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Occupational Therapy

TO STUDY THE EFFECTIVENESS OF BALANCE TRAINING ON FUNCTIONAL INDEPENDENCE IN GUILLAIN BARRE SYNDROME (GBS): RANDOMISED CONTROLLED TRIAL

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ABSTRACT

BACKGROUND: GBS is considered as the most disabling neurological condition in current scenario worldwide. GBS affects nerve roots, peripheral nerves, leading to motor neuropathy and flaccid paralysis with possible sensory and autonomic nervous system effect. All these factors are the major cause of balance, gait impairment and increase in risk of fall in patients. Therefore, it is important to undergo rehabilitation in order to increase the likelihood of achieving functional independence in activities of daily living (ADL) and improve muscular fitness.

OBJECTIVE:

1) To assess the effectiveness of balance training on functional independence in GBS.
2) To assess pre and post intervention scores of ADL.
3) To correlate the pre and post intervention scores of balance to the risk of falls

STUDY DESIGN: A prospective, Randomized control trial design

Methods: 30 participants, both male and female with age 20 years and above, diagnosed with Guillain Barre Syndrome and falling in Hughes GBS Disability stage 3 and above were recruited and intervened for 2 months.

Group A (control group) received Strengthening exercises and Group B (Experimental group) received Strengthening exercises and Balance Training. 15 eligible participants were randomly allocated in each group and received 45 minutes of respective training session for 3 days per week. They were assessed on Functional Independence Measure scale (FIM) , Berg Balance Scale (BBS) and Lower Extremity Functional Scale (LEFS) as an outcome measures.

RESULTS: Our study showed that there was statistical significant improvement (p value < 0.05) in FIM, LEFS and BBS test scores in Group A and Group B after respective Occupational Therapy intervention. But more significant improvement (p value < 0.05) in functional independence was observed with the combined effect of balance training and strengthening exercises on experimental group B.

CONCLUSION: Our study supports the evidence that balance training is effective and has a positive impact on performance in ADL and thus improves functional independence of patients.

KEYWORDS : ADL, Balance, GBS, Independence, Mobility

INTRODUCTION

Guillain Barre Syndrome (GBS) is considered as the most disabling neurological condition in current scenario worldwide. It can strike anyone without warning regardless of gender, age, or ethnic background.

GBS affects nerve roots, peripheral nerves, leading to motor neuropathy and flaccid paralysis with possible sensory and autonomic nervous system effect. Weakness develops (e.g. Difficulty walking, climbing stairs, getting up from a chair and cramping). These impairments cause balance problems, postural instability, gait disturbances and increase in risk of falls of patients.

Recovery can be extremely slow (stretching over the course of 6 months to 2 years or longer) and 5 to 20 percent of patients are left with significant residual symptoms that lead to long term disability and prevent a successful return to their prior lifestyle or occupation.

In a Cochrane review of exercise in people with peripheral neuropathies, case-report studies or only few randomized controlled trials were identified for patient with GBS. However, some treatment program used for patients with other neuromotor dysfunction can be adapted for use with patients with GBS. Since, there is little evidence documenting the impact of balance training on functional independence, therefore, the aim of the present study was to compare the effectiveness of strengthening exercises alone versus combined strengthening and balance training to improve functional independence in people with GBS, to assess pre and post intervention scores of activities of daily living and to assess risk of fall status.

METHODS

We designed a randomized controlled trial (RCT) to compare the effects of strengthening exercises alone versus the effects of strengthening plus balance training exercises on functional independence for people with GBS (Flowchart of Recruitment Process provided in tables and graphs section)

Participants*:* People were included if they met the following inclusion criteria: 1) The patients who were diagnosed as GBS or was a known case of GBS since less than 12 months were included (all the subtypes of GBS were included), 2) Both male and female participants were included of adult age group [i.e. 20 and above], 3) Patients whose Hughes GBS Disability Scale score was 0 to 3 were included, 4) Patients who were willing to maintain the follow ups were included. Exclusion Criteria: 1) Patients who were on assisted ventilation, bedridden and admitted due to GBS were excluded because they were not medically stable, 2) Patient who is a known case of GBS since more than one year, 3) Patient who could not follow-up on the outpatient basis, 4) Patients who had a relapse or recurrence of GBS were excluded, 5) Patients who had developed contractures or deformity were excluded.

The study protocol was approved by institutional ethics committee and all participants gave written informed consent prior to participating.

Intervention*:* Participants were randomly assigned into control group or experimental group (3 sessions /week for 2 months). Each session lasted for 45 minutes. Total participants recruited were 30 (15 in group A and 15 in group B). Group A which is a control group received strengthening exercises and Group B which is an experimental group received strengthening plus balance training exercises.

Reassessment was done on 1st week, 3rd week, 5th week, 7th week in order to match with the patient's exercise capabilities and functioning level at that week. The upgradation in the study protocol was done after every two weeks. Final assessment was done on 8th week of study period i.e after 2 months.

Strengthening exercises of upper-limb and lower-limb were common to both groups which included progressive resistive exercises by increasing weights and repetitions within patient's tolerance level. PNF diagonal pattern with and without weights. Use of therapeutics equipment and machines like stationary cycling, inclined sanding, shoulder wheel, hand gym, medicine ball kicking in sitting, sit-to-stand activity, mini-squats and lunges with support. Sensory re-education was given to patients with sensory impairment. ADL simulated activities started related to upper limbs namely fine motor hand activities like cutting paper, dressing and folding clothes, writing.

Balance training exercises for experimental group B progressed from simple to gradually increasing challenging complex activities with respect to patients improving capacity from day 1 till two months. Exercises like spot marching, one leg standing, stepping in multi-direction, step-ups on stool, walking on dynamic surfaces like mattress or treadmills with and without support. Facilitation of equilibrium reactions using wobble board and therapeutic ball by giving reach-out or object transfer activities and perturbations in all directions. For ADL mimicking movements PNF diagonal patterns of both upper-limb and lower-limb was given followed by ADL activities related to lower limbs was be practiced like lower limb dressing, wearing shoes in standing, ball kicking, ball catching etc. Outdoor activities like stair-climbing or slope-walking in forward, backward and sideway direction etc. Training progression during the intervention period was reached by reducing or manipulating sensory information, necessary to obtain balance and by adding movement to make the activity more dynamic. Visual information for example was disturbed by closing the eyes. Proprioceptive feedback was manipulated by standing on different unstable surfaces instead of normal over ground followed by one-leg ball balancing and rolling. Challenges were further increased by performing few of above activities by visually blinding the patient, crossing over obstacles courses, adding of speed variation component during performance.

Outcomes Measures*:* Patients were screened using the inclusion and exclusion criteria then case record forms were filled and pre-intervention assessment (day 1) was done on Berg Balance Scale (BBS), Functional Independence Measure (FIM) scale and Lower Extremity Functional Scale (LEFS).

Functional Independence Measures (FIM) : which was used to assess patient's changes in the functional ability or level of assistance in activities of Daily Living performance. Inter-rater reliability is 0.86 to 0.88 and validity is 0.83.

Berg Balance Scale (BBS) : to determine balance and risk of fall. It has a high relative reliability with inter-rater reliability estimated at 0.97 and intra-rater reliability estimated at 0.98.

Lower Extremity Functional Scale (LEFS) : to assess for lower extremity functioning about patient's ability to perform everyday tasks related to lower extremity use. The LEFS is a questionnaire containing about a person's ability to perform everyday tasks. Test-retest reliability was 0.94.

Hughes GBS disability Scale: used as a screening tool and to assess the functional mobility of the patients. This study included patients whose Hughes GBS disability status was 3 to 0. The scores in this scale in inversely related to functional mobility status in GBS patients i.e. high scores indicates poor functioning of patient, whereas, low scores indicates good functioning. The scores range of functional status is from 0 to 6 where, 0 is healthy and 6 is death.

Statistical Analysis*:* Assessment scores considered for statistical analysis were of baseline (day 1) and of last day of intervention after 2 months.

The data was entered using MS-EXCEL 2016 and data analysis was done by using SPSS Statistical Software version 24.0. The data was initially tested for Normal Distribution using Shapiro – Wilk's Test for Normality.

Our study data was normally distributed so therefore following statistical test of significance were used :

- The Paired sample t test : to assess the statistical significance of two successive assessments (baseline and 8th week) of experimental and control group over two related samples for total scores of each outcome measures FIM, LEFS, BBS.
- The Independent sample t test : to assess statistically significant difference between the means in two unrelated groups i.e experimental and control group for total scores of each outcome measures FIM, LEFS, BBS.
- The Spearman's rank correlation test: to assess the association or relationship between two unrelated variables in a given population data and to measure if their association is statistically significant or by chance.

The P value less than 0.05 was taken as statistically significant at 95% confidence level

RESULTS

Baseline data in table no.1 shows no significant differences in the demographic or baseline variables between the two groups. Our study data was normally distributed when tested using Shapiro – Wilk's Test for Normality.

Baseline variables	Group A (control) n=15	Group B (Experimental) n=15
Age	39.73±13.14	42.06 ±13.81
No. of female subjects	2 (6.6%)	2 (6.6%)
No. of male subjects	13 (86.6%)	13 (86.6%)
AIDP subtype	10 (66.6%)	9 (60%)
AMAN subtype	4 (26.6%)	5 (33.3%)
AMSAN subtype	1 (6.6%)	1 (6.6%)
MFS subtype	0	0

Table no.1: Baseline variables. If not indicated differently, values are either mean ± SD or number and percentage. AIDP (Acute inflammatory Demyelinating Polyradiculopathy), MFS (Miller-Fisher Syndrome), AMAN (acute motor axonal neuropathy), AMSAN (acute sensory axonal neuropathy)

The following tables show the results of the following outcome measures at baseline (Day 1) and post-treatment (week 8) in both group:

A) Table no. 2 : A Paired Sample t test performed in Group A and Group B after 8 weeks of respective training protocol showed statistical very highly significant improvement in FIM scores, BBS scores and LEFS scores among GBS patients with p = .000 at 95% confidence level ($p \leq 0.001$ – results are very highly significant). Indeed, mean score rating also improved in both groups.

GROUP	Outcome measures	No. of patients	Mean pre	Mean post	Std. Deviation pre	Std. Deviation post	Sig. (2-tailed) p – value
Group A	FIM	15	104.40	117.26	4.83	2.12	.000
Group B	FIM	15	99.00	119.66	7.09	2.71	.000
Group A	BBS	15	37.46	55.40	4.88	1.242	.000
Group B	BBS	15	38.33	55.86	4.71	.516	.000
Group A	LEFS	15	38.06	63.60	7.44	5.44	.000
Group B	LEFS	15	37.46	67.93	5.74	5.750	.000

Table no.2 : Paired sample t test performed in Group A and Group B for outcome measures showing difference in pre and post therapy scores.

B) Table no. 3: An Independent Sample t test performed between Group A and Group B after 8 weeks of respective training protocol showed statistical improvement in FIM scores (p = .012) and LEFS scores (p = .043) among GBS patients since difference between the means of post training scores is statistically significant as p value is <0.05, which lead to acceptance of alternative hypothesis i.e. balance training was more effective improving functional independence in GBS. But BBS scores (p = .195) showed no statistical significant improvement among GBS patients.

LEFS when compared to BBS showed better improvement in experimental group B than control group A. This may be explained that LEFS has no ceiling effect, but BBS has ceiling effect, therefore, no significant difference was observed between two groups on BBS measures and thus led to acceptance of null hypothesis i.e. both the trainings were equally effective in improving functional independence in GBS[23,28]

	Levene's test for equality Sig.	T	Df	Sig. (2-tailed) / p – value
Post therapy FIM	.356	-2.697	28	.012
Post therapy BBS	.016	1.344	18.699	.195
Post therapy LEFS	.839	-2.119	28	.043

Table no. 3 : Independent Sample t test performed between Group A and Group B after 8 weeks of respective training protocol

C) Table no. 4 : Spearman's rank correlation was used to correlate improving functional independence with the decrease in risk of fall in GBS patients in both groups. Table shows that correlation between FIM scores and BBS scores in both groups are not statistically significant as p- value is >0.05. But has a weak to moderate negative relationship as r value is -0.23 for group A and -0.31 for group B which

means that there is an inverse relationship between improving functional independence and decreasing risk of fall.

Correlation of Group post-therapy FIM scores and BBS scores	Spearman's Rho (r value)	p-value p-value > 0.05	Statistical Significance
Group A	-0.23	0.39	weak negative correlation: but not significant
Group B	-0.31	0.99	weak negative correlation but not significant

Table no. 4 : Correlation of post intervention FIM scores to BBS scores (on 8th week) using Spearman's rank correlation test.

Additional from table no. 5 findings, it shows that the Hughes GBS disability status of most patients were improved in experimental group i.e. no patients were in disability status 2 whereas in control group two patients were in disability status 2.

		Hughes GBS status 0	Hughes GBS status 1	Hughes GBS status 2	Hughes GBS status 3
Group A	Pre	0	0	6	9
	Post	6	7	2	0
Group B	Pre	0	0	5	10
	Post	6	9	0	0

Table no. 5 : Number of patients in Hughes GBS disability status pre and post intervention in both groups

DISCUSSION

The aim of the study was to find the effectiveness of balance training on functional independence in patients with Guillain Barre Syndrome.

The need of rehabilitation is to restore balance, muscle strength and maintain person's functional independence as soon as the patient is medically stable. The literature review indicates that most of the studies, either case report or RCT, done on GBS population had conducted using unstructured, multidisciplinary strength or balance retraining alone as the protocol for GBS patient's to allow early resumption of normal life. However, there has been no RCT reported to compare the effect of muscle strengthening alone vs. combined balance retraining and muscle strengthening. Hence, in this study, we tried to project the effect of combined results to enhance early return to normal daily activities, prevent a decline in the clinical and functional status of the patient by following the protocol that has been described in the methodology.

Our findings of improvement in functional independence in activities of daily living, after intervention in group A and group B, on GBS patients, are consistent with study of *F Khan* (RCT) who in the year 2011 conducted an RCT on total 79 GBS patients to assess the effectiveness of high- vs low-intensity multidisciplinary ambulatory rehabilitation program for a period of 2 to 3 times per week for 12 weeks. He used FIM total and FIM motor subscale to assess the activity limitation and he found that the high intensity rehabilitation program showed statistical significant improvement (p-value < 0.001) in reducing disability in post therapy FIM domain (self care, mobility, transfer and locomotion). The treatment group compared with control group showed significant improvement in function (FIM scores): 68% vs 32% [2].

A limited number of studies on the human and animal have demonstrated that exercises stimulates endothelium dependent vasodilation and vascular endothelial growth factor expression, increasing endoneurial blood flow , oxygen and glucose to mitochondria to produce energy in a more efficient manner. Progressive resistive strength training has improved the strength component of balance. There has been some evidence of improvement in proprioception of the trunk, postural compensatory strategy between ankle and hip joints and improved rate of force development through balance training. Exercises with eye closed conditions, walking on dynamic surface and PNF diagonal patterns has facilitated sensory organization of sensory inputs. Balancing on the wobble board and therapy ball has facilitated the equilibrium reactions. Perturbation based training can facilitate reactive balance control, in-place strategies (on small perturbations) and enhance stepping strategy (through fast and large perturbation)[9, 13]. One more study discusses about neural adaptations within CNS i.e. adaptation in gray and white brain matter followed by a decrease in the excitability of spinal reflex.

Thus, it can be said that in our study the combined effect of balance training and strengthening exercises may have stimulated the endoneurial blood flow, due to facilitation of endothelial vascularity, and might have enhanced early recovery of neural structures which were damaged due to GBS. Also, improved ankle, knee, hip and stepping strategy after balance training has led to facilitation and improvement of static and dynamic balance, joint proprioception, muscle growth and recovery of these patient populations during ADL performance.

Previously, no study has been done, which examines the lower limb functioning in GBS patients using LEFS scale. Our study contributes to a better understanding of GBS related peripheral neuropathy and lower limb functioning. One study of *Abraham C Munemo* results showed strong test-retest reliability and good internal consistency of LEFS measures among HIV-related distal sensory peripheral neuropathy. Their results also showed significantly lower LEFS scores in HIV patients with foot neuropathy[15]. Hence, LEFS questionnaire can be considered reliable as a standard for monitoring lower extremity functioning in these disease populations.

Further, in our study there was a correlation done between post intervention FIM scores and BBS scores in both groups. Previously, no correlational studies have been conducted for finding association between BBS scores and FIM scores in peripheral neuropathy patients on outpatient rehabilitation. In support of our study, we found a case report on rehabilitation done by *Timothy Hill* on an admitted GBS patient who used FIM as an outcome measure of functional independence and as a prognostic measure for fall risk. He considered that FIM might be useful to predict fall risk, but for inpatient rehabilitation and further more sensitive prognostic tools such BBS, Timed-Up-and-Go (TUG) or Tinetti balance assessment is needed for predicting long term fall risk following discharge[18]. We can correlate our results that improved balance and strength in both groups has led to decrease in risk of fall and thus increase in functional independence in GBS patients.

In our study, every subtypes of GBS were included (as shown in table no. 1) and post-intervention working status of the patients from both the groups revealed that AIDP group (without axonal involvement) showed better and early recovery as compared to AMAN group who had axonal involvement of the peripheral nerves. Also, the patients with a younger age group resumed their duties by the end of intervention period and for the patients with an older age group we could not predict their working level as their roles were different and their activity level was less as compared to younger age group patients. Individualized improvement in the patient post - intervention could be attributed to type of peripheral nerve involvement in GBS, their age.

This study also provides insight into assessment and treatment of lower extremity impairments i.e. balance, gait, sensory and strength deficits on a sample of the Guillain Barre Syndrome population in India. There were few limitation to our study like the study was conducted on mixed group, i.e. all subtypes of GBS were involved, it was conducted on small sample size and for a short time period and it involved a wide range of age group patients, i.e. upper limit was 62 and lower limit was 22. This preliminary evidence could perhaps serve as ample motivation for those who wish to carry out similar studies on a larger population, to assess for long term effectiveness of intervention and to study the effect of intervention on specific subtype of GBS separately.

Despite the limitations of the current study, a combination of overview of prior research and findings of current study provides evidence that the combined effect of balance training plus strengthening exercises is more effective than only strengthening exercises, in GBS patients, to improve functional independence in ADL performance.

CONCLUSION

This study supports the evidence that balance training is effective and has a positive impact on performance in activities of daily living and thus improves functional independence of GBS patients.

The results of our study show that there was improvement in FIM, LEFS and BBS test scores in Group A and Group B after respective Occupational Therapy intervention. But more significant improvement in functional independence was observed with the combined effect of balance training and strengthening exercises on experimental group B. In addition, our study reflects that more structured program was useful and desirable in monitoring conditions like GBS rather than having an unstructured and combination program for rehabilitation.

Thus balance training plus strength training is more effective than strength training alone in improving functional independence in GBS patients and should be included in the rehabilitation protocol of these patients.

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REFERENCES

1. Khan F, Stevermuer T, Simmonds F. Rehabilitation for Guillain Barre Syndrome: Analysis of the Australian rehabilitation outcomes dataset: Journal of Clinical Medicine and Research. 2010: 2. 91-97.
2. Khan F, Pallant J, Amatya B, Ng L, Gorelik A, Brand C. Outcomes of high- and low-intensity rehabilitation programme for persons in chronic phase after Guillain-Barre syndrome- A randomized controlled trial: J Rehabil Med. 2011:43(7). 638-646.
3. Hansen M. Guillain-Barré syndrome, CIDP and Variants guideline for physical and occupational therapy: GBS/CIDP foundation International.
4. Orsini M, de Freitas MRG, Presto B, Mello MP, Reis CHM et al. Guideline for Neuromuscular Rehabilitation in Guillain-Barré Syndrome: What can we do. 322/1001 CEP24230-240
5. Ng YS, Lo YL, Lim PAC. Characteristics and acute rehabilitation of Guillain-Barre syndrome in Singapore: Ann-Acad Med Singap. 2004:33.314-9.
6. Shah Nehal, Shrivastava Manisha.Role of Physiotherapy in Guillain Barre Syndrome-A Narrative Review: International Journal of Health Sciences & Research (www.ijhsr.org).September 2015: 529 Vol.
7. Nicholas Simatos Arsenault, Pierre-Olivier Vincent,Yu Bai He Shen, Robin Bastien,Aaron Sweeney,Sylvia Zhu. Influence of Exercise on Patients with Guillain-Barre´ Syndrome-A Systematic Review:From the Rehabilitation Science in Physical Therapy Program.2016:68(4);367–376; doi:10.3138/ptc.2015-58
8. Sarah Rodger, A. Williams Andrews. Effects of Dynamic Balance Training and Progressive Ambulation on Functional Mobility in an Individual with Vaccine-Associated Guillain-Barre Syndrome: A Case Report : Journal of student physical therapy research, 2017; 9(3)
9. Cindy Tofthagen. Strength and balance training for adults with peripheral neuropathy and high risk of fall: current evidence and implications for future research, Oncol Nurs Forum, 2012 September; 39(5): E416–E424
10. S.Sathish Kumar, Dr. Vijay Batra. Occupational Therapy perspective for enhancing functional independence in geriatric population:
11. Tuacek TA, Tsukimoto GR, Figliolia CS, Cardoso MCC, Tsukimoto DR, Rosa CDP, et al. Neuropathies - Guillain-Barré syndrome: rehabilitation Authorship-The Brazilian Association of Physical Medicine and Rehabilitation Final. July 2013: 20(2):89-95
12. Khanzada FJ and Zameer S. Effectiveness of Occupational Therapy in Rehabilitation of Guillain Barre Syndrome-A Case Study: Phys Med Rehabil Int. 2016: 3(2);1083.
13. Anne Shumway – Cook. Control of Normal Mobility: Motor Control translating research into Clinical Practice .2012: 4th Edition; 315-347
14. Anne Shumway – Cook. Normal Posture Control: Motor Control translating research into Clinical Practice .2012: 4th Edition; 161-193
15. Abraham C Munemo. The test- retest reliability of the lower extremity functional scale in HIV-related distal sensory peripheral neuropathy: A research project, 2018:1 -85

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