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STUDYING SEPSIS IN THE INTENSIVE CARE UNIT OF THE OBSTETRICS DEPARTMENT CONCERNING THE SCORING SYSTEM AND BIOMARKERS

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ABSTRACT

Background: Early initiation of treatment and early diagnosis of sepsis can help in preventing the progression of sepsis to septic shock and severe sepsis. Considering a continuous increase in the severity and rate of maternal sepsis globally and limited literature data showing the actual burden of maternal sepsis.

Aim: The purpose of this study was to evaluate the specificity and sensitivity of several biomarkers in patients diagnosed with sepsis and admitted to the obstetrics department's intensive care unit (ICU). The biomarkers were compared to clinical criteria in these patients.

Methods: Procalcitonin, serum lactate, and CRP were among the quantitative biomarkers for sepsis that were tested for 104 patients who were clinically evaluated using SOFA and q SOFA scores after being hospitalized to the obstetrics department's critical care unit. Additionally, research was done on the biomarkers' and clinical criteria's specificity and sensitivity.

Results: Serum lactate and procalcitonin were shown to have a high specificity and sensitivity among biomarkers of sepsis patients. In the current study, q SOFA scores demonstrated a low specificity of 57.58% and a high sensitivity of 78.7%; in contrast, total SOFA scores demonstrated a high specificity of 84.78%, indicating the role of total SOFA scores as confirmatory criteria and q SOFA as a screening-criteria in subjects with sepsis.

Conclusion: The current study suggests that serum lactate combined with procalcitonin is the most sensitive and specific predictor of prognosis in patients with maternal sepsis, while CRP is the least specific biomarker for maternal sepsis. Maternal sepsis can be detected early with the use of total SOFA and q SOFA scores.

Keywords: CRP, maternal sepsis, procalcitonin, serum lactate, SOFA scores

INTRODUCTION

Maternal sepsis is a major cause of death for mothers worldwide, even though it may be prevented. Maternal sepsis was the cause of almost half of maternal mortality in the days before antibiotics. One reason for maternal fatalities

after sepsis in poor and middle-income nations like India is the lack of access to quality prenatal care in these areas. According to the World Health Organization, puerperal and obstetric sepsis is regarded as the third leading cause of maternal fatalities in affluent nations. (1)

The highest rates of maternal death and morbidity are associated with maternal sepsis, hypertension, and bleeding. Maternal sepsis is responsible for around 11% of maternal mortality cases in industrialized nations and 5% of cases in developing countries. It also accounts for 27% of ICU admissions in the obstetrics department during the pregnancy phase, which results in a high maternal death rate of approximately 55% of females admitted to the ICU. Due to a lack of reliable research, it is uncertain how often sepsis is worldwide, especially in India. (2)

The 2017 international consensus defines septic shock as "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." Sepsis is defined as "a life-threatening organ dysfunction caused by a dysregulated host response to infection." (3) rapid SOFA, also known as q SOFA (rapid sequential organ failure assessment), is a commonly used bedside assessment procedure that is typically utilized for the evaluation of people who exhibit symptoms suggestive of sepsis. Low blood pressure (systolic blood pressure <100 mmHg), rapid respiratory rates (>22 breaths/min), and disturbed mental state (GCS ≤14) are given a score of 1 on the q SOFA.

These q SOFA items should notify the medical staff to perform a thorough assessment in order to determine whether the patient needs to be admitted to the intensive care unit (ICU), as well as to start or escalate therapy, enhance patient monitoring, or both, and to check for any organ dysfunction. (4) It is inappropriate to formulate medications targeting specific illnesses using outdated technology and procedures, as this may cause a delay in the identification of the infection. The existing diagnostic techniques are not appropriate for sepsis cases that have been sufficiently documented since they rely on outdated criteria.

A Any delay in diagnosing sepsis results in a delay in initiating therapy, which increases the risk of antibiotic overuse. Therefore, for better management of sepsis patients, sepsis-specific biomarkers for assessing host response in pathogen identification are required. Procalcitonin is said to be the most accurate sepsis-specific biomarker in the majority of instances, even in situations where traditional approaches proved to be unsatisfactory. (5) Sepsis should be identified promptly and appropriately, and treatment should begin as soon as possible to prevent the development of severe sepsis and septic shock.

Considering the rapid and constant increase in the severity and rate of maternal sepsis, this study aimed to assess the impact of maternal sepsis to determine the clinical outcomes along with the role of biomarkers and clinical criteria in judging the prognosis and outcomes of maternal sepsis.

MATERIALS AND METHODS

The present clinical study was designed to assess the specificity and sensitivity of different biomarkers in subjects diagnosed with sepsis and admitted to the ICU of the Obstetrics Department with the diagnosis of sepsis and compared biomarkers to clinical criteria in these subjects. The study population was selected from the Department of Obstetrics and Gynecology of the institute. Written and verbal informed consent were collected from all the participants before participation. 104 female patients who satisfied the diagnostic criteria for sepsis and were hospitalized to the obstetrics department's critical care unit during the designated research period were included in the study.

The study's inclusion criteria included subjects with organ dysfunction related to sepsis, subjects exhibiting any of the four Ts—tachycardia, elevated temperature, raised total counts, or tachypnea—as well as subjects admitted with other conditions who were later diagnosed with sepsis in the intensive care unit. Subjects who did not meet the study's inclusion requirements as stated and those who were unwilling to participate were the study's exclusion criteria. A comprehensive examination and history recording were finished after the final inclusion. The current investigation's inclusion of participants was based on the 2017 definition of sepsis provided by Gul F et al. (6). This classification is predicated on the presence of at least two SIRS criteria, a positive q SOFA score of seven, or a highly suspected or microbiologically confirmed infection. SIRS (systemic inflammatory response syndrome) is indicated by a body temperature of 36°C or higher, a heart rate of greater than 90 beats per minute, and a respiratory rate of greater than 20 breaths per minute.

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Following data collection, suitability and completeness were assessed, and replies that were deemed irrational or unsuitable were modified. The Microsoft Excel spreadsheet was updated using the collected data. Both qualitative and categorical data were quantitatively inputted and represented as frequencies and percentages. To evaluate the result variables for the variations in a frequency distribution, the Chi-square test was employed. Fisher's exact test was used to data when the frequency was less than five. The SPSS (Statistical Package for the Social Sciences) program, version 21.0 (IBM Corp., Armonk, NY, USA), was used to conduct each statistical test. At $p<0.05$, the statistical significance was maintained.

RESULTS

7169 females were admitted to the Institute's Department of Obstetrics and Gynecology over the study's period. Just 10.72% (n=769) of the 7169 female individuals were hospitalized to the intensive care unit (ICU), and 13.52% (n=104) of these women developed sepsis. Sepsis-related mortality was 36.53% (n=38) among the individuals. After evaluating the different cultures of the research participants, it was discovered that 38 subjects—36.84% of whom were non-survivors and 36.36% of whom were survivors—had sterile cultures. Of the non-survivor individuals, 26% (n = 2) had positive CSF cultures. 6.06% (n=4) of the survivors had an infected wound.

In 18.1% (n=12) of the survivor individuals and 5.26% (n=2) of the non-survivor subjects, the vaginal swab culture was positive. In 3.03% (n = 2) and 10.52% (n = 6) of the survivors and non-survivors, respectively, the tracheal aspirate tested positive. 9.09% (n = 6) of the survivors and 5.26% (n = 2) of the non-survivors had positive urine cultures. As seen in Table 1, blood cultures were positive in 15.1% (n = 10) of survivors and 5.26% (n = 12) of non-survivors, respectively. The viral markers were positive in 22 patients who were culture-negative. While E. coli and Klebsiella were the most often seen bacteria, TB bacilli, MRSA, staphylococcus, and streptococcus were the most frequently isolated microbes in culture-negative cases.

In terms of delivery location, 69.6% (n=46) of survivors and 73.6% (n=28) of non-survivors had their babies in hospitals. In 30.3% of the survivors (n = 20) and 26.3% of the non-survivor individuals (n = 10), home births took place. With p=0.74, the difference was statistically not significant. With p=0.01, the non-survivor research subjects' SOFA scores of 13–18 and 19–24 were considerably higher than those of the survivors. individuals with SIRS criterion of ≥2 exhibited noticeably greater death rates; this was the case for all 38 (100%) non-survivor individuals (p=0.02). In a similar vein, participants with q SOFA scores of ≥2 had much greater death rates (p=0.01): 42.4% of survivors and 78.94% of non-survivor subjects had these scores.

Serum lactate levels of 4 mmol/L or above were found to be substantially greater in 84.21% (n=32) of non-survivor individuals in Biomarkers than in 42.4% (n=28) of survivor subjects, indicating significantly increased death rates (p=0.01). CRP levels in sepsis patients who survived and those who did not (p=0.46) revealed no statistically significant difference. Table 2 shows a similar non-significant effect of procalcitonin (p=0.24) on the research patients' death rates.

Table 3 presents the findings of a multivariate and univariate logistic regression analysis of mortality and its predictors among research participants. Results for SOFA scores and serum lactate levels were noteworthy. With p=0.03, it was shown that patients with serum lactate levels of ≥2 mmol/L had a 9-fold increased risk of dying compared to those with serum lactate levels of <2 mmol/L. Individuals with higher SOFA and q SOFA scores (p=0.001 and 0.01 respectively) also showed an increased chance of dying. Subjects with PCT ≥2 compared to those with PCT <2 ng/ml had a greater likelihood of dying by 2.7 times, according to univariate and multivariate analysis. Regarding the occurrence of multiorgan dysfunction syndrome in study participants, the findings indicated that it was seen in 54.5% (n=36) of survivor patients and 100% (n=38) of non-survivor individuals. As shown in Table 4, the most prevalent organ dysfunction in the non-survivor group was respiratory, followed by cerebrovascular, and

cardiovascular, which affected 100% (n = 38), 89.47% (n = 34), and 84.21% (n = 32) of the study participants, respectively.

DISCUSSION

Severe sepsis is a potentially fatal illness that is more common in impoverished countries like India. It is typically observed as a result of immunological dysregulation brought on by bacterial, viral, or fungal infections. The key to providing the best care for patients with sepsis is early detection. Early diagnosis and immediate initiation of treatment. However, as advised by Gary T (8) in 2016 and Albright CM et al (9) in 2015, it is best to permit diagnosis of infection prior to the emergence of clinical symptoms and indicators before any organ damage is apparent. The current study comprised primipara young female participants. 26.92% (n=28) of the research subjects were illiterate, making up the bulk of the individuals. This was consistent with the 2020 study by Shamanewadi AN et al. (10) that found moms with lower levels of education are less knowledgeable about prenatal care. This finding is further corroborated by the fact that only 10.57% (n=11) of the individuals used healthcare facilities during their pregnancies.

According to a 2020 study by Foeller ME et al. (11), a significant risk factor for maternal sepsis was the unsupervised delivery that the majority of the participants experienced since they did not have access to medical services. Referral delays were observed in most research participants who had sepsis, indicating that primary care physicians are not as familiar with the warning signs and symptoms of sepsis and the rapid course of the illness. In order to forecast the mortality of sepsis individuals, the current study also examined the effectiveness of clinical scoring systems, such as the SIRS criteria, q SOFA scores, and total SOFA scores, in subjects admitted to the Department of Obstetrics' ICU.

Study participants who were not survivors had substantially higher SOFA scores (13–18 and 19–24) than survivors (p=0.01). individuals with SIRS criterion of ≥2 exhibited noticeably greater death rates; this was the case for all 38 (100%) non-survivor individuals (p=0.02). In a similar vein, participants with q SOFA scores of ≥2 had much greater death rates (p=0.01): 42.4% of survivors and 78.94% of non-survivor subjects had these scores. These outcomes were similar to those reported by authors in studies conducted by Agarwal M et al. (12) in 2022 and Guwlani P et al. (13) in 2023. Subjects with q SOFA scores of ≥2 had considerably greater death rates than survivors, while non-survivor study participants' SOFA scores of 13–18 and 19–24 were significantly higher than those of survivors.

Procalcitonin's effectiveness as a diagnostic tool for sepsis patients hospitalized to the obstetrics department's intensive care unit was also evaluated in this study, and a comparison with serum lactate and CRP was conducted. According to the study's findings, serum lactate levels of ≥4 mmol/L were substantially greater in 84.21% (n=32) of non-survivor patients than in 42.4% (n=28) of survivor subjects, who had significantly higher death rates (p=0.01). CRP levels in sepsis patients who survived and those who did not (p=0.46) revealed no statistically significant difference. Procalcitonin had a comparable non-significant effect (p=0.24) on the trial subjects' death rates.

These results were in line with those of Muller B et al. (14) in 2008 and Simon L et al. (15) in 2005, where the authors proposed that procalcitonin is the most accurate biomarker for diagnosis in sepsis subjects and that it can also be used to determine which subjects with low-risk acuity of infection should receive antibiotic therapy. Additionally, the authors suggested that serial PCT examination be performed in most situations as opposed to a single evaluation. An additional often employed biomarker in the evaluation of sepsis is CRP, an acute-phase protein generated by the liver following tissue injury and the commencement of inflammation.

The concentration of CRP steadily rises and peaks 36 hours after infection. According to Jeon JH et al. (16) in 2014, CRP values of ≥ 20 mg/dl often indicate a moderate degree of sepsis.Using CRP as a sepsis biomarker reveals a biospecificity. Due to its great sensitivity, CRP is mostly used in clinical settings for early sepsis onset detection. Tschaikowsky K et al. (17) reported in 2011 that CRP concentrations in plasma can be high for many days after the illness has abated. Thyroid C-cells and minor amounts of neuroendocrine cells contain procalcitonin, which is frequently employed in the evaluation of patients with sepsis. After a bacterial infection, parenchymal tissues begin to produce procalcitonin.

Procalcitonin can be detected 3–4 hours after infection, peaking in concentration at 6–12 hours and having a half-life of 24 hours. As a biomarker for sepsis diagnosis and illness progression, PCT is seen to be the most promising because to its high sensitivity, specificity, and kinetic profile. According to studies conducted in 2014 by Meisner M

et al. and in 2017 by Vijayan AL et al., PCT levels of > 2 ng/ml are suggestive of systemic bacteremia. Serum lactate levels of 4 mmol/L or above were found to be substantially greater in 84.21% (n=32) of non-survivor individuals in Biomarkers than in 42.4% (n=28) of survivor subjects, indicating significantly increased death rates (p=0.01).

In anaerobic metabolism, serum lactate levels are often elevated as a result of aerobic glycolysis, tissue hypoxia, and hypoperfusion. Serum lactate values of >2 mmol/L and ≥ 4 mmol/L, respectively, indicate severe tissue hypoxia and tissue hypoxia. During pregnancy, elevated blood lactate levels may cause sepsis and other harmful consequences for the mother. According to the current study's multivariate and univariate analysis, serum lactate is the biomarker that most accurately predicts death in individuals suffering from maternal sepsis.

These results were in line with the findings of Agarwal R et al (20) in 2018 and Albright CM et al (21) in 2016.

In this study, sepsis-ridden obstetric patients were evaluated using biomarkers and clinical grading systems in an Indian context. Procalcitonin and serum lactate are valid indicators in individuals with maternal sepsis, according to study data. These indicators, in conjunction with several clinical scoring systems like the q SOFA scores, assisted in the assessment of sepsis-afflicted patients in critically sick subjects. For a confirming diagnosis, SOFA scores should be evaluated in people with high q SOFA levels. A basic grading method that is used by bedside is called q SOFA. Antibiotics should be given promptly and microbiological identification should be completed in those with positive biomarkers and clinical characteristics.

CONCLUSION

One of the most common causes of maternal mortality in Indian subjects is maternal sepsis. SOFA scores and q SOFA scores are the most reliable clinical scoring systems in subjects with maternal sepsis. Also, procalcitonin is a reliable biomarker in subjects with maternal sepsis. The study also concludes that the most specific and sensitive predictor for prognosis in subjects with maternal sepsis is serum lactate along with procalcitonin, whereas, the least specific biomarker for maternal sepsis is CRP. Total SOFA and q SOFA scores can be used for early screening of maternal sepsis.

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TABLES

S. No	Positive culture	Survivors		Non-survivors		Total (n=104)
		n=66	%	n=38	%	
1.	**Sterile**	24	36.36	14	36.84	38
2.	**CSF**	0	0	2	5.26	2
3.	**Infected wound**	4	6.06	0	0	4
4.	**Vaginal swab**	12	18.1	2	5.26	14
5.	**Tracheal aspirate**	2	3.03	4	10.52	6
6.	**Urine**	6	9.09	2	5.26	8
7.	**Blood**	10	15.1	2	5.26	12

Table 1: Grouping of study subjects depending on the culture reports

S. No	Positive culture	Survivors		Non-survivors		Total (n=104)
		n=66	%	n=38	%	
1.	**Delivery place**					
a)	Hospital	46	69.6	28	73.6	0.74
b)	Home	20	30.3	10	26.3	
2.	**SOFA score**					
a)	1-6	20	30.3	4	10.52	**0.01**
b)	7-12	28	42.4	6	15.78	
c)	13-18	12	18.1	18	47.36	
d)	19-24	6	9.09	10	26.31	
3.	**SIRS criteria**					

a)	<2	14	21.1	0	0	**0.02**
b)	≥2	52	78.7	38	100	
4.	**q SOFA score**					
a)	<2	38	57.5	8	21.05	**0.01**
b)	≥2	28	42.4	30	78.94	
5.	**Serum lactate (mmol/L)**					
a)	<2	22	33.3	2	5.26	**0.01**
b)	2-3.99	16	24.2	4	10.52	
c)	≥4	28	42.4	32	84.21	
6.	**CRP (mg/dl)**					
a)	<20	18	27.2	14	36.84	0.46
b)	20-49.9	28	42.4	18	47.36	
c)	≥50	20	30.3	6	15.78	
7.	**Procalcitonin (ng/ml)**					
a)	<2	16	24.2	4	10.52	0.24
b)	≥2	50	75.7	34	89.47	

Table 2: Distribution of study subjects based on delivery place, severity score, and biomarkers

S. No	Variables	Multivariate Odds ratio	p-value	Univariate Odds ratio	p-value
1.	**Culture**				
a)	Positive			0.33 (0.02-2.86)	0.306
b)	Negative			Reference	
2.	**SIRS criteria**				
a)	<2			Reference	
b)	≥2			1	
3.	**q SOFA score**				
a)	<2	3.85 (0.86-17.14)	0.09	Reference	**0.01**
b)	≥2			5.07 (1.36-18.72)	
4.	**SOFA score**				
a)	<15	7.22 (1.72-30.83)	**0.006**	Reference	**0.001**
b)	≥15			9.4 (2.51-36.3)	
5.	**Serum lactate (mmol/L)**	3.87 (0.43-37.13)	0.21		
a)	<2	3.87 (0.43-37.13)	0.21	Reference	**0.03**
b)	≥2			9.2 (1.04-76.46)	
6.	**CRP (mg/dl)**				
a)	<20			Reference	0.31
b)	≥20			0.53 (0.14-1.85)	
7.	**PCT (ng/ml)**				
a)	<2			Reference	0.22
b)	≥2			2.74 (0.53-14.43)	

Table 3: Multivariate and univariate logistic regression analysis of death and its predictors in study subjects

S. No	Multiorgan dysfunction syndrome	Survivors		Non-survivors		p-value
		n	**%**	**n**	**%**	
1.	**Yes**	36	54.5	38	100	**<0.0001**
2.	**No**	30	45.5	0	0	

Table 4: Presence of multiorgan dysfunction syndrome in study subjects