Validating the performance of 3 sepsis screening tools in patients with clinical chorioamnionitis

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BACKGROUND: Maternal sepsis is a leading cause of maternal death in the United States. Approximately two-thirds of maternal deaths because of sepsis are related to delayed recognition or treatment. New early warning systems using a 2-step approach have been developed for the early recognition of sepsis in obstetrics; however, their performance has not been validated.

OBJECTIVE: This study aimed to assess the performance of 3 primary screening tools introduced by the Society of Obstetric Medicine Australia and New Zealand and the California Maternal Quality Care Collaborative for use in the first step of their 2-step early warning systems. The obstetrically modified quick Sequential (sepsis-related) Organ Failure Assessment score tool, the obstetrically modified Systemic Inflammatory Response Syndrome tool, and the obstetrically modified Systemic Inflammatory Response Syndrome 1 tool were evaluated for the early detection of sepsis in patients with clinically diagnosed chorioamnionitis.

STUDY DESIGN: This was a retrospective cohort study using prospectively collected clinical data at a tertiary care center and an affiliated healthcare system. The electronic health records were searched to identify and verify cases with clinically diagnosed chorioamnionitis between November 2017 and September 2022. The flow sheet for every patient was reviewed to determine when criteria were met for any of the 3 tools. The performance of these tools was analyzed using their sensitivity, specificity, positive and negative predictive values, and receiver operating characteristic curve for the identification of sepsis.

RESULTS: There were 545 cases that had the requisite data for inclusion in the analysis. Of note, 11 patients met the criteria for sepsis. Both the obstetrically modified Systemic Inflammatory Response Syndrome and obstetrically modified Systemic Inflammatory Response Syndrome 1 tools had overall similar test characteristics, which were notably different from the obstetrically modified quick Sequential Organ Failure Assessment tool. The screen-positive rate of the obstetrically modified quick Sequential Organ Failure Assessment tool (1.5%; 95% confidence interval, 0.6%−2.9%) was lower than that of the obstetrically modified Systemic Inflammatory Response Syndrome tool (60.0%; 95% confidence interval, 55.7%−64.1%) and the obstetrically modified Systemic Inflammatory Response Syndrome 1 tool (50.0%; 95% confidence interval, 45.8%−54.3%). The sensitivities of the obstetrically modified Systemic Inflammatory Response Syndrome tool (100.0%; 95% confidence interval, 71.5%−100.0%) and the obstetrically modified Systemic Inflammatory Response Syndrome 1 tool (100.0%; 95% confidence interval, 71.5%−100.0%) were higher than that of the obstetrically modified quick Sequential Organ Failure Assessment tool (18.0%; 95% confidence interval, 2.3%−51.8%). All 3 tools had high negative predictive values; however, their positive predictive values were poor.

CONCLUSION: This study demonstrated that all 3 tools had limitations in screening for sepsis among patients with a clinical diagnosis of chorioamnionitis. The obstetrically modified quick Sequential Organ Failure Assessment tool missed more than half of the sepsis cases and, thus, had poor performance as a primary screening tool for sepsis. Both the obstetrically modified Systemic Inflammatory Response Syndrome and obstetrically modified Systemic Inflammatory Response Syndrome 1 tools captured all sepsis cases; however, they tended to overdetect sepsis.

Key words: 2-step approach, chorioamnionitis, early warning systems, intra-amniotic infection

Introduction

Maternal sepsis, defined as sepsis with onset during pregnancy or after delivery, is the second leading cause of maternal death in the United States.[1,2] A recent US data report revealed that maternal sepsis complicates 4 to 10 per 10,000 live births. Independent reviewers found that approximately

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Why was this study conducted?

This study aimed to assess the performance of 3 primary screening tools (obstetrically modified quick Sequential Organ Failure Assessment [omqSOFA], obstetrically modified Systemic Inflammatory Response Syndrome [omSIRS], and obstetrically modified Systemic Inflammatory Response Syndrome 1 [omSIRS1]) used in the first step of the 2-step early warning system for sepsis in obstetrics.

Key findings

In this study cohort of patients with chorioamnionitis, the omqSOFA tool had low sensitivity and missed more than half of the sepsis cases. Both the omSIRS and omSIRS1 tools captured all sepsis cases with apparent high sensitivity but with a screen-positive rate of >50%.

What does this add to what is known?

All 3 tools have not been previously validated. Among patients with chorioamnionitis, the omqSOFA tool had poor performance as a primary screening tool for sepsis. Both the omSIRS and omSIRS1 tools had high sensitivity but tended to overdetect sepsis.

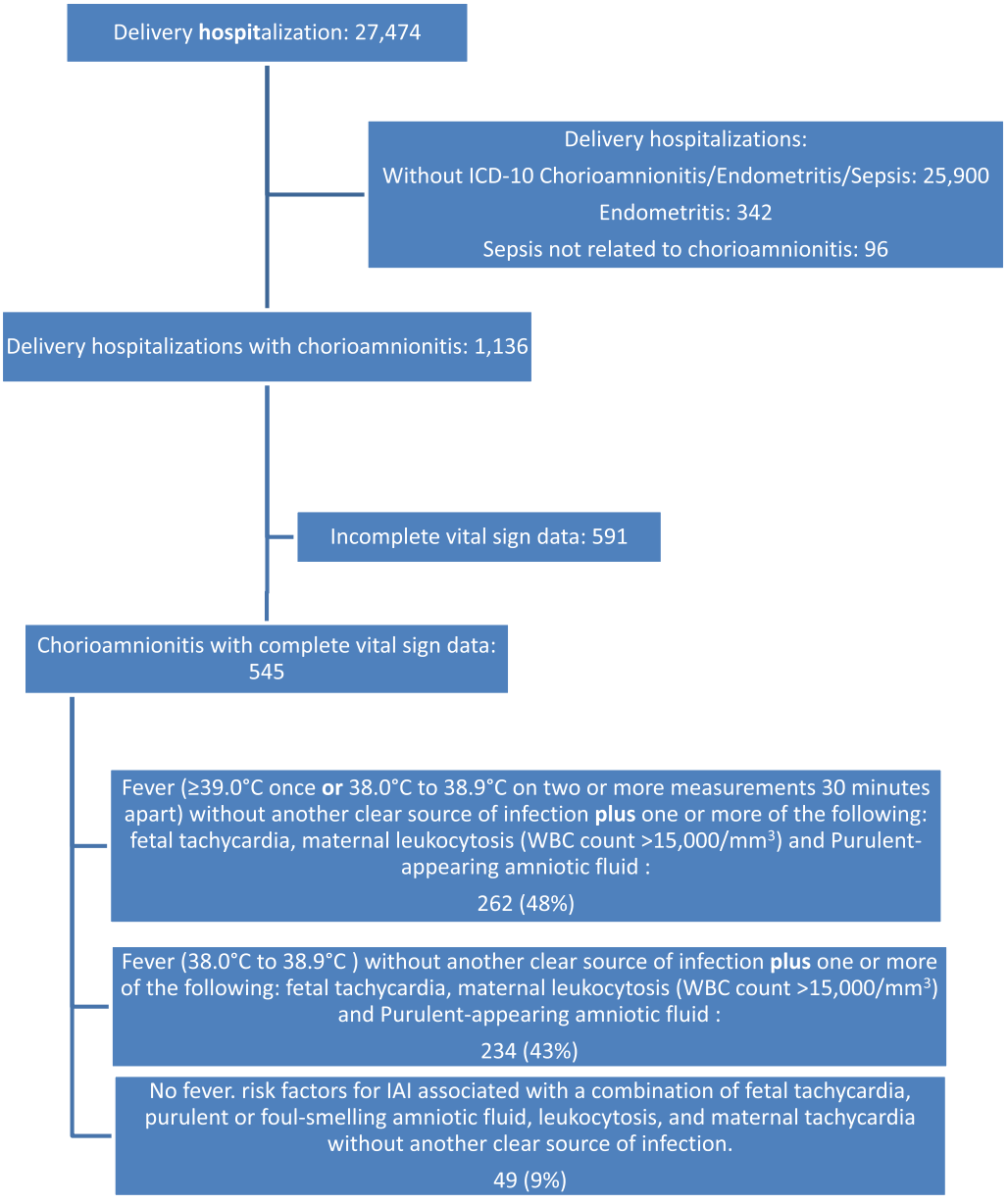
two-thirds of maternal sepsis deaths were preventable and most often related to a delay in recognition or management.[3,4] Thus, prompt recognition and rapid treatment of sepsis are cornerstones in the effort to reduce its effect on maternal morbidity and mortality. Studies on the early warning systems used for nonpregnant adults and those modified for use in pregnancy found that those systems perform poorly in screening for sepsis in the obstetrical population. Those studies suggested that a better early warning system would incorporate a 2-step approach, using a high-sensitivity screening tool that can trigger confirmatory secondary testing.[5–7] Subsequently, the Society of Obstetric Medicine Australia and New Zealand (SOMANZ) and the California Maternal Quality Care Collaborative (CMQCC)[8,9] each introduced their 2-step approach for screening and diagnosis of sepsis in obstetrics. The screening tools introduced had a fundamentally different design. The CMQCC tool measures the immune response, whereas the SOMANZ tool measures organ dysfunction. With chorioamnionitis being one of the most common causes of sepsis during delivery admissions,[10–12] this study aimed to assess the performance characteristics of those novel tools in the early detection of sepsis among patients diagnosed with chorioamnionitis.

Materials and Methods

This was a retrospective cohort study using clinical data at a tertiary care center and an affiliated healthcare system. The study application was reviewed by the Mayo Clinic Institutional Review Board (IRB) and determined to be exempt from the requirement for IRB approval. The study was conducted on patients with a clinical diagnosis of chorioamnionitis during their delivery admission between November 2017 and September 2022 at a tertiary care hospital and a network of community hospitals covering more than 40 communities in 4 regions of the Midwest. The study period was determined by the accessibility of obstetrical records. Thus, the starting point for our timeframe was the year obstetrical records were available for review in electronic format. The electronic health record (EHR) was searched for obstetrical delivery encounters using the International Classification of Diseases, Tenth Revision, codes for endometritis, chorioamnionitis, or sepsis. The records of all patients from this search were reviewed in detail to verify the diagnosis of chorioamnionitis and the completeness of vital sign data. Patients were only included in this analysis if they had a clinical diagnosis of chorioamnionitis documented by the obstetrical provider in the medical record and had one or more of the following: fever (≥38.0° C), fetal tachycardia, maternal leukocytosis (white blood cell [WBC] count of >15,000/mm^3), or purulent-appearing amniotic fluid, in the absence of another clear source of infection. Patients who met the inclusion criteria but had incomplete vital sign records were excluded from the analysis. In the final study cohort, 48% of patients met the diagnostic criteria for intra-amniotic infection (IAI) as suggested by a National Institute of Child Health and Human Development Workshop expert panel and endorsed by the American College of Obstetricians and Gynecologists. Those criteria are based on the presence of fever either ≥39.0°C once or 38.0°C to 38.9°C on ≥2 measurements 30 minutes apart without another clear source of infection plus one or more of the following: fetal tachycardia, maternal leukocytosis (WBC count of >15,000/mm^3), and purulent-appearing amniotic fluid.[13] Approximately 43% of patients did not meet the diagnostic criteria for IAI, because of the lack of a second documented fever 30 minutes after the first. In 9% of patients, there was no fever documented. Those patients without a documented fever were diagnosed with chorioamnionitis based on the presence of risk factors for IAI associated with a combination of fetal tachycardia, purulent or foul-smelling amniotic fluid, leukocytosis, and maternal tachycardia (Figure 1).

The criteria for the obstetrically modified Systemic Inflammatory Response Syndrome (omSIRS) tools were obtained from the CMQCC 2020 toolkit for improving the diagnosis and treatment of maternal sepsis.[9] We labeled the omSIRS primary screening tool endorsed by the CMQCC as omSIRS and the one described without the laboratory component as omSIRS1. The obstetrically modified quick Sequential (sepsis-related) Organ Failure Assessment score (omqSOFA) criteria were obtained from the SOMANZ guidelines for the investigation and management of sepsis in pregnancy.[8] The components and scoring for

FIGURE 1
Flow diagram of the case recruitment



IAI, intra-amniotic infection; *ICD-10*, International Classification of Diseases, Tenth Revision; *WBC*, white blood cell.

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each of the primary screening tools are outlined in Table 1. The diagnosis of sepsis was made when patients met the criteria for end-organ injury. The criteria we used for end-organ injury were developed by the CMQCC and published in their 2020 toolkit for improving the diagnosis and treatment of maternal sepsis (Table 2).

Maternal demographic information and obstetrical data, including age, race, gravidity, parity, gestational age at presentation, body mass index (BMI) at time of delivery, and route of delivery, were abstracted by review of EHR. In addition, we recorded information on the presence of medical comorbidities, including hypertension (preeclampsia, gestational hypertension, and preexisting hypertension), chronic infection (hepatitis B, hepatitis C, and latent tuberculosis), pregestational diabetes mellitus, gestational diabetes mellitus, asthma, and substance use disorder (Table 3). The infection section under comorbidities includes patients with uncomplicated chronic hepatitis B, chronic hepatitis C, and latent tuberculosis. Each set of vital sign and laboratory data for every patient was sequentially reviewed from the time of admission to discharge to determine whether the criteria were met for any of

TABLE 1
Primary sepsis screening tools

Variable
omqSOFA[7] Positive if ≥2 criteria are met: • Systolic blood pressure of ≤90 mm Hg • Respiratory rate of ≥25 cpm • Altered mentation (any state other than "alert" on maternal observation charts)
omSIRS[8] Positive if ≥2 criteria are met: • Oral temperature of <36°C (96.8°F) or ≥38°C (100.4°F) • Heart rate of >110 bpm and sustained for 15 min • Respiratory rate of >24 cpm and sustained for 15 min • White blood cell count of >15,000/mm^3 or <4000/mm^3 or >10% of immature neutrophils (bands)
omSIRS1[8] Positive if ≥2 criteria are met: • Oral temperature of <36°C (96.8°F) or ≥38°C (100.4°F) • Heart rate of >110 bpm and sustained for 15 min • Respiratory rate of > 24 cpm and sustained for 15 min

Adapted with permission from Bowyer et al[9] and Gibbs et al.[9]

omqSOFA, obstetrically modified quick Sequential Organ Failure Assessment; *omSIRS*, obstetrically modified Systemic Inflammatory Response Syndrome; *omSIRS1*, obstetrically modified Systemic Inflammatory Response Syndrome 1.

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the 3 tools. Given the transient changes in vital signs associated with regional anesthesia, we excluded vital signs recorded within 30 to 60 minutes of such procedures. The mental status evaluation was based on the Richmond Agitation Sedation Scale (RASS), which is routinely documented on all patients every 4 hours throughout their hospital stay and every hour on patients while on regional anesthesia. Any score other than zero prompted a review of the clinical documentation to determine whether the patient had a pathologic altered mental status. Data on the percentage of immature neutrophils were not available for most patients. Thus, for this laboratory component, we only looked at the WBC count. As per CMQCC guidelines, WBC counts obtained within 24 hours of vital sign data that met the threshold were used in the screening tools.

This study aimed to assess the performance of the screening tools for the early detection of sepsis among patients with chorioamnionitis. We calculated the percentage of patients who the met criteria for each one of the tools, with 95% confidence intervals (CIs). The performance characteristics for each tool, including sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) in the prediction of sepsis, were determined. The receiver operating characteristic (ROC) curve and the area under the ROC (AUROC) were calculated as a summary measure of the diagnostic performance for each tool. All statistical analyses were performed using SAS (version 9.4; SAS Institute Inc, Cary, NC).

Results

During the study period, 27,474 delivery hospitalizations were recorded. A total of 1136 hospitalizations had a diagnosis of chorioamnionitis, of which 545 had the requisite vital sign data available and were included in the study (Figure 1). Maternal demographic and obstetrical data are shown in Table 3. The study cohort was mostly White nulliparous patients with a median BMI at the time of delivery of 32 kg/m^2. Most patients had one or more associated comorbidities with 23% having a hypertensive disorder and 12% having a diabetic disorder at their delivery admission. Of the 545 patients, 11 patients met the criteria for a sepsis diagnosis, and 3 patients were admitted to the intensive care unit (ICU).

The test characteristics of each tool for the prediction of sepsis are shown in Table 4. The omSIRS and omSIRS1 tools had overall similar test characteristics. There were notable differences in the performance of the omqSOFA tool compared with the omSIRS and omSIRS1 tools. This study demonstrated that the omSIRS (AUROC, 0.70; 95% CI, 0.68−0.72) and omSIRS1 (AUROC, 0.75; 95% CI, 0.73−0.77) tools had moderate discriminatory power to predict sepsis in an obstetrical population with a clinical diagnosis of chorioamnionitis. The omqSOFA tool (AUROC, 0.58; 95% CI, 0.46−0.70) was no better than chance at predicting sepsis in this population (Figure 2). The screen-positive rate (SPR) of the omqSOFA tool (1.5%; 95% CI, 0.6%−2.9%) was notably lower than that of the omSIRS (60.0%; 95% CI, 55.7%−64.1%) and omSIRS1 (50.0%; 95% CI, 45.8%−54.3%) tools, whereas the sensitivities of the omSIRS (100.0%; 95% CI, 71.5%−100.0%) and omSIRS1 (100.0%; 95% CI, 71.5%−100.0%) tools were numerically higher than that of the omqSOFA tool (18%; 95% CI, 2.3%−51.8%). The omSIRS and omSIRS1 tools had high sensitivities; however, because of the small number of events, the CIs were wide so that the sensitivities could be as low as 71.5%. The NPV of the omSIRS (100.0%; 95% CI, 98.3%−100%) and omSIRS1 (100.0%; 95% CI, 98.6%−100%) tools were high, and both tools excluded all sepsis cases. In addition, the NPV of the omqSOFA tool (98.3%; 95% CI, 96.8%−99.2%) was high; however, it missed more than half of the sepsis cases. All 3 tools had poor PPVs. The small number of events did not allow for a direct comparison between the tools.

Comment

Principal findings

The omqSOFA had low sensitivity as a primary screening tool for sepsis among

TABLE 2
Criteria for end-organ injury for the diagnosis of maternal sepsis[8]

Variable	Outcome
Respiratory function	• Acute respiratory failure as evidenced by acute need for invasive or noninvasive mechanical ventilation • PaO2 or FiO2 of <300
Coagulation status	• Platelet count of $<100 \times 10^9$/L • International normalized ratio of >1.5 • Partial thromboplastin time of >60 sec
Liver function	• Bilirubin level of >2 mg/dL
Cardiovascular function	• Persistent hypotension after fluid administration: ○ SBP of <85 mm Hg ○ MAP of <65 mm Hg ○ >40 mm Hg decrease in SBP
Renal function	• Creatinine level of >1.2 mg/dL • Doubling of creatinine level • Urine output of <0.5 mL/kg/h (for 2 h)
Mental status assessment	• Agitation, confusion, or unresponsiveness
Lactic acid	• 2 mmol/L in the absence of labor (lactic acid is not used for the diagnosis in labor but remains important for treatment. Please see discussion.)

Only 1 criterion is sufficient for the diagnosis. Adapted with permission from Gibbs et al.[9]

FiO2, fraction of inspired oxygen; *MAP*, mean arterial pressure; *PaO2*, partial pressure of oxygen; *SBP*, systolic blood pressure.

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patients with a clinical diagnosis of chorioamnionitis. The omSIRS and omSIRS1 tools had similar performance characteristics. Both tools captured all sepsis cases with an estimated sensitivity and NPV of 100%. The downside was in their high SPR among our study cohort.

Results in the context of what is known

Early warning systems that were developed for nonobstetrical patients, such as the Systemic Inflammatory Response Syndrome (SIRS) tool, the Modified Early Warning score tool, and the quick Sequential Organ Failure Assessment (qSOFA) tool, were evaluated in the obstetrical population and found to have suboptimal performance.[5,6,12] Several early warning systems were developed specifically for the obstetrical population, including the maternal early warning trigger, the modified early warning scoring systems, and the sepsis in obstetrics score. Those systems had considerable variation in their predictive ability and overall performed poorly as screening tools for the early detection of sepsis.[6,7,14]

Here, we assessed the performance of 3 primary screening tools that were recently introduced by the CMQCC and SOMANZ. Overall, there were notable differences in the performance of the SIRS based tools compared with the qSOFA-based tool. This is likely related to the design of those tools where the omqSOFA tool measures organ dysfunction and the omSIRS and omSIRS1 tools measure the host's inflammatory response. The omqSOFA tool was derived from the qSOFA tool, which was originally designed and validated to be used on nonobstetrical patients with suspected or confirmed infection, to predict poor outcomes specifically mortality and prolonged ICU stay (≥3 days).[15] In a previous study on obstetrical patients, the qSOFA tool was shown to have a sensitivity of 50% with a specificity of 95%[12]. Given the low sensitivity of the qSOFA, there were concerns that the omqSOFA tool with the more stringent criteria would also have poor sensitivity. In our cohort, this tool had an SPR of 1.5% and a high NPV of 98%; however, its sensitivity was low at 18% and missed 9 of 11 sepsis cases. Despite its high NPV, this tool did not reliably exclude sepsis. The omSIRS tool, which was developed by the CMQCC, was based on a meta-analysis that assessed the distribution of temperature, heart rate, and respiratory rate among healthy pregnant patients.[16] It was expected that ≤2.5% of patients would meet the proposed screening criteria because of physiological changes of pregnancy rather than infection. In our cohort, both tools captured all sepsis cases, and both tools had high NPVs, indicating that they can reliably exclude sepsis. Both tools had sensitivities of 100%; however, the accuracy of this parameter is limited by the small number of events. The SPRs of the omSIRS (60%) and omSIRS1 (50%) tools were much higher than expected and indicated that the tools have a high rate of false-positive results. This high SPR could be related to the basic design of the tool, which measures the host's inflammatory response, which might not necessarily indicate a dysregulated, life-threatening response but rather an appropriate host response to an infection.[15]

Clinical implications

This analysis showed that the omqSOFA tool had low sensitivity in identifying sepsis among patients with chorioamnionitis and, thus, might not be an effective screening tool for sepsis. The omSIRS and omSIRS1 tools had high sensitivity in our cohort, although with a high SPR, which would trigger a sepsis workup in more than half of patients with a clinical diagnosis of chorioamnionitis. Thus, those tools seem to have a high false alarm rate and might not be cost-effective. Perhaps a more prudent approach would be for those tools to trigger a clinical evaluation by a

TABLE 3
Maternal demographic characteristics

Characteristic	Mean±SD or %
Age (y)	28.5±5.4
BMI (kg/m^2)	33.0±6.3
Nulliparous	80.2
Gestational age (wk)	
<24	2.6
24–36	7.3
37–40	78.4
>41	11.7
Mode of delivery	
Vaginal	55.8
Cesarean	44.0
Dilation and evacuation	0.2
Race	
White	72.1
Black	5.1
Hispanic	9.9
Asian	7.1
Other	4.8
Comorbidities	
Hypertension[a]	23.1
Gestational diabetes mellitus	9.7
Diabetes mellitus	2.0
Asthma	7.2
Infection[b]	8.1
Substance use disorder[c]	2.6

BMI, body mass index; *SD*, standard deviation.

[a] Preeclampsia, gestational hypertension, and preexisting hypertension; [b] Chronic hepatitis B and C and latent tuberculosis; [c] Tobacco, tetrahydrocannabinol, stimulants (amphetamine or methamphetamine), and alcohol.

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senior obstetrical provider rather than a full-scale sepsis workup.

Research implications

More research to examine the performance of the omSIRS and omSIRS1 tools is needed to further validate their observed high sensitivity in this study and to optimize their use as primary screening tools. In addition, those tools need to be evaluated in pregnant and postpartum patients with other types of infection and in different clinical settings. Furthermore, research is needed to assess the performance of all 3 tools in the prediction of poor outcomes, such as maternal mortality or prolonged ICU stay. Such outcomes are associated with more severe and complex infections that better characterize sepsis.

Strengths and limitations

The study used data extracted from delivery encounters of patients being admitted for routine obstetrical indications. The vital signs, laboratory results, and clinical data were sequentially reviewed for each patient from the time of admission to discharge. We believe that this more closely resembles how the tools would be used in real-life clinical operations and would allow for a more accurate assessment of the performance of those tools. In addition, how the data were reviewed should limit bias and enhance the validity of the study. The study included a large number of patients from 1 tertiary center and an affiliated healthcare system. Thus, findings from this study are likely to be representative and generalizable to similar

TABLE 4
Test characteristics for the prediction of sepsis

Variable	SPR % (95% CI)	Sensitivity % (95% CI)	Specificity % (95% CI)	PPV % (95% CI)	NPV % (95% CI)	AUROC
omSIRS	60.0 (55.7–64.1)	100.0 (71.5–100.0)	41.0 (36.6–45.1)	3.4 (1.7–5.9)	100.0 (98.3–100.0)	0.70 (0.68–0.72)
omSIRS1	50.0 (45.8–54.3)	100.0 (71.5–100.0)	51.0 (46.6–55.2)	4.0 (2.0–7.1)	100.0 (98.6–100.0)	0.75 (0.73–0.77)
omqSOFA	1.5 (0.6–2.9)	18.0 (2.3–51.8)	99.0 (97.6–99.6)	25.0 (3.2–65.1)	98.3 (96.8–99.2)	0.58 (0.46–0.70)

AUROC, area under the receiver operating characteristic curve; *CI*, confidence interval; *NPV*, negative predictive value; *omqSOFA*, obstetrically modified quick Sequential Organ Failure Assessment; *omSIRS*, obstetrically modified Systemic Inflammatory Response Syndrome; *omSIRS1*, obstetrically modified Systemic Inflammatory Response Syndrome 1; *PPV*, positive predictive value; *SPR*, screen-positive rate.

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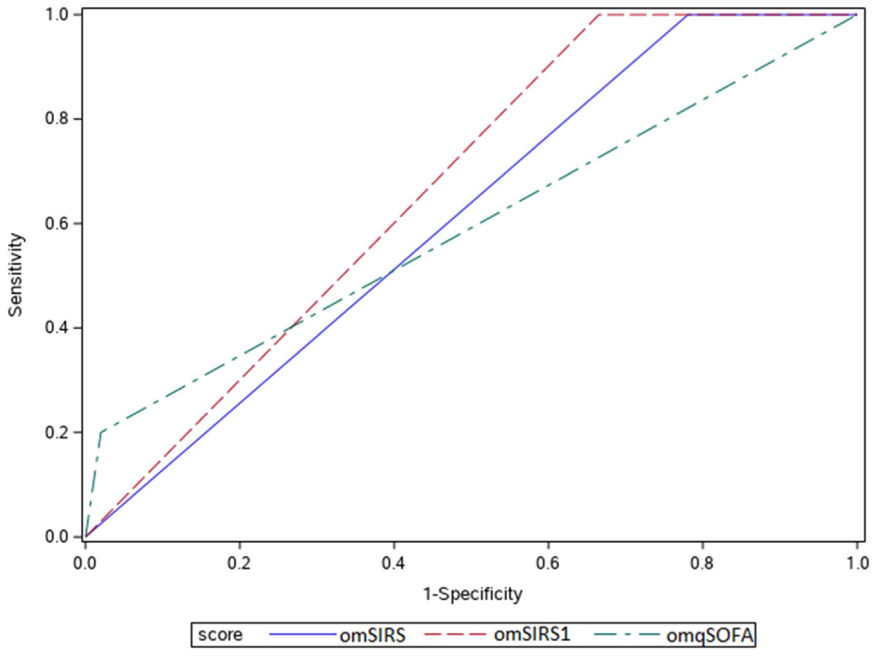
FIGURE 2
ROC curve of the three screening tools for sepsis outcome



omqSOFA, obstetrically modified quick Sequential Organ Failure Assessment; *omSIRS*, obstetrically modified Systemic Inflammatory Response Syndrome; *omSIRS1*, obstetrically modified Systemic Inflammatory Response Syndrome 1; *ROC*, receiver operating characteristic.

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settings. The study is limited by the frequency of documentation of the different parameters. Maternal heart rate was the most closely tracked and documented parameter, whereas mental status was the least documented parameter. In some instances, information on the heart rate or respiratory rate was not available at 15-minute intervals, and thus, in those situations, a longer interval was used to determine the persistence of tachycardia or tachypnea. It is hard to determine how this could have affected the performance of the tools because, in several instances, those parameters were documented almost continuously and show that some patients frequently went in and out of reaching the threshold for tachycardia or tachypnea even over short time intervals. We were unable to incorporate the percentage of immature neutrophils in determining whether the SIRS-based tools met the threshold. The only potential effect in our cohort would have been to increase the false-positive rate and subsequently lower the specificity and PPV of those tools.

The assessment of mental status for the omqSOFA tool was difficult to determine in a standardized manner. We looked at the RASS score and any documented clinical comments to determine whether the mental status element met the criteria. This study was limited by the exclusion of patients with incomplete vital sign data. This is a commonly reported limitation among retrospective studies assessing the performance of early warning systems.[5,6,17] The exclusion of a large number of patients could reduce the generalizability of the findings and limit the ability of the study to reflect the function of those tools in real clinical settings where data used in those tools are often incomplete. Another limitation of the study is the small number of events, which prevented accurate assessment of certain performance parameters, such as sensitivity. Moreover, the small number of events did not allow for a comparison between the tools.

There was no case of maternal mortality or prolonged ICU stay (≥3 days), and thus, we were unable to assess the performance of those tools in predicting such poor outcomes.

Conclusion

This study showed that all 3 tools had limitations in screening for sepsis among patients with a clinical diagnosis of chorioamnionitis. The previous concerns related to the low sensitivity of the omqSOFA tool were validated in this analysis. The omSIRS tools seemed to capture all sepsis cases but with a high SPR, which raises concerns about their use as primary screen tools. Additional research is needed to optimize the performance of those tools among patients with chorioamnionitis and to examine their use in different settings and other types of infection. ■

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