WESTERN AND TRADITIONAL CHINESE MEDICINE APPROACHES TO STROKE REHABILITATION: A DESCRIPTIVE STUDY

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Abstract

The aim of this study is to investigate the functional recovery of stroke patients according to their walking activity and to monitor their global improvement in activities of daily living after undergoing Western and traditional Chinese medicine (TCM) rehabilitation programmes. The study was designed to describe the clinical diagnostic path followed by Western and TCM practices for stroke rehabilitation, and to determine the progressive patient improvements gained during these programmes. The measures used are clinical and functional evaluations, and gait analysis (GA). This finally provided a comparison of the results of clinical and functional evaluations obtained through internationally used scales, and of instrumental evaluation through GA. Here, we present the study design and results and argue that as GA has non-invasive, high precision and user friendly characteristics, it is particularly suited to the evaluation of improvements to walking impairment in stroke patients. By measuring the movements of the body in space (kinematics) and the forces involved in producing those movements (kinetics), GA is very useful for qualitative and quantitative data regarding locomotory patterns, which cannot be followed using clinical or video observation. Use of GA thus helps in the assessment of the rehabilitation process and contributes to the quantification of post-stroke rehabilitative interventions; in the final analysis, GA provides the ideal characteristics for the assessment of the effectiveness of TCM in stroke rehabilitation.

1. Introduction

According to WHO, stroke is the second commonest cause of mortality worldwide, causing about 5.54 million deaths worldwide each year; it is the third leading cause of death in Italy and the leading cause of severe disability in Europe. [1] By the year 2020, stroke and coronary-artery disease together are expected to be the leading causes of lost healthy life-years[2].

According to the data from the ministry of Health of P.R.China, stroke is the most and second common cause of death in cities, and the third cause of death in rural areas in 1990s and rose to the second recently. Based on this, the overall crude incidence rate was 2.19 per 1000 people every year in China[3]. The crude incidence rate in southern, central, and northern Italy is 1.8, 2.2, and 2.8 per 1000 respectively[4,5,6]. An estimated one-third to one-half of all patients affected by stroke have disabilities, and therefore it is the most common reason for rehabilitation. As a leading cause for disability—about 40% of stroke survivors are left with some degree of functional impairment, stroke is a major burden for both families and societies. Stroke accounts for about 3%of annual health care expenditure in developed countries[7] and the costs of rehabilitation and long-term nursing home care for disabled survivors contribute substantially to this total[8].

In developed countries, cerebral infarction represents the most common type of stroke[9] and may be further differentiated in subtypes each presenting specific clinical and epidemiological aspects. [10]

Stroke rehabilitation is the process of assisting a person who has become disabled as a result of a stroke to return to an optimal level of health, activity e.g. walking, and participation e.g. employment, within the limits of the persisting stroke impairment. The goals of stroke rehabilitation are to prevent, recognize, and manage comorbid medical conditions, maximize functional independence, optimize psychosocial adaptation of patients and families, enhance quality of life.

Effective physical therapy for stroke patients involves intensive training related to targeted activity and must also include training of activities such as reaching and manipulation, sitting, sit-to-stand, standing and walking[11,12,13,14].

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[2] WHO op.cit. 2000.

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Mobility recovery is therefore part of the rehabilitation process, and is fundamental for the patient to regain independence in everyday activities. In particular, walking after a stroke is characterized by altered activation patterns, reduced walking speed, and balance impairment, which all lead to decreased autonomy, increased risk of falling, and large energy costs.

Western rehabilitation has an holistic and comprehensive approach that addresses the specific needs of each patient by means of an interdisciplinary treatment. There are several different approaches to physiotherapy treatment after stroke. Despite considerable research efforts into multiple treatment modalities[15], there is still no single intervention that is recommended unequivocally for stroke rehabilitation.[16]

In China, traditional Chinese medicine (TCM), such as acupuncture, massage and Chinese herbal medicines, are regularly given to patients who have suffered from stroke, and they are usually used in combination. Although many clinical studies have indicated that TCMs appear to be safe and effective for stroke rehabilitation, whether or not these treatments are truly effective after stroke is still not known.[17]

Objective measurement of function is central to rehabilitation. Western rehabilitation procedures are generally assessed through validated scales that consider different aspects of the pathology, such as muscle tone (modified Ashworth scale), health status after the stroke (National Institute of Health stroke scale), disability and functional independence (Barthel index, Functional Independence Measure), and through functional instrumental evaluation, such as movement analysis and, in particular, gait analysis (GA). Three-dimensional GA is a technique that provides quantitative data on the kinematics and kinetics of motor behaviour in the sagittal, horizontal and frontal planes. Its main application is for the quantification of functional limitations related to pathological situations.

Following the 2004 Memorandum of Understanding on Scientific and Technological Cooperation in the Field of Traditional Chinese Medicine between the Chinese Ministry of Science and Technology and the Italian Ministry of Health, the Italian National Institute of Health (ISS) and the Tianjin University of Traditional Chinese Medicine (TUTCM) signed an agreement in November 2006 for the establishment of the *Sino-Italian Joint Laboratory on Traditional Chinese Medicine*. The project was financed by the Italian Ministry of Health and the Chinese Ministry of Science and Technology. In this framework, the ISS, the Department of Physical Medicine and Rehabilitation of 'La Sapienza' University of Rome, and the First Teaching Hospital of Medicine of TUTCM, conducted a descriptive study on Western and TCM approaches to stroke rehabilitation.
The aim of the study was to describe the Western and TCM approaches to stroke rehabilitation and determine the progressive improvements gained during both Western and TCM rehabilitation programmes.

Here we present the study design and results, arguing for an important role for GA combined with clinical and functional evaluation scales in the future assessment of post-stroke rehabilitation

[15] A recent systematic review on physiotherapy treatment approaches for the recovery of postural control and lower limb function concluded that a mixed approach was significantly more favorable than no treatment or a placebo control in the recovery of functional autonomy after stroke. Pollock et.al 2008.
[16] Intercollegiate Stroke Working Party, 2004; SPREAD, 2007
[17] Sze FK et al., 2002.

programmes and TCM effectiveness. Indeed, GA has proven to be of great use for the provision of qualitative and quantitative data on locomotory patterns, which cannot be seen with clinical or video observations. This can help in the rehabilitation process and contribute to the quantification of post-stroke rehabilitation interventions.

2. Study Objectives

This study is aimed at describing the Western and TCM approaches to stroke rehabilitation, and determining the progressive improvements gained during both of these rehabilitation programmes. The specific objectives of the study are:

1. To describe TCM classification systems for stroke and post-stroke.
2. To describe TCM clinical diagnosis criteria and therapeutic protocols for stroke rehabilitation.
3. To measure physical improvement after TCM treatment through clinical and functional evaluation and GA in acute post-stroke patients in China.
4. To measure physical improvement after Western medicine treatment through clinical and functional evaluation and GA in acute post-stroke patients in Italy.
5. To compare the degree of agreement between the evaluation scales used to measure physical improvement after both treatments with the results obtained through GA.

Thus, the results of the clinical and functional evaluation obtained through internationally used scales can be compared with the instrumental evaluation performed through GA. The assessment of the efficacy of both approaches and the comparison of the functional outcomes of the rehabilitation programmes are, however, beyond the scope of the present study.

3. Study Design and Methodology

As described in Figure 1, the study was divided into two phases: an observational study of the clinical practice and records, and a descriptive study of the clinical, functional and instrumental evaluation of the patients.

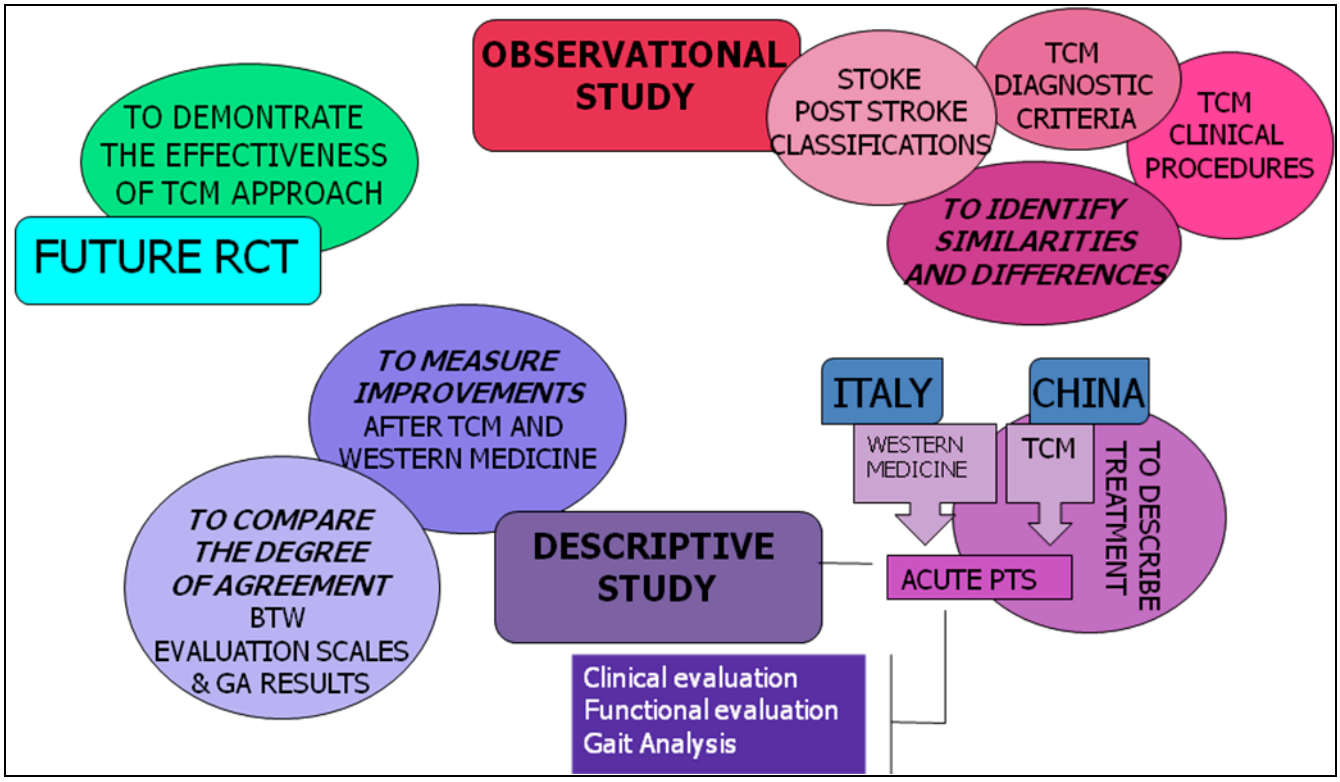
The observational study was aimed at describing the clinical diagnostic protocol used by TCM in stroke rehabilitation, according to the available documentation and the observation of the clinical practice and the clinical records at the First Teaching Hospital of Tianjin University of Traditional Chinese Medicine. This phase included a review of the diagnostic criteria and the clinical procedures used to identify similarities and differences in both Western and TCM practices and to facilitate the description and operational practicalities in terms of future clinical and epidemiological studies.

The descriptive study was aimed at describing the acute stroke patients' treatment in Italy (Western medicine) and in China (TCM approach) and measuring the physical improvements after treatment, monitored through clinical, functional and instrumental evaluation.

In China the study was conducted at the First Teaching Hospital of Tianjin University of Traditional Chinese Medicine. In Italy the study was conducted by the Department of PM&R - 'La Sapienza' University of Rome in cooperation with San Giovanni Battista Hospital, Stroke Unit.

Since the assessment of the effectiveness of both approaches goes beyond the scope of this study, the study design did not foresee control groups.
The results of this study may be useful to justify future RCT to demonstrate the effectiveness of TCM approach for stroke rehabilitation.

Figure 1: Study Conceptual Map



a. Recruitment of Study Participants

Patients of both sexes afferent in a rehabilitation unit for right or left hemiplegia following a first time ischemic stroke were considered eligible for the present research and formed the study group. Stroke was defined according to World Health Organization (WHO) recommendations (WHO, 2000) as ‘‘rapidly developing clinical symptoms and/or signs of focal, and at times global, loss of cerebral function, with symptoms lasting more than 24 h or leading to death, with no apparent cause other than that of vascular origin”.

Inclusion Criteria:
In-patients in a rehabilitation department, of either sex (age 40-75 years), affected by acute right or left hemiplegia following an ischaemic or haemorrhagic stroke, as documented by computer tomography or magnetic resonance imaging and by ability to walk autonomously (including using a cane). An acute condition is defined with reference to the period from two weeks to one month after the stroke event.

Exclusion Criteria:
Lesions of both hemispheres; brain stem lesions, cerebellar lesions, whole hemisphere lesions, neglect, severe deficit of comprehension, global aphasia, or life-threatening diseases; medical history of previous peripheral or central neurological disease; previous orthopaedic surgery to lower

limbs; severe heart failure; cognitive impairment as evaluated by crude Mini Mental State Examination (MMSE) (≤23); or illiteracy. Exclusion also include patients mistreated or treated in other hospitals or clinics other than Tianjin Hospital after release and before T2 follow up.

b. Treatment

In China, each patient was treated according to the TCM approach (acupuncture, herbs, tuina), under the guidelines for the management of in-patients affected by stroke (the "Xing Nao Kai Qiao" 'Activating the Brain and Opening the Orifices' acupuncture therapy for the treatment of stroke). These are as used in the Acupunture and Moxibustion Department (Stroke Rehabilitation Unit) of the First Teaching Hospital and as personalised by treating physicians. Some patient conditions require the addition of Western drug therapy, such as for hypertension, chronic heart disease, diabetes, and antiplatelet agents.

In Italy, each patient was treated according to the Western post-stroke rehabilitation approach, which is performed as a team approach, with contributions from different health and social operators, under the Italian SPREAD guidelines for stroke and the Intercollegiate Stroke Working Party guidelines.[18]

c. Evaluation

Each patient included in the study was evaluated as follows:

- Clinical evaluation
    - Range of motion (ROM) of right and left shoulder, elbow, wrist, hip, knee and ankle (manual goniometric evaluation).
    - Mini Mental State Examination (MMSE)
    - Evaluation of spasticity in the musculature involved (modified Ashworth scale; MAS).
    - Neurological deficit assessment (C-NIHSS).

- Functional evaluation
    - Functional independence (Barthel index)
    - Assessment through TCM

- Instrumental evaluation
    - Gait analysis.

d. Timing of data acquisition

For each patient, clinical and functional evaluations were performed as follows:

- T_0: pre-treatment acquisition at patient recruitment, or as soon as the patient is able to walk.
- T_1: first post-treatment acquisition, 1 month from T_0
- T_2: second post-treatment acquisition, 3 months from T_0

[18] SPREAD - Stroke Prevention and Educational Awareness Diffusion (2007); Intercollegiate Stroke Working Party (2004).

Instrumental evaluation was performed for each patient at T0 and T1 (see above).

e. Gait Analysis Procedures for Data Collection and Analysis

Gait analysis was performed using the SMART-D stereophotogrammetric system (BTS, Milano, Italy) with 6 infrared video cameras (TVC) for the acquisition of kinematic variables. All kinematic data were acquired and digitized with a sampling rate of 250 Hz.
Anthropometric data were collected for each subject and retroreflective spherical markers placed according to Davis et al. (1991).

In Italy, the Movement Analysis Laboratory at S. Giovanni Battista Hospital used an Elite System. The same system and equipment, provided under a loan for use agreement by BTS, Milano and Samwell Testing Inc. was installed at the First Teaching Hospital of TCM.

Subjects were instructed to walk at a self-selected speed along a level surface approximately 10 m in length and practice until they could consistently and naturally make contact with both the force platforms. Five trials were acquired for each subject and mean values considered for further analysis.

Data elaboration, including determination of joint centres of rotation and calculation of joint angular excursion and internal moments (Davis et al., 1991; Vaughan et al., 1999), were performed by means of Smart Analyzer software (BTS, Milano, Italy). Within the stance phase, the two subphases of stance and swing were considered.

As time-distance data, we evaluated:

- *stride length* (SL) (i.e., the distance between two consecutive heel-floor contact) (Perry, 1992, Oken, 2007)
- *double support time percentage* (Goldie et al, 2001) (percentage of the double support time duration with respect to the gait cycle)
- *walking velocity* and *comfortable speeds* (Oken, 2007, Chen, 2005, Kwakkel, 2002)
- *stance percentage of paretic side* (Perry, 1992) (duration of stance phase of gait cycle of paretic limb in percentage of the whole gait cycle duration of the same limb)
- *cadence* (Perry, 1992) (steps/minute)

As kinematic variables we calculated the total *range of movement (ROM)* of paretic hip, knee and ankle joint during the whole gait cycle (Perry, 1992).

f. Statistical Analysis

To investigate the presence of significant differences within each group, a two wy analysis of variance ANOVA (repeated measurement data), t-test (Paired t-test, Two independent-samples t-test), two independent-samples nonparametric tests (wilcoxon signed-rank test, wilcoxon rank sum test) R*C chi-square test were used. A Bonferroni post-hoc comparison was used to determine significant differences between mean values when significant main effects and interactions are found. A P value less than 0.05 is considered statistically significant.

4. Results

a. Observational Study: TCM stroke classifications and clinical-diagnostic criteria.

Although in modern TCM structures (such as the Tianjin Hospital) both Western diagnosis and TCM 'syndrome' are recorded in case histories, it is important to note that there are some basic differences between allopathic diagnosis and Chinese *bian zheng* (syndrome differentiation) that need to be taken into account.

Bian Zheng considers the characteristics of the affected subject as the mainframe. The relationship between constitution, semeiotics and disease is then abstracted into a 'syndrome' combining a given set of options into a personalized but systematic taxonomy. In short, syndrome differentiation identifies *how* that particular disease manifests itself in a given patient, rather than defining the disease alone. The principles for treatment and the choice of protocols to use are selected accordingly.

According to the observational study of clinical diagnostic practice for TCM and the records at the First Teaching Hospital of TUTCM, no exact matches can be traced between Western and TCM classifications of stroke. In Western medicine stroke is divided into two kinds, ischemic and haemorrhagic, the diagnosis of which mainly base on the symptoms and signs of patients' neurologic impairment, as well as the imaging examinations.

In TCM, syndrome differentiation is the base of stroke treatment. Here, stroke is divided into two categories: attacking meridians and collaterals, attacking viscera and bowels (the zang and fu organs). For the latter, there are two subtypes: excess (closed) patterns and depletion (opened/flaccid) patterns. According to the characteristics of patients' syndromes, the stroke also can be divided into seven patterns of syndromes:

- *fire sufficiency with wind and phlegm*： hemiplegia, deviation of mouth and tongue, dysphasia or aphasia, numbness, dizziness, abrupt onset , upset and tantrum, rigidity of limbs and body, excessive and viscous phlegm, red tongue with yellow greasy fur, string-tight and slippery pulse.
- *wind fire upper-disturbance* : hemiplegia, deviation of mouth and tongue, dysphasia or aphasia, numbness, abrupt change of disease, coma, neck stiffness, rough breath, dry stool and constipation, oliguria with deep-colour urine, deep red tongue with dry and yellow greasy fur, string-tight and rapid pulse.
- *phlegm-heat and fullness in fu-organs :* hemiplegia, deviation of mouth and tongue, dysphasia or aphasia, numbness, headache and dizziness, excessive phlegm, abdominal distension , dry stool or constipation, dark red tongue with yellow greasy fur, string-tight and slippery pulse or large string-tight and slippery pulse in the paralysis side.
- *block of wind and phlegm* : hemiplegia, deviation of mouth and tongue, dysphasia or aphasia, numbness, dizziness, excessive and viscous phlegm, dark tongue with thin and white or white and greasy fur, string-tight and slippery pulse.
- *phlegm-dampness masking spirit* : hemiplegia, deviation of mouth and tongue, dysphasia or aphasia, numbness, coma, wheezy phlegm, urinary and fecal incontinence, body clamminess, purple and dark tongue with white greasy fur, sunken and slow slippery pulse.

- *qi deficiency and blood stasis* : hemiplegia, deviation of mouth and tongue, dysphasia or aphasia, numbness, pale complexion, shortness of breath and fatigue, spontaneous perspiration, dark and light tongue, white greasy tongue fur or with teeth mark, sunken and thready pulse.
- *wind movement due to yin deficiency (kidney and liver*) : hemiplegia, deviation of mouth and tongue, dysphasia or aphasia, numbness, dizziness and tinnitus, feverish palms and soles, dry throat and mouth, red thin tongue with little or without fur, string-tight and thready rapid pulse.

b. Descriptive study.

Western rehabilitation interventions during the acute phase.

Effective stroke rehabilitation requires the coordinated skills of a wide range of professionals (neurologist, physiotherapist, occupational therapist, psychologist and social assistant) coordinated by a physiatrist, who defines the main rehabilitative goals

In Italy, each patient was treated according to a rehabilitation project which included:

- *Physical therapy.*

  Therapeutic Exercises are performed following different techniques: in case of flaccid or low tone muscles passive ROM are indicated to prevent joint contractures, appropriate positioning to maximize joint protection and synergy facilitator patterns are commonly used; in case of high-tone or spastic muscles, others techniques such as Neuro-developmental techniques (Bobath, Proprioceptive Neuromuscular Facilitation) or Neurocognitive Rehabilitation (Perfetti) are administered. Long and slow stretching is used to prevent contractures. Splints and orthoses can help to prevent contractures and to improve function.
- *Functional Skills Training.*

  The aim of conventional therapeutic approaches is to increase physical independence through the facilitation of motor control and skill acquisition.

  Intensive therapy for the upper limb is considered to improve arm function in patients with mild impairment. Bilateral arm training may improve motor performance of the upper limb. Gait re-education techniques to improve walking ability based on recognized therapy approaches was offered. Walking sticks were considered to increase standing stability in patients with severe disability

  For the specific objectives of improving reaching for objects and increasing walking speed, a task-specific approach was used rather than an impairment-focused approach

  Functional rehabilitation interventions are designed to help patients adapt to their impairments, so that they may participate as fully as possible in their chosen daily activities of life. Adaptive therapies include the teaching of new skills, the provision of information, the use of problem-solving aids or appliances and environmental modification. The topics covered range from a relatively restricted area such as self-care to environmental changes.

  Much of stroke rehabilitation aims, directly or indirectly, to increase independence and ability in all activities of daily living (ADL), not only personal (e.g. dressing) but also domestic (e.g. cooking) and communal (e.g. shopping). Furthermore it has been convincingly shown that organized rehabilitation directly improves ADL.
- *Spasticity Management.*

  Spasticity is a motor disorder characterized by a velocity-dependent increase in tonic stretch

reflexes. Spasticity may lead to secondary complications such as muscle and joint contractures. Antispastic drugs, developed for use in spinal cord disease, are widely promoted, and botulinum toxin (BTX) is now becoming available. After stroke, spasticity was treated if it was causing problems, using physical treatments and possibly drugs (although the functional benefit is uncertain). Spasticity should not limit the use of strength training.

In patients with disabling or symptomatically distressing spasticity, injection of botulinum toxin was considered in conjunction with physiotherapy for reducing tone and/or increasing the range of joint motion. Additional electrostimulation was considered for increasing the effectiveness of botulinum toxin.

- *Prevention of Deconditioning and Contractures.*
  Through positioning and support interventions; positioning of stroke patients and provision of appropriate seating may prevent the development of contractures, pain, skin breakdown and respiratory complications. Sitting in upright position to improve orthostatic tolerance.
- *Prevention of Medical Complications.*
  Venous thrombo- embolism often occurs within the first week of a stroke, and most often in immobile patients with paralysis of the leg, but its impact after stroke is still unclear.[19]
- *Bladder and Bowel Management.*
  Most patients with moderate to severe stroke are incontinent of feces and urine at presentation, and many are discharged incontinent. Incontinence is a major burden on careers once the patient is discharged home. Management of both bladder and bowel problems were therefore seen as an essential part of the patient's rehabilitation, as they can seriously hamper progress in other areas.
- *Communication: aphasia, dysarthria and articulatory dyspraxia.*
  Stroke can affect communication in different ways. The patient may have impaired motor speech production (dysarthria) or impaired planning and execution of motor speech (articulatory dyspraxia) resulting in changes to their intelligibility. They may have impaired language skills (aphasia or dysphasia) resulting in difficulties in generating or understanding words, reading and/or writing. Accurate diagnosis is essential to guide and inform the team and the family. Patients with aphasia had their suitability for intensive speech and language therapy assessed by a speech and language therapist.
- *Identification and Treatment of Depression (psychological Counseling)*
  Disturbance of mood is common after stroke. Diagnosis of an abnormal mood state is difficult, particularly in the presence of speech disturbance. Diagnostic separation is also difficult, especially as different abnormalities may coexist. Treatments included antidepressant medication or psychological therapy, such as cognitive behavioural therapy.

TCM approach to stroke rehabilitation during the acute phase.

While in Western medicine stroke treatment in the acute phase is focused primarily on patient stabilization and on patient recovery from the impairment through rehabilitation, TCM provides a comprehensive integrated approach to stroke patients. Acupuncture has an important role in the

[19] Studies using radio-labeled fibrinogen leg-scanning suggest that deep venous thrombosis (DVT) occurs in up to 50% of patients with hemiplegia but clinically apparent DVT probably occurs in fewer than 5%. Similarly, although autopsy series have identified pulmonary embolism (PE) in a large proportion of patients who die, clinically-evident PE occurs in only 1–2% of patients.

treatment of patients affected by cerebrovascular diseases. At the same time, other treatments, such as Tuina (Chinese massage) and Chinese herbal therapy, are fundamental in the management of stroke.

- *Acupuncture*.
  According to TCM theories, stroke happens because of the closed orifices and the hidden mind failing to guide the qi, so acupuncture should be practiced as early as possible, in order to activate the brain and open the orifices, dredge the meridians, invigorate the kidney and liver, and regulate the imbalance of yin and yang.
  In the First Teaching Hospital of TUTCM, which is known for its outstanding treatment of stroke patients, an acupuncture therapy is now used, known as *Xing Nao Kai Qiao*（XNKQ“activating the brain and opening the orifices）.
  The main points are: Neiguan, Renzhong, Sanyinjiao
  The auxiliary points are:
  - Upper limbs: Jiquan, Chize,
  - Lower limbs: Weizhong
  - Dysphagia or dysarthria: fengchi, wangu, yifeng, shanglianquan, jinjing, yuye, renying and neidaying
  - Aphasia: scalp acupoint（speech area）
  - Subluxation of the shoulder: jianyu, jianliao, jianneiling, jianzhen, jianzhongshu, jianwaishu
  - Cross-foot: qiuxu directed towards zhaohai
  - Constipation: waishuidao, waiguilai and fenglong
  - Urinary retention or incontinent: zhongji, qugu, guanyuan and shuidao
  - Ataxia: fengfu, yamen and jiaji of cervical
  - Diplopia: tianzhu, jingming and qiuhou
  - Post stroke epilepsy: daling and jiuwei
  - Cognitive impairment: tanzhong, zhongwan, qihai, xuehai, zusanli, waiguan
  - Dyssomnia: shangxing and shenmen

- *Chinese herbs*.
  Chinese herbal prescription is formed by various herbs through formula compatibility principle and has the effects of driving away wind, enriching blood, activating meridians and collaterals, nourishing liver and kidney, reinforcing qi and restoring yang for patient with stroke.
  For stroke involving meridians and collaterals
  - wind fire upper-disturbance: Tianma Gouteng Decoction
  - wind movement due to yin deficiency (kidney and liver) : : Zhengan Xifeng Decoction.

  For stroke involving viscera and bowels
  - excess（closed） pattern
    - fire sufficiency with wind and phlegm: An gong niu huang pill and Lingyang Gouteng Decoction
    - phlegm-dampness masking spirit: Su he xiang pill and Ditan Decoction
    - phlegm-heat and fullness in fu-organs: Taoren Chengqi Decoction

- depletion (opened/flaccid) pattern: Shenfu Decoction and Shengmai Powder

In the post acute phase:

- block of wind and phlegm: Jieyu dan
- qi deficiency and blood stasis: Danqi piantan capsule, Buyang Huanwu Decoction

- *Tuina (Chinese massage)*

  In order to improve the functions of patients' limbs, tuina therapy was operated, with the functions of dredging meridians, coordinating qi and blood, strengthening body resistance and driving away pathogenic factors.

  In the acute stage, the function of the upper limbs is impaired; Yin meridian points should be adopted through the following techniques: pressing, circle-moving, line-moving, grasping, pinching-grasping, kneading, rolling, plucking, pointing, tapping and knocking, and so on, should be given according to different conditions.

  As for manipulation: point the points till the local skin is hot, the strength should not be too heavy, and be given a few times. Then pressing-kneading points to dredge meridians. After that, pinch-grasp the upper affected limb for six times in order to promote blood flow and unfold tendon. If the extremity of the affected limb is swollen, the pinching-grasping manipulations should be given from the distant to proximal end.

The study in China: measuring improvements after TCM treatments

A total of 2520 hemiplegic stroke patients admitted to the hospital for treatment were screened for this study from December 2007 to June 2008. Of these, 75 fulfilled the inclusion criteria and agreed to join the study as subjects. Ten of the 75 subjects admitted to the study did not attend all their TCM rehabilitation (all were discharged from the hospital before completion of the 1-month intervention period). Sixty-five patients completed the treatments and were included in the analysis, accounting for a 13.33% dropout rate. Out of 65 patients, 60 had ischemia stroke and 5 had hemorrhage stroke. Table 1 shows the baseline characteristics of all the subjects.

TABLE 1 Baseline Characteristics of the Chinese Stroke Patients (N=65)

Variables		n	%
Gender	Male	54	83.08
	Female	11	16.92
Hemiplegic Side	Left	34	52.31
	Right	31	47.69
Diagnosis	Ischemia	60	92.31
	Hemorrhage	5	7.69
School Education	illiterate	0	0.00
	primary	16	21.62
	secondary	50	67.57
	graduate	8	10.81
History of TCM Treatment	Yes	57	87.69
	No	8	12.31
Past history	Yes	42	64.62
	No	23	35.38
Age	X±SD)	58±7	

All patients receiving TCM rehabilitation treatment tolerated it well without side effects. Thirty five subjects (ischemia) received antihypertensive agents. Seventeen patients (12 ischemia, 5 hemorrhages) received Hypoglycemic Agents, thirty seven subjects (ischemia) received reduce blood cholesterol agents; sixty patients (ischemia) received antiplatelet agents.

Patients by TCM syndromes:

- Fire sufficiency of wind and phlegm：9
- Wind Fire upper-disturbance：3
- Phlegm-Heat and fullness in fu-organs：4
- Stagnation of wind and phlegm：19
- Phlegm-dampness：5
- Qi-deficiency and blood stagnation：9
- Wind movement due to Yin-deficiency：16

The results of the clinical and functional evaluations performed at T_1 an T_2 are presented in Tables 2-6.

First post-treatment clinical and functional evaluation (after 1 month)
Subjects showed significant improvement in MMSE, NIHSS, BI total scores and MAS(P<.0001). Data analysis revealed that the mean MMSE, NIHSS and BI (total) scores changed from 28, 4 and 61 to 29, 3 and 77 respectively. Regarding each sub-score of BI, subjects in China showed significant improvement in feeding, bathing, grooming, bladder, transfers, mobility, toilet use and stairs after 1 month of TCM rehabilitation ttreatment, except for bowel. The great improvement is shown in the affected side active-ROM of Chinese patients, except the knee flexion.

Second post-treatment clinical and functional evaluation (after 3 months)
To assess long-term effect, all outcomes of the study were reassessed 3 months after the intervention period. All subjects who came back for this follow up showed continued improvement in NIHSS, MAS Active-ROM and BI after the completion of the 1-month intervention. NIHSS score decreased compared to the end of treatment. In active-ROM, progress was gained in the most aspects excluding hip adduction and knee flexion. BI total score was improved from 77 to 84, and similar change was seen in the score of MAS. Regarding to BI, all of items but the bowel had advancement.

TABLE 2 MMSE NIHSS BI (total) Score Of Chinese Patients (X±SD,N=65)

	T0	T1	T2	P value○	P value●	P value□
MMSE	28±2	29±2	29±2	0.0004	0.0003	0.4500
NIHSS	4±2	3±1	3±1	<.0001	<.0001	0.0022
BI (total)	61±13	77±12	84±12	<.0001	<.0001	<.0001

P value○: T_0 vs T_1, P value● T_0 vs T_2, P value□: T_1vs T_2

TABLE 3 BI Score Of Chinese Patients （N=65）

		0 N %	5 N %	10 N %	15 N %	P value○	P value●	P value□
Feeding	T_0	4 6.15	50 76.92	11 16.92	0 0.00	0.0001	0.0011	<.0001
	T_1	1 1.54	31 47.69	33 50.77	0 0.00			
	T_2	1 1.54	22 33.85	42 64.62	0 0.00			
Bathing	T_0	60 92.31	50 7.69	0 0.00	0 0.00	0.0005	0.0217	<.0001
	T_1	44 67.69	21 32.31	0 0.00	0 0.00			
	T_2	32 49.23	33 50.77	0 0.00	0 0.00			
Dressing	T_0	9 13.85	50 76.92	6 9.23	0 0.00	0.0003	0.0019	<.0001
	T_1	1 1.54	30 46.15	34 52.31	0 0.00			
	T_2	1 1.54	42 64.62	22 33.85	0 0.00			
Grooming	T_0	44 67.69	21 32.31	0 0.00	0 0.00	0.0019	0.0255	<.0001
	T_1	15 23.08	50 76.92	0 0.00	0 0.00			
	T_2	9 13.85	56 86.15	0 0.00	0 0.00			
Bowels	T_0	0 0.00	1 1.54	64 98.46	0 0.00			
	T_1	0 0.00	0 0.00	65 100.00	0 0.00			
	T_2	0 0.00	0 0.00	65 100.00	0 0.00			
Bladder	T_0	0 0.00	1 1.54	64 98.46	0 0.00	<.0001	<.0001	<.0001
	T_1	0 0.00	1 1.54	64 98.46	0 0.00			
	T_2	0 0.00	1 1.54	64 98.46	0 0.00			
Toilet use	T_0	2 3.08	56 86.15	7 10.77	0 0.00	0.0013	0.0605	<.0001
	T_1	0 0.00	34 52.31	31 47.69	0 0.00			
	T_2	0 0.00	20 30.77	45 69.23	0 0.00			
Transfers	T_0	0 0.00	11 16.92	45 69.23	9 13.85	<.0001	0.0002	<.0001
	T_1	0 0.00	0 0.00	37 56.92	28 43.08			
	T_2	0 0.00	0 0.00	29 44.62	36 55.38			
Mobility	T_0	4 6.15	13 20.00	38 58.46	10 15.38	<.0001	0.0122	<.0001
	T_1	0 0.00	5 7.69	29 44.62	31 47.69			
	T_2	0 0.00	0 0.00	26 40.00	39 60.00			
Stairs	T_0	15 23.08	45 69.23	5 7.69	0 0.00	0.0232	0.2665	<.0001
	T_1	2 3.08	47 72.31	16 24.62	0 0.00			
	T_2	1 1.54	37 56.92	27 41.54	0 0.00			

P value○: T_0 vs T_1, P value● T_0 vs T_2, P value△: T_1vs T_2

TABLE 4 MAS Score Of Chinese Patients (N=65)

	0 N %	1 N %	2 N %	3 N %	P value○	P value●	P value△
T_0	55 84.62	7 10.77	2 3.08	1 1.54	<.0001	<.0001	<.0001
T_1	58 89.23	3 4.62	3 4.62	1 1.54			
T_2	58 89.23	5 7.69	1 1.54	1 1.54			

P value○: T_0 vs T_1, P value● T_0 vs T_2, P value△: T_1vs T_2

TABLE 5 The Affected Side Active-ROM Of Chinese Patients (N=65)

	T_0	T_1	T_2	P value○	P value●	P value△

SHOULDER						
Frontal flexion	88±61	117±56	126±53	<.0001	<.0001	0.0005
Abduction	51±31	67±26	72±24	<.0001	<.0001	0.0224
External rotation	35±31	48±28	51±28	<.0001	<.0001	0.0004
Internal rotation	47±36	60±31	63±28	<.0001	<.0001	<.0001
HIP						
Flexion	55±16	64±14	66±16	<.0001	<.0001	0.0204
Abduction	29±13	32±9	33±9	0.0004	0.0005	0.1246
Adduction	18±11	22±9	25±8	<.0001	<.0001	0.0001
WRIST						
Flexion	28±25	36±23	40±23	<.0001	<.0001	0.0002
Extension	29±28	36±26	42±26	<.0001	<.0001	0.0001
KNEE						
Flexion	71±31	95±31	100±31	＞.05	＞.05	＞.05
ANKLE						
Plantar flexion	17±14	23±13	25±13	<.0001	<.0001	0.0001
Dorsal flexion	15±15	22±13	25±13	<.0001	<.0001	<.0001
ELBOW						
Flexion	80±48	94±42	100±40	<.0001	<.0001	0.0188

TABLE 6 The Affected Side Passive-ROM Of Chinese Patients （N=65）

	T_0	T_1	T_2	P value○	P value●	P value△
SHOULDER						
Frontal flexion	161±31	168±19	168±20	0.0066	0.0080	0.8389
Abduction	85±16	88±7	87±10	＞.05	＞.05	＞.05
External rotation	70±25	73±22	74±22	0.0137	0.0031	0.0840
Internal rotation	79±23	82±17	84±15	0.0245	0.0071	0.0867
HIP						
Flexion	77±12	78±10	78±11	＞.05	＞.05	＞.05
Abduction	41±8	41±8	40±7	＞.05	＞.05	＞.05
Adduction	27±6	28±6	29±6	0.0007	0.0007	0.0538
WRIST						
Flexion	53±22	56±21	57±20	0.0007	0.0007	0.2185
Extension	58±26	60±23	62±23	0.0577	0.0093	0.0828
KNEE						
Flexion	100±15	100±16	101±19	＞.05	＞.05	＞.05
ANKLE						
Plantar flexion	29±14	32±13	33±13	0.0001	<.0001	0.0121
Dorsal flexion	28±16	31±13	35±15	<.0001	0.0002	0.0195
ELBOW						
Flexion	120±26	124±25	127±26	0.0010	0.0006	0.0377

P value○: T_0 vs T_1, P value● T_0 vs T_2, P value△: T_1vs T_2

The study in Italy: measuring improvements after Western rehabilitation treatments

A total of 1789 patients were considered for eligibility for the present study. After considering inclusion and exclusion criteria, 60 patients (see Table 7) were recruited and were evaluated according to the above described evaluation protocol.

Table 7: Demographics baseline characteristics of the Italian patients

Variables		n	%
Gender	Male	50	83.3
	Female	10	16.7
Hemiplegic Side	Left	22	36.7
	Right	38	63.3
Diagnosis	Ischemia	50	83.3
	Hemorrhage	10	16.7
Age (years)	(X±SD)	63±11	

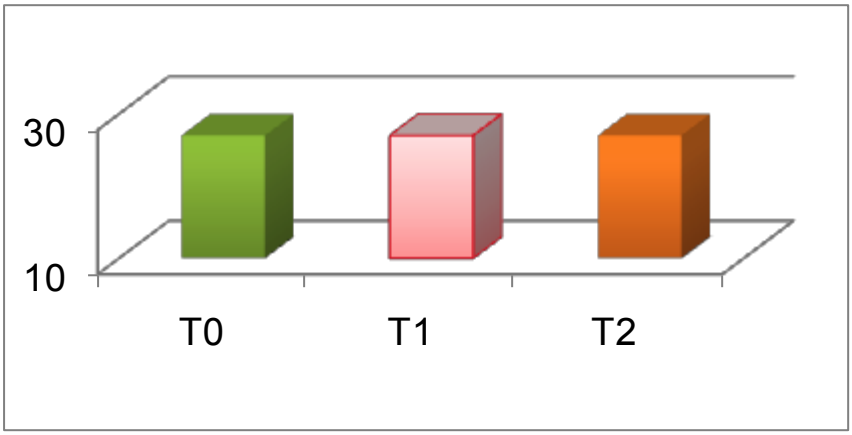
The clinical baseline characteristics of our sample are shown in Table 8 below.

Table 8: Baseline values of MMSE, NIHSS and Barthel index in the Italian sample

Variables	N	Mean	SD	MIN	MAX	median
MMSE	60	27	2	24	30	28
NIHSS	60	3	2	0	8	3
Barthel Index	60	26	8	10	45	25

MMSE score evaluation revealed no significant changes between T0 (27±2) T1 (27±2) and T2 (27±3) (p=0.39) as shown in Figure 2 below:

Figure 2: Mini mental status examination (MMSE) at T0, T1 and T2 in the Italian sample.



NIHSS results show decreased values from T0 (3±2) to T2 (2±2), the difference between T1(3±2) and T2 being significant (p<0.01)

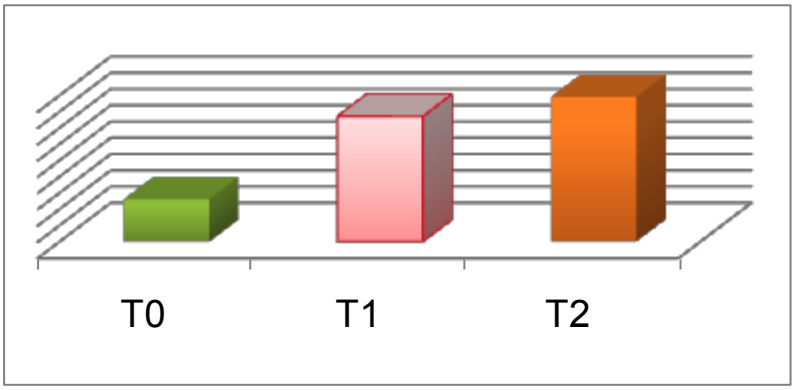
Regarding MAS score, results are showed in table 3.

Table 9: number of patients classified according to MAS score at each follow-up

	0	1	2	3
T0	47	9	3	1
T1	31	20	4	5
T2	28	19	4	5

Analyzing Barthel Index score modifications, a significant improvement of the mean values of the Barthel index score is observed between T0 (26±8), T1 (77±12) and T2 (89±6) (p=0.0004), as shown in Figure 3 below:

Figure 3: Barthel index score at T0, T1 and T2 in the Italian sample.



Instrumental evaluation: Gait Analysis results in China and in Italy

Time distance data analysis in the Chinese group revealed a significant gait speed improvement between T0 and T1 (Figure 4) and stride length of paretic side between T0 and T1 (Figure 5), while stance percentage of paretic side significantly diminished between pre- and post-treatment follow up (Figure 6)

Figure 4: Gait speed at T0 (blue column) and T1 (red column) in the Chinese group.

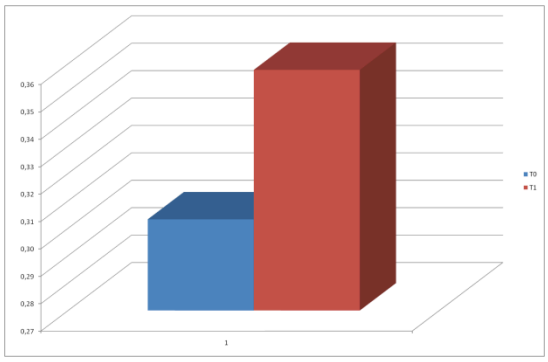


Figure 5: Stride length of paretic side at T0 (blue column) and T1 (red column) in the Chinese group.

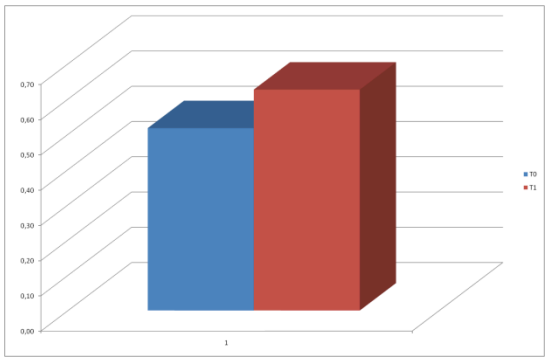
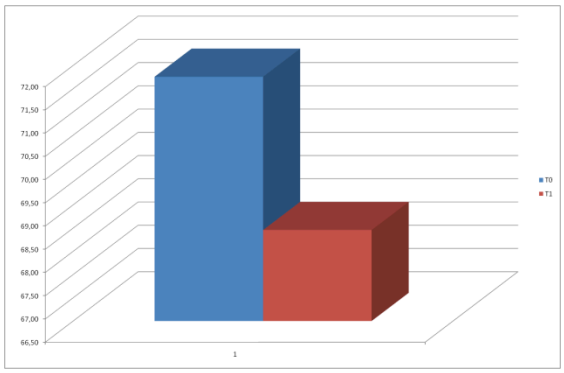


Figure 6: percentage of stance duration of paretic side at T0 (blue column) and T1 (red column) in the Chinese group.



Patients in Chinese group also showed a significant increased cadence between T0 and T1 (figure 8), while duration of double support of both paretic and normal limb appear to be diminished between T0 and T1, despite the difference not reaching significance (figure 7).

Figure 7: Duration of double support of both paretic (on the left) and normal (on the right) side in the Chinese group. Blue columns represent T0 values, red columns T1 values

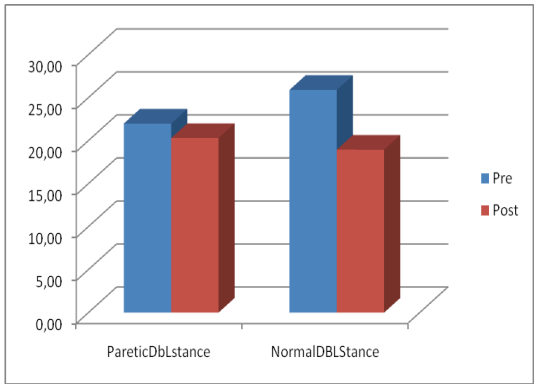
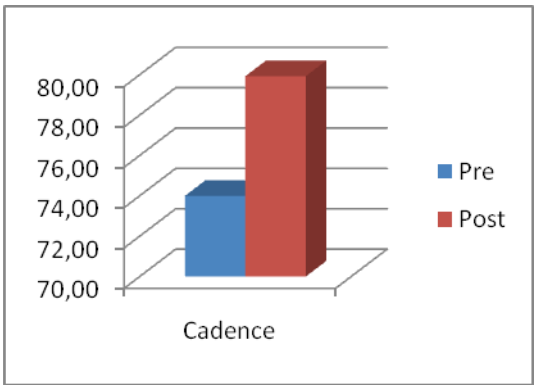
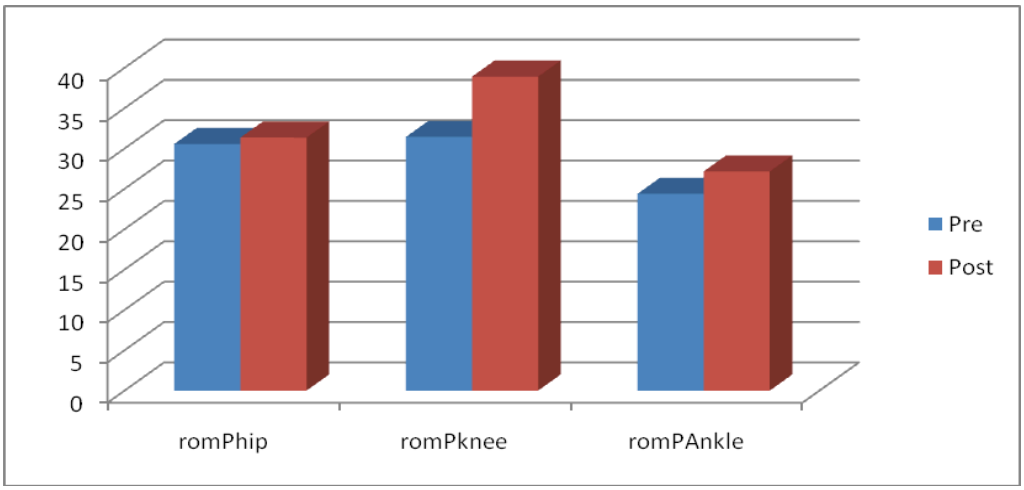


Figure 8: Cadence at T0 (blue column) and T1 (red column) in the Chinese group.



Kinematic data analysis in the Chinese group revealed a slight improvement in hip and ankle ROM between T0 and T1 and a significant improvement in knee ROM between T0 and T1 (Figure 9).

Figure 9: Kinematic features of Chinese group. romPhip= hip ROM of paretic side; romPknee= knee ROM of paretic side; romPAnkle= ankle ROM of paretic side. Blue columns represent T0 values, red columns T1 values



Time distance data analysis in Italian group revealed a significant gait speed improvement between T0 and T1 (Figure 10) and stride length of paretic side between T0 and T1 (Figure 11), while stance percentage of paretic side significantly diminished between pre- and post-treatment follow up (Figure 12)

Figure 10: Gait speed at T0 (blue column) and T1 (red column) in the Italian group.

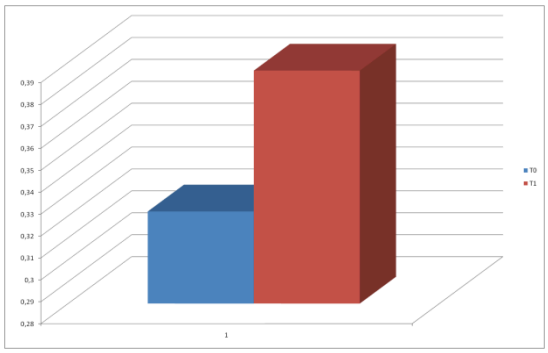


Figure 11: Stride length of paretic side at T0 (blue column) and T1 (red column) in the Italian group.

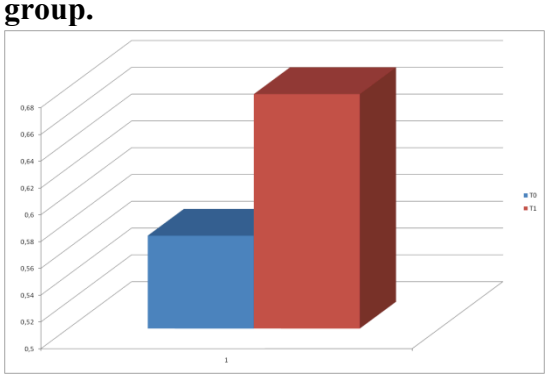
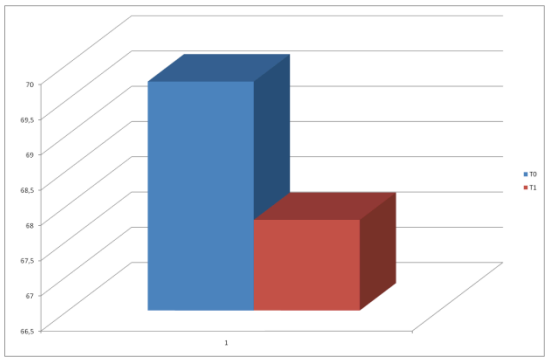


Figure 12: percentage of stance duration of paretic side at T0 (blue column) and T1 (red column) in the Italian group.



Patients in Italian group also displayed a significant increased cadence between T0 and T1 (figure 13), while duration of double support of both paretic and normal limb appear to be diminished between T0 and T1, the difference being significant only for paretic side (figure 14).

Kinematic data analysis in the Italian group revealed a slight improvement in hip and ankle ROM between T0 and T1 and a significant improvement in knee ROM between T0 and T1 (Figure 15).

Figure 13: Cadence at T0 (blue column) and T1 (red column) in the Italian group.

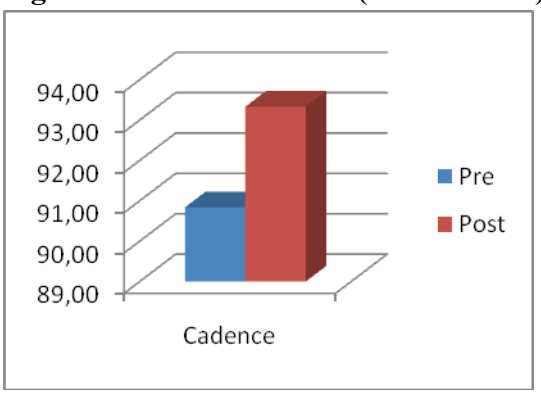


Figure 14: Duration of double support of both paretic (on the left) and normal (on the right) side in the Italian group. Blue columns represent T0 values, red columns T1 values.

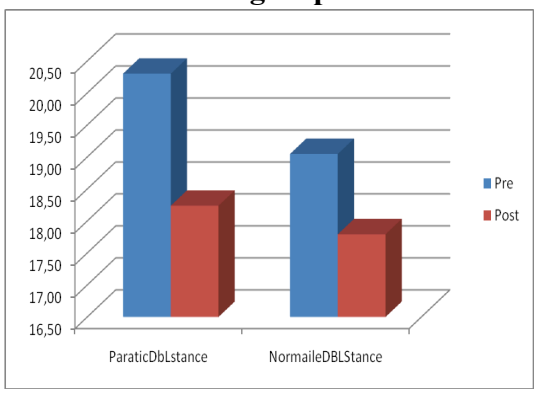
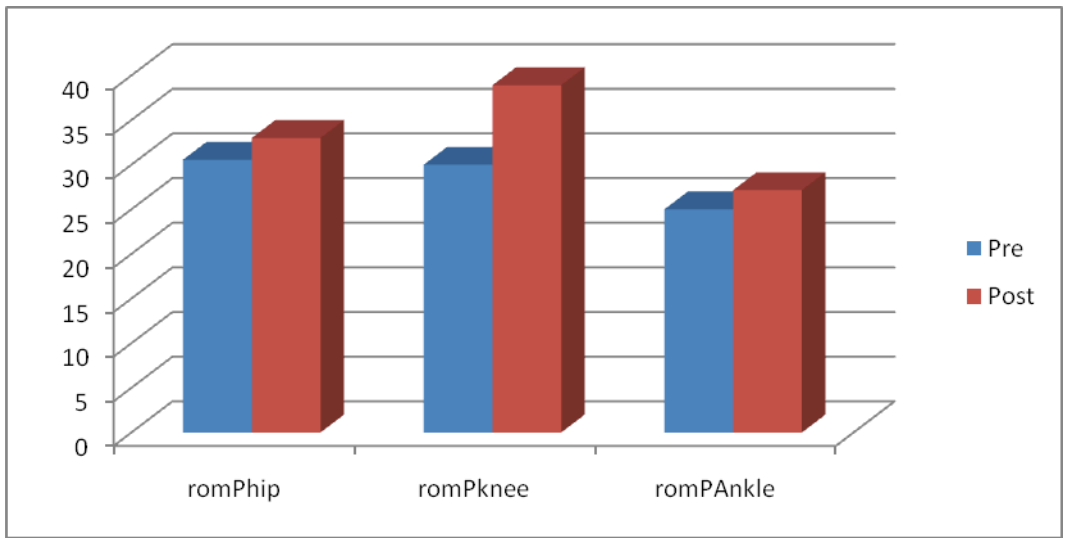


Figure 15: Kinematic features of Italian group. romPhip= hip ROM of paretic side; romPknee= knee ROM of paretic side; romPAnkle= ankle ROM of paretic side. Blue columns represent T0 values, red columns T1 values.



5. Discussion

The Mini Mental Status Examination (MMSE) is a tool used to detect cognitive deficits seen in syndromes of dementia and for measuring these monitor cognitive changes and its severity over time. The MMSE has a maximum score of 30 points, with different domains being assessed: orientation in regard to time and place (10 points), registration of three words (3 points), attention and calculation (5 points), recall of three words (3 points), language (8 points), and visual construction (1 point). Scores below 24 are considered abnormal and this is the cut-off used for dementia. The result of the study conducted in China show that TCM approaches, and particularly acupuncture, can improve the cognitive function of patients with stroke. Indeed, clinical studies suggest that acupuncture treatment may be able to relieve vascular dementia (VaD) symptoms and improve cerebral blood supply[20,21,22]. The results of our previous study showed that acupuncture may be useful in relieving symptoms of VaD[23].

The National Institute of Health Stroke Scale (NIHSS) is a quantitative measure of neurological deficits[24], generally accepted because of its simplicity and relatively rigorous design[25,26]. The NIHSS contains 15 items, including level of consciousness, eye movement, visual field deficit, motor and sensory involvement[27,28]. The items are summarized (maximum 34) and a lower score indicates fewer deficits. In general, an NIHSS score of less than 8 reflects a mild stroke, 8–15 a moderate to severe stroke and more than 15 a severe stroke. The stroke severity of the subjects admitted to our study in Tianjin was mild. The results of our study showed that the extent of patients' neurological function deficit could be improved by TCM approach. The NIHSS score decreased from pre-treatment (T0) to post-treatment (T1) and follow-up (T2), but the difference between T1 and T2 group was not significant. It suggested that the mild stroke patients can get beneficial effects on the neurological function recovery during treatment period, but the long-term effects maybe slight.

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Improving joint activity and reducing the muscle tonus are of great significance to the ability of patients' daily lives. Range of Motion (ROM) was determined with the subject's joints attached to the motor and manually moved to maximum. The active joint Range of Motion were measured with the patients achieve their joint angle in the largest activity. The passive joint Range of Motion were measured with the Patients achieve their joint angle by external force. Mean displacement amplitude was assessed 3 times by slowly moving the joint until the examiner perceived rapidly increasing resistance or the subject reported discomfort.[29]

Spasticity is a common impairment that follows stroke, and it results typically in functional loss. For this reason, accurate quantification of spasticity has both diagnostic and therapeutic significance. The most widely used clinical assessment of spasticity is the modified Ashworth scale (MAS). All stroke subjects were evaluated clinically using the MAS to assess muscle spasticity (range 1 to 5)[30] . The MAS give a 0–5 score range (1+ became 2, 2 became3, and so on). In our study, the modified Ashworth scale [2–4] was used to assess muscle tone in the upper extremities (elbow flexion).

For the paretic arm, other studies showed the 60 degrees AROM was (60%) which was smaller than the non-paretic arm and a slightly slower movement and less smooth trajectory than the normal arm[31]. As ROM and MAS reflected in our study in China that the muscle tone of 10 patients which were higher than normal were reduced in some degree after 1 month TCM treatment and 3 month follow up. The AROM of all joints but hip in affected side get increased by the end of treatment and follow up. Our previous study suggested that acupuncture was effective in reducing spastically increased muscle tone and motor neuron excitability in spastic hemiplegia, and could improve spastic states of stroke patients[32].

BI is a recommended measure for disability after stroke which was widely used in hospitals to assess the progress in rehabilitation[33] . BI includes a total of 10 items for assessing self care (feeding, bathing, grooming, dressing, toilet use, bowel and bladder control) and mobility (transfers, ambulation and stair climbing). It has scores ranging from 0 to 100 (100 indicating maximum degree of autonomy) and it is commonly and widely used in rehabilitation. Recently (Huybrechts et al, 2007) a literature review supported the use of BI also as a prognostic factor for long term-outcome after stroke. As in other studies that have investigated the value of acupuncture[34], we found that Chinese patients made improvements in the degree of independent performance of daily activities through global measures. When subscores of the global measures were used, differences between pre-treatment and post-treatment were apparent. Patients who received TCM approach demonstrated increased gains in the ability of self care (feeding, bathing, grooming, dressing, toilet use and bladder control) motor recovery in transfers, ambulation and stair climbing. There is no

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difference in the bowel control of pre-treatment compare to post-treatment. Since only one patient suffer from bowel occasional incontinent before treatment, and was recovery after one month treatment. Nevertheless, the proportion of the patients demonstrated increased gains was too small to result in the statistical difference.

As for mechanisms of acupuncture, recent work has specifically investigated the physiological mechanisms that may underlie the therapeutic effect of acupuncture. Acupuncture may provide a form of sensory stimulation that stimulates polymodal type receptors providing a source of peripheral afferent stimulation via the spinal cord to central nervous system structures[35,36.] After stroke, acupuncture has been found to induce changes in regional cerebral blood flow (rCBF) that may increase flow to hypoperfused areas of the ischemic penumbra[37]. Changes in rCBF have also been attributed to acupuncture in the hypothalamus-limbic systems in response to stimulation of analgesic points, providing further support for localized cortical effects attributable to acupuncture stimulation[38]. Additionally, stroke recovery has also been associated with neurotrophic factors that are capable of supporting neuronal survival after stroke[39]. Recent animal work is beginning to demonstrate that acupuncture can enhance neurotrophic factor expression that promotes cell survival and prevents apoptosis.[40,41]

As for the study conducted in Italy, the results confirm that WM approach to stroke rehabilitation is useful and lead to clinical and functional improvement, as assessed by common used clinical scales. The overall increasing of BI scores is associated, in our sample, with an improvement of patients' neurological function deficit, as revealed by the NIHSS score between T1 and T2, therefore suggesting a long-lasting effect of rehabilitative approach.

The study aimed at assessing the possibility of evaluating stroke patients evolution after a rehabilitative approach in different countries, with different therapeutic strategies and different operators, by means of the same reproducible instrumental evaluation. For this purpose, we chose to assess motor recovery in the Chinese and Italian patients through instrumental gait analysis (GA).

In the past, deambulation was recorded through a camera system that provided a qualitative measure of the patient locomotion, which was then interpreted subjectively by the clinicians. This type of detection, however, proved to be too qualitative and incomplete. Indeed, the video analysis does not provide information on the force exchanges (dynamics) and muscular activity (electromyography) of the movement analysed. These limits can be overcome by using a quantitative analysis of deambulation, such as GA, which provides quantitative information with

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reference to the movement kinematics as well as the dynamics and electromyography. Three-dimensional kinematic and kinetic studies, which are among the available technological investigations for gait, can help in the identification of abnormal gait patterns (Patrick, 2007). GA is important to assist in the rehabilitation procedures, as has been said and discussed for decades (Takebe, 1976, Knutsson, 1994), and GA procedures have been used to assess the validity for both local (Johnson et al, 2004, Hirsch et al, 2005, Intiso et al, 1994) and general (Yang, 2005, Remy-Neris, 2003, Lennon, 2006) treatment strategies.

Several components affect gait performance in hemiplegic patients: gain in standing balance control, for example, seems to be more important than improvement in leg strength or synergism to achieve better walking abilities, whereas reduction in visuo-spatial inattention is independently related to gait performances. Finally, time itself is an independent covariate that is negatively associated with change on functional ambulation, suggesting that most pronounced improvements occur earlier after stroke (Kollen et al, 2006). Post- stroke gait characteristics have been widely described (Perry et al, 1995) as well as the effect of different physical impairments on hemiplegic's walking (Hsu et al, 2003).

The GA evaluation revealed in both studies in China and Italy a significant increase in gait speed. As gait speed is considered to be an important marker of deficit severity and functional ability after stroke (Schmid et al, 2007), speed gains resulting from the application of physical treatments are the object of considerable interest in clinical gait studies (Dickstein, 2008). In the literature, the speed threshold that distinguishes individuals who are able to return home after a stroke from those who need long-term care is reported to be 0.15 m/s; restricted and unrestricted indoor ambulation can be achieved at mean walking speeds of 0.16-0.25 m/s and 0.26-0.42 m/s, respectively; speeds of 0.43-0.79 m/s permit restricted community ambulation, while speeds of 0.80-1.20 m/s permit slow unrestricted walking in the community (Dickstein, 2008). In both groups speed gain was associated with an increase in cadence, which thereby could be identified as a main contributor for increasing gait velocity. It's noteworthy, however, that also kinematic changes could be observed in both groups, which could justify the observed increased gait speed. Particularly, increasing ankle ROM probably allowed our subjects to improve both the foot clearance during the swing phase and the foot position during initial contact in the stance phase at the post-treatment evaluation. Foot clearance, which represent a detrimental factor in determining final gait velocity, could be further ameliorated by increased knee ROM during the whole gait cycle. Increasing ROM at lower limb joints also account for a final stride length improvement. This factor should be important in order to determine a functional gait, especially in the outdoor.

Patients in both studies also displayed a better loading transfer function at T1, as revealed by the reduction in double support duration of both paretic and normal side and by the reduction of percentage of stance phase in the paretic limb at post-treatment evaluation.

A significant result of the present research is represented by the concordance between gait analysis results obtained in Chinese and Italian groups. This would probably represent that gait analysis evaluation could be considered as a sensitive evaluation method, in order to detect functional improvement in gait functioning as the result of a given therapy.

We may however confirm the initial hypothesis that an objective instrumental evaluation, such as GA, could be useful in assess motor recovery after stroke, also when different therapeutic approaches are considered and when it is performed in different settings.

6. Conclusion

This study described the diagnosis and classification of stroke in TCM as well as TCM approaches for stroke rehabilitation. We evaluated the effectiveness of TCM therapy on stroke by clinical measures. The results of this study showed that TCM approaches may improve the cognitive function, neurological impairment and independent performance of daily activities, reduce the muscle tone and enlarge the active range of motion.

At the same time, the evaluation of a set of time-distance parameters (stride duration, step length, step width, percentage swing phase duration, and swing velocity) allowed a thorough analysis of gait. The analysis show a significant improvement of some of these parameters in both Chinese and Italian acute patients treated respectively with TCM and Western rehabilitation approach.

Finally, the study results show see a correlation between the clinical data and the parameters acquired through GA, since the improvements in walking are documented by both the Barthel index and other clinical evaluation scales, as well as the GA acquisitions.

In future, we should carry out the well-design randomized controlled trial to confirm the effectiveness of TCM approaches for stroke rehabilitation.

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