PERFORMANCE OF SEPTICYTE® RAPID FOR DETERMINING PROBABILITY OF SEPSIS IN IMMUNOCOMPROMISED PATIENTS OR THOSE ON IMMUNOSUPPRESSANT THERAPY

Krupa Navalkar, PhD[1], Tom van der Poll, MD, PhD[2], Robert Balk, MD[3], Richard Brandon, BVSc (Hons) PhD, MBA[1], Roy Davis, MD, PhD, MHA[1]

1. Immunexpress Inc. Seattle, Washington. 2. Center of Experimental and Molecular Medicine (CEMM), Academic Medical, Center Division of Infectious Diseases, Academic Medical Center, Amsterdam, Netherlands and on behalf of the MARS consortium. 3. Rush Medical College and Rush University Medical Center, Chicago, Illinois.

Immunexpress SeptiCyte® RAPID

INTRODUCTION

The SeptiCyte® RAPID test is an FDA 510(k) cleared, CE marked gene expression assay that quantifies relative expression levels of two host genes in whole blood of patients suspected of sepsis. A score between 0 – 15 (SeptiScore®) is generated in ~1 hour in a fully self-contained and single-use Idylla™ cartridge and increases with the likelihood of sepsis.

Patients that are immunocompromised, or on immunosuppressant therapy, have an increased risk of infection [1], and often have abnormal white cell counts (WCC) [2] which could limit the ability of routinely used sepsis diagnostics to generate an accurate result. The purpose of this study was to evaluate the performance of SeptiCyte® RAPID in these patient populations.

METHODS

Figure 1 shows the Idylla™ instrument and cartridge on which all samples were processed to generate SeptiScore®. SeptiCyte® RAPID performance was compared to a Retrospective Physician Diagnosis (RPD.) [3] Consensus call for 378 patients (SIRS, n=224; sepsis, n=154). Total WCC were available for all patients. ROC curves were compared using the bootstrap method.

Immunocompromised patients (n=33) included 15 with SIRS and 18 with sepsis. These patients had pre-existing comorbidities such as adrenal insufficiency, splenectomy, asplenia or HIV/AIDS or were on corticosteroids.

Patients on a broad range of immunosuppressants (n=56) at the time of blood collection included 30 with SIRS and 26 with sepsis. The duration of use of these therapies was not taken into consideration.

Figure 1. SeptiCyte® RAPID Cartridge and Idylla™ Instrument from Biocartis

SeptiCyte® RAPID

Visit SeptiCyte.com for more information.

RESULTS

The SeptiScores® of patients diagnosed with sepsis were not statistically different regardless of whether they were immunocompromised or not (Figure 2, p=0.81). A similar trend was observed for the SIRS cases when comparing immunocompromised patients vs. not (p=0.18). The assay was able to discern sepsis patients from SIRS irrespective of whether they were immunocompromised (AUC=0.79) or not (AUC=0.85), respectively.

There were no significant differences observed between patients with sepsis (p=0.84) or SIRS (p=0.47) whether they were administered immunosuppressant therapy or not (Figure 3). The assay correctly discriminated sepsis patients from SIRS irrespective of whether they were administered immunosuppressant therapy (AUC=0.81) or not (AUC=0.85), respectively. Differences between ROC test p-values for all ROCs in both comparisons were not significant.

WCC in immunocompromised patients and those on immunotherapy varied widely from 0.3 – 37.2 x 10^3cells/µL indicating that abnormally low or high WCC did not affect generation of a SeptiCyte® RAPID result.

Figure 2. SeptiCyte® RAPID Performance in Patients Stratified by Whether They Were Immunocompromised or Not

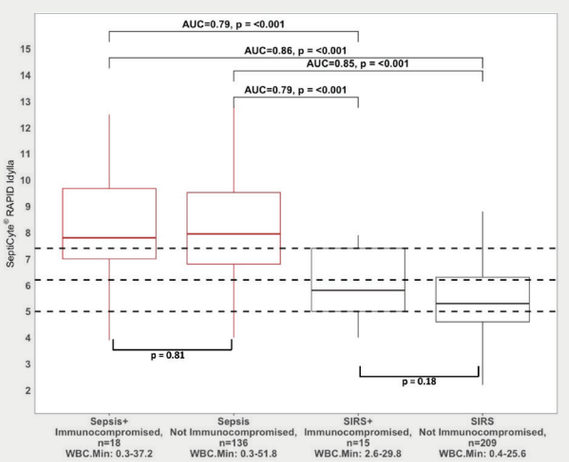
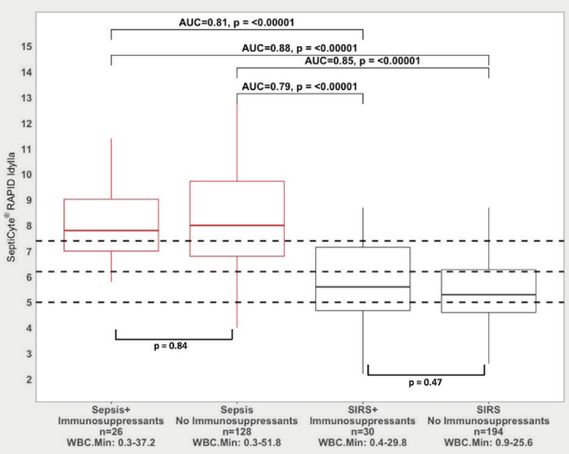


Figure 3. SeptiCyte® RAPID Performance in Patients Stratified by Whether They Were on Immunosuppressant Therapy or Not



CONCLUSION

SeptiCyte® RAPID is reliable for the determination of probability of sepsis in immunocompromised patients, or for patients on immunotherapy, and across a broad range of white cell counts.

References

1 Dropulic LK, Lederman HM. Overview of Infections in the Immunocompromised Host. Microbiol Spectr. 2016;4(4).
2 Coiffard B, Pelardy M, Loundo AD, et al. Effect of Immunosuppression on Target Blood Immune Cells Within 1 Year After Lung Transplantation: Influence of Age on T Lymphocytes. Ann Transplant. 2018;23:11-24.
3 Miller III RRM, Lopansri BK, Burke JP, et al. Validation of a Host Response Assay, SeptiCyte® LAB, for Discriminating Sepsis from Systemic Inflammatory Response Syndrome in the ICU. Am J Resp Crit Care. 2018;198(7):903-913.

Visit SeptiCyte.com for more information.