Journal of Caring Sciences 2018; 7 (2): 89-93
doi:10.15171/jcs.2018.014
http:// journals.tbzmed.ac.ir/ JCS

Original Article

The Effect of Biofeedback on the Motor– Muscular Situation in Rehabilitation of Stroke Patients: a Randomized Controlled Trial

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ARTICLE INFO

Article History:
Received: 9 Jan. 2017
Accepted: 2 Dec. 2017
ePublished: 1 June 2018

Keywords:
Biofeedback, Stroke, Rehabilitation

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ABSTRACT

Introduction: Stroke is the most common debilitating neurological disease in adults. Therefore, rehabilitation is a major consideration to reduce costs and relief disabilities. Biofeedback, a newly recommended method is claimed to be able to improve the consequences following stroke by enhancing the understanding of the psychological functions of the body. The purpose of this study was to investigate the effects of biofeedback on the motor– muscular situation in balance and ability to walk, muscle stiffness (spasticity), hand muscles strength of stroke patients.
Methods: The present study was a randomized clinical trial done in 2016. The participants were randomly divided into 2 groups (case and control group). In the intervention group, biofeedback was performed. The check list of main variables, including balance and ability to walk, muscle stiffness (spasticity) and hand muscles strength was completed by a physician before the intervention and at the end of the intervention (16th session). The statistical analysis was conducted, using SPSS version 13.
Results: The mean score of balance in intervention group versus control group showed significant differences. The results showed that by eliminating the effects of muscular strength before the intervention, this variable had made improvements and significant differences in both intervention and control groups after the intervention. Comparison of the average spasticity showed that spasticity evaluation score before and after the intervention revealed no significant difference between the two groups.
Conclusion: Biofeedback therapy is a promising treatment modality for improving the motor– muscular situation of patients after stroke.

Citation: Najafi Z, Rezaeitalab F, Yaghubi M, Manzari ZS. The effect of biofeedback on the motor– muscular situation in rehabilitation of stroke patients: a randomized controlled trial. J Car Sci 2018; 7 (2): 89-93. doi:10.15171/jcs.2018.014

Introduction

Stroke is the most common debilitating neurological disease in adults and the third leading cause of death worldwide after cardiovascular diseases and cancer.[1] A statistical analysis revealed that>50% of patients who survive a cerebrovascular accident experience long-term disabilities.

One hundred and thirty-two people out of every 100,000, suffer their first stroke annually in Iran- a rate which is considerably higher than that in developed countries.[2,3]

After a stroke, patients who lack independence may be affected with musculoskeletal, swallowing, and bowel and bladder dysfunction, loss of skin integrity, and self-care inability.[4,5] All of these problems can impair a patient's self-image and decrease their quality of life and performance.[6] The most common and worst complication of stroke consists of motor disabilities, such as hemiplegia, hemiparesis, partial or complete loss of limb muscle force on one side of the body.[7,8] Post-stroke spasticity results in decreased flexibility, limb deformities, reduced motor function, joint pain, and further decreases in motor function.[1] Also, 55–75% of stroke patients have limited upper-limb function and mobility .[9]

Because of complications caused by functional disorders in stroke patients, cerebrovascular diseases require prolonged hospitalization and home care, which yield huge economic and social challenges.[10] Therefore, rehabilitation is a major consideration to relieve costs and minimize disability. The purpose of rehabilitating patients with hemiplegia following stroke is to enable patients to achieve maximum functional capacity and independence as soon as possible.[11] Accurate and timely rehabilitation can reduce the degree of disability. Studies revealed that within 6 months of stroke, 64% of patients are able to walk without help versus 22% who are not able to walk. Upper- and lower-limb motion can be recovered within 3–6 months in approximately 80% of patients.[12] In recent years, a new method known as functional movement therapy has gained popularity for treating hemiplegia. This method consists of a combination of traditional methods and functional movements, involving weight-bearing or no weight-bearing types to increase joint mobility and reduce hyper tonicity in the affected limbs. Several methods including acupuncture, electrical and functional stimulation, training methods of evolution in the motor nerves, and biofeedback for rehabilitation are available and used for this purpose.[13]

Biofeedback is a treatment technique by which individuals are trained to improve their health through using their physical signs.[14] One of the aims of biofeedback is to enhance the understanding of the body's psychological functions. The main goal of biofeedback training sessions is to train individuals to self-regulate their psychological processes. Biofeedback process includes 3 cognitive methods in the rehabilitation of stroke patients; first, the data are obtained from sensory electrodes and then, biofeedback augmented this signals and finally, this signal is interpreted as a warn to increase or decrease biological function for medical groups. Biofeedback is reportedly able to improve the consequences of stroke, including memory deficits, headache, dizziness, confusion, and distraction as well as lower-extremity motor dysfunction.[9,14]

The ability of biofeedback to improve the lower-limb motor function and walking performance in stroke patients has been investigated in other studies.[9] These authors have reported that, after a 4-week rehabilitation program, the walking ability, walking speed, and lower-limb motor function in the intervention group were not significantly improved. Maciaszek et al.,[13] investigated the effect of biofeedback training performed on a balance plate on the dynamic balance of stroke patients. In the final study follow-up, relative improvements in balance were seen in intervention group.

In the past two decades, biofeedback has been used as a clinical patient training technique for regaining muscle control. Today, with the advent of new therapeutic methods, mortality rates have been reduced, but the demand for rehabilitation has increased. However, the absolute efficacy of biofeedback to improve motor function in patients after stroke is unclear and the few available studies have reported paradoxical results.

Objectives

The purpose of this study was to investigate the effects of biofeedback on the motor– muscular situation in balance, the ability to walk, muscle stiffness (spasticity) and hand muscles strength of stroke patients.

Materials and methods

The primary goal of this investigation was to evaluate the effect of biofeedback on the motor- muscular situation in the rehabilitation of stroke patients.

The present randomized clinical trial was conducted from May to September 2016.

The sample size was determined to be 60 individuals, considering mean space and hypothesis of the same study (10), the mean deviations of $S_1 = 30.6$, $S_2 = 29.8$, $X_1 = 41.3$ and $X_2 = 56.7$, resulted in a group size of $n = 30$.

The inclusion criteria for this study encompass all the patients with stroke for the first time according to computed tomography (CT) scan and magnetic resonance imaging (MRI), with the length of disease exceeding 3 months and lower than 3 years, within the age bracket of 18-65 years, with the ability to walk for 10 meters with or without assisting devices, with hemiplegia and without any cognitive, verbal and visual disorders. Also, the exclusion criteria included an unwillingness to participate in the study, being absent for 3 sessions in biofeedback exercise, being hospitalized during intervention and death.

This study included all patients with stroke who attended the physiotherapy center of Imam Raza Hospital in Mashhad, Iran. The participants were randomly divided into two groups, based on block randomization (case and control) after screening based on the inclusion and exclusion criteria. The control group performed routine physical exercises. In the intervention group, biofeedback (20-min sessions, twice weekly, for 8 weeks) was performed. A demographic information questionnaire was completed by all participants.[15] A checklist of main variables, including balance and ability to walk, muscle stiffness (spasticity) and hand muscles strength was completed by a physician before the intervention and at the end of intervention (16 session).[15]

The main variables of the checklist were reassessed by the researchers who were blinded to the patients' information. Possible confounding variables including aphasia, severe visual disorders, previous musculoskeletal disorders, and peripheral neuropathy detected via the exclusion criteria were excluded from the study. Background variables in monitoring the method during interventional procedures were followed by the control of confounding variables. Before the intervention, educational session was conducted, and the benefits of using a biofeedback device was fully explained to each participant. Two connection channels (Rehab Kit or MyoPFR), were provided to patients and designed for dual purposes. EMG (electromyography) signals can also be used to provide electrical stimulation. The Electrodes are initially placed on the body surface as follows:

1. The patient is in a seated or standing position.
2. The insertion plates of the electrodes are cleaned with alcohol.
3. Two biofeedback electrodes are placed at the two ends of a muscle and one green and one red wire are connected to them.
4. A biofeedback electrode is inserted around the muscle, tendon, or bone protrusion and a black wire is attached to it.

The numbers representing the electrical conductivity of the skin were displayed on the screen to demonstrate the patient's physiological condition. In feedback on the picture, when the amount was higher than the number assigned to the device, we completed our achievement.

The Berg Balance Scale (BBS) was used to determine each patient's balance ability. The validity and reliability of this instrument were evaluated in a similar study.[16]

The BBS is used to objectively determine a patient's ability or inability to safely balance during a series of predetermined tasks. The Berg Balance Test (BBT) evaluates the functional balance of the older adult using 14 simple balance-related tasks. Each of the tasks is graded on an ordinal scale of 0–4, where 0 indicates the lowest level of function and 4 indicates the highest level of function. The total BBT score is 56, indicating the highest possible balance level. Each item is given a score of 0–4 based on a five-point ordinal scale, where 0 indicates the lowest level of function and 5 indicates the highest level of function. Scores of 0–20 indicate "little balance" and a high risk of falling, scores of 21–40 represent "adequate balance" and a medium risk of falling, and scores of 41–56 represent "high balance" and a low risk of falling. The test, which takes approximately 20 minutes to complete, was performed by a researcher.

A modified Ashworth scale was used to evaluate spasticity. The validity and reliability of this instrument in an Iranian population was evaluated by Tahereh Haji-Ahmad et al.[17] This six-grade scale, which is routinely used to evaluate spasticity in stroke patients, was completed before and after the intervention by a neurologist.

A dynamometer (model T.K.K.540) was used to measure muscle strength. The purpose of this test is to measure the maximum isometric strength of the hand and forearm muscles. The patients were instructed to perform maximum isometric contractions during the dynamometric measurement.

Demographic variables including age, sex, educational level, and marital status were recorded. Disease duration, stroke type (ischemic or hemorrhagic), dominant hemisphere, injured hemisphere, cerebrovascular disease risk factors (hypertension, diabetes mellitus, hyperlipidemia, smoking, and cardiac arrhythmias) were recorded in a separate checklist.

The statistical analysis was done using SPSS software version 16. The data were analyzed by a descriptive statistics method, variance analysis, repeated measure, a correlation coefficient, and a non-parametric test such as the Wilcoxon or Mann–Whitney. The level of significance was 0.05.

The aim of the study was explained to the patients and their written informed consent was obtained according to the Declaration of Helsinki. Furthermore, it was explained that the patients could withdraw from the study at any time.

Results

The demographic variables in this study were age, gender, type of stroke and region of stroke, educational level of patients, duration of stroke, marital status, history of hypertension, diabetes mellitus and smoking and history of anti-coagulation therapy. In our study, 60 patients participated of whom 35 (58.3%) were male and 25 (41.7%) were female. The mean age was 59.78 (9.0) years. There was no significant difference in the demographic variables between the intervention and control groups, except for educational level (P= 0.014), since most participants in the intervention and control groups had a high educational level. The left hemisphere was dominant in both groups 24 participants (80%) and 16 participants (53.3%) in the control and intervention groups, respectively). Half of the patients 50% in the control and intervention groups had hypertension, but Fisher's exact test revealed no significant correlations between hypertension and other risk factors such as diabetes mellitus and smoking (P = 0.445).

Table 1 shows the mean other demographic variables and standard deviation of the biofeedback and control groups.

Table 1. Distribution of the patients in biofeedback and control groups based on demographic variables

Variables	Intervention N (%)	Control N (%)	P
Age*	58.46 (9.19)	61.10 (8.80)	0.262*
Gender			1.00
Male	13(43.3)	12(40)	
Female	17(56.7)	18(60)	
Type of stroke			0.209
Ischemic	21(70)	26(86.7)	
Hemorrhagic	9(30)	4(13.3)	
Duration of stroke*	8.26 (1.3)	8.2 (1.4)	0.854
Marital status			0.836
Single	28(93)	23(76)	
Married	2(7)	7(14)	
Anti-coagulant therapy			0.748
Yes	5(16.7)	7(23.3)	
No	25(83.7)	23(76.7)	

*Mean (SD)

Comparison of mean balance ability on the BBS, using the independent t-test showed that the mean pre-intervention score did not differ significantly (P= 0.503), whereas the mean post-intervention score did differ significantly (P=0.014). This finding revealed that at the post-intervention stage, patients in the biofeedback group had higher scores than those in the control group.

In addition, the comparison of the average ability to walking, before and after use of biofeedback treatment, had no significant differences between 2 groups. Comparison of the average spasticity, using the Mann-Whitney test showed that spasticity evaluation scores pre- and post-intervention did not differ between the two groups (P= 1.00).

Comparison of muscle strength, using dynamometer pressure showed that the mean pre-intervention muscle strength in the control group was significantly higher than that in the intervention group (P= 0.041), while there were no significant intergroup differences in the post-intervention scores (P= 0.279). Since the pre-intervention variables were not homogenous, analysis of covariance was used to compare them between the two groups. The results showed that elimination of the effects of muscular strength before and after the intervention in both groups improved these variables significantly (P= 0.005).

Discussion

The aim of this study was to determine the effect of biofeedback on the motor–muscular situation in the rehabilitation of stroke patients. The most important finding of this study was the lack of significant intergroup differences in mean pre- and post-intervention BBS balance scores and muscle strength. This finding was consistent with those of other studies.[17,18] On the other hand, other studies[19-21] reported different findings. This paradox may be due to the use of various scales to evaluate the mentioned indexes. This theory was proven further when Tahereh Haji-Ahmad et al.,[17] and Ehsan Ghasemi et al.,[18] used the same scales as our investigation, while other studies[19-21] reported different results using different scales. The use of various scales with different items might have changed the results.

Walking and balance ability in natural daily life activities in stroke patients is the goal of physiotherapy and biofeedback.[1] In our study, no significant intergroup difference in walking ability was seen before versus after the use of biofeedback. This finding is not parallel in similar studies.[22,23] States et al.,[24] noted that the short-term use of physical therapy and biofeedback did not significantly improve walking or standing ability in stroke patients. The difference in the results of our and other studies[22,23] may be due to differences in the definitions of standing and walking abilities. To explain this issue, Jan Mehrholz et al.,[25] defined this issue as the ability to walk and stand 6 months after the first physiotherapy session. Thus, this parameter should be evaluated in the long run (approximately 6 month after the first physiotherapy session) since a shorter-term assessment may be unreliable. Louise Ada et al.,[26] noted that biofeedback rehabilitation had very little effect on spasticity.

This study had limitations including lack of long-term follow-up. Further studies will help resolve these limitations and improve the rehabilitation guidelines for the use of biofeedback therapy in stroke patients.

Conclusion

Biofeedback therapy is a promising treatment modality for improving the motor–muscular situation of patients after stroke.

Acknowledgments

This article is the result of a research project by Mashhad University of Medical Sciences with the code of 940946, sponsored by Mashhad University of Medical Sciences.

The research group appreciates the authorities of the School of Nursing and Midwifery Mashhad University of Medical Sciences and Shahid Beheshti University of Medical Sciences

Ethical issues

None to be declared.

Conflict of interest

The authors declare no conflict of interest in this study.

References

1. Doğan-Aslan M, Nakipoğlu-Yüzer GF, Doğan A, Karabay İ, Özgirgin N. The effect of electromyographic biofeedback treatment in improving upper extremity functioning of patients with hemiplegic stroke. J Stroke Cerebrovasc Dis 2012; 21 (3): 187-92. doi: 10.1016/j.jstrokecerebrovasdis. 2010.06.006.
2. Hosseini AA, Sobhani-Rad D, Ghandehari K, Benamer HTS. Frequency and clinical patterns of stroke in Iran-Systematic and critical review. BMC Neurology 2010; 10 (1): 72. doi.org/10.1186/1471-2377-10-72.
3. Ghandehari K. Epidemiology of stroke in Iran. GMJ 2016; 5 (S1): 3-9.
4. Pinter MM, Brainin M. Rehabilitation after stroke in older people. Maturitas 2012; 71 (2): 104-8. doi: 10.1016/j. matur itas.2011.11.011.
5. Oujamaa L, Relave I, Froger J, Mottet D, Pelissier JY. Rehabilitation of arm function after stroke. Literature review. Ann Phys Rehabil Med 2009; 52 (3): 269-93. doi: 10.1016/j.rehab.2008.10.003.
6. Cirstea MC, Levin MF. Improvement of arm movement patterns and endpoint control depends on type of feedback during practice in stroke survivors. Neurorehabil Neural Repair 2007; 21 (5): 389-411. doi: 10.1177/1545968 306 298414.
7. Tijs E, Matyas TA. Bilateral training does not facilitate performance of copying tasks in post stroke hemiplegia. Neurorehabil Neural Repair 2006; 20 (4): 473-83.
8. Raju PS. Handbook of neurological physical therapy.1st ed. India: Jaypee Brothers Medical Publishers (P) Ltd 2012.
9. Yang HC, Lee CL, Lin R, Hsu MJ, Chen CH, et al. Effect of biofeedback cycling training on functional recovery and walking ability of lower extremity in patients with stroke. Kaohsiung J Med Sci 2014; 30 (1): 35-42. doi: 10.1016 /j.kjms.2013.07.006.
10. Winstein CJ, Stein J, Arena R, Bates B, Cherney LR, Cramer SC, et al. Guidelines for adult stroke rehabilitation and recovery: a guideline for healthcare professionals from the American heart association/American stroke association. Stroke 2016; 47 (6): e98-e169. doi: 10.1161 /STR .0000000000000098.
11. Cargnin DJ, Cordeiro d'Ornellas M, Cervi Prado AL. A serious game for upper limb stroke rehabilitation using biofeedback and mirror-neurons based training. Stud Health Technol Inform 2015; 216: 348-52.
12. Dozza M, Chiari L, Peterka RJ, Wall C, Horak FB. What is the most effective type of audio-biofeedback for postural motor learning? Gait Posture 2011; 34 (3): 313-9. doi: 10.1016/j.gaitpost.2011.05.016.
13. Maciaszek J, Borawska S, Wojcikiewicz J. Influence of posturographic platform biofeedback training on the dynamic balance of adult stroke patients. J Stroke Cerebrovasc Dis 2014; 23 (6): 1269-74. doi: 10.1016/j.jstr okecer ebrovasdis.2013.10.029.
14. Frank DL, Khorshid L, Kiffer JF, Moravec CS, McKee MG. Biofeedback in medicine: who, when, why and how? Ment Health Fam Med 2010; 7 (2): 85-91.
15. Badke MB, Sherman J, Boyne P, Page S, Dunning K. Tongue-based biofeedback for balance in stroke: results of an 8-week pilot study. Arch Phys Med Rehabil 2011; 92 (9): 1364-70. doi:10.1016/j.apmr.2011.03.030.
16. Berg KO, Maki BE, Williams JI, Holliday PJ, Wood-Dauphinee SL. Clinical and laboratory measures of postural balance in an elderly population. Arch Phys Med Rehabil 1992; 73 (11): 1073-80.
17. Haji-Ahmad T, Allah Haghgoo H, Pishyareh E, Biglarian A. The effect of biofeedback therapy on hand function and daily activities in stroke survivors. Zahedan Journal of Research in Medical Sciences 2015; 17 (10): e2204. doi: 10.17795/zjrms-2204.
18. Ghasemi E SV JS, Rezaiean F, Armak M, Mahmoodi Z. The effectiveness of functional electrical stimulation (FES),

biofeedback and exercise therapy on various parameters of lower limb muscle strength, kinematics of gait and balance in stroke patients: a comparative study. Journal of Research in Rehabilitation Sciences 2010; 6 (1). (Persian)
19. Cargnin DJ, d'Ornellas MC, Prado AL. A serious game for upper limb stroke rehabilitation using biofeedback and mirror-neurons based training. In Med Info 2015; 348-52. doi:10.3233/978-1061499-564-7-348.
20. Jonsdottir J, Cattaneo D, Recalcati M, Regola A, Rabuffetti M, Ferrarin M, et al. Task-oriented biofeedback to improve gait in individuals with chronic stroke: motor learning approach. Neurorehabil Neural Repair 2010; 24 (5): 478-85. doi: 10.1177/1545968309355986.
21. Mirelman A, Patritti BL, Bonato P, Deutsch JE. Effects of virtual reality training on gait biomechanics of individuals post-stroke. Gait posture 2010; 31 (4): 433-7. doi: 10.10 16/j.gaitpost.2010.01.016.
22. Dobkin BH, Plummer-D'Amato P, Elashoff R, Lee J; SIRROWS Group. International randomized clinical trial, stroke inpatient rehabilitation with reinforcement of walking speed (SIRROWS), improves outcomes. Neurorehabil Neural Repair 2010; 24 (3): 235-42. doi: 10. 1177/1545968309357558.
23. Kwakkel G, Wagenaar RC, Twisk JW, Lankhorst GJ, Koetsier JC. Intensity of leg and arm training after primary middle-cerebral-artery stroke: a randomised trial. Lancet 1999; 35 (9174): 191-6. doi: 10.1016/S0140-6736(98)09477-X.
24. States RA, Pappas E, Salem Y. Overground physical therapy gait training for chronic stroke patients with mobility deficits. Stroke 2009; 40 (11): 627-28.
25. Mehrholz J, Wagner K, Rutte K, Meissner D, Pohl M. Predictive validity and responsiveness of the functional ambulation category in hemiparetic patients after stroke. Arch Phys Med Rehabil 2007; 88 (10): 1314-9. doi:10. 1016/j.apmr.2007.06.764.
26. Lo HC, Tsai KH, Su FC, Chang GL, Yeh CY. Effects of a functional electrical stimulation-assisted leg-cycling wheelchair on reducing spasticity of patients after stroke. J Rehabil Med 2009; 41 (4): 242-6. doi:10.2340/16501977-0320.