REUE | Original Article

Can we rescue the Quick Sepsis-related Organ Failure Assessment?

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BACKGROUND. Early warning scores (EWSs) or scales for risk assessment have been shown to have good predictive value for identifying patients at high risk of a poor clinical course. Which EWS is best for assessing risk for sepsis, however, is much disputed.

OBJECTIVE. To compare the predictive value of 8 EWSs to identify which patients with infections are likely to have a poor clinical outcome, defined as death or admission to an intensive care unit (ICU) within 30 days.

METHODS. Prospective observation study of patients treated in our emergency department in 2020 in whom infection was suspected. We assessed each patient's risk for a poor clinical outcome with each EWS and calculated each EWS's ability to predict a composite outcome of death or ICU admission within 30 days.

RESULTS. One hundred four patients were enrolled; 53 patients (51%) were women and the median age was 77 years (interquartile range, 28.7) years. The composite 30-day outcome occurred in 18 patients (17.3%). The National EWS 2 (NEWS2) had the highest sensitivity (88.9%) and second-best area under the receiver operating characteristic curve (AUC) of 0.772. However, its specificity was low (48.9%). The Quick Sepsis-related Organ Failure Assessment (qSOFA), on the other hand, had low sensitivity (50%) but the highest specificity (87.2%) and AUC (0.796). The qSOFA fulfilled its screening function, however, if the score was 0 (no patient with this score died or entered the ICU) or 2 or more (the composite outcome occurred in 45% of such patients). The lactate-enhanced qSOFA-L increased the tool's sensitivity to 77.8% and moderately decreased specificity (to 69.9%) and the AUC (to 0.753). All 3 scores had high negative predictive values.

CONCLUSIONS. The EWS most appropriate for predicting complications in patients suspected of having sepsis was the NEWS2. However, the qSOFA-L gave similar results and might become a useful screening tool for managing sepsis appropriately.

Keywords: Sepsis. Risk assessment. Quick Sepsis-related Organ Failure Assessment (qSOFA). Lactate-enhanced qSOFA (qSOFA-L). National Early Warning Score 2 (NEWS2). Modified Early Warning Score (MEWS).

¿Podemos rescatar el q-SOFA?

INTRODUCTION. Las Escalas Precoces de Riesgo (EPR) han demostrado una buena capacidad predictiva para detectar pacientes con alto riesgo de mala evolución. Sin embargo, en los pacientes con sospecha de sepsis existe mucha controversia sobre qué EPR es la más adecuada.

OBJETIVO. Comparar, en pacientes con sospecha de infección, la capacidad de distintas EPR para detectar pacientes con alto riesgo de mala evolución, definido este como presentar mortalidad o ingreso en la unidad de cuidados intensivos (UCI) en los 30 días.

MATERIAL Y MÉTODO. Estudio observacional prospectivo de pacientes que acudieron a nuestro servicio de urgencias con sospecha clínica de infección en el año 2020. Tras calcular las distintas escalas, se determinaron los valores predictivos de cada índice para la mortalidad y/o ingreso en UCI a los 30 días.

RESULTADOS. Se estudiaron 104 pacientes, el 51% (53) mujeres, con mediana de edad 77,0 (RIC: 28,7) años. El 17,3% (18) de los pacientes cumplieron la variable combinada de muerte o ingreso en UCI a los 30 días. NEWS2 fue el índice con mayor sensibilidad (88,9%) y el segundo mejor área bajo la curva (ABC) (0,772), pero su especificidad fue baja (48,9%). Por el contrario, q-SOFA presentó una baja sensibilidad (50%), aunque fue el índice con mayor especificidad (87,2%) y ABC (0,796). q-SOFA cumplió su función de *screening* si presentaba valores de 0 (ningún paciente presentó la variable combinada) o ≥ 2 (hasta el 45% de los pacientes la presentaron). qSOFA-lactato elevó la sensibilidad, con respecto a q-SOFA, al 77,8%, con una moderada reducción de la especificidad (69,9%) y ABC (0,753). Todas las escalas presentaron valores predictivos negativos elevados.

CONCLUSIONES. La EPR aislada más adecuada para predecir complicaciones en pacientes con sospecha de sepsis fue NEWS2. Sin embargo, qSOFA-lactato tuvo resultados similares y puede convertirse en un método de *screening* útil para identificar de forma adecuada la sepsis.

Palabras clave: Sepsis. Escalas precoces de riesgo. q-SOFA. qSOFA-Lactato. NEWS2. MEWS.

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Introduction

Sepsis is one of the major public health problems worldwide, both because of its high incidence rate and its elevated mortality. A meta-analysis by Bauer et al. reviewing 170 studies published in Europe, North America, and Australia between 2009 and 2019 found a 30-day mortality rate of 24.4% for sepsis and 34.7% for septic shock.[1] Early recognition and initiation of treatment within the first hours after onset are key to improving survival.[2] In both tasks, Emergency Medical Services play a crucial role.

Early Warning Scores (EWS) have demonstrated good predictive accuracy in identifying patients at high risk of poor outcomes, particularly early or in-hospital mortality,[3,4] including in sepsis.[5] The most widely used in sepsis are the MEWS (Modified Early Warning Score),[6] the NEWS2 (National Early Warning Score),[7,8] and the qSOFA (Quick Sepsis-related Organ Failure Assessment).[9] In many emergency departments it is now possible to rapidly measure serum lactate, and adding lactate to these scores appears to improve their reliability.[9,10] We do not consider SIRS (Systemic Inflammatory Response Syndrome) or SOFA (Sepsis-related Organ Failure Assessment) to be early warning scores, because both require laboratory values for their calculation.

There is, however, substantial controversy regarding which EWS is most appropriate for use in the infected patient. In 2016, the Sepsis-3 Consensus recommended the use of qSOFA for this purpose in patients not admitted to intensive care units (ICUs).[11] This recommendation generated criticism[12] and led to numerous studies assessing its utility vs other indices. Overall, these studies show that qSOFA has poor Se for detecting patients at risk of deterioration.[13-19] As a result, the most recent Surviving Sepsis Campaign update, published in November 2021, did not recommend the use of qSOFA alone as a sepsis screening tool vs SIRS, NEWS, or MEWS.[20] This recommendation was a setback for those who considered qSOFA a quick and easy scale to apply in the often overloaded emergency care setting.

Some studies have proposed alternative scales derived from qSOFA that offer higher Se. Seymour *et al*.[9] in the same article validating qSOFA, found that hospital mortality among patients with qSOFA = 1 and serum lactate ≥ 2 mmol/L was similar to that of patients with qSOFA ≥ 2 (qSOFA-Lactate). Churpek *et al*.[13] proposed lowering the positivity threshold to qSOFA ≥ 1 (qSOFA1), as these patients behaved similarly to those with SIRS ≥ 2.

Endpoint

The endpoint of this study was to compare, in patients presenting to our emergency department (ED) with suspected infection, the ability to detect those at high risk of poor outcomes—defined as death or ICU admission within the following 30 days—across the following EWS: qSOFA, qSOFA1, qSOFA-Lactate, NEWS2, NEWS2-Lactate, MEWS, and MEWS-Lactate. Additionally, we analyzed the isolated measurement of lactate.

Materials and methods

We conducted a prospective observational study of adult patients who presented to our ED with clinical suspicion of infection between January 1st and December 31st, 2020, and were initially evaluated by participating physicians. Exclusion criteria were age < 18 years; pregnancy (because these risk scores are not recommended due to physiological differences); patients with spinal cord injuries (high paraplegia or tetraplegia), because of autonomic nervous system alterations; and patients who, after initial evaluation, were considered mild cases and did not require laboratory testing, thus preventing SOFA calculation. Eligible patients were informed about the study and asked to provide written informed consent before enrollment.

During the initial clinical assessment, qSOFA, NEWS2, and MEWS were calculated, and management proceeded as follows (Figure 1). If qSOFA = 0 and NEWS2 and MEWS < 5, routine clinical management was followed. Patients were included in the study if laboratory testing was required, which had to include the values needed to calculate SOFA (platelet count, bilirubin, creatinine) to determine the degree of organ dysfunction. If qSOFA = 1 and NEWS2 and MEWS were negative, serum lactate was measured using venous blood gas analysis (arterial if respiratory failure was suspected) using the on-site analyzers. If lactate < 2 mmol/L, routine clinical management continued. If lactate ≥ 2 mmol/L (in the setting of qSOFA = 1) or if any score was positive (qSOFA ≥ 2 and/or NEWS2 ≥ 5 and/or MEWS ≥ 5; in NEWS2, any single item with ≥ 3 points is also considered positive), sepsis code management was initiated: sepsis laboratory panel—including lactate—and blood gas analysis (venous or arterial depending on the case), blood cultures and other cultures as indicated, aggressive fluid resuscitation, and empirical antibiotic therapy.

During the initial assessment, demographic variables (age, sex, Charlson comorbidity index) and clinical variables (blood pressure, heart rate, respiratory rate, oxygen saturation –SpO_2–, inspired oxygen fraction, Glasgow Coma Scale, and temperature) were recorded, as well as serum lactate if measured, allowing calculation of the various EWS. Subsequently, laboratory variables (platelets, bilirubin, creatinine, and serum procalcitonin if obtained) were collected, SOFA was calculated, and outcomes were recorded, including ED disposition, need for ICU admission, and mortality within 3 days, during hospitalization, or within 30 days after the ED visit.

The collected data were processed using the statistical software package IBM® SPSS® Statistics, version 26. Qualitative variables are expressed as percentages; quantitative variables with a normal distribution as mean with standard deviation, and those with a non-normal distribution as median and interquartile range (IQR). Based on the cross-tabulations generated in SPSS for each score with respect to fulfilling or not the combined outcome variable, and using the Bayesian Calculator (version 2.0) provided by our hospital's Research Support Unit, we calculated sensitivity (Se), specificity (Sp), positive predictive value (PPV), negative

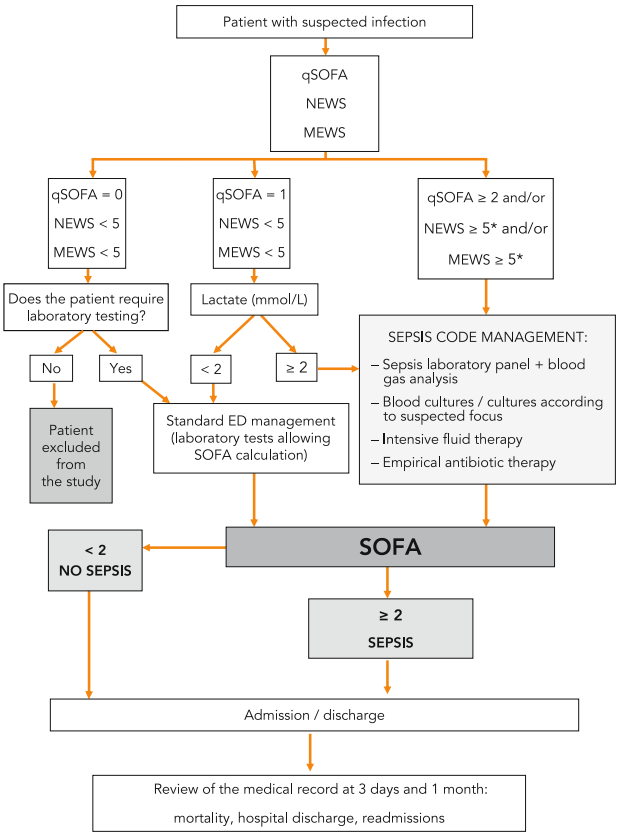

Figure 1. Study methodology.
*If any single item ≥ 3 points, or if the score plus lactate value was ≥ 7, it was considered positive.

predictive value (NPV), and area under the curve (AUC), each with its corresponding 95% confidence interval (CI), for each score in relation to the combined variable of 30-day mortality and/or ICU admission. A statistical significance level of 5% ($P < .05$) was applied in all cases.

This study was approved by the Research Ethics Committee for Medicinal Products of the Eastern Health Area of Valladolid.

Results

A total of 104 patients were analyzed. Patient characteristics are shown in Tables 1A and 1B. A total 51% (53) were women. The median age was 77.0 years (IQR, 28.7). At ED arrival, 45.2% (47) met criteria for sepsis (SOFA ≥ 2).

Table 1A. Characteristics of study patients (quantitative variables with normal distribution)

Variable	N	Minimum	Maximum	Mean	SD
SBP	104	71	188	121.2	27.71
DBP	104	35	110	69.2	14.08
MAP	104	48	127	86.4	17.48
HR	104	59	166	101.1	21.09
pO_2/FiO_2*	48	119.0	423.8	279.6	66.20
Platelets (× 1,000)	104	14	523	222.61	93.89
Days until ICU admission	5	0	24	7	10.63

*Calculated only in patients with arterial blood gas analysis.
SD: standard deviation; HR: heart rate; DBP: diastolic blood pressure; MAP: mean arterial pressure; SBP: systolic blood pressure; ICU: intensive care unit.

An additional 1.9% (2) developed sepsis subsequently during hospitalization. The most common ED disposition was hospital admission (69.2%, n = 72), with 4.2% (3) directly admitted to the ICU. One patient (1.0%) died in the ED, and 29.8% (31) were discharged home.

The 30-day mortality rate was 13.5% (14), with 28.6% (4) occurring within the first 72 hours. ICU admission occurred in 4.8% (5), of which 60% (3) were admitted directly from the ED. Overall, 17.3% (18) of the patients met the combined outcome of death and/or ICU admission within 30 days.

Table 2 illustrates the predictive values for the combined outcome for each index, and Figure 2 displays the AUC curves of the EWS. First, the low Se (50%) of qSOFA in our sample stands out. By contrast, this was the score with the highest Sp (87.2%) and AUC (0.796).

However, as illustrated in Figure 3, qSOFA seems to fulfill its screening function when values are either 0 (no patient with qSOFA = 0 met the combined outcome) or ≥ 2 (45% of patients with qSOFA ≥ 2 met the outcome). If patients with qSOFA = 1 were excluded from the analysis, the predictive values of qSOFA for the combined outcome would be: Se, 100%, Sp, 76.6%, PPV, 45%, NPV, 100%, and AUC, 0.903 (95% CI, 0.824–0.982; $P = .000$).

Among the EWS derived from qSOFA, using qSOFA1 yielded a Se of 100%, although with reduced Sp (42%) and AUC (0.709). The other strategy, qSOFA-Lactate, increased sensitivity to 77.8%, with a moderate reduction in Sp (69.9%) and AUC (0.753).

Apart from qSOFA1, the score with the highest Se in our study was NEWS2 (88.9%), with the second-best AUC (0.772). Its Sp was low (48.9%). Taken together, NEWS2 appears to be the single most useful index for sepsis screening in our cohort.

The performance of MEWS was very similar to that of qSOFA and did not provide additional benefit. Isolated

Table 1B. Characteristics of patients (quantitative variables with non-normal distribution)

Variable	N	Minimum	Maximum	Median	IQR
Age	104	18	100	77.0	28.8
GCS score	104	8	15	15	0
RR	104	12	46	21.5	12
O_2 saturation (%)	104	80	100	93.9	5.8
Temperature (°C)	104	35.0	39.9	37.5	1.7
Charlson comorbidity index	104	0	11	2.0	4.0
Lactate (mmol/L)	74	0.7	23.0	1.9	1.2
qSOFA	104	0	3	1.0	1.0
NEWS2	104	0	14	5.0	5.0
NEWS2-L	74	2.2	29.0	8.3	5.1
MEWS	104	0	11	3.0	2.8
MEWS-L	74	1.9	25.0	5.9	4.8
SpO_2/FiO_2	104	234.8	476.0	442.8	33.3
Creatinine (mg/dL)	104	0.3	10.4	0.9	0.6
Bilirubin (mg/dL)	104	0.1	6.4	0.5	0.4
SOFA on admission	104	0	8	1.0	2.0
Length of stay (days)	72	1	60	8.0	10.5
Days until death	14	0	30	12.5	25.5

RR: respiratory rate; GCS: Glasgow Coma Scale; IQR, interquartile range.

Table 2. Ability of early warning scores to predict 30-day mortality or intensive care unit admission

Parameter	q-SOFA N = 104	q-SOFA1 N = 104	qSOFA-L N = 100*	NEWS2 N = 104	NEWS2-L N = 74	MEWS N = 104	MEWS-L N = 74	Lactate N = 74
Se % (95% CI)	50.0 (24.1-75.9)	100 (97.2-100)	77.8 (55.8-99.8)	88.9 (71.5-100)	77.7 (55.8-99.8)	55.5 (29.8-81.3)	72.2 (48.8-95.7)	66.7 (42.1-91.2)
Sp % (95% CI)	87.2 (79.6-94.8)	42.0 (30.8-52.9)	69.9 (59.4-80.3)	48.9 (37.3-60.0)	39.3 (25.6-53.0)	81.4 (72.6-90.2)	75.0 (62.8-87.2)	58.9 (45.2-72.7)
Positive predictive value % (95% CI)	45.0 (20.7-69.3)	26.0 (15.2-37.7)	35.9 (19.5-52.2)	26.7 (14.6-38.7)	29.2 (15.3-43.1)	38.5 (17.8-59.1)	48.1 (27.4-68.8)	34.3 (17.1-51.4)
Negative predictive value % (95% CI)	89.3 (82.1-96.5)	100 (98.6-100)	93.5 (86.6-52.2)	95.5 (88.2-100)	84.6 (68.8-100)	89.7 (82.4-97.1)	89.4 (79.5-99.2)	84.6 (72.0-97.2)
Area under the curve (95% CI)	0.796 (0.697-0.895)	0.709 (0.604-0.814)	0.753 (0.624-0.882)	0.772 (0.659-0.886)	0.748 (0.603-0.892)	0.697 (0.549-0.845)	0.735 (0.575-0.895)	0.690 (0.535-0.846)
P	.000	.005	.001	.000	.002	.009	.003	.016

*In 4 patients with qSOFA = 1, serum lactate was not measured. In all cases, NEWS2 ≥ 5.

lactate measurement did not show good predictive ability for complications. When combined with qSOFA or MEWS, lactate substantially improved their Se, although this was not the case with NEWS2.

All scores demonstrated high NPV, particularly qSOFA1 (100%), NEWS2 (95.5%), and qSOFA-Lactate (93.5%). Therefore, these scores are highly effective for identifying patients at low risk of poor outcomes.

Discussion

There is considerable controversy regarding which EWS is most appropriate for suspected sepsis. However, most efforts have focused on comparing qSOFA (the EWS proposed by the Sepsis-3 Consensus) with SIRS, which in our opinion is not an EWS, and whose purpose is to define sepsis; therefore, it should be vs SOFA. Meta-analyses and multicenter studies that attempt to compare different EWS either do not do so specifically in infected patients3,4 or compare qSOFA with SIRS.[14-19] Our study evaluates the ability of 8 different EWS—each applicable in routine clinical practice—to detect infected patients at high risk of poor outcomes.

Given the high mortality of sepsis, the screening method used must prioritize Se, even at the expense of reducing Sp. Based on this principle, and considering the AUC as well, NEWS2 appears to be the single index that best identifies severe cases in our study. Other studies, both in patients with infection[13] and in other conditions,[3,16] have reached the same conclusion.

Our findings, consistent with most former studies, show that qSOFA has low Se (50%), preventing us from recommending its isolated use—consistent with the most recent Surviving Sepsis Guidelines. However, we did find that qSOFA showed excellent discrimination in predicting poor outcomes at scores of 0 and ≥ 2, a group-based differentiation not previously described. To improve qSOFA's reliability, we must focus on patients with qSOFA = 1, who are also the most frequent. We found no studies—other than the original proposals—that assessed the usefulness of the alternatives to qSOFA (qSOFA1 and qSOFA-Lactate). In our study, the low Sp (42%) of qSOFA1 makes it unsuitable, since it would trigger sepsis-code measures in many patients who do not require them, causing increased workload. In contrast, the qSOFA-Lactate strategy demonstrated adequate predictive values and AUC, with Se and AUC slightly lower than NEWS2 but higher Sp. Serum lactate measurement is now rapidly available in most EDs and is recommended by the

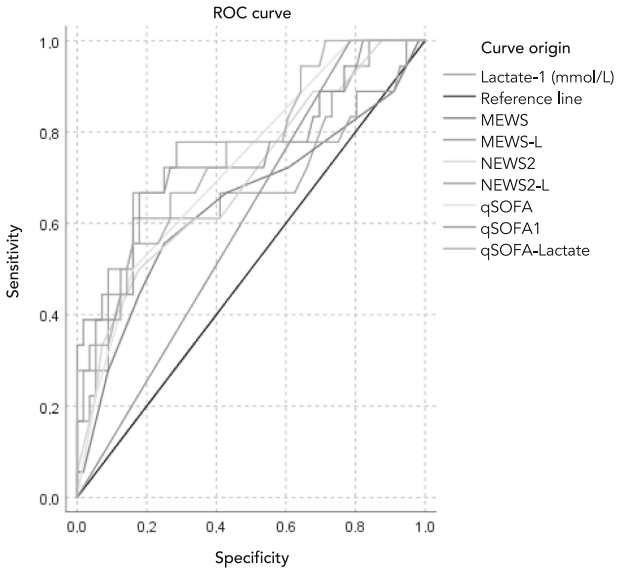

Figure 2. AUC curves of the different Early Warning Scores evaluated in relation to the combined outcome of 30-day mortality or intensive care unit admission.

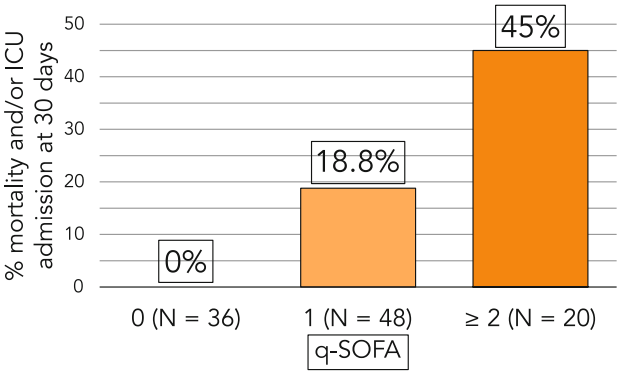

Figure 3. Prevalence of the combined outcome across qSOFA scores.
ICU: intensive care unit.

Surviving Sepsis Campaign[20] when sepsis is suspected, so its use should not increase workload. Furthermore, NEWS2 is not easy to memorize, and its calculation is less intuitive than qSOFA, requiring printed or digital tools. Using qSOFA-Lactate may therefore offer a simple, rapid, and effective strategy to identify high-risk patients in the emergency evaluation of suspected sepsis. Larger studies are needed to confirm our findings.

Of note, all EWS evaluated in our study demonstrated high NPV. Thus, they proved very useful for identifying patients at low risk of complications—an observation not highlighted in former articles.

This study has limitations. The most important is the small sample size. Our sampling strategy was not intended to be consecutive; instead, each investigator aimed to include as many patients as possible depending on workload. Given the high prevalence of infectious diseases, obtaining a large sample over one year seemed feasible. However, the emergence of the COVID-19 pandemic—with the creation of contaminated ("dirty") circuits (where most suspected infections, especially respiratory infections, were seen), the use of personal protective equipment (PPE), difficulty obtaining written consent—especially in cognitively impaired and frequently unaccompanied patients—the prohibition vs removing written documents (consent forms, data sheets, etc.) from "dirty" areas, and an overwhelming workload, all resulted in a much smaller sample than expected. Despite this, statistical significance was reached in our analyses. Other limitations include: the single-center design; non-consecutive patient selection, which may have influenced severity; and not considering the infection source. It is likely that respiratory infections—which were evaluated mostly in the "dirty" area—were underrepresented. Finally, lactate interpretation did not account for patient factors (age, liver disease, metformin use), which may affect lactate levels.

Despite these limitations, it is notable that we did not find any studies comparing as many EWS as we did. Moreover, unlike many previous studies, we did not mix these EWS—designed to detect patients at high risk of deterioration—with scales such as SIRS or SOFA, whose purpose is to identify organ dysfunction and/or define sepsis and are relevant only after laboratory results are available, not during initial assessment. Lastly, most prior studies are retrospective and based on older clinical data, whereas our prospective design provides evidence of higher scientific quality.

In conclusion, our study indicates that NEWS2 is the most appropriate standalone EWS for predicting complications in patients with infection and sepsis. However, because it is not easy to memorize, the strategy of calculating qSOFA and, if the score is 1, rapidly measuring serum lactate—and considering patients positive if lactate ≥ 2 mmol/L (qSOFA-L)—yields similar results and may become a useful screening method for appropriate sepsis management. Larger studies are needed to validate this strategy.

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