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Original Article

Physiotherapy Section

Effect of Retro Walking Combined with Lagos Neuropathy Protocol on Balance and Spatiotemporal Parameters of Gait among Patients with Diabetic Neuropathy: A Prospective Interventional Study

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ABSTRACT

Introduction: Diabetic Peripheral Neuropathy (DPN) clinically manifests as a sensorimotor disturbance that leads to complications in gait alteration and balance impairment. Balance and locomotion are the most critical aspects of an individual's independence.

Aim: To assess the effect of Retro walking with Lagos Neuropathy Protocol (LNP) on balance and spatiotemporal parameters of gait among patients with Diabetic neuropathy.

Materials and Methods: The present prospective interventional Study was conducted in the Outpatient Department (OPD), Krupanidhi College of Physiotherapy, Bengaluru, Karnataka, India, from October 2022 to June 2023. The sample size was 60 individuals, 30 in each group (experimental and control group). Group 1, the control group, received the conventional LNP. Group 2, the experimental group, received the LNP combined with backward walking. The interventions were given to the patients four times/week for eight weeks. Subjects were assessed at the initial stage and following the end of the intervention. The parameters assessed were balance and spatiotemporal parameters of gait, in which balance was assessed by using the Mini Balance Evaluation Systems Test (Mini-BESTest) and gait speed using a 10 m walk test; other gait parameters cadence, step length, and stride length were measured individually using a stopwatch and inch tape. The statistical software used was Statistical Package for the Social Sciences (SPSS) software version 29.0, and the tests included were paired t-tests and independent t-tests for data analysis.

Results: The mean±Standard Deviation (SD) age of the experimental group participants was 51±3.24 years, and the control group was 50.87±3.12 years. A significant improvement was seen in cadence, step length, stride length, gait speed, and balance in the control and experimental group (p-value <0.001) Greater improvement was found in the experimental group when compared with the control group in all the outcome measures. Significant improvement was seen in all parameters in the experimental group when compared to the control group at post-test (p-value <0.05).

Conclusion: The study concluded that the LNP combined with backward walking had a significant positive effect on balance and spatiotemporal determinants of gait than the LNP alone among DPN patients.

Keywords: Action anticipation, Diabetic peripheral neuropathy, Mini-BESTest, Movement, Reaction, Retropulsion

INTRODUCTION

Diabetes Mellitus (DM) is a chronic metabolic disorder with elevated plasma glucose levels [1]. In DM type 2, non insulin, accounts for approximately 90% of all cases of diabetes [2]. India is the world's centre for diabetes, with a prevalence of six million people, and 65.1 million suffer from diabetes [3]. According to projections, this will reach over 134 million by 2045, with about 57% of those still undiagnosed [4]. DPN is defined as the presence of symptoms and signs of peripheral nerve dysfunction in people with diabetes after the exclusion of other causes [5].

Clinically, DPN shows symptoms in the stocking-like presentation, which starts distally from the legs and hands and, progresses upward in direction; along with sensory disturbance, there will be motor dysfunctions also present in diabetic neuropathy [6]. DPN is one of the most dangerous health problems, having an incidence of almost 40-59% of the total population with diabetes [7]. The highest prevalence of DPN is among the middle-aged group between the ages of (40-60 years) and in the elderly over 60 years of age; an increase in age and duration of diabetes increases the prevalence of diabetic neuropathy [8]. DPN is a long-term sequela; in addition to neuropathy, other major organs like the heart, blood vessels, and kidneys are also getting affected, and complications and severity increase with an increase in the duration of diabetes [9].

Increased glucose levels affect many cells like Schwann cells, neurons of the Peripheral Nervous System (PNS) and Central Nervous System (CNS), and others causing health issues like retinopathy, nephropathy and neuropathy [10]. In diabetes, the order course goes distal-to-proximal regarding damage; most of the demonstration is bilateral and symmetrical [11]. The amount of information from mechanoreceptors declines with foot sensation and proprioception information disruption. In diabetic neuropathy, somatosensory input gets affected, and visual systems sometimes disturb the balance [12]. Sensory and motor deficits, along with muscular atrophy and biomechanical alterations caused by DPN underpin alteration in gait in many ways, which will also have an impact on balance and, in turn, increase fall risk [13]. Gait alterations were noted like reduced gait speed, fewer steps per minute, as well as, shorter strides than in healthy people [14].

Effective interventions for gait alteration in DPN include multisensory training, sensorimotor training, functional strength training [15] and body weight training. Balance impairment is a severe complication frequently addressed through sensory and motor training, specifically

Proprioceptive Neuromuscular Facilitation (PNF) [16]. Balance training has significantly improved balance and reduced the risk of falls in individuals with DPN [17]. Backward walking is an effective intervention for improving balance impairment by stimulating the facilitation of proprioception training in the form of sensory training [18]. LNP is a recent protocol that consists of 10 stations of training, concentrating on sensation, proprioception, ankle movement, strength, balance and pain management almost all the complications of DPN [19]. Hence, interventions focusing on balance and gait alterations have become essential to address it. In a recent study, by Gbiri CAO et al., the authors concluded that LNP improves the symptoms of Diabetic Peripheral Sensory-motor Polyneuropathy (DPSP) was safe, clinically appropriate, convenient for use at home and clinically effective in improving functional independence in individuals [19].

Earlier studies have mostly focused on complications relating to diabetic neuropathy, like either balance or proprioception or any gait component [15-18]. The present study attempted to concentrate on the main issues and related aspects among the population with diabetic neuropathy, such as balance and impairment related to balance, as well as, the majority of potential gait changes like gait speed, cadence, step length and stride length. Thus, the aim of the present study was to assess the effect of Retro walking with LNP on balance and spatiotemporal parameters of gait among patients with diabetic neuropathy. The null hypothesis has been framed as, there would be no significant difference post-intervention and alternate hypothesis as, there would be a significant difference.

MATERIALS AND METHODS

The present prospective interventional study was conducted in the OPD, Krupanidhi College of Physiotherapy's (KCPT), Bengaluru, Karnataka, India, from October 2022 to June 2023 after receiving the clearance from Institutional Ethical Committee (IEC) (ECMPT/2022/PHY/017).

Inclusion criteria:

- Patients clinically diagnosed with diabetes type 2, having a duration of more than five years [20],
- Pain scale {Visual Analogue Scale (VAS) score less than 5},
- Sensory impairment verified using an examination version of the Michigan Neuropathy Screening Instrument (MNSI) scores ≥2.5 in the legs [21].
- The study comprised both males and females.
- The age range of 40-55 years was considered.

Exclusion criteria:

- Participants with foot ulcers, gangrenous foot and amputation.
- Patients with other neurological conditions like peripheral nerve injury, orthopedics conditions like postsurgery and deformities that influence gait [22].

Sample size estimation: Sample size was calculated using the formula [23]:

$$SS = \frac{\left(Z_{1-\alpha/2}\sqrt{\left(1+\frac{1}{m}\right)P(1-P)} + Z_{1-\beta}\sqrt{P_1(1-P_1)/m + P_2(1-P_2)}\right)^2}{(P_1-P_2)^2}$$

$Z_{1-\alpha/2}$=standard normal variate=90%=1.65

$Z_{1-\beta}$=standard variate of derived power=80%=0.84

P_1=possibility of an event in the control group=0.5

P_2=proportion of the positive impact following the interventions in the experimental group=0.8 [24].

$P=(P_1+P_2)/2$=possibility of event=0.65

m=no. of control subject per experimental subject=1

$$SS = \frac{\left(1.65\sqrt{(1+1)0.65(1-0.65)} + 0.84\sqrt{0.5(1-0.5)/1 + 0.8(1-0.8)}\right)^2}{(0.5-0.8)^2}$$

$$SS = \frac{((1.65*0.674)+(0.84*0.64))^2}{(0.3)^2}$$

$$SS = \frac{(1.112+0.537)^2}{0.09} \approx 30$$

N=30

Sixty DPN patients were randomly allocated into two groups using simple randomisation method, by random tables generated through Microsoft excel, assigning 30 subjects in each group, based on inclusion and exclusion criteria. A purposive sample strategy was employed for sampling.

Study Procedure

The experimental group received the LNP coupled with backward walking and the control group was given only the LNP. The parameters assessed were balance and spatiotemporal parameters of gait, in which cadence, step length, stride length and gait speed were measured.

Lagos Neuropathy Protocol (LNP) [19]: The experimental group was given the LNP and backward walking. LNP consists of 10 components, in which the first to sixth concentrated on sensation and proprioception training using different texture surfaces like foam, dry grains/beans, mat, cotton wool and mat with contours, and patients were asked to walk over it, by dragging their feet, the seventh component on ankle movement, an elastic band used to concentrate on strengthening, the eighth and ninth components on balance training where a wobble board has been used and the last component tenth, a contrast bath focused on sensory perception, draining swelling and pain management.

Backward walking [18]: Backward walking was given in which subjects were asked to walk backward at their average pace for 15 minutes in which three-minute walk following a one-minute rest in between given three times. In the barrier-free hallway, the runway provided was longer than 10 meters long and spacing in width was five meters; tracts were marked using colored sticky tape and then the patient was asked to walk barefoot with a normative gait in the backward direction [18].

The combined rehabilitation training of (LPN coupled with backward walking) sessions lasted an hour each and was held four days a week for eight weeks. Considering the exhaustion level of subjects, one minute rest was allowed between each set of exercises.

Measurement tool: The measuring equipment consisted of a stopwatch to check the time taken to cover a marked distance. The steps covered by the subject in a minute were counted manually while the subject walked in a straight-line, barrier-free corridor using a stopwatch. A measuring tape was used to check the distance covered in a step. Patients were guided to walk at their tempo and gait determinants such as cadence, step length and stride length were assessed. With the use of measuring tape, the 10-meter distance was marked. Using a stopwatch, a distance of six meters was timed in seconds. Because the rate of acceleration and deceleration varied, affecting the walking pace, the first and last two meters were not counted. An average of three speed trials was taken. Subjects were supervised by walking alongside for safety reasons.

Outcome measures: The following outcome measures were assessed in the study: cadence, step length, stride length, gait speed and balance using different scales. Cadence was measured using a stop watch, subjects were asked to immerse their feet in ink and walk at their fast pace for a minute with a set timer. Step length and stride length were measured using the same method of feet immersed in ink post-walk measurement was done using inch tape, seeing marks on the floor. Mini-BESTest was used for Balance assessment [25], having four different subcomponents.

I. Anticipatory postural adjustment consisting of three tasks: Sit to stand, rise to toe, stand on one leg (rt/lt);
II. Postural response to external perturbations, having three tasks: compensatory stepping forward, compensatory stepping backwards, compensatory stepping lateral;
III. Sensory orientation, which consisted of three tasks: Stance, eye open firm surface, stance, eye open, foam surface, incline, eye closed;
IV. Stability in gait, consisting of five tasks: Change in gait speed, Walk with head turns horizontal, walk with pivot turns, step over obstacles, time up and go with dual task.

Scoring was measured based on 3-point scale, which is (0,1,2). A total score of 28 could be attained gait speed was measured using the 10-meter walk test using inch tape and a stop-watch. Individuals were asked to walk 10 meters without assistance and simultaneously time was recorded using a stopwatch for a 6-meter distance. The initial and last two meters were excluded to allow for acceleration and deceleration to avoid any alteration in gait speed [26].

STATISTICAL ANALYSIS

The independent t-test and the paired t-test were used for between and within the groups, respectively. The SPSS software version 29.0 was used to analyse the data with a confidence level of 95% and an error of 5% to determine the significant value of the outcome measures.

RESULTS

The mean±SD age of the experimental group participant was 51±3.24 years and the control group was 50.87±3.12 years, with a p-value of 0.823 indicating that the participants' distribution was homogeneous. The gender distribution in the experimental group was, females, 15 (50%), males, 15 (50%); and in the control group, females, 13 (43.3%) and males, 17 (56.7%) [Table/Fig-1].

Variables	Experimental group Mean±SD	Control group Mean±SD	p-value
Age (years)	51.00±3.24	50.87±3.13	0.875
BMI (kg/m²)	26.10±1.79	26.05±2.17	0.922
Type 2 DM duration (years)	5.99±0.67	6.13±0.58	0.390
MNSI questionnaire (score)	7.67±0.80	7.43±0.50	0.168
MNSI physical examination (score)	2.58±0.44	2.73±0.38	0.163
VAS (score)	4.03±0.72	4.2±0.71	0.361

[Table/Fig-1]: Demographic data of the groups.
BMI: Body mass index

Data analysis revealed that the experimental group showed significant improvement in cadence, step length and stride length using individual measurement methods, as well as, gait speed by 10-meter walk test and balance using the Mini-BESTest (p-value=0.001) [Table/Fig-2].

A significant improvement was also seen in cadence, step length, stride length, gait speed and balance using the same measurement scale in the control group (p-value <0.001) [Table/Fig-3]. The experimental group showed a higher improvement level than the control group based on mean difference.

No discernible difference between the groups in the mean pretest value of all the variables (p-value >0.05) was observed; hence, whereas a notable difference was seen in the mean value in the post-test between the group (p-value <0.05), an alternate hypothesis was accepted [Table/Fig-4].

The above [Table/Fig-1] shows the mean values of demographic details {age, Body Mass Index (BMI), MNSI questionnaire and physical examination and VAS score} of the participants of both groups.

DISCUSSION

Among the DPN population, gait alteration in the form of slower speed, shorter step length and stride length, decreased cadence and other forms of gait deviations have been seen due to sensory-motor deficits that underpin marked balance impairment [27]. The present investigation aimed to see the combined influence of LNP and backward walking on balance and spatiotemporal gait parameters among the DPN population. After analysis by an independent t-test, the result revealed that the experimental group (combined) showed more effective results than the control group for all the parameters of gait and balance. Gbiri CAO et al., earlier explained that LNP significantly increases pressure perception on the foot and also helps to reduce the non sensitive areas on the foot due to stimulation of proprioception and mechanoreceptors of the foot [19].

The nerve conduction study is considered as the gold standard for the diagnosis of peripheral neuropathy of lower limb. However, Caronni A et al., in their study found that balance and mobility examination had high sensitivity for the diagnosis of peripheral neuropathy of lower limb [28]. Hence, assessment of balance and gai was done in this study.

In the present study, all the parameters of balance and gait improved significantly in the group with LNP and backwards walking when compared to the group with LNP alone. Similar to the present study, Saleh MS and Rehab NI, concluded that using ankle proprioceptive

Experimental group		Pre-Post Mean	SD	Mean	SD	Difference Mean	SD	t-value	p-value
Cadence (Steps per minute)		89.07	3.65	99.03	3.15	9.96	2.38	-22.89	0.001
Step length (cm)		62.93	3.805	66.87	4.18	3.94	1.5	-14.29	0.001
Stride length (cm)		110.87	3.85	118.37	3.80	7.5	2.01	-20.41	0.001
Gait speed (m/s)		0.78	0.16	1.01	0.14	0.23	0.14	-8.67	0.001
MBT	Anticipation	3.57	0.50	4.6	0.49	1.03	0.55	-10.18	0.001
	Reaction	3.07	0.45	4.43	0.50	1.36	0.76	-9.79	0.001
	Sensory	3.6	0.49	4.91	0.66	1.31	0.76	-9.79	0.001
	Dynamic gait	4.87	0.73	6.27	0.58	1.4	0.77	-9.96	0.001
	Total	15.1	0.923	19.87	1.10	4.77	0.97	-26.88	0.001

[Table/Fig-2]: Comparison of mean value in gait parameters and balance within the experimental group.

Control group	Pre-Post Mean	SD	Mean	SD	Difference Mean	SD	t-value	p-value
Cadence (Steps per minute)	89.47	2.25	96.3	1.76	6.83	1.74	-21.46	<0.001
Step length (cm)	62.1	3.86	64.7	4.04	2.6	1.19	-11.95	<0.001

Stride length (cm)		110.6	3.67	114.93	3	4.33	1.47	-16.15	<0.001
Gait Speed (m/s)		0.77	0.13	0.86	0.16	0.09	0.066	-7.22	<0.001
MBT	Anticipation	3.63	0.49	4.13	0.5	0.5	0.57	-4.78	<0.001
	Reaction	3	0.52	3.83	0.53	0.83	0.79	-5.77	<0.001
	Sensory	3.53	0.5	4.37	0.61	0.84	0.53	-8.6	<0.001
	Dynamic gait	4.93	0.58	5.43	0.56	0.5	0.73	-3.75	<0.001
	Total	15.1	1.15	17.93	1.11	2.83	0.69	-22.2	<0.001

[Table/Fig-3]: Comparison of mean value in gait parameters and balance within the control group.
MBT: Mini-BESTest

Variables		Pre/Post	Experimental group		Control group		Mean diff	SD Diff	t-value	p-value
			Mean	SD	Mean	SD				
Cadence (Steps/minute)		Pre	89.07	3.65	89.47	2.25	-0.400	1.4	-0.510	0.612
		Post	99.03	3.15	96.30	1.76	2.73	1.39	4.14	<0.001*
Step length (cm)		Pre	62.93	3.80	62.10	3.86	0.833	-0.06	0.842	0.403
		Post	66.87	4.18	64.70	4.04	2.16	0.14	2.04	0.046*
Stride length (cm)		Pre	110.87	3.85	110.60	3.67	0.267	0.18	0.274	0.785
		Post	118.37	3.80	114.93	3.00	3.43	0.8	3.88	<0.001*
Gait speed (m/sec)		Pre	0.7803	0.164	0.770	0.134	0.009	0.03	0.249	0.804
		Post	1.004	0.149	0.858	0.164	0.146	-0.01	3.59	<0.001*
MBT	Anticipation	Pre	3.57	0.504	3.63	0.490	-0.067	0.01	-0.519	0.605
		Post	4.60	0.498	4.13	0.507	0.467	-0.07	3.59	<0.001*
	Reaction	Pre	3.07	0.450	3.00	0.525	0.067	-0.07	0.528	0.599
		Post	4.43	0.504	3.83	0.531	0.600	-0.02	4.49	<0.001*
	Sensory	Pre	3.60	0.498	3.53	0.507	0.067	-0.01	0.513	0.610
		Post	4.97	0.669	4.37	0.615	0.600	0.08	3.61	0.001*
	Dynamic gait	Pre	4.87	0.730	4.93	0.583	-0.067	0.14	-0.391	0.697
		Post	6.27	0.583	5.43	0.568	0.833	0.01	5.60	<0.001*
	Total	Pre	15.10	0.923	15.10	1.15	0.00	-0.22	0.00	1.00
		Post	19.87	1.10	17.93	1.11	1.93	-0.01	6.75	<0.001*

[Table/Fig-4]: Comparison of mean value in gait parameters and balance between the groups.
*The p-value <0.05 was considered statistically significant

training on gait significantly improved gait and reduced risk of falling in patients with diabetic neuropathy [29]. Ahmad I et al., concluded that using sensorimotor and gait training significantly improved nerve function and proprioception in DPN patients [8]. Similarly, Ahmad I et al., in another study stated that the enhancement of sensory input in proprioception, mechanoreceptors and somatosensory happens through sensorimotor training, which helps muscle balance and ensures motor programming in the correct ways directly from higher centers. That also improves the walking pattern of the DPN patients [7].

Choi JY et al., stated that backward walking enhances joint position sense and facilitates righting and equilibrium reactions for sustaining posture because it relies on the auditory and sensory systems rather than visual systems, which help to improve balance and functionality in form of ambulation gait. Also, stated in backward walking, there will be an eccentric contraction of the quadriceps, enhancing muscular strength and energy consumption rather than a concentric contraction [24]. Similar studies from the literature have been compared in [Table/Fig-5] [7,8,19,29-32].

S. No.	Author's name and year	Place of study	Number of subjects	Intervention given	Parameters assessed	Conclusion
1	Saleh MS and Rehab NI, (2019) [29]	Cairo University, Egypt	30 subjects	Ankle active range of motion, gait training on heel, sideways, marching, tendam	Gait velocity, step length, step time, cadence and double support time Risk of fall	Proprioceptive-based training improves gait and reduces fall risk.
2	Ahmad I et al., (2020) [8]	New Delhi, India	44 subjects included	Sensorimotor training, balance and gait training	Nerve Conduction Study (NCV); Electromyography (EMG)	Proprioceptive-based training improves NCV and muscle function.
3	Maritz CA et al., (2020) [30]	University of the Sciences, Philadelphia, Pennsylvania, USA	60 subjects	Backward walking	Endurance dynamic gait parameters	Endurance and dynamic gait parameters improved.
4	Wang J et al., (2018) [31]	Department of Physical Education, Dalian, China	Identified 5668 articles, including 17 full-text articles	Backward walking	Spatiotemporal parameter of gait	Forward gait speed and stride length improved.
5	Kalidasan V et al., (2019) [32]	Karnataka, India	30 subjects	Backward walking	Gait parameters	Improvement in gait performance, speed and cadence.
6	Ahmad I et al., (2019) [7]	Jamia Millia Islamia, New Delhi, India	37 subjects	Sensorimotor training	Static and dynamic balance measures, Center of Pressure (COP) range, COP, sway, and proprioception	Improved static and dynamic balance as well as, proprioception measures.

7	Gbiri CAO et al., (2021) [19]	The Lagos University Teaching Hospital, Nigeria	31 subjects	Comparison b/w Buerger- Allen exercise and Lagos Neuropathy Protocol (LNP)	Balance, gait parameters, sensation	Improvement in sensory and pressure perception, balance, pain and functional performances.
8	Present study (2023)	KCPT, Bengaluru, India	60 subjects	LNP+backward walking	Balance, spatiotemporal parameters of gait	Improvement in balance and gait parameters.

[Table/Fig-5]: Similar studies from the literature [7,8,19,29-32].

Limitation(s)

The intervention's long-term impact was not assessed and it can be examined to evaluate the persistence of improvement achieved. The study focused on functionality in terms of gait and balance; protocol can also be explored regarding the sensory aspects of interceptors and exteroceptors of DPN populations.

CONCLUSION(S)

The present study concluded that the combined effect of the LNP with backward walking was more effective in improving gait characteristics like the number of steps per minute, length between both feet, walking speed and functional balance compared with the LNP alone. The results also showed that the LNP alone is also beneficial in improving the balance and gait parameters of the DPN population. Therefore, LNP can be combined with backward walking or any other adjuvant to improve DPN populations' functionality. LNP can also be suggested as a preventive measure for DPN following complications.

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