[Original Research]

CHEST

A Comparison of the Quick-SOFA and Systemic Inflammatory Response Syndrome Criteria for the Diagnosis of Sepsis and Prediction of Mortality

A Systematic Review and Meta-Analysis

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BACKGROUND: Several studies were published to validate the quick Sepsis-related Organ Failure Assessment (qSOFA), namely in comparison with the systemic inflammatory response syndrome (SIRS) criteria. We performed a systematic review and meta-analysis with the aim of comparing the qSOFA and SIRS in patients outside the ICU.

METHODS: We searched MEDLINE, CINAHL, and the Web of Science database from February 23, 2016 until June 30, 2017 to identify full-text English-language studies published after the Sepsis-3 publication comparing the qSOFA and SIRS and their sensitivity or specificity in diagnosing sepsis, as well as hospital and ICU length of stay and hospital mortality. Data extraction from the selected studies followed the recommendations of the Meta-analyses of Observational Studies in Epidemiology group and the Preferred Reporting Items for Systematic Reviews and Meta-Analyses statement.

RESULTS: From 4,022 citations, 10 studies met the inclusion criteria. Pooling all the studies, a total of 229,480 patients were evaluated. The meta-analysis of sensitivity for the diagnosis of sepsis comparing the qSOFA and SIRS was in favor of SIRS (1.32; 95% CI, 0.40-2.24; $P < .0001$; $I^2 = 100\%$). One study described the specificity for the diagnosis of infection comparing SIRS (84.4%; 95% CI, 76.2-90.6) with the qSOFA (97.3%; 95% CI < 92.1-99.4); the qSOFA demonstrated better specificity . The meta-analysis of the area under the receiver operating characteristic curve of six studies comparing the qSOFA and SIRS favored the qSOFA (0.03; 95% CI, 0.01-0.05; $P = .002$; $I^2 = 48\%$) as a predictor of inhospital mortality.

CONCLUSIONS: The SIRS was significantly superior to the qSOFA for sepsis diagnosis, and the qSOFA was slightly better than the SIRS in predicting hospital mortality. The association of both criteria could provide a better model to initiate or escalate therapy in patients with sepsis.

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KEY WORDS: qSOFA; sepsis diagnosis; SIRS criteria

ABBREVIATIONS: AUROC = area under the receiver operating characteristic curve; LOS = length of stay; NOS = Newcastle-Ottawa scale; qSOFA = quick Sepsis-related Organ Failure Assessment; SIRS = systemic inflammatory response syndrome

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In February 2016, the new criteria for sepsis, called Sepsis-3 Third International Consensus Definitions for Sepsis and Septic Shock, were published,[1] aiming to replace the previous criteria (Sepsis-1[2] and Sepsis-2[3]). The Sepsis-3 consensus definitions were developed by a task force appointed by the European Society of Intensive Care Medicine and the Society of Critical Care Medicine and were endorsed by more than 30 scientific societies. Nonetheless, they were severely criticized.[4,5]

One of the major criticisms was the development and proposal of a new tool, the quick Sepsis-related Organ Failure Assessment (qSOFA), which was derived from large databases of North American patients. Additionally, there were concerns that the qSOFA may defer diagnosis and case recognition until infection-related organ dysfunction is clearly established.

The qSOFA uses three routinely available clinical parameters (systolic blood pressure, mental status, and respiratory rate) without the need for laboratory tests. Accordingly, a qSOFA $\geq$ 2 identifies patients with suspected infection who have a higher risk of poor outcomes, namely, a prolonged ICU stay and death.[6] The qSOFA was specifically designed to be used outside the ICU to enable clinicians to improve resource allocation by the identification of patients in need of further investigation, to initiate or escalate therapy if appropriate, and to consider further monitoring or transfer to an ICU.[1] In the original study, its predictive ability of hospital mortality was higher than that of the SIRS criteria.[1]

However, before wide implementation, there is a need to validate the qSOFA in different settings, as its ability to predict poor outcomes, mortality, and longer ICU stay could occur at the expense of a lower sensitivity for the diagnosis of the early stages of severe infections, with the consequent delay of diagnosis and a potential delay in the prescription of antibiotics.[4,5,7,8]

Several studies were recently published to validate the qSOFA, namely by comparing it with the SIRS criteria, assessing its performance in the identification of patients with poor outcomes as well as for the diagnosis of sepsis.[6,9,10] In the present study, we performed a systematic review of the literature and a meta-analysis to describe the performance of the qSOFA and compare it with the SIRS for the diagnosis of sepsis and its ability to predict hospital mortality.

Methods

Data Sources and Study Selection

We conducted a systematic review and meta-analysis of prospective observational studies following the recommendations of the Meta-analysis of Observational Studies in Epidemiology (MOOSE) group[11] and according to the recommendations of the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement.[12] We searched MEDLINE, CINAHL, and the Web of Science databases during the period of February 23, 2016 to June 30, 2017 to identify full-text English-language studies published after the Third International Consensus Definitions for Sepsis and Septic Shock (Sepsis-3)[6] that described clinical criteria for sepsis. The most recent search was performed on July 10, 2017. Reference lists of retrieved articles and relevant review articles, as well as personal files were searched manually. Search terms included: "qsofa" OR "sofa" OR "sirs" OR "sequential organ failure assessment" OR "systemic inflammatory response syndrome" OR "sepsis/diagnosis." We considered the following criteria for study inclusion: (1) full-length reports published in peer-reviewed journals, (2) prospective observational cohorts or clinical trials of adult (> 16 years) patients, (3) data describing sepsis assessment using the qSOFA and SIRS criteria, and (4) the relationship between sepsis screening criteria and at least one of the following reported outcomes: sensitivity or specificity for the diagnosis of sepsis, hospital and ICU length of stay (LOS), death in the hospital, or any outcomes after hospital discharge. Articles were excluded (1) if they described data about only a specific population (patients with neutropenia, liver failure) and (2) if they were case studies or case series.

Three investigators (R. S., P. P., J. A. G.) performed the study selection process, including the initial search for the identification of references and the selection of potentially relevant titles for review of abstracts, including those chosen for review of the full-length reports. All selections were decided by consensus. This report was prospectively registered with the PROSPERO database of systematic reviews (CRD42017067645).

Data Extraction and Study Quality Assessment

Data extraction from the selected articles was independently performed by two authors (R. S., J. A. G.). The following data were recorded (when available): study characteristics (type of study, selection of patients, number of patients enrolled, criteria to diagnosis of infection, diagnosis of sepsis), patient characteristics (age, sex, setting in which patient was seen), and outcomes (organ dysfunction, mortality, ICU and hospital LOS).

To assess the methodological quality of the studies, we used the Newcastle-Ottawa Scale (NOS).[13] The scale evaluates three aspects of study methods: the selection of study groups (range, 0-4), the comparability of groups (range, 0-2), and the quality of outcome ascertainment (range, 0-3). The total score ranges from 0 to 9, and an acceptable methodological design is reflected by a score of > 5.

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