Journal of Critical Care 36 (2016) 69–75

Contents lists available at ScienceDirect

Journal of Critical Care

journal homepage: www.jccjournal.org

Cost-effectiveness analysis of early point-of-care lactate testing in the emergency department☆,☆☆

Michael J. Ward, MD, MBA [a,*], Wesley H. Self, MD, MPH [b], Adam Singer, MD [c], Danielle Lazar, MPH [d], Jesse M. Pines, MD, MBA, MSCE [e,f]

[a] Department of Emergency Medicine, Vanderbilt University School of Medicine, 1313 21st Ave South, Nashville, TN 37232
[b] Department of Emergency Medicine, Vanderbilt University School of Medicine, Nashville, TN
[c] Department of Emergency Medicine, Stony Brook Medicine, Stony Brook, NY
[d] Office for Clinical Practice Innovation, George Washington University School of Medicine and Health Sciences, Washington, DC
[e] Department of Emergency Medicine, George Washington University School of Medicine and Health Sciences, Washington, DC
[f] Department of Health Policy, George Washington University School of Medicine and Health Sciences, Washington, DC

ARTICLE INFO

Available online xxxx
Keywords:
Economic analysis
Sepsis
Resuscitation
Emergency department

ABSTRACT

Purpose: To determine the cost-effectiveness of implementing a point-of-care (POC) Lactate Program in the emergency department (ED) for patients with suspected sepsis to identify patients who can benefit from early resuscitation.
Materials and methods: We constructed a cost-effectiveness model to examine an ED with 30 000 patients annually. We evaluated a POC lactate program screening patients with suspected sepsis for an elevated lactate ≥4 mmol/L. Those with elevated lactate levels are resuscitated and their lactate clearance is evaluated by serial POC lactate measurements. The POC Lactate Program was compared with a Usual Care Strategy in which all patients with sepsis and an elevated lactate are admitted to the intensive care unit. Costs were estimated from the 2014 Medicare Inpatient and National Physician Fee schedules, and hospital and industry estimates.
Results: In the base-case, the POC Lactate Program cost $39.53/patient whereas the Usual Care Strategy cost $33.20/patient. The screened patients in the POC arm resulted in 1.07 quality-adjusted life years for an incremental cost-effectiveness ratio of $31 590 per quality-adjusted life year gained, well below accepted willingness-to-pay-thresholds.
Conclusions: Implementing a POC Lactate Program for screening ED patients with suspected sepsis is a cost-effective intervention to identify patients responsive to early resuscitation.

1. Introduction

Sepsis is a common, resource-intensive condition that frequently requires admission to the hospital [1]. There were more than 500 000 cases treated annually in US hospitals [1], accounting for nearly 1 in 10 of all admissions to intensive care units (ICU) [1]. In 2013, sepsis was the most expensive condition treated in US hospitals with an estimated $23.7 billion in costs representing 3.2% of all hospital stays [2]. Between 1997 and 2011, costs have increased by an average of 11.5% annually and mean cost per hospital stay has increased more than 75% to $18 600 per stay [3].

The ED plays a central role in the recognition, initial resuscitation, and disposition of patients with sepsis [4]. Over the past decade, the ED treatment for sepsis has changed dramatically, with greater focus on early identification and early treatment with antibiotics, aggressive fluid resuscitation, use of vasopressors, and frequent re-evaluation.

Because of the time-sensitive nature of sepsis, early recognition is central to effective resuscitation. While some cases of sepsis are clinically apparent upon ED arrival, others cases are clinically occult and associated with delayed recognition [7]. One of the key ways to identify patients with occult sepsis is the use of blood lactate testing [8-10]. A high blood lactate can indicate tissue hypoperfusion, and the need for more urgent interventions [8-10]. Further, serial lactate testing can risk-stratify patients based upon an initial response to resuscitation efforts as measured by a patient's lactate clearance [11-14]. Lactate clearance is defined as the percent decrease in lactate between initial and subsequent measures [13]. For patients with sepsis and septic shock with adequate lactate clearance, decreases in in-hospital, 28-day, and 30-day mortality of between 10 and 40% have been reported [12-14]. While the frequency lactate clearance as a strategy to determine

☆ Conflict of Interest: Abbott Point of Care provided a research grant to conduct this analysis; however, Abbott Point of Care was not involved in the preparation, analysis, or writing of this manuscript. Adam Singer is a paid speaker for Abbott Point of Care.
☆☆ Meeting Presentations: None.
* Corresponding author. Tel.: +1 615 936 8379; fax: +1 615 936 3754.
E-mail address: michael.j.ward@vanderbilt.edu (M.J. Ward).

http://dx.doi.org/10.1016/j.jcrc.2016.06.031
0883-9441/

location of care once the patient is hospitalized is unknown, its use provides a rationale based upon patient mortality, to treat patients in the ICU versus a medical floor bed.

A key practical limitation to the implementation and subsequent use of lactate clearance in the ED is the ability to conduct rapid lactate testing that allows for serial testing. If testing turnaround time is too long, multiple measurements of serum lactate levels cannot be completed before the patient leaves the ED. However, given the advancement of point-of-care (POC) laboratory testing technology (i.e., testing performed in close proximity to the patient), more rapid measurements of serum lactate levels can occur [15]. As a result, POC lactate testing can facilitate early detection of elevated lactate and may hasten treatment of sepsis [15,16]. POC testing also facilitates the use of serial testing by providing near real-time data on lactate clearance. POC lactate measurements offer two potential benefits for the management of sepsis in the ED: (1) earlier recognition of hypoperfusion, leading to more timely treatment and improved patient outcomes; and (2) rapid serial measurements demonstrating lactate clearance, facilitating de-escalation of critical care in the ED and avoidance of an otherwise unnecessary ICU admission.

Given the cost of hospitalized sepsis care in the US, we sought to examine whether the rapid identification of occult hypoperfusion in patients presenting to the ED with suspected sepsis would be a cost-effective intervention.

2. Methods

2.1. Overview

We used computer-based modeling to examine the cost-effectiveness of implementing a POC serial lactate screening program for patients with suspected sepsis in the ED. Our model examined the cost-effectiveness of strategies to evaluate patients presenting to the ED with systematic inflammatory response syndrome (SIRS) and the clinical suspicion for an infectious etiology (suspected sepsis) [17-20]. Although the use of SIRS can be nonspecific for sepsis, the new definition of sepsis has not made its way into existing ED research of septic patients [6]. Thus, our best estimates of the septic population come from prior definitions comprising the older definition of sepsis incorporating SIRS. Our average patient was assumed to be 76 years-old because that is the mean age of patients presenting to the ED with severe sepsis [15,21,22]. Our model assumed that the ED treats an average of 30 000 patients per year. We evaluated two possible scenarios: a point-of-care lactate program (POC Lactate Program) that measures lactate with a bedside device in the ED and a Usual Care Strategy in which a single lactate level was measured on ED patients in the hospital laboratory.

In the POC strategy, patients with sepsis and a lactate ≥4 mmol/L are resuscitated with a subsequent lactate measured to evaluate lactate clearance. We selected a threshold of ≥4 mmol/L as a meaningful threshold which could affect clinical-decision-making of the emergency physician due to the much higher probability of progression to septic shock [23], and likelihood of death [7,24,25]. Those with adequate lactate clearance are admitted to a medical floor and the remaining patients are admitted to the intensive care unit (ICU).

Alternatively, patients in the Usual Care Strategy were assumed to have no POC lactate testing and traditional laboratory lactates were obtained within 3 hours as recommended by the Surviving Sepsis Guidelines [5]. We assumed no serial lactate testing in the Usual Care strategy due to the long turn-around time for results using standard laboratory testing. All patients in the Usual Care Strategy with sepsis and a lactate greater than 4 mmol/L were assumed to be admitted to an ICU. We dichotomized clinical outcomes into those who survived and those who died based on epidemiological data for these populations.

2.1.1. Model structure

We constructed our models using software (TreeAge 2015, Williamstown, MA) commonly used to evaluate decision models and perform sensitivity analyses (Fig. 1). We constructed a cost-effectiveness model in which long-term patient outcomes differed between the POC Lactate Program and Usual Care Strategy. The models estimated costs, quality-adjusted life years (QALYs), and incremental cost-effectiveness ratios (ICERs). A QALY is a year of life lived in perfect health [26]. An ICER is used to estimate the cost necessary to achieve one additional QALY. The standard threshold, considered the maximum dollar amount society should pay for a single QALY, was conservatively assumed to be $50 000 in this study. Recent papers suggest potentially higher thresholds (ie, $100 000 to $200 000/QALY) [27], which were evaluated in sensitivity analyses. This study was approved as exempt from institutional review board review as non-human subjects research.

3. Model parameters/input parameters

3.1. Clinical probabilities

Clinical probabilities were obtained from published, peer-reviewed research (Table 1). When available, multiple studies were combined to determine mean probabilities for particular events and their accompanying ranges. If no data were available, we used expert opinion from the investigators for the base-case and range values. In the base-case scenario, we assumed that among our annual ED patient volume, 17.8% of ED patients had SIRS [28], and 0.7% of all ED patients had sepsis [4]. Further, we assumed that among these patients with sepsis, 21% had an initial lactate ≥4 mmol/L [7,15,29]. Among the patients in the POC Lactate Program with an elevated lactate who were resuscitated and had a second lactate checked in the ED, 68% of patients would demonstrate an adequate lactate clearance of at least 10%, with an associated in-hospital mortality of 19.2% [12-14,30]. On the other hand, patients with an inadequate lactate clearance had an in-hospital mortality rate of 61.4% [12-14,30]. For patients in the Usual Care Strategy, we assumed that the overall mortality was a weighted average of those with both adequate and inadequate lactate clearance. Thus, for both strategies in the decision model, if the ED population had an increased prevalence of adequate lactate clearance, the collective population would have a lower mortality rate. Further, we estimated that earlier recognition of occult sepsis and the accompanying resuscitation facilitated by the POC Lactate Program would confer an in-hospital mortality benefit above and beyond typical ED resuscitation of 2% combined for both the responders and non-responders resuscitated in the ED. This estimate is conservative compared with the 13% absolute reduction in mortality found by Singer et al [15], and is explored by sensitivity analyses in the model.

For the Usual Care Strategy, we assumed that a patient's ability to clear lactate was unknown in the ED because only a single value was obtained to guide initial resuscitative efforts. We assumed that only this single lactate value would influence the care they received in the ED and the disposition location (ie, medical floor versus ICU).

3.2. Costs

We modeled three sources of costs in our decision tree (Table 2): (1) physician costs; (2) hospital costs; and (3) fixed and variable costs of the iSTAT laboratory equipment commonly used for POC testing. We used 2014 Centers for Medicare and Medicaid data for diagnosis related groups (DRGs) and relative value units as surrogates for charges [26]. Hospital charges were calculated using DRGs 871 and 872 (septicemia or severe sepsis with major critical care and with/without mechanical ventilation) from the Centers for Medicare & Medicaid Services inpatient files [31]. Consistent with prior analyses, we assumed that deaths would result in charges that were two standard deviations beyond the mean charges for DRG 871, and 872 [32]. Professional charges were based on the 2014 National Physician Fee Schedule for outpatient treatment as well as the mean length of stay for inpatient treatment [33]. Current Procedural Terminology code 99 222 (initial hospital