

Aerobic treadmill plus Bobath walking training improves walking in subacute stroke: a randomized controlled trial

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Received 27th December 2003; returned for revisions 6th February 2004; revised manuscript accepted 6th April 2004.

Objective: To evaluate the immediate and long-term effects of aerobic treadmill plus Bobath walking training in subacute stroke survivors compared with Bobath walking training alone.

Design: Randomized controlled trial.

Setting: Rehabilitation unit.

Subjects: Fifty patients, first-time supratentorial stroke, stroke interval less than six weeks, Barthel Index (0–100) from 50 to 80, able to walk a minimum distance of 12 m with either intermittent help or stand-by while walking, cardiovascular stable, minimum 50 W in the bicycle ergometry, randomly allocated to two groups, A and B.

Interventions: Group A 30 min of treadmill training, harness secured and minimally supported according to patients' needs, and 30 min of physiotherapy, every workday for six weeks, speed and inclination of the treadmill were adjusted to achieve a heart rate of HR: $(HR_{max} - HR_{rest}) * 0.6 + HR_{rest}$; in group B 60 min of daily physiotherapy for six weeks.

Main outcome measures: Primary outcome variables were the absolute improvement of walking velocity (m/s) and capacity (m), secondary were gross motor function including walking ability (score out of 13) and walking quality (score out of 41), blindly assessed before and after the intervention, and at follow-up three months later.

Results: Patients tolerated the aerobic training well with no side-effects, significantly greater improvement of walking velocity and capacity both at study end ($p = 0.001$ versus $p = 0.002$) and at follow-up ($p < 0.001$ versus $p < 0.001$) in the experimental group. Between weeks 0 and 6, the experimental group improved walking speed and capacity by a mean of 0.31 m/s and 91 m, the control group by a mean of 0.16 m/s and 56 m. Between weeks 0 and 18, the experimental group improved walking speed and capacity by a mean of 0.36 m/s and 111 m, the control group by a mean of 0.15 m/s and 57 m. Gross motor function and walking quality did not differ at any time.

Conclusions: Aerobic treadmill plus Bobath walking training in moderately affected stroke patients was better than Bobath walking training alone with respect to the improvement of walking velocity and capacity. The treatment approach is recommended in patients meeting the inclusion criteria. A multicentre trial should follow to strengthen the evidence.

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Introduction

Stroke is the leading cause of disability and handicap in the industrialized world. Restoration and improvement of walking is highly relevant for the social and vocational reintegration of stroke survivors.

In this context, treadmill training with partial body weight support has evolved as a promising task-specific repetitive treatment concept,¹⁻³ but the evidence for nonambulatory patients in the acute phase is still conflicting.⁴⁻⁷ Two large randomized controlled trials with a total of 129 subacute stroke survivors did not find any difference in walking ability and function between treadmill training and physiotherapy stressing the walking practice on the floor.^{5,6}

For less affected patients, Macko and co-workers showed that three 40-min sessions of aerobic treadmill training weekly for six months improved the physiologic fitness reserve and walking energy cost of nine chronic ambulatory stroke patients.⁸ Pohl *et al.* studied speed-dependent treadmill training in ambulatory hemiparetic patients, which achieved a much faster walking speed than conventional therapy or treadmill training with no or a very little increase of speed over the treatment period. Further, Ada *et al.* showed that a 30-min treadmill and overground walking training programme, three times a week for four weeks, was more effective than conventional physiotherapy in improving walking speed and walking capacity of ambulatory people residing in the community after stroke.⁹

The present randomized controlled trial was set up to study the effect of aerobic treadmill plus Bobath walking training compared with Bobath walking training alone in a homogeneous group of moderately affected hemiparetic subjects within six weeks of their stroke who still needed intermittent help or stand-by while walking. The treadmill training incorporated principles of aerobic exercise training by a graded increase of belt speed and/or inclination to elicit adequate cardiovascular stress to induce an aerobic training effect.

The study was designed to answer the following research questions in stroke patients newly able to walk: Does six weeks of aerobic treadmill training plus Bobath walking training increase maximum

walking speed and capacity more than Bobath walking training alone? Does it decrease the quality of walking, and are any gains maintained 18 weeks after the cessation of training?

Methods

Patients

Between 1 September 2001 and 1 June 2003 we recruited 50 hemiparetic patients after stroke from one centre out of a pool of 578 stroke patients referred for inpatient rehabilitation (Figure 1). All participants gave written consent to participate in the study approved by the local ethical committee.

Inclusion criteria were:

- age range from 50 to 75 years,
- first-time supratentorial stroke,
- stroke interval less than six weeks before study onset,
- able to walk a minimum distance of 12 m with either intermittent help or stand-by while walking,
- moderately affected with a Barthel Index (0–100) ranging from 50 to 80,
- participation in a 12-week comprehensive rehabilitation programme,
- cardiovascular stable, according to 12-lead ECG, bicycle ergometry reaching at least 50 W and examination by a cardiologist,
- no other neurologic or orthopaedic disease impairing walking,
- able to understand the purpose and content of the study

Prior treatment included acute care on a specialized stroke unit with referral to the rehabilitation unit after 1–2 weeks. In the rehabilitation unit, the patients participated in a comprehensive rehabilitation programme including physiotherapy, occupational therapy following the Bobath approach, speech and neuropsychological therapy according to individual needs.

Bicycle ergometry helped to define the maximum heart rate and served as a stress test. Common guidelines were used to determine whether the exercise test should be terminated early, and included, among others, ST-segment depression more than 2 mm, systolic blood pres-

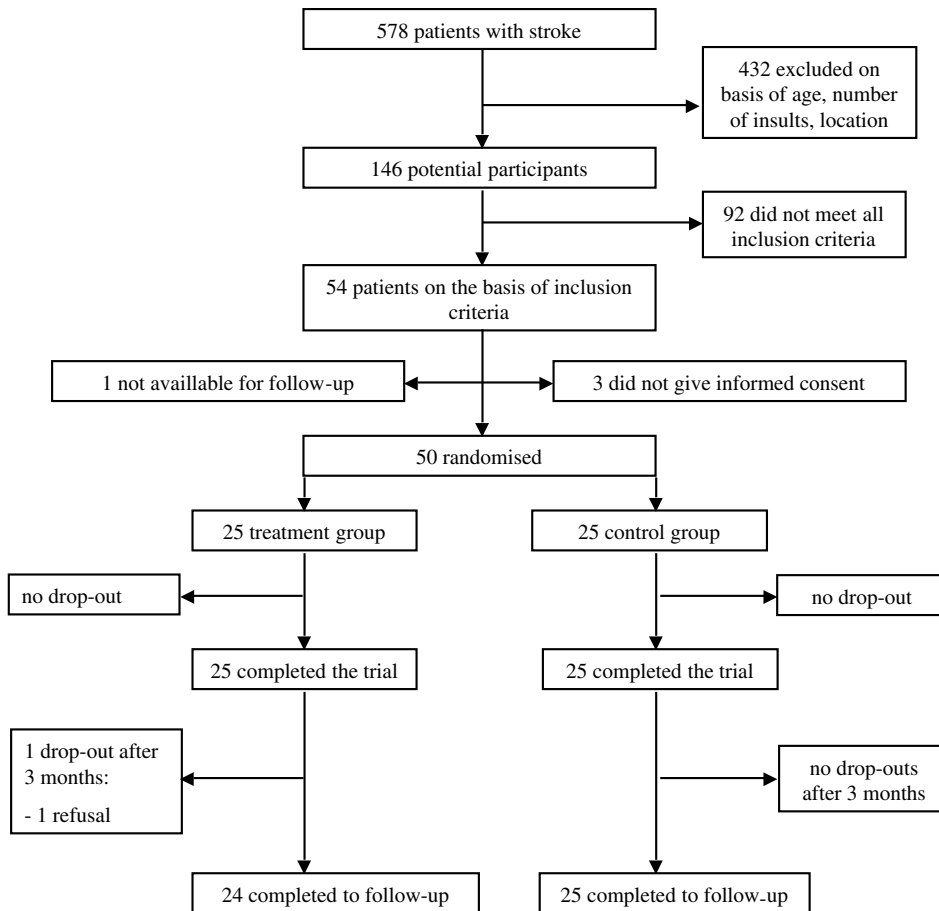


Figure 1 Flow diagram of the study.

sure >220 mmHg, sustained ventricular tachycardia, increasing nervous system symptoms (i.e., ataxia, dizziness) and perceived overexertion.

Assignment

Patients were randomized to the treatment group (A) or control group (B) by an independent person who chose one of (initially) 50 sealed envelopes 30 min before the start of the intervention, thus randomly allocating 25 to the experimental and 25 to the control group. The sample size was calculated to corroborate a minimum important difference of 20% of the improvement of gait speed and endurance with alpha set at 0.05 and beta at 0.2.

Treatment

All patients received 60 min of individual therapy time on each of 30 consecutive working days. Patients of group A received treadmill training for 30 min and other individual physiotherapy for 30 min. Patients of group B received 60 min of individual physiotherapy.

During treadmill training, patients wore a modified parachute harness to prevent falls. The body weight (BW) was either not supported or supported to a maximum of 15% of BW according to individual needs. If necessary, one or two therapists provided help with setting the paretic limb or assisting weight-sifting and hip extension.

The aerobic treadmill training programme consisted of 30 sessions of 30 min of graded

treadmill walking (see above) at a defined training heart rate (THR). THR was determined according to the following formula: $THR = (HR_{max} - HR_{rest}) * 0.6 + HR_{rest}$, and controlled during the treatment with the help of a chest belt electrocardiography and a display mounted on the treadmill. Maximal heart rate was defined as the highest observed during a preceding bicycle ergometry (see inclusion criteria). Short treadmill warm-up and cool-down periods of 1–2 min duration accompanied each training session, two short pauses were optional. Further, blood lactate levels, taken immediately from the hyperaemized ear lobe after the 5th, 10th, 15th, 20th and 25th session, were analysed by photometer to ensure aerobic training conditions.

The individual physiotherapy in both groups was Bobath oriented; it exclusively concentrated on walking rehabilitation. It included tone-inhibiting and gait preparatory manoeuvres (comprising approximately 20–30% of each session) and walking practice on the floor and on the stairs. Necessary orthoses and walking aids were provided at the beginning of the study.

Occupational therapy, speech therapy and neuropsychology were administered according to individual needs.

Patients were assessed before and after the six-week treatment period and at follow-up 12 weeks after the cessation of the treatment. The primary outcome measures were the absolute improvement of walking velocity, and walking capacity.

Velocity (m/s) was assessed with the 10-m test, the patients walked a distance of 14 m (2 m for acceleration and deceleration) at their maximum speed twice, the maximum speed was chosen to minimize external factors. The time was taken and the mean velocity (m/s) calculated. Data were averaged on two 10-m trails. Patients used the same walking aids throughout all measurements. One therapist was in charge and was instructed to support the patients as little as possible.

For the assessment of walking capacity (m), the patients were asked to walk as far as possible without interruption in 6 min.¹² Short breaks due to stumbling etc. were allowed, longer pauses due to fatigue stopped the assessment with the distance covered so far noted.

Secondary outcome measures were the gross motor functions including walking ability (score

out 13), and a quality assessment score (score out of 41).

To assess disabled gross motor functions after stroke, the Rivermead Motor Assessment Score (RMA) for gross functions (0–13) was used.¹³ Two physiotherapists not involved in the therapy were responsible for the assessment of the RMA. They were supposedly blind with respect to the group belonging, but disclosure by patients and team mates could not be fully excluded.

Walking quality was assessed with the help of a customized score (see Appendix), adapted in part from the Los Ranchos Los Amigos *Gait analysis handbook*.¹⁴ It covered four areas (ankle, knee and hip movement and trunk/arm movement during walking), 13 items were rated on a four- (3–0) and one item on a three-point (2–0) scale totalling 41 points. A lateral and a rear video were taken while the patient walked on the floor; the camera position was kept constant. An experienced therapist, staff member of the clinic, assessed the blinded videos. She was blind with respect to the group assignment of each patient, as she was on maternity leave and rated the videos at home. The assessor had been training with the help of videos of another group of patients to then reach a test–retest reliability of 0.87 for a second set of 20 videos of hemiparetic subjects. Inter-rater reliability was not assessed.

Statistical analysis

Distribution of the variables is given as mean, standard deviation (SD), 95% confidence intervals, medians and ranges. The last available value completed missing values at follow-up (intention-to-treat analysis). In a first step, a two-way ANOVA (Kolmogorov–Smirnov test confirmed normally distributed metric data) for repeated measurements with age as a covariate was calculated for the primary outcome variables. In the case of a significant interaction between time and group belonging, between-group differences were calculated for both at the end of the study and at follow-up. Adjusted alpha was set at 0.025. For the ordinal scaled values, Rivermead Gross Functions and the customized gait quality score, a Mann–Whitney *U*-test was applied (alpha level of 0.025).

Results

In groups A and B, all patients completed the treatment. At the three-month follow-up, one patient in group A did not attend (refusal). In group B all patients showed up. Hence, 24 patients in the treatment and 25 in the control group completed the three-month study (Figure 1).

Treadmill training (mean (SD)) was initiated at a mean of 0.35 (0.11) m/s, and gradually increased to 0.44 (0.14) m/s (week 2), 0.49 (0.15) m/s (week 3), 0.56 (0.17) m/s (week 4), 0.59 (0.15) m/s (week 5) and 0.64 (0.15) m/s (week 6). The treadmill was inclined to 4° for one subject (week 1), to a mean of 6° for seven subjects (week 2), to a mean of 5.2° for 11 subjects (week 3), to a mean of 4.8° for 18 subjects (week 4), to a mean of 5.2° for 18 subjects (week 5) and to a mean of 6.2° for 20 subjects (week 6).

Side-effects did not occur. All patients in the experimental group tolerated the 30-min treadmill aerobic training, reaching the THR right from the first session taking advantage of two optional pauses, body weight relief of up to 15% and therapeutic assistance during gait. They did not feel overexerted, the lactate blood level measurements confirmed aerobic training conditions in all but three subjects, whose values in week 1 (two cases) and in week 2 exceeded a blood level of 3.0 mmol/litre.

Before treatment, there were no significant differences between the experimental and control groups in selected patient characteristics or outcome measures (Table 1).

The two-way ANOVA showed a positive interaction between time and group (i.e., a between-group difference regarding the type of therapy). Age did not interact.

The between-group comparisons (Table 2, Figure 2) revealed the following differences: between weeks 0 and 6, maximum walking speed had increased significantly more in the experimental group than the control group ($F_{(1,48)}=12.6$, $p=0.001$). The experimental group continued to improve such that between weeks 0 and 18, the maximum walking speed had still increased significantly more than that of the control group ($F_{(1,48)}=15.9$, $p<0.001$).

Between weeks 0 and 6, walking capacity had increased significantly more in the experimental

Table 1 Clinical data for both groups at study onset

	Group A (treadmill therapy)	Group B (conventional therapy)
<i>n</i>	25	25
Diagnosis	25 = ischaemia	25 = ischaemia
Affected side	14 = left, 11 = right	14 = left, 11 = right
Interval (weeks)	6.10 (±2.2)	6.32 (±2.53)
Age (years)	62.4 (±4.8)	64.0 (±6.0)
Sex	F8; M17	F9; M16
Height (cm)	170.1 (±8.3)	170.8 (±8.8)
Weight (kg)	83.3 (±15.6)	81.0 (±13.7)
Barthel Index (0–100)	67.8 (±13.6)	65.6 (±14.9)

group than in the control group ($F_{(1,48)}=10.3$, $p=0.002$). The experimental group continued to improve such that between weeks 0 and 18, their walking capacity had still increased significantly more than that of the control group ($F_{(1,48)}=18.7$, $p<0.001$). The gross motor functions and the walking quality did not differ at any time between groups (Figure 3).

Table 3 shows the distribution of the work (Watts) performed during the bicycle ergometry in subjects of both groups at all measurement points. Over time, more subjects of the experimental group reached higher levels. Breaking-off criteria were cardiac in most subjects of both groups (17 versus 19) before therapy; after therapy and at follow-up perceived overexertion stopped most subjects in the experimental group (22 and 18), whereas cardiac criteria remained the commonest reason in the control group (20 and 21).

Discussion

As a result of the six weeks of intervention, subjects in the experimental group improved their walking by a mean maximum speed of 0.15 (95% CI 0.12–0.18) m/s and by a mean walking capacity of 34.9 (95% CI 14.8–55.0) m more than the control group, arguably a clinically significant result.

During follow-up, subjects in the experimental group had further improved their walking by a mean maximum speed of 0.22 (95% CI 0.12–0.32) m/s and by a mean walking capacity of 54.3 (95% CI 29.8–78.2) m more than the control group.

Table 2 Mean (SD) or median (IQR) scores and change scores for the experimental and control groups for all outcomes

Outcome	Week 0 (n = 50)		Week 6 (n = 50)		Week 6-Week 0 (n = 50)		Week 18 (n = 49)		Week 18-Week 0 (n = 49)	
	Exp (n = 25)	Con (n = 25)	Exp (n = 25)	Con (n = 25)	Exp (n = 25)	Con (n = 25)	Exp (n = 24)	Con (n = 25)	Exp (n = 24)	Con (n = 25)
Max walking speed ^a	0.40	0.44	0.71	0.60	0.31	0.16	0.77	0.58	0.36	0.15
10-m walk test (m/s)	(±0.17)	(±0.22)	(±0.30)	(±0.22)	(±0.17)	(±0.13)	(±0.35)	(±0.22)	(±0.22)	(±0.15)
Walking capacity ^a	108.1	108.9	198.8	164.4	90.6	55.7	224.8	163.0	111.1	56.8
6-min walk test (m)	(±50.8)	(±60.1)	(±81.1)	(±69.3)	(±43.5)	(±32.6)	(±90.0)	(±70.2)	(±50.8)	(±36.8)
Rivermead Gross Function (0-13) ^b	9	9	11	11	2	2	11	11	2	2
Walking quality	(7-10)	(6-10)	(11)	(10-11)	(1-4)	(1-4)	(11)	(10-11)	(1-4)	(0-3)
14-item scale (score 0-41) ^b	18	19	24	24	6	5	24	23.5	6	5.5
	(15-24)	(15-23)	(18-27)	(19-29)	(3-7)	(2.5-7.5)	(19-30)	(11.25-29.75)	(2.5-6)	(0.25-9)

^a Mean (SD).

^b Median (IQR).

IQR, interquartile range; SD, standard deviation.

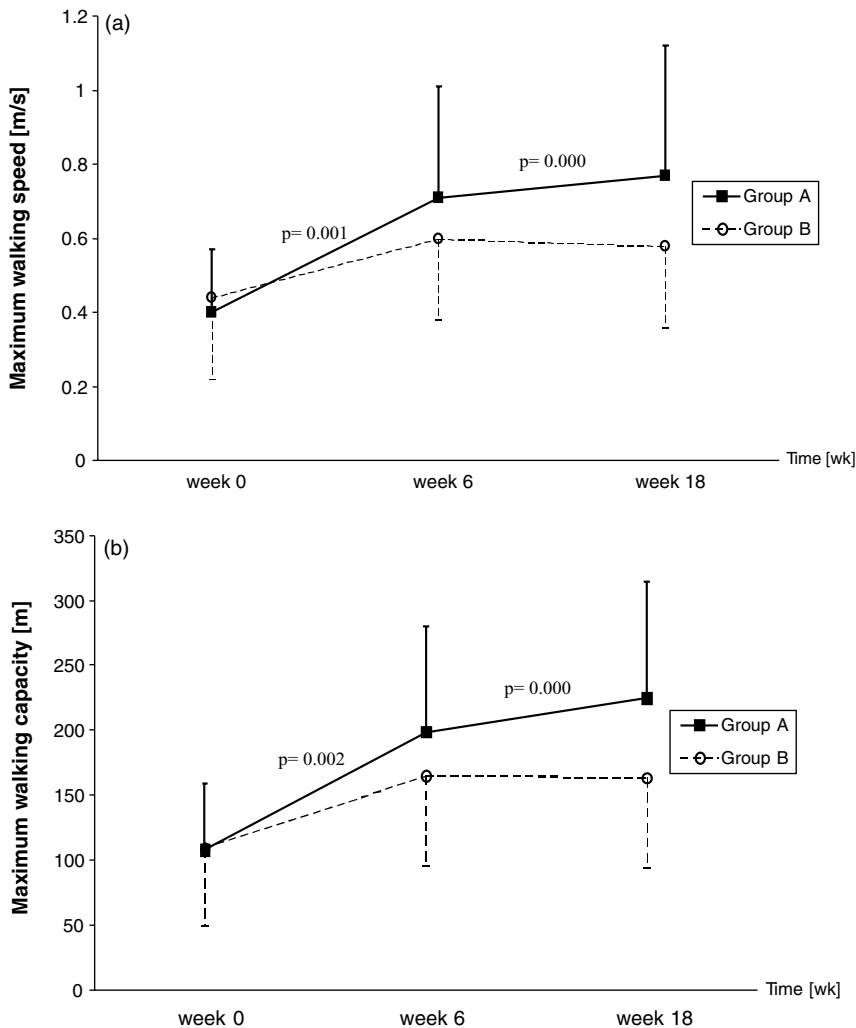


Figure 2 Means and standard deviations for the experimental group (filled squares) and the control group (open circles) at weeks 0, 6 and 18 for (a) maximum walking speed, and (b) walking capacity.

The current aerobic treadmill training programme and the inclusion criteria followed the guidelines of the rehabilitation of cardiac patients in Germany,¹⁵ adapted to the needs of moderately affected hemiparetic subjects. The selected, relatively young patients tolerated the treadmill training well, side-effects did not occur and the blood lactate levels confirmed aerobic training conditions. Accordingly, the protocol seemed feasible for subacute hemiparetic subjects still requiring intermittent help or stand-by while walking. The

inclination of the treadmill was necessary in most subjects to reach the targeted THR, as the patients could not easily follow higher belt speeds or only when walking quality was poor.

Both groups were comparable at study onset with respect to their clinical data and outcome parameters, age did not influence the results, and the net treatment duration did not differ, which supports the superior treatment effect of the aerobic treadmill plus Bobath training programme. Furthermore, conventional physiotherapy sessions

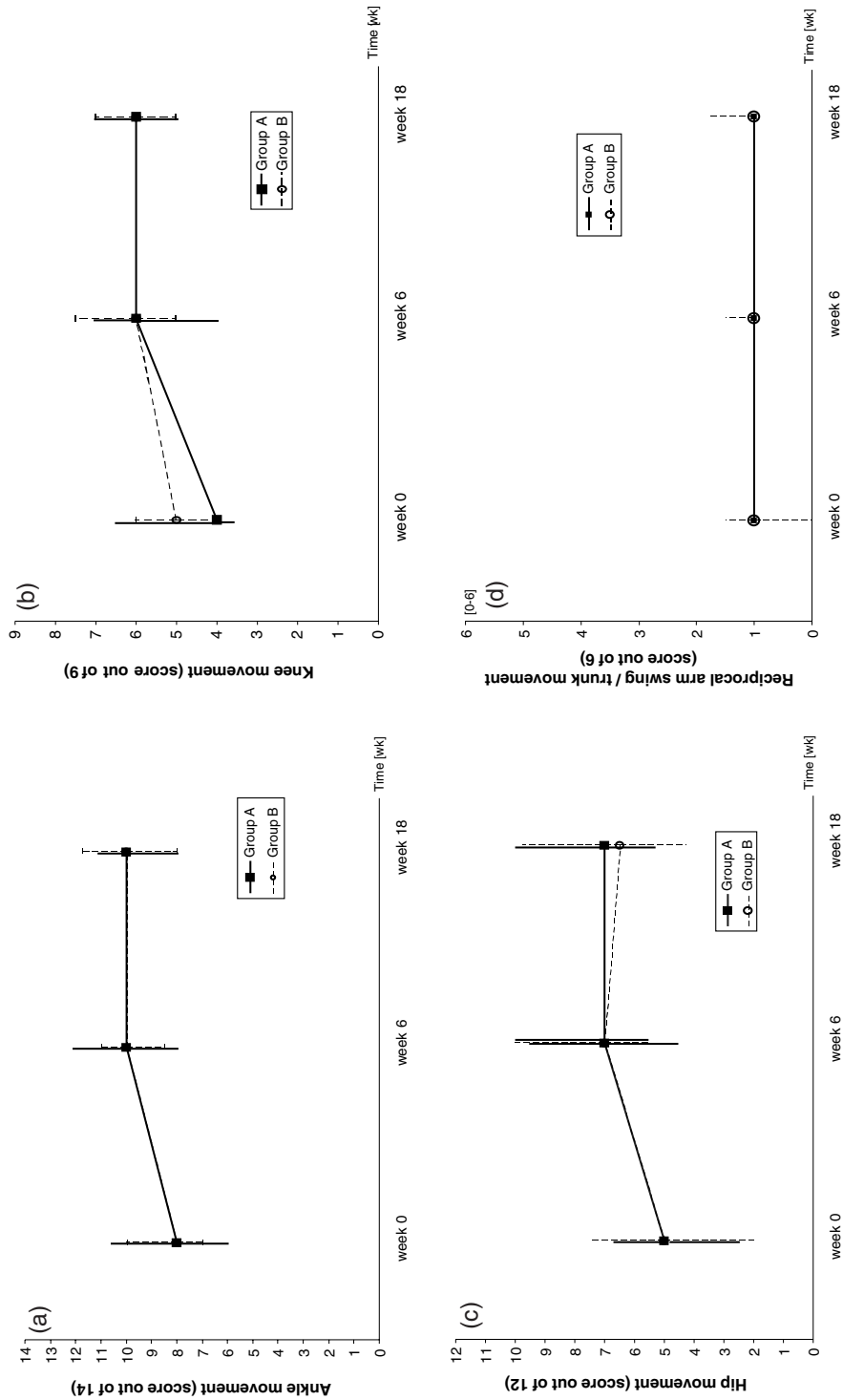


Figure 3 Median and interquartile ranges for the experimental group (filled squares) and the control group (open circles) at weeks 0, 6 and 18 for (a) ankle movement, (b) knee movement, (c) hip movement and (d) reciprocal arm swing/trunk movement of the affected side during walking.

Table 3 Distribution of power during bicycle ergometry for the experimental and control groups

Power	Week 0 (n=50)		Week 6 (n=50)		Week 18 (n=49)	
	Exp (subjects) (n=25)	Con (subjects) (n=25)	Exp (subjects) (n=25)	Con (subjects) (n=25)	Exp (subjects) (n=24)	Con (subjects) (n=25)
50 W	18	19	3	11	4	14
75 W	6	5	16	11	15	8
100 W	1	1	5	3	4	3
125 W	–	–	1	–	2	–
Median (W) (IQR)	50.0 (50–75)	50.0 (50–62.5)	75.0 (75–87.5)	75.0 (50–75)	75.0 (75–87.5)	50.0 (50–75)

IQR, interquartile range; Exp, experimental group; Con, control group.

between two and 14 weeks post stroke did not elicit adequate cardiovascular stress to induce an aerobic training effect.¹⁶

In contrast to the studies of Kosak and Reding⁵ and Nilsson *et al.*,⁶ the specific group of subacute stroke survivors in the present study improved their walking speed and capacity to a larger extent both during the treatment period and at follow-up. On the other hand, the lack of a difference in walking ability and other motor functions between groups corresponded with the results of these earlier studies. However, the subjects of the present study were less affected than those in the studies of Kosak and Reding and Nilsson and co-workers, rendering a direct comparison difficult.

The aerobic training may have resulted in more efficient walking, allowing the patients to walk faster and for a longer distance at a comparable ability level. Unfortunately, the authors were unable to measure energy expenditure (the results of the bicycle ergometry indicated better performance), but Macko *et al.*⁸ and a preceding controlled study of bicycle ergometry training in hemiparetic subjects¹⁷ concurrently reported that better walking efficiency and cardiovascular fitness following aerobic training enabled patients to walk faster and longer.

The protocol of the present study probably also resulted in higher treadmill training speeds than in the studies by Kosak and Reding⁵ and Nilsson *et al.*⁶ Unfortunately neither of these studies reported exact numbers. Two preceding studies had already shown the value of a higher treadmill speed, with ambulatory patients either following a speed-dependent paradigm in the study by Pohl *et al.*¹⁰ or a gradually increase of belt

speed in the study by Sullivan and co-workers.¹¹ In the latter study, patients walked at a velocity of 2.0 mph in the fast group, which exceeded the values we used, but the patients of both studies had a higher walking level at study onset.

The further improvement of walking speed and capacity during follow-up in group A was unexpected. The relatively young patients reported that they had enjoyed the challenge of the demanding aerobic training so that they continued walking fast and for longer distances after the end of the study. Accordingly, Ada *et al.* also reported in their study on a treadmill walking training programme in chronic ambulatory patients that the gains in walking speed were largely maintained three months after the end of the study. The patients of the experimental group went out more after the cessation of treadmill training.⁹ On the other hand, Katz-Leurer *et al.*, who studied an eight-week aerobic training using a leg cycle ergometer in subacute hemiparetic subjects, failed to show any preserved effect in functional independence six months later.¹⁸

Walking quality was another aspect of the study; the even improvement of quality in both groups could not confirm any fears that the high-intensity practice of fast walking on the belt while wearing a harness for safety reasons resulted in poor walking quality. Previous gait analysis studies also could not support this notion, as hemiparetic subjects walked more symmetrically and less spastically on the belt than on the floor.^{19,20} Further, higher walking speeds on the belt facilitated relevant weight-bearing muscles and improved walking efficiency in hemiparetic subjects.²¹

Clinical messages

- Aerobic treadmill plus Bobath walking training effected a significant better improvement of maximum walking speed and capacity in moderately affected hemiparetic subjects early after stroke compared with Bobath walking training alone.
- These effects in favour of the experimental group even further improved during the follow-up period of 12 weeks.
- Gross motor functions including gait ability and gait quality did not differ between the two groups at any time.

Limiting factors of the study were the missing assessment of energy expenditure (see above), the inclusion of only moderately affected and relatively young patients, the poorly documented content of the therapy of the control group, and the fact that the outcome observers may not have been totally blind in the given clinical setting. Further, the number of patients was relatively small and one could not fully exclude the possibility that the outcome observers were not totally blind. On the other hand, the study included a rather homogeneous group of patients quite early after stroke.

In conclusion, the six-week aerobic treadmill plus Bobath walking training resulted in a better improvement of gait velocity and capacity in subacute, moderately affected hemiparetic stroke subjects compared with Bobath walking training alone. Other motor functions including walking ability and quality did not differ between groups. The protocol of a graded treadmill walking at the defined THR proved viable and side-effects did not occur in patients meeting the inclusion criteria. A multicentre trial is warranted to further strengthen the evidence.

Acknowledgements

The authors are indebted to the Ms Parchmann for her help with the qualitative gait assessment, and the physiotherapy staff of the Neurologische Fachklinik Schwaan-Waldeck.

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Appendix – Gait quality chart

The following gait abnormalities of the affected ankle, knee, and hip joint movements and of the trunk movement/arm swing were rated during walking from 3 to 0 with 3 = absent, i.e., normal pattern, 2 = mildly, 1 = moderately and 0 = strongly expressed; only the mode of initial foot contact was rated from 2 to 0.

Ankle joint

- Initial contact: 2 = heel, 1 = entire sole, 0 = forefoot
- Inversion/eversion during stance (3–0)
- Inversion during swing (3–0)
- Missing dorsiflexion during stance, i.e., poor ankle rocker (3–0)
- Asymmetry of step length (3–0).

The total ankle score ranged from 14 (normal pattern) to 0 (i.e., initial forefoot contact and all abnormalities strongly expressed).

Knee joint

- Knee hyperextension during stance (3–0)
- Excessive knee flexion during stance (3–0)
- Missing selective knee flexion during swing (3–0).

The total knee score ranged from 9 to 0.

Hip joint and pelvis

- Pelvis retraction (3–0)
- Insufficient hip extension during stance (3–0)
- Missing weight acceptance (3–0)
- Circumduction during swing (3–0).

The total hip score ranged from 12 to 0.

Arm swing, trunk movement

- Missing arm swing (3–0)
- Rotation and one-sided shortening of the trunk (3–0).

The total trunk score ranged from 6 to 0.