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Effects of Virtual Reality on the Upper Extremity Spasticity and Motor Function in Patients with Stroke: A Single Blinded Randomized Controlled Trial

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***Abstract*—**Background: Stroke is a disabling neurological disease. Rehabilitative therapies are important treatment methods. This clinical trial was done to compare the effects of virtual reality (VR) beside conventional rehabilitation versus conventional rehabilitation alone on the spasticity and motor function in stroke patients. Materials and methods: In this open-label randomized controlled clinical trial, 40 consecutive patients with stable first-ever ischemic stroke in the past three to 12 months that were referred to a rehabilitation clinic in Tehran, Iran in 2020 were enrolled. After signing the informed written consent form, subjects were randomly assigned by block randomization of five in each block as cases with 1:1 into two groups of 20 cases; conventional plus VR therapy group: 45-minute conventional therapy session plus 15-minute VR therapy, and conventional group: 60-minute conventional therapy session. VR rehabilitation is designed and developed with different stages. Outcomes were Modified Ashworth scale, Recovery Stage score for motor function, range of motion (ROM) of shoulder abduction/wrist extension, and patients' satisfaction rate. Data were compared after study termination. Results: The satisfaction rate among the patients was significantly better in combination group ($P = 0.003$). Only wrist extension was varied between groups and was better in combination group. The variables generally had statistically significant difference ($P < 0.05$). Conclusion: VR plus conventional rehabilitation therapy is superior versus conventional rehabilitation alone on the wrist and elbow spasticity and motor function in patients with stroke.

***Keywords*—**Stroke, virtual therapy, efficacy, rehabilitation.

I. Introduction

STROKE is a disabling neurological disease with current progressive trend of incidence especially due to urbanization [1]-[4]. Stroke affects ~800.000 people in the United States annually [5]. In Iran, a systematic review reported a prevalence of stroke from 23 to 103 per 100,000 population [6]. Globally, a study reported ~25.7 million people with stroke [7]. It is estimated nearly 62 million people with stroke across the world, of which one-third have severe disability [8]. Stroke remains a major health issue considering the longevity and increase in the elderly population [5]. After stroke onset, nearly 60–80% of patients present with motor impairments [9] and approximately two-thirds of the patients after stroke suffer from impairments in the arm motor function and disability for a long-term [9], [10]. It follows that the neurorehabilitation strategies of repetitive, intensive, and task-orientation are needed to boost neuroplasticity and recovery.

There are various rehabilitation strategies to enhance the post stroke recovery, one of which is VR. VR is important type of technology for rehabilitation that allows users to safely interact with a multi-sensory simulated natural environment and receive real-time feedback on their performance [11], [12]. A recent systematic review and meta-analysis of 87 studies with 3540 subjects identified that VR is effective in improving motor function of patients after stroke [13]. However, a Cochrane systematic review on VR in stroke rehabilitation included 72 studies with 2470 patients after stroke concluded the quality of the evidence was generally low to utilize it without being in combination with other interventions [14]. A study recently used Xbox Kinect in combination with physiotherapy exercises to train the upper limb function in patients with chronic function and concluded that it is effective to enhance upper limb motor function after stroke [15]. There are a few studies using VR in combination with conventional rehabilitation programs in treating upper limb function in patients with stroke. Hence, this study aimed to investigate the effects of VR plus conventional rehabilitation therapy versus conventional rehabilitation alone on the upper limb spasticity and motor function in patients with stroke.

II. Methods and Materials

In this pilot study that was performed as an open-label randomized controlled clinical trial, 40 consecutive patients with age range from 20 to 80 years with stable first-ever ischemic stroke in past three to 12 months that were referred to a rehabilitation clinic in Tehran, Iran in 2020 were enrolled. The exclusion criteria were affected shoulder pain, severe spasticity, cognitive and visual problems and inability to follow the instructions. The ethical approval was received from ethical committee in Tehran University of Medical Sciences. This clinical trial has been approved in Iranian Registry of Clinical Trials (subsidiary of ICTRP) at 2020-10-16. Registration reference is IRCT 20200811048372N1.

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each block as cases with 1:1 into two groups of 20 cases. A 6-week continuous program was designed for all of the study participants. Both of the conventional and combination groups received 1-hour sessions of three times per week conventional; for the VR therapy group: 45-minute conventional therapy session plus 15-minute VR therapy, and the conventional group: 60-minute conventional therapy session. In this trial, we used VR rehabilitation games which were designed and developed by our technical team. The therapeutically designed system experimented in this study was adopted to provide intervention and evaluation, concurrently. This product consists of different stages based on upper extremity rehabilitation for post-stroke patients to improve the affected upper limb function.

The concept of this multi-level game is to reach out and take hold of different colored balls that appear on the monitor and toss them into baskets matching the color of the ball. The difficulty of the game increases with each level reached with a reward for each successful level. The outcomes were assessed before at baseline and after a six-week period of 18 treatment sessions. Age, sex, time from onset of the stroke, and involved hemisphere were matched across the groups. All the interventions and data collections were performed by one trained examiner to increase the accuracy.

Data gathered include age, sex, time since stroke, affected side, reliable and valid Modified Ashworth scale for assessing wrist flexor spasticity, elbow flexor spasticity [16]-[20], and upper extremity ROM of shoulder abduction and wrist extension by goniometer (both by manual and by computer program), and patients' satisfaction rate. A blinded assessor assessed all outcomes. Patients' satisfaction was rated on a five-point Likert scale ranging from "completely satisfied" ("4") to "completely dissatisfied" ("0") and high, medium, and low categories were those higher than mean plus standard deviation, mean ± standard deviation, and mean minus standard deviation, respectively.

Data analyses were performed using SPSS software version 26.0 (Statistical Procedures for Social Sciences; Chicago, Illinois, USA). Effect size was measured as large (d = 0.8) by Cohen's d test. Chi-Square (for comparison of categorical data between groups), Fisher (for comparison of categorical data between groups with 2*2 crosstabs), Independent-Sample-T (for comparison of numerical parametric data between groups), Mann-Whitney (for comparison of numerical non-parametric data between groups), and Kolmogorov-Smirnov tests were used. Changes were considered statistically significant at P values less than 0.05.

III. Results

The mean age was 54.35 ± 13.82 and 49.55 ± 13.87 years in the combination and control groups, respectively (P = 0.280). The cases were male in 12 and 11 cases in the combination and control groups, respectively (P = 0.749). Affected side was left in 11 and 10 cases in the combination and control groups, respectively (P = 0.752). As shown in Table I by Chi-Square test, the satisfaction rate among the patients was significantly better in the combination group (P = 0.003).

TABLE I
SATISFACTION RATE ACROSS THE GROUPS

Group	High	Medium	Low
Combination	15 (75%)	5 (25%)	---
Control	5 (25%)	10 (50%)	5 (25%)

According to Table II, the baseline characteristics were similar across the groups before the intervention (P > 0.05). About the final assessment, there were significant differences between groups for all except one variable (wrist extension) in favor of the combination group. In both groups, all variables except elbow spasticity had significant difference in paired sample analysis (P < 0.05). All variables were considered as continuous and also no ordinal test was measured during analysis, as seen in Table II.

TABLE II
MEASUREMENTS ACROSS THE STUDY IN TWO GROUPS

Variable	Time	Combination	Control	P Value
Brunnstorm	Before	3.6 ± 0.8	3.6 ± 0.7	1.000
	After	4.3 ± 0.7	3.6 ± 0.7	0.003
Elbow Spasticity	Before	0.7 ± 0.5	0.9 ± 0.6	0.153
	After	0.3 ± 0.5	0.9 ± 0.6	0.001
Wrist Spasticity	Before	0.7 ± 0.6	0.9 ± 0.6	0.171
	After	0.4 ± 0.6	0.9 ± 0.6	0.003
Shoulder Abduction	Before	84.0 ± 41.3	91.3 ± 37.8	0.566
	After	136.3 ± 41.2	105.0 ± 41.1	0.021
Wrist Extension	Before	21.3 ± 14.0	21.0 ± 14.3	0.956
	After	32.3 ± 15.1	23.0 ± 16.0	0.068
Elbow Extension	Before	94.3 ± 48.9	88.8 ± 51.5	0.731
	After	144.0 ± 41.7	99.0 ± 55.7	0.006

IV. Discussion

In this study, conventional therapy plus VR versus conventional therapy alone had better outcomes as shown by the meta-analysis of [21] in Iran. Few studies have [21], [15] investigated the efficacy of using VR in stroke patients in Iran and the novelty of our study is that it was a preliminary investigation on the Iranian population. Participation in VR treatment increased their satisfaction. In the majority of studies, Nintendo Wii video game has been represented and it was decided to develop and customize a VR program for the purpose of this study.

The study by Fishbein et al. [22] also demonstrated that VR-based treatment improves walking and balance in post-stroke phase and also suggested to combine training sessions that require the performance of simultaneous multiple tasks. But we had higher sample population. Wiley et al. [23] assessed 124 participants and concluded no significant effects of VR therapy for improving global cognition, memory, attention or language and it was concluded that VR therapy was not better than control interventions in improving cognition in cases with stroke [23]. However, current study showed good outcomes in cognition in combination therapy groups.

A study by Cortes-Perez et al. [24] among three patients with chronic ischemic stroke showed higher effect of VR versus conventional approach for improvement of balance and

reduction in falls risk in active upright work. But some pitfalls such as small sample population and various duration and sessions were seen in their study that was not observed in our study. On the other hand, results of clinical trial by Turolla et al. [25] among 376 stroke patients with treatment consisting two hours of daily therapy for 20 days, showed that VR rehabilitation was more effective than conventional intervention in restoring upper limb motor impairments and the motor related functional status. Similar outcomes were seen in our study.

The study by Yin et al. [26] was done only among 23 stroke cases in VR versus control groups. The VR group received nine 30-minute upper extremity VR therapy sessions and the control group received only conventional therapy, which was comparable to the total training time in the VR group and although additional VR training was not better than conventional therapy alone, VR was feasible in early stroke cases. Regarding higher satisfaction rate in our study by combination therapy, it is recommended. The larger sample size in our study also led to more reliability of the outcomes. A randomized controlled trial was conducted by Schuster-Amft et al. [27] among 54 patients at least six months after stroke onset in VR and control groups, in which both received 16 sessions of 45 minutes. The results show that less impaired patients displayed higher improvements in favor of the experimental group [27]. For reduction of the confounding effects, such factors were matched across the groups in our study. In the controlled trial by Park et al. [28], only 26 stroke survivors were enrolled and the findings for combination VR therapy were in congruence with our findings.

Use of non-medical treatments can help to decrease the therapeutic adverse effects in stroke patients. These patients usually are critically ill and require further cares with special concern about therapeutic safety. Also, comparison of these treatments with conventional modalities can increase data about both efficacy and safety in stroke patients. Patients' satisfaction is another important measure outcome than can represent both efficacy and safety of treatments in the patients. It can demonstrate both early and late outcomes in these patients. However subjective status of this measure outcome may decrease the applicability of satisfaction rate in stroke patients.

V. Conclusion

VR in addition to conventional rehabilitation therapy is better versus conventional rehabilitation alone on the motor function and also wrist and elbow spasticity in patients with stroke. Therefore, our recommendation is the use of a combination of VR technology along with the traditional techniques in order to gain more efficient results in upper extremity functional activity among stroke patients. However further interventional studies with larger sample size are required to attain more definite evidence in this area.

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