Blood culture-independent rapid diagnostic technology for improvement of time to bacterial species ID and earlier targeted antibiotic therapy.

Introduction

Early appropriate empirical antibiotic treatment is associated with reduced all-cause mortality in septic patients.1,2 Delays in antibiotic administration have also been associated with increases in long-term, residual adjusted sepsis mortality in patients admitted to the emergency department.3 However misuse and overuse of antibiotics contributes to increased drug related toxicity, the selection of pathogenic organisms (such as Clostridium difficile) and the emergence of resistance.4,5 Therefore a balance between prevention of infection related mortality and judicious antibiotic use should exist.

The Infectious Diseases Society of America/Society for Healthcare Epidemiology of America Stewardship Guidelines suggest various strategies to promote judicious use of antimicrobials in order to improve patient outcomes, control resistance and decrease healthcare expenses.6 One strategy the guidelines suggest is antibiotic stewardship based on diagnostic results. Blood cultures, the gold standard in bacteremia diagnostics, however detect bacteremia in only about 50% of patients who are clinically suspected of having sepsis and that value may decrease after antibiotic administration.7 In addition, blood culture and subsequent antimicrobial susceptibility testing, can take 2-5 days.8 During this time no clinical data is available to support patient treatment, therefore patients are typically treated empirically. However, in a meta-analysis of 70 studies, empiric antibiotic therapy was not appropriate in 46.5% of patients, indicating that nearly half of infected patients are not treated optimally in the absence of diagnostic information. In addition, these patients showed over two times higher odds of death.9

Rapid diagnostic assays have been associated with improvements in time to appropriate antibiotic therapy by enhancing early identification of causative organisms.10,11 Data supports bundling rapid diagnostic technology and antimicrobial stewardship programs to reduce antibiotic utilization and improve empirical therapy and time to de-escalation.

Research Question

• The T2Bacteria Panel is an FDA and CE Mark cleared and blood culture-independent assay for detection of bacteremia due to the most common ESBL pathogens: Escherichia coli, Enterococcus faecium, Staphylococcus aureus, Klebsiella pneumoniae, and Pseudomonas aeruginosa, and provides species identification within 3 to 5 hours after blood culture.

• In this study, we hypothesized that the T2Bacteria Panel, a direct from-whole blood diagnostic assay, has the potential to provide accurate and timely diagnosis of bacteremia, which might support the direct therapeutic management of ED patients in the emergency department.

Methods

As part of the prospective, non-interventional T2Bacteria Panel clinical study, a subset of ED patients were enrolled from Ochsner Medical Center (New Orleans, LA) and Tampa General Hospital (Tampa, FL). The study was approved by the review boards of both institutions.

Inclusion Criteria

• Patients ≥ 18 years old with blood culture ordered per standard of care

Exclusion Criteria

• Patients who could not provide consent

• Any subject that was previously enrolled in the study (i.e., subjects were unique and had exactly one result)

• Patients that did not have sufficient blood collected for T2 testing (at least one tube ≥ 3 mL)

Blood Collection

Two blood cultures were collected from each patient in an air of blood were drawn from each site.