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ORIGINAL ARTICLE

Comparison of Sequential Organ Failure Assessment (SOFA) and Sepsis in Obstetrics Score (SOS) in Women with Pregnancy-Associated Sepsis with Respect to Critical Care Admission and Mortality: A Prospective Observational Study

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Abstract

Objective We aimed to determine performance of sequential organ failure assessment (SOFA) and Sepsis in Obstetrics Score (SOS), in women with pregnancy-associated sepsis (PAS) with respect to critical care admission and mortality.

Methods Obstetric patients with PAS fulfilling any 2 of the quick SOFA (qSOFA) criteria were enrolled as cases. The various parameters of SOFA and SOS were recorded at admission and compared for outcomes.

Results Critical care was required in 32 (50.7%) patients and associated mortality was high (31.7%). For our study population, a threshold of SOFA ≥ 6 had the best combination of sensitivity (84.4%) and specificity (61.3%) for critical care admission. For SOS, a cut-off value of ≥ 6 gave best sensitivity (64%) and specificity (40%) for the same.

Conclusions SOFA was far more predictive of patient's critical condition as well as mortality compared to SOS. SOFA was superior to SOS in determining critical care admission and mortality for PAS.

Keywords SOFA · SOS · Obstetric sepsis · Pregnancy-associated sepsis

Introduction

Pregnancy-associated sepsis (PAS) is responsible for significant maternal morbidity and mortality world over. Even in high-income nations, pregnancy-associated sepsis complicates approximately 4–10 per 10,000 live births [1, 2]. In a report from UK, sepsis was responsible for nearly a quarter of maternal deaths, the chief reasons being delay in recognition or management [3].

Sepsis overall and specifically PAS have been on the priority list of researchers and policy makers. New definitions of sepsis and evaluation scales [(Third International Consensus Definitions for Sepsis and Septic Shock Task force, 2016), sequential organ failure assessment (SOFA), quick SOFA] [4, 5], new pregnancy-specific scores [the Sepsis in Obstetrics Score (SOS), Society of Obstetric Medicine Australia and New Zealand (SOMANZ) guidelines] [6–8] have been introduced in obstetric clinical practice. Furthermore, a recent shift in PAS management is to initiate targeted therapy to improve outcomes [2]. This has necessitated early diagnosis of PAS and enhanced monitoring of the affected mother.

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The Third International Consensus Definitions for Sepsis and Septic Shock Task force (2016) defined sepsis as "life threatening organ dysfunction caused by a dysregulated host response to infection" [4, 9]. Organ dysfunction is denoted by an increase in the SOFA score by 2 or more points [5]. The detailed SOFA dates into account the parameters of respiratory system (peripheral arterial oxygen pressure and saturation), coagulation (platelet count), hepatobiliary system (bilirubin level), cardiovascular (mean arterial pressure), central nervous system (Glasgow Coma score) and renal system (creatinine or urine output) [5]. To evaluate a suspected case of sepsis, a bedside clinical scale known as quick SOFA is available [4]. It is based on three criteria, one point each assigned for decreased blood pressure (systolic blood pressure (SBP) $\leq$ 100 mmHg), increased respiratory rate (RR) ($\geq$ 22 breaths per min) or abnormal mentation (Glasgow Coma Scale < 15). The presence of 2 or more criteria is considered a strong indicator of sepsis [4].

Multiple investigators have reported pregnancy-specific sepsis scales as well [6, 7]. Albright et al. (2014) focused on pregnant and post-partum women and developed an obstetric sepsis scoring system, the Sepsis in Obstetrics Score (SOS), to describe their risk of critical care admission [6, 7]. The score took into account parameters which are physiologically altered in pregnancy [SBP, heart rate (HR) and total leucocyte count (TLC)], combined them with those of Acute Physiology and Chronic Health Evaluation (APACHE) II and Rapid Emergency Medicine Score (REMS), i.e. temperature, HR, RR, oxygen saturation and TLC and the Systemic Inflammatory Response Syndrome (SIRS) criteria (SBP, TLC, percentage of immature neutrophils in blood and lactic acid levels) for PAS. A SOS $\geq$ 6 carried risk of positive blood cultures, increased critical care admissions and fetal tachycardia [6].

The main challenge with these recent scales is the determination of their precise thresholds which could potentially indicate the risk, their diagnostic accuracy (specificity and sensitivity) and lastly and, validation with a larger population and in different clinical settings [10]. These aspects hold key to their usage in low-income countries where sepsis stands as a foremost cause of maternal morbidity and mortality. These countries have limited resources, and priority allocation of critical care facilities is needed. Furthermore, the patient prognostication is a major issue at the time of admission. We therefore planned the current prospective study to determine the performance (threshold values, specificity and sensitivity) of two diagnostic scales—SOFA and SOS, in obstetric patients with PAS with respect to critical care admission and mortality. Both are organ dysfunction-related scores. We aimed to find out how a general sepsis warning scale (SOFA) compared with a pregnancy-specific scale (SOS).

Methods

The prospective study (November 2017–October 2018) was carried out at a tertiary care obstetric health facility located in suburb of a low-income country. Informed written consent from the patients and Institutional Ethical Committee Clearance was obtained for the study. This study was a part of a larger research involving serial diagnostic scores (SOFA and SOS), biochemical (lactic acid) and laboratory parameters, organ failures and mortality in obstetric patients admitted with a diagnosis of PAS.

Inclusion Criteria

Pregnant, post-abortal (up to 2 weeks) and post-partum ($\leq$ 6 weeks) obstetric patients in the age group 20–35 years with clinical sepsis fulfilling qSOFA criteria were enrolled as cases.

Exclusion Criteria

We excluded subjects with previously known history or diagnosed pathology of pulmonary, cardiac, renal, hepatobiliary and nervous system.

Sample Size Calculation

We could not trace similar studies comparing SOFA and SOS for critical care admission in obstetric sepsis in a thorough search of indexed medical literature. The sepsis rate at our institution is approximately 3.23 per 1000 deliveries and 3.27 per 1000 live births. There were 19,459 deliveries (including live, stillbirths and abortions) and 19,216 live births for the said study period of 12 months. There were 70 patients with suspected PAS. Sixty-three PAS patients who fulfilled our inclusion criteria were enrolled for the study. Out of these, 32 patients (50.7%) required admission to critical care units (Group A). The basis for critical care admission was requirement of life support (invasive ventilation, continuous renal replacement therapy, invasive hemodynamic support) for organ failure, intensive monitoring and appropriate therapy (Priority 1 Nates et al. criteria) [11]. The remaining 31 (49.2%) patients formed Group B. Twenty (31.7%) out of 63 patients expired. All maternal deaths occurred in Group A.

Methodology

For all enrolled patients, a detailed general and obstetric examination was performed. Relevant laboratory and imaging tests were also undertaken. A blood sample, a high

vaginal swab and any purulent discharge (if present) were sent for microbial culture and sensitivity. Specimen culture positivity was based on single organism growth from any of the above samples. Haematological investigations were collected at the time of admission. SOFA and SOS were applied prospectively to enrolled patients. For organ failure assessment, key body systems assessed and monitored were: pulmonary, cardiac, renal, hepatobiliary and nervous system. The important criteria representing organ failure used were: altered mental status; arterial hypoxemia ($PaO_2/FiO_2 < 300$); acute oliguria (urine output < 0.5 mL/kg/h for at least 2 h); creatinine increase more than 0.5 mg/dL; coagulation abnormalities (INR > 1.5 or aPTT > 60 s); thrombocytopenia (platelet count $< 100 \times 10^3/mm^3$); hyperbilirubinaemia (plasma total bilirubin > 4 mg/dL) [12]. Further management of the patients was done as per hospital protocol and their medical condition.

Statistical Analysis

Patient characteristics were recorded in excel sheet and compared using SPSS software. The AUC and diagnostic thresholds for SOFA and SOS were obtained using ROC plots. Statistical relationships between various clinical and laboratory parameters between groups were calculated using parametric *t* tests and Chi-square test. A *p* value of < 0.05 was taken significant.

Results

The mean patient age was 26.1 ± 5.0 years. Out of 63 patients with PAS, 35 (55.5%) were post-partum, 21(33.3%) antenatal and 7(11.1%) postabortal. The mean patient age was 26.1 ± 5.0 years. Multigravida constituted 74.6% of PAS cases. Forty one (64%) subjects had unsupervised pregnancy. History of dai handling as a risk factor for sepsis was elicited in 18 post-partum subjects. Anaemia was noted in 54 (85.7%) subjects, and 25 (39.6%) subjects came with diagnosis of intrauterine death. Vaginal delivery was in 42 subjects out of whom 12 were home deliveries. Rest were caesarean sections. Overall, 33 (52.4%) patients had positive cultures of which 18 were positive blood culture. Although not statistically significant, there were more positive blood and urine cultures in Group A compared to Group B patients. Organ failures were far more common in Group A with renal and pulmonary systems predominating (Table 1). There were 16 multiorgan failures in Group A compared to just 3 in Group B. Table 2 depicts the overall clinical and laboratory parameters in the various groups. The pH and urea values were more disturbed in Group A patients ($p < 0.05$) corresponding to organ failures mentioned above. Compared to overall SOS, SOFA was significantly altered in critical care and mortality groups.

Table 1 Organ failures in Group A and B

Organ involvement	Group A	Group B	*p-value
Hepatobiliary	10	08	0.197
Renal	16	08	0.03
Pulmonary	26	09	0.00
Nervous	01	00	0.508
Number of organ failures	0	00	07
	1	16	21
	2#	11	3
	3#	05	00

#Multiorgan failure ≥ 2 organ failure; *Chi-square test, *p* value < 0.05 significant

For our study population, a cut-off of SOFA ≥ 6 had the best combination of sensitivity (84.4%) and specificity (61.3%) for critical care admission on ROC analysis (AUC = 0.841; *p* value < 0.001). SOFA threshold for maternal mortality was also ≥ 6 with sensitivity and specificity at 95% and 63.4%, respectively (AUC = 0.872; *p* value < 0.001) (Table 3).

A SOS cut-off of ≥ 6 gave a sensitivity (64%) and specificity (40%) for critical care admission on ROC analysis (AUC = 0.589; *p* value = 0.224). SOS threshold for maternal mortality was also ≥ 6 with sensitivity and specificity at 65% and 63%, respectively (AUC = 0.599; *p* value = 0.207) (Table 3).

Forty-four patients out of 63 (69.8%) had SOFA ≥ 6; 28 (63.6%) of these were admitted to critical care units. SOFA (≥ 6) was statistically different in Group A from B as well as predicted mortality (Table 4). Forty-three out of 63 (68.2%) PAS patients had SOS ≥ 6. Twenty-two patients (51.2%) were admitted to critical care units. However, there was no statistical difference between Group A and B based on this SOS threshold.

Discussion

The obstetric patients in low-income countries still face troublesome burden of PAS, and priority allocation of resources remains a challenging task. The requirement for critical care in a large number of PAS patients (50.7%) and high associated mortality (31.7%) indicated the severity of sepsis and morbid condition of women prior to admission in our study. Our study tested two diagnostic scales—SOFA and SOS—in a suburb tertiary care centre for PAS with reference to critical care admission and mortality. The majority of our patients were post-partum (55.5%), positive cultures in clinically diagnosed PAS patients were moderate (52.4%), and

Table 2 Comparison of clinical and laboratory parameters between various groups

Characteristics Mean (Range)	Total (n = 63)	Group A (n = 32)	Group B (n = 31)	*p* value*	Mortality (n = 20)	Survivor (n = 43)	*p* value*
Systolic BP (mmHg)	90.4 (60–190)	90.7	90.3	0.93	90.1	90.7	0.9
Diastolic BP (mmHg)	55.6 (30–110)	55.3	55.9	0.889	55.2	55.8	0.89
Pulse rate (/min)	115.4 (68–160)	116.8	114.0	0.5	117.4	114.5	0.524
Respiratory rate (/min)	30.6 (14–46)	31.6	29.6	0.22	33.1	29.5	0.03
Haemoglobin (gm/dL)	8.0 (3.4–12.5)	7.8	8.3	0.36	7.8	8.1	0.673
Total leukocyte count (10^3/mm^3)	19.6 (2.6–47)	19.8	19.4	0.863	18.5	20.1	0.499
Platelet count (10^3/mm^3)	140 (0–520)	140	140	0.898	110	140	0.346
Total bilirubin (mg/dL)	4.2 (0.2–28.2)	5.3	3.1	0.137	5.3	3.7	0.336
Urea (mg/dL)	57.0 (10–168)	70.1	43.5	0.005	74	49	0.014
Serum creatinine (mg/dL)	1.9 (0.4–7.5)	2.2	1.6	0.125	2.3	1.6	0.1
pH	7.3 (7–7.5)	7.2	7.3	< 0.001	7.2	7.3	< 0.001
PaO_2 (mmHg)	85.5 (30–186)	83.2	107.3	0.06	77.7	103.2	0.064
$PaCO_2$ (mmHg)	32.4 (10.3–60.4)	35.0	29.8	0.076	37.6	30.1	0.014
Total SOFA	8.1 (0–20)	10.7	5.3	< 0.001	12.1	6.2	< 0.001
Total SOS	7.7 (2–22)	8.3	7.0	0.15	8.9	7.2	0.09

*Paired *t* test, *p* value < 0.05 significant

Table 3 Comparison of mortality in SOFA versus SOS subgroups

SCORE	Total number of cases n = 63 (%)*	Mortality n = 20 (%)*
A. SOFA score		
0–6	24 (38.1)	1 (5)
7–9	18 (28.6)	5 (25)
10–12	11 (17.5)	5 (25)
13–14	4 (6.3)	4 (20)
15–24	6 (9.5)	5 (25)
B. SOS score		
< 6	20 (31.7)	6 (30)
≥ 6	43 (68.3)	14 (70)

*Figures in brackets represent percentages

the major reason for life support was renal or pulmonary failure. For our study population, a threshold of SOFA ≥ 6 had the best combination of sensitivity (84.4%) and specificity (61.3%) for critical care admission. For SOS, a cut-off value of ≥ 6 gave best sensitivity (64%) and specificity (40%) for the same. SOFA was far more predictive of patient's critical condition as well as mortality compared to SOS.

Studies on SOFA and SOS in PAS (Table 5) show that different clinical setup, patients' condition, diagnostic threshold and outcome make comparison difficult [6, 7, 13–17]. SOFA was developed primarily from non-obstetric patients in a critical care setting to predict mortality. A meta-analysis showed SOFA to possess high discrimination ability with respect to maternal mortality even when its use was extended to the obstetric population with a pooled AUC of 0.92 (95% CI 0.81–0.95) [16]. On the other hand, SOS is a newly developed obstetric scale with few supporting studies [6, 7, 15]. It was developed for use in an emergency department to predict critical care need for women with obstetric sepsis. The score made adjustments for known physiological changes in pregnancy. In the original study of 850 women, SOS ≥ 6 represented a sensitivity 88.9% and specificity 99.2% for critical care admission with an area under the

Table 4 Diagnostic accuracy of SOFA and SOS for critical care admission and maternal mortality in PAS patients

At admission	Critical care admission			Maternal mortality		
	Sensitivity	Specificity	*p* value*	Sensitivity	Specificity	*p* value*
SOFA ≥ 6	84.4%	61.3%	< 0.001	95%	63.4%	< 0.001
SOS ≥ 6	64%	40%	0.224	65%	63%	0.207

*Chi-square test, *p* value < 0.05

Table 5 Studies on SOFA and SOS with outcome as critical care admission/ mortality in obstetric population with PAS

Author/s	Study type	Study population	Region	Diagnostic scale	Outcome	Threshold	Sensitivity (%)	Specificity (%)	AUC
Oliveira-Neto et al. [13]	Retrospective	673	Brazil	SOFA	ICU mortality	SOFA ≥ 6	88.9	91.1	0.958 (95% CI 0.914–1.0)
Kallur et al. [cited by 16]	Retrospective	69	India	SOFA	ICU Mortality	SOFA ≥ 10–12	60	96.88–98.44	0.77 (95% CI 0.46–1.00)
Albright et al. [6]	Retrospective	850	Rhode Island	SOS	Critical care admission	SOS ≥ 6	88.9	99.2	0.92
Vasquez et al. [17]	Prospective	362	Argentina	APACHEII, SOFA	Hospital mortality	SOFA ≥ 6.5	69	93	0.892 (95% CI 0.831–0.953)
Jain et al. [14]	Prospective	90	India	SOFA	ICU mortality	SOFA ≥ 8.5	86.7	90	0.949
Albright et al. [7]	Retrospective	425	Rhode Island	SOS	Critical care admission	SOS ≥ 6	64	88	0.85 (95% CI 0.76–0.95)
Aarvold et al.* [15]	Retrospective	146	Mixed population	SOFA, SOS*, APACHE II, SAPSII, MODS	ICU mortality	–	–	–	SOFA 0.79 SOS 0.67
Current study	Prospective	63	India	SOFA, SOS	Critical care admission	SOFA ≥ 6 SOS ≥ 6	84.4 64	61.3 40	0.841 0.589
					Mortality	SOFA ≥ 6 SOS ≥ 6	95 65	63.4 63	0.872 0.599

*Modified SOS which excluded immature neutrophil counts

curve of 0.92 [6]. There were just 9 critical care admissions (1.1%) and no mortality in this series. Besides a retrospective study design, a high percentage of missing parameters (23%) was an obvious limitation. In a follow-up validation study of SOS in 425 women, the same researchers found 14 (3.3%) critical care admissions and no maternal deaths [7]. SOS predictive value for critical care admission at threshold of ≥ 6 was sensitivity 64% and specificity of 84% (AUC 0.85; 95%CI 0.76–0.95) [7].

Aarvold et al. in a retrospective study conducted in various critical care units, evaluated 5 different scales [SOS, APACHEII, SAPSII, SOFA and Multiple Organ Dysfunction Scores (MODS)] for mortality -related outcomes in 146 women with sepsis [15]. An age-matched non-obstetric cohort (n = 299) was kept as control. Twenty-eight (19.18%) women died in this series. In the obstetric cohort, the area under the receiver-operator curves for prediction of mortality by SOS, APACHE II, SAPS II, SOFA and MODS scores was **0.67**, 0.68, 0.72, **0.79** and 0.84, respectively. In the non-obstetric cohort, the respective values were **0.64**, 0.72, 0.61, **0.78** and 0.74. SOFA performed better than SOS in predicting mortality both in obstetric and non-obstetric populations.

For our cohort too, the general diagnostic scale SOFA fared better than pregnancy-specific SOS in predicting critical care admission and mortality.

The careful use of diagnostic scales may help identify the women at risk and promote increased monitoring or preventive measures. Our study inferred that SOFA score had robust diagnostic powers to predict critical care admission and mortality for PAS patients in a premorbid, high mortality situation like ours. Thus, one could utilize a common scale in the emergency setting for allocating critical care

beds or triaging obstetric as well as non-obstetric sepsis patients. A further substantiation of SOS utility and its validation in a similar high volume obstetric health care facility is suggested.

Our study reported a high mortality rate in PAS despite use of life support services. This throws light on the peculiar socioeconomic and social conditions prevailing in low-income countries. It exposes the gap between the disease profile and health care support available. This seriously endeavours to check the application and validity of various diagnostic scales across diverse clinical settings, different patient characteristics and clinical practices. Diagnostic scales, especially those that obstetric based, need better parameters to sharpen their discriminative ability.

This is probably the first comparison of SOFA versus SOS in obstetric population with severe morbidity (and associated mortality) characteristics for predicting both critical care requirement and mortality. We used a stout study design of applying two different diagnostic scales on the same population, that too prospectively. Patient characteristics, physiological and laboratory data for all enrolled patients were available permitting accurate assessment of the scales. Our research was carried out in a referral tertiary obstetric centre. The results of our study might not find application for other setups and patient groups. We did not perform an exclusive analysis of predictive value of each variable independently or within the diagnostic scales but rather focused on aggregated scores.

Conclusions

SOFA was superior to SOS to decide critical care admission and predict mortality in pregnancy-associated sepsis when tested in a severe morbidity and high mortality clinical setting.

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Compliance with Ethical Standards

Conflict of interest The authors declare that they have no conflict of interest.

Consent for Publication The work submitted has not been published before; that it is not under consideration for publication anywhere else; that its publication has been approved by all co-authors, if any, as well as by the responsible authorities and at the institute where the work has been carried out.

Ethical Approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

Ethical Clearance Institutional Ethical committee, University College of Medical Sciences, Delhi-110031 dated 17 October 2017.

Informed Consent Informed consent was obtained from all individual participants included in the study.

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