Who May Have Durable Benefit From Robotic Gait Training?

A 2-Year Follow-Up Randomized Controlled Trial in Patients With Subacute Stroke

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Background and Purpose—Robotic-assisted walking training after stroke aims to enhance the odd of regaining independent gait. Recent studies have suggested that this approach is more effective than conventional therapy alone only in severely affected patients. We determined whether these results persist at long-term follow-up.

Methods—Forty-eight nonambulant participants after subacute stroke were stratified by motricity index into high (<29) and low (≥29) motor impairment groups. Each arm was randomized to a robotic or control group at a mean of 20 days after stroke. All patients underwent 2 therapy sessions per day, 5 days per week, for 3 months. Robotic group subjects underwent 20 sessions of robotic-assisted gait training in the first 4 weeks of inpatient therapy and abbreviated conventional therapy, whereas control group patients received only conventional gait training. The primary outcome was Functional Ambulation Category, and secondary measures were the Rivermead Mobility Index and Barthel Index scores. The scales were administered before and after the inpatient stay and 2 years after discharge.

Results—At follow-up, as at discharge, the low motricity robotic group improved more than the control group counterpart with regard to functional ambulation category (4.7±0.5 versus 3.1±1.5, P=0.002), Barthel Index (76.9±11.5 versus 64.7±14.0, P=0.024), and Rivermead Mobility Index (11.8±3.5 versus 7.0±3.6, P=0.010), whereas conventional and robotic therapies were equally effective in the high motricity groups.

Conclusions—The higher efficacy of the combination of robotic therapy and conventional therapy versus conventional therapy alone that was observed at discharge only in patients with greater motor impairments was sustained after 2 years. **(*Stroke*. 2012;43:1140-1142.)**

Key Words: functional recovery ■ gait ■ outcomes ■ robotic-assisted therapy ■ rehabilitation

Despite >20 years of studies on robotic devices, including a system for body weight support for walking recovery after stroke, their true efficacy is unknown.[1] In nonambulant patients with subacute stroke, electromechanically assisted walking training resulted more effective[2] (or equally effective but less strenuous[3]) than floor-assisted therapy out to 6 months of follow-up. Conversely, Duncan and colleagues recently reported that long-term (1-year follow-up) body weight-supported treadmill training is not superior to home-based rehabilitation in patients with autonomous ambulatory capacity.[4] Thus, the efficacy of robotic-assisted devices in gait recovery in patients with subacute stroke remains unknown.

Data on those patients who benefit from these devices have recently been generated. In a recent trial, more severely affected patients with subacute stroke were the ideal candidates for effective electromechanically assisted walking training.[5] Conversely, conventional and robotic therapies are equivalent in patients with greater lower limb motricity on discharge from a rehabilitation hospital. However, this study did not perform a follow-up assessment to verify whether this efficacy persisted.[5]

The aim of this study was to determine the long-term effects of robotic gait training in patients with a mild or severe leg paresis. The primary outcome measure was the independency in gait, and secondary ones were activities of daily living and mobility.

Methods

Forty-eight nonambulant participants with motor and gait dysfunctions due to subacute stroke were stratified by motricity index into high motricity (≥29, HM) and low motricity (<29, LM) groups (Table). Each arm was randomized to a robotic or control group (RG

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Table. Patient Assessment

Characteristics	RG_{LM}	CG_{LM}	P_{LM}	RG_{HM}	CG_{HM}	P_{HM}
Age, y (at admission)	55.58±13.35	60.17±9.59	0.443	68.33±9.11	62.92±17.43	0.514
Ischemic/hemorrhagic	9/3	11/1	. . .	9/3	12/0	. . .
Right/left hemiparesis	9/3	7/5	. . .	4/8	8/4	. . .
Motricity index	16.1±11.4	16.2±9.5	0.887	52.0±10.2	51.2±12.7	0.843
Scale						
Time	RG_{LM}	CG_{LM}	P_{LM}	RG_{HM}	CG_{HM}	P_{HM}
FAC						
Admission	0.1±0.3	0.0±0.0	0.755	0.0±0.0	0.4±0.7	0.178
Discharge	4.0±0.9	2.1±1.2	0.001*	3.8±1.1	3.7±1.0	0.799
Follow-up	4.7±0.5	3.1±1.3	0.002*	4.3±0.9	4.0±1.0	0.630
BI						
Admission	14.2±11.8	7.9±8.9	0.160	20.0±17.2	24.6±15.3	0.551
Discharge	69.6±15.1	52.1±14.1	0.005*	64.2±21.2	74.2±20.3	0.266
Follow-up	76.9±11.5	64.7±14.0	0.024*	74.3±18.7	77.6±20.4	0.478
RMI						
Admission	1.6±0.8	1.3±0.9	0.319	1.8±1.4	2.2±1.9	0.755
Discharge	9.4±2.7	4.9±2.0	0.001*	7.4±4.1	10.1±4.0	0.101
Follow-up	11.8±3.5	7.0±3.6	0.010*	10.4±3.6	10.6±3.9	0.977

Patient characteristics (at admission) and mean±SD of clinical scale scores. The *P* values were obtained using Mann-Whitney *U* test for the comparisons between low motricity groups (P_{LM}) and between high motricity groups (P_{HM}).

RG indicates electromechanically assisted group; CG, control group; LM, low motricity; HM, high motricity; FAC, Functional Ambulation Classification; BI, Barthel Index; RMI, Rivermead Mobility Index.

*Statistically significant (<0.05).

or CG) at a mean of 20 days after stroke. All patients underwent 2 therapy sessions per day, 5 days per week, for 3 months. RG subjects underwent 20 sessions of robotic-assisted gait training using the Gait Trainer (GT II; Rehastim, Berlin, Germany) in the first 4 weeks of inpatient therapy using controlled end point trajectories and abbreviated conventional therapy, whereas CG patients received only conventional gait training. The primary outcome was Functional Ambulation Category score. The secondary outcomes were Barthel Index and Rivermead Mobility Index scores.

All patients had been recruited in our previous study, in which outcomes were measured only at admission and discharge from our rehabilitation hospital.[5]

This new study was approved by the local ethical committee, and written informed consent was given by all patients. Patients were evaluated by a physician who was blinded to the group allocation. The follow-up assessment was performed approximately 2 years after discharge from our rehabilitation hospital during an outpatient consultation.

Like in our previous report, in which scale scores were analyzed at admission and dismissal,[5] the follow-up data were analyzed by Mann Whitney *U* test to evaluate the differences between RG and CG subjects in the LM and HM groups. An intention-to-treat analysis was performed for the missing data, and discharge values were used at follow-up to allow us to make longitudinal comparisons. The significance level was set at 0.05.

Results

Two of 48 patients were unavailable for the follow-up assessment: 1 in the RG_{HM} group due to a hip fracture and 1 fatality in the CG_{HM} group. No significant differences were observed between RG_{HM} and CG_{HM} or between RG_{LM} and CG_{LM} with regard to Functional Ambulation Category, Barthel Index, and Rivermead Mobility Index scores at admission. Significant differences in Functional Ambulation Category, Barthel Index, and Rivermead Mobility Index scores were observed at dismissal between the 2 low motricity groups (RG_{LM} versus CG_{LM}), which persisted at follow-up, as shown in the Table. No significant differences arose between the 2 HM groups at follow-up or discharge (see the Table and the Figure).

Discussion

In this study, we assessed the long-term efficacy of robotic gait training in patients with stroke at approximately 2 years after being discharged from our hospital. In our earlier study, only patients with more severe impairments in motor leg function benefited from robotic-assisted therapy in combination with conventional therapy. This result was maintained at follow-up: robotic walking training had positive long-term effects only in more severely affected patients on walking capacity; disability, as measured by Barthel Index score; and mobility, as measured by Rivermead Mobility Index score.

For more impaired groups, robotic devices allow an efficient amount of early walking, like training in the subacute phase.[4] The results of our study demonstrate that this positive effect of robotic walking training is maintained at long-term follow-up. The efficacy of early, intensive rehabilitation also persists at follow-up.[3]

Our results, obtained 2 years after discharge, are consistent with the literature. The higher efficacy of electromechanically assisted walking training in nonambulant patients is sustained at the 6-month follow-up.[2,3] Conversely, multicenter studies on autonomous ambulant patients reported that mechanically assisted training[4] and body weight-supported treadmill train-

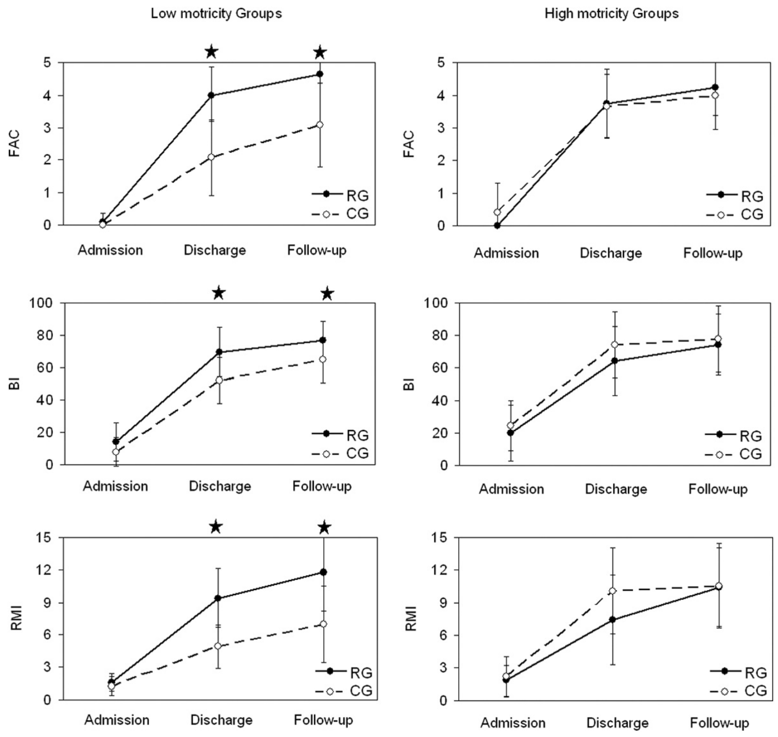

Figure. Mean and SD of the recorded scale scores. FAC indicates Functional Ambulation Classification; BI, Barthel Index; RMI, Rivermead Mobility Index; RG, robotic group; CG, control group. Stars indicate a difference statistically significant.

ing[6] were not superior or even less effective[7] than overground walking training.

For patients who can walk independently, there may not be a benefit of having them walk in a robotic device; for them, such machines might not be the best option to improve their walking ability or capacity. This hypothesis is supported by the finding that in healthy subjects, physiological walking patterns change when they are constrained in robotic machines.[8]

When patients can perform intensive overground walking training, the neurorehabilitator might prefer varied and less constrained walking exercises that are more effective in improving balance and preventing falls,[3,4] yet severely affected patients may benefit from repetitive and intensive gait training, early performing hundreds of steps each session,[9] which might be impossible without a robotic device that provides external body weight support.

Patients might benefit from machines providing external support until overground walking is possible with a decrease in support depending on their level of dependency of gait.[9]

As demonstrated by our 2-year follow-up study, it may be the time to change the research question (as also suggested by Cochrane[10,11]) from "Is robotic-assisted walking training effective …?" to "Who may benefit from robotic gait training?"

Future research on robotic devices should match treatments with motor impairments and postonset time.

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Disclosures

None.

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