Lampah DA et al (8), where P. falciparum was responsible in 67% of cases, followed by P. vivax in 21% of cases. In contrast to the findings of this study predominance of P. vivax as compared to P. falciparum was reported by another study (9), who also found that mixed infection contributed to about 10% to 22% of the cases.

Amongst study population Of the 20 patients with comorbidities, 15% had diabetes mellitus, 11.66 % had hypertension, 3.33% had both diabetes mellitus and hypertension, 1.66% had chronic kidney disease, and 1.66% had liver cirrhosis. A case control study conducted in Ghana (10) among 1,466 urban adults found that patients with type 2 diabetes mellitus had a 46% increased risk of Plasmodium falciparum infection. An increase in the

prevalence of diabetes mellitus may increase personal risk for malaria infection. Parasite count play a crucial role in the determination of the prognosis of malaria as mortality significantly increased in patients with high malarial parasite count in the present study .

Finally to comparatively assess the two scores an ROC curve was constructed. Using the area under curve value SOFA score has got the excellent predictive ability when both the scales are compared . A significant difference (0.0002) in the mean SOFA scores was found between the two groups at all three time points. The results of present study found that increased SOFA scores were associated with an increased mortality risk. This corroborates with the findings of another study (11) in which SOFA score ≥12 was associated with a significantly increased risk of mortality and poor outcome.

Another study (12) found that the initial SOFA scores is a sensitive and specific predictor of mortality with higher SOFA scores corresponding to poorer outcome in patients with multi organ failure due to infectious diseases. Desai S (13*)* concluded that it is preferable to assess the SOFA scores on through the entire first week rather than only on the day of admission as increasing trend of SOFA score is predictive of poor outcome. In contrast to the results of above studies, a study from Angola (14) found that the SOFA score was readily applicable and efficient in monitoring daily organ dysfunction but was not effective enough in predicting the outcome of severe malaria patients.

In the present study though MSS gave prediction, it was giving inferior results when compared with SOFA score. Aharwar S et al (15) reported that mortality was seen in patients with MSS score greater than 10 and 60% of those who died had a score greater than 16. This was similar to the findings in the present study where higher MSS correlated to higher mortality risk. In a study done by Mahapatra et al (5) concluded that patient of malaria can be stratified as low, intermediate, and high risk depending on the MSS. With the help of MSS daily risk estimates recovery time can be determined. Another study conducted in Gujarat (16) recommended that Sequential measurement of MSS should be recorded as compared to onetime score measurement. Parasite count can be added in prognosis scoring system as it is the specific indicator for malaria severity.

In a retrospective study (17) conducted in hospitalized patients in Rome, Italy, clinical severity at ICU admission was assessed using both SOFA and q- SOFA scores. Most ICU patients had an medium SOFA score with a high SOFA -related mortality predictive value. The use of both malaria-specific (GCRBS) and general (SOFA) scores in severe malaria patients may be the best approach to assess the need for ICU care

CONCLUSION

The outcome of malaria patients is independent of the age. Diabetes Mellitus patients are at increased risk of malaria infection and further studies are required for detailed evaluation among such patients. Parasite count has linear relation with outcome. Higher the count, more are chances of mortality. A statistically significant difference was found between the mean scores of the surviving and dying groups on the day of admission however this was not the case on day 2 and 7. Thus validation of MSS was present on day 0. Mean SOFA score of survived group and mortality group was statistically significant on day 0, day 2 and day 7. It proved to be the score with excellent prediction ability when compared with MSS. Adding co-morbidity status and parasite count, we may be able to generate better scoring system.

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