Can we improve gait skills in chronic hemiplegics? A randomised control trial with gait trainer

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Aim. **Partial body weight support (PBWS) is an accepted treatment for hemiplegic patients. The aim of this study is to compare the efficiency of gait trainer with conventional treatment on the gait management after stroke.**

Method. **Forty chronic post-stroke hemiplegics were part of a prospective research. Inclusion criteria were: first ever stroke in a chronic stage with stabilised motor deficits; age >18 and <80 years; cognitive and communication skills to understand the treatment; absence of cardiac, psychological and orthopedic contraindications. Patients were randomised into two groups: the control group (CG) that used the Bobath method in 40 minutes sessions, 5 times a week, for 5 weeks, and the experimental group (EG) that used the gait trainer, for the same period of time and frequency. Assessment tools: Motricity Index (MI); Toulouse Motor Scale (TMS); modified Ashworth Spasticity Scale (mASS); Berg Balance Scale (BBS); Rivermead Mobility Index (RMI); Fugl-Meyer Stroke Scale (F-MSS); Functional Ambulation Category (FAC); Barthel Index (BI); 10 meters, time up and go (TUG), 6 minutes, and step tests. EG and CG did the assessments before treatment (T_0), right after treatment (T_1), and on follow-up, 3 months later (T_2).**

Results. **CG and EG were homogenous in all the variables at T_0. CG and EG showed improvement in almost all the assessment scales after treatment, although only some with relevant differences. EG showed statistically relevant improvement on T_1 and on T_2 in several of the assessment tools, whereas CG only showed statistically significant improvement after T1 and only in some of the assessment tools.**

Conclusion. **Both groups of chronic hemiplegic patients improved after either PBWS with gait trainer or Bobath treatment. Only subjects undergoing PBWS with gait trainer maintained functional gain after 3 months.**

KEY WORDS: Body weights and measures - Gait - Cerebrovascular accidents.

Stroke is the third most common cause of mortality in developed countries. In addition, several long-term disabilities occur after stroke, including loss of motor, sensory and cognitive functions.[1, 2] Gait in hemiplegic patients can be greatly disrupted. Restoration of gait is a major goal in the rehabilitation of stroke patients. Modern concepts favour a task-specific, repetitive approach to walking training, and clear benefit from more intensive therapy has been demonstrated.[3-7] In others words, a patient who has lost gait capacity has to walk repetitively in an adequate manner to relearn walking.[5]

Partial body weight support (PBWS) is an effective method in the management of the hemiplegic patients, according to Mauritz.[8] This technique, studied by several authors, including Visintin, Barbeau and Hesse, consists of using an overhead suspension system and harness to support a percentage of the patient's body weight as the patient walks on a treadmill.[9, 10] During the treatment, the PBWS is progressively decreased.

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As a task-specific training, it allows practise of complete gait cycles with many repetitions instead of single elements or preparatory manoeuvres even at an early stage of gait rehabilitation.[11]

Hesse *et al.* created an electromechanical gait trainer to practice a gait-like movement with minimal assistance. He published several papers showing the efficacy and efficiency of his device on ambulatory and non-ambulatory hemiplegic patients,[10-12] but none used a randomised controlled trial or a blind assessment in chronic patients.

The aim of our study is to compare the efficacy and efficiency of the gait trainer with conventional treatment on gait treatment of chronic vascular hemiplegic patients.

Methods and materials

A single-blind randomised controlled trial was done with a sample of 40 chronic post-stroke hemiplegic patients (>12 months of evolution). The inclusion/exclusion criteria comprise:

1) first ever stroke;
2) chronic stage with more than 12 months of evolution;
3) motor stabilisation;
4) lower limb motor deficit (motricity index [MI]<100; >0);
5) age between 18 and 80 years;
6) cognitive status measured with mini mental state examination (>19);
7) communication skills to understand the treatment;
8) absence of cardiac, psychological and orthopedic conditions that might interfere with the results;
9) no rehabilitation management on the last 6 months.

The patients were randomised into two groups: the control group (CG) and the experimental group (EG). For the randomisation process the authors used the permuted-block randomisation design, also known as blocked-randomisation.[13] The patient was asked to choose one of four note papers from inside a bag, two indicating the experimental treatment and the other two the control treatment. An administrative secretary was responsible for the randomisation, which was unknown to the researchers.

From an initial total of 47 patients, and based on the inclusion criteria, 40 patients were chosen, 20 for each group: the EG and CG.

TABLE I.—*Homogeneity in the dependent and independent variables at T_0 .*

Gender	Group		Total
	EG	CG	
Male	16	14	30
Female	4	6	10

EG: experimental group; CG: control group. χ^2=0.533; P=0.465.

TABLE II.—*Homogeneity in the dependent and independent variables at T_0.*

	Group	Mean	SD	t test	P
Age	EG	70.35	7.36	0.810	0.423
	CG	68.00	10.69		
Time after stroke	EG	47.10	63.83	0.086	0.932
	CG	48.45	29.51	0.086	0.932

EG: experimental group; CG: control group.

For a five-week period and for 5 times a week, the CG followed the classical Bobath method, rehabilitation management, including an initial 20 min session for joint mobilisation and muscle strengthening, plus 20 min of a balance and gait training session using the Bobath methods.[14]

During the same period of time and frequency, the EG followed the gait trainer (REHA-STIM). The gait trainer is based on a doubled crank and rocker gear system, consisting of two footplates positioned on two bars (couplers), two rockers, and two cranks that provide the propulsion. In this device patients are harness secured and positioned on two footplates, whose movements simulate stance and swing phases, with a ratio of 60% to 40% between the two phases.[15] A servo-controlled motor assists the gait movement by controlling the gear velocity and comparing it to the preselected velocity. The rotation of the planetary gear system, equalling one gait cycle, controls the movement of the centre of mass (CoM) in vertical and horizontal directions. Also, a pulley relieves part of the body weight, as required.[15] The experimental treatment was also composed of a first 20 min session of joint mobilisation and muscle strengthening. In the following 20 min, patients were managed in the gait trainer and secured in a harness, with a maximum of 30% body weight relief during the first sessions, according to Hesse's methodology.[11] During the treatment the PBWS was progressively decreased. Each

TABLE III.—*Homogeneity in the dependent and independent variables at T_0.*

Variables	Groups							
	EG				CG			
	Mean	SD	Median	Range	Mean	SD	Median	Range
Motricity index – lower limb T0	51.5	14.02	56	41.33	56.2	10.46	56.67	41.33
TMS Item 1 to 10 T0	19.80	3.82	20.56	14.00	19.65	4.75	19.43	19.00
TMS Item 11 to 20 T0	10.55	2.93	10.22	13.00	11.10	4.12	10.75	15.00
TMS Total T0	30.35	6.09	30.33	27.00	30.75	7.74	28.75	29.00
BBS T0	36.85	13.09	40.50	46.00	34.60	13.85	39.00	47.00
RMI T0	10.55	3.72	12.00	13.00	10.00	3.63	10.67	12.00
BI T0	74.75	16.02	80.00	60.00	74.50	19.12	81.00	55.00
BI Mobility items T0	35.00	10.64	38.18	35.00	33.00	10.69	33.75	30.00
F-MSS Lower limb items T0	15.90	6.30	16.00	25.00	19.10	6.17	20.00	17.00
F-MSS Balance T0	9.60	2.04	9.64	7.00	9.65	2.56	10.33	10.00
F-MSS T0	25.50	7.84	26.00	31.00	28.75	7.50	30.00	25.00
10 meters walking test With gait aid – step cadence T0	59.33	16.75	62.70	46.00	54.60	23.31	51.20	67.50
10 meters walking test With gait aid – velocity T0	0.29	0.14	0.27	0.41	0.29	0.19	0.33	0.51
10 meters walking test With gait aid – step length T0	55.95	18.47	54.10	63.70	55.80	21.54	62.50	68.40
10 meters walking test Without gait aid – step cadence T0	70.12	26.46	69.00	92.70	79.73	32.19	71.10	110.50
10 meters walking test Without gait aid – velocity T0	0.42	0.25	0.38	0.83	0.53	0.33	0.51	1.09
10 meters walking test Without gait aid – step length T0	65.32	23.66	55.60	88.70	71.81	22.23	66.90	83.20
6 minutes walking distance test T0	140.20	90.07	137.00	380.50	141.48	102.22	141.75	346.00
Step test T0	6.07	1.66	6.50	5.00	6.50	2.72	7.00	11.00

EG: experimental group; CG: control group; TMS: Toulouse Motor Scale; BBS: Berg Balance Scale; RMI: Rivermead Mobility Index; BI: Barthel Index; F-MSS: Fugl-Meyer Stroke Scale.

patient was supervised by a physiotherapist who corrected knee motion manually, whenever needed.

The treatment time in each session was the same for both groups, *i.e.* approximately 40 min.

Assessment tools

For clinical evaluation the authors used the following tools: 1) MI;[16] 2) Toulouse Motor Scale (TMS);[17] 3) modified Ashworth Spasticity Scale (mASS);[18] 4) Berg Balance Scale (BBS);[19] 5) Rivermead Motility Index (RMI);[20] 6) Fugl-Meyer Stroke Scale (F-MSS) (lower limb and balance);[21] 7) Functional Ambulation Category (FAC);[22, 23] 8) Barthel Index (BI);[24] 9) 10 meters walking test and gait cycle parameters;[25] 10) time up and go (TUG);[26] 11) 6 minutes walking distance test (6MWT);[27] 12) step test.[28]

EG and CG did these assessments before treatment (T_0), just after treatment (T_1), and at follow-up, three months later (T_2). One of the authors (DD) did a blind assessment, without knowing to which group the patient belonged.

Statistical analysis

As groups are relatively small, we decided to perform a separate statistical analysis, using the SPSS software, version 14.5.

TABLE IV.—*EG- evolution before (T_0) and after treatment (T_1).*

EG	Paired differences (T_0 ? T_1) Mean (SD)	T test	Paired Differences (T_1 ? T_2) Mean (SD)	T test
MI-lower limb	-3.13 (5.42)	0.018	-5.32 (9.14)	0.018
TMS item 1 to 10	-1.80 (2.17)	0.001	-1.40 (3.00	0.050
TMS item 11 to 20	-1.40 (1.73)	0.002	-1.30 (2.13)	0.013
TMS total	-3.10 (3.16)	0.000	-2.80 (4.54)	0.012
BBS	-3.90 (6.53)	0.015	-1.65 (1.90)	0.001
RMI	-0.35 (0.75)	0.049	-1.35 (3.38)	NS.
BI-mobility items	0.50 (7.93)	NS	-3.50 (6.51)	0.027
F-MSS-lower limb items	-1.90 (3.43)	0.023	0.15 (4.07)	NS
10 meters walking test – without gait aid – step cadence	-11. 66 (23.84)	0.041	16.52 (47.12)	NS
10 meters walking test – without gait aid – velocity	-0.11 (0.17)	0.011	0.13 (0.36)	NS
10 meters walking test – without gait aid – step length	-13.33 (21.88)	0.013	18.50 (45.03)	NS
6 minutes walking distance test	-18.92 (26.33)	0.005	9.88 (34.80)	NS
Step test	-1.30 (1.58)	0.002	-0.35 (2.15)	NS

TABLE V.—*CG- evolution before (T_0) and after treatment (T_1).*

EG	Paired differences (T_0 ? T_1) Mean (SD)	T test	Paired Differences (T_1 ? T_2) Mean (SD)	T test
MI – lower limb	-3.71 (6.17)	0.017	-1.33 (6.85)	NS
TMS item 1 to 10	-2.00 (2.16)	0.001	-0.84 (2.29)	NS
TMS item 11 to 20	-1.63 (2.33)	0.007	0.00 (2.38)	NS
TMS total	-3.52 (3.70)	0.001	-0.95 (4.18)	NS
BBS	-3.42 (6.69)	0.039	-1.42 (4.00)	NS
RMI	-1.26 (1.82)	0.007	-0.16 (0.90)	NS
10 meters walking test-without gait aid – step cadence	-0.01 (0.15)	NS	14.94 (23.20)	0.017
10 meters walking test-without gait aid – step length	-2.11 (18.51)	0.017	18.52 (29.41)	0.019
6 minutes walking distance test	-23.28 (2.16)	0.001	-0.56 (22.65)	NS
Step test	-0.11 (2.33)	0.007	-1.05 (1.78)	0.026

The authors used t test, a parametric statistic evaluation, as groups were equal in size, homogeneous and tested simultaneously three times with scales or tests which proved to have good validity and reliability.[29] Finally, other authors used parametric tests to study size effect or even organise meta-analysis.[30]

We looked for both a main effect (that is to say a change in outcome measures within each group) and an interaction effect (that is to say a change in outcome measures between groups, over time).

Results

The two groups (CG and EG) were homogenous in the dependent and independent variables at T_0 (P>0.05), as shown in Tables I-III.

Using *t* test for dependent variables, and regarding the EG, the evolution before (T_0) and after treatment (T_1) (Table IV) shows significant differences in MI-lower limb, TMS, BBS, RMI, 10 meters walking test (velocity, step cadence, step length), 6 minutes walking test, step test, and F-MSS-lower limb.

Considering once again the EG, the evolution T_1-T_2 (Table IV) shows an increasing improvement in MI-lower limb, TMS, and BBS, while indicating a progress in Barthel-mobility scores (transfers, mobility and stairs).

During the period T_0-T_1 (Table V) in the CG, there were significant differences in MI-lower limb , TMS, BBS, RMI, and 6 minutes walking test.

As for the CG, during the period T_1-T_2 (Table V) the follow-up assessment shows improvement in 10 meters walking test (step cadence and step length), and step test.

Discussion

Several authors recommend a task-specific repetitive approach for gait rehabilitation management, benefiting from intensive therapy, including those that use mechanical and robotic equipment. Most papers showed that chronic stroke patients could exhibit some motor improvement after participating in rehabilitation programmes requiring task-specific repeated motor practice.[5-7, 31-33]

The major disadvantage of treadmill training with BWS is the intense physical effort, requiring at least two physiotherapists to assist the hemiplegic's gait. Asymmetry of stance and swing is a major characteristic of hemiparetic gait, and physiotherapists aim to re-establish a balanced gait. This requires manual guidance by at least two physiotherapists to move the paretic limb and control trunk movements. This probably impeded the widespread use of treadmill training.[34]

Hesse *et al.* created an electromechanical gait trainer to practice a gait-like movement with minimal assistance from only one therapist. He showed that with gait trainer one single session enables the practice of up to 1 000 repetitions of a gait-like movement. Most importantly, for the management of gait trainer it is only necessary to have minimal assistance from one physiotherapist, in opposition to gait training on a treadmill with partial body weight support. The physiotherapist must pay attention to knee motion in order to prevent knee hyperextension, which frequently occurs in the first sessions. Hesse *et al.* published several papers showing the efficacy and efficiency of his device on ambulatory and non-ambulatory hemiplegic patients.[10, 12, 35]

Besides the advantage of gait training allowing practice of a complete gait cycle with many repetitions instead of single elements or preparatory manoeuvres, Hesse also showed that with gait training we can achieve a better symmetric gait in hemiplegic patients with a better control of the CoM and, consequently, a better physiological movement of the trunk,[10, 15, 34, 35] so that patients can relearn walking as they walk repetitively in an adequate manner.[5]

Our data show that both groups (CG and EG) of chronic hemiplegic patients improved after treatment. It is important to remember that these patients have not done any rehabilitation management for more than 6 months. This improvement is in agreement with the literature: chronic hemiplegic patients should do periodic rehabilitation management. As others showed, further rehabilitation after an initial phase can also bring improvements, even more than one year after a stroke, also allowing prevention of functional worsening.[31, 36-38]

Interestingly, the group that did partial body weight walking training continued improving in almost all the evaluated scores, even after three months on follow-up, as previously referred, whereas in most of the scores on the CG there was a tendency for worsening or maintenance of the skills, with improvements in only two of the items (10 meters and step tests).

Both Eg and CG improved with treatment, the EG even improving on follow-up. Both groups showed improvement in almost all the assessment scales after the treatment (T_1), showing a main effect=$P<0.001$, but not in interaction effect ($P>0.05$). So, we can say that there are only statistically significant differences in both treatments, possibly because of the short size of the groups (EG and CG with N=20).

Conclusions

In this sample and with these results, PBWS proved to be a promising management for gait training in stroke rehabilitation. PBWS with gait trainer, like Bobath method, showed significant improvement after treatment. PBWS with gait trainer maintained these progresses after 3 months what did not happen with the Bobath method.

Since the improvements in the several assessment tools and functional gains are not clinically very important and only with little differences between the EG and CG, there is a need of further studies or researches based on larger patients' samples randomised control trials to present PBWS as superior alternative management for gait training in hemiplegics patients.

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