Lower limb rehabilitation robot combined with acupuncture on improving the walking dysfunction in patients with sub-acute stroke is more effect

Hui Ouyang [1], Longbin Shen [1], Xuechang He [1], Yuan Qiu [2], Zhuoming Chen [1, *]

[1]The First Affiliated Hospital of Jinan University, Guangzhou, China

[2]Guangzhou Medical University, Guangzhou, China

Abstract

Objectives To investigate the effect of lower limb rehabilitation robot combined with acupuncture on improving the walking dysfunction in patients with sub-acute stroke. Patients and Methods Fifty stroke patients with walking dysfunction within 6 months were randomly divided into experimental group (n = 24) and control group (n = 26). Both groups received conventional rehabilitation therapy, including neurodevelopmental therapy, joints movement training, lower extremity strength training, balance training, etc. The experiment would last for 8 weeks. The experimental group had lower limb rehabilitation robot-assisted walking training as the first part of rehabilitation treatment (4 weeks) on the conventional rehabilitation therapy; the second part of treatment (4 weeks) included the acupuncture on the motor cortical area and the lower limb rehabilitation robot-assisted walking training. The control group on conventional rehabilitation treatment would receive therapist-assisted walking training as the first part of rehabilitation treatment (4 weeks). The acupuncture on the motor cortical area of the head would be added to the therapist-assisted walking training at the same time in the second course of treatment (4 weeks). Fugl-Meyer Assessment of Lower Extremity (FMA-LE), Berg Balance Scale (BBS), Holden Walking Function Classification, Modified Barthel Index (PADL) and the feedback system of lower limb rehabilitation robot were used to assess the lower limb motor function and walking ability of the two groups of patients. Assessments were conducted before the treatment, four weeks after the treatment and 8 weeks after treatment. Results Statistically significant difference between the two groups ($P < 0.05$) can be found in the within group comparison of FMA-LE score, BBS, Holden grading, PADL score and the feedback value of the lower limb robot. After the first course of treatment, all the outcome measure of the experimental group was significantly different from the control group ($P < 0.05$). The between group comparison showed significant difference after the second part of treatment ($P < 0.05$).There was no significant difference in the control groups ($P > 0.05$). The experimental showed significant improvement when the subjects finished the second part of treatment ($P < 0.05$). Conclusions Lower limb rehabilitation robot showed better improvement on patients with sub-acute stroke than walking training assisted by therapist in the recovery of walking ability. The lower limb rehabilitation robot training combined with acupuncture is better than that of lower limb robot training in improving the lower limb walking ability of patients with sub-acute stroke.

Keywords

Stroke; lower limb rehabilitation robot; acupuncture; walking dysfunction; rehabilitation.

1. Introduction

Stroke is currently the first caused of mortality and disability in China, about 2/3 of patients suffer from dysfunction, the motor dysfunction of the hemiplegic limb is most common after stoke. According to the relevant statistics, about 80% of stroke survivors left walking dysfunction, and mainly manifest as the slower walking speed and abnormal temporal - spatial parameters [1, 2]. How to improve the walking function of hemiplegic patients after stroke, in order to improve the quality of life of patients, reducing disability rate has become an important issue of clinical rehabilitation.

Most of the traditional rehabilitation training would be applied the therapist-assisted walking training. The deficiency is that it cannot be implemented on the patients in early flaccid paralysis period. The training effects depend on the experience of the therapists, which differ greatly among the therapists. The training on the range of motion of the hip, knee and ankle cannot be unified and precise. Most hemiplegic patients are not positive and compliant because of the poor situation of muscle strength, psychology factors and so on. The lower limb rehabilitation robot training system provides safe, effective and repeatable quantitative exercise input [3], allowing patients to carry out walking training in the early stage, which is of positive significance to the reorganization of cerebral nerve function.

Either traditional or modern rehabilitation training methods showed a sensitive declining problem in the training method, with the extension of training time and progress of disease, the speed of training effect and function recovery will slow down. Before and after the plateau period, more methods or greater stimulation are needed to improve the recovery rate of the patients. Acupuncture is a traditional Chinese medicine treatment, one study suggested that acupuncture head acupuncture can promote cerebrovascular regeneration, promote the establishment of collateral circulation and activate the excitement of the brain motor area. Thereby, it can promote the recovery of motor function of the affected limbs. There are many studies of acupuncture and modern rehabilitation training method combined with the treatment of hemiplegia motor dysfunction [4-6], but acupuncture and lower limb rehabilitation robot training synchronization is not reported. This study was designed to compare the efficacy of the lower limb rehabilitation robot training and the therapist-assisted training on the early-stroke hemiplegic patients in improving the walking function. This study will observe the lower limb rehabilitation robot training or the therapist-assisted training combined with the acupuncture of the head movement area to know whether synchronous treatment of the two has synergistic effect, so as to develop a new clinical treatment and ideas.

2. Patients and Methods

2.1 Ethics statement

This study was approved by the human Research Ethics Committee of Jinan University, Guangzhou, China, as well as those of co-operating institutions and was performed in accordance with the principles of the Declaration of Helsinki. Written informed consent was obtained from all participants.

2.2 General information

50 subjects in our hospital neurology and rehabilitation from August 2005 to August, 2016. Inclusion criteria: (1) meet the fourth session of the National Cerebrovascular Disease Conference to determine the criteria for the diagnosis of stroke; (2) transcranial CT or MRI and other imaging diagnosis; (3) the first occurrence of cerebral infarction or cerebral hemorrhage, with hemiplegic limb, stable state of the illness and good cognition; (4) onset time < 6 months, Glasgow (GCS) score > 8 points; (5) age 35 to 75, weight < 100kg. Exclusion criteria: (1) associated with severe heart, liver, lung and other diseases of the internal medicine system, a history of dementia or sensory aphasia or serious cognitive dysfunction; (2) unstable fractures; (3) severe skeletal muscle disease (such as amputation) or severe contracture of lower limbs that affects joint activity; (4) refractory epilepsy. Finally, 50 patients were randomly divided into experimental group (n = 24) and control group (n = 26) according to random number table method. There are 18 males and 6 females in experimental group, whose ages are 46 to 75, average value (62.7 ± 9.3) years, the courses of disease are 1 to 6 months, average

value (3.74 ± 1.87) months. There are 20 males and 6 females in control group, whose ages are 43 to 75, average value (60.8 ± 11.3) years, duration are 1 to 6 months, average value (3.23 ± 2.1) months. There was no significant difference between the two groups in the general data ($P > 0.05$, Table 1).

Table 1. Two groups of patients with general data comparison (mean ± standard deviation)

Group	Number of cases	Gender (case)		Age	Course of the disease (month)	Type (case)		Hemiplegia side (case)	
		male	female			cerebral hemorrhage	cerebral infarction	left side	right side
Experimental	24	18	6	62.7±9.3	3.23±2.10	4	20	12	12
Control	26	20	6	60.8 ±11.3	3.74±1.87	5	21	15	11

2.3 Treatment

On the basis of basic drugs treatment, the two groups of patients were treated with conventional basic rehabilitation, including neurodevelopmental therapy, joint movement training, lower limb muscle training, balance training. There were 2 assessment sessions, each group has two session2 of treatment, each session lasts for 4 weeks.

Experimental group: the first session of treatment (4 weeks), based on the conventional basic rehabilitation, the lower limb rehabilitation robot (Shanghai Jing and technical equipment Co., Ltd. Flexbot-B) training was carried out. Robot operation method: (1) Preparation: Before the training, the patient should be placed on the supporting plane of the robot, and the patient's body will be fixed with the robot suspension device. After determining the safety, the distance between the hip and knee joint and the tightness of the ankle joint will be adjusted according to the patient's body type and the length of the lower limb. Adjust the angle of the lifting bed and the tension of the suspension device. (2) Set the robot training mode and exercise prescription: the angle of lifting bed is 70°, the training pace is 1.25-1.80km / h, walking duration 20 min / time, once / day, 5 times / week. The second course of treatment (4 weeks), basic rehabilitation was the same as the first course of treatment, the acupuncture treatment on the exercise area of head and the lower limb rehabilitation robot walking training were carried out at the same time. Head movement area: equivalent to the anterior central gyrus of the cerebral cortex.

The upper point is 0.5 centimeters behind the midpoint of the midline; the lower point is at the intersection of the eyebrow pillow line and the front temples; the connection between the upper and lower points is the movement area. The exercise area is divided into five equal parts, the upper 1/5 is the lower limbs and trunk movement area, the middle 2/5 is the upper limb motor area, the lower 2/5 is the head and face movement area.

Acupoints: take the needle side of the contralateral, acupuncture scalp movement area on one-fifth of the ends, the thorns of a needle, the needle angle of about 15 degrees, the direction of the scalp to the other end of the movement, the needle length and scalp movement One fifth of the area is equal in length. After the needle, every 5 minutes line method once, every treatment time, to be 4 times a day, once a day, every 20 minutes, 5 days a week treatment, 4 weeks for a course of treatment, a total of 4 weeks of treatment.

Control group: the patient would receive the therapist assisted walking training on the basis of the basic treatment for 20min to improve the walking ability, the training is required to be completed by the physiotherapists who are experienced and familiar with walking training. For patients with severe dysfunction and poor muscle strength1, they carried on training torso stability, lower limb motor function control and balance coordination, when the patient's motor function met the requirements of walking training, took the therapist assisted walking training, Treatment were 20min each time, 5 times a week, 4 weeks for a course of treatment. The first course of treatment, simple artificial assisted walking training. The second course of treatment, artificial assisted foot training combined with the head movement area acupuncture treatment. Acupuncture point method was the same as experimental group. It was treated for 8 weeks.

2.4 Evaluation of efficacy

The motor function and walking ability of the lower limbs of the two groups were evaluated before treatment, after 4 weeks of treatment and after 8 weeks of treatment. The assessment indicators include: Fugl-Meyer Lower Limb Rating Scale (FMA-LE), Berg Balance Scale (BBS), Holden Walking Function Classification, Modified Pasteurian Index (PADL), Lower Limb Robot Data Feedback System.

FMA-LE: the scale is mainly used to evaluate the hemiplegia patients with ipsilateral lower extremity motor function and exercise quality, a total of 34 points, the higher the score, the better the function, the quality of movement closer to normal.

BBS: the scale is used to assess the balance function, BBS includes 14 evaluation items. Each score range of 0-4 points, the higher the score the better the balance function.

Holden classification: this is used to assess the walking function, divided into five levels, from the 0 level of no function to the V-level completely independent, the higher the level that the better walking function.

PADL: this is used to assess the daily living activities, including toilet control, dressing, decoration, toilet, bathing, eating, transferring, operating wheelchair, walking, up and down the stairs. It is 100 points totally, the higher the score, the better the daily ability.

Lower extremity robot data feedback system: the trajectory is the change of the force of the bilateral hip joint in the range of joint mobility and change in force per unit time. The horizontal axis represents the time and the vertical axis represents the force. The degree of recovery of the patient's muscle strength was measured on the basis of the magnitude of the change in each line.

2.5 Statistical analysis

SPSS statistics software package, version 13.0 (SPSS Inc., Chicago, Illinois, USA) was used for statistical analysis. The measurement data are expressed as mean ± standard deviation, which would be analysed by independent sample T-test or rank sum test. $P < 0.05$ indicated the significant difference.

3. Results

3.1 Assessing the scale of two groups

This is a comparison of FMA-LE scores, BBS, Holden grading, and PADL scores in both groups.

Inter-group comparison: before training, there was no statistical significance between the two groups ($P > 0.05$). After 4 weeks of training, the scores of FMA-LE, BBS and PADL in the experimental group were higher than those in the control group ($P < 0.05$). After 8 weeks of treatment, the difference of the indicators between the two groups was statistically significant ($P < 0.05$).

Intra-group comparison: in the experimental group, after training for 4 weeks, the indexes were compared with before training, the difference was statistically significant ($P < 0.05$); after 8 weeks of training, the indexes were compared with the training before training ($P < 0.01$). In the control group, after 4 weeks training, there was no significant difference between the indexes and the training before training ($P > 0.05$); after 8 weeks training, the indexes were compared with before training, the difference was statistically significant ($P < 0.05$).

The control group of patients with two courses of assessment scores improved the differentiation was not statistically significant ($P > 0.05$). The improvement rate of the second course of treatment in the experimental group was higher than that in the first course ($P < 0.05$). See Table 2 for further details.

Table 2. The comparison of two groups before and after treatment of various functional assessment (mean ± standard deviation)

Group	Number of cases	FMA-LE (points)	BBS (points)	Holden (level)	Improved ADL (points)
Control					
Before training	26	12.0±6.1	16.4±7.8	1.3±1.2	43.8±9.7
Training 4w	26	15.2±5.9e	23.5±8.3e	1.9±1.0e	51.4±9.5e
Training 8w	26	18.0±5.7fh	29.8±9.5fh	2.6±0.9fh	59.6±11.5fh
Experimental					
Before training	24	12.4±6.5	16.6±9.1	1.3±1.1	46.5±12.6
Training 4w	24	18.0±5.5ac	26.9±7.6ac	2.1±1.1c	57.3±11.0ac
Training 8w	24	25.0±5.3bdeg	39.0±8.1bdeg	3.2±1.0bdeg	73.5±10.6bdeg

Compared with the control group, after 4 weeks of training, P(a) $<$ 0.05; after 8 weeks of training, P(b) $<$ 0.05. The experimental group compared with the pre-training, after 4 weeks of training, P(c) $<$ 0.05; after 8 weeks training, P(d) $<$ 0.01. Compared with 4 weeks after the training, after training for 8 weeks, P(g) $<$ 0.05. The control group compared with the training before, after training for 4 weeks, P(e) $>$ 0.05, after training for 8 weeks, P(f) $>$ 0.05. Compared with 4 weeks after the training, after training for 8 weeks, P(h) $>$ 0.05.

3.2 Robot assessment of two groups

Comparison of data feedback values (maximal feedback torque of the hip and knee) of the lower limb robot before and after treatment in the two groups: there was no significant difference in the maximal feedback torque between the hip and the knee in the two groups before training ($P > 0.05$). After 4 weeks of treatment, the difference between two groups was statistically significant ($P < 0.05$). After 8 weeks of treatment, the difference between groups was statistically significant ($P < 0.01$). In comparison of two groups, the experimental group of hip and knee maximum feedback torque, the difference between the first course of treatment and before treatment has statistical significance ($P < 0.05$), the difference of the second course of treatment compared with before was statistically significant ($P < 0.01$), there was a significant difference between the second course and the first course ($P < 0.05$). There was no significant difference in the control group ($P > 0.05$). See Table 3 for further details.

Table 3. Evaluation information feedback of two groups of hip knee joint robot

	Hip joint (maximum, N)		Knee joint (maximum, N)	
	Experimental	Control	Experimental	Control
Before training	24.6±4.4	23.8±5.7	7.2±2.2	6.4±2.4
Training 4w	29.1±3.5ac	26.9±6.3ed	9.6±2.1ac	8.0±2.6ed
Ttraining 8w	35.1±3.6bce	29.4±7.5edf	13.2±2.7bce	9.0±2.5def

Compared the experimental group with the control group, after 4 weeks training , P(a) $<$ 0.05, after 8 weeks training, P(b) $<$ 0.01. In the experimental group, after 4 weeks training or after 8 weeks training vs. before training, P(c) $<$ 0.05; in the control group, after 4 weeks training or after 8 weeks training vs. before training, P(d) $>$ 0.05. In the experimental group, after 4 weeks of training vs. after 8 weeks training, P(e)$<$0.05; in the control group, after 4 weeks of training vs. after 8 weeks training, P(f) $>$ 0.05.

4. Discussion

The recovery rate of stroke was time-dependent, one to three months after the onset is the golden time of rehabilitation and functional recovery. Six months after the onset is still the best period of rehabilitation. Therefore, searching the best rehabilitation regimen to improve the motor function and the ability of daily living faster and better is the popular issue of the current research.

The lower limb motor dysfunction is the most prominent for stroke, often manifest as asymmetry gait, slow pace, poor center of gravity shifting and abnormal parameters in gait time-space [7], which is often caused by the lack of muscle strength for hemiplegic limb and insufficient range of motion for ankle, knee and hip, poor balance and coordination. Traditional walking function training is often assisted by the therapist, which can promote the excitability of nerve and muscle in hemiplegic limb. To a certain extent, it can promote the recovery of walking function of patients, improve abnormal gait posture, while a patient often need 1 to 2 therapist because of the long training cycle. It takes time, energy and high human cost, and the training effect is related to the therapist's technical level and experience, which are not quantitative and standardized, thus fail to meet the medical requirements. And for patients in ultra-early stage, dysfunction is relatively serious and muscle strength is relatively insufficient, which make the patient's walking training time is lagging behind. The lower limb motor function recovery of stroke patients should be aimed at increase muscle strength， increase the sensory input of the body，establishing a voluntary, coordinate and normal movement mode

The artificial assistant walking training has many deficiencies in the ultra-early hemiplegia patients' training, so more and more clinical research on the walking training of the lower limb rehabilitation robot for improve the balance and lower limb motor function [8, 9]. It can provide physiological gait rehabilitation training mode through the coordination of the hip, knee and ankle and balance control. Patients can imitate and rebuild the normal physiological gait, and avoid abnormal hemiplegic gait.

The lower limb rehabilitation robot has many characteristics that showed advantage when compared with human, such as long-term, stable quantitative input, providing real-time feedback, ensuring consistency and continuity in the training process and implementing the parameterization of training programs and rehabilitation assessment. In this study, the evaluation results of first course treatment were better than the control group, except the Holden grade. The lower limb robot data feedback (hip & knee joint torque feedback) was better than the control group. It showed lower limb rehabilitation robot for early hemiplegia in patients with lower limb movement dysfunction training is more effective than the therapist assisted by the walking.

For the reasons: firstly, lower limb rehabilitation robot can provide normal gait training mode. Early programmed and formal training can promote the cerebral cortex motor area "movement stereotypes", and the movement of muscle and joint provide the stimulation of proprioception to the central nervous system in turn; secondly, lower limb rehabilitation robot can provide passive, active, active and passive, assisted, these four modes of movement, thus, it can provide passive training for stroke patients with insufficient muscle strength in the early stage, while active training can enhance muscle strength and stimulate the compensation and reconstruction of the damaged central nervous system structure and function as early as possible; thirdly, it might be related to the weight support device of the lower limb rehabilitation robot help to reduce part of the body weight of the patient, so that the hemiplegic lower limb in the support phase of walking cycle period can bear part of the weight and maximize the remaining function of the limb to prevent the compensation of limbs and avoid excessive load that induces spasm and abnormal movement patterns [10]; fourthly, the dynamic balance training and closed-chain movement of the lower limb rehabilitation robot are beneficial to the symmetrical distribution and stability of the patient's center of gravity, and the walking independence and the balance function of the patients are improved obviously [11]; fifthly, the patients produce movement adaptation with learning by repeating the specific action to restore the motor system, as the result of repetitive movement adaptation and constant feedback can lead to the formation of new sports standards, it can change the patient's movement mode on the basis of a longer time to achieve the purpose of gait rehabilitation [12]; sixthly, the virtual reality technology of lower limb rehabilitation robot provides visual feedback that has incomparable advantages over the manual assisted training. In this study, the Holden Classification of the first course of treatment in the experimental group and the control group were not statistically significant. The reason might be related to that Holden has only 5levelsand the experimental time was not long enough.

With the training time and the duration of the disease, the excitability of the nerve function to the same stimulus will decline, and the functional recovery will enter a plateau stage. However, how to promote the excitability of the cerebral cortex and functional reparation in the late golden recovery period will be attention. Studies show that acupuncture at the movement area of the head can promote the revascularization after ischemic brain injury, stimulate the opening of the collateral circulation, increase cerebral blood flow, repair damaged brain tissue, reduce the neuronal apoptosis caused by ischemic brain injury [13].

By changing the input of peripheral stimulation, the functional areas of cerebral cortex can be reconstructed and the intrinsic neural pathways can be activated, which induces the emergence of the stroke hemiplegic limb tension in early stage and shorten the period of flaccid paralysis. Thus, it could be useful for the inhibition and control of the spastic pattern and the convention of synergic movement to associated movement. Related research through blood oxygen level dependent (BOLD) fMRI observed that scalp acupuncture combined with rehabilitation training can activate the volume of the primary sensorimotor cortex in the contralateral hemisphere, which is beneficial to the functional recovery of the hemiplegic ankle.

In this study, after 4 weeks of walking training, the second course of treatment is the exercise combined with head exercise area acupuncture treatment. The two treatment methods was combined organically and dynamically to observe the effect of the acupuncture needle retaining in the corresponding movement area of the head for improving the movement of the lower limbs. The results showed that the improvement of the second course of treatment in the experimental group was higher than the first course of treatment. This indicate that the lower limb rehabilitation robot can change the abnormal motion pattern through the specific, repeated and correct motor mode, and the correct motion of the limbs can generate positive stimulus feedback to the brain nerve. At the same time, the addition of acupuncture therapy can enhance the positive feedback effect of the robot while promoting blood circulation of the head and increasing cerebral oxygen metabolism. The two treatment methods have complementary superimposition effect from top to bottom and bottom up. It is conducive to the functional recovery of the whole brain loop.

Moreover, the improvement of the control group assessment in the second course make no difference. The principal reason including: firstly, the time of artificial walking training is lagging behind, leading to the lack of early stimulation of the proprioception, which may have an impact on the late recovery; secondly, for the second course of treatment, the patients' subjective initiative and compliance are reduced, this study suggests that the worst time of training for hemiplegic patients occurs at 24th week, which may lead to a decrease in the training effect of the patient, and the robot training is a regular and quantitative training which was not affected by the subjective nature of the patient. The results of Qin et al. [14] also indicated that 4 weeks after the rehabilitation intervention, the FMA scores of stroke patients with hematopoietic for 2 to 12 weeks significantly increase compared with the beginning of treatment, and are significantly higher than the scores after 8 weeks of treatment; thirdly, the intervention of acupuncture is difficult to effect with the premise of insufficient active movement of patients.

To sum up, the author believes that lower limb rehabilitation robot training combined with acupuncture treatment has a synergistic effect to promote early stroke patients with lower limb motor function. The next step is to explore the mechanism, the timing of intervention, the best time of treatment and so on by using PET and fMRI technology.

5. Conclusion

In conclusion, the lower limb rehabilitation robot has better effect on the lower limb walking function of the patients with early stroke than that of the walking function training assisted by therapist. The lower limb rehabilitation robot training combined with acupuncture has a significant improvement in the lower limb motor function, balance function and gait and better than which of single lower limb rehabilitation robot training in curative effect, and the two have synergistic effect. Inducing the recovery of the central nervous system function and enhancing the lower limb muscle strength and the balance function, establishing the normal motor function mode by stimulating the peripheral nerve, which can be popularized in clinical practice.

Competing Interests

The authors declare that they have no competing interests.

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