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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