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ORIGINAL ARTICLE

A Comparison of Robotic Walking Therapy and Conventional Walking Therapy in Individuals With Upper Versus Lower Motor Neuron Lesions: A Randomized Controlled Trial

Ana Esclarín-Ruz, PhD, MD,[a] Monica Alcobendas-Maestro, PhD, MD,[a] Rosa Casado-Lopez, MD,[a] Guillermo Perez-Mateos, PT,[a] Miguel Angel Florido-Sanchez, PT,[a] Esteban Gonzalez-Valdizan, BS,[a] Jose Luis R. Martin, PhD[b]

From the [a]Department of Physical Medicine and Rehabilitation, National Hospital for Paraplegics, Toledo; and [b]European University of Madrid, Madrid, Spain.

Abstract

Objective: To compare a walking reeducation program with robotic locomotor training plus overground therapy (LKOGT) to conventional overground training (OGT) in individuals with incomplete upper motor neuron (UMN) or lower motor neuron (LMN) injuries having either traumatic or nontraumatic nonprogressive etiology.

Design: Randomized open controlled trial with blind evaluation by an independent observer.

Setting: An inpatient spinal cord injury rehabilitation center.

Participants: A total of 88 adults within 6 months of spinal cord injury onset (group A, 44 with UMN injury, and group B, 44 with LMN injury) were graded on the American Spinal Injury Association Impairment Scale as C or D. Each of these groups was then randomly allocated to conditions 1 or 2.

Interventions: Condition 1: Subgroups A1 and B1 were treated with LKOGT for 60 minutes. Condition 2: Subgroups A2 and B2 received 60 minutes of conventional OGT 5 days per week for 8 weeks. Subjects with UMN and LMN were randomized into 2 training groups.

Main Outcome Measures: Ten-meter walk test and 6-minute walk test (6MWT). Walking Index for Spinal Cord Injury II, lower extremity motor score (LEMS), and the FIM-Locomotor were secondary outcome measures.

Results: By using the LKOGT program compared with OGT, we found significant differences in the 6MWT for groups A1 and B1. LKOGT also provided higher scores than did OGT in secondary outcomes such as the LEMS and the FIM-Locomotor.

Conclusions: Robotic-assisted step training yielded better results in the 6MWT and the LEMS in patients with UMN and LMN.

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Both manual and robotic-assisted body weight–supported treadmill training (BWSTT) is based on the principles of activity-dependent plasticity and automaticity.[1-3] This type of treatment provides the damaged nervous system with appropriate sensory input to stimulate the remaining spinal cord networks, known as central pattern generators (CPGs).[4-8] Ever since the studies reported by Dietz,[9] Colombo,[10,11] and colleagues outlining the neurophysiological basis of such treatment, articles have been published describing significant improvements in the use of lower limbs and, thus, in short- and long-term walking ability[12-15] in patients with both acute[12,13] and chronic[12,14] spinal cord injury (SCI).

Comparative case-control studies report that robotic-assisted BWSTT or BWSTT with functional electrical stimulation is equivalent to overground practice. A Cochrane Library review[15] suggested that there was insufficient evidence to decide whether either of these SCI treatments was better than conventional interventions.

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In longer-term BWSTT programs, such as that used by Dietz[9] and more recently by Colombo,[10] the authors concluded that functional improvements could not be exclusively accounted for by spinal circuitry responses to sensory input but rather that muscle strengthening played a fundamental role in individuals with incomplete SCI. Similarly, researchers such as Werning et al[12] have found an improvement in tolerance to exercise. Yet we were unable to trace any previous study that had compared the effect of BWSTT programs between patients with upper motor neuron (UMN) and lower motor neuron (LMN) injuries. In the latter, the lack of intervention of spinal circuitry means that any improvement must be due to the effect of the exercise.

On the basis of these conclusions, it might be thought that in terms of walking ability and quality, positive results could be obtained for LMN injuries such as those obtained for UMN injuries on which most of the studies have been undertaken.

To address this problem, we compared a walking reeducation program with robotic locomotor training plus overground therapy (LKOGT) to conventional overground training (OGT) in individuals with incomplete UMN or LMN injuries having either traumatic or nontraumatic nonprogressive etiology. We hypothesized that on comparing LKOGT with OGT in patients with UMN and LMN injuries, these 2 types of injuries might respond similarly in terms of walking speed and distance, walking ability, and muscle strength.

Methods

We conducted a randomized open controlled trial with blind evaluation by an independent observer. The assessors were blinded for treatment allocation and were familiar with the test battery.

This study was undertaken at the National Paraplegics Hospital (Hospital Nacional de Parapléjicos), a 210-bed, specialist SCI center. Prior approval for the study was obtained from the ethics and research committees.

Participants

From among all patients admitted from November 2007 to December 2010, we assessed 667 and selected 2 groups of subjects with incomplete SCI: group A with 44 subjects with UMN injuries and group B with 44 subjects with LMN injuries. Both groups met the inclusion-exclusion criteria outlined in appendix 1. After the study subjects had been selected, their demographic and injury characteristics were recorded (level, American Spinal Injury Association grade,[16,17] and time course). Subjects in each group were randomly assigned to 2 conditions. Condition 1: Subgroups A1 and B1 (LKOGT) were imparted 30 minutes of conventional mobility training plus 30 minutes of robotic-assisted mobility training. Condition 2: Subgroups A2 and B2 (OGT) were imparted 60 minutes of conventional mobility training. No subjects were familiar with the Lokomat[a] robotic-assisted mobility training system before participating in the study.

Patients were randomized to the LKOGT and OGT groups using an appropriate, centrally computerized allocation-concealment process.

List of abbreviations:

BWSTT	**body weight–supported treadmill training**
CPG	**central pattern generator**
LEMS	**lower extremity motor score**
LKOGT	**robotic locomotor training plus overground therapy**
LMN	**lower motor neuron**
OGT	**overground therapy**
SCI	**spinal cord injury**
6MWT	**6-minute walk test**
10MWT	**10-meter walk test**
UMN	**upper motor neuron**

Losses to follow-up

A *loss to follow-up* was defined as any patient included who, once the study had begun, was unable to complete it for any reason. Such subjects were analyzed on an intention-to-treat basis to eliminate or control for possible bias due to loss of patients during the study.

Baseline measurements of outcome variables were taken before patients underwent the intervention corresponding to the condition to which they had been allocated, and again at the end of session 40. In addition, we took an intermediate measurement on reaching the 20-session mark, so as to ensure that in any case in which patients might be unable to complete the treatment, they could be evaluated on an intention-to-treat basis. All outcome measures were evaluated by a person external to the study.

Intervention

All patients underwent the standard physical treatment program, based on daily 60-minute sessions of joint mobilization below the level of the spinal injury, strengthening of supralesional musculature and remaining motor functions, muscle stretching and postural relaxation techniques to treat spasticity, trunk stabilization, rotation work, and practice of self-care skills. Within this routine, the main component of their mobility training consisted of 30 minutes of walking with either LKOGT or OGT over 40 sessions (8wk). They did not receive any formal training for walking other than during these sessions. The necessary orthoses were prescribed in accordance with patients' injury levels and remaining motor functions.

Lokomat is a driven gait orthosis that automates locomotion therapy on a treadmill with a partial body weight–support system. For treatment, the amount of body weight supported was initially set at 60% of each individual's weight and then decreased in accordance with load tolerance, but in no case was it set at <25% support. The speed selected was the one at which the patient worked most comfortably. Treatment sessions were in all cases conducted under the supervision of a trained physiotherapist.

Outcome measures

The principal outcome variables were walking speed measured with the 10-meter walk test (10MWT)[18] and walking distance measured with the 6-minute walk test (6MWT).[19]

Of the various possibilities of performing the 10MWT, a distance of exactly 10 meters was taken into account for study purposes and incorporated into the measurement of acceleration and deceleration times that occurred at the extremes.

The 6MWT[19] determines how far one can walk in 6 minutes. It is a test of submaximal effort with the highest reliability coefficient (.75) and is one of the most valid and highly sensitive gait assessment measures in spinal injury.[20] When performing both tests, each individual was allowed to use the necessary orthoses and technical aids, and was asked to walk in a straight line at a comfortable pace to cover the distance and time.