Clinical Value of Point-of-Care Lactate in Adult Patients with Sepsis

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Introduction: Over 750,000 patients in the United States acquire sepsis annually. Sepsis is a severe response to infection that exhibits a mortality ranging from 28 to 50%. Early recognition of sepsis is instrumental to patient survival. The use of electronic health record (EHR) based sepsis alert systems combined with rapid biomarker testing represents the current state-of-art. Electronic sepsis alert systems incorporate vital sign and laboratory data to prompt patient care providers of potential sepsis in real-time. Sepsis biomarkers include lactate, c-reactive protein, and procalcitonin (PCT). Lactate remains the most common sepsis biomarker due to its wide availability with current guidelines recommending lactate cut offs of 4 mmol/L for severe sepsis/septic shock. Unfortunately, pre-analytical delays in the measurement of lactate may cause falsely elevated results. Point-of-care measurement of lactate may reduce pre-analytical delays and accelerate early recognition of severe sepsis and septic shock.

Methods: One hundred adult (age ≥ 18 years) emergency department patients with suspected sepsis using our EHR alert system. The EHR sepsis alert system is based on meeting two or more of the following cut-offs: (a) temperature >38.5C or <36C, (b) respiratory rate > 20 breaths/min, (c) heart rate >90 beats per minute, and (d) white blood cell count >12,000 cells/uL or <4,000 cells/uL, or >10% immature neutrophils. Upon arrival at the Emergency Department and meeting the EHR sepsis alert criteria, 1.2 microliters of blood was aliquoted from routinely collected laboratory specimens for lactate determination using the POC device (StatStrip Lactate, Nova Biomedical, Waltham, MA). Point-of-care lactate results were compared to the laboratory (RAPIDLab 1200 blood gas analyzer, Siemens, Malvern, PA). The POC results were not reported for patient care. In parallel, laboratory reporting of PCT results were also compared. Analytical performance was compared using the paired *t*-test. Time-and-motion analysis was performed to determine the clinical impact of POC lactate testing on the ED workflow. Non-value added (NVA) time was also calculated and defined as the total analytical TAT for the laboratory method minus the total analytical TAT for the POC method. Patient chart review evaluated sepsis cases which may have benefited from POC lactate measurements. Receiver operator characteristic curve analysis was performed to compare lactate to PCT.

Results: Patients (n = 100) were enrolled between December 2014 and December 2015. Mean (SD) age was 38.7 (19.1) years. Fifty-one patients were men and 49 patients were women. Forty-seven patients had culture confirmed sepsis, and of these, 22 experienced severe sepsis or septic shock. Point-of-care lactate values were significantly lower than laboratory results with a mean bias of 1.7 (2.3) mmol/L, n = 100, P < 0.001. Analytical correlation was shown to have an $R^2 = 0.96$, with an equation of the line of y = 0.97x + 0.76. Mean total analytical TAT's for the POC measurements were significantly faster than the laboratory method (3.7 [5.5] mins vs. 15.0 [8.9] mins, n = 100, p < 0.001). Total analytical turnaround time for PCT was 41.7 (10.8) mins. Mean no-value added time was determined to be 12.3 (8.2) mins for laboratory lactate alone, and 38.0 (15.9) minutes when compared to PCT. Fifteen patients meeting the 4 mmol/L lactate cut-off based on laboratory results were missed identified for having severe sepsis and septic shock. These same patients were correctly determined to have sepsis based on POC results when combined with patient chart review. Clinical performance of POC lactate results were comparable to PCT values for early recognition of severe sepsis and septic shock with area under the receiver operator characteristic curve of 0.80 and 0.84 respectively (P=0.060).

Conclusion: The POC lactate device exhibited a negative bias compared to the laboratory method. Patient case review determined this negative bias may be partially attributed to pre-analytical testing delays resulting false elevations with the laboratory method. Point-of-care lactate measurements correctly identified severe sepsis and septic shock in all 22 patients. The use of point-of-care testing also yielded significantly faster results than laboratory methods for lactate and PCT. Lactate performance was comparable to PCT for the early recognition of severe sepsis and septic shock. Further studies are needed to evaluate the clinical impact of POC lactate measurements for sepsis in the emergency care setting.