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Early Identification of Circulatory Shock in Critical Care Transport

Francis X. Guyette, David Hostler, Jaun Carlos Puyana, John S. Cole, Michael R. Pinsky, Brian Suffoletto

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Recognizing and treating shock is essential to saving the lives of injured or ill war fighters. Current methods for diagnosing shock are unreliable and may lead to delayed treatment, further injury, or even death. This study will examine the feasibility of new methods of detecting shock using non-invasive devices during critical care transport. We tested point of care lactate and tissue oximetry devices under variations of environmental temperature, regional ischemia, and the austerities of the air medical environment. We simulated commonly encountered field conditions in the laboratory to determine the impact on tissue oximetry (StO2) and lactate. We simulated extremes of environmental temperature by performing a heat exposure test and a five-minute, cold-pressor test (ice-water forearm immersion). We simulated impaired circulatory states with a five-minute total occlusion of the forearm and a five-minute partial occlusion of the forearm. We evaluated differences in StO2 and lactate from baseline by repeated measures ANOVA. Following the laboratory testing we trained flight crews in the use of the devices and they performed testing on healthy volunteers during flight. We surveyed flight crew members regarding their perceptions of the testing devices using a five point Likert scale

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INTRODUCTION

Recognizing and treating shock is essential to saving the lives of injured or ill war fighters. Emerging data suggests that early aggressive resuscitation of critically ill patients may limit or reverse tissue hypoxia progressing to organ failure.[1] Unfortunately, many patients have compromised regional oxygen delivery despite adequate traditional hemodynamic parameters.[2,3] Therefore, vital signs such as blood pressure, heart rate and O_2 saturation (StO2) may not significantly deviate from normal values due to the patient's physiologic compensatory mechanisms. Current methods for diagnosing shock are unreliable and may lead to delayed treatment, further injury, or even death. This study will examine the feasibility of new methods of detecting shock using non-invasive devices during critical care transport. We tested point of care lactate and tissue oximetry devices under variations of environmental temperature, regional ischemia, and the austerities of the air medical environment.

HYPOTHESIS

It is feasible for air medical providers to use serum lactate and tissue oximetric monitoring (StO_2) devices in early shock contemporaneously with their care.

BODY

IRB Approval

In order to investigate the use of lactate and tissue oximetry for the early detection and treatment of circulatory shock, we conducted a feasibility study of the use of these devices in the air medical environment. Institutional Review Board (IRB) approval was obtained for a study utilizing lactate and StO2 in healthy volunteers. Following the healthy volunteer study, we sought IRB approval for an observational study of trauma patients flown to UPMC Presbyterian hospital. This study will be conducted using waiver of informed consent and the non-invasive monitoring technologies previously tested in the human volunteer study. We will conduct an interventional study directing patient care with non-invasive monitoring under the exception from informed consent rules. This IRB approval will be sought during the observational trial and will require public disclosure and community consultation.

Community consultation for this process will entail meetings with community representatives and stakeholders. Public meetings to address questions and concerns will be held in the county seats of areas serviced by our helicopters. Mixed media advertisements will be used to notify the public of these meetings. Bracelets will be provided for those who wish to opt out of the study. Concomitant with these efforts, the protocol will be submitted for second level review by the Air Force Surgeon General's Office (SGRC office).

Clinical Protocols

A clinical protocol for monitoring serum lactate on all trauma patients flown by STAT MedEvac has been developed and instituted. Venous lactates are drawn on all trauma patients during the initial patient contact from an existing IV site. Venous lactates greater than four require a consult to the faculty command physician. The physician determines if additional resuscitation is necessary for the patient based on the aggregate data available including vital signs clinical picture and lactate. Development of this clinical protocol was approved by the Medical Advisory Committee of STAT MedEvac and is now standard clinical care for our service. Data regarding lactate is collected under the auspices of quality assurance and is not research. Preliminary data are available for 243 trauma patients with a median lactate of 2.6; (25-75% 2-3.8). Initial vital signs (HR $p=0.22$, SBP $p=0.95$, RR $p=0.96$), lowest SBP ($p=0.64$), highest HR ($p=0.84$) need for endotracheal intubation ($p=0.87$) and Revised Trauma Score (RTS) ($p=0.82$) do not differ significantly between patients with lactate levels less than 4 mmol/L or greater than 4 mmol/L. There was a significant increase in the administration of crystalloid among patients with elevated lactate ($p=0.02$) and all patients requiring blood in flight had a serum lactate greater than 4 mmol/L. These data are currently being linked to patient records and in hospital outcomes. All materials and costs related to the use of point of care lactate testing are the responsibility of STAT MedEvac and no Air Force funds are used for lactate monitoring.

We also developed a clinical protocol for the use of the StO2 monitor on trauma patients. The protocol directs our flight crews to apply the StO2 monitor to all trauma patients in flight to UPMC Presbyterian and conduct a tissue occlusion test to evaluate for decreased

tissue perfusion and evidence of shock. The data gathered during the flight will be used to refine assumptions regarding tissue oximetry and vascular occlusion test values at which patients will be resuscitated in future studies. No change in clinical care will be initiated during the flight based on this observational data. We will place this protocol into service pending second level review by the SGRC and the Air Force Surgeon General. Flight crews have tested this protocol on healthy volunteers in flight.

Training of Flight Crews

All STAT MedEvac flight crew have been trained on the use of the Lactate Pro point of care lactate meter. All crewmembers have used the device in the evaluation of trauma patients and all uses are reviewed for the purpose quality assurance. Crewmembers also use a special reporting function in our electronic medical record to alert the medical direction staff of any values greater than four, any equipment malfunctions, any capillary derived samples, or other concerns. Errors in the use of the device result in retraining of the crew and have included 1) failing to load the sample properly, 2) use of capillary lactate when venous access was available and 3) use of sample diluted by flushing of the IV port without wasting a portion of the sample.

All flight crewmembers participated in a webinar to provide didactic instruction on the use of the StO_2 meter. The webinar included two-way communication to allow the crews to ask questions about the device. The didactic material was placed in our document warehouse to allow crews to reference the material at their convenience. Crews at the bases directly serving UPMC were in-serviced on the StO_2 meter in face-to-face sessions and those involved in healthy volunteer study were given additional instruction as required. A research assistant was trained to download and catalog the data recorded during the healthy volunteer studies and assist in consenting volunteers.

Testing of Lactate and StO_2 Meters in Flight

The point of care lactate meter and tissue oximeter was evaluated in our laboratory on healthy volunteers to determine the effects of field conditions and the prehospital environment. We subjected fifteen healthy volunteers to extremes of temperature and regional ischemia. This testing demonstrated that data could be obtained despite complete

and partial limb ischemia and exposure to temperatures of 4 and 40 ºC. Differences in StO_2 and lactate from baseline was tested by repeated measures ANOVA.

We tested the effects of regional ischemia using partial and total forearm occlusion tests. The means and SD are in the table below. There was a significant difference over time for the occlusion test ($F_{10,18}$=61.7, $p < 0.001$) indicating that StO_2 decreases with decreased perfusion to the thenar tissue and rapidly recovers with reperfusion. There was no difference between partial occlusion and total occlusion (Table 1, Figure 1).

Table 1. Occlusion and Partial Occlusion Test

	Baseline		Min 1		Min2		Min 3		Min4		Min 5	
	Occlusion	Partial Occlusion	Occlusion	Partial Occlusion	Occlusion	Partial Occlusion	Occlusion	Partial Occlusion	Occlusion	Partial Occlusion	Occlusion	Partial Occlusion
Mean	81.1	81.7	69.4	69.5	58.1	62.0	47.9	53.5	39.3	47.7	33.9	42.9
SD	2.5	3.3	5.7	5.7	6.9	7.4	6.9	9.4	5.7	10.3	4.3	12.1

	Recovery 1		Recovery 2		Recovery 3		Recovery 4		Recovery 5	
	Occlusion	Partial Occlusion	Occlusion	Partial Occlusion	Occlusion	Partial Occlusion	Occlusion	Partial Occlusion	Occlusion	Partial Occlusion
Mean	92.8	88.0	86.5	82.3	82.5	81.1	81.0	80.7	80.2	80.8
SD	3.3	7.1	4.2	5.5	3.8	3.9	3.3	4.5	3.6	3.7

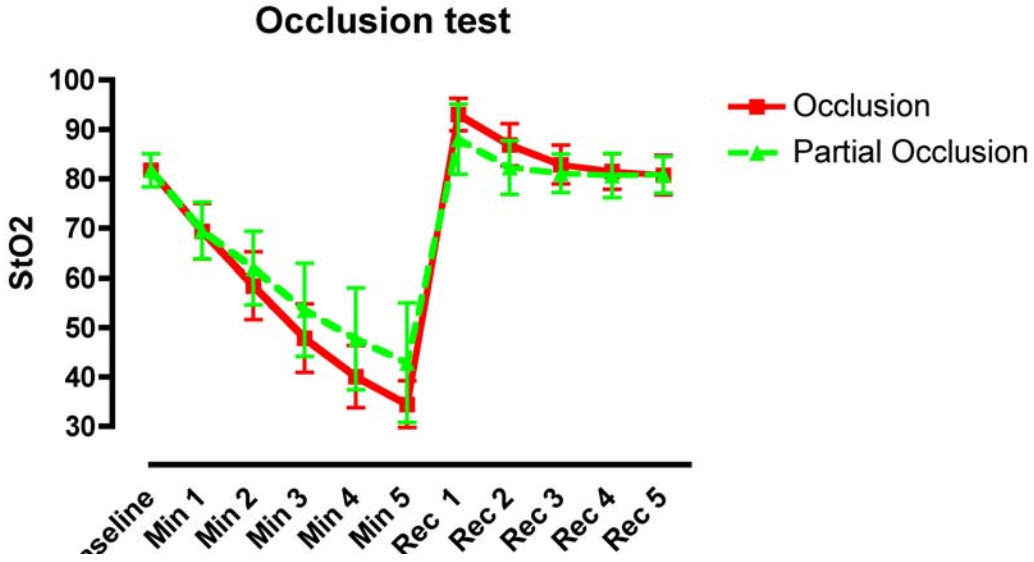

Figure 1. Graphic Depiction of the Results From the Occlusion and Partial Occlusion Test

We also evaluated the effect of temperature changes on serum lactate and tissue saturation using either immersion of the forearm in a 4-ºC water bath or exposure to a heating pad (tables 2 and 3). The temperatures shown in the table are the difference between two measured sites (shoulder and finger or arm and finger) in ºC. The temperature gradient from shoulder to finger changed with cooling but the arm to finger temp gradient did not. This suggests that we achieved regional cooling without altering core body temperature similar to brief exposures to extreme field environments. Despite local cooling, there was no change in StO_2 ($p=0.935$) or lactate ($p=0.431$) values. When exposed to heat, no changes in StO_2 ($p=0.198$) or Lactate ($p=0.327$) were observed. With a constant normothermic core temperature, we conclude that serum lactate and StO_2 will remain accurate despite changes in environment temperature. Prolonged exposure resulting in changes in core temperature could not be assessed by this experiment.

Table 2. Cold Trial Results (Forearm temperature at 4^{o} C)

	Mean	SD	p-value over time
Shoulder Finger Baseline	2.28	4.04	0.007
Shoulder Finger Cooled	3.52	4.42	
Shoulder Finger Recovered	3.63	4.63	
Arm Finger Baseline	0.90	3.80	0.364
Arm Finger Cooled	1.43	4.0	
Arm Finger Recovered	1.74	4.41	
StO2 Baseline	82.80	5.58	0.431
StO2 Cooled	82.53	6.74	
StO2 Recovered	83.60	5.55	
Lactate Baseline	1.95	0.71	0.935
Lactate Cooled	2.00	1.15	
Lactate Recovered	1.91	0.71	

Table 3. Warm Trial (forearm temperature at 50^{o} C)

	Mean	SD	p-value over time
Shoulder Finger Baseline	4.72	4.20	0.034
Shoulder Finger Cooled	4.27	4.53	
Shoulder Finger Recovered	4.63	4.54	
Arm Finger Baseline	2.02	3.72	0.257
Arm Finger Cooled	1.74	4.13	
Arm Finger Recovered	1.94	4.25	
StO2 Baseline	82.46	5.11	0.198
StO2 Cooled	82.13	6.02	
StO2 Recovered	80.86	5.56	
Lactate Baseline	2.30	1.18	0.327
Lactate Cooled	1.87	0.93	
Lactate Recovered	1.65	0.81	

After approval from the medical advisory committee the Lactate meters went into service on all aircraft. The devices have been operating now for four months and have had over

500 uses. Our quality assurance program noted six failures but most have been resolved as operator error. One instance required the meter being taken out of service and returned to the company. Compliance with use of the calibration strips had been 100%. The StO_2 meters were also evaluated by the aviation department with the help of materials from Hutchinson Technologies, the manufacturer of the device, and were tested during non-patient flights. We conducted safety interference testing in all aircraft models utilized by the aviation department of STAT MedEvac (see appendix). The devices have only been used on healthy subjects during maintenance flights and non-patient legs. Crew compliance with device calibration has been 100% and no problems have been reported during their limited use. We surveyed flight crewmembers regarding their perceptions of the testing devices using a five point Likert scale.

Flight-testing on healthy volunteers was originally allotted six weeks to accrue 20 subjects. Enrollment has taken longer then anticipated due to the unpredictable nature of flights and completion of this phase of the project will likely take 10 weeks.

Flight Crew Training Program

A program of instruction on how to conduct the healthy volunteer experiments and how to interpret the data from the StO_2 occlusion test was instituted at MedEvac 1 and 4 the bases directly involved in the healthy subject study. Instruction sessions were conducted by my research assistant or myself and involved a review of the consent document and an introduction to the study protocol. Flight crewmembers that volunteered as subjects were given an instructions on how to record data from the experiments.

Between and Within-Trial Reliability of Lactate and StO_2 in Flight

Our goal for the feasibility study is to show (1) healthcare provider technicians can be trained to use the lactate meter and StO2 device in-flight (2) the measurements obtained within technicians and between technicians will not vary by a clinically meaningful amount. The study design for the feasibility study involves the testing of one healthy subject by previously trained technicians (nurse, paramedic, physician) on different flights. On each flight lactate is measured up to four times (pre-occlusion, T2 and T3 during occlusion, post-occlusion) and O2 saturation response is measured during a

vascular occlusion test to obtain rate of StO2 decrease during occlusion and rate of StO2 recovery during release. We recruited and trained 20 flight medics and flight nurses to use the devices in flight. We conducted 20 experiments in flight using 17 individual crewmembers. Three crewmembers performed the test twice. We conducted experiments in two aircraft types (Eurocopter EC 135 and EC 145), in IFR weather conditions, and during both day and night operations. We calculated the standard deviations of lactate measurements across the time points for each trial. We then calculated the range of the standard deviations across trials to assess the magnitude of the within-trial variability. The consistency of the measurements is indicated by relatively small standard deviations (0.05-0.63) given the range of normal for the lactate measure (0.5-2.0). Results from 18 of the 20 trials had standard deviations below 0.5.

Following this strategy, we calculated the means, standard deviations, and confidence intervals of lactate for each time point across trials to assess between trial variability. These data demonstrate that flight crewmembers can reliably obtain serum lactate values in flight. There is variability in the measurements due to technician skills, flight conditions, and day-to-day lactate differences for an individual. However, variations in lactate measurements were within normal values for healthy volunteers and had a small range of standard deviations indicating that there was reasonable inter-trial reliability (Table 4). The range of standard deviations across time points was very small from 0.38 to 0.54, indicating that the individual technician accounts for over half the variability (52%) in lactates sampled during flight. We also ran a mixed model with fixed time effects and random technician effects to partition the variability in the lactate measures and to estimate the correlation of measurements within technicians. We did not observe differences related to aircraft type or operational conditions. Overall, the observed standard deviations were acceptable and would not be likely to yield a false signal leading to inappropriate patient management.

Table 4. Descriptive Statistics of Lactate Measurements

Lactate Measurements All observations, all clinicians				
N	**Mean**	**Std Dev**	**Minimum**	**Maximum**
66	1.27	0.45	0.50	2.30

Obs	N	Mean	Std Deviation	Min	Max
1	0	.	.	.	.
2	2	1.75	0.21	1.6	1.9
3	4	1.05	0.06	1.0	1.1
4	4	2.05	0.19	1.9	2.3
5	2	1.80	0.28	1.6	2.0
6	4	0.93	0.15	0.8	1.1
7	3	0.97	0.15	0.8	1.1
8	4	0.80	0.35	0.5	1.1
9	4	0.88	0.05	0.8	0.9
10	4	1.15	0.51	0.8	1.9
11	4	0.88	0.10	0.8	1.0
12	0	.	.	.	.
13	4	1.38	0.40	0.8	1.7
14	4	1.58	0.13	1.4	1.7
15	4	1.65	0.29	1.3	2.0
16	4	1.38	0.63	0.9	2.3
17	4	1.68	0.29	1.3	1.9
18	3	1.57	0.25	1.3	1.8
19	4	0.90	0.08	0.8	1.0
20	4	0.98	0.13	0.8	1.1

Range of the standard deviations across clinicians			
N	**Mean**	**Minimum**	**Maximum**
18	0.24	0.05	0.63

StO_2 Analysis

Analysis for the StO_2 outcomes were also evaluated using descriptive statistics including means, standard deviations, and confidence intervals for each time point across technicians (Table 5). StO_2 measurements in and of themselves are not better able to predict shock states than existing vital signs.[4] Use of the occlusion test increases the utility of StO_2 measurement by allowing the determination of tissue metabolic needs during the period of ischemia described as T1 (time from occlusion of forearm blood vessels to limb ischemia) and the time of recovery T2 (time from release of the BP cuff until the StO_2 level has returned to the subjects baseline) which indicates the state of perfusion of the forearm. If the patient is in compensated shock and regional perfusion is compromised, the slope of T2 will be decreased.[4] The distributions for the T1 and T2 slopes were highly skewed. The median slope for T1 was -0.24 with an IQR of -0.38 to -0.18. Sixty-five percent of the T1 slopes were within .1 of the median value; the T1 slope values ranged from a minimum of -1.00 to a maximum of -0.12. The median slope for T2 was 0.82 with an IQR of 0.31 to 1.57. Forty-five percent of the slopes were below 0.40; 40% were within 0.5 of the median; the T2 slope values ranged from a minimum of 0.17 to a maximum of 5.00. These data indicate that the flight crewmembers are able to reliably perform the tissue occlusion test and record T1 and T2 with little variability in healthy volunteers. The ranges of slopes for the T1 and T2 data points are represented in the histograms below (Figures 2 and 3).

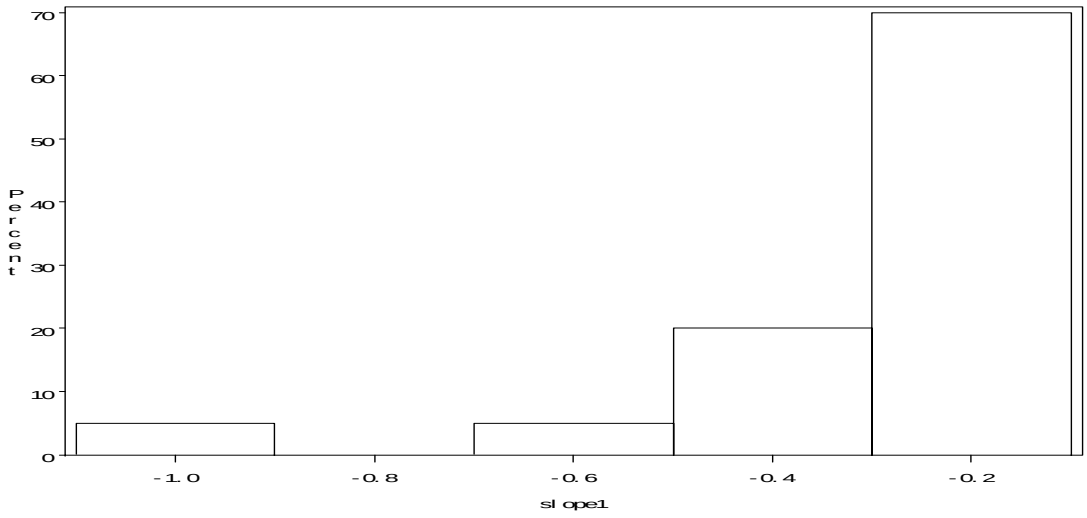

Figure 2. Histogram of Slope for T1

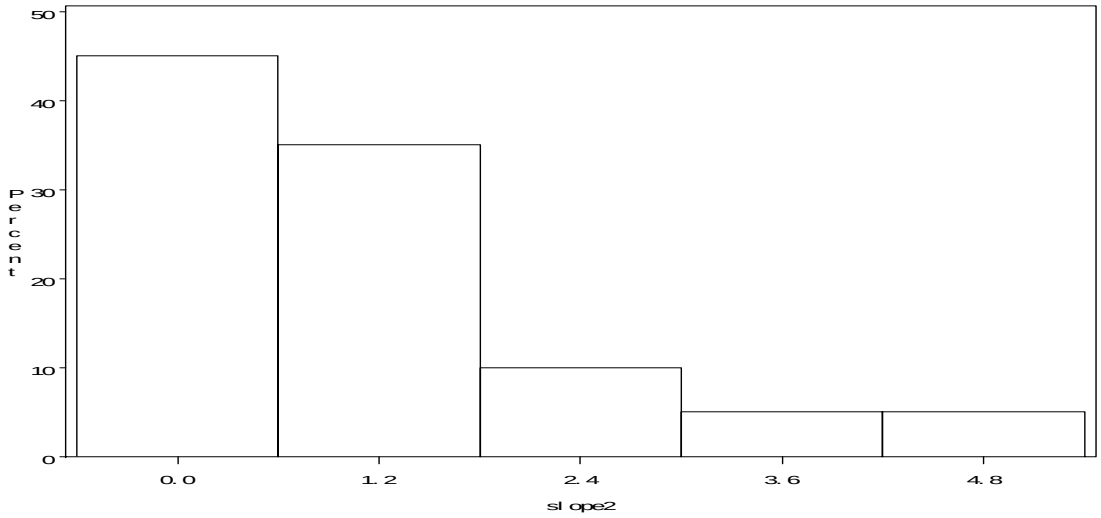

Figure 3. Histogram of Slopes for T2

Initiation of the Observational Study

The observational study is designed as an interim step to validate the assumptions of the clinical protocol based on StO_2 values. Current shock protocols initiate crystalloid resuscitation if the patient is noted to have a systolic blood pressure less than 90 mmHg. Under the study protocol data on the patient's tissue oxygen saturation will be collected but will not alter treatment during flight. This is a waiver of informed consent study as trauma patients requiring air medical transport are not likely to be capable of informed consent. The University of Pittsburgh recently approved this study as it represents minimal risk to the patient (non invasive monitoring) and may provide direct benefit thought better patient monitoring and increased quality assurance. Data analysis will involve correlation between StO_2 values and patient outcomes including multi system organ failure (MSOF), need for surgery, need for blood products (first 24 hours), need for admission to the ICU, length of stay, number of ventilator days, total fluid requirement (first 24 hours), need for pressors and mortality. Our current assumption is that values less than 70% are correlated with the adverse outcomes noted above and indicate the need for resuscitation despite normal vital signs. The observational study will not be conducted under this contract.

Training of a Second Research Assistant

A second research assistant was not trained, as second level approval was not received from the Air Force.

Problems Associated with this Study

Waiver of informed consent process for the observational study

The observational study uses a minimal risk waiver of informed consent mechanism that has been approved by the University of Pittsburgh. The University IRB considers it minimal risk because it involves only prospective recording of data without changes in patient care protocols during transport. A requirement of the SGRC waiver of informed consent mechanism is that it provides direct benefit to the patient. In this case the direct benefit is the more vigilant monitoring of the patient including the ability to monitor the progress of resuscitation for patients who will receive fluid and blood products based on vital sign parameters. The contract was completed prior to obtaining a waiver of informed consent.

Correlation of StO2 and Serum Lactate with Adverse Outcomes

The outcome of the observational study that will justify continuing the interventional study would be the ability of lactate and StO_2 to predict an elevated MODS score (>6). This is a surrogate marker of clinically significant circulatory shock. If the StO_2 and lactate cannot identify circulatory shock then there is no need to complete the intervention. In regard to the correlation of shock with StO_2 and lactate being insufficient to justify the intervention, lactate is a product of hypoperfused tissue. It is a very sensitive indicator of shock but not specific. That is why it must be paired with StO_2. StO_2 is a measure of regional hypoperfusion and existing data describe decreased StO_2 and increased recovery of StO_2 following the occlusion test as a consequence of shock. Shock is defined as the hypo perfusion of tissue. Eastern Association of Surgery of Trauma (EAST) has suggested these measures as guidelines for the endpoints of resuscitation.[5] We hope to continue this line of investigation and demonstrate that the StO_2 occlusion test is sensitive for detecting early or compensated shock.

Determination of the optimal cutoff for StO2

Current data using $StO_2$for the monitoring of patients suffering traumatic shock suggests increased organ dysfunction with StO_2values less than 65% correlate with increased incidence of organ dysfunction.[6] StO_2values less than 70% are indicative the need for transfusion of blood products and longer hospital length of stay.[7] We hypothesize that StO_2 levels less than 70% may represent an additional endpoint for resuscitation. In order to further investigate that hypothesis the observational trial will involve the recording StO_2 levels on all trauma patients taken to UPMC Presbyterian hospital. These patients would be enrolled under waiver of informed consent in this minimal risk trial. No changes will be made in their treatment during the transport and patient records will be examined to define associations between StO_2 levels in this prehospital population and Multi system organ failure as well the need for blood products, fluids, ICU admission, length of stay, surgery, intubation and mechanical ventilation, and mortality.

Potential for over resuscitation

The risks and hazards of unnecessary resuscitation with normal saline include pulmonary edema, dilution of coagulation factors, abdominal compartment syndrome, and dislodging clots in uncontrolled hemorrhage. Pulmonary edema may occur inpatients with unrecognized kidney failure or congestive heart failure. This could result in a decreased ability to oxygenate the patient possibly requiring endotracheal intubation. Monitoring the patients breathing and oxygen saturations will minimize the risk of volume overload. Physiological monitoring in this patient population is routine and includes SPO_2, $EtCO_2$, ECG, and non-invasive blood pressure. Large volume resuscitation with crystalloid will dilute clotting factors potentially increasing the severity of hemorrhage. There is a theoretical risk of dislodging blood clots in penetrating or vascular injuries worsening ongoing bleeding and requiring additional resuscitation. Studies involving the administration of aggressive early resuscitation have identified these issues in penetrating trauma. Investigators have suggested that resuscitating to a given blood pressure is fraught with complication and that other endpoints of resuscitation should be studied including lactate and measures of tissue oxygenation.[8,9]

Capillary lactate:

The point of care lactate device used in this study is marketed as being able to receive samples from capillary, venous or arterial sources. Arterial lactates are the gold standard but recent publications have indicated that venous lactate is equivalent.[10] Venous samples are the preferred means of obtaining lactate for this study as the patients are required to have venous access making the test essentially non invasive. We tested capillary lactate as an alternative in both the laboratory and in flight. It was noted that lactate values are falsely elevated if the alcohol used to cleanse the finger was not completely evaporated or if the finger required milking to extract a sample. Under ideal circumstances in the lab these risks could be minimized but in the field and air medical environments capillary lactate is not reliable. As a corrective action, only venous samples are to be used in future studies.

Waste for venous samples

Erroneous lactate values have been noted when venous lines were flushed or already had saline running through them. Crews have been instructed to waste a 5cc sample of fluid in order to ensure accurate venous measurements of lactate.

Lactate device failures

The point of care lactate devices have had seven failures during the past four months now totaling more than 500 uses by >150 crew members. All but one has been identified as operator error. The crews were retrained on the appropriate use of the device and notices sent to all employees were sent out when possible systems issues were identified.

Key Research Accomplishments

- IRB approval for the laboratory phase of the study obtained
- SGRC second level review obtained
- Laboratory validation completed
    - Data collected on lactate and StO_2 measurements during abnormal external temperature
    - Data collected under conditions of regional ischemia
- IRB approval for observational trial received

- Clinical protocols for serum lactate use initiated
    - Over 500 uses documented in the first six months
    - Increased need for fluids and blood among patients with elevated lactate
    - Continued data analysis underway to link lactate levels with clinical outcomes
- Clinical protocol for use of StO_2 monitoring written
- Flight crew training program completed
    - Quality assurance program initiated
    - Retraining conducted as necessary.
- Devices evaluated in flight
    - 3 StO_2 monitors- no monitor or disposable failures
    - 17 point of care lactate meters- 1 device failure after 3 months of use.
- Intra and inter rater reliability of lactate measurements assessed among flight crews
    - Crewmembers can reliably obtain serum lactate values in flight
    - Greatest variability observed is between technicians
- Intra and inter rater reliability of StO2 measurements including the vascular occlusion test assessed among flight crews
    - Crewmembers can reliably obtain StO_2 values in flight
    - Crewmembers can reliably conduct the StO_2 occlusion test in flight
    - Greatest variability observed is between clinicians
- Observational study prepared

Reportable Outcomes

We presented a portion of this data at the ATACCC conference in August of 2008. This abstract is included in the Appendix.

Conclusions

Point of care lactate and tissue oximetry can be reliably obtained under extremes of temperature and impaired circulatory states. It is feasible for nurses and paramedics to use lactate and tissue oximetry, including the forearm occlusion test, in the air medical environment. Inter rater reliability for obtaining serial lactate and StO_2 values in flight is acceptable and variations among individuals, time, and aircraft were minimal.

Serum lactate and tissue oximetry have been used in the controlled environment of the intensive care unit and the emergency department as diagnostic adjuncts to vital signs for the prediction of poor outcomes in trauma patients. Use of these adjuncts in the air medical environment may allow for early identification and treatment of shock states. These preliminary studies demonstrate the feasibility of using lactate and tissue oximetry in the austere conditions of the air medical environment. In addition, we also show that nurses and paramedics can reliably obtain lactate and StO_2 values with minimal training and without the supervision provided in the hospital.

Further studies should demonstrate that prehospital tissue oximetric values below a given threshold correlate with adverse outcomes including multi system organ failure, need for blood products and increased hospital length of stay. This step is necessary because the current literature supports an association between StO_2 and adverse outcomes in trauma patients followed from the Emergency Department or ICU. The association between serum lactate and tissue oximetry closer to the time of injury is unknown. If there is no correlation between prehospital lactate or tissue oximetry and severity of injury then there is no need to pursue this line of research. An observational trial will also allow us to determine if changes in lactate and tissue oximetry can predict the adequacy of resuscitation. Patients meeting criteria for resuscitation based on our shock protocol will receive fluids and blood products during the flight. Changes in serial lactate levels (delta lactate) and StO_2 values may correlate with the volume of resuscitation and improvements in tissue perfusion. If these hypotheses are confirmed then a trial of resuscitation based on parameters of lactate, tissue oximetric values and vital signs is warranted.

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APPENDIX

Feasibility of Using Non-Invasive Measurements of Circulatory Shock in Critical Care Transport

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Introduction

•Recognizing and treating shock is essential to saving the lives of injured or ill war fighters.

• Current methods for diagnosing shock are unreliable and may lead to delayed treatment, further injury, or even death.

Objectives

•We tested point of care lactate and tissue oximetry devices under variations of environmental temperature, regional ischemia, and the austerities of the air medical environment

•To examine the feasibility of new methods of detecting shock using non-invasive devices during critical care transport

Acknowledgements

• This project is being developed under Contract Number FA701-11-07-C-4053, with the U.S. Air Force Surgeon General's Office (AF SG) and administered by the Air Force District of Washington (AFDW). The Air Force has not yet accepted the products depicted and assistance of a contract does not constitute Federal endorsement.

Methods

• We simulated commonly encountered field conditions in the laboratory to determine the impact on tissue oximetry (StO_2) and lactate.

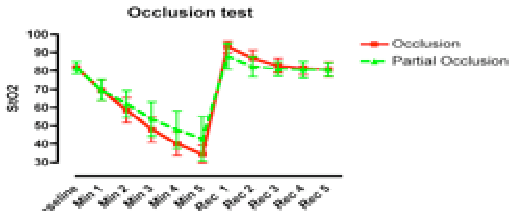
• We reproduced extremes of environmental temperature by performing a heat exposure test and a five minute, cold pressor test (ice-water forearm immersion).

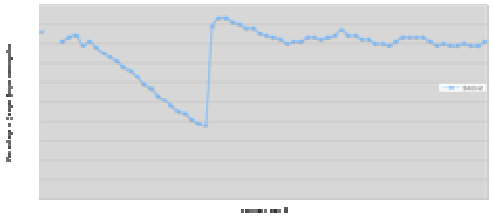
•We simulated impaired circulatory states with a five-minute total occlusion of the forearm and a five-minute partial occlusion of the forearm.

•We evaluated differences in StO_2 and lactate from baseline by repeated measures ANOVA.

•Following the laboratory testing, we trained flight crews on the use of the devices and they performed testing on healthy volunteers during flight

•We surveyed flight crew members regarding their perceptions of the testing devices using a five point Likert scale.





Results

• Fifteen healthy volunteers participated in the laboratory phase of the study.

• Despite local cooling, there was no change in StO_2 (p= 0.935) or lactate (p= 0.431) values

•When exposed to heat, no changes in StO_2 (p= 1.198) or Lactate (p= 0.327) were observed.

•Variations in StO_2 were observed with the vascular occlusion demonstrating decreased tissue perfusion consistent with previous studies.

• We also studied the ability of flight crew to monitor healthy volunteers in flight.

• All ten flight crew members tested could obtain lactate levels and monitor StO_2.

•Flight crew members strongly agreed that their training was adequate (Lactate 5, IQR 5-5, StO_2 5, 4-5) and that the devices are easy to use (Lactate 5, IQR 5-5; StO_2 5, IQR 5-5).

Conclusions

•Point of care lactate and tissue oximetry can be obtained under field conditions of temperature and impaired circulatory states

• Changes in external environmental temperature do not influence StO_2 and lactate in the absence of changes in core temperature.

• It is feasible for nurses and paramedics to use lactate and tissue oximetry in the air medical environment