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The Effect of Early Passive Range of Motion Exercise on Motor Function of People with Stroke: a Randomized Controlled Trial

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ABSTRACT

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Introduction: Frequent and regular exercises in the first six months of stroke may cause return of a significant portion of sensory and motor function of patients. This study aimed to examine the effects of passive range of motion exercise in the acute phase after stroke on motor function of the patients.

Methods: A randomized controlled trial study was conducted. The patients with first ischemic stroke were randomly allocated to either experimental (n=33) or control (n=19) group. Passive range of motion exercises was performed in the experimental group during the first 48 hours of admission as 6 to 8 times of 30 minute exercise. Before intervention, and one and three months after intervention, motor function were measured by muscle strength grading scale (Oxford scale) and compared. SPSS version 13.0 for Windows was used for statistical analysis. Frequency distribution was used to describe the data. For comparisons, paired t-test, independent t-test was used, and repeated measures test was used. **Results:** In acute phase, the intervention in the experimental group led to significant improvement

Results: In acute phase, the intervention in the experimental group led to significant improvement of motor function between the first and third month in both the upper and lower extremities. In control group, improvement was observed only in the muscle strength of upper extremity in the first and third month compared to pre-intervention measurement. The greatest improvement was observed in the interval from base to one month in the upper extremity, and base to the first month and the first to the third month in the lower extremity.

Conclusion: It is recommended to use early passive range of motion exercise as part of care for people with stroke during the acute phase of the disease.

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Introduction

Cerebrovascular disease is the second leading cause of death and the third most common cause of disability in the world.¹ In developed countries, one out of four men over 85 years of age, and one out of every five women over 85 experience the stroke.² The annual incidence of stroke in the United States is equivalent to 700,000, with the prevalence of 5.5 million.³ The results of a study in Iran showed that 139 out of 100,000 people annually suffer from stroke, which is a significant rate compared to that of the Western countries. Based on the results of this study, the incidence of stroke in the age group 45 to 84 years is higher compared to Western countries.⁴ The occurrence of motor defects in upper and lower extremities following stroke and damage to the motor cortex is common. Hemiparesis, paralysis, weakness, abnormal muscle tone, spasm, abnormal postures, abnormal function of synergic muscles, and loss of interjoint coordination are the most common injuries due to damage to the motor cortex.5 Out of eighty percent of patients who experience acute upper extremity paresis after stroke, only one third reach full recovery of their function.6.7 Those patients with longer period of disability need to be cared for by a caregiver who is most often a family member. Family member caregivers are also affected by the stroke; a negative change in caregivers' lives after taking responsibility of caring for their stroke

survivors has been reported.8 According to the theory proposed by Monakow in the twentieth century, local damage to brain tissue causes suppressed function of the motor cortex, and temporary reduction of blood flow and metabolism in the opposite hemisphere, which is called Diaschisis; recovery results from the gradual reversal of the Diaschisis process.9 Over the past decade, numerous neuroanatomical studies in animals as well as neurophysiological studies of the nervous system and other non-invasive studies in human has provided strong evidence of cerebral cortex flexibility features. The imaging studies of the nervous system after brain injury confirms the brain's motor system restitution during the recovery period. Several functional neuroimaging studies suggest that activity within the sensorimotor network, not exclusively ipsilesional motor cortex, is most abnormal early on after a hemiparetic stroke, and that motor recovery is related to normalization of its activity.¹⁰ It has been shown that in the chronic phase after cerebral infarction, restructuring functional circuits are working; this provides for the local expansion of cerebral activation areas and recruitment of parallel projecting cortical areas in the ipsilesional and contralesional hemispheres.¹¹ It has been hypothesized that the mechanism of effect of active and passive motion exercises on the nervous system is reactivation of the existing nerve connections, development of new connections, and axonal regeneration.12 Doing a range of

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motion exercises after stroke leads to changes in the sensorimotor cortex and improved motor functions in the patients.13 Lack of attention to the rehabilitation in the acute phase after stroke has led most of the providers of rehabilitation services to focus on compensatory strategies to improve the function instead of restoration of motor control.¹⁴ Reconstructing and organizing the cerebral cortex at an early stage of stroke and afterward is considered as a potential factor for improvement in the performance of these patients; also, the range of motion exercise after stroke leads to changes in the sensory and motor cortex and improves motor function in patients.¹² Early mobility (sitting, standing and walking) in the acute phase after a stroke, and repeating these activities until the patient's discharge can improve the patients' ability and reduce their need for further care as well as improve self-care activities.² According to Cramer (as cited by Hancock and Shepstone, 2011), the golden time to initiate rehabilitation program is in the early days of the onset of symptoms of stroke and the continuation of these measures for several weeks.¹⁵ Also, the findings of the studies on therapy-induced brain plasticity in chronic stroke patients may not be generalizable to patients early on after stroke.16

Early passive range of motion exercises improves motor function of the people with stroke within three months after the event. The objective of this study was to examine the effect of early passive range of motion exercises on the motor function of people with stroke.

Materials and methods

An unblinded randomized controlled trial design was used, with two groups and three measurement times (before intervention, one month and three months after intervention). We randomized patients who were admitted to the emergency and neurology units in an unblinded randomized controlled trial to examine the effects of early passive range of motion exercise on motor function of people with stroke. The study population was patients over 18 years with a diagnosis of ischemic stroke, who had been referred to Poursina teaching hospital in the city of Rasht, Iran, within 6 hours after the onset of symptoms. The patients were recruited based on the inclusion criteria. The inclusion criteria included no history of previous strokes, the diagnosis of stroke (except for transient ischemic attack and hemorrhagic stroke) by a physician, experiencing the first 6 hours of onset of stroke, level of consciousness 14 to 16 based on the FOUR (Full Outline of Unresponsiveness), moderate stroke (score 5-15) according to the NIHSS (National Institute of Health Stroke Scale), age over 18 years, the absence of aphasia according to NIHSS criteria, stable vital signs, no significant fracture and orthopedic defects of the extremities, the absence of acute coronary syndrome, respiratory failure or heart failure based on hospital records, absence of life-threatening conditions, and no contraindication of mobility. The exclusion criteria included death of the patient during the intervention period, the number of passive range of motion exercises less than 6 times, exercise intolerance,

patient discharge before completing 48 hours of intervention, and unstable clinical conditions.

The patients were randomly allocated to either experimental or control groups based on a randomization ratio of 1: 2 in favor of the experimental group by the main researcher. For allocation, a six-sided dice was used. The sides 1-4 were allocated to the experimental group, with the sides 5-6 allocated to control group. Each potential participant was allocated to the groups by rolling the dice. After random allocation, 45 and 25 patients were allocated to the experimental and control groups, respectively. This study was not blinded to the and researcher. participants А demographic characteristics form and muscle strength grading scale (Oxford scale) was used to collect the data. Muscle strength is graded 0 to 5. The lowest score is given to flicker of movement. The grades 2, 3, 4 and 5 concerned, respectively to through full range actively with gravity counterbalanced, through full range actively against gravity, through full range actively against some resistance and through full range actively against strong resistance.17

Muscle strength testing involves testing key muscles from the upper and lower extremities against the examiner's resistance and grading the patient's strength on a 0 to 5 scale accordingly: No muscle activation. 1) Trace muscle activation, such as a twitch, without achieving full range of motion. 2) Muscle activation with gravity eliminated, achieving full range of motion. 3) Muscle activation against gravity, full range of motion. 4) Muscle activation against some resistance, full range of motion. 5) Muscle activation against examiner's full resistance, full range of motion.

To ensure validity, the instruments were reviewed by 10 faculty members. In order to ensure the reliability of the muscle strength criteria, motor function of 10 patients was measured by the principal researcher and another individual and the correlation between the scores was measured (r=0.989). The study was conducted from July 2013 to January 2014 at Poursina teaching hospital affiliated to Guilan University of Medical Sciences in Rasht, Iran. Having obtained the required permission, the main researcher entered the emergency and neurology wards and explained the purpose of the study and details of the procedure to the head nurse and personnel. After written informed consents were obtained from the patients, the demographic data and basic information were extracted from the patients' hospital records. Before the intervention, and one month and three months after the intervention, the motor function of the patients in both groups was assessed and recorded, using muscle strength grading scale. To do so, the researcher moved the joints passively and examined the spasticity and muscle tone. In the experimental group, passive range of motion exercises in the involved extremities were done within the first 48 hours after stroke according to "passive range of motion exercises for the post-stroke" protocol four times a day by the main researcher who was an MSc nursing student, with each session lasting for 15-40 minutes. In case of activity intolerance and instability in vital signs, the intervention was stopped and postponed to a later time.

In this case, the patient practice turn was not eliminated and only delayed until the patient's condition returned to stable. Therefore, the exercise interval in some patients was changed. A maximum of eight and a minimum of six were planned and executed for all patients. The reason for not applying exercise during the night time was to prevent interruptions and avoid causing sleep disorders in patients. The intensity of exercise (the number of repeats for each passive motion and the duration of each exercise session) started from average and continued with low intensity and was gradually increased, depending on the patient tolerance.

Exercise was tailored to each person's health status and in some cases, each turn was different. In the control group, only the routine therapeutic program was implemented and motor function assessment was achieved in the time intervals similar to those of the experimental group. Motor function of patients in the experimental and control groups were measured at the end of the first month after the exercises, and then three months later by the same researcher. The steps of the study are shown in Figure 1.



Figure 1. Flowchart of the study

The project was approved by the ethics committee of TUMS Institutional Board (647/p). The study was enrolled in Iranian Registry of Clinical Trials (IRCT) under the ID IRCT2017020213785N4. The researchers also gained the approval of the hospital under study to access patients with stroke. All participants in the study were informed of the aim of the study in detail and were assured of its confidentiality. They gave a written informed consent documenting that their participation in the study is voluntary, and that they would have right to withdraw from the study whenever they wanted. The

researchers avoided coercion, undue influence, and unjustifiable pressures. The SPSS version 13 was used.

Analytical and descriptive statistics were used to analyses the data. Frequency distribution was used to describe the data. To compare motor function between the experimental and control groups, independent t-test was used. In addition, the repeated measures test was used to determine the effectiveness of the intervention over time. An alpha of 0.05 was used as the cut-off for significance.

Results

The study was conducted at Poursina teaching hospital affiliated to Guilan University of Medical Sciences in Rasht, Iran, from July 2013 to January 2014. After being informed of the study's aim, along with other relevant details, 70 patients agreed to participate in the study. Of all the patients in the study, 18 cases were excluded from the study due to the following reasons: withdrawal from further cooperation with the researcher (n=7), recurrence of stroke that affected limbs and made comparison impossible (n=2), withdrawal from the study to continue treatment in other health care settings (n=4), decreased level of consciousness and transfer to ICU (n=2), death following cardiac arrest (n=1), exclusion due to a change of residence and lack of participation in the third month (n=1), and hospitalization for severe weakness and infection (n=1). In the end, 33 patients in the experimental group and 19 patients in the control group terminated the study. Table 1 shows the characteristics of the patients in the two groups, and the result of the chisquare test for evaluating group comparability. The groups were homogeneous in terms of demographic variables.

Table 1. Frequency distribution of demographic

 characteristics of the experimental and control groups

Variable	Group		Р	
	Control (n=19) N (%)	Experimental (n=33) N (%)		
Gender			0.77*	
Male	9 (47.4)	17 (51.5)		
Female	10 (52.6)	16 (48.5)		
Age			0.38**	
30-60	5 (26.3)	13 (39.4)		
61-90	14 (73.7)	20 (60.6)		
History of hypertension			0.27*	
Yes	11 (57.9)	24 (72.7)		
No	8 (42.8)	9 (27.3)		
History of diabetes			0.62*	
Yes	7 (36.8)	10(30.3)		
No	12 (63.2)	23 (69.7)		
History of hyperlipidemia			0.19*	
Yes	5 (26.3)	4 (12.1)		
No	14 (73.7)	29 (87.9)		
History of ischemic heart disease			0.46*	
Yes	3 (15.8)	3(9.1)		
No	16 (84.2)	16 (90.9)		
History of acute coronary syndrome			0.44*	
Yes	0 (0.0)	1 (3.0)		
No	19 (100.0)	32 (97.0)		
Side of disability			0.38*	
Right	8(57.9)	15(45.5)		
Left	11(42.1)	18(54.5)		

*Chi-square test,**Fisher exact test

Table 2 depicts the motor function of upper and lower extremities in the experimental and control groups. One and three months after the intervention, the mean scores for motor function of the upper and lower extremities in the experimental group was higher than that of the control group, but the difference was not statistically significant. Therefore, we examined if the changes in motor function of the groups are different. A comparison of the groups in terms of changes in the motor function during the first month after the intervention showed that the upper extremity muscle strength in the experimental group improved more than that in the control group 1.09 (0.84) vs. 0.58 (0.90), P=0.045 (Table 3). Also, for lower extremity, the muscle strength in the experimental group improved more than that in the control group during the first month after the intervention 0.76 (0.71) vs. 0.00 (1.11), (P=0.004). As shown in table 3, changes in motor function of both upper and lower extremities were not statistically significant between the experimental and control groups three months after the intervention and within the time period of the first and third month after the intervention. Our findings seem to suggest that the intervention in the acute phase after stroke improved motor function in both upper and lower extremities, one month after intervention. It is important to note that, we found a statistically significant improvement, through within-group comparisons, in the upper extremity motor function of the control group, one month (P= 0.012) and three months after the intervention (P=0.004) relative to the basement measurement. This finding shows that part of the improvement in the motor function of the experimental group might well be attributed to time rather than the intervention (Figure 2 and 3).

 Table 2. Comparison of the mean upper and lower extremity motor function between the experimental and control group during time

Motor function	Group		Ρ*
	Control (n=19) Mean (SD)	Experimental (n=33) Mean (SD)	
Baseline of upper extremity motor strength	2.47 (1.31)	2.36 (1.58)	0.79
Baseline of lower extremity motor strength	2.53 (1.39)	2.64 (1.30)	0.77
Upper extremity motor strength in the first month	3.05 (1.72)	3.45 (1.54)	0.38
Upper extremity motor strength in the third month	3.11 (1.49)	3.39 (1.56)	0.51
Lower extremity motor strength in the first month	2.53 (1.84)	3.39 (1.50)	0.70
Lower extremity motor strength in the third month	2.84 (1.66)	3.21 (1.58)	0.42

 Table 3. Comparison of the mean change of upper and lower extremity motor function in experimental and control group

Motor function	Group		
	Control (n=19) Mean (SD)	Experimental (n=33) Mean(SD)	
Baseline and first month upper extremity motor strength	0.58 (0.91)	1.09 (0.84)	0.04
Baseline and third month upper extremity motor strength	0.63 (0.83)	1.03 (0.68)	0.06
First and third month upper extremity motor strength	0.63 (0.62)	1.03 (0.68)	0.06
Baseline and first month lower extremity motor strength	0.00 (1.11)	0.75 (0.71)	0.004
Baseline and third month lower extremity motor strength	0.32 (1.20)	0.58 (0.80)	0.32
First and third month upper extremity motor strength	0.32 (0.67)	-1.18 (0.64)	0.01









Discussion

In the experimental group, improvement in muscle strength score in the first and third months were observed in both upper and lower extremities in comparison with the baseline measurement. The greatest improvement in the experimental group occurred in the first month relative to the baseline measurement in the upper extremity. Although in the first and third months after the intervention, the mean score of motor function in the experimental group was higher than that of the control group, the difference was not statistically significant. It seems that the improved muscle function is affected by the continuation of the rehabilitation programs along with the mechanisms of spontaneous recovery. Based on the findings, in the control group, the improved muscle strength in the first and the third month after baseline measurement was observed only in the upper extremities. Not surprisingly, the slight improvement in muscle strength score was mostly affected by the spontaneous mechanism and most patients suffered from significant muscle weaknesses until the third month. In the experimental group, the highest change was related to the muscle strength of the upper extremity one month after the intervention, and that of the lower extremity, three months after the intervention. The highest change observed in the control group was related to the muscle strength of upper and lower extremities three months after the intervention.

Most of the patients in the control group experienced improvements in a longer period (three months) compared to the experimental group. On the basis of the results, it seems that passive exercise in the acute phase after stroke according to the protocol implemented in this study was not considered as a powerful and decisive factor in improving motor function in the experimental group. In a study by Tsai and Yeh, who investigated the effect of long stretch on the status of muscle spasticity at a medical session, a modified version of Ashworth scale was employed to measure the dependent variable. This study focused on the ankle range of motion in dorsal flexion status before, immediately after, and 45 minutes following the intervention, and the intervention was reported to have been effective in improving the range of motion of the ankle.18 In the study by Lum and et al., based on the Fugl Meyer test, the greatest improvement was observed in the proximal movements of upper extremities of the subjects treated by motor exercise applied by the robot in the first month. In the second month, the group under intervention had a better muscle strength compared with the control group. After six months, the groups did not differ in terms of Fugl Meyer examination, but the experimental group showed more improvements in terms of Functional Independence Measure score.¹⁹ Another study showed that there was no difference between the control group and the group treated by constraint-induced movement in terms of Action Research Arm Test (ARAT) score in the acute phase in patients with stroke, and that the arm function improved within 90 days in both groups. According to this study, Constraint-Induced Movement showed more

limited benefits based on ARAT assessment of base to 90 days after treatment as compared to the treatment group with the standard dose in patients with stroke.²⁰

Hankey investigated the motor function in patients with stroke through repetitive task specific training, and reported no improvements in hand and arm function and maintaining balance while sitting.^{21,22} In a study conducted by Hejazi, with the aim of examining the effect of sensory retraining (fine touch in the finger tips) on the hemiplegic upper extremities in 5 patients with chronic stroke, Fugl Meyer test score changed from 3.31 to 5.67 in the sixth week. Also, upper extremity motor defects and manual skills of patients improved (based on motoricity Index test and box and block test, respectively).²³

Beebe and Lang studied the effect of active range of motion exercise on predicting the movement function after three months on patients with stroke and found that active range of motion in the first month is highly related with the upper extremity function in the third month. The results confirmed the significant positive effect of time on active range of motion of upper extremity in the first and third month.6 In a study conducted by Bovolenta, the effect of robot-aided therapy in patients with stroke between T₀ (immediately before treatment) and T₁ (immediately after treatment), improved the upper extremity function. During the first month after stroke, the highest improvement occurs in motor function; and thereafter, through gradually reducing stimulation, continued improvement in motor function of patients is probably due to spontaneous mechanisms of recovery over time. In the present study, after passing through the acute phase, the patients received less or irregular rehabilitation programs. Regular rehabilitation programs along with spontaneous mechanisms of recovery during the first three months after the stroke are significantly effective in improving motor function of patients.24

Conclusion

The use of passive exercises not only prevents the local complications, but also improves motor function after stroke. In the present study, both groups experienced improvements in the upper and lower muscle strength during the first month. At first glance, it seems that the intervention in the experimental group in the acute phase after stroke was ineffective in improving motor function of this group and both groups had the same behavior in terms of improved muscle strength. However, the changes in motor function score confirmed the effectiveness of the intervention in the intervals from baseline measurement to the first month in both upper and lower extremities, and from the first to the third month in the lower extremities. In other words, despite the improved motor function in both groups, changes in motor function were more significant in the experimental group due to the effect of intervention.

This study had limitations. After discharge, the patients may have participated in physiotherapy sessions, which might have influenced the results of the study. The researchers recorded these events in both

groups and no statistically significant difference was found between the groups in terms of participating in physiotherapy sessions after discharge.

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Ethical issues

None to be declared.

Conflict of interest

The authors declare no conflict of interest in this study.

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