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A comparison of regular rehabilitation and regular rehabilitation with supported treadmill ambulation training for acute stroke patients

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Abstract—The purpose of this pilot study was to compare differences in motor recovery between regular rehabilitation (REG), and regular rehabilitation with supported treadmill ambulation training (STAT) using the performance on a bicycle exercise test and the locomotor scale of the Functional Independence Measure (FIM-L). Twelve patients with acute strokes were randomly assigned to either REG or STAT for 2 to 3 weeks. The STAT group received daily gait training utilizing a treadmill with partial support of body weight. After intervention, the STAT group had higher oxygen consumption (11.34 ± 0.88 vs 8.32 ± 0.88 ml/kg/min, p=0.039), total workload (58.75 ± 7.09 vs 45.42 ± 7.09 watts, p=ns), and total time pedaling the bike (288.91 ± 30.61 vs 211.42 ± 30.61 s, p=ns) compared to the REG group. The FIM-L scores were not different for the two groups. This pilot study suggests that the STAT intervention is a promising technique for acute stroke rehabilitation, and that future studies with larger sample sizes are warranted to establish the effectiveness of this intervention.

Key words: *acute stroke, bike stress test, rehabilitation, supported treadmill ambulation training.*

INTRODUCTION

About 730,000 Americans suffer a stroke each year, and nearly 350,000 of them have some residual neurological deficits that impair their functional capacity (1,2). Residual motor weakness, poor motor control, and spasticity result in an altered gait pattern, poor balance, risk for falls, and increased energy expenditure during walking. The functional consequences of the primary neurological deficits often predispose the stroke survivor to a sedentary lifestyle, which further reduces the individual's activity of daily living (ADL) and cardiovascular reserves, increasing the risk for additional strokes. Limitations in quality of life and higher levels of physical functioning are usually underestimated in stroke patients (3).

The energy expenditure required to perform routine ambulation is elevated approximately 1.5- to 2.0-fold in hemiparetic stroke patients compared to normal control subjects (4). Increased energy costs foster less willingness to move, favoring further decline in cardiovascular

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fitness, disuse atrophy, and weakness (5). Although one of the main goals in the treatment of stroke patients is to restore a proper gait pattern, the emphasis in rehabilitation has been the improvement of self-care through muscle-strength and coordination training. Intervention normally starts with careful preparation of required muscle activity in the supine position, and progresses to work on the individual components of gait while standing (6). Patients are discouraged from walking for long periods of time to avoid stereotyped mass synergies that would occur without sufficient trunk and lower limb control (7).

Recent evidence has shown that repetitive task-oriented exercise programs improve functional capabilities in individuals with neurological deficits. The degree of locomotor recovery was significantly related to the training strategy used in patients with neurological conditions (8–11). Some animal studies have shown that a near-normal walking pattern can be achieved after a period of locomotor training in which support for the hindquarters and stepping on a treadmill are provided (11–14).

Supported treadmill ambulation training (STAT) is a recent therapeutic approach that minimizes the delay during which gait training can be initiated with neurological patients. The patients are provided with the body-weight support (BWS) needed to initiate walking early in the rehabilitation process (10). The treadmill stimulates repetitive and rhythmic stepping while the patient is supported in an upright position and is bearing weight on the lower limbs (15). However, there have been no studies on the effects of STAT on functional outcomes during the acute phases of rehabilitation. Therefore, the main purpose of this study is to compare functional recovery attained with regular rehabilitation and regular rehabilitation combined with STAT intervention in a group of acute stroke patients.

The STAT can be used for patients with severe gait impairments. The severity of the impairments may limit the utility of gait measures as a baseline measure prior to rehabilitation. Therefore, outcome measures other than gait should be used to detect changes following STAT. Since pedaling is a functional activity that can be used by stroke patients at a very early stage of rehabilitation and has also been used as a tool to evaluate aerobic capacity in this population, a bicycle ergometer protocol was utilized to compare physical performance recovery for patients before and after the two rehabilitation strategies. Pedaling requires reciprocal, symmetrical, and bilateral movements of the lower extremities and can evaluate the ability to generate power (16–18). Smith et al. demonstrated a pronounced normalization of the torque ratios between the paretic and non-paretic limbs of chronic stroke patients following 3 months of treadmill training conducted 3 times a week (19). The investigators suggested that the improvement observed in volitional torque production in the paretic limbs of stroke patients might be a consequence of central neural plasticity. Therefore, the ability to generate force while pedaling may be a useful means to evaluate functional ability after a stroke.

This report presents the results of a pilot study to compare regular in-patient rehabilitation with regular rehabilitation combined with STAT for patients with acute strokes in relation to performance on a bicycle ergometer test and the locomotor scale of the Functional Independence Measurement (FIM-L). It was hypothesized that the regular care combined with STAT group would develop better lower extremity functional abilities compared to regular care alone. Better function would be demonstrated by higher performance on the bicycle protocol, such as workload, biking time, and oxygen consumption and higher scores on the FIM-L, as compared to the regular intervention. A second objective was to compare the performance-based measures of function from the bike test to the FIM-L scores. It was hypothesized that FIM-L scores would correlate with performance on the bike protocol.

METHODS

Subjects

Fifteen stroke survivors were recruited from a sample of convenience among the stroke patients admitted to the Rehabilitation Medicine Service, Nursing Unit 2-B at the Veterans Affairs Medical Center, in Houston, Texas. Participants had a recent unilateral stroke based upon the clinical evaluation. They were recruited to participate in this study after meeting specific criteria and voluntarily signing an informed consent agreement approved by the Institutional Review Board of the Houston VAMC and the Human Subjects Review Committee of Texas Woman's University. They were enrolled in the study regardless of gender or race, although males are prevalent in this facility.

Inclusion/Exclusion Criteria

The *inclusion criteria* were:

- recent history of stroke (less than 6 weeks post event) secondary to cerebrovascular accident (CVA) based on the clinical presentation (hemiparesis) and/or magnetic resonance imaging (MRI);

- display a significant gait deficit as evidenced by a gait speed of 36 meters per minute or less and a score of 0, 1, or 2 on the Functional Ambulation Category (i.e., needs assistance);
- sufficient cognition to participate in the training (Mini-Mental State Exam—MMSE ≥21);
- ability to stand with or without assistance and to take at least one or more steps with or without assistance.

The *exclusion criteria* were:

- patients with any co-morbidity or disability other than hemiparesis (e.g., amputation, spinal cord lesion) that would preclude gait training;
- recent (within four weeks) myocardial infarction;
- any uncontrolled health condition for which exercise is contra-indicated such as uncontrolled diabetes (blood sugar levels consistently higher than 250 mg/dl);
- severe lower extremity joint disease or rheumatoid arthritis that would interfere with gait training;
- obesity (body weight over 110 kg);
- cognitive impairment (Mini-Mental State Examination—MMSE score <21)

Patient Characteristics

On entry into the study, descriptive details of the subjects such as age, height, weight, side and location of lesion, and number of days since the stroke were recorded. Each patient was also characterized according to cognitive impairment, stroke-related impairment, gait impairment, and the total time spent in rehabilitation. Medication intake was documented at baseline and at time of discharge from the study.

Cognitive impairment was evaluated by the MMSE, which is a brief, valid, and reliable instrument commonly used with elders (20,21). The utilization of a cut-off score of 21 on the MMSE was based on a report of Small et al., and focused on excluding patients with more than moderate cognitive deficits (22).

The National Institute of Health (NIH) Stroke Scale was used to characterize the patient's impairment as a result of the stroke. This is a 15-item scale evaluating specific domains related to consciousness, vision, extraocular movements, facial palsy, limb strength, ataxia, sensation, speed, and language. This scale has been validated and its reliability is good (23–24). The NIH Stroke Scale as well as the MMSE were used descriptively.

Gait impairment was based on the Functional Ambulation Category (FAC) scale (26,27). Participants were rated as one of 6 levels according to the personnel support needed for gait, regardless of use of an assistive device. The patient would receive a zero if he/she could not walk or required the help of two or more people; a score of one if requiring firm continuous support from one person who helped with carrying weight and with balance; a score of two if the patient needed continuous or intermittent support of one person to help with balance or coordination; a score of three if the patient required verbal supervision or stand-by help from one person without physical contact; a score of four if the patient could walk independently on level ground, but required help on stairs, slopes, or uneven surfaces; and a score of five if the patient could walk independently. The measure was rated by the investigator and based on the participant's ability to walk a distance of 15 meters (7). This measure was used before and after the intervention.

In order to assure that each group had the same duration of rehabilitation, the total time spent in rehabilitation was determined from each patient's medical record. The number of hours spent in physical therapy, kinesiotherapy, and occupational therapy were summed. In addition, for those in the STAT group, the time spent in STAT training was added into the total rehabilitation time.

Measurements

Exercise performance was tested on a bike ergometer. An electronic bike (Tunturi™ Model EL 400, Turku, Finland) was utilized so that workloads could be progressively increased as the test progressed. The initial workload was zero and increased at a rate of 25 watts every 2 minutes, up to a participant's volitional fatigue, request to stop, achieving a respiratory exchange ratio greater than 1.0 or his/her heart rate was within 10 beats of age predicted maximal heart rate. The physician and physical therapist also stopped the test based on clinical judgment, such as observed signs of marked dyspnea, pallor, volitional fatigue, significant electrocardiogram (EKG) changes or blood pressure exceeding 190/110 mmHg. The highest oxygen consumption, heart rate, workload, and time achieved by the patient were recorded.

The participants had both feet strapped to the pedals of the bike, and utilized the unaffected side as the main source of force for pedaling. A 12-lead EKG was used to monitor heart rate and electrophysiological behavior of the heart (Medical Graphics Cardiopulmonary Exercise System—CPX/D, Minneapolis, MN). The subject

pedaled while sitting in a chair behind the bike rather than on the ergometer seat. This positioning minimized balance instability during the test. Blood pressure was measured during the last 30 seconds of each 2-minute workload. The average heart rate during the last 30 seconds of exercise was recorded as the highest exercise heart rate.

Measurements of oxygen consumption, carbon dioxide, and minute ventilation were continuously recorded during the graded bike protocol utilizing a computerized, breath-by-breath respiratory gas analyzer (Medical Graphics Cardiopulmonary Exercise System—CPX/D, Minneapolis, MN). The highest oxygen consumption (VO_2) was the average during the last 30 seconds of exercise. The reliability of VO_2 measurements in stroke patients utilizing an electronic bike has been reported as 0.94 (16). The test was conducted on admission to the rehabilitation unit and at discharge.

Functional outcomes were assessed by the Functional Independence Measure (FIM scale). Reports on reliability and validity of the FIM scale are excellent (28–30). The FIM assessments were performed by a study physician both at the time of admission to the Physical Medicine and Rehabilitation Service and at the time of patient's discharge. Due to the fact that the intervention of interest was locomotion, only the subscore related to locomotion was utilized for data analysis. The locomotion subscore is composed of two sub-items: walk and stairs. If the patient cannot ambulate, the walk component is evaluated by wheelchair mobility. Therefore, the locomotion subscore ranges from 2 to 14.

Procedure

A random number table was utilized to pre-assign subjects based upon recruitment order. Patients were assigned to one of two groups: a group undergoing regular rehabilitation care and a second group undergoing regular rehabilitation care plus STAT, at the Houston VAMC.

Regular training at this hospital consists of daily sessions of physical therapy, kinesiotherapy, and occupational therapy. The usual amount of time is 3 hours daily, consisting of 1 hour for each therapy. Physical therapy focused on strengthening, function, and mobility activities including gait training. The objectives of kinesiotherapy were to increase strength and endurance; while occupational therapy intervention related to activities of daily living.

Both groups underwent the regular training. However, the STAT group received treadmill training instead of the 20 minutes of gait training the REG group received. The gait training for the STAT group was conducted, for 20 minutes, 5 days a week, by means of the body-supported treadmill ambulation system. Stair climbing, locomotion on uneven surface, and training on how to handle walking devices, when needed, were allowed during regular intervention for both groups. A harness consisting of a thoracic belt was attached snugly around the hips and chest to minimize upward shift (Quinton Pneu-weight harness). Two thigh straps with anterior and posterior attachments to the thoracic belt were fitted loosely on the patient. The harness was attached to an overhead bar on the BWS system. The system has a suspension mechanism with a force transducer that signals the amount of weight being supported (Vigor Corp., Ann Arbor, MI).

Training was started with support of up to 30 percent of body weight, and was progressively decreased as the patients acquire the capability of more self-support. The exact amount of BWS was determined by the therapist based upon observing the support required to facilitate proper trunk, and limb alignment and transfer of weight onto the hemiparetic limb. The BWS was decreased as much as possible while still allowing the hemiparetic limb to support weight during stance phase with less than 15 degrees of knee flexion. As the protocol progressed, the percentage of BWS was decreased, aiming for zero BWS, so that the subject would be training with full body weight at faster speeds. The therapist followed the rule of reducing BWS and/or increasing treadmill speed as quickly as possible. The BWS was reassessed during every training session and a daily log sheet was utilized to record gait speed, amount of support, and cardiovascular responses.

The treadmill utilized for training allowed walking to be initiated at a speed as slow as 0.01 m/sec and to be increased by increments of 0.01 m/sec (Woodway Treadmill, Bonn, Germany). The therapist determined the initial speed and progression. Speed was increased when a usual step length could be taken at a higher speed. The patients were checked for progression during every training session.

Subjects were trained 5 days per week on the STAT, until discharge from the Rehabilitation Unit, usually 2 to 3 weeks. Missing more than 3 consecutively scheduled visits for medical reasons, or inability to participate in a minimal of 9 sessions, resulted in the patient being dropped out from the study.

STATISTICAL ANALYSES

Descriptive statistics were utilized to characterize demographics and to establish initial scores on the MMSE, FAC, NIH Stroke Scale, and FIM-L scores at the beginning of the study. Independent T-tests were utilized to compare mean differences between groups for data reported in continuous, interval/ratio scales. A non-parametric equivalent (Wilcoxon) was utilized to analyze data reported in ordinal scales.

Analysis of covariance (ANCOVA) was completed on the dependent bike variables (oxygen consumption, workload, heart rate, blood pressure, and pedaling time) between the two groups using the pre-scores as covariates. When the outcome variable was expressed in ordinal scales such as FIM-L and FAC scores, the baseline and the post-intervention raw scores were ranked, and the ANCOVA was conducted based on the ranks, using the baseline ranks as the covariates (31). An alpha level of 0.05 was required for statistical significance. Considering that this was a pilot study and exploratory in nature, no correction for type I error was completed.

Since FIM-L scores are recorded in an ordinal scale, the Spearman's correlation coefficient was utilized to establish the strength of association between functional measures and the measures of performance on the bike protocol.

RESULTS

Fifteen male subjects fulfilled the criteria and voluntarily agreed to participate in this study. After randomization, eight participants were assigned to the regular group intervention, and the remaining seven were assigned to the STAT intervention. All participants had cerebral vascular accidents documented clinically, and often also by magnetic resonance imaging (MRI). In the regular rehabilitation group, four participants had right-sided and four had left-sided hemiparesis. In the STAT group, right side hemiparesis was present in five subjects, while two participants had left-sided hemiparesis.

One participant from the control left the hospital prior to medical discharge, and was tested only at baseline. Another participant from the control group had pulmonary complications and was dropped from the study. One subject in the STAT group had less than nine sessions of STAT training. Therefore, the data from the remaining 12 participants were analyzed.

Table 1 depicts information on demographics, level of cognition (MMSE), impairment (NIH), functional independence measures on locomotion subscores (FIM-L), and the number of days since the stroke on admission to rehabilitation. There were no significant differences between the two groups at baseline. However, the regular intervention group demonstrated more variability in age and impairment. A mean MSSE score of 26 for both groups revealed that the participants had only mild cognitive impairments. A mean score less than 6 in the NIH scale for both groups revealed that the subjects were moderately impaired, which, according to Adams et al., predicts good chances of recovery (32). There were no major changes in medications from baseline time to time of discharge from rehabilitation. The number of days elapsed from the onset of symptoms to the first baseline measurements for both groups was 15.00 ± 6.62 days.

Table 1.
Sample characteristics

	Regular (n=6)		**STAT (n=6)**		
	Mean ± SD	**Min − Max**	**Mean ± SD**	**Min − Max**	**p**
Age (yr)	59.67±13.58	44 − 75	57.83 ± 5.56	49 − 63	0.77
Height (cm)	177.81 ± 8.67	167.60 − 188.00	172.53 ± 9.35	159.00 − 185.40	0.51
Weight (kg)	86.3 ± 24.87	57.60 − 113.40	78.13 ± 13.49	61.20 − 118.80	0.33
MMSE	26.50 ± 2.58	24 − 30	26.67 ± 3.14	22 − 29	0.63*
NIH	5.16 ± 2.40	1 − 8	3.50 ± 1.97	0 − 5	0.22*
Days since stroke	14.33 ± 6.06	8 − 21	15.67 ± 7.66	8 − 28	0.75
FIM-L	2.83 ± 1.60	2 − 6	3.83 ± 2.79	2 − 9	0.58*

n: number of participants; MMSE: Mini-Mental State Examination; NIH: National Institutes of Health stroke scale FIM-L (functional independence measure – locomotor subscores) p: significance level. *nonparametric procedure (Wilcoxon) utilized for statistical significance.

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The analysis of the Functional Ambulatory Capacity (FAC) scores in **Figure 1** revealed that at baseline the regular group had two participants who required the help of two or more people in order to walk (score of zero), one participant who scored one (required firm continuous support of one person), and three participants who scored two (required continuous or intermittent support of one person). For the STAT group, the distribution was more even, with two participants scoring zero, two participants scoring one and the other two participants with a score of two.

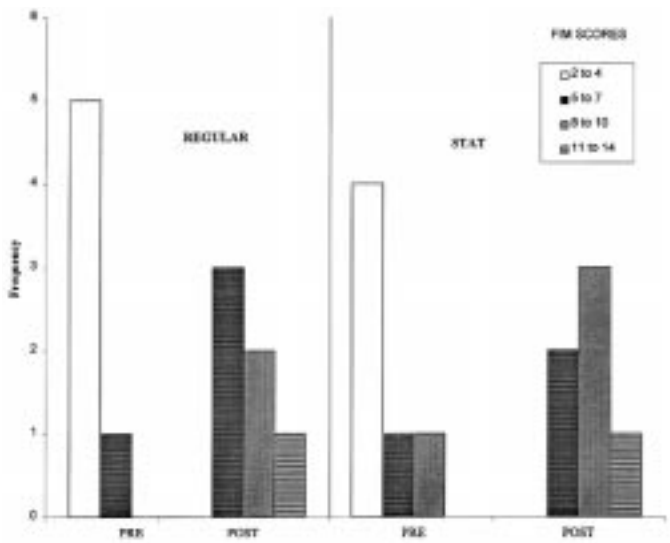

Figure 1.
Frequency distribution of the Functional Ambulation Category (FAC). Measurement of FAC scores before and after regular rehabilitation or regular rehabilitation with supported treadmill ambulation training.

After intervention, the two participants in the regular group who scored zero at baseline still scored zero, demonstrating no change due to the treatment. The three participants who scored two improved their score to three (required verbal supervision or stand-by), and one participant whose initial score was one changed to four (walk independently on level ground). The results after intervention with the STAT group revealed that one participant still scored zero, three participants scored two, one participant scored three, and another participant scored four. The ANCOVA based on ranks using the baseline FAC scores as covariates revealed no statistical difference between the two interventions. Clinically, this scale did not demonstrate meaningful changes for this sample.

Table 2 depicts the variables obtained with the bike protocol during pre- and posttesting for both regular and STAT interventions, and the probability levels found based on the analysis of means adjusted for pretest scores. There were no major ECG abnormalities while performing the exercise test in any of the subjects either at baseline or during post-intervention testing. Considering the acuteness of the stroke and the level of disability of the subjects, it was not expected that the exercise test would reach maximal exercise. During baseline evaluation, the main factor determining the end of the test was reaching a blood pressure of 190/110 mmHg (70 percent). The second most common factor that led to test termination was leg fatigue (30 percent). At post-intervention, leg fatigue and blood pressure were still the most common reasons for test termination (57 percent and 43 percent, respectively).

Table 2.
Bike ergometer variables

Bike parameters	Regular (n=6) Mean ± SD		STAT (n=6) Mean ± SD		
	Pre	Post	Pre	Post	p
Oxygen consumption (ml/kg/min)	8.02 ± 2.05	8.12 ± 2.30	8.57 ± 2.09	11.55 ± 2.76	0.039
Heart rate (BPM)	98.67 ± 12.08	100.00 ± 16.65	106.00 ± 20.40	120.33 ± 18.39	0.066
SBP (mmHg)	172.43 ± 24.99	165.00 ± 28.81	180.00 ± 24.49	191.33 ± 9.93	0.534
DBP (mmHg)	99.71 ± 16.95	94.33 ± 10.54	93.33 ± 7.55	95.33 ± 9.69	0.418
Workload (W)	25.00 ± 22.36	41.67 ± 12.91	41.67 ± 34.67	62.50 ± 26.22	0.226
Total time (s)	139.50 ± 11.15	162.00 ± 66.27	258.33 ± 137.90	338.33 ± 31.21	0.134

n = sample size; SBP (systolic blood pressure); DBP (diastolic blood pressure); SD (standard deviation); p (alpha level based on adjusted means); Regular and STAT: regular intervention and STAT intervention; Total time = total time pedaling the bike.

The ANCOVA based on adjusted means revealed that the oxygen consumption for the STAT group was significantly higher as compared to the regular group after intervention ($F=5.86$ $p=0.039$). Although the mean highest heart rate for the STAT group was about 20 beats higher than the regular group after intervention, this difference failed to achieve statistical significance ($F=4.36$ $p=0.066$). Likewise, there were no significant differences in blood pressure or total time pedaling on the bike test.

The total time spent in rehabilitation was not significantly different between the two groups (51 ± 26.41 vs 41.83 ± 17.44 hours for regular and STAT intervention, respectively). Out of the mean of 41.83 hours that the STAT spent in rehabilitation, an average of 4 ± 1.15 hours was dedicated to supported treadmill training. However, one subject in the regular intervention was in rehabilitation far longer (108 hours compared to an average for 43 hours for all others). Excluding this outlier, the two groups had equal rehabilitation time.

The initial amount of support was no more than 30 percent of body weight, which was decreased in association with a progressive increase in treadmill speed as the patient improved. At the end of STAT protocol the maximal speeds utilized to train ranged from 0.20 m/sec to 0.80 m/sec, according to the patient's ability.

Table 3 depicts results of oxygen consumption and time spent at the workload of 25 watts, pre- and postintervention for each group. Two patients in the regular group and one in the STAT group could not pedal against a 25-watt resistance at baseline. All participants were able to pedal at this workload after intervention. The statistical analysis based on the adjusted means (baseline scores at 25 watts) was conducted only on the subjects who could pedal at that workload for both baseline and after interventions (4 in the regular group and 5 in the STAT group). None of these differences reached statistical significance. In both groups, the patients increased the oxygen consumption at 25 watts. However, the STAT group had a concomitant increase in time while pedaling at this workload, while the regular group experienced a decrease.

The FIM-L scores were not statistically different on admission, as revealed by the Wilcoxon statistic (**Table 1**). Clinically, the initial difference between the two groups was not substantial either, as revealed by contrasting the mean FIM-L scores. A mean score between 2 and 4, which was observed for both groups, indicated that the patients, on average, required between maximal to total assistance for locomotion at the initiation of rehabilitation. The analyses of the FIM-L scores after intervention were conducted by ranking the pre- and postscores and applying the ANCOVA technique, with the ranked scores at baseline as covariates. This procedure revealed that there was no statistical difference between the two groups. Accordingly, the analyses of the mean FIM-L scores indicated that both groups improved similarly clinically (8.67 ± 1.86 vs 8.50 ± 2.17, for the regular and STAT groups, respectively). These mean scores indicated that, at discharge, patients required minimal assistance for locomotion. **Figure 2** depicts the frequency distribution of FIM-L scores pre- and postintervention for both groups.

Table 4 shows the correlation coefficients between FIM-L scores and the variables related to seated functional ability. In the regular group, at baseline, the strength of association between FIM-L scores and the highest pre-VO_2, longest time pedaling and the highest pre-workload was minimal (Spearman correlation coefficient of 0.05, 0.05, and 0.12, respectively). In the STAT

Table 3.
Performance at 25 watts

	Regular Mean ± SD		STAT Mean ± SD		
	Pre	**Post**	**Pre**	**Post**	**p**
N	4	5	4	5	
Oxygen consumption (ml/kg/min)	8.03 ± 1.66	8.35 ± 2.41	7.38 ± 2.58	7.70 ± 2.58	ns
Time (s)	112.50 ± 15.00	105.00 ± 17.32	102.00 ± 26.83	114.00 ± 13.41	ns

Time: time spent pedaling at 25 watts; SD: standard deviation; Regular: regular intervention; STAT: STAT intervention; N = sample size; p: alpha level; ns: not significant difference between pre- and postinterventions, based on adjusted means.

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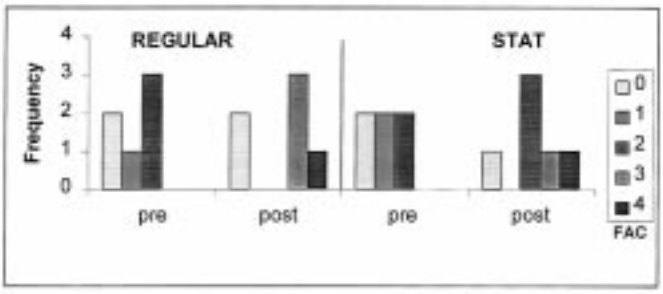

Figure 2.
Frequency distribution of the locomotor scale of the Functional Independence Measurement (FIM-L) before and after either regular rehabilitation or regular rehabilitation with supported treadmill ambulation training.

group, the baseline correlation coefficients between the FIM-L were somewhat higher than the regular group for time spent pedaling the bike (r=0.33), and workload (r=0.28), but minimal for pre-VO_2. None of these correlations was significant. Therefore, there was no association between estimation of functional locomotion and the measures of performance at baseline in either group.

The strength of association between the post-FIM-L scores and the bike protocol variables increased at the end of both interventions. For the regular group, oxygen consumption and workload had moderate but not significant correlations with post-FIM-L (correlation coefficients equals to 0.68 and 0.67, respectively). There was a small correlation with bike time and post-FIM-L scores (r=0.24). With the STAT group, the correlations between the highest post-VO_2, total time spent pedaling the bike, highest post-workload and the FIM-L after intervention were more consistent, but not significant (Spearman correlation coefficient of 0.44, 0.52, and 0.68, respectively).

DISCUSSION

The utilization of STAT in this pilot study for early intervention in acute stroke rehabilitation revealed that the procedure was safe and well tolerated. Likewise, the use of the bicycle protocol to evaluate the outcomes after regular and STAT interventions was meaningful and feasible to be used with stroke survivors even during inpatient rehabilitation. The participants involved in this study were individuals with moderate compromise following a CVA, who could benefit from a gait intervention. Therefore, they were not representative of the entire stroke population.

Few studies are available on the peak oxygen consumption in stroke survivors at an acute stage. The use of a bike protocol with the patients seated on a chair behind the bike and both feet strapped onto the pedals proved to be a safe and effective modification to perform an exercise test in these patients. Tsuji et al. reported the use of bridging activities as a mode of stress testing for CVA survivors in a group of subjects hospitalized for rehabilitation at a tertiary rehabilitation facility (33). Although the median length of days since the stroke in the population studied was 105 days, the highest peak VO_2 was 6.54 ml/O_2/kg/min and the peak heart rate was 80.57 bpm. There was no report on blood pressure responses. With our protocol, we were able to use another functional activity with a higher exercise intensity on a more acute population of stroke survivors. The cycle ergometer test resulted in higher VO_2 and heart rate values compared to the study of Tsuji et al. (33).

We did not anticipate that a true maximal oxygen consumption based on metabolic criteria would be attainable in these patients. A conservative cutoff for the blood pressure of 190/110 mmHg was utilized as one of the criteria to interrupt the test. High blood pressure in response to activity is one of the main concerns with acute stroke patients. Out of 15 participants evaluated at baseline, 11 patients had tests interrupted due to blood pressures that reached this cutoff. This is a clinically relevant finding if one considers that the mean duration of the baseline test was around 3 minutes, with a corresponded metabolic cost of 2.37 metabolic equivalents (METS). Although the patients were clinically stable at rest, low bouts of exercise might lead to exaggerated blood pressure responses. This underscores the need to carefully monitor blood pressure responses during rehabilitation, since some activities might impose levels of stress similar to the exercise test.

The utilization of STAT as an adjunct to gait training with acute stroke survivors led to improvements in seated functional ability (ability to use the affected limb, ability to exert force, and improved coordination between the affected and unaffected limbs, while pedaling) as compared to regular gait intervention. Potempa et al. demonstrated changes in seated functional ability utilizing the bike as a mode of training and evaluating chronic stroke survivors (16). They reported, however, that a 14-percent increase in maximum oxygen consumption (VO_2max) did not reflect the increase in peak workload (44 percent) and in maximal exercise time (40 percent) in patients who had a stroke. It was suggested that, because the ability to

pedal higher workloads improved to a greater extent than did aerobic capacity, the exercise training could have a positive effect on the efficiency of motion.

In our study, the change in oxygen consumption relative to the change in workload was also different. The percent improvement in workload (67 percent) observed with the regular group was large compared to the percent improvement in exercise time (16 percent) and oxygen consumption (1.2 percent). Therefore, with the regular group, improvement in motion efficiency (greater work output compared to the increase in oxygen consumption) might have been the primary source of change observed in seated functional ability. With the STAT group, improvement in motion efficiency could also have been related to the 50-percent increase in the workload after intervention. However, the 35-percent increase in VO_2 and the 31-percent increase in the pedaling time are also indicative that the ability to manage oxygen delivery and/or consumption had improved. So, in the STAT group, improvement in seated functional ability, besides being related to improvement in motor function, might have also been accompanied by changes in aerobic function.

Since the difference between the groups was greatest for VO_2 as compared to workload, heart rate, or time on bike, VO_2 may be more sensitive to the changes occurring in motor recovery as a result of this intervention. However, with the small number of patients in this pilot study, we did not have sufficient power for significant differences in the other variables. These observations warrant a larger patient trial.

We further contrasted the relative oxygen consumption in both groups at the absolute workload of 25 watts, pre- and postintervention. Since 3 out of 12 patients were unable to pedal against this workload initially, a measure using a single workload may not be as valuable in comparing changes in acute stroke patients. However, the relative oxygen consumption using a 25-watt workload may indicate that the effect of training between the two groups was dissimilar. The STAT group compared to the regular group was able to pedal longer with a lower oxygen cost. This might also indicate that STAT could have a potential benefit in efficiency during submaximal work, as compared to the regular intervention.

The participants were already clinically stable upon entering rehabilitation, so that medications were not substantially changed during the study. Therefore, the difference in performance between baseline and post-intervention outcomes could not be attributed to changes in medication.

The impact of STAT training on the ability to generate aerobic work has been reported elsewhere, but only after several months of intervention (6,9,11). The reduced aerobic capacity of stroke subjects is related to low endurance, reduction in number of motor units capable of being recruited during dynamic exercise, and to a reduced oxidative capacity of paretic muscle. Hoskins et al. demonstrated that the absolute amount of oxygen consumed per submaximal workload in these patients is greater than that observed in normal subjects of similar age and body size (34). Landin and collaborators, in a study of one-leg and two-leg exercise in hemiparetic subjects, showed reduced blood flow, augmented lactic acid production, and decreased capacity to oxidize free fatty acids in paretic muscles (35). However, studies examining the aerobic capacity of a more acute stroke population have not been reported. The patients in our study were most likely affected by the acuteness of the neurological event, even though poor conditioning may not be completely disregarded. Further studies are needed to demonstrate that STAT intervention could enhance aerobic function beyond the limits of natural recovery seen with acute stroke patients.

The majority of studies using STAT is usually of longer duration and utilizes a more chronic population. In our study with acute stroke patients, we were able to demonstrate different outcomes after STAT in a short intervention period of 2 to 3 weeks. The similarity in the total rehabilitation time between the two groups demonstrates that we were able to standardize the amount of time the patients received the two interventions. The outcomes that resulted from combining regular care with STAT were not due to more intervention time for the STAT group.

This pilot data suggests that regular rehabilitation combined with STAT resulted in improvement in functional abilities as reflected by the improved performance on the bicycle ergometer test. This is an interesting trend considering that our sample size was small, and that the intervention time was short. STAT enables symmetric unloading of both lower extremities, and lessens the chance of developing compensatory strategies compared to gait training with walking aids and full weight bearing during the regular intervention. Therefore, STAT may result in more effective daily gait training in appropriate patients.

The FIM-L data in this study was not as convincing. A correlational study between predicted peak VO_2 and total FIM scores in chronic stroke survivors reported that lower initial predicted peak VO_2 values were associated with lower initial FIM scores, and longer rehabilitation length of stay (36). FIM scores are widely used as a

clinical outcome measure, and are part of the routine classification, goal setting, evaluation, and discharge criteria for stroke patients in different rehabilitation settings. Since this study was primarily interested in the gait outcomes following a new strategy for gait training, only the locomotion subscores of the FIM scale were analyzed. However, because the FIM is scored on a 7-point ordinal scale it may not be sensitive enough to pick up the small changes in locomotion typically observed after 2 to 3 weeks of in-patient stroke rehabilitation. FIM-L scores qualitatively demonstrated the improvement in both groups, but could not differentiate between the two interventions. At baseline, the pattern of correlations between FIM-L and the bike variables were quite inconsistent. However, after both interventions, the correlations were stronger and more consistent, revealing moderate associations with the outcome variables.

Another way to analyze correlations is based on the effect size calculated from the shared variance between the dependent and the independent variables. According to Lipsey, the magnitude of an effect size is not the strength of the statistical relation represented, but the significance in terms of the proportion of people who attained a given level of benefit as a result of treatment (37). If we consider that a successful locomotion subscore on FIM would be 8 to 10 (patient requiring minimal assistance to supervision in that item) after 2 to 3 weeks of rehabilitation for these acute stroke survivors, the regular intervention had a 50-percent rate of success and a 50-percent rate of failure. With the STAT group, the success rate was 67 percent and the failure rate was 33 percent. Based on the success-to-failure ratio between these two interventions, the STAT group generated an effect size of 0.7 standard deviations. However, a closer analysis of this effect size indicates that it corresponds to an r-squared of just 0.11. Thus, only 11 percent of change in the FIM-L can be accounted for by this intervention, which further illustrates the small sensitivity of this scale. Therefore, these results suggest that objective assessment of functional performance, such as the pedaling task, may be preferable to evaluate a patient's recovery, since the measures detect pre- and postintervention changes and can discriminate between different rehabilitation approaches.

CONCLUSION

We conducted a pilot study to determine the value of supported treadmill ambulation training compared to regular rehabilitation during the acute recovery phase in hemiparetic stroke patients. Significant improvement was found in oxygen consumption during bicycle ergometry in the STAT intervention group compared to the regular therapy group. No other significant benefits in other physiologic or functional measures were found. This study suggests that larger trials are warranted to determine the value of this intervention.

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