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The Effectiveness of Lower-Body Positive Pressure Treadmill Gait Training on Mobility Function and Quality of Life in Individuals with Chronic Stroke: Prospective Cohort Study

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Abstract

Background: Lower body positive pressure (LBPP) emerges for rehabilitation practice tool for athletic and orthopedic conditions. However, LBPP may provide an opportunity therapeutic intervention for gait training in neurological conditions.

Objectives: To assess the effectiveness of LBPP gait training on ambulation ability, gait speed, walking endurance, dynamic and static balance, and quality of life in individuals with chronic stroke.

Methods: Participants performed LBPP gait training three days a week for six weeks. The main outcome measures were functional ambulation categories (FAC), 10-meter walk test (10-MWT), 6 minutes walking test (6MWT), timed up and go (TUG), functional reach test (FRT), and short-form (SF-36) health survey.

Results: Nine chronic stroke (one female, eight males) aged 57 ± 15.4 years with stroke since 4.8 ± 3.9 years participated in LBPP gait training. participants showed significant improvement in FAC (pre, 4 ± 2; post, 5 ± 1; P = 0.034); 10-MWT (pre, 16.35 ± 9.34 s; post, 13.25 ± 7.57 s; P = 0.021) and 6 MWT (pre, 166.22 ± 94.15; post, 206.66 ± 103.64; P = 0.048). No significant differences were observed in the other outcomes.

Conclusions: Six weeks of LBPP gait training may potentially improve ambulation ability, gait speed, and walking endurance in individuals with chronic stroke.

Keywords: Stroke Rehabilitation, Walking Speed, Assistive Technology, Gait Disorder, Body Weight

1. Background

Stroke is the third most common cause of disability worldwide (1) However, stroke incidence studies in Saudi Arabia are scarce. According to the first incident of stroke report in the last decade, there are 29.8 cases of stroke per 100,000 people each year (2). Stroke survivors usually receive rehabilitation interventions after an injury. However, many of these patients have residual functional deficits, particularly ambulation difficulties. Therefore, effective rehabilitation tools and interventions are essential to eliminate the remaining disability.

Gait recovery is a critical function in stroke patients and their relatives (3). Body weight-supported treadmill training (BWST) is commonly used for gait training in individuals with stroke (4). More often, BWST uses harness systems to increase safety during gait training for individuals with gait impairments and lower extremity weakness. However, many patients find the harness system uncomfortable (5). Furthermore, several studies have reported that using a harness system during gait training may alter kinematic and kinetic parameters (6, 7). Moreover, BWST gait training often requires at least two therapists to assist paretic lower limbs during stepping and trunk control (8).

A treadmill with lower-body positive pressure (LBPP) in a waist-high-pressure chamber is a new modality that may be better for body unloading (9). It has a treadmill for gait training within the chamber. To use LBPP, the patient donning a neoprene kayak-type skirt that was secured over a lip in the aperture opening of the chamber. The pressure inside the chamber was raised above the external ambient (atmospheric) pressure using an air compressor. The pressure difference around the waist seal produces an upward force that unloads the patient's body weight (10).

LBPP has been evaluated for safety in healthy individuals before its use as a rehabilitation tool for patients (10-13). Thus, LBPP has been used successfully as an intervention tool after knee and ankle surgery (14, 15), in individuals with osteoarthritis (16), children with cerebral palsy (17), and in individuals with stroke (9). According to these preliminary research findings, LBPP is a secure and reliable rehabilitation tool for gait training.

Recently, LBPP has been used as a rehabilitation tool for stroke patients. Current data regarding its therapeutic use and effectiveness in the stroke population with locomotor deficits is insufficient. We are only aware of seven studies that examine the effect of LBPP on the stroke population (9, 18-21); two of them are case studies (22, 23). Further studies are warranted to confirm the findings of previous studies. Calabro et al. (9) focused on temporal gait parameters and muscle activation. Usually, these gait assessment parameters require expensive laboratory tools that are not applicable to clinicians. Sukonthamarn et al. (21) and Duran et al. (20) recruited acute and subacute stroke patients. Oh et al. (19) and Park and Chung (18) found that LBPP improved balance and walking ability compared to the control group in chronic stroke patients.

Clinicians and researchers widely use gait speed, walking endurance, and balance as predictor factors to categorize post stroke survivors into ambulation categories. In particular, gait speed values measured using the 10 meter walk test (10-MWT) categorized poststroke survivors as household ambulators (< 0.40 m/s), limited community ambulators (0.40 - 0.80 m/s), and full community ambulators (> 0.80 m/s) (24). Furthermore, the 6-minute walk test (6MWT) revealed that walking distances ≥ 205 m discriminates between household and community ambulators (25).

2. Objectives

The study aimed to assess ambulation ability, gait speed, walking endurance, dynamic and static balance, and quality of life (QoL) in individuals with chronic stroke.

3. Methods

The study design was repeated measure with one group of stroke patients who received the same intervention, and measures during pre- and post-intervention. All procedures and intervention were carried out in compliance with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards, as well as the ethical standards of the institutional research committee. The local institutional review board at Qassim University approved the study (reference number 20-05-04), and the study was registered at ClincalTrials.gov (ID number NCT04767334).

Convenience sampling of 13 participants were enrolled as per the following inclusion criteria: (1) Age between 18 and 70 years; (2) hemiparesis due to stroke; (3) stroke happened at least six months prior to the study time frame; (4) the ability to walk ≥ 10 m with or without an assistive device; (5) no further neurological and/or orthopedic conditions that hinder ambulation; (6) walking ability of ≥ 3 on functional ambulation category (FAC) (26); (7) no history of cardiac, respiratory, or cardiovascular conditions interfering with LBPP; and (8) ability to understand simple instructions. The exclusion criteria were: (1) Recurrent stroke; (2) lower limb spasticity of modified Ashworth scale > 3; and (3) ataxia or tremor of the lower limb. All the participants provided and signed written informed consent. All data collection and intervention held on physical therapy department, Qassim University Medical City, Saudi Arabia.

The outcomes variables were functional ambulation category (FAC) (26), 10-meter walk test (10-MWT) (27), six minute walk test (6MWT) (25), functional reach test (FRT) (28), Timed Up and Go (TUG) (29), Quality of life (QoL) (Short Form 36) (30). For the outcome measures, all participants were evaluated at the beginning (baseline) and after six weeks of the intervention. The 10MWT test was performed twice at a comfortable walking speed and twice at a fast walking speed. The average was calculated separately for each speed and was used for the analysis. The FRT used twice for each participant and the average of two trials used for the analysis.

Participants completed an intake form and provided demographic data. The inclusion and exclusion criteria were screened. Participants who met the inclusion criteria were enrolled. Each participant started with a 5 - 10 minute warm-up on a standard cycle ergometer, manual and therapeutic therapy, and gait training using LBPP. LBPP is commercially available (Figure 1) (Alter G Inc., Fremont, CA, USA). Manual and therapeutic therapy consisted of passive and active range of motion, joint mobilization, passive and active stretching, manual resistance exercise, postural control and balance exercises, and upper extremity control exercises. To use the LBPP, participants wore a neoprene short with a kayak-type skirt attached at the waist level. Then, the participants stepped into the LBPP chamber, usually with assistance from one or two physical therapists, to ensure safe transfer. Once the participant entered the chamber, the neoprene skirt was comfortably sealed over the lip at the top of the chamber. Once participants felt comfortable standing inside the chamber, the physical therapist instructed them to be ready for gait training and not lean on the seal for support. For gait training, all participants walked in LBPP one session per day (for up to 40 min), three days a week, for six weeks. At the first session, the LBPP pressure chamber was set to unload 50% of patient's body weight (10). In the following sessions, the percentage of unloaded patient body weight was gradually decreased each session by approximately 2%. Physical therapist assistance and treadmill speed were evaluated and altered according to the patient's capacity. The participant could rest whenever needed.

3.1. Statistical Analyses

All statistical analyses were performed using SPSS Statistics version 28.0 (IBM Corp., Armonk, USA). Descriptive statistics, including means (with standard deviations (SD)) and medians (with interquartile range (IQR)), were calculated for the demographic variables and main outcome measures where appropriate. Comparisons between pre- and post-intervention were assessed using a dependent *t*-test (continuous variables) to determine whether there were significant differences between the two different time points. Wilcoxon Signed-Rank test used to analysis ordinal data. Differences between two variables were statistically significant at $P < 0.05$. Effect sizes were defined as small ($d < 0.41$), medium ($0.41 \geq d \leq 0.70$), and large ($d > 0.70$) to estimate the effect of the LBPP gait training intervention (31).

4. Results

Thirteen participants were recruited for the study. Four participants dropped out because of their inability to complete the required sessions. One participant completed 16 sessions and dropped out because of cold weather and transportation issues, one participant completed six sessions and dropped out due to family circumstances, two participants completed 12 sessions and dropped out due to orthopedic problems (falls; knee pain). The fall and knee pain were not related to study intervention. Therefore, nine participants completed the 18 sessions and were included in the analysis. Participants (one female, eight males) were aged 57 ± 15.4 years with chronic stroke since 4.8 ± 3.9 years. The average height of the participants was 164 ± 6.9 cm, and their average weight was 80 ± 11.6 kg. Table 1 shows the participants' demographic characteristics.

Compared to the baseline, participants showed significant improvement in FAC (pre, 4 ± 2; post, 5 ± 1; P = 0.034); 10-$MWT_{comfortable}$ (pre, 16.35 ± 9.34 s; post, 13.25 ± 7.57 s; P = 0.021) and 6MWT (pre, 166.22 ± 94.15; post, 206.66 ± 103.64; P = 0.048). Although there were improvements in dynamic balance (TUG) pre intervention (30.95 ± 19.42 s) compared to post-intervention (28.28 ± 20.38 s) (P = 0.077), static balance (FRT) pre intervention (22.05 ± 12.09 cm) compared to post-intervention (26.25 ± 9.01 cm) (P = 0.069), gait speed (10-MWT_{fast}) pre intervention (13.02 ± 8.35 s) compared to post-intervention (12.81 ± 11.24 s) (P = 0.883), and QoL (SF-36) pre intervention (69.95 ± 17.60%) compared to post-intervention (81.57 ± 18.61%) (P = 0.225); however, the results of these outcome measures were not statistically significant (Table 2).

5. Discussion

The current study investigated the efficacy of gait training for six weeks on LBPP on ambulation ability, gait speed, walking endurance, dynamic and static balance, and QoL in individuals with chronic stroke. LBPP is used in rehabilitation clinics mostly for orthopedic conditions and athletes (14, 15). However, neurological patients require a tool that relieves body weight during gait training to support weak muscles. Several tools have been developed to support body weight during gait training, including the BWST (4), robotic exoskeletons (32), and LBPP. However, studies on the use of LBPP in individuals with chronic stroke are scarce. As a result, the purpose of this study was to assess the effect of LBPP gait training on functional outcomes, such as gait speed, walking endurance, dynamic and static balance, and QoL in individuals with chronic stroke.

Although the treadmill speed was slow based on patient comfort during gait training sessions, with an average of 0.83 km/h (0.23 m/s), this study reported that LBPP significantly improved the FAC measure, preferred walking speed, and walking endurance after 18 sessions compared to the baseline. A treadmill speed of 0.83 km/h is slow, so increase an average speed during gait training to challenge level or minimal walking speed for community ambulation > 0.80 m/s (33), would potentially result in more improvement (34, 35). The difference in the participant's gait speed was 0.09 m/s with a large effect size (0.95), which exceeded the minimal clinical important difference that ranges from a small meaningful change (0.06 m/s) to a substantial meaningful change (0.14 m/s) (36). In fact, gait training on LBPP in this study placed our participants in the community ambulation category (0.45 m/s) instead of household ambulator category (0.37 m/s). As described in the literature, a gait speed of ≥ 0.42 m/s could distinguish between home and community ambulation (25).

Similarly, the walking endurance difference was 40.44 meters with a moderate effect size (0.77), which also exceeded the MDC, which was 36.6 meters (29). Walking endurance measured using the 6MWT was considered the strongest predictor of community ambulation (25). In this study, the participants' walking endurance exceeded the minimum distance of 205 m, which is the value that discriminates between household and community ambulators (25). Functional outcomes, such as the FAC, 10-MWT, and 6MWT, are often easy to demonstrate and interpret.

Figure 1. Lower body positive pressure (Alter G).

Table 1. Participants' Demographic Characteristics (n = 9)

Participant Number	Age (y)	BMI	TSS (y)	Gender	Involved Side	Chronic Conditions	Marital Status	AFO	Assistive Device
1	70	28.24	0.5	M	Right	DM+HTN+DYS	Married	No	Cane
2	67	36.05	8	M	Left	DYS	Married	No	Cane
3	60	26.65	2	M	Right	DM	Married	No	Cane
4	28	21.19	7	M	Left	None	Single	No	No
5	33	35.06	6	F	Left	None	Married	Yes	No
6	63	30.84	3	M	Right	DM+HTN	Married	No	Cane
7	66	35.08	1.5	M	Right	DM+HTN+DYS	Married	No	Cane
8	64	27.24	3	M	Left	DM+DYS	Married	Yes	Cane
9	64	26.45	13	M	Right	DM+HTN+DYS	Married	No	Cane
T, mean ± SD	57 ± 15.4	29.64 ± 5	4.8 ± 3.9	-	-	-	-	-	-

Abbreviations: T, total; m, mean; SD, standard deviation; BMI, body mass index; TSS, time since stroke; M, male; F, female; DM, diabetes mellitus; HTN, hypertension; DYS, dyslipidemia; AFO, ankle-foot orthosis.

Table 2. Pre and Post Descriptive Statistics and Analysis of Outcome Measures

Outcome Measures	Pre-intervention (Mean ± SD)	Post-intervention (Mean ± SD)	95% CI	Effect Size (Cohen's d)	P-Value
FAC (median ± IQR)	4 ± 2	5 ± 1	-	-	0.034[a]
10-MWT$_{comfortable}$(s)	16.35 ± 9.34	13.25 ± 7.57	.135, 1.73	0.95	0.021[a]
6MWT (M)	166.22 ± 94.15	206.66 ± 103.64	-1.51, -0.005	0.77	0.048[a]
TUG (s)	30.95 ± 19.42	28.28 ± 20.38	-0.070, 1.39	0.67	0.077
FRT (cm)	22.05 ± 12.09	26.25 ± 9.01	-1.41,.052	0.70	0.069
10MWT$_{fast}$(s)	13.02 ± 8.35	12.81 ± 11.24	-0.605,.703	0.05	0.883
SF-36 (%)	69.95 ± 17.60	81.57 ± 18.61	-1.11,.260	0.43	0.225

Abbreviations: SD, standard deviation; cm, centimeter; s, second; %, percentage; M, meter; CI, confidence interval; IQR; interquartile range.
[a] $P < 0.05$

Moreover, these outcomes measure the functional aspects of walking, which are often important for poststroke survivors and their relatives. Furthermore, these outcome measures are useful as clinical gait assessment tools and for research purposes (26).

The findings of this study are consistent with the previous studies. Park and Chung. (18) reported that LBPP was superior to the control group in balance and walking ability measured by the Berg Balance Scale, TUG, and 10MWT after four weeks of treatment in chronic stroke patients. Similarly, Oh et al. (19) found that the use of an anti-gravity treadmill has been proven to be an effective intervention approach for lowering the risk of falling in stroke patients, as measured by the Tinetti Performance-Oriented Mobility Assessment, the BBS and the TUG. Sukonthamarn et al. (21) and Duran et al. (20) recruited acute and subacute stroke patients who were more susceptible to spontaneous recovery than the effect of the intervention (37). Compared to BWST, A systematic review of 26 BWST studies found that BWST significantly increased walking speed in individuals with stroke (38). However, walking endurance did not increase significantly. In this study, the significant improvements in preferred gait speed and walking endurance after LBPP gait training highlighted additional positive implications. Gait speed is strongly associated with functional ability and balance and can be a discriminating factor for community ambulators (33). Furthermore, gait speed is a significant factor in fall prediction and fear of falling and is a good indicator of QoL (39).

Although the statistical analysis was not significant for fast gait speed, balance, or QoL, the findings showed a trend of improvement. We believe that because of the small sample size, the analysis failed to detect any significant changes because the probability values were highly affected by the sample size (40). Despite the absence of significance, there was a medium effect on dynamic and static balance and QoL (0.67, 0.70, and 0.43, respectively). Therefore, these statistics may be misleading because large improvements were present but a significance level of 0.05 was not reached.

The current study had a few limitations, including the relatively small sample size, which makes it difficult to generalize the findings. LBPP gait training requires individuals to be ambulatory; therefore, only individuals with stroke who are able to stand and walk can be trained. Furthermore, this study did not include a control group for comparison, so we could not confirm that the results were solely due to LBPP gait training. Lastly, we did not assess the long-term effects with a follow-up study. Further exploration of these effects with a comparison group and long-term follow-up studies are warranted. Moreover, further research should examine the effects of LBPP gait training on different neurological populations.

In summary, this preliminary investigation showed that LBPP gait training resulted in significant improvements in walking ambulation, preferred walking speed, and walking endurance in individuals with chronic stroke. In addition, improvements in dynamic and static balance, and QoL were observed. Therefore, the use of the LBPP for gait training in individuals with chronic stroke may be appropriate for clinical practice.

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Footnotes

Authors' Contribution: S.A. designed the study, collected the data, analyzed the data, interpreted the results, and wrote and approved the final draft.

Clinical Trial Registration Code: NCT04767334 (Link: https://clinicaltrials.gov/ct2/show/NCT04767334)

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Data Reproducibility: The dataset presented in the study is available on request from the corresponding author during submission or after publication.

Ethical Approval: The local institutional review board at Qassim University approved the study (reference number 20-05-04).

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Informed Consent: All the participants provided and signed written informed consent.

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