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And FOR RESERVED

THE PRESENT STUDY WAS AIMED TO COMPARE SOS, QSOFA, AND SOFA SCORING SYSTEMS IN THE PREDICTION OF MORBIDITY AND MORTALITY

AMONG MOTHERS PRESENTING WITH SEPSIS.

Dr Amrita ChaurasiaMBBS MS (Obg and Gyn)Dr Ritika RaiMBBS MS (Obg and Gyn)Dr. Nidhi SachanMBBS MS (Obg and Gyn)

Original Research Paper

ABSTRACT Objectives The present study was aimed to compare SOS, qSOFA, and SOFA scoring systems in the prediction of morbidity and mortality among mothers presenting with sepsis. Materials and methods A prospective observational study was conducted from March 2021 to April of 2022 among 164 mothers admitted with maternal sepsis diagnosed by modified SIRS criteria. After conducting detailed physical, obstetric, and biochemical checkup for each mother, they were scored as per the three scoring systems at the time of admission and followed up till death or discharge Results The mean age of 25.6±3.5 years. Most of the participants were from rural areas, and belonged to the poorer socioeconomic strata. Of the mothers, most were post-natal mothers (55.5%), and 6.7% were admitted in the post-abortal period, after suffering from septic abortions. At the time of admission, the mean SOS score was 7.6±7.1, Mean SOFA score was 10.3 ± 4.9 and the mean qSOFA score of the participants was 1.3 ± 1.2 . Of the study participants, 24.2% required admission in the intensive care unit (ICU), 22% required ventilatory support, and 21.3% died as a complication of maternal sepsis. Receiver Operating Characteristic (ROC) curve analysis found that at a cut-off of 13 and 2 respectively, the SOFA and qSOFA scores predicted ICU admission, ventilator support requirement, and death with higher sensitivity and specificity than the SOS scores. SOFA scores of \geq 13 and qSOFA score of \geq 2 were significantly associated with ICU admission, ventilator support requirement, and mortality among the study participants. However, a cut-off of 6 for the SOS score was not found to be statistically significantly associated with any of the three clinical outcomes of maternal sepsis.

KEYWORDS : Maternal sepsis, SOFA, qSOFA, SOS, India, maternal mortality

INTRODUCTION

As per the third international consensus on sepsis, the term 'Sepsis' is clinically defined as a life-threatening disease complex which is characterized by severe organ dysfunction resulting from a disbalanced host response to an infection. [1] While it is relatively well-understood condition, managing sepsis properly is a daunting task, as it is associated with a significant morbidity and mortality due to the potential risk of septic shock. While sepsis can occur as a complication of any infection, maternal sepsis is defined as a life-threatening condition associated with organ dysfunction which is caused by an infection during pregnancy, delivery, puerperium, or after an abortion. [2] Despite being highly preventable, maternal sepsis continues to be a major cause of death and morbidity of pregnant women, especially in developing countries such as India.

It is challenging to diagnose sepsis in pregnancy and puerperium period due to masking or similar features of sepsis with pregnancy induced changes, like increase in heart rate, slight fall in diastolic blood pressure etc. Delayed diagnosis of maternal sepsis can lead to fulminant, rapidly fatal sepsis hence quick and accurate identification of this condition is necessary. According to the most recent bulletin on maternal mortality published by the Sample Registration System (SRS) of India, the maternal mortality rate of the country is 103 per 100000 live births.[3] It has been estimated that around one-fifth of all these deaths are caused by sepsis associated with pregnancy, making the condition an important public health problem in the country.[4] Therefore, predicting high-risk mothers in order to prevent the condition from worsening is of utmost importance. Several different evaluation scales and scores have been developed, which have been different prediction rates.

The sequential organ failure assessment score (SOFA) has been in use since 1994, having been validated in various scenarios. The score uses simple measurements of major organ function derived from routine investigation to calculate a severity score. The different organ systems assessed as per the SOFA scores are the respiratory, cardiovascular, hepatic, coagulation, renal and neurological systems.[5] However, since the scoring requires measurements of biochemical parameters of the patients and therefore requires laboratory investigations, they might not always be available in a timely manner. Hence an easier bedside and simplified and quicker version of the SOFA score, called qSOFA was introduced in year 2016, which uses only three parameters (systolic blood pressure, tachypneoa, and altered mental status) to classify women into high-risk and low-risk categories. Another tool which was developed as a specialized tool for sepsis in obstetric patients is the Sepsis in Obstetrics Score (SOS). [6] This was introduced in the year 2014 and has since been utilized widely in obstetrics settings worldwide. [7]

The major challenge, however, is that there is till date no consensus regarding the ideal scoring system for the classification of maternal sepsis to predict and prevent sequelae. The present study was therefore designed in order to address this gap in the literature by providing data regarding the effectiveness of each of these scores (SOS, qSOFA, and SOFA) in the prediction of morbidity and mortality among mothers presenting with sepsis and compare them with each other.

MATERIALS AND METHODS

Study design and area:

The present study was a prospective observational study, conducted in the department of Obstetrics and Gynaecology of Swaroop Rani Nehru Hospital, Moti Lala Nehru Medical College and Kamla Nehru Memorial Hospital, Prayagraj, India.

Study period:

The period of the present study was one year, conducted from March 2021 to April of 2022.

Study population and exclusion criteria:

The study population consisted of antenatal mothers, postabortal (up to 2 weeks) or postpartum mothers (≤ 6 weeks) admitted with maternal sepsis. In these mothers, the sepsis was diagnosed using the modified SIRS criteria as depicted in

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[Table 1]. Women unwilling to take part in the study and those with known history or diagnosed pathology of pulmonary, cardiac, renal, hepatobiliary and nervous system were excluded from the present study.

Sampling:

A thorough review of records of the previous 2 years showed that on an average 156 patients were admitted with sepsis in the hospital yearly. Based on that, the final sample size for the present study was considered to be 156. A complete enumeration sampling technique was adopted for the present study. All mothers admitted to the study institution during the study period were included as the final sample for the study. The total number of patients admitted during the period of the study after fulfilling the inclusion criteria and being excluded as per the exclusion criteria was 164.

Study technique:

After approval from institutional ethics of the study institution and informed consent from the patients, the study was conducted. A detailed clinical history was collected of each participant which included data pertaining to their sociodemographic characteristics, past history, personal history, obstetric, menstrual, and family history. Then a complete physical examination was performed, including general, systemic, and obstetric examination. After that, from each patient, 10 ml of venous blood was collected and sent to the laboratory for routine pathological and microbiological examination for the confirmation of sepsis.

During the admission of each of the participants, all the patients were assessed for the SOFA, qSOFA, and SOS scoring systems to classify them as either high risk or low risk groups of patients. A cut off of 13 of the SOFA score, 2 for qSOFA score, and 6 for SOS scores were considered to classify the mothers as either high risk or low risk for mortality and morbidity. Further management was done according to hospital protocol and each patient was assessed for following parameters

Statical analysis:

The collected data were checked for consistency, completeness and entered into Microsoft Excel (MS-EXCEL, Microsoft Corp.) data sheet and then analyzed with the statistical program Statistical Package for the Social Sciences (IBM SPSS, version 22). Data were organized and presented using the principles of descriptive and inferential statistics. A p-value of <0.05 was considered to be statistically

RESULTS

A total of 164 women were recruited as participants for the present study. It was observed that most of the participants were aged between 25 and 29 years, with a mean age of 25.6 ± 3.5 years. Most of the participants (76.8%) were from rural areas, and belonged to the poorer socioeconomic strata as per the modified B.G. Prasad Scale of socioeconomic classification of Indian population. [8] Of the mothers recruited to the present study, most were post-natal mothers (55.5%), and of those who were admitted in their antenatal period were primarily primigravida mothers. Of the total participants, 6.7% were admitted in the post-abortal period, after suffering from septic abortions. [Table 2]

When the sepsis related characteristics of the study participants were considered, it was seen that at the time of admission, 71 (43.3%) of the mothers had an SOS score 6 or more, with a mean SOS score among the participants being 7.6 \pm 7.1. The SOFA scores of the study participants ranged from 1 to 24 (mean \pm SD 10.3 \pm 4.9), and 32.3% of the patients had a score of 13 or higher on the SOFA scale. With respect to qSOFA scores, it was observed that the mean qSOFA score of the participants was 1.3 \pm 1.2, with 43.3% of them having a score of 2 or higher. Of the study participants, 24.2% required admission in the intensive care unit (ICU), 22% required ventilatory support, and 21.3% died as a complication of maternal sepsis. [Table 3]

Receiver Operating Characteristic (ROC) curve analysis of SOFA and qSOFA scores in predicting adverse clinical outcomes found that at a cut-off of 13, the SOFA score predicted ICU admission of mothers with suspected maternal sepsis with a sensitivity of 100% and a specificity of 94.4% (AUC 0.994, 95% CI 0.987, 1.000). For the qSOFA, a cut-off of 2 predicted ICU admission with a sensitivity of 97.5% and a specificity of 74.2% (AUC 0.957, 95% CI 0.925, 0.989). At a cutoff of 13, the SOFA score predicted ventilator support requirement of mothers with a sensitivity of 100% and a specificity of 86.7% (AUC 0.969, 95% CI 0.943, 0.994). For qSOFA score, at a cut-off of 2, the sensitivity was 97.2% and specificity was 96.1% (AUC 0.969, 95% CI 0.939, 0.999). For the prediction of death among mothers with maternal sepsis, a SOFA cut-off of 13 had a sensitivity of 100% and a specificity of 86.0% (AUC 0.997, 95% CI 0.993, 1.000), and for qSOFA, a cutoff of 2 had a sensitivity of 97.1% and a specificity of 71.3% (AUC 0.933, 95% CI 0.893, 0.974). [Figures 1 and 2]

At a cut-off of 6, the calculated sensitivity, specificity, positive predictive value, and negative predictive value of SOS score in predicting ICU admission were 45%, 57.3%, 25.4%, and 76.3% respectively. For predicting ventilatory support requirement, these values were 47.2%, 57.8%, 23.9%, and 79.5% respectively, and for predicting death, the sensitivity, specificity, positive predictive value, and negative predictive value of SOS score were 42.9%, 56.6%, 21.1%, and 78.5% respectively.

On statistical analysis, it was seen that SOFA scores of ≥ 13 and qSOFA score of ≥ 2 were significantly associated with ICU admission, Ventilator support requirement, and mortality among the study participants. However, a cut-off of 6 for the SOS score was not found to be statistically significantly associated with any of the three clinical outcomes of maternal sepsis.

DISCUSSION

Maternal sepsis is a serious condition that can lead to serious sequelae like admission to the intensive care units (ICU), ventilation support, and even death. While several scales and scores have been devised to grade maternal sepsis in a way that it adverse events can be predicted, debate is still ongoing regarding their effectiveness in accomplishing it. This study therefore aimed at comparing and contrasting the three most commonly used scales, the SOS scale, SOFA scale and the qSOFA scale in predicting adverse outcomes among women of maternal sepsis. Three individual high-risk events were considered and assessed as a part of this study, the incidence of ICU admission of the patients, incidence of ventilator support required, and the incidence of maternal mortality.

A total of 164 women diagnosed with maternal sepsis as per the modified SIRS criteria were assessed as a part of the study, they were scored with SOFA, SOS and qSOFA scores and their characteristics were analysed using appropriate statistical methods.

It was observed that more than half of the study participants were aged between 25 and 29 years of age, with the mean age of 25.6 ± 3.5 years. This is in contrast to studies such as those conducted by Agarwal et al. and Knowles et al. which reported that the most common age of mothers with maternal sepsis was >30 years. [9,10] The findings of the present study might be due to the fact that in India, the age of marriage and childbirth is commonly between 25 and 30 yrs. This, combined with several other factors such as high prevalence of malnutrition; lack of awareness regarding danger signs of pregnancy, and lack of access to quality healthcare predispose women to developing sepsis during their pregnancy at an earlier age. Most of the mothers assessed in the present study hailed from rural areas (76.8%) and belonged to the lower socioeconomic status families. This is due to the fact that the study institution largely caters to the rural and urban poor population of the geographical area, and their socioeconomic makeup is reflected in the study sample.[11]

When the pregnancy and maternal sepsis related characteristics of the study participants were evaluated, it was observed that 55.5% were postnatally admitted, and 6.7% were post-abortal mothers. It has been well-reported that a postnatal and post-abortal physiological status are important risk factors for the development of maternal sepsis, and a high prevalence of these physiological conditions among the participants support this assertion. [12,13] An important finding of the present study was the observed incidence of septic abortions (6.7%). [14] While the incidence of septic abortion was relatively high in the present study, it was lower than that reported in other parts of India.[15,16]

In the present study, three separate scales were applied to each mother at the time of their admission, and the scores were utilized to predict the outcome of maternal sepsis. These scales were the Sepsis in Obstetrics Score (SOS), Sequential Organ Failure Assessment scale (SOFA), and the quick-SOFA (qSOFA). Of them, the SOS scores were classified as <6 (low risk), and \geq 6 (high risk), while the other scales were taken as individual scores and a cut-off for the prediction of adverse maternal outcomes was ascertained for each of them. Comparison of the three scores in predicting different adverse maternal outcomes provided important insights. While there is widely reported evidence regarding a cut-off of the SOS score as 6, none such exist for the SOFA and the qSOFA

In the present study, it was observed that ICU admissions, ventilatory support requirement, and deaths in patients with SOS either \ge 6 or < 6 had similar distributions, and a cut-off of 6 was not found to be a statistically significant predictor of adverse clinical outcomes in the mothers. Furthermore, the calculated sensitivity, specificity, PPV and NPV were also not satisfactory in predicting any of the assessment parameters of the study. This is in stark contrast to the findings reported by Albright et al., who conducted a similar study among US women and found that an SOS score cut-off of >6 was associated with a sensitivity of 88.9% and specificity of 99.2% for critical care admission.[6] This observation might be due to the fact that Albright et al. conducted a retrospective analysis, which might have been affected by information bias. This observation might also be due to the geographical differences between populations of the US and India, an assertion which is lent credence by the findings of Agarwal et al., who also reported poor sensitivities of SOS scores in predicting ICU admissions and mortalities.[9]

In the present study, Receiver-Operating-Characteristics curve (ROC) analysis yielded a cut-off value of 13 for the SOFA score and 2 for the qSOFA score, with the highest sensitivity and specificity in the prediction of adverse clinical outcomes such as ICU admission, ventilation requirement, and death among mothers. This is similar to the cut-offs proposed by Agarwal et al. and Srivastav et al. in India and Arrvold et al. overseas.[9,18,19] As SOFA score takes all the organ functions into account it has a robust diagnostic power to predict maternal morbidity and mortality, and a high sensitivity and specificity of the scale observed in the present study supports this assertion.

Since SOFA score was observed to perform well in the present

study, as an extension of it, the qSOFA was also therefore expected to perform well in the prediction of adverse outcomes in maternal sepsis. This was found to be the case in the present study, as an ROC curve generated cut-off of 2 was found to have high sensitivity and specificity in the prediction of all assessment parameters. The cut-off of 2 for the qSOFA that was generated in the current study conformed to that proposed by authors such as Raith et al. and Koch et al. [20,21] The high sensitivity and specificity values offered by the qSOFA in identifying ICU admissions and mortality among mothers with suspected sepsis indicate that the qSOFA score can be an effective tool in the triage of maternal sepsis. As it is a simple tool and can be easily used at peripheral centres even by allied health personnel, qSOFA can be valuable in identifying high-risk maternal sepsis and refer patient to higher centre.

Among the three scoring systems, the SOFA score, at a cut-off of 13, was found to be the most accurate in the prediction of ICU admission requirement of the study participants (sensitivity 100%, specificity 94.4%), followed by the qSOFA at a cut-off of 2 (sensitivity 97.5%, specificity 74.4%), and SOS at a cut-off of 6 (sensitivity 45%, specificity 57%). Such a finding was expected for the SOFA score, as it takes into account a number of both clinical as well as laboratory parameters such as arterial blood gases, liver and kidney function, as well as platelet function in its measurement. However, it was seen that qSOFA score at a cut-off of 2 was also much better at the prediction of ICU admission than the SOS score, which points to its value as a bedside screening tool for ICU requirement in a maternal sepsis patient

In predicting the ventilator support requirement of the patients, it was seen that similar to the ICU requirement prediction, the SOS scale performed the most poorly among the three scales. However, it was seen that in this parameter, the qSOFA scale edged out over the SOFA in the prediction of ventilation support requirement (sensitivity 97.2%, specificity 96.1% versus sensitivity 100%, specificity 86%). qSOFA score of 2 or more as an excellent predictor of ventilator support requirement has also been reported in studies by Park et al. [22]

Finally, when the scores were compared with respect to their ability to predict maternal death, it was seen that the SOFA score had performed best (sensitivity 100%, specificity 86%), followed by qSOFA (sensitivity 97.1%, specificity 71.3%). These observations are in line with that reported by other studies on the topic such as those conducted by Raith et al. and Koch et al. In India, Agarwal et al. also concluded that SOFA is a better mortality predictor than SOS in case of maternal sepsis. [17, 20, 21]

CONCLUSIONS

The findings of the present study establish the diagnostic value of SOFA, qSOFA and SOS score in the prediction of inhospital mortality and of other adverse events in patient of maternal sepsis. The findings confirm that both the SOFA and the qSOFA scales can be utilized in the management protocols for maternal sepsis. As per the present study's observations and findings, cut-off values of 13 for the SOFA and 2 for the qSOFA scores are effective in the prediction of the prognosis and clinical outcomes of maternal sepsis among Indian women, and arguably better than the SOS score in this regard.

Parameter (Any two)	Criterion
Temperature	<360 or >380 C
Heart Rate	>110 bpm
Respiratory rate	>22 breaths/min
Total leukocytes	<4000/cc or >14000/cc
Immature neutrophils	>10%

Table 1. Modified SIRS criteria

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Table 2. Sociodemographic characteristics of the study participants (n=164)

Parameters		Frequency Percentage				
Age						
<19		4	2.4			
19-24		54	32.9			
25-29		84	51.2			
>29		22	13.4			
Residence						
Rural		126	76.8			
Urban		38	23.2			
Socioeconomic status						
Class I (below	7₹1211)	3	1.8			
Class II (₹121	1 - ₹ 2341)	20	12.2			
Class III (₹234	l2 - ₹3956)	40	24.4			
Class IV (₹395	57 - ₹7991)	57	34.8			
Class V (₹799	2 and above)	44	26.8			
Type of admis	sion					
Antenatal	Primigravida	47	28.7			
	Multigravida	15	9.1			
Postnatal	Parity 1	43	26.2			
	Parity > 1	48 29.3				
Post-abortal	11	6.7				

*Modified B.G. Prasad socioeconomic scale (AICPI Jan 2022)

Table 3. Sepsis related characteristics of the study participants (n=164)

Parameters	Frequency	Percentage				
SOS Score at admission						
<6	93	56.7				
≥6	71	43.3				
SOFA score at admission						
<13	111	67.7				
≥13	53	32.3				
qSOFA score at admission						
<2	93	56.7				
≥2	71	43.3				
ICU admission required						
Yes	40	24.4				
No	124	75.6				
Ventilator support required						
Yes	36	22				
No	128	78				
Death						
Yes	35	21.3				
No	129	78.7				

Table 4. Association between SOS, SOFA, and qSOFA scores with clinical outcomes of participants (n=164)

Clinical outcome		SOS		SOFA		qSOFA	
		<6	≥6	<13	≥13	<2	≥2
ICU	Yes	22	18	0	40	1	39
admissi		(23.7%)	(25.4%)	(0%)	(75.5%)	(1.1%)	(54.9%)
on	No	71	53	111	13	92	32
		(76.3%)	(74.6%)	(100%)	(24.5%)	(98.9%)	(45.1%)
p-value		0.802		< 0.001*		< 0.001*	
Ventilat	Yes	19	17	0	36	1	35
or		(20.4%)	(23.9%)	(0%)	(67.9%)	(1.1%)	(49.3%)
support	No	74	54	111	17	92	36
		(79.6%)	(76.1%)	(100%)	(32.1%)	(98.9%)	(50.7%)
p-value		0.590		< 0.001*		< 0.001*	
Death	Yes	20	15	0	35	1	34
		(21.5%)	(21.1%)	(0%)	(66.1%)	(1.1%)	(47.9%)
	No	73	56	111	18	92	37
		(78.5%)	(78.9%)	(100%)	(33.9%)	(98.9%)	(52.1%)
p-value		0.953		< 0.001*		< 0.001*	

*Statistically significant



A – ICU admission; B – Ventilator support requirement; C – Death

Figure 1. Receiver Operating Characteristic (ROC) curve showing sensitivity and specificity of SOFA score in predicting clinical outcomes of study participants (n=164)



A – ICU admission; B – Ventilator support requirement; C – Death

Figure 2. Receiver Operating Characteristic (ROC) curve showing sensitivity and specificity of qSOFA score in predicting clinical outcomes of study participants (n=164)

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