Academic Journal of
Pediatrics & Neonatology
ISSN 2474-7521

Juniper Publishers
key to the Researchers

Review Article
Volume 13 Issue 1 - October 2023
DOI: 10.19080/AJPN.2023.13.555907

Acad J Ped Neonatol
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Predictive Value of Elevated Lactate and Normalization Time in Sick Newborns in a Tertiary NICU: A Retrospective Study

Akpoembele D Madise-Wobo[1,2], Ewa Sucha[2,3], Nick Barrowman[2,3] and Nicole G Rouvinez Bouali[1,2]

[1]*Department of Pediatrics, Children's Hospital of Eastern Ontario, Ottawa Ontario, Canada*

[2]*University of Ottawa, Canada*

[3]*CHEO Research Institute, Ottawa, Ontario, Canada*

Submission: September 23, 2023; **Published:** October 10, 2023

***Corresponding author:** Akpoembele D Madise-Wobo, Department of Pediatrics, Children's Hospital of Eastern Ontario, Ottawa Ontario, University of Ottawa, Canada

Abstract

Objective: To investigate if a single value of elevated blood lactate and normalization time predict immediate adverse outcomes in sick late preterm and term babies.

Method: Retrospective review of neonates with elevated blood lactate admitted between October 1, 2017, and March 31, 2020. We evaluated 174 babies with 913 lactate measurements in the first three days of admission. Individual trajectories of serum lactate were plotted. A linear model with patient-specific random slopes and random intercepts was used to estimate each patient's time to normalization of lactate. Meantime to normalization relative to the outcome amongst all the cohorts was derived. Receiver Operator Curve (ROC) was produced to examine the sensitivity and specificity of different lactate thresholds.

Results: The most common etiology of elevated lactate in the cohort was HIE followed by congenital heart disease with a prevalence of 30.5% and 17.8% respectively. Of the 174 patients, there were 15 mortalities (8.6%) and 19 morbidities (11%). Lactate value >7.5mmol/L at 48 hours of admission was a predictor of adverse outcomes with a sensitivity and specificity of 54.3 and 64.2 respectively with an AUC of 61% (CI 49-72). Amongst the subgroup with HIE, the mean time to normalization increased with the severity of HIE (p <0.001). Mean time to normalization and the adverse outcome was not significant in the other etiologies.

Conclusion: A single value of elevated lactate was an unreliable predictor of adverse outcomes in sick neonates with varying etiologies. Time to normalization was predictive of outcome only in neonates with HIE.

Keywords: Neonates; Lactate; HIE

Abbreviations: ROC: Receiver Operator Curve; HIE: Hypoxic-Ischemic Encephalopathy; NICU: Neonatal Intensive Care Unit; CHEO: Children's Hospital of Eastern Ontario; CHEO-RI REB: CHEO-Research Institute Research Ethics Board; IMD: Inherited Metabolic Diseases; LBW: Low Birth Weight

Introduction

Blood lactate is a byproduct of anaerobic respiration. Sustained lactate levels may result from dysfunction in the normal physiologic process involved in its production, persistence of cellular hypoxia or delayed clearance [1]. Human studies have suggested that elevated lactate is associated with mortality and morbidities [2-6]. Researchers have investigated blood lactate in different clinical settings amongst sick neonates and reported values predictive of adverse effects in those subjects. For example, blood lactate was studied in ventilated preterm infants with central arterial lines and the authors reported value of more than 2.5mmol/l was predictive of adverse outcomes [7]. In another study amongst low birth weight (LBW) preterm infants, the most informative cut-off value for predicting mortality was 6.9 mmol/l with a sensitivity and specificity of 77% and 78% respectively [8]. Studies on babies with congenital heart disease who underwent surgical correction of cardiac defects showed that a single value above 6mml/L had poor sensitivity for adverse outcomes, but

rising values of 0.75mmol/l per hour or more were associated with the poor outcome with increased sensitivity, specificity and positive predictive value [9]. Amongst studies in asphyxiated babies with hypoxic-ischemic encephalopathy (HIE), values reportedly associated with adverse outcomes were 7.5 mmol/l [10] and 8.6 mmol/l [11]. In all, elevated levels of blood lactate indicated poor outcomes such as death. But there is no consensus on the value related to poor outcomes in neonates because of variations in study subjects and methods. Most studies investigated outcomes in a single etiology. For example, most reports in the literature were on asphyxia or HIE, ventilated sick preterm, sepsis and post-surgical correction in cardiac anomalies. Thus, the results available are not generalizable on all sick neonates.

In adult patients with severe illness and sepsis, lactate clearance and time to normalization have been shown to impact outcome [12,13]. For example, in the report by Ryoo SM et al; [12] the rate of lactate normalization with 6 and 24 hours after a bundled treatment in adults with septic shock was investigated. It was shown that the rate of lactate normalization within 6 and 24 hours was significantly higher in the survivor groups compared to those who died. Multivariate analysis showed that both 6- and 24-hour lactate normalization were independent predictors (OR 0.58, 95% CI 0.45-0.75, p<0.001 and OR 0.42, 95% CI 0.33-0.54 p<0.001 respectively) of the outcome [12]. Additionally, in five randomized control trials involving adult patients with severe sepsis, a significant reduction in poor outcomes were observed in lactate-guided resuscitation compared to that without lactate monitoring (RR 0.67;95%CI, 0.53-0.84) [14-18]. Compared to the adult population, time to normalization and its impact on outcome has not been defined in neonates. Whether the same impact will be seen in the neonate is not known.

The goal of the current study was to identify if a single value of elevated blood lactate measured in sick late preterm and term babies admitted to a tertiary neonatal intensive care unit (NICU) and time to normalization can predict adverse outcomes and guide treatment amongst sick neonates irrespective of the etiology.

Methods

This was a retrospective chart review conducted at the neonatal intensive care unit (NICU) of the Children's Hospital of Eastern Ontario (CHEO). This is a 20-bed level three NICU that receives referrals and caters to critically sick infants in the region with an in-house neonatal transport team. The participants were neonates admitted to CHEO-NICU between October 1, 2017, and March 31, 2020, who were ≥ 35 weeks' gestation and had at least one value of blood lactate obtained. These were neonates less than four days old with initial serum lactate of more than 2mmol/L. At CHEO-NICU, sick babies have lactate measurements as one of their diagnostic workups depending on the clinical scenario and at the discretion of the attending neonatologist or his/her delegate. Babies with high lactate (≥ 2mmol/l) have serial lactate measurements until the results are normal. For babies with hypoxic-ischemic encephalopathy (HIE) on cooling protocol, serial measurements are obtained for the duration of therapeutic hypothermia (72 hours).

The objectives of this study were to document: the etiologies of elevated lactate amongst neonates admitted to a tertiary NICU; if a single value of elevated blood lactate was predictive of adverse outcome irrespective of the etiology; and the association between each patient's estimated time to normalization of lactate and adverse hospital outcome relative to the etiology of elevated lactate. The primary outcome was adverse hospital outcome defined as death or any two of prolonged hospitalization (more than three weeks), mechanical ventilation (more than one week), inability to feed by mouth (more than two weeks) and recurring seizures requiring treatment. Babies with incomplete data were excluded. We choose these outcomes based on commonly reported outcomes of infants with HIE in the literature [19,20].

We performed a chart review of all babies with elevated lactate available in the EPIC Data Warehouse, as well as data available on EPIC but not in the Data warehouse. Serial lactate values in the first 72 hours of admission were documented. Additionally, the etiology of high lactate, time to normalization of lactate and the relationship between time to normalization of lactate and adverse outcome were documented. In the subgroup of patients with HIE, the degree of severity of HIE according to clinical Sarnat and Sarnat stage was documented as well as the relationship between blood lactate and severity of HIE. Lactate analysis was performed with a commercial Radiometer blood gas analyzer by Radiometer®. The sample was obtained from arterial or capillary sampling. Previous studies have shown satisfactory agreement comparing capillary or venous lactate levels with arterial [21,22].

Ethical approval was obtained from CHEO-Research Institute Research Ethics Board (CHEO-RI REB). Each patient was recorded with a single, non-identifiable research number so that personal identifiers were stripped from any analysis.

Data analysis

Descriptive statistics were used to summarize the demographic and clinical characteristics of the infants. Individual trajectories of serum lactate were plotted. A linear model with patient-specific random slopes and random intercepts was used to estimate each patient's time to normalization of lactate. Since lactate measurements under 2mmol/L are considered normal, time to normalization for patient i was estimated by $(2- \alpha i)/ \beta i$ where αi is the estimated intercept for patient i and βi is their estimated slope. Next, a logistic regression model of the adverse outcome on each patient's time to normalization was carried out. For the evaluation of elevated lactate on adverse outcomes, Receiver Operator Curve (ROC) was produced to examine the sensitivity and specificity of different thresholds of lactate at different time intervals relative to the outcome amongst babies with HIE and the other etiologies. Ordinal logistic regression was used to examine the prediction of the severity of HIE (none, mild, moderate, severe) by lactate level. p-values <0.05 was statistically significant.

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Results

Study Subjects

A total of 352 neonates with 2380 lactate measurements >2mmol/L were identified in the study period. Of these, 178 patients (1467 lactate measurements) with gestational age less than 35 weeks and those who were more than 4 days of age at admission were excluded as per study protocol. We analyzed the result for 174 babies with 913 lactate measurements who met the study criteria. They were 103 males with a male-female ratio of 1.5:1. The mean birthweight and gestational age were 2.9±0.49kg and 39±1.4 weeks respectively.

Etiology of Elevated Lactate

Table one highlights the etiology of elevated lactate. We categorized this into HIE, perinatal depression, congenital heart disease, gut pathology, respiratory and others as shown in Table 1. HIE accounted for the most common etiology followed by those with congenital heart disease and respiratory pathology.

Table 1: Etiology of elevated lactate.

Variable	n=174 (%)
HIE Mild Moderate Severe	53 (30.5) 9(5.2) 29(16.7) 15(8.6)
Perinatal Depression without HIE	14 (8)
Congenital heart disease	31 (17.8)
Gut pathology (gastroschisis, omphalocele, intestinal atresia)	14 (8)
Respiratory: RDS, TTN, MAS, pneumothoraces, PPHN	26 (15)
Hypoglycemia (IUGR, Hyperinsulinism)	9 (5.2)
Anemia from ABO incompatibility, extra-axial hemorrhages	5 (2.9)
Others*	22 (12.6)

*Others: seizures (NYD), multiple congenital disorders (NYD), CNS malformations, sepsis, stroke, and biventricular hypertrophy (NYD).

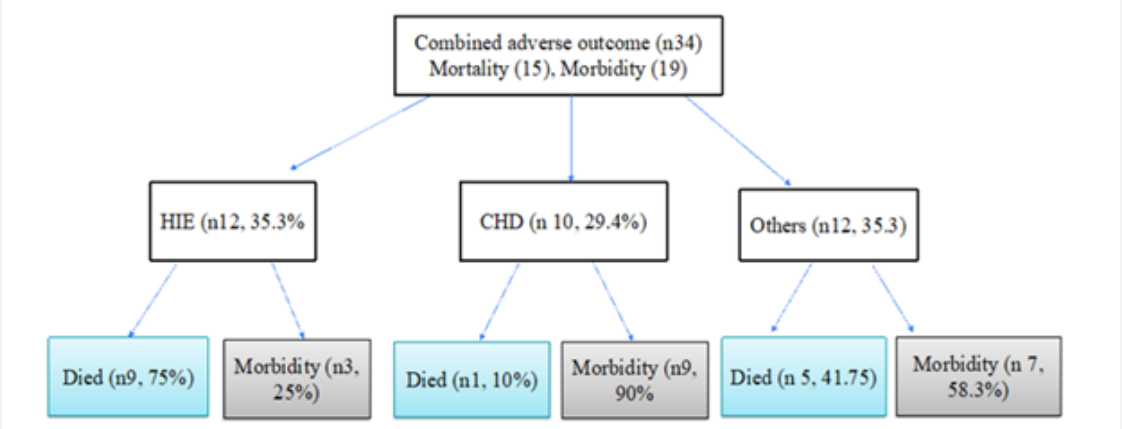

Figure 1: Distribution of adverse outcome based on etiology.

Outcome

Of the 174 patients, there were 15 mortalities (8.6%) and 19 (11%) morbidities (> 2 adverse outcomes). In total, there were 34/174 (19.6%) patients with adverse outcomes. Figure 1 illustrate the distribution of adverse outcome relative to etiology. Of those with poor outcomes, the subgroup with HIE was the most prevalent. The relationship between a single elevated lactate and adverse outcome irrespective of the etiology was investigated at various time intervals; 8, 12, 24 and 48 hours. The value and time interval with the highest sensitivity and specificity was >7.5mmol/l by 48 hours. This is depicted in the graph in Figure 2. The sensitivity and specificity were 54.3 and 64.2 respectively with an AUC: of 61% (CI 49-72).

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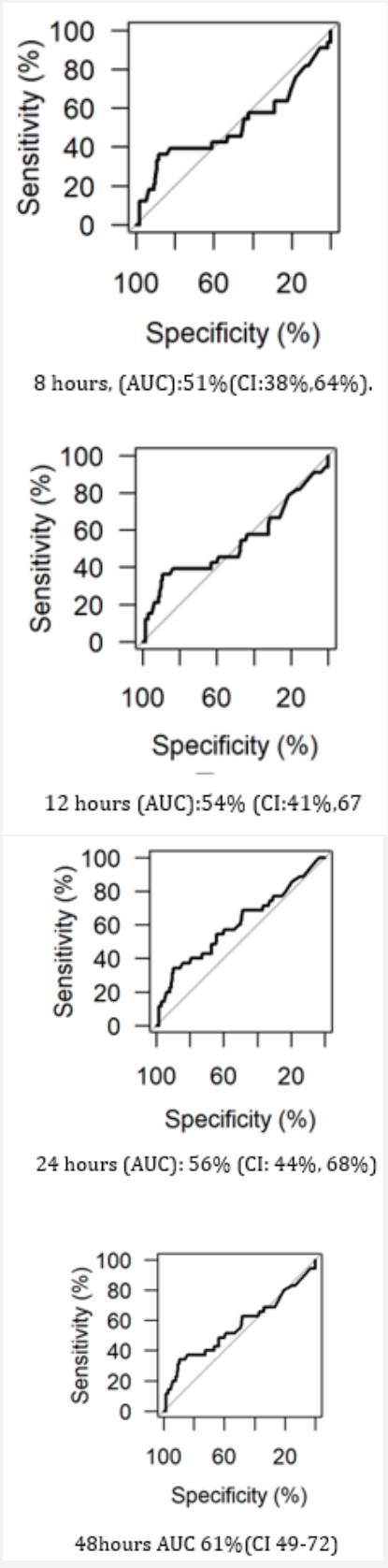

Figure 2: Relationship between single lactate measurement and adverse outcome at differential times (hours).

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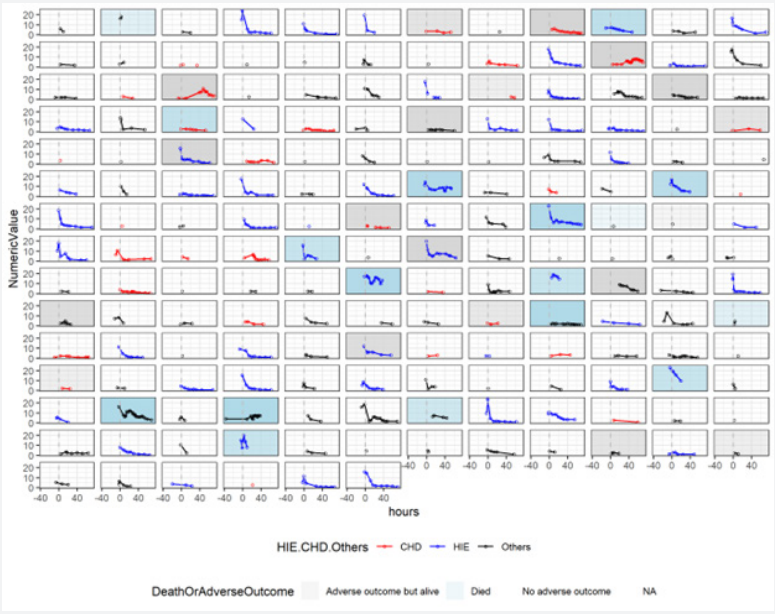

Figure 3: Observed time to normalization and adverse hospital outcome in the study subjects. The X-axis represents numerical lactate values while the y-axis was time intervals. The different colour codes represent the etiology and outcome subgroups.

Mean Time to Normalization and Adverse Outcome

A linear model with patient-specific random slopes and intercepts was used to observe each patient's time to normalization. This is depicted in Figure 3. Given all patients were referred from other centers, some had lactate measurements before arrival. These were also captured in random slopes when estimating the meantime to normalization for each patient. The lactate values in front of the vertical line in each graph represent lactate values before arrival at CHEO. For ease of representation, we summarized the aetiologies into three major subgroups, HIE with perinatal depression, congenital heart disease and others.

The mean time (in hours) to normalization relative to the adverse outcome was estimated on all subjects. Amongst the subgroup with HIE and perinatal depression, the mean time to normalization increased with the severity of HIE ($p < 0.001$) as shown in Table 2. The odds of adverse outcome increased almost five times for every 12 hours increase in time to normalization of lactate {OR 4.83 (95%CI 2.19-16.36) p 0.002}. The mean time to normalization was 39.0±19.5 hours, and 23.8±5.7 hours for respiratory and gastrointestinal pathologies respectively. Mean time to normalization and the adverse outcome was not significant in the other etiologies.

Table 2: Estimated meantime (hours) to normalization according to the severity of HIE.

	Mean (SD)	p-value[1]
HIE group		<.001*
Severe (n=15)	68.7 (34.8)	
Moderate (n=29)	32.9 (17.4)	
Mild (n=9)	29.3 (9.2)	
Perinatal depression (n=14)	34.1 (11.9)	

Analyzed with ANOVA F-Test

Discussion

The current study investigated the immediate outcome of elevated lactate in sick late preterm and term neonates admitted to a level three neonatal intensive care unit. We demonstrated that more than a single value, the persistence of and time to normalization of lactate may be used as a surrogate of adverse outcomes in neonates with HIE. However, it has limited usefulness for clinical guidance when the etiology is mixed.

In the literature, many reports on elevated lactate in the newborn are amongst subjects with asphyxia and or HIE. In older

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children and adult series, reports on sepsis and septic shock are prevalent. Our result showed that HIE was the most common cause of elevated lactate followed by cardiac diseases. This was not surprising given the pathophysiologic mechanism in both clinical conditions. Surprisingly, there was no confirmed metabolic condition and .and only two cases of culture-proven sepsis in our study population. Overall, specific inherited metabolic diseases (IMD) are not common [23]. This may explain the absence of confirmed IMD in our cohort. We defined neonatal sepsis based on positive blood culture. Hence, we could not exclude culture-negative sepsis or non-bacterial causes of infection.

Concerning the predictive effect of elevated lactate for adverse outcomes, a value of 7.5mmol/L after 48 hours of admission was predictive of adverse outcomes with a sensitivity and specificity of 54.3 and 64.2 respectively and an area under the curve of 61%. Unfortunately, the sensitivity and specificity were low; this was the best we could get after looking at various values and time intervals. The inability to identify a single elevated lactate value and time of peak elevation with strong sensitivity and specificity may be because of the heterogenous disease entities and underlying pathophysiologic process. For example, among the subjects with cardiac anomalies, we observed that the trajectory of lactate was unpredictable with swinging values. These were patients awaiting surgical intervention. Whether this impacted hemodynamics and perfusion is not immediately clear. In contrast, those with HIE had more linear lactate values with the highest numbers at admission followed by a steady decline with ongoing treatment. Another plausible explanation may be because of the smaller number of subjects in the other etiologies. At the core of this research was to investigate if a single value was predictive of adverse outcomes irrespective of the etiology, hence we did not analyze peak lactate value amongst individual etiologies. Overall, albeit a poor predictor for adverse outcomes in all sick neonates, one is tempted to imply that a lactate value of more than 7.5mmol/L after 48 hours of admission has implications for mortality and morbidities in sick neonates.

It is difficult to compare results from the current study with previous reports for the following reasons. First, the current study investigated elevated lactate in all sick late preterm and term infants with varying etiologies. On the other hand, most of the reports in the literature are on a single etiology. Furthermore, our outcome measures were different. Many reports are on mortality and long-term neurodevelopmental impact while we looked at mortality and other morbidities before discharge. For example, Polackova et al. [24] in their study on the relationship between persistently elevated lactate and outcome in neonates with HIE, the outcome variable was psychomotor development at 24 months. Thus, comparing the results herein documented with others was difficult. That said, we have shown that elevated lactate has a poor discriminative power for immediate adverse outcomes in a heterogenous group of sick neonates. The different pathophysiological mechanisms underlying persistent lactate value may have played a role in this.

More than a single value, time to normalization of lactate has been demonstrated to impact the short-term outcome in adults and older children in intensive care units. To the best of the authors' knowledge, this is the first report on the time to normalization of blood lactate and its impact on short-term outcomes in sick neonates with diverse etiologies. In the index study, the time to normalization was higher amongst infants with severe HIE with an increased risk of morbidity and mortality amongst those with a longer time to normalization. There were five times increased risks of a poor outcome for every 12 hours increase in time to normalization. However, we did not demonstrate a similar trend in the other etiology subgroup with an insignificant difference in the time to normalization between those with and without adverse outcomes. Importantly, for most of the other etiology subgroups, lactate was back to baseline between 24 and 36 hours. The implication is that amongst those with HIE, the longer it takes for lactate to return to baseline, the higher the risk of adverse outcomes. Thus, lactate normalization time may be used as a surrogate of adverse outcomes in these subjects. It is unclear why lactate normalization time was not significant in the other etiologies. Plausible explanations may be small numbers amongst some of the groups and different lactate trajectories (not linear) amongst the other subgroups as alluded to previously.

This study has a few limitations. Given it is a retrospective review we had to exclude subjects with missing data resulting in fewer cohorts among the different subgroups. This skewed the distribution of the different etiology groups with disproportionately larger numbers in some groups and smaller in others. This made concluding difficult, especially concerning the time to normalization of lactate in the other subgroups. However, we had a decent number of subjects and lactate samples. Additionally, there were different time intervals for a sampling of lactate, with more frequent sampling amongst those with HIE compared to the other subgroups. This may have biased our result.

Conclusion

In all, the persistence of lactate and time to normalization may be used as surrogates for short-term morbidity and mortality amongst infants with HIE. When considering the value of elevated lactate in predicting immediate adverse outcomes irrespective of the etiology, neither a single value nor time to normalization may reliably predict short-term adverse outcomes.

Brief Point

What is already known: Elevated blood lactate may predict immediate adverse outcomes in hospitalized neonates with specific disease etiologies. Time to normalization has been shown to impact immediate outcomes in adults with sepsis.

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What this paper adds is: A single value of elevated lactate was not helpful in predicting immediate adverse outcomes when the etiology was heterogeneous. Time to normalization was only useful in predicting outcomes in babies with hypoxic-ischemic encephalopathy.

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DOI: 10.19080/AJPN.2023.12.555907

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