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PRINCIPAL INVESTIGATOR: Peter Gorman, M.D.

CONTRACTING ORGANIZATION: University of Maryland
Baltimore, MD 21201

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14. ABSTRACT During the first year of this study, we have completed all case report forms, data collection sheets and informed consent documents. All necessary IRB approvals have been obtained, and all regulatory documents have been submitted to the Baltimore VA Medical Center Research Committee. A local IRB modification has been submitted to clarify exclusion criteria as it relates to the assessment of diabetic subjects. All personnel have obtained appropriate certifications in order to participate in research. Multiple meetings have occurred, both in person and via teleconference in order to coordinate activities between the Baltimore and the Atlanta sites. The research protocols have been initiated, with nine individuals screened and seven progressing to study participation. In Baltimore one participant completed 3 month outcome data assessment and crossed over to the other exercise arm. The other six individuals are in the first exercise arm. Two enrollees at the Baltimore site were withdrawn from the protocol, one because of a burning sensation in the left foot during Lokomat participation, and the other because of asymptomatic blood pressure elevation during Lokomat training. At the end of year one, the research has not as of yet produced any presentations or published reports, but this was not expected.					
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Table of Contents

	<u>Page</u>
Introduction.....	1
Body.....	1
Key Research Accomplishments.....	4
Reportable Outcomes.....	5
Conclusion.....	5
References.....	5
Appendices.....	5

INTRODUCTION

The goal of this research is to compare the effects of three months, three times a week aquatic therapy with similar intensity robotically assisted, body weight supported aerobic treadmill training upon functional ambulatory ability, cardiovascular fitness, and metabolic changes in individuals with chronic (greater than 12 months post injury) motor incomplete spinal cord injury (MISCI). It is anticipated that 36 individuals with chronic MISCI will enroll in this study. We hypothesize that aquatic therapy will be more effective than robotically assisted aerobic locomotor training in improving functional ability as measured by timed walks, a gait mat device and community step activity monitors. Furthermore, we also hypothesize that aquatic therapy will be more effective than robotic locomotor therapy in improving cardiovascular fitness as measured by open circuit spirometry during arm ergometry in these individuals. This work will provide preliminary evidence-based information as to the efficacy of aquatic therapy and robotically assisted, body weight supported aerobic treadmill training in chronic spinal cord injury motor system rehabilitation. A need for empirical data exists, as there is little objective data examining either of these two interventions after spinal cord injury.

BODY

Statement of Work (SOW) Tasks are listed below, and are followed (in blue and bold font) with description of the actual accomplishments during this annual study period.

Task 1: Implement plans, obtain IRB study approval and start up. (Month 1-6)

- 1a. Complete the formal study protocol, case report forms, data collection sheets, and informed consent documents. Ensure consistency in these documents across the two sites. (Month 1-2)
- 1b. Concurrently submit the protocol and regulatory documents to the University of Maryland at Baltimore and the Shepherd Center IRBs. (Month 2-6)
- 1c. Obtain research certification for all study personnel if not already obtained. Renew this certification annually or as required.
- 1d. Once IRB approval has been obtained, submit the protocol and regulatory documents to the respective VA Research Committees and the Medical Executive committee at Kerner Hospital. (Month 3-6)
- 1e. Develop an organizational meeting in Baltimore or Atlanta to allow for concurrent initiation and coordination of the research study (Month 5-6).

1a-e. As reported in each quarterly report, all of these tasks were completed in alignment with the SOW.

Task 2: Implement Randomized Clinical Trial (Months 7-42)

- 2a. Initiate screening of potential individuals for the research study (General medical and ASIA examination, blood tests, EKG, Standing frame challenge) (Months 7-9)
- 2b. Obtain baseline measurements (VO₂max, Timed walked tests, GAITRite, Step activity monitor studies) on individual study participants as they pass screening.

- 2c. Initiate the stratified randomization of subjects into the Lokomat versus aquatic therapy protocols with exercise occurring 3 times per week for 3 months. (Months 7 -9)
- 2d. Recruit twelve individuals across both sites during year one (approximately six per site approximately equally divided between tetraplegic and paraplegic individuals (Months 7-19).
- 2e. Obtain 3 month outcome measurements after participants complete their first exercise intervention (Months 10-39).
- 2f. Cross over participants to the other exercise intervention after outcome measurements have been performed (Months 10-42).
- 2g. Obtain 6 month outcome measurements after participants complete their second exercise interventions (Months 12-42).

2a,b,d. 23 individuals were screened in Baltimore with 19 progressing to study participation. Three potential participants failed to meet screening criteria and one potential participant is waiting for an orthopedic issue to be addressed prior to committing to DOD study. Six individuals were screened in Atlanta at the Shepherd Center and all progressed to study participation. Participation included obtaining baseline measurements per SOW 2b. The delay, especially in Atlanta, was secondary to the long review time of study documents (consent forms and other IRB material, etc). The DOD IRB permitted Kernan recruitment to begin in April 2011, and Shepherd recruitment to begin in July 2011.

2c. Kevin Chen, our consultant statistician, created a blocked randomization schedule and maintains this schedule separate from participant recruiters and PIs.

2e. 14 participants completed 3 month outcome data assessment.

2f. 14 participants crossed over from exercise condition I to exercise condition II.

2g. 7 total participants completed the final data collection.

Task 3. Implement Analysis of Data, Presentation and Publication (Months12-45).

3a. Provide annual reports to the Data Safety Management Board at the Baltimore site (Months 12-36).

3b. Complete proposed statistical analysis of the study data and submit the results for scholarly presentation and publication. In addition provide outcome information in the form of a report to the granting agency. (Months 36-45).

3a. The third DSMB report will be submitted November 2012 and will include both Kernan and Shepherd data as appropriate. The first two DSMB reviews were positive. University of Maryland Baltimore IRB renewal was obtained and provided to DOD in November 2011. The IRB Continuing Review for University of Maryland will be submitted by end of October 2012.

3b. Data analysis is not yet possible; however, several DOD related presentations and one publication were completed in 2012.

Presentations:

Comparison of Aquatic Therapy and Robotic Treadmill Training in SCI Protocol

1) World Aquatic Health Conference, Norfolk, VA, Oct 2012

2) Association of Spinal Cord Professionals, Las Vegas, NV, Sept 2012

Peer Reviewed Article

Atypical Autonomic Dysreflexia during Robotic Assisted Body Weight Supported Treadmill Training in an Individual with Motor Incomplete Spinal Cord Injury. JSCM, Fall 2012. Paula R. Geigle PT PhD, Sara Kate Frye MS OTR/L, John Perreault CRNP, William H. Scott MA, Peter H. Gorman MD

Prose Summary Description of Recruitment Accomplishments:

The first Baltimore recruitment actually started in April 2011. Since then 23 individuals were screened with 19 progressing to study participation. Atlanta study recruitment began in July 2011 with 6 individuals screened and engaged in study participation. Recruitment at both sites began as soon as the Department of Defense (DOD) IRB review was complete. In Baltimore 5 participants and at Shepherd 2 participants completed the entire study with final data collection at 6 months; 3 participants in Baltimore are in the second 3 month study arm. Currently 4 individuals (3 in Baltimore and 1 in Atlanta) are in the first exercise arm. Demographic breakdown for all screened individuals includes the following:

I=first exercise arm, II=second exercise arm

1=Baltimore, 2=Atlanta

gender	Race/ethni	veteran	Age	Level	status	site
M	AA	no	41	C7	withdrawn-II	1
M	Asian	no	20	C5	Withdrawn--I	1
F	Caucasian	no	48	T9	completed	1
M	Caucasian	no	36	T6	Screen failure: Open skin lesions	1
F	AA	no	28	T12	Screen failure: ASIA B	1
M	Caucasian	no	60	C5-6	completed	1
M	Caucasian	no	61	C5-6	completed	1

M	AA	yes	61	C4	completed	1
M	Caucasian	no	41	T1	Withdrawn--I	1
M	Caucasian	yes	35	C4	completed	1
M	AA	no	51	T1	deferred start	1
M	AA	yes	65	L2	Screen failure	1
M	Caucasian	no	51	C4	Enrolled-II	1
F	Caucasian	no	44	T10	Enrolled-II	1
M	AA	no	27	T1	Withdrawn-I	1
M	Am Indian	yes	49	C8	Enrolled-II	1
M	Caucasian	no	46	C4	Enrolled-I	1
M	Caucasian	no	55	T1	Enrolled-I	1
F	Caucasian	No	30	C7	Enrolled-I	1
F	Caucasian	no	54	T3	completed	2
M	Caucasian	no	39	C5	completed	2
M	Caucasian	no	60	C4	Enrolled-II	2
M	Caucasian	no	37	T8	Enrolled-II	2
F	Caucasian	no	27	T1	Enrolled-II	2
M	Caucasian	yes	65	C2	Enrolled-I	2

Participants who were withdrawn:

Four individuals at the Baltimore site were withdrawn from study participation. One enrolled participant (at the Baltimore site) was withdrawn at his fourth training Lokomat exercise session secondary to his inability to tolerate Lokomat setup. Specifically, the fourth and final session was terminated during the warm-up period after the participant reported experiencing a “burning” sensation in the left foot. This participant reported similar symptoms during the two prior Lokomat training sessions but he did not report this symptom to the research team during

the set-up and acclimation sessions. The reported paresthesia was not in a classical neuro-anatomic distribution. For two of the last four attempted training sessions the participant actually reported paresthesia before leaving the exercise mat and being suspended in the Lokomat harness. To diminish or prevent this problem, the research team attempted to re-position the Lokomat straps, but was unsuccessful in ameliorating the condition during Lokomat suspension. The PI ultimately terminated the subject's participation for safety reasons.

The second participant was withdrawn on his 11th Lokomat session (after he completed the entire Aquatic therapy arm of the study with no problems) when asymptomatic autonomic dysreflexia (AD) occurred. This was detected after the participant described a 'feeling of warmth' while exercising on the Lokomat. The blood pressure taken at the time was 210/100 mmHg. The subject was otherwise asymptomatic, i.e. there was no headache or diaphoresis. The blood pressure returned to normal after the subject was taken out of the Lokomat straps. Several attempts were made to modify the straps to see if this elevation in BP could be avoided. Unfortunately it could not.

Autonomic dysreflexia is a known complication of persons with spinal cord injury at or above the T6 level, usually caused by some sensory irritation below the level of injury. We discussed this incident with the IRB at the time it occurred. Since AD is a known complication, no reported new information (RNI) report was required. Because of the persistent elevation in BP during the Lokomat component of the protocol (i.e. silent AD), this individual was withdrawn from the study.

An unfortunate non-study activity related, lower leg fracture necessitated withdraw of the third participant. He was casted for 6 weeks sp fracture.

An unreported skin irritation on the plantar surface of his foot facilitated the removal of the fourth research participant. This individual does not routinely examine his skin integrity, or follow up with recommended and scheduled clinical care. Once the irritation was researcher identified, the area was examined and treated until the participant no longer returned to our facility. Attempts were made to contact him via phone and mail with no success.

All of these individuals were medically evaluated by the PI (PHG) who excluded other feasible pathology and determined that no further intervention was necessary other than withdrawal from participation. Two individuals are currently engaged in our wellness aquatic programs as a secondary outcome of study participation. We will continue to diligently monitor all study participants to insure safe participation in this DOD protocol. Additionally, these two more recent events will be reported through our established DSMB in the upcoming November 2012 report.

KEY RESEARCH ACCOMPLISHMENTS

- Completed the formal study protocol, case report forms, data collection sheets, and informed consent documents
- Ensured consistency in these documents across the two study sites
- Obtained necessary IRB (University of Maryland Baltimore, Shepherd, and DOD) study approval
- Filed required regulatory documents with the Baltimore VA Medical Center VA Research Committee
- Obtained research certification for all study personnel if not already current
- Orchestrated organizational face to face meetings in Baltimore or Atlanta to allow for concurrent initiation and coordination of the research study
- Held weekly DOD research study meetings including all team members
- Planned and executed at minimum monthly phone conferencing with both study sites
- Scheduled weekly site meetings to discuss all aspects of this DOD study and review study protocol and procedures
- Initiated research protocol at both sites as detailed in this report
- Submitted local IRB modification to clarify exclusion criteria so that they better align with the current clinical definition of diabetes.

Our plan for year three of the DOD study includes:

- Continue to recruit participants at the rate of 6 per year per site
- Obtain 6 month outcome measurements after current participants complete their second exercise interventions
- Continue to provide quarterly and annual reports to the DOD and appropriate documentation to UMB IRB
- Submit our third DSMB report in November 2012
- Continue to enter demographic and outcome data into our study database using the established common data base SCI template
- Draft a case report for publication discussing clinical concepts learned from first year of DOD study

REPORTABLE OUTCOMES: No reportable outcomes anticipated or occurred to date.

CONCLUSION: At the conclusion of year 2 of the DOD study we are on track for all planned activities: regulatory compliance, recruitment (given the fact that the Shepherd site could not begin data collection until month 9 of first year), data collection, and fiscal responsibility.

REFERENCES: NA

APPENDICES: see attached publication

CASE REPORT

Atypical Autonomic Dysreflexia during Robotic Assisted Body Weight Supported Treadmill Training in an Individual with Motor Incomplete Spinal Cord Injury

Paula R. Geigle PT PhD, Sara Kate Frye MS OTR/L, John Perreault CRNP, William H. Scott MA, Peter H. Gorman MD

Abstract

Context/Objective: JW, a 41 year old man with a chronic history of C6 AIS(American Spinal Injury Association Impairment Scale) C spinal cord injury, enrolled in an IRB approved, robotic assisted body weight supported treadmill training (BWSTT) and aquatic exercise research protocol presented with asymptomatic autonomic dysreflexia during training. Little information is available regarding the relationship of robotic assisted BWSTT and autonomic dysreflexia.

Findings: After successfully completing 36 sessions of aquatic exercise, JW reported exertion fatigue during his tenth intervention and presented with asymptomatic or silent autonomic dysreflexia during this and the 3 subsequent BWSTT sessions. Standard facilitators of AD were assessed and no obvious irritant identified other than the actual physical exertion and positioning required during robotic assisted BWSTT.

Conclusions/ Clinical Relevance: Clinician increased awareness of potential silent AD presenting during robotic assisted BWSTT training for individuals with motor incomplete spinal cord injury is required as in this case AD clinical signs were not concurrent with occurrence. Frequent vital sign assessment before, during and at conclusion of each BWSTT session is strongly recommended.

Key words: *autonomic dysreflexia, body weight support treadmill training, motor incomplete spinal cord injury, robotic assisted exercise*

INTRODUCTION

Autonomic Dysreflexia occurs frequently for individuals with spinal cord injury (SCI) at T6 or above, including both autonomic dysreflexia (AD) with greater than 20-30 mmHg BP change and relative bradycardia (slow heart rate).^{1,2} AD with elevated BP is a known risk factor for intracerebral hemorrhage, and therefore treated as a medical emergency.³⁻⁵ AD can be precipitated by various afferent irritants from below the level of the injury particularly novel stimuli such as electrical stimulation and body weight supported exercise.⁶ Alan et al report that injury induced vasculature changes may contribute to AD occurrence via circulatory changes and the altered ability to tolerate novel sensory input.⁶

The syndrome is commonly associated with headache and diaphoresis, but sometimes can be asymptomatic. There are reports of silent AD during voiding⁷, bowel programs⁸, sperm retrieval⁹, and possibly acupuncture¹⁰. It is unclear what long term impact these large systolic

blood pressure (SBP) changes cause, or what mechanism(s) stimulate these SBP fluctuations.¹¹ Upright walking-like exercise is also reported to increase BP via exaggerated spinal reflexes in individuals with SCI at T6 or above.¹²

The Consortium for Spinal Cord Medicine Clinical Practice Guidelines for the acute management of autonomic dysreflexia emphasize the need to be aware of AD symptoms while noting that AD clinical signs are not always present.⁴ Currently it is unclear exactly how robotic assisted BWSTT impacts potential AD. Autonomic regulation of blood pressure with a positive impact upon blood flow in the femoral and carotid arteries is reported to improve during BWSTT.¹³ Krassioukov and Harkema reported the need to carefully assess cardiovascular responses in individuals with upper thoracic and cervical SCI while in the BWSTT harness system, finding significant increase in arterial pressure while sitting in the harness. This pressure abrogated however when standing without gait training.¹⁴ This case report details the potential relationship between robotic assisted BWSTT and autonomic dysreflexia in an individual with C6 AIS C chronic SCI.

CASE REPORT

JW, a 41-year old African-American man with C6 AIS C Impairment Scale tetraplegia secondary to a sports injury 23 years ago participated in a body weight supported robotic treadmill training (BWSTT) and aquatic exercise research protocol. The participant enrolled in an ongoing randomized clinical trial, approved by the University of Maryland Baltimore and Department of Defense Institutional Review Boards, to evaluate the cardiovascular and mobility effects of three months of robotic assisted BWSTT exercise versus three months of aquatic-based exercise in people with chronic (> 1 year) cervical and thoracic motor incomplete spinal cord injury. Therapist directed exercise interventions under each arm of the protocol occurred three times per week, every other day, for 40 minutes in an outpatient rehabilitation setting.

JW uses a power wheelchair for mobility and is actively employed as a computer programmer specialist. His spasticity, primarily of the lower extremities, is well managed with oral baclofen at ten mg three times per day. He manages his bladder with external condom catheter drainage and his bowel routine includes every other day bisacodyl suppositories. His remote history includes renal stones and headache in the context of bladder distension and the passage of renal calculi. Serial imaging studies of his collecting system during the last few years however demonstrated no hydronephrosis or renal stones, and serial blood tests document normal renal function.

Randomized to start in the aquatic therapy intervention, JW completed 36 aquatic therapy sessions over 12 weeks with no known AD occurrence. Vital signs were assessed at the beginning and end of each aquatic therapy session with no significant changes noted. Blood pressures were also unchanged during peak VO₂ arm ergometry testing, a study outcome measure, and his pre-study standing frame assessment.

The robotic assisted body weight supported treadmill training (Lokomat®) intervention consisted of the standard partial weight support using the appropriate straps, harness system, and limb lengths determined based on prior measurements. Weight support was initiated at 80-100% with treadmill speed initiated at 1.5 mph (0.42 m/s) to 1.8 mph (0.5

m/s) km/h and adjusted to the predetermined optimal treadmill speed (3.2 mph as a target) measured during the acclimation training session. Treadmill speed was modified, as tolerated, to provide an additional aerobic challenge during the peak assessment. JW viewed his effort via the real-time visual feedback of lower extremity force on a screen display. A Polar® monitor recorded continuous heart rate.

JW's initial nine Lokomat sessions were significant only for some minor knee pain, which resolved spontaneously, and discomfort from the harness, which was resolved with repositioning. On the tenth session, pre-exercise blood pressure was 104/52. Twenty minutes into the session, JW complained of exertional fatigue. The Lokomat was stopped. His blood pressure at that time was 220/80 and rose to 260/110 on a repeat measure with no symptoms other than exertional fatigue. Upon removal from the BWSTT device, his blood pressure quickly fell to 98/50. No skin changes were noted as possible friction points. The Lokomat straps were not obstructing urine flow from his external collecting system. No other alternate cause for the BP change could be found. The subsequent three sessions followed a similar course with regard to blood pressure and the lack of any AD clinical symptoms, exertional fatigue report only occurred during session ten. (Table 1) A pre-exercise post void residual obtained before the twelfth session was unremarkable. Seated blood pressures in the harness before and after suspension were normal prior to robotic activation and without volitional movement. Blood pressure rose sharply only after commencing the tenth robotic assisted BWSTT exercise session. The participant's blood pressure returned to normal immediately following the termination of each session. JW's participation in the research study was terminated due to concern about these repeated episodes of symptomatic elevation in blood pressure during robotic assisted BWSTT.

DISCUSSION

This individual with longstanding motor incomplete tetraplegia experienced atypical autonomic dysreflexia during the active component of robotic assisted BWSTT training using the Lokomat device. This finding was replicated across four different sessions on four different days. JW experienced no recent similar episodes but holds a past history of AD associated headache during voiding while dealing with renal stone disease with 1-2 occurrences of symptomatic dysreflexia in 23 years, and none in the past 10 years. JW described headache and flushing as symptoms of his prior symptomatic dysreflexia. Being strapped into the BWSTT harness with body weight unloaded did not appear to be directly causal to the elevation of blood pressure as only during the aerobic exercise facilitated by the robot exoskeleton that the BP sharply increased. In addition, JW's screening standing frame vital signs did not display any dysreflexia during the 30 minute time span. (Table 2) The clinical decision was made to stop further robotic assisted BWSTT because of this asymptomatic AD and the concern that this activity might be harmful to JW.

Prior to BWSTT, this individual tolerated rather strenuous aerobic exercise in an upright position in an aquatic environment without observed adverse BP changes. However, midpoint blood pressure readings were only completed through the first eight aquatic

sessions with no abnormal BPs obtained. Additionally, during aggressive arm cycle ergometry BP was assessed at several midpoints with no abnormal elevation. The combination of the harness system and the aerobic stimulus (rate perceived exertion 10/10) in this individual seemed to be a crucial AD precipitating factor. With harness suspension and aerobic exercise, the modulation of vascular and sensory feedback may be diminished secondary to the SCI.^{12, 14} A larger clinical matter, is the health cost-benefit analysis of exercise on cardiovascular health and the potential AD which may occur during robotic assisted BWSTT for individuals with level of SCI at or above T6.^{11, 13, 14-16}

The presence of atypical AD in this case report provides evidence that one individual with incomplete SCI experienced sharply increased blood pressure during robotic assisted BWSTT activities with exertional fatigue reported in only the tenth session manifesting as the only AD clinical symptom. Identification of AD may be confounded as symptoms such as perspiration and flushing also occur with aerobic exercise. Both aerobic exercise exertion and AD may be new occurrences, therefore difficult for the individual with SCI as well as the practitioner to identify the precise cause of the clinical presentation. More research is indicated to continue to investigate how SCI impacts cardiovascular function across the lifespan. The stimuli of these BP fluctuations are unknown, but silent AD is potentially detrimental to health, and should thereby be monitored and avoided as part of best practice.

Conclusion/Clinical Relevance

This robotic assisted BWSTT experience provides data indicating the existence of AD during Lokomat training for one individual with motor incomplete tetraplegia or paraplegia above the T6 level. Increased awareness of AD occurring during BWSTT for individuals with motor incomplete SCI is recommended for all clinicians conducting robotic assisted BWSTT interventions. Frequent vital sign assessment before, during and at the conclusion of each BWSTT training session is recommended to prevent possible complications from silent AD.

With the advent of increased access to aquatic exercise and BWSTT, it is equally important to assess midpoint BPs on all individuals with SCI exercising at moderate to high intensity. Currently we use a wrist blood pressure cuff to provide easier midpoint blood pressure and heart rate data during both aquatic and Lokomat sessions. These devices do require a short exercise interruption of 30 seconds. Investigation is ongoing of a blood pressure system capable of providing ongoing blood pressure data during Lokomat sessions.

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