

**Using fMRI and sEMG to Evaluate the Effects and Mechanism on Abdominal Acupuncture Combined With Upper Limb Rehabilitation Training on Brain Plasticity of Hemiplegic Patients With Stroke**

**Head of Clinical Research Unit:** Guangdong Provincial Hospital of Chinese Medicine

**Director of Clinical Research:** Chen Hongxia

**Clinical Research Participating Unit:** Guangdong Provincial Hospital of Chinese Medicine ,Chinese University of Hong Kong .

**Reporting Unit:** Guangdong Provincial Hospital of Chinese Medicine

**Research Director:** Chen Hongxia

## 1. Title

Using fMRI and sEMG to Evaluate the Effects and Mechanism on Abdominal Acupuncture Combined With Upper Limb Rehabilitation Training on Brain Plasticity of Hemiplegic Patients With Stroke.

## 2. Background

Cerebral infarction is the main type of stroke which has become hotspot and difficulty of the research in medical science because of its high morbidity, disability and mortality. Stroke has caused great harm and burden to patients' family and society. It was reported by WHO that 80% of stroke patients have different degrees of limb dysfunction. With the intervention of rehabilitation therapy, some patients would recover in different degrees within 6 months. However, more than 60% of patients still remain upper limb dysfunction in chronic phase. According to the literature, only 15% of patients with stroke can recover to 50% of the original hand function. Only 3% of them can recover to more than 70% of the original. Because the motor function recovery of upper limb and hand is more difficult than that of lower limb. So we often pay more attention to the motor function recovery of lower limb and ignore the motor function rebuilding of upper limb. In addition, the disuse of affected hand and compensatory of unaffected hand of stroke patients lead to "learning without practice" and hand muscles contracture. If we start rehabilitation training now, the effects of rehabilitation training will be unpleasant and reduce the activities of daily living and quality of life seriously. Professor Bo, the famous abdominal acupuncture expert, using abdominal acupuncture treated hemiplegic patients with stroke and achieved remarkable effects. The acupuncture points of abdominal acupuncture form a turtle chart at the abdomen. Zhongwan point is on behalf of head, Shangqu point is on behalf of neck and shoulder joint, Wailing point, Upper rheumatic point and Upper rheumatic external point are on behalf of shoulder in the turtle figure. The affected upper limb motor function can be improved by acupuncture the Zhongwan, Shang Qu, Wailing, Upper rheumatic and Upper rheumatic external points. Because it can regulate and control the head, shoulder and hemiplegic limb and achieve the "holographic feedback" phenomenon. But the exact mechanism is not yet clear. Therefore, it is very important and urgent to use modern medical technology to elucidate its treatment mechanism.

## 3. Purpose

3.1 Hemiplegic patients with first onset stroke were treated with abdominal acupuncture combined with upper limb rehabilitation training to observe the recovery of upper limb motor function, the muscles synergy monitored by sEMG, local brain area activation by fMRI and the integrity of pyramidal tract of cerebral white matter.

3.2 To analyze the changes of upper limb motor function the relationship between the changes and sEMG or brain fMRI

3.3 to explore the possible mechanism of abdominal acupuncture combined with upper limb rehabilitation training on brain plasticity of upper limb motor function recovery in hemiplegic patients with stroke.

#### **4. Reporting Units and Research Units**

Reporting unit: Rehabilitation Department of Guangdong Provincial Hospital of Chinese Medicine

Address: No.111,Dade Road, Yuexiu District, Guangzhou City, Guangdong Province

Research Director: Chen Hongxia e-mail:chx2004@126.com

Clinical Auditor: Chen Hongxia e-mail:chx2004@126.com

Head of Clinical Research Unit: Rehabilitation Department of Guangdong Provincial Hospital of Chinese Medicine

Address: No.111,Dade Road, Yuexiu District, Guangzhou City, Guangdong Province

Research Director: Chen Hongxia e-mail:chx2004@126.com

Participating Units:

Rehabilitation Department of Guangdong Provincial Hospital of Chinese Medicine

Director: Chen Hongxia

Chinese University of Hong Kong

Director: Vincent Chi-kwan Cheung

#### **5. Research Design**

5.1 Case selection: 66 patients diagnosed with initial stroke by CT/MRI and hospitalized in rehabilitation department of our hospital who meet the inclusion criteria will be included.

5.2 Random method: Patients met the inclusion criteria will be randomized into 3 groups by MATLAB stratified randomization software:

Treatment group A: abdominal acupuncture +upper limb rehabilitation training, 22 cases;

Treatment group B: Sham abdominal acupuncture +upper limb rehabilitation training, 22 cases;

Control group : upper limb rehabilitation training only , 22 cases.

Sample size calculation: Using the SAMPsizePWR function calculation of MATLAB software Statistic Toolbox (Statistics Toolbox) to calculate, it is assumed that Fugl-meyer assessment (FMA) is the outcome index, and the FMA before rehabilitation training is also assumed to be  $30 \pm 10$  (average  $\pm$  Standard deviation), the FMA after rehabilitation training is 37 (average). The amount of effect between groups is  $\sim 0.7$ . If 0.8 of the statistical verification force is required, the sample size is 19 cases calculated by T-Test. Taking some uncontrollable factors that may causing dropping off into consideration, each group increases 3 cases with a 15% fall rate. Each group will include 22 cases.

### 5.3 Inclusion Criteria:

- ① First onset stroke, Left hemiplegia, Right-handed, and diagnosed by brain CT or MRI;
- ② Age 35 to 75 years old;
- ③ Course of disease 0.5 to 3 months with stable vital signs;
- ④ No cognitive impairment. Can understand and execute commands. MMSE score more than 7 points. ;
- ⑤ Can control the sitting balance. Brunnstrom stage of hemiplegic upper limb and hand is IV or V , Fugl-Meyer Motor Assessment score of upper limb 20-50 point;
- ⑥ Agree to sign the informed consent;
- ⑦ Unilateral neglect.

### 5.4 Exclusion Criteria:

- ① Recurrent stroke, subarachnoid hemorrhage, brain tumors patients;
- ② Contraindication to undergo a 3T MR imaging;
- ③ Claustrophobia;
- ④ Have severe heart, hepatic or renal failure;
- ⑤ Don't cooperate with the treatment;
- ⑥ Have participated in other clinical trials recently.

### 5.5 Treatment Method:

Treatment group A: abdominal acupuncture +upper limb rehabilitation training;

Treatment group B: Sham abdominal acupuncture +upper limb rehabilitation training;

Control group : upper limb rehabilitation training only .

All the treatments above last for 30mins a time, once a day, five times a week, totally 4 weeks.

Upper limb Rehabilitation Training programme is based on the recommendations of the American AHA-ASA-2016-Stroke Rehabilitation Guideline , including instrumental activities of daily life training and upper limb operation therapy.

A: Instrumental activities of daily life training:

Extend elbow (side): Subject attempts to reach across the table by extending the elbow (to the side).Extend elbow (to the side), with weight: Subject attempts to push the sandbag against outer wrist joint across the table by extending the elbow.Extend elbow (to the side), with weight: Subject attempts to push the sandbag against outer wrist joint across the table by extending the elbow. Hand to box (front): Subject attempts to place hand on the box.Pick up paper clip (front): Subject attempts to pick up paper clip by using a pincer grasp.Stack 3 checkers and flip 3 cards.Turning the key in the lock,fold towel,pick up the basket by grasping the handle and place it on the beside

table. Treatment Duration: 45 minutes a session, once a day, 5 times a week for 4 weeks.

B: Upper limb operation therapy:

According to the patient's specific situation, take the routine operation treatment. It includes the training of shoulder blades loosening, the active assistant and active training of the side upper limb, the joint activity training of the upper limb, the upper extremity training, and the grasping and opening of the side finger. Mainly with the side training, but also included a small number of contralateral auxiliary side training. Treatment time: 30 minutes/times, 1 times/day, 5 days/week, total 4 weeks.

#### 5.6 Evaluation Method:

##### (1) Screening Assessment

Simple intelligent mental state scale (MMSE), and Brunnstrom upper limb movement staging will be evaluated once when included.

##### (2) Primary Outcome Measure:

Functional magnetic resonance imaging (fMRI) and surface electromyography (sEMG) are the two primary outcome, which will be tested before and 4 weeks after treatment, twice totally.

##### (3) Secondary Outcome Measure:

Wolf Motor Function Test; Brunnstrom staging of upper limb movement; Fugl-Meyer Motor Assessment of upper limb; Modified Barthel Index.

Time Frame: Before treatment, 2 weeks and 4 weeks after treatment, 3 times totally.