Predictive Value of Point-of-care Lactate Measurement in Patients Meeting Level II and III Trauma Team Activation Criteria that Present to the Emergency Department: A Prospective Study

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Abstract

Background: The aim of this study was to investigate the utility of early point-of-care (POC) lactate levels to help predict injury severity and ultimate emergency department (ED) disposition for trauma patients meeting Level II and III activation criteria. Methods: This was a blinded, prospective cohort study including a convenience sample of patients meeting our triage criteria for Level II or III team activation with stable vital signs. Bedside lactate samples were collected during the secondary survey. Clinical care/disposition was at the discretion of physicians who remained blinded to the bedside lactate result. An elevated lactate was defined as >2.0 mmol/L. Results: Ninety-six patients were in the study group; mean age was 41 ± 17 years, 26% were female, 57% were Hispanic, and 60% admitted. We found no difference in initial mean POC lactate levels (mmol/L) for admitted versus discharged groups and Injury Severity Score (ISS) ≥9 versus ISS <9 groups (3.71 [95% confidence interval (CI): 3.1–4.4] vs. 3.85 [95% CI: 2.8–4.9]; P = 0.99 and 3.54 [95% CI: 2.7–4.4] vs. 3.89 [95% CI: 3.1–4.6]; P = 0.60, respectively). Performance characteristics of early elevated lactate levels were poor both to predict need for hospital admission (sensitivity = 77% [65%–87%]; specificity = 26% [13%–43%]; negative predictive value [NPV] = 43% [27%–61%]; and positive predictive value [PPV] = 62% [56%–67%]) and to identify patients with ISS scores ≥9 (sensitivity = 76% [59%–89%]; specificity = 24% [14%–37%]; NPV = 65% [47%–80%]; and PPV = 36% [30%–41%]). Conclusions: For Level II/III, we found that early bedside lactate levels were not predictive of ISS ≥9 or the need for admission. Level of Evidence: III (diagnostic test).

Keywords: Bedside testing, lactate, point of care, trauma

INTRODUCTION

Produced by most body tissues, primarily muscle, lactate is usually cleared rapidly from the bloodstream by the liver in normal circumstances. It is understood that lactate is a product of glycolysis, and serum levels are, therefore, increased in states where anaerobic metabolism predominates. Although lactate is not exclusively elevated due to tissue hypoperfusion, any shock state will cause increased lactate levels in the bloodstream. Elevation in serum lactate during shock is thought to be due to tissue hypoperfusion caused by several factors including mitochondrial dysfunction, a hypermetabolic state, as well as macro- and microcirculatory dysfunction. Physicians are utilizing lactate measurements as a diagnostic tool for a variety of disease states including infection, shock, medication toxicity, liver disease, and seizure. Despite extensive research regarding the relationship of sepsis and lactate, evidence that lactate levels alone can predict

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morbidity, mortality, or intensive care unit (ICU) admission remains inconclusive.\textsuperscript{[3-7]} Investigators have shown that the clearance of lactate as an endpoint of resuscitation may be beneficial, as decreased lactate clearance has been found to be associated with increased mortality for patients with sepsis and trauma.\textsuperscript{[1-8-10]} There is also evidence that measurement of serum lactate levels can reveal evidence of occult hypoperfusion in patients with normal vital signs.\textsuperscript{[12,13]} In addition to the hospital setting, Jansen et al.\textsuperscript{14} reported that lactate appears to have potential as a tool in the prehospital setting to predict mortality in patients with abnormal vital signs due to trauma or illness. For that purpose, they found that serum lactate had a better sensitivity than heart rate and/or blood pressure measurements.\textsuperscript{[14]}

There have been numerous reports in the literature revealing the promise of lactate measurement as an adjunct to the evaluation of shock in the setting of trauma. Lactate measurement in trauma is used to increase early recognition of severe injury and occult hypoperfusion in patients in which traumatic shock is not immediately apparent.\textsuperscript{[13,15]} It has also been suggested that elevated lactate levels are associated with increased injury severity and as an indicator of poor prognosis.\textsuperscript{[16]} When trauma patients fail to clear elevated lactate levels, there is a higher risk of inhospital mortality within the first 24 h of presentation.\textsuperscript{[11,17]}

When one considers the utility of lactate measurements as a measure of serious injury for trauma patients, physicians would seemingly benefit from the opportunity to test for this marker at bedside. Previously, for nontrauma patients, researchers have reported on the benefits of point-of-care (POC)-handheld measurement devices in the emergency department (ED), which have been shown to reduce the time to administration of IV contrast, time to receive IV fluids, length of ED stay, and time to clinical decision-making and improve overall patient outcome by treating physiologic deterioration more quickly than traditional laboratory measurements.\textsuperscript{[16-24]} Singer et al.\textsuperscript{25} found that bedside POC lactate measurements in patients with suspected sepsis reduced time to intravenous fluids and antibiotics and were associated with reduced rates of both ICU admission and mortality.\textsuperscript{[19]}

Surprisingly, to date, there is a paucity of literature on the use of POC lactate in the setting of trauma.\textsuperscript{[22,23]} We conducted a prospective observational study to investigate the relationship of POC lactate levels to Injury Severity Score (ISS) and need for hospital admission. We hypothesized the elevated POC lactate levels would be predictive of patients with normal vital signs but who had suffered serious injuries despite apparent hemodynamic stability.

**Methods**

**Study design**

This was a blinded, prospective cohort study of a convenience sample of consenting adult patients with stable vital signs evaluated initially in the ED and meeting our triage criteria for Level II or III team activation [Level 1 highest acuity, Appendix 1]).

**Setting**

This study was conducted at the Christus Spohn-Memorial Hospital in Corpus Christi, Texas (USA). The hospital is affiliated with the Texas A and M University Health Science Center and is a Level II trauma center. The annual ED census is 45,000 patients. The CHRISTUS Health Institutional Review Board approved the study prior to the initiation of patient enrollment and data collection.

**Materials**

Bedside lactate samples were collected during the secondary survey by the patient’s nurse or technician (StatStrip, Nova Biomedical\textsuperscript{19}).

**Population**

Patients meeting triage criteria for Level II or III team activation (Level I highest acuity) with stable vital signs and significant traumatic mechanisms were eligible for inclusion. Criteria were based on guidelines from the National Expert Panel on Field Triage. Patients who were unable to consent, under 18 years of age, in the custody of law enforcement or clinically intoxicated were excluded from the study.

**Study protocol**

The personnel obtaining the level recorded the POC lactate level on a secure document separate from the patient’s medical record. Treatment and disposition decisions were at the discretion of the treating physician who remained blinded to the result of the bedside lactate throughout the ED course of each patient. Clinical data were recorded in a structured fashion.

**Statistical analysis**

Continuous data were reported as mean ± SD and analyzed by Mann–Whitney U-test. Sensitivity, specificity, negative predictive value (NPV), and positive predictive value (PPV) with associated 95% CIs were calculated. An elevated lactate was defined as >2.0 mmol/L. Based on the findings of Lavery et al., for the purposes of our sample size calculation, we assumed the following: 1) a mean venous lactate of 3.3 mmol/L, 2) admitted patients would have elevated lactates in 60% of cases, and 3) patients discharged from the ED would have elevated lactate levels in 30% of cases. To detect a similar difference with 80% power required a sample size of 74 patients. Data were collated and analyzed within Excel for Windows (Microsoft Corporation, Redmond, WA).

**Results**

Ninety-six patients were enrolled in the study group that had a mean age of 41 ± 17 years. Most patients were of Hispanic ethnicity and male. Table 1 summarizes the demographic characteristics of the study group.

The performance characteristics of bedside lactate measurement to dichotomize patients with serious and less injuries were generally poor [Tables 2 and 3]. We did not find a significant
difference between initial mean POC lactate levels (mmol/L) for admitted versus discharged groups (3.71 [95% confidence interval (CI): 3.1–4.4] vs. 3.85 [95% CI: 2.8–4.9]; P = 0.991). Similarly, we did not observe differences in levels for patients with ISS scores ≥9 versus ISS scores <9 groups (3.54 [95% CI: 2.7–4.4] vs. 3.89 [95% CI: 3.1–4.6]; P = 0.605). While we found reasonably good sensitivity of early bedside lactate to identify patients with serious injury, specificity was quite poor. This was true respectively to predict the need for hospitalization (sensitivity = 77.6% [64%–87%]; specificity = 26.3% [13.4%–43.1%]; NPV = 43.5% [27.3%–61.1%]; and PPV = 61.6% [55.9%–67%] and to identify those patients with ISS scores ≥9 (sensitivity = 76.5% [58.8%–89.2%]; specificity = 24.2% [14.2%–36.7%]; NPV = 65.2 [46.9%–79.9%]; and PPV = 35.6% [30.5%–41.1%]).

**DISCUSSION**

Lactate level has been studied extensively in a number of disease processes,[13–7] and the utility of serum lactate measurement of tissue perfusion for the evaluation of trauma patients has been relatively well established in the literature for nearly two decades.[24] In 1999, Blow et al. for their pilot study included patients with an ISS >20 and a stay in the ICU >48 h; the prospective arm of the study used a 24-h stay in the ICU and ISS >20 for inclusion in the study, which showed increases in mortality with lactate elevation. They also found that the early detection and rapid correction of lactic acidosis were associated with improved survival, decreased incidence of pulmonary complications, and reduced occurrence of multisystem organ failure.[13] Other papers also evaluated severely injured patients, the definition of which varied from those with ISS ≥15 or ICU stay, and each found that lactate was significantly higher in nonsurvivors than survivors.[25,26] Further, Baxter et al. conducted a large systematic review that further supported the utility of lactate measurements in the care of trauma patients.[24] They evaluated 21 studies and found that there was an association between elevated lactate and risk of mortality.

Our study excluded patients with high probability for admission secondary to abnormal presenting physiological or injury mechanism associated with high mortality (our Level 1 trauma activation), in view of the fact that those patients are readily identified as a priority to go to a major trauma center without adjunctive POC testing. Rather, we utilized a protocol with a single, early POC lactate measurement for low-to-moderate risk trauma patients to evaluate its potential utility as an early gauge of injury severity/hypoperfusion with the potential to eventually assist emergency medical service (EMS) field triage of patients toward facilities requiring the resources of higher level trauma center care.[27] While we found relatively good sensitivity of elevated lactate for predicting hospitalization (77.6%) and for ISS score ≥9 76.5%, we do not believe that our data support the use of this modality alone for early hypoperfusion risk assessment for this subset of trauma patients.

Our findings support questions raised by other studies regarding the overall performance characteristics of lactate for trauma patients, including the investigation of Vohra and Paxton who found that elevated serum lactate levels only predicted hospital admission with 59.8% sensitivity and 54.2% specificity.[23] Further, they concluded that abnormal lactate did not change management or discharge rates in those with traumatic injury on computed tomography of the chest, abdomen, or pelvis.[26] In the aforementioned Baxter et al.[24] systematic review, the utility of lactate to predict mortality in unselected trauma patients was investigated by six studies.[11,29–33] Two studies revealed sensitivities of 85% and 95% but poor specificities of 38% and 43%, respectively, with a lactate threshold of >2.0 or ≥2.0 mmol/L.[29,32]

Recently, investigators have investigated POC lactate performance in the setting of trauma.[22,23] Bouzat et al. conducted a prospective, observational study of a cohort of 120 adult, normotensive trauma patients (systolic blood pressure of 90 mmHg or higher) for whom beside capillary lactate

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**Table 1: Patient demographics**

| Lactate ≤2 | Lactate >2 |
|------------|------------|
| Number of patients | 23 | 73 |
| Age, median (IQR) | 44 (30-63) | 34 (27-48) |
| Females, n (%) | 7 (30) | 18 (25) |
| Race, n (%) | | |
| Asian | 1 (4) | 0 |
| Black | 0 | 2 (3) |
| Hispanic | 10 (43) | 45 (62) |
| White | 12 (52) | 26 (36) |
| IQR: Interquartile range |

**Table 2: Initial lactate levels (mmol/L)**

| ISS <9 (95% CI) | ISS ≥9 (95% CI) | P |
|----------------|----------------|---|
| Initial lactate (mean) | 3.89 (3.1-4.6) | 3.54 (2.7-4.4) | 0.605 |
| Discharged (95% CI) | 3.85 (2.8-4.9) | 3.71 (3.1-4.4) | 0.991 |

**Table 3: Predictive value of elevated initial lactate levels**

| Lactate ≤2 | Lactate >2 | Sensitivity (95% CI) | Specificity (95% CI) | NPV (95% CI) | PPV (95% CI) |
|------------|------------|---------------------|---------------------|-------------|-------------|
| Number of patients | 23 | 73 | | | |
| ISS<9 (<9) | 8 (15) | 26 (47) | 76.5 (58.8-89.2) | 24.2 (14.2-36.7) | 65.2 (46.9-79.9) | 35.6 (30.5-41.1) |
| Admitted (DC’d) | 13 (10) | 45 (28) | 77.6 (64.7-87.5) | 26.3 (13.4-43.1) | 43.5 (27.3-61.1) | 61.6 (55.9-67.0) |

ISS: Injury Severity Score, CI: Confidence interval, NPV: Negative predictive value, PPV: Positive predictive value, DC’d: Discharged
measurement was obtained. The primary outcome parameter of their study was defined as significant transfusion within the first 48 h of evaluation. Similar to our results for patients with lower risk of hypoperfusion, they found that while elevated POC lactate levels were associated with worse outcome, the specificity was poor. Further, Bouzat et al. described very large differences between bedside capillary lactate and those measured from blood. The American College of Surgeons has a goal to limit field undertriage to <5% for severely injured patients away from a trauma center. Within our study data, a threshold lactate level of 2 as a predictor for hospital admission would have potentially undertriaged 13 (56%) patients who were ultimately admitted. The ISS score, based on the nature of the calculation, is heterogenetic with the potential of three different systems contributing to the total score. We utilized an ISS threshold of 9 in an attempt to limit undertriage since mortality in ISS from 1 to 8 is typically 1%. Within our study group, eight patients with lactates <2 had an ISS >9 (35% undertriage). Other literature mirrors the findings of Guyette et al. who found that 8% of trauma patients with a normal POC lactate had mortality, emergent surgery, or multiorgan dysfunction syndrome. Thus, although more investigation is warranted, our study adds to a growing body of data that calls into question the utility of POC lactate for early assessment of hypoperfusion in trauma patients.

Limitations and future questions

Our study has several limitations that warrant discussion. First of all, we did not control for the amount of time that had passed between time of initial presentation and bedside lactate measurement, nor did we record the amount of crystalloid or blood product administration that the patient received from EMS and in the ED prior to lactate measurement. While bedside measurements were typically taken early in the ED course, we cannot account for how this methodological issue may have impacted our results. Due to concerns regarding consent, we did not include patients who were clinically intoxicated. This represents another key segment of the trauma population for which further study is warranted. Finally, with respect to study limitations, our study group did not include Level I trauma team activations (highest acuity). We excluded this segment of the trauma population as our goal was to evaluate the utility of POC lactate for a cohort of patients where trauma triage criteria defined risk of injury as moderate to low.

Larger, multicenter studies are warranted to further evaluate the utility of POC lactate for injured patients. We believe that such study scale is necessary to provide tighter CIs for the operating characteristics of the test. In addition, a study of greater size would allow for analysis of POC lactate utility across a more broad array of ISS score subgroups as well as key population segments that we excluded, such as those with alcohol intoxication.

Conclusions

Most studies suggest that lactate is a useful marker of traumatic injury and efficacy of resuscitation. However, we did not find that a single POC lactate measurement was predictive of ISS >9 and the need for admission in our cohort of low-to-moderate risk patients evaluated in the ED.

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Conflicts of interest
There are no conflicts of interest.

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Appendix 1: Trauma level activations criteria

Level I Trauma Activation Criteria

a. Traumatic arrests
b. Sufficient facial trauma as to compromise the airway
c. Signs of hemodynamic instability (age appropriate):
   1. Respiratory rate < 10 or > 30
   2. Systolic blood pressure < 90 mmHg
   3. Documented head injury and a GCS < 12
   4. Intubated trauma patients.
d. Penetrating injuries to the head, neck, torso, or to extremities with vascular insults, i.e. pulse deficits
e. Any trauma patient who presents with acute limb paralysis
f. Two or more proximal long-bone fractures
g. Amputation proximal to the wrist or ankle
h. Burns > 15% (second and/or third degree) or with respiratory distress, inhalation injury
i. Transfer patients receiving blood to maintain vital signs
j. Pelvic instability with hypotension
k. Pregnant trauma patients of 20-week gestation or greater.

Level II Trauma Activation Criteria

a. Pelvic instability
b. Flail chest
c. Open or depressed skull fracture
d. Ejection from the vehicle
e. Falls greater than 20 feet for adult, 10 feet for children
f. Acetabular fracture

Level III Trauma Activation Criteria

a. Loss of consciousness at the scene with spontaneous return in a patient on anticoagulation
b. Death in the same compartment
c. Auto-pedestrian/bicycle
d. Motorcycle collision
e. Single system injuries
f. Transfer of injured patients into facility for surgical specialty care
g. Admission to nonsurgical service with surgical consultation