A Single Blind, Single Center, Two Group Pretest-posttest Randomized Controlled Trial to Determine the Efficacy of Vestibular Rehabilitation and Conventional Balance Training Programmes in the Management of Diabetic Peripheral Neuropathy

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ABSTRACT

Introduction and Aim: Diabetic peripheral neuropathy (DPN) is defined as the presence of signs and symptoms of peripheral nerve dysfunction in subjects with diabetes. Vestibular dysfunction accounted to be greater than 70% in people with diabetes which eventually increases the risk of fall. Conservative treatment methods like vestibular rehabilitation (VR) and conventional balance training (CBT) programmes are available to treat them. More efficient among them is not known. The aim of the study was to compare the efficacy of VR and CBT programmes in the management of individuals with DPN.

Materials and Methods: A total of 60 individuals with DPN were recruited by the simple random sampling to participate in this two group pretest-posttest, single blind, single center randomized clinical study. Recruited individuals with DPN were randomly allocated into two groups, Group A and Group B. Group A were provided with VR programme. for 60 seconds duration x 5 repetition / session / day x 3 days / week x 12 weeks. While group B received CBT programme. Both the groups received the treatment for 12 weeks, totaling 36 sessions (three sessions per week). Level of confidence [Activities specific Balance Confidence (ABC) Scale] and functional mobility [Timed up and go test (TUG)] were documented at baseline and 12th week after intervention and analyzed.

Results: Group A demonstrated significance difference ($p<0.05$) in ABC scale and TUG when compared to group B.

Conclusion: Twelve week VR programme has the sufficient potential to increase the level of confidence and functional mobility among individuals with DPN.

Key Words: Diabetic neuropathy, Falls, Physical therapy techniques, Single-blind study.

INTRODUCTION

Diabetes is a serious and chronic metabolic disorder that occurs when the body cannot effectively use the insulin that it produces, or when the pancreas does not produce enough insulin (1). Diabetes and its complications, especially retinopathy and peripheral neuropathy, is steadily increasing over the past few decades and The increased risk of complications of diabetes has led to 1.6 million (2.8%) deaths in 2015 across the world (2). Diabetic peripheral neuropathy (DPN) is defined as the presence of signs and symptoms of peripheral nerve dysfunction in subjects with diabetes after the exclusion of other cause (3). Peripheral neuropathies, commonly seen in subjects with diabetes mellitus are due to the chronic hyperglycemia (1). In type 1 diabetes mellitus, distal polyneuropathy typically becomes symptomatic after many years of chronic prolonged hyperglycemia, but in cases of type 2 diabetes mellitus, the subjects may present with distal polyneuropathy only after a few years of known poor glycaemic control (1). It is always necessary to take into account the following changes in the subjects like Touch sensitivity symptoms which include pain, numbness, and altered pain sensation in hands, legs, and feet leading to skin damage (1).

The complication of diabetes which is least understood in its effect on the vestibular system (4). Due to diabetes, pathophysiological changes in central and peripheral vestibular structures have been noted (3). If the vestibular system is adversely affected by diabetes, it is necessary to consider its impact of

diabetes on the risk of falls in older adults and other population (5). Although vestibular system dysfunction is not commonly recognized as a microvascular complication of diabetes, a recent epidemiological study reported that vestibular dysfunction was 70% higher in people with diabetes than in people matched for age and serving as controls (6). In addition, decreased vibration sense and loss of pressure sensitivity have been shown to be associated with recurrent falls (7). Because of decreased proprioceptive feedback during walking, older adults with diabetes walk slower and have greater stride variability; these factors increase the risk of falls (8).

Physiotherapists play a vital role in improving the general condition and fall prevention in subjects with diabetic peripheral neuropathy. The need to consider vestibular rehabilitation (VR) exercise becomes essential due to the involvement of vestibular system in people with DPN. VR exercises aim at training the eye and head movements and thereby improving general coordination. The comprehensive evaluation of the vestibular system may be necessary for people who have diabetes along with balance impairment. Hence the purpose of this study was to compare the effects of vestibular rehabilitation (VR) exercises and conventional balance training (CBT) program in subjects with DPN.

MATERIALS AND METHODS

Recruitment and Allocation

The study protocol was approved by the university research and ethics committee (ACS/2016/68) and the study was done strictly in accordance with the guidelines of Helsinki declaration, revised 2013 (9). A total of 30 individual with DPN were recruited by the simple random sampling (random number tables from standard statistics book) to participate in this two group pretest-posttest, single blinded randomized clinical study. After the demographics, 60 recruited individual with DPN were randomly divided into two groups, group A and group B with, 30 in each by block randomization. There were ten blocks, with the matrix design of 6 x 10, where 6 being rows. Each block contained 6 chits (3 chits for each group), totaling 60. The subjects were allotted to the group based on the randomly chosen chit. Once the block was allotted, next row block was opened. Thus, equal number of subjects was assigned to each group over time. Group A received vestibular rehabilitation (VR) exercises. While Group B received conventional balance training (CBT) programme. Both the group received the interventions for 12 week period, totaling 36 sessions (3 sessions / week). First session was performed under supervision, and other at their home without supervision. The Consolidated Standards of Reporting Trials (CONSORT) (10) flow chart describing the details of the study is displayed in Figure 1.

Vestibular Rehabilitation Exercise in Group A

Group A (30 subjects) received vestibular rehabilitation exercises. The vestibular rehabilitation exercises consist of the Cawthorne Cooksey exercises and the gaze stabilization exercises. All the exercises were performed daily with 8 repetitions for each exercise / session. They performed single session / day x 3 days / week x 12 weeks. The first session of VR exercises were demonstrated and supervised by qualified person who have more than five years' experience in training VR exercises.

Conventional balance training (CBT) programme in Group B

Group B received CBT program, which includes the exercises like single limb stance (30s x 3 repetitions / limb), staggered stance (30s x 3 repetitions / limb), side stepping (3m/side x 3 repetition) and crossed stepping (3m/side x 3 repetition) exercises for single session aimed at improving the balance of the subjects. These exercises were performed single session / day x 3 days / week x 12 weeks.

Outcome Measures

Both the group were measured for their level of confidence [Activities specific Balance Confidence (ABC) Scale] (11) and functional mobility [Timed up and go test (TUG)]12 between Group- A and Group- B at baseline and 12th week post intervention.

Data Analysis

The collected demographic and outcome measures were assessed for their normality using Kolmogorov–Smirnov test. As the data follow normal distribution, all the descriptive were expressed in mean ± standard deviation. Paired t test was adopted to find out the differences within Group- A and group-B for pre-post intervention changes. While independent t-test was used to compare the changes in mean values of ABC scale and TUG test between Group- A and Group- B at baseline and end of 12 week intervention. The data was analysed using statistical software, statistical package for social science (SPSS),

CONSORT
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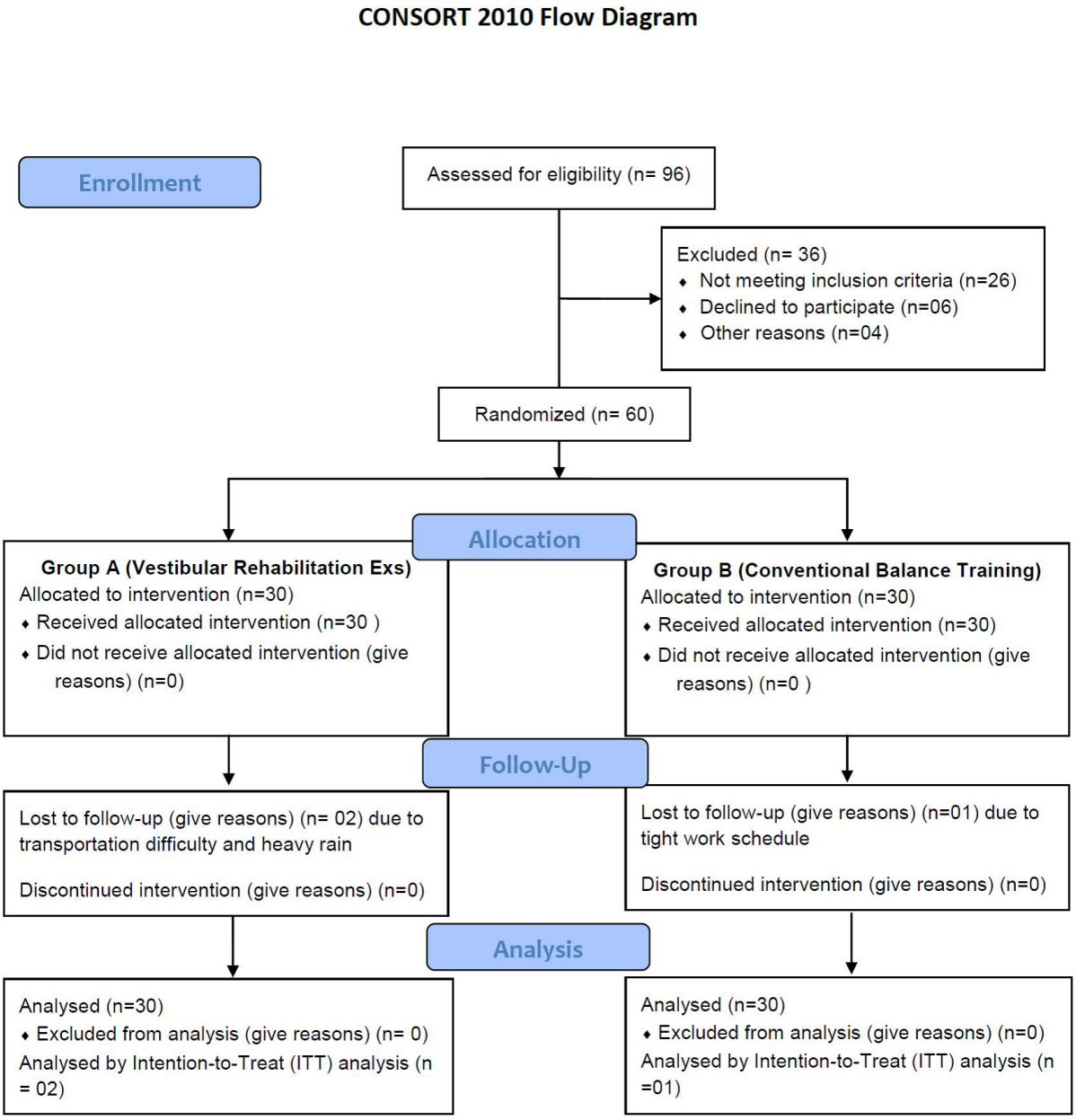


Figure 1: CONSORT diagram describing the study flow

IBM SPSS version 20.0 (Armonk, NY: IBM Corp.). The p-value ≤0.05 was considered to be statistically significant.

RESULTS

Sixty individuals with DPN were recruited for the study. The demographic characteristic of the individuals with DPN recruited were displayed in Table 1. The demographic characteristics were elaborated in Table 1. There exists no significance difference between the two groups. Between the session and group comparison at baseline and end of 12 weeks exercise intervention for the outcome measures ABC scale (Figure 4) and TUG test (Figure 5) were displayed. In all the outcome measures, group A shows significant ($p<0.05$) improvement when compared to group B.

Table 1: Demographic characteristic of the individuals with diabetic peripheral neuropathy recruited in group A and group B.

Table 1: Demographic characteristic of the individuals with diabetic peripheral neuropathy recruited in group A and group B

Parameters	Group A	Group B	p-value
N	30	30	-
Age (years)	53.2±3.8	51.7±3.1	0.71
Weight (kg)	75.4±7.5	79.2±5.6	0.23
Height (cm)	165.2±9.2	167.5±6.9	0.13
BMI (kg/m2)	27.7±2.1	28.4±2.9	0.09

Figure 2: Mean Activities specific Balance Confidence (ABC) Scale score at baseline and end of 12th week intervention between Group A and Group B

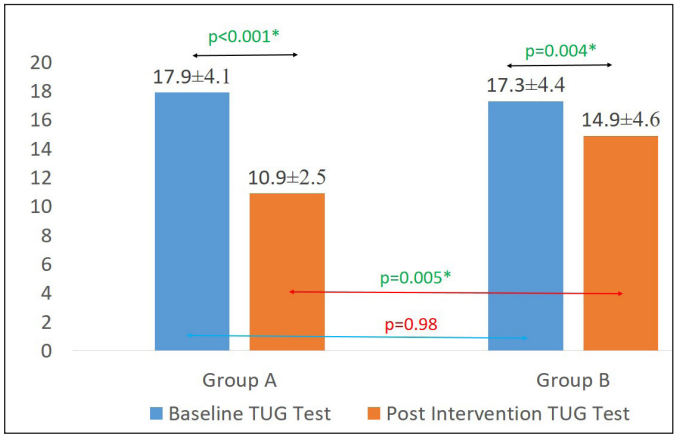
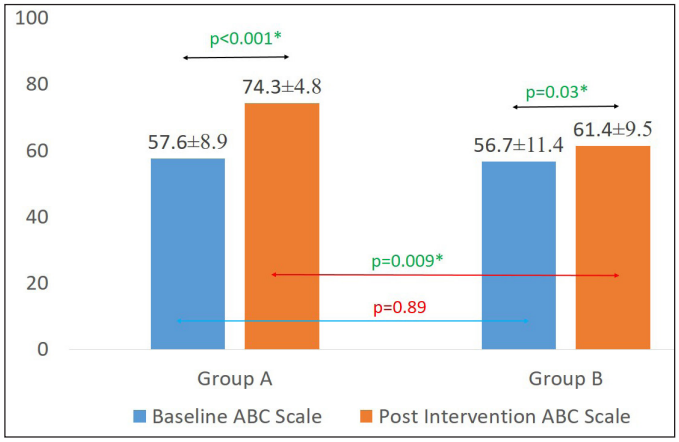


Figure 3: Mean Timed up and go test (TUG) at baseline and end of 12th week intervention between group A and group B



DISCUSSION

The individual with DPN has increased chances of developing an unsteady movement pattern that is due to the decline in the balance and proprioception. Lack of proprioception in the subjects with diabetic peripheral neuropathy may affect the quality of life of the patients and their dynamic balance. Studies suggest that the complications of the diabetics are more severe when the disease is for the prolonged period. Balance problems are one among the common problem faced by the subjects with DPN in which all the three somatosensory systems are affected.

The conventional balance training program was the treatment strategies for the subjects with balance impairment in the diabetics, Allet et al. (8) reported that the balance training program had an excellent outcome in improving the dynamic balance of the subjects (8). It is mandatory that the subjects with balance impairment should follow the balance training because it was the older population who were more prone to the fall risk. The conventional balance training program aims at improving the balance of the patients and thereby prevents the risk of fall. The balance training programme includes gait and balance exercises combined with strengthening that improves gait speed and balance, and increase both muscle strength and joint mobility of diabetic patients (6,8,13). This supports the findings of our study that CBT improves confidence level and functional mobility in individuals with DPN.

Recent studies suggested that the balance impairment in the diabetics is also due to vestibular dysfunction. D'Silva et al (14) reported the relationship among diabetes, vestibular function, and the fall risk are complex (14). People with diabetes have many deficits, including neuropathy, retinopathy, all of which would compromise the activity and their functional status. Vestibular dysfunction is another possible complication of diabetes and may increase the risk of falls. Understanding this relationship, identifying and treating, and working toward integrating all systems visual, vestibular, and somatosensory to improve balance are the ways in which physical therapists can prevent falls. Hence, treating vestibular dysfunction by the vestibular rehabilitation exercises may also have an impact on improving both the static and dynamic balance of the subjects.

The present study was conducted in 60 subjects with Diabetic Peripheral Neuropathy. 30 subjects were included in each Group in which Group A received the Vestibular rehabilitation exercises, and Group B received the Conventional balance training program. The study intended to compare the effectiveness of vestibular rehabilitation exercises and conventional balance training program in DPN subjects with balance impairment. This study showed that both the treatment program worked well on both the groups, in which vestibular rehabilitation exercises were considered to be more effective than the conventional balance training program in order to maintain the

balance while performing different activities.

The possible reasons behind the effectiveness of treatment with vestibular rehabilitation exercises are due to the involvement of the visual, vestibular and somatosensory system by the process of vestibular compensation (14). It is the process which allows the brain to regain the balance control when there is an imbalance between the right and left vestibular organs in the ear. It is achieved when the brain copes with disorienting signals from the inner ear by learning to rely on the alternative signals coming from eye, neck, and legs to maintain balance (14-16). Hence incorporating vestibular rehabilitation exercises in the general treatment protocol for treating subjects with DPN is considered to be beneficial in improving balance and reducing the risk of falls

CONCLUSION

Twelve-week VR programme has the potential to increase the level of confidence and functional mobility among individual with DPN when compared with CBT programme.

REFERENCES

1. Alberti, K.G., and Zimmet, P.Z. Definition, diagnosis and classification of diabetes mellitus and its complications. Part 1: diagnosis and classification of diabetes mellitus provisional report of a WHO consultation. Diabet Med. 1998; 15(7): 539-553.
2. WHO | World Health Organization [Internet]. WHO. World Health Organization; 2017 [cited 2017 Sep 9]. Available from: http://www.who.int/gho/mortality_burden_disease/en/
3. Whiting, D.R., Guariguata, L., Weil, C., and Shaw, J. IDF diabetes atlas: global estimates of the prevalence of diabetes for 2011 and 2030. Diabetes Res Clin Pract. 2001; 94(3): 311-321.
4. Morrison, S., Colberg, S.R., Mariano, M., Parson, H.K., and Vinik, A.I. Balance training reduces falls risk in older individuals with type 2 diabetes. Diabetes Care. 2010; 33(4): 748-750.
5. Singh, G.M., Danaei, G., Farzadfar, F., Stevens, G.A., Woodward, M., Wormser, D., et al. The age-specific quantitative effects of metabolic risk factors on cardiovascular diseases and diabetes: a pooled analysis. PLoS One. 2013; 8(7): e65174.
6. Kruse, R.L., Lemaster, J.W. and Madsen, R.W. Fall and balance outcomes after an intervention to promote leg strength, balance, and walking in people with diabetic peripheral neuropathy: "feet first" randomized controlled trial. Phys Ther. 2010; 90(11): 1568-1579.
7. Roman de Mettelinge, T., Cambier, D., Calders, P., Van Den Noortgate, N., and Delbaere, K. Understanding the relationship between type 2 diabetes mellitus and falls in older adults: a prospective cohort study. PLoS One. 2013; 8(6): e67055.
8. Allet, L., Armand, S., de Bie, R.A., Golay, A., Monnin, D., and Aminian, K., et al. The gait and balance of patients with diabetes can be improved: a randomised controlled trial. Diabetologia. 2010; 53(3): 458-466.
9. World Health Organisation. Declaration of Helsinki World Medical Association Declaration of Helsinki Ethical Principles for Medical Research Involving Human Subjects. J Am Med Assoc. 2013; 310(20): 2191-2194.
10. Consort - Welcome to the CONSORT Website [Internet]. 2010 [cited 2017 Aug 23]. Available from: http://www.consort-statement.org/
11. Powell, L.E., and Myers, A.M. The Activities-specific Balance Confidence (ABC) Scale. J Gerontol A Biol Sci Med Sci. 1995; 50A(1): 28-34.
12. Shumway-Cook, A., Brauer, S., and Woollacott, M. Predicting the probability for falls in community-dwelling older adults using the Timed Up & Go Test. Phys Ther. 2000; 80(9): 896-903.
13. Salsabili, H., Bahrpeyma, F., Forogh, B., and Rajabali, S. Dynamic stability training improves standing balance control in neuropathic patients with type 2 diabetes. J Rehabil Res Dev. 2011; 48(7): 775-786.
14. D'Silva, L.J., Lin, J., Staecker, H., Whitney, S.L., and Kluding, P.M. Impact of Diabetic Complications on Balance and Falls: Contribution of the Vestibular System. Phys Ther. 2016; 96(3): 400-409.
15. Kim, S.K., Lee, K.J., Hahm, J.R., Lee, S.M., Jung, T.S., Jung, JH., et al. Clinical significance of the presence of autonomic and vestibular dysfunction in diabetic patients with peripheral neuropathy. Diabetes Metab J. 2012; 36(1): 64-69.
16. Morrison, S., Colberg, S.R., Parson, H.K., and Vinik, A.I. Relation between risk of falling and postural sway complexity in diabetes. Gait Posture. 2012; 35(4): 662-668.