MEMED BV DISTINGUISHES BETWEEN VIRAL AND BACTERIAL INFECTION IN SEPSIS PATIENTS

MeMed

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Background:

Sepsis is a life-threatening organ dysfunction syndrome caused by the body's response to infection. Timely and appropriate sepsis management, including appropriate treatment of bacterial infection, improves outcomes. MeMed BV® (BV), a test for differentiating between bacterial and viral infection, is based on computational integration of the circulating levels of three proteins (TRAIL, IP-10, CRP). Here we evaluate its ability to differentiate bacterial from viral infection in sepsis patients.

Methods:

This was a sub-analysis of sepsis patients recruited prospectively in the Apollo study (NCT04690569). Apollo eligibility required the attending physician's clinical suspicion of acute infection and reported fever. Sepsis was defined as two or more SIRS criteria and a suspected bacterial or viral infection classified by expert adjudication. A bacterial or viral classification required at least 2/3 experts to assign the same etiology label with confidence ≥90% or all 3 assign with confidence ≥70%. BV was measured using a platform generating a bacterial likelihood score (0-100). Based on pre-defined thresholds, scores 0-34 indicated viral (or other non-bacterial) infection, scores 35 to 65 were equivocal and 66-100 indicated bacterial infection (or co-infection). BV performance was assessed against expert panel classifications.
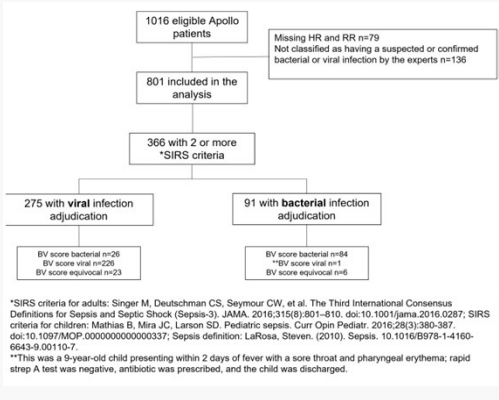
Conclusions:

BV accurately distinguished bacterial from viral infection in sepsis patients. This new triage tool has potential to help with timely identification of bacterial infection, enabling prompt treatment.

Results:

Seventy-nine out of 1016 eligible Apollo patients had missing heart rate and respiration rate data and a further 136 could not be classified by the experts. Out of the remaining 801 patients, 217 adults with median age of 41.8 years (IQR: 29.2-61) and 149 children with median age of 2.4 years (IQR: 1.4-5.4) had 2 or more SIRS criteria. 119 patients had at least 3 SIRS criteria and 39.6% (145/366) of the patients were hospitalized with a median duration of 4 days (IQR: 3-6 days). In the sepsis cohort, 91 patients were classified as bacterial and 275 as viral. BV yielded sensitivity and specificity of 98.8% (95%CI: 93.6-100) and 89.7% (95%CI: 85.3-93.2) and NPV of 99.6% (95%CI: 97-99.9), outperforming PCT (cut-off 0.5 ng/mL; sensitivity 52.8% (95%CI: 42-63.3); specificity 86.2% (95%CI: 81.5-90); NPV 84.6% (95%CI: 81.5-87.3)).

Patient enrollment flow

1016 eligible Apollo patients → Missing HR and RR n=79. Not classified as having a suspected or confirmed bacterial or viral infection by the experts n=136

801 included in the analysis

366 with 2 or more *SIRS criteria

275 with **viral** infection adjudication:
BV score bacterial n=26
BV score viral n=226
BV score equivocal n=23

91 with **bacterial** infection adjudication:
BV score bacterial n=84
**BV score viral n=1
BV score equivocal n=6

*SIRS criteria for adults: Singer M, Deutschman CS, Seymour CW, et al. The Third International Consensus Definitions for Sepsis and Septic Shock (Sepsis-3). JAMA. 2016;315(8):801–810. doi:10.1001/jama.2016.0287; SIRS criteria for children: Mathias B, Mira JC, Larson SD. Pediatric sepsis. Curr Opin Pediatr. 2016;28(3):380-387. doi:10.1097/MOP.0000000000000337; Sepsis definition: LaRosa, Steven. (2010). Sepsis. 10.1016/B978-1-4160-6643-9.00110-7.
**This was a 9-year-old child presenting within 2 days of fever with a sore throat and pharyngeal erythema; rapid strep A test was negative, antibiotic was prescribed, and the child was discharged.

BV outperforms PCT (n = 366)

BV Score (AUC = 0.97)
PCT (AUC = 0.73)