

SGRD-UE-EMT

20 April 1994

MEMORANDUM FOR Commander, USARIEM

SUBJECT: Completion of Testing for Study, # HURC 400

1. As Principal Investigator of # HURC 400, entitled: Interaction of hydration and exercise intensity on thermoregulatory responses during exercise-heat stress, I wish to report that this study began 18 AUG 1992, and all testing and other use of human subjects was completed 1 FEB 1994.

2. Testing for this study was begun on 14 subjects and completed on 10 subjects.

3. During the course of the study:

The incidents listed below as involving an adverse consequence as a result of participation in the study resulted in termination from the study, receipt of medical treatment, or temporary removal from the study that required medical evaluation before re-admission to the study, and occurred on the dates indicated. For each incident, a report by the assigned Medical Monitor was submitted to you and this report is presently part of the study file in the RPOD office. A summary report of these incidents, together with copies of the Medical Monitor's reports, is enclosed.



SCOTT J. MONTAIN
CPT, MS
Thermal Physiology and
Environmental Medicine

Encl*

October 9, 1992

MEMORANDUM FOR Commander, USARIEM

SUBJECT: Report of Medical Incident

1. Study: Interaction of hydration and metabolic intensity on thermoregulatory responses during exercise-heat stress (HURC #400)

2. Responsible Investigator: CPT Scott J. Montain

3. Test Volunteer: PFC Harry Towle, 014-58-5394

4. Nature of Medical Incident:

a. On 9 October 1992, PFC Towle exercised at approximately 65% of his $\dot{V}O_{2max}$ under environmental conditions of 30°C and 50% relative humidity in the environmental chamber in room 236-B, USARIEM as part of his participation in the study referenced above. After exercising for approximately 20-30 minutes, he developed discomfort in the anterior precordial region of his chest. He characterized the discomfort as "tightness." His heart rate was 150 bpm and there were no abnormalities noted on the heart rate monitor. At that time, testing was terminated and PFC Towle was placed supine on a cot. His blood pressure was 138/82 in his right arm, and his heart rate was 108 bpm. Auscultation showed his heart to be regular in rate and rhythm without murmur or extra heart sounds. Intravenous fluids were started through a catheter that had been previously placed in a vein in his right arm for purposes of the study. He was transported to the Emergency Ward at Leonard Morse Hospital in Natick, MA.

b. PFC Towle was evaluated in the EW at Leonard Morse Hospital. His symptoms were reportedly attributed to a musculo-skeletal etiology and were not felt to be cardiac in origin. He was released from the EW to follow up with the Test Volunteer Medical Officer at NRDEC.

2. Disposition: PFC Towle is scheduled to continue in the study pending evaluation and approval by the Test Volunteer Medical Officer.



PAUL B. ROCK
LTC, MC, FS

HURC 400 SUMMARY INCIDENT REPORT

<u>DATE</u>	<u>SUBJECT NAME AND ID#</u>	<u>INJURY/ILLNESS</u>	<u>EFFECT ON PARTICIPATION</u>	<u>PRESENT STATUS</u>
9/10/92	Harry Towle 014-58-5394	Chest Pain	Transferred to Leonard Morse Hospital for eval. (See attached sheet)	Healthy

MEMORANDUM TO THE MEDICAL ADVISOR, USARIEM.

SUBJECT: Esophageal probe; a possible cause of chest pain.

REFERENCE: Memo to Cmdr. regarding medical incident involving PFC Towle, from LTC Rock, dtd 9 October.

1. The circumstances and nature of the related medical incident are set forth in the referenced memorandum. The ensuing medical evaluation by the emergency department of Leonard Morse Hospital was unremarkable for cardiovascular abnormality or dysfunction, and the chest symptomatology has subsequently resolved uneventfully. A follow up two dimensional echocardiogram has been requested to rule out possible hypertrophic myocardial or valvular abnormalities known to precipitate exertional chest pain. In view of the test subject's past medical history, level of physical conditioning, and negative preliminary medical evaluations, it is not expected that the results of this study will prove diagnostic. An underlying cardiac etiology for PFC Towle's symptoms is therefore considered to have been confidently ruled out.

2) However, subsequent discussions with PFC Towle and CPT Scott Montain (Responsible Investigator) prompt consideration of an alternative, and perhaps iatrogenic, etiology; namely, exercise related trauma to the distal esophagus, caused by forceful impingement of the rigid probe tip upon the mucosal lining, in close proximity to the heart's left atrium. This possibility derives from the probe's considerable rigidity, as a result of which any pre-existing tortuosity, resulting from either improper storage or prior, unsuccessful attempts at insertion, would likely remain prominent after eventual placement, thereby compromising the coaxial orientation of the probe tip within the lumen of the distal esophagus. Normal exercise related anatomical distortions could then forcefully imbed the probe tip into the adjacent mucosa, resulting in the centrally focused, non-cardiac, thoracic pain of the nature experienced by PFC Towle.

3) In an effort to determine the prevalence of similar and other difficulties encountered by other users of this thermo-sensing device, I have telephonically contacted Mr. Ronald Feller, President of PhysiTemp Instruments, our procurement source, and Mr. William Landis, Product manager of Sorin Biomedical (formerly Shiley Instruments) in Irvine California. The latter company markets hundreds of these devices for use by perfusionists and cardiovascular surgeons in monitoring anesthetized patients during bypass procedures. Neither of these gentlemen were aware of any FDA registered complaints which have ensued from the use of this device for this specifically indicated purpose; nor did they recall having marketed the probe for research purposes. They both concurred in the plausibility of the etiology set forth in paragraph 2, while neither could recall any relevant experience with the product which would permit their unqualified endorsement

of the probe's use in ambulatory patients at this time.

4) Assessment of the above etiologic scenario by other USARIEM medical and research personnel is strongly recommended preliminary to the implementation of measures whereby recurrences of similar episodes of esophageal trauma, as well as the more ominous possibility of esophageal perforation, will be avoided. To this end, the following safeguards are recommended for your consideration:

A) Routine prior inspection of esophageal probes for undue tortuosity.

B) Prohibition of multiple attempts to insert the same esophageal probe. If the initial insertion effort is unsuccessful, subsequent attempts should be made with another coil-free probe. Coiled probes could subsequently be straightened over a several hour period, prior to reuse.

C) Restriction of exercise intensity for probe wearing volunteers to modestly fast walking; avoiding all running. This precaution should reduce the likelihood of high impact impingement of the probe tip upon the esophageal wall, and conform more closely to the currently approved uses of the device.



William Curtis, Jr.
LTC, MC
Primary Medical Monitor

CF:

LTC Rock, Medical Monitor

MAJ Boosalis, Human Research Medical Officer

CPT Montain, Responsible Investigator

Dr Wenger, HURC