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ORIGINAL ARTICLE

Activity-Based Therapy for Recovery of Walking in Chronic Spinal Cord Injury: Results From a Secondary Analysis to Determine Responsiveness to Therapy

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Abstract

Objective: To gain insight into who is likely to benefit from activity-based therapy (ABT), as assessed by secondary analysis of data obtained from a clinical trial.

Design: Secondary analysis of results from a randomized controlled trial with delayed treatment design.

Setting: Outpatient program in a private, nonprofit rehabilitation hospital.

Participants: Volunteer sample of adults (N=38; 27 men; 11 women; age, 22–63y) with chronic (≥12mo postinjury), motor-incomplete (American Spinal Injury Association [ASIA] Impairment Scale [AIS] grade C or D) spinal cord injury (SCI).

Interventions: A total of 9h/wk of ABT for 24 weeks including developmental sequencing; resistance training; repetitive, patterned motor activity; and task-specific locomotor training. Algorithms were used to guide group allocation, functional electrical stimulation utilization, and locomotor training progression.

Main Outcome Measures: Walking speed and endurance (10-meter walk test and 6-minute walk test) and functional ambulation (timed Up and Go test).

Results: This secondary analysis identified likely responders to ABT on the basis of injury characteristics: AIS classification, time since injury, and initial walking ability. Training effects were the most clinically significant in AIS grade D participants with injuries <3 years in duration. This information, along with information about preliminary responsiveness to therapy (gains after 12wk), can help predict the degree of recovery likely from participation in an ABT program.

Conclusions: ABT has the potential to promote neurologic recovery and enhance walking ability in individuals with chronic, motor-incomplete SCI. However, not everyone with goals of walking recovery will benefit. Individuals with SCI should be advised of the time, effort, and resources required to undertake ABT. Practitioners are encouraged to use the findings from this trial to assist prospective participants in establishing realistic expectations for recovery.

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Activity-based therapy (ABT) interventions continue to emerge as a promising intervention for functional recovery in people with spinal cord injury (SCI).[1] Findings of a recent randomized controlled trial (RCT) demonstrated that a comprehensive ABT program, including intensive strengthening and locomotor training, resulted in significant improvements in walking outcomes of people with chronic, motor-incomplete SCI.[2] However, considerable variability was also noted in response to therapy. Who is likely to benefit and the extent of recovery that may be expected from ABT remain important but underinvestigated considerations.

High variability in response to therapy focused on recovery of function has been noted previously. For example, Harkema et al[3] reported that 12% of their participants with SCI failed to respond

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to intensive locomotor training focused on recovery of walking. Responsiveness to therapy did not appear to be related to level of injury, severity of injury (based on classification using the ASIA Impairment Scale [AIS][4]), or time since injury. All these factors have been identified previously as potential predictors of responsiveness to therapy.[5-7]

Other investigators have examined factors associated with response to therapy. For example, Field-Fote et al[8] reported a difference in response to different locomotor training interventions based on initial walking speed in individuals with chronic, motor-incomplete SCI. Individuals with slower initial walking speeds (<0.1m/s) improved more than did those who started the trial with faster walking speeds (≥0.1m/s). Winchester et al[9] developed and tested a model for predicting recovery of over-ground walking speed after 36 sessions of body-weight–supported and over-ground locomotor training in individuals with motor-incomplete SCI. The model included time since injury, presence of voluntary bowel and bladder voiding, absence of severe or excessive spasticity, and baseline over-ground walking speed as predictors. The model accounted for 78.3% of the variability in actual over-ground walking speed after locomotor training.

Few studies have examined the dose response for rehabilitation interventions, which is crucial if we are to use health care dollars effectively and efficiently. Moreover, the clinical utility of any intervention depends in part on the carryover of effects from the clinic to the community, and long-term changes from the intervention. Wirz et al[10] found that individuals who continued walking after the completion of a locomotor training trial maintained the changes in electromyogram activity up to 3 years after the completion of the training. Those who did not achieve a certain level of walking did not maintain the gains attained after locomotor training. Because of the cost of including follow-up assessments in intervention trials, few studies have included this type of follow-up. Yet, this is a critical element to understanding the long-term benefit, as well as use, of any intervention for people with chronic impairment.

This article reports on secondary analyses of data obtained from the RCT that attempted to identify the factors associated with responsiveness to ABT. These analyses attempted to answer the following questions: (1) who responds to this ABT program, (2) can we predict the degree of improvement likely, (3) do interim (12- and 18-wk) results improve the ability to predict outcomes, (4) are improvements maintained 6 months posttreatment, and (5) what factors are associated with maintenance of effects?

Methods

Participants

Participation of human subjects was approved by an institutional review board before the initiation of the study. All the participants provided informed consent. We enrolled a total of 48 adults (age, 18y or older) in the RCT, all with motor-incomplete (AIS grade C or D) SCI, at least 12 months postinjury. The sample was stratified by level of injury (tetraplegia/paraplegia) and baseline lower extremity motor functioning (lower extremity motor score ≤25/>25), with random assignment to experimental and control groups. A total of 21 participants randomized to the experimental group completed treatment; 20 participants randomized to the control group completed initial pretesting and posttesting 24 weeks later.

A delayed-treatment design was used for the RCT, wherein individuals in the control group participated in the intervention after the 24-week delay (and completion of the first round of posttesting). This approach allowed us to examine the effects of ABT with a larger sample size, comparing pre- and posttreatment results for all participants. Three participants in the control group chose not to complete the intervention (because of transportation issues [n = 2] or unrelated illness [n = 1]), resulting in a total sample of 38 participants for the secondary analyses—21 participants in the experimental group and 17 participants in the control group.

List of Abbreviations:

6MWT	6-minute walk test
10MWT	10-meter walk test
ABT	activity-based therapy
AIS	ASIA Impairment Scale
RCT	randomized controlled trial
SCI	spinal cord injury
TUG	timed Up and Go

ABT intervention

The ABT intervention consisted of 3 elements: developmental sequence activities, resistance training, and locomotor training. Details about the intervention and underlying principles supporting the therapeutic approaches are presented in Jones et al.[2]

Measurement of outcomes

The following dependent variables were examined: neurologic function was assessed using the International Standards for Neurological Classification of Spinal Cord Injury; walking was assessed using the 10-meter walk test (10MWT) and the 6-minute walk test (6MWT); functional ambulation was assessed using the timed Up and Go (TUG) test. Details about the outcome measures used and the data collection process are presented in Jones.[2] In addition to pre- and postintervention assessment of all outcome measures, interim 12-week and 18-week assessments and 6-month follow-up assessments were completed on primary outcome measures.

Data analysis

Paired-sample *t* tests were used to examine the significance of differences in pre/post scores for all outcome measures. Bivariate and multivariable regression analyses were computed to examine possible predictors of treatment outcomes, responsiveness to treatment, and maintenance of effects. All data analyses were performed using SPSS 14.0.[a] Statistical significance was set at $P \leq .05$ for all statistical analyses. Values are presented as mean ± SD, unless otherwise noted.

Response to treatment

Following recommendations by Musselman,[11] distribution-based estimates of minimally important difference were calculated for each walking variable. These values reflect the amount of change necessary to detect differences beyond expected measurement error and provide an estimate of clinically significant improvement. We compared these calculated values to smallest-real-difference values for each outcome measure on the basis of normative data reported by Lam et al[12] in a systematic review of functional outcome measures in SCI. We used the most conservative estimate of clinically meaningful improvement (smallest-real-difference values for the 10MWT and the 6MWT and minimally important difference for the TUG test) to characterize intervention "responders" as those whose change scores pre-/postintervention met

or exceeded the clinically significant value: >0.13m/s for the 10MWT, >45.1 meters for the 6MWT, and a reduction of >25.7 seconds for the TUG test elapsed time. We calculated odds ratios for associations between possible predictor variables and responders versus nonresponders.

Predicting walking improvement

We attempted to replicate the Winchester[9] model using the same predictor variables, although our measures of bowel and bladder function and spasticity involved different methodologies (Spinal Cord Independence Measure, version III,[13] assessment of bowel/bladder function and Spinal Cord Injury Assessment Tool for Spasticity[14]). Because interim assessments were collected on walking tests after 12 and 18 weeks of the ABT intervention, we also examined whether predictability of the Winchester model could be improved by adding information about responsiveness to therapy after 12 and 18 weeks. We added a fifth variable to the model—the change in gait speed from baseline to the 12-week interim assessment. We also tested the model using change in gait speed from baseline to 18 weeks as a predictor.

We also examined whether changes in walking at 18 weeks were more accurate than changes at 12 weeks in predicting final walking outcomes. For the 6MWT (total distance) and the 10MWT (gait speed), we performed linear regressions with the pre-to posttest change score as the dependent variable and baseline + 12-week or baseline + 18-week scores as predictors. We calculated the difference between the predicted and actual pre/post change scores and determined the percentage of participants who met or exceeded their predicted improvement.

Maintenance of effects

We obtained 6-month follow-up assessments for 31 of the 38 participants who completed the ABT intervention. Records of self-reported maintenance exercises during the 6 months post-intervention were available for 24 of these 31 participants. We compared performance at the 6-month follow-up with performance at posttest on the 10MWT and the 6MWT to determine maintenance of treatment effects. Maintenance was defined as performance at 6-month follow-up meeting or exceeding performance at posttest, but only for participants who demonstrated *some* improvement (even if not clinically significant) from pre-to posttreatment (ie, no change from pre-to posttreatment to follow-up was *not* considered maintenance of effects). We also examined the relation between maintenance of gains and reported exercise (those reporting >3h/wk or <3h/wk of exercise) and reported walking (those who regularly walk in the community vs non-walkers and home-only walkers).

Results

Table 1 summarizes pre- and posttreatment results for all participants on the 2 measures of neurologic recovery and 3 walking tests. Statistically significant pre-to posttest differences were noted for all outcome measures. Considerable variability was noted in response to treatment, and, overall, only modest effect sizes were observed for the ABT intervention.

Response to treatment

On the basis of the most conservative estimate, 18%, 26%, and 32% of the participants demonstrated clinically significant improvements on the TUG test, the 10MWT, and the 6MWT, respectively. Table 2 presents responders (Yes) and nonresponders (No) on each outcome measure, calculated odds ratios for 5 participant variables, and the confidence intervals and *P* values for each. Greater responsiveness to therapy was associated with the following participant characteristics: paraplegia, AIS grade D, American Spinal Injury Association lower extremity motor score >25, time since injury <3 years, and participants who were walking at speeds >0.4m/s at baseline (ie, functional walkers at home).[15] However, only 2 participant variables were statistically reliable predictors of responsiveness to ABT, as evidenced by significant odds ratios. Participants with AIS grade D and those <3 years postinjury were more likely to achieve meaningful improvement in walking endurance, as measured by the 6MWT total distance. Based on the most conservative estimate for each measure, 8 of the 38 participants (21%) demonstrated clinically significant improvements on at least 2 of the 3 walking tests. Seven of these 8 were AIS grade D and <3 years postinjury. Only 2 of the 8 were functional walkers at baseline.

Predicting improvement in walking ability

Presented in table 3A, our replication of the Winchester model accounted for 90.1% of the variability in over-ground walking speed at posttest. The revised model with the addition of baseline-to 12-week improvement (table 3B) accounted for 94.9% of the variability in over-ground walking speed at posttest. We found essentially no difference between 12-week and 18-week (table 3C) improvements in the amount of variability accounted for by the model.

Table 4 summarizes results of our regression analyses to examine the value of interim results in predicting final walking outcomes. The baseline + 12-week model accounted for 88.9% of the variability in final 6MWT change scores, whereas the baseline + 18-week model accounted for 94.8%. The baseline + 12-week model for the 10MWT accounted for 90.9% of the variability in final 10MWT change scores,

Table 1 Neurologic and walking outcomes for all participants completing the ABT intervention (n=38)

Measure	Pretreatment	Posttreatment	Difference	95% CI	*P**
ISNCSCI total motor score	63.68±18.27	67.18±18.19	3.5±5.41	1.72 to 5.28	.000
ISNCSCI LEMS	26.03±12.23	28.76±12.23	2.74±4.35	1.31 to 4.17	.000
10MWT speed (m/s)	0.304±0.404	0.364±0.389	0.061±0.15	0.01 to 0.11	.021
6MWT total distance (m)	96.30±115.15	129.35±127.08	33.05±52.40	15.82 to 50.27	.000
TUG test total time (s)	149.50±130.39	124.99±126.21	−24.52±61.97	−44.88 to −4.14	.020

Abbreviations: CI, confidence interval; ISNCSCI, International Standards for Neurological Classification of Spinal Cord Injury; LEMS, lower extremity motor score.
* $P<.05$.

Table 2 Odds of responding to ABT

	10MWT (>0.13-m/s Increase)					6MWT (>45.11-m Increase)					TUG test (>25.7-s Decrease)				
Variable	Yes	No	Odds Ratio	95% CI	*P*	Yes	No	Odds Ratio	95% CI	*P*	Yes	No	Odds Ratio	95% CI	*P*
Injury level															
Tetraplegia	6	22				7	21				5	23			
Paraplegia	4	6	2.44	0.53–11.57	.260	5	5	3.00	0.67–13.53	.153	2	8	1.15	0.18–7.14	.881
AIS grade															
C	1	13				1	13				2	12			
D	9	15	7.80	0.87–70.08	.067	11	13	11.00	1.24–97.97	.032*	5	19	1.58	0.26–9.48	.617
LEMS															
<26	3	13				3	13				4	12	2.11	0.40–11.13	.378
>25	7	15	2.02	0.43–9.46	.371	9	13	3.00	0.66–13.66	.156	3	19			
Time since injury (y)															
<3	7	12	3.11	0.66–14.60	.150	9	10	4.80	1.04–22.10	.044*	4	15	1.42	0.27–7.44	.677
>3	3	16				3	16				3	16			
Walker pre (>0.4 m/s)															
No	6	21				7	20				7	20	8.42	0.44–161.16	.157
Yes	4	7	2.00	0.43–9.21	.374	5	6	2.38	0.55–10.32	.246	0	11			

Abbreviations: CI, confidence interval; LEMS, lower extremity motor score.
* $P<.05$.

whereas the baseline + 18-week model accounted for 92%. Predictive accuracy was higher for 10MWT than for 6MWT change scores. However, the degree of improvement in predictive accuracy between 12-week and 18-week deltas was negligible, particularly for the 6MWT.

Table 3 Final gait speed multivariable regression

Variable	Coefficient (B)	SE (B)	*P*
A. Winchester et al[9] model			
Voluntary bowel and bladder function	.083	.045	.075
Functional spasticity score	−.007	.008	.357
Initial walking speed	.898	.054	.000
Time since injury	−.006	.003	.024
Constant	.148	.070	
R^2 .901			
B. With 0- to 12-wk change score			
Voluntary bowel and bladder function	.066	.033	.057
Functional spasticity score	.004	.006	.549
Initial walking speed	.992	.043	.000
Time since injury	−.008	.002	.000
Change in walking speed (0–12wk)	.918	.169	.000
Constant	.027	.056	
R^2 .949			
C. With 0- to 18-wk change score			
Voluntary bowel and bladder function	.014	.037	.698
Functional spasticity score	.005	.006	.427
Initial walking speed	.957	.042	.000
Time since injury	−.008	.002	.002
Change in walking speed (0–18wk)	.619	.122	.000
Constant	.100	.054	
R^2 .945			

Maintenance of effects

At 6-month follow-up, 16 of 31 (52%) participants met or exceeded their posttest 10MWT speed and 12 of 31 (39%) met or exceeded their 6MWT distance. Table 5 gives odds of maintaining gains on each outcome measure, with calculated odds ratios, confidence intervals, and *P* values for 5 participant variables and, for the 24 participants with available information, 2 measures of reported activity postintervention. AIS grade (D) and lower extremity motor score (>25) were statistically reliable predictors of maintained gains, as evidenced by significant odds ratios for both walking speed (10MWT) and endurance (6MWT). Participants who were functional walkers (>0.4m/s) on completion of the ABT intervention were also statistically more likely to maintain gains in walking endurance. The odds of maintaining gains were slightly higher for those who exercised more than 3h/wk and walked in the community. However, the only odds ratio to approach statistical significance was for maintenance of walking endurance among individuals who walked regularly (>3 times a week) in the community.

Discussion

Considerable variability was noted in response to ABT, with only 10 of the 38 (26%) participants achieving clinically meaningful improvements in walking speed (>.13m/s) and 12 of the 38 (32%) in walking endurance (>45.1m). This ABT program appears to have a greater impact on walking endurance than on speed as indicated by improvements in distance on the 6MWT. This may be expected because the multifocused ABT intervention included progressive resistance training, which distinguishes this approach from locomotor training only. Only 2 participants made the transition from functional nonwalker (<0.4m/s) to walker (>0.4/s) after treatment. However, at least modest gains were observed in 22 of the 38 participants (58%), most notably in walking endurance.

Table 4 Linear regressions with baseline + 12- and 18-wk scores as predictors of posttest outcomes

Test score	R^2	SE	Mean Difference	Predictive Accuracy (%)
6MWT				
Baseline + 12-wk score	.889	142.9	1.16m	55
Baseline + 18-wk score	.948	97.5	0.42m	56
10MWT				
Baseline + 12-wk score	.909	0.12	0s	47
Baseline +18-wk score	.920	0.11	0s	53

Our secondary analyses suggest that it is possible to identify likely responders to ABT on the basis of injury characteristics—AIS classification, time since injury, and initial walking ability. These factors, along with information about preliminary responsiveness to therapy (gains at 12wk), can help predict the degree of recovery likely from an intensive ABT intervention. Given the time, expense (typically $75–150/h and not covered by health insurance), and odds of responding, interim assessment of efficacy should be an expectation of all ABT programs. Information should be shared with participants concerning the likelihood of recovery on the basis of injury characteristics and preliminary response to therapy. This disclosure is especially important because the gains reported here required significant resource utilization. At a typical cost of $100/h, participants would have paid over $21,000 out of pocket for a 24-week ABT program similar to that delivered in the present study.

Although not everyone demonstrated clinically meaningful improvements in walking, a number of those who did make any gains (52% and 39% for walking speed and endurance, respectively) were likely to maintain those gains for at least 6 months. This finding suggests that improvements, particularly among those who are able to walk functionally in the community (>0.9m/s), may have a lasting impact. Moreover, these findings suggest that the improvements noted may have resulted from neurologic recovery and motor relearning not simply greater strength and conditioning. Lasting improvements may be expected for some of these individuals, as they reached a level of function allowing them to sustain independent walking on a regular basis. This has been described as "getting over the hump," when individuals can complete their own task-specific practice leading to long-term functional recovery.[16]

Finally, even among those who maintained improvements, given the time and effort required to walk, it is not likely that walking will become their primary means of community mobility if it was not so before treatment. In this respect, it is important to keep the implications of our findings in perspective. ABT may play an important but not sufficient role in recovery of walking after motor-incomplete SCI. But coupled with continued advances in locomotor training and assistive technology (eg, personal robotic exoskeletons), it may contribute to a changing paradigm of walking recovery.

Study limitations

We noted previously that the sample size, which was driven largely by financial constraints posed by the trial, was a weakness of both our primary and secondary analyses.[2] Examination of a standardized

Table 5 Odds of maintaining gains—Performance at 6-mo follow-up meets or exceeds performance at posttest

	10MWT Speed					6MWT Distance				
Variable	Yes	No	Odds Ratio	95% CI	*P*	Yes	No	Odds Ratio	95% CI	*P*
Injury level										
Tetraplegia	11	14				10	15	1.33	0.20–8.70	.764
Paraplegia	5	1	6.36	0.65–62.69	.113	2	4			
AIS grade										
C	2	10				1	11			
D	14	5	14.00	2.25–87.25	.005*	11	8	15.13	1.61–142.16	.018*
LEMS										
<26	4	10				1	13			
>25	12	5	6.00	1.26–28.55	.024*	11	6	23.83	2.4–229.36	.006*
Time since injury (y)										
<3	8	7	1.14	0.28–4.68	0.853	6	9	1.11	0.26–4.72	.887
>3	8	8				6	10			
Walker post (>0.4m/s)										
No	9	12				5	16			
Yes	7	3	3.11	0.63–15.49	0.166	7	3	7.47	1.39–40.25	.019*
Reported exercise (h/wk)										
<3	4	5				4	5			
>3	9	6	1.88	0.35–9.98	0.461	7	8	1.09	0.21–5.76	.916
Reported walking										
No/home only	4	5				2	7			
Home/community	9	6	1.88	0.35–9.98	0.461	9	6	5.25	0.80–34.43	.084

Abbreviations: CI, confidence interval; LEMS, lower extremity motor score.
* $P<.05$.

"dosage" of ABT was a second limitation of the study and related to this was the high degree of variability in the amount of each intervention component delivered to participants. This was driven in part by participants' tolerance for therapy, ability to participate, and the amount of assistance needed to prepare for and complete different therapeutic modalities. As a consequence, it is difficult to determine more specific dose-response relations. More impaired individuals required more labor- and time-intensive interventions, thus limiting dose and repetition, and masking any correlation between therapy intensity and effect.

Another notable limitation was the delayed treatment design used in the study. The design afforded a larger treated sample to conduct secondary analyses of intervention effects. However, we were also limited in our ability to examine, with an untreated control group, the longer-term benefits of ABT, particularly the impact on functional activity, community participation, and metabolic health. Secondary analyses with all treated individuals indicated that there were limited improvements pre-to posttreatment and posttreatment to 6-month follow-up on any of these outcome measures. An experimental-control group comparison at 6 months posttreatment may have identified differences, but the likelihood of statistically significant differences seems remote, given limited pre-to posttreatment differences.

Conclusions

This study demonstrates that although intensive ABT has the potential to promote neurologic recovery and enhance walking ability in some individuals with chronic, motor-incomplete SCI, not everyone benefits from ABT. Even those who do may not achieve clinically meaningful recovery. Moreover, the secondary health and quality-of-life benefits are not clear. Individuals with incomplete SCI who are considering participation in an ABT intervention should be advised of the time, effort, and resources required to undertake such an endeavor, the characteristics of those likely to achieve meaningful gains (AIS grade D, <3y postinjury), and the effort needed to maintain any gains that are achieved. They should approach ABT with realistic expectations about the odds of recovery and the cost of the program in time, money, and sacrifice of other interests. Practitioners are encouraged to use the findings and recommendations from this trial to assist prospective participants in establishing realistic expectations for recovery.

Supplier

a. SPSS Inc, 233 S Wacker Dr, 11th Fl, Chicago, IL 60606.

Keywords

Exercise therapy; Gait disorders, neurologic; Motor activity; Rehabilitation; Spinal cord injuries

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