

Summary

Prehospital Lactate for the Identification of Shock in Trauma

Primary Aim: To compare prehospital lactate (P-LAC) levels to systolic blood pressure (SBP) ≤ 90 to predict the need for resuscitative care (the administration of packed red blood cells (PRBCs), emergent intervention for hemorrhage control using thoracotomy, laparotomy, pelvic fixation or interventional radiologic control) or death within 6 hours of ED arrival in patients with $70 < \text{SBP} \leq 100$ in the prehospital setting.

Secondary Aim: To evaluate the usefulness of P-LAC, when combined with other prehospital variables (age, heart rate, systolic blood pressure, GCS, mechanism of injury), in predicting the need for resuscitative care.

Primary Null Hypotheses: The null hypotheses are that lactate has the same (under the alternative hypothesis higher) sensitivity (without any concomitant loss of specificity) as SBP ≤ 90 to predict the need for resuscitative care (the administration of PRBCs, emergent intervention for hemorrhage control) or death prior to or within 6 hours of ED arrival in patients with SBP between 70 and 100 ($70 < \text{SBP} \leq 100$) treated by ground or air medical services who have not received lactated ringers prior to lactate measurement.

Secondary Null Hypotheses: The secondary null hypotheses are that there is no association between P-LAC and the need for resuscitative care after taking other pre-hospital covariates into account.

Inclusion Criteria: Patients meeting local trauma triage criteria for traumatic injury, a systolic blood pressure ≤ 100 , placement of an IV, and transported to a level I or II trauma center or died in the field or en route (with $\text{SBP} \leq 100$ and after placement of an IV).

Exclusion Criteria: Known prisoners, age < 15 years, obvious isolated penetrating head injury, hanging, drowning, primary burn related injury, and blunt or penetrating injury with burns $> 20\%$ of total body surface area.

Design: A prospective observational study. These data will be used to determine the utility of prehospital lactate as a triage tool as well as for identifying patients that may benefit from future ROC interventional trials. No intervention will be performed and pre-hospital providers and clinicians will be blinded to the prehospital lactate results.

Setting: EMS agencies with a limited number of ALS units responding to a high volume of patients with traumatic injury and $\text{SBP} \leq 100$ and transporting to a small number of trauma centers to facilitate data collection.

Sample Sizes: a) Air medical services: The study has 90% power to detect a difference in sensitivity of 12.9% if 235 patients with SBP between 70 and 100 are enrolled (two-sided test with $\alpha = 0.025$). b) Ground medical services: The study has about 90% power to detect a difference in sensitivity of 10.5% if 360 patients with SBP between 70 and 100 are enrolled (two-sided test with $\alpha = 0.025$).

Statistical Analysis: (Primary hypotheses) We will use McNemar's test comparing sensitivity of SBP ≤ 90 and a lactate cutpoint (with the same specificity as SBP ≤ 90) separately for patients treated by ground and air medical services (two-sided tests with $\alpha = 0.025$ for each test). Other analyses: descriptive statistics for lactate level; baseline and prehospital characteristics will be reported. Multivariable logistic regression and classification and regression tree methodology

will be used to explore the effect of other factors that might be related to the need for advanced care or might improve identification of patients in need of advanced care.

Anticipated Significance: Previous studies have indicated that a prehospital lactate ≥ 2.5 mmol/L can identify trauma patients at increased risk of death or need for resuscitative resources utilization. If prospectively validated, prehospital lactate might be useful for triage and identification of a patient population suitable for future ROC studies.

Human Subjects Protection: We will seek a waiver of informed consent because this is a minimal risk observational study in which a diagnostic test will be performed on a drop of blood obtained from an existing intravenous line.