EARLY PREDICTION OF SEPSIS IN INTENSIVE CARE PATIENTS
USING A MACHINE LEARNING ALGORITHM, A RANDOMIZED CLINICAL VALIDATION TRIAL

INTRODUCTION

Despite the updated Sepsis-3 criteria, the diagnosis of sepsis is still difficult. Especially in the ICU setting where many patients have other conditions with similar physiological alterations. The primary objective of this trial was to, in an ICU setting, externally validate the prognostic accuracy of the machine learning sepsis prediction algorithm that uses routinely collected vital parameters, blood gas values, and lab values as input. An improved detection of sepsis will enable earlier treatment that may influence outcome. The tested algorithm, NAVOY® Sepsis, has previously retrospectively demonstrated the ability to detect ICU patients at high risk of developing sepsis within the coming hours [1].

METHODS

Adult patients admitted to the ICU at Skåne University Hospital Malmö from December 2020 to September 2021 were eligible for recruitment to the trial. A total of 304 subjects were randomized into one of two groups: Active algorithm, with sepsis alerts, or Standard of care. The algorithm made predictions in the whole cohort but was not displayed in the Standard of care group, in order to evaluate its performance without disturbing the outcome. The study was blinded, i.e. study personnel did not know for which subjects the algorithm was being used. The ICU followed standard practices in assessing possible development of sepsis and intervening accordingly. The subjects were followed in the study until ICU discharge.

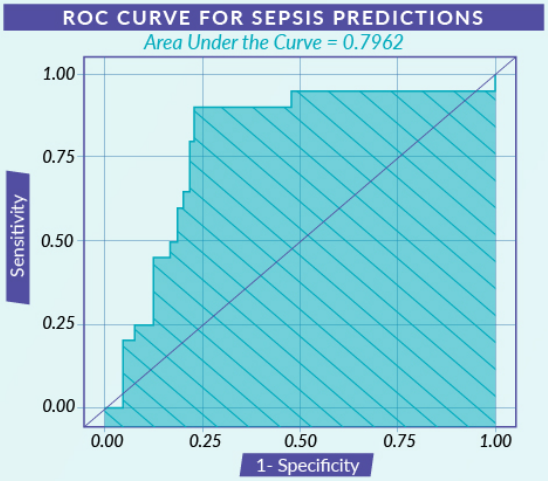

Figure 1. *ROC curve of the algorithm for predictions 3 hours before sepsis onset.*

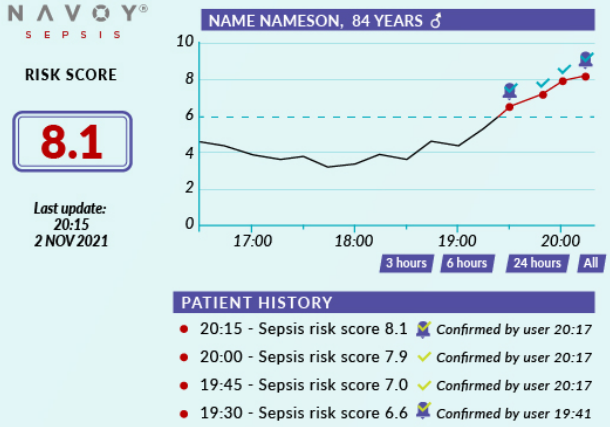

Figure 2. *Suggested user interface for the NAVOY Sepsis algorithm displaying a continuously updated risk score for development of sepsis in the individual patient. Dashed line indicate the threshold set and can be adjusted according to desired sensitivity and specificity.*

RESULTS

The algorithm could identify patients with high risk of developing sepsis, with high performance (accuracy 0.79; sensitivity 0.80; specificity 0.78) for predictions 3 hours before sepsis onset. The algorithm could predict sepsis with the same accuracy also for the Covid patients included in the trial.

PERFORMANCE METRIC	VALUE
AUROC	0.80
Accuracy (95% CI)	0.79 (0.70-0.88)
Sensitivity	0.80
Specificity	0.78

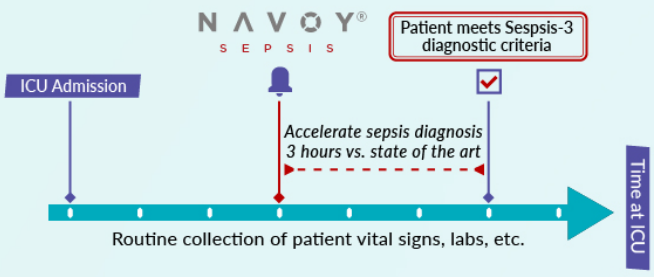

Figure 3. *Workflow intergration.*

CONCLUSIONS

The accuracy, sensitivity, and specificity were all high, validating the prognostic accuracy of the algorithm in an ICU setting. The results indicate that the algorithm can diagnose sepsis well in advance compared to clinical standard. This is, as far as the authors are aware, the largest clinical trial ever conducted with a machine learning sepsis prediction algorithm, and the first that clinically validates a sepsis prediction algorithm against the Sepsis-3 criteria.

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