Article

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Does altering inclination alter effectiveness of treadmill training for gait impairment after stroke? A randomized controlled trial

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Abstract

Objective: To assess whether a downhill walking training programme is more effective than the same amount of training applied uphill in chronic stroke survivors.

Design: Randomized, single-blind study.

Setting: Outpatient rehabilitation service.

Methods: Thirty-eight adults with hemiplegia from stroke lasting more than three months were randomly allocated to one of the two groups: 'UP' – 45 minutes of physical therapy + 30 minutes of treadmill with 5% ascending slope; and 'DOWN' – 45 minutes of physical therapy + 30 minutes of treadmill with 5% descending slope. Both groups were treated 5 times a week for six weeks. Patients were evaluated before treatment, at the end of treatment and after three months.

Outcome measures: Primary outcome measure was the number of patients showing an improvement in 6-minute walking test (6MWT) greater than 50 m. Secondary outcome measures were: (1) number of patients showing a clinically relevant improvement of gait speed during 10-m walking test (10mWT); (2) number of patients showing an improvement in timed up and go (TUG) greater than minimal detectable change.

Results: Both groups had a significant improvement after treatment and at follow-up. At the end of treatment, compared to UP group, more patients in the DOWN group showed clinically significant improvements in primary and secondary outcomes (16/19 patients for 6MWT, 11/19 patients for 10mWT and 9/19 patients for TUG compared with 3/19, 4/19 and 2/19 patients, respectively, $P < 0.01$). At follow-up, results were similar except for 10mWT.

Conclusions: In chronic stroke patients, downhill treadmill training produces a bigger effect than uphill training.

Keywords

Exercise, treadmill training, slope

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Introduction

Following a stroke, gait and mobility are commonly impaired, and walking on a treadmill is a treatment that is becoming increasingly popular.[1] Treadmill training, even if it has not clearly shown significant advantages compared to overground gait training,[1] has the advantages that it allows constant-speed training, requires little space and has a relative low cost. Another possible advantage is that most treadmill devices can perform both uphill and downhill training, which is not always possible with gait training over ground.

An uphill treadmill inclination from 2% to 8% has been suggested to be useful in improving symmetry[2] and cardiovascular conditioning[3] in patients with stroke, while downhill treadmill training has not been explored as a modality of exercise in these patients. Notwithstanding, preliminary data obtained in healthy subjects showed that walking downhill can reduce trunk flexion,[4] which is a common gait deviation in patients with hemiplegia. Moreover, a recent randomized controlled trial in patients with Parkinson's disease has shown that downhill walking training is beneficial for improving walking performance,[5] although this study did not compare downhill with ground walking or uphill training.

In light of these considerations, we hypothesized that, in addition to usual care (physical therapy provided according to current standards of practice), the provision of a locomotor training programme incorporating downhill treadmill walking would increase the proportion of study subjects showing a clinically relevant improvement in walking endurance and speed more than would a comparable intervention using uphill treadmill walking.

Methods

The study is a prospective, single-centre, single-blind randomized controlled trial. We screened all patients referred to the outpatient clinic of the Physical Medicine and Rehabilitation Unit of the University Hospital of Novara, Italy. Adults aged <80 years with a diagnosis of hemiparesis resulting from stroke (both ischaemic and haemorrhagic) from at least three months, who were able to walk alone indoors (Functional Ambulation Categories (FAC)[6] score ≥3) were enrolled.

We excluded patients with previous medical or neurological conditions that contributed significantly to gait dysfunction, such as musculoskeletal disease, severe osteoarthritis, peripheral neuropathy, previous lower limb joint replacement, cardiovascular disease (recent (<4 weeks) myocardial infarction or uncontrolled hypertension with blood pressure >180/110 mmHg at rest), heart failure (New York Heart Association (NYHA) ≥3), severe respiratory disease, other neurological diseases, dementia, depression, or uncorrected visual disturbances. The use of an ankle-foot orthosis was not considered an exclusion criterion, but patients who needed one were trained and tested always with the same one.

We randomly assigned eligible patients in a one-to-one ratio to two arms: a group that received gait training on a treadmill set with uphill belt inclination of 5% (UP group) and a group that received gait training on a treadmill set with a downhill belt inclination of 5% (DOWN group). A randomization list was made using a web-available application.[7] Each patient who was considered eligible was consecutively allocated by a physical therapy student to one of the two groups following the pattern of the randomization list (for example A–B–A–A–B etc.).

Patients in both groups had a session of 45 min/day of conventional physical therapy (stretching, postural exercises, overground gait training and muscular strengthening exercises, according to neurodevelopmental treatment practice), five times per week, for six weeks, followed by 30 minutes of treadmill (RHC770CE, RAM Medical srl, Camin (PD), Italy) gait training each. The speed of the treadmill belt was decided according to the patient's mean speed during a 6-minute walk test (6MWT)[8] administered after the patient was allocated to one of the two treatment arms. Patients were trained using 80% of the speed they had reached during the 6MWT for the first five sessions, then 90% for the next five, and then 100% for the remaining sessions.

All sessions had to be completed within eight weeks from the beginning of treatment.

The primary outcome measure was the number of patients in each of the two groups who showed a clinically significant improvement in 6MWT, chosen as an increase of at least 50 m.[9]

We considered two secondary outcome measure:

- The number of patients in each of the two groups who showed a clinically significant improvement in their walking speed. We considered a gait speed (measured during the 10-m walking test (10mWT)[10]) increasing from <0.4 to 0.4–0.8 m/s or rising from 0.4–0.8 m/s to >0.8 m/s[11] or from 0.8–1.49 m/s to >1.49 m/s to be a clinically significant improvement.
- The number of patients in each of the two groups who were able to show an improvement at the timed up and go test (TUG)[12] which was higher than the minimal detectable change, that is a reduction of at least 2.9 seconds.[13]

We choose an intention-to-treat approach, and missing data were considered to be patients who did not reach the outcome.

Patients were evaluated at the beginning of treatment (T_0), immediately after (T_1) and three months after the end of the treatment (T_2).

All patients were assessed by a senior physical therapist who was not involved in the treatment, even if strict blinding could not be warranted.

Patients gave their informed consent, and the institutional review board approved the study, which was conducted in accordance with the guidelines of the Declaration of Helsinki for Human Research.

Statistical analysis

Within-group comparisons were made using Wilcoxon signed rank test. Between-group comparisons were done using the Fisher's exact test. An alpha error level of 0.05 was chosen.

Working from the assumption that 20% of the patients in the UP group would have shown a clinically significant improvement in the 6MWT, we calculated that a sample size of at least 13 patients for each group was necessary to show an increase of 50% in the proportion of patients who showed an clinically significative improvement in the primary outcome measure, with a power of 0.8. The value of this increase was arbitrarily chosen.

Statistical analysis was performed with Graphpad Prism 1.4 and power calculation was performed with GraphPad StatMate for Macintosh OS10.6.

Results

From September 2010 to July 2011 we recruited 81 adult patients with hemiparesis following stroke; 43 were excluded (8 were too old, 33 had a severe gait impairment and 2 had severe hip osteoarthritis) (Figure 1). Baseline characteristics of the two groups are shown in Table 1, and they did not differ statistically. We allocated 38 patients at random to the two treatment groups (UP and DOWN group) with a 1 : 1 ratio. All patients received the allocated intervention and completed the treatment. During the study no relevant side-effects were reported in either group.

Eight patients (four in each group) did not complete follow-up. The reasons for drop-out are listed in Figure 1.

Patients in both groups showed a statistically significant improvement in the 6MWT and 10mWT at the end of treatment and at follow-up ($P < 0.01$). For the TUG, the improvement was significant in both groups at the end of treatment ($P < 0.01$), but the result was not maintained at follow-up in patients of the UP group ($P = 0.3$) (Tables 2 and 3).

The between-groups comparison showed that after treatment the number of patients showing a clinically significant improvement in both the 6MWT and the 10mWT was significantly higher in the DOWN group than in the UP group ($P < 0.01$ for 6MWT and $P = 0.045$ for 10mWT) (Table 4).

For the TUG the difference between the two groups was not statistically significant ($P = 0.063$).

At three months follow-up, the number of patients who showed a clinically significant improvement in the 6MWT in the DOWN group was significantly higher than in the UP group ($P = 0.02$). For the 10mWT, the between-groups

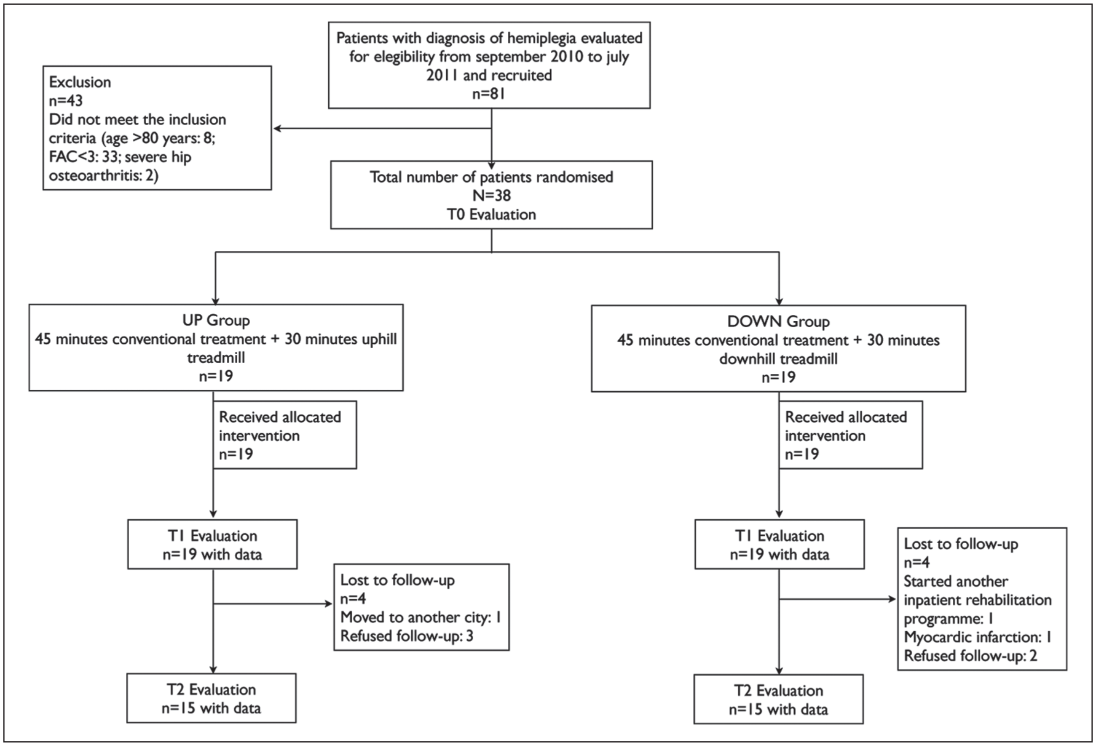

Figure 1. CONSORT diagram for the study.

Table 1. Baseline characteristics of the study population.

	Mean (SD)	95% CI
UP group (*n* = 19)		
Age, years	58.26 (8.41)	54.2–64.2
Time from stroke, days	823.3 (878)	400–1246
Barthel Index	84.2 (12.2)	78.4–90.1
Functional Ambulation Categories	4.11 (0.88)	3.7–4.5
Motricity Index lower limb	64.3 (14.4)	57.3–71.2
DOWN group (*n* = 19)		
Age, years	54.16 (12.49)	48.1–60.2
Time from stroke, days	970.4 (1271)	358–1271
Barthel Index	87.4 (10.2)	82.5–92.3
Functional Ambulation Categories	4.11 (0.88)	3.7–4.5
Motricity Index lower limb	62.53 (15.77)	54.9–70.1

SD, standard deviation; CI, confidence interval.

comparison did not reveal any statistical difference ($P = 0.063$) at this time point.

At follow-up, regarding TUG, the comparison between the two groups showed that the difference

Table 2. Outcome variables at baseline and follow-up.

	T_0 (n = 38)		T_1 (n = 38)		T_2 (n = 30)	
	Mean (SD)	95% CI	Mean (SD)	95% CI	Mean (SD)	95% CI
UP group (n = 19)						
6MWT, m	232 (115.2)	176.5–287.5	268.6 (128.5)*	206.7–330.6	277.1 (134.8)*	202.4–351.7
10mWT, m/s	0.71 (0.35)	0.54–0.88	0.8 (0.4)*	0.61–0.99	0.8 (0.39)*	0.58–1
TUG, s	17.3 (8.59)	13.2–21.4	16.65 (8.18)*	11.7–19.6	16.16 (10.23)	10.5–21.8
DOWN group (n = 19)						
6MWT, m	259.3 (123.1)	200–318.6	341.4 (155.2)	266.6–416.2	324.6 (139.7)*	247.3–401.9
10mWT, m/s	0.76 (0.41)	0.56–0.96	1.09 (0.6)	0.8–1.4	0.98 (0.48)*	0.71–1.3
TUG, s	16.67 (11.29)	11.23–22.11	12.82 (8.88)	8.5–17.1	13.13 (9.01)*	8.1–18.1

T_0, before treatment; T_1, at the end of treatment; T_2, three months after the end of the treatment; 6MWT, 6-minutes walking test; 10mWT, 10-m walking test; TUG, timed up to go test; SD, standard deviation; CI, confidence interval.
*$P < 0.05$ compared to T_0, within group.

Table 3. Outcome measures variations.

	T_0–T_1	T_0–T_2
	Mean (SD)	Mean (SD)
UP group		
6MWT, m	36.63 (25.68)	33.13 (24.81)
10mWT, m/s	0.08 (0.09)	0.06 (0.07)
TUG, s	−1.65 (0.88)	−0.55 (2.17)
DOWN group		
6MWT, m	82.11 (55.05)	83.47 (44.89)
10mWT, m/s	0.33 (0.28)	0.32 (0.19)
TUG, s	−3.85 (3.47)	−4.75 (5.06)

T_0–T_1, variation between baseline and the end of treatment; T_0–T_2, variation between baseline and the end of follow-up; SD, standard deviation; 6MWT, 6-minute walking test; 10mWT, 10-m walking test; TUG, timed up and go test.

in favour of the DOWN group was statistically relevant ($P < 0.01$).

Discussion

Our results show that even if both groups showed a significant improvement in gait speed and endurance, the group who trained with downhill treadmill walking performed significantly better than the group who trained uphill. The effect was not only present at the end of the training, but also at follow-up after three months, showing that these favourable results can be maintained.

The main finding of this work is that the difference between the two groups, especially for the primary outcome measure, is not only statistically significant but also clinically relevant. Our data show that the improvement was more durable and relevant for the 6MWT than for the 10mWT. A possible explanation for this finding could be that, with our protocol, patients were trained mainly for endurance rather than for maximal speed. In fact, it may be that choosing a treatment that is more focused on

Table 4. Number of patients showing a significant variation[a].

	T_1		T_2	
	UP group (n = 19)	DOWN group (n = 19)	UP group (n = 15+4)	DOWN group (n = 15+4)
	Improved [n]	Improved [n]	Improved [n]	Improved [n]
6MWT	3	16	4	12
10mWT	4	11	2	8
TUG	2	9	0	9

6MWT, 6-minute walking test; 10mWT, 10-m walking test; TUG, timed up and go test; T_0–T_1, difference between T_1 and T_0; T_0–T_2, difference between T_2 and T_0; T_0, before treatment; T_1, at the end of the treatment; T_2, three months after the end of the treatment. Note that in T_2 the number of patients considered is 19 for each group (n = 15+4) missing data was considered as patients that did not improve.
[a]See methods for the definition of significant variation.

regaining gait speed, as Ada and co-workers did,[14] would have led to slightly different results. Notwithstanding, a significant effect on gait speed was also present, which can be explained by a general retraining effect.

Our study has several limitations. First, it was performed in a single centre, with a relatively small sample size. Another limitation is that the evaluator was not blinded to treatment. This may explain some observer bias, even if outcome measures chosen are well validated and reliable in stroke patients.

In stroke survivors, gait velocity is one of the most important indicators of functional status and clinical improvement.[15] Even if a strong relationship between gait velocity and functional independence has still not been demonstrated, there is evidence that gait velocity correlates with walking independence,[16] which may be important regarding functional mobility recovery.[17]

Another consideration should be made about the improvement obtained in the TUG test. TUG is strongly negatively correlated with Berg Balance Scale,[12,18] which is one of the most important parameters predicting falls after stroke.[19] The improvement in TUG may indicate a general reduction in the risk of falls.

Another possible explanation could be that downhill gait training is mainly an eccentric exercise, while uphill gait training is mainly a concentric one, and during normal level walking, muscles contract using mainly an eccentric modality.[20] By using downhill training we may have trained patients with a modality that is closer to the physiological activation usually utilized during the real task.

Moreover, downhill gait training requires the subject to extend the trunk,[4] while a common deformity in gait of stroke survivors is trunk flexion.[21] The forced extension of the trunk may be another possible explication for speed and endurance observed in our patients.

Since these are the first data on downhill gait training in stroke patients, our results cannot be directly compared to others. However, if we compare the improvement observed in the UP group after treatment, we observe that it is slightly less than that observed in other studies,[3,14] but it should also be noted that in these studies patients had better performance status at baseline compared to our patients. Thus we can state that the results obtained in the UP group are in line with previously published data, and this observation underlines the fact that patients in the UP group were not undertreated.

A possible evolution of this study is to assess the potential impact of our results on patients' everyday living. This could be done by evaluating mobility using portable step monitors, which have been shown to be a reliable indicator of walking capacity in real life,[22,23] even if the correlation with some clinical tests, such as 6MWT, is high.[24]

Clinical messages

- Gait training with a treadmill with either negative or positive slope may be useful in improving gait speed and endurance in chronic stroke survivors.
- The use of downhill treadmill walking training may be more beneficial than uphill training in improving gait endurance and speed.

Authors' note

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Conflict of interest

The author declares that there is no conflict of interest.

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