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Western and Traditional Chinese Medicine Approaches to Stroke Rehabilitation: a Descriptive Study Protocol

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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 is thus 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 will finally provide 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 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

Stroke is the third leading cause of death in the World.[1] In China, stroke is the second most common cause of death in cities, and the third most common cause of death in rural areas.[2] Each year, approximately 780,000 people experience a stroke and about 600,000 of these are first attacks. With stroke accounting for approximately one out of every 16 deaths in the United States of America in 2004, approximately 54% of these stroke deaths occurred out of hospital.[3] Fifty percent of survivors experience significant disability and 10% require long-term institutional care.[4] As such, stroke is a major burden for both family and society.

Rehabilitation following acute stroke needs to be a comprehensive tool in which all of the impairments derived from the cerebrovascular accident are considered, to improve function and to help the patient gain new autonomy. Mobility recovery is 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.

There are several different approaches to physiotherapy treatment after stroke. However, despite considerable research efforts into multiple treatment modalities[5], there is still no single intervention that is recommended unequivocally for stroke rehabilitation.[6]

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

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[1] Bonita R. Epidemiology of stroke. *Lancet*. 1992;339:342–344.
[2] Chinese Health Statistical Digest. Ministry of Health, People's Republic of China 2000;200:260.
[3] Rosamond W, Flegal K, Furie K, et al. Heart Disease and Stroke Statistics 2008 Update: A Report from the American Heart Association Statistics Committee and Stroke Statistics Subcommittee. *Circulation*. 2008;117:e62–63.
[4] Director of Public Health. Annual Report. Southampton and South West Hampshire Health Commission, 1994.
[5] 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.
[6] Intercollegiate Stroke Working Party, 2004; SPREAD, 2007

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.

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.[7]

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 is 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, are conducting a descriptive study on Western and TCM approaches to stroke rehabilitation. The aim of the study is to investigate the functional recovery in patient walking activity and to monitor the global improvement in their activities of daily living. The study is currently ongoing, and the results will be presented at the end of the project, in November 2008.

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[7] Sze FK et al., 2002.

Here we present the study design and argue for an important role for GA combined with clinical and functional evaluation scales in the future assessment of post-stroke rehabilitation 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 and in chronic post-stroke patients.
4. To measure physical improvement after Western medicine treatment through clinical and functional evaluation and GA in acute post-stroke patients and in chronic post-stroke patients.
5. To compare the degree of agreement between the evaluation scales used to measure physical improvement after both Western and TCM 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

The study is 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 is aimed at describing the clinical diagnostic protocol used by TCM in stroke rehabilitation, according to the available documentation, the observational activity of clinical practice, and the records at the First Teaching Hospital of Tianjin University of Traditional Chinese Medicine. This phase includes 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 is aimed at acquiring sufficient data from two different groups of patients, one with acute stroke and the other with a chronic condition related to an earlier stroke, with patients selected according to the inclusion and exclusion criteria specified in the study protocol. This phase consists of a descriptive study of the patient treatment (Western and TCM) and the measurement of physical improvements after the Western and TCM treatments, monitored through clinical and functional evaluation and GA. Since the assessment of the effectiveness of both approaches goes beyond the scope of this study, the study design does not foresee control groups.

a. Recruitment of Study Participants

Inclusion Criteria:

A. Acute Post-Stroke Patients
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.

B. Chronic Post-Stroke Patients

In-patients in a rehabilitation department, of either sex (age 40-75 years), affected by chronic right or left hemiplegia following a first ischaemic or haemorrhagic stroke event documented by computer tomography or magnetic resonance imaging and ability to walk autonomously (including using a cane). A chronic condition is defined as when an event occurred at least three months before.

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) ($\leq$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 is 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 is 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.[8] The team leader is a physiatrist, who coordinates the team work and defines the main rehabilitative goals. A neurologist,

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

physiotherapist, occupational therapist, psychologist and social assistant collaborate with the physiatrist. Rehabilitation following acute stroke is performed in an in-patient setting for a period of 40-60 days, and in an out-patient setting afterwards, as necessary.

c. Evaluation

Each patient included in the study is 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, all clinical, functional and instrumental evaluations are 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

4. Gait Analysis Procedures for Data Collection and Analysis

GA is performed using the SMART-D stereophotogrammetric system (BTS, Milan, Italy)[9] with six infrared video cameras (TVC) for the acquisition of the kinematic variables. A Kistler platform (Kistler Instruments, Winterthur, Switzerland) is used to acquire ground reaction forces.

The surface myoelectric signals are acquired with a sampling rate of 1,000 Hz using a Wi-Fi transmission surface electromyograph (FreeEMG System, BTS, Milan, Italy). The patients are instructed to walk at a self-selected speed along a level surface approximately 10 m in length and practice until they can consistently and naturally make contact with both of the force platforms. Five trials are acquired for each patient.

a. Data Analysis

The data elaboration includes the determination of joint centres of rotation and the calculation of joint angular excursion and internal moments (Davis et al., 1991; Vaughan et al., 1999). These are performed by means of Smart Analyzer software (BTS, Milan, Italy). Within the stance phase, the two sub-phases of stance and swing are considered.

As time-distance, the following are evaluated:

Rhythm and Asymmetry:
- *step length* (SL) (i.e., the distance between two consecutive heel-floor contacts) (Perry, 1992, Oken, 2007),
- *single support time percentage* (Oken, 2007) (percentage of the single support time duration with respect to the gait cycle),
- *walking velocity* and *comfortable speeds* (Oken, 2007, Chen, 2005, Kwakkel, 2002),
- *Spatial Asymmetry Index* (Chen, 2005):
- *Temporal Asymmetry Index* (Chen, 2005):

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[9] The equipment of the Movement Analysis Laboratory installed at the First Teaching Hospital of Traditional Chinese Medicine was provided under a loan for use agreement by BTS, Milan, Italy and Samwell Testing Inc.

Load Transfer

- *Double support time percentage* (Goldie et al, 2001) (percentage of the single support time duration with respect to the gait cycle)

Equilibrium:

- *step width* (Chen, 2005)

b. Statistical Analysis

To investigate the presence of significant differences within each group for the kinematic and kinetic parameters, a two-way analysis of variance (ANOVA) is used. A Bonferroni *post-hoc* comparison is 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. Multivariate analysis is performed to determine the correlations between the clinical, functional and biomechanical protocols.

5. Preliminary Results and Discussion

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. Whereas in Western medicine stroke is divided into two kinds, ischaemic and haemorrhagic, according to TCM, 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. The patient with stroke can manifest seven patterns of syndromes in TCM: fire sufficiency of wind and phlegm, wind fire upper-disturbance, phlegm-heat and fullness in fu-organs ,stagnation of wind and phlegm, phlegm-dampness masking spirit, qi deficiency and blood stasis, wind movement due to yin deficiency (kidney and liver).

For clinical practice, in Western medicine, stroke treatment is focused primarily on patient stabilization in the acute phase, and on patient recovery from the impairment through rehabilitation; in contrast, TCM provides a comprehensive integrated approach to stroke patients, which is aimed at:

- activating the brain and open the orifices;
- dredging and activating the meridians and collaterals;
- invigorating and nourishing the *shen* (kidney) and *gan* (liver);

- regulating the imbalance of yin and yang;

- enriching the *xue* (blood);

- reinforcing the *qi* and restoring the yang.

Acupuncture has an important role in the 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. Indeed, according to TCM theories, *Acupuncture* should be practiced as early as possible, and it can activate the brain and open the orifices, dredge the meridians, invigorate the *shen* (kidney) and *gan* (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, a new acupuncture protocol is now used, known as *Xing Nao Kai Qiao* (XNKQ; "activating the brain and opening the sensory orifices")[10], which is particularly different from the traditional systems of acupuncture point selection, and from the traditional needle methods used elsewhere in the treatment of stroke.[11]

Moreover, Chinese *herbal* prescriptions, which are formed from various herbs through a formula compatibility principle, can drive away the *feng* (wind), enrich the *xue* (blood), activate the meridians and collaterals, nourish the *gan* (liver) and the *shen* (kidney), reinforce the *qi* and restore the yang for patients with stroke. Finally, *Tuina* is a Chinese massage technique that helps to improve motor skills, and has peripheral and systemic effects.

At this stage of the descriptive study, with the data collection for the two, acute and chronic, groups of patients still ongoing in China and Italy, we have chosen to evaluate a set of time-distance parameters with the Chinese acute patients treated with TCM. These allow a thorough analysis of gait, as: stride duration, step length, step width, percentage swing phase duration, and swing velocity. The preliminary and partial results of the data analyzed to date show a significant improvement of some of these parameters in the Chinese patients treated with TCM in Tianjin. Indeed, the patients

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[10] The protocol was developed by Prof. Shi Xuemin, Academician of the China Academy of Engineers, Professor and Honorary President of Tianjin University Hospital. The "Xing Nao Kai Qiao" acupuncture therapy was given practical clinical application in the treatment of 9,005 cases following strokes in three stages, included 5,928 cases of patients with cerebral infarction and 3,077 cases with cerebral hemorrhage.

[11] Du Li *Treatment of stroke with acupuncture* http//nccam.nih.gov/health/acupuncture.

analyzed at the first follow up (T_1) show a significant longer stride duration, lower swing velocity, shorter step length and greater step width, than at T_0. At this stage, it is also possible to 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.

The partial and provisional results of this study thus confirm an important role for the use of GA, along with the clinical and functional evaluation scales, for the assessment of post-stroke rehabilitation programmes. In particular, all of the professionals working on stroke rehabilitation feel particularly the need for a quantitative measure of deambulation.

Post-stroke gait characteristics have been widely described (Perry et al, 1995), along with the effects of different physical impairments on deambulation of the hemiplegic patient (Hsu et al, 2003). 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 reference to the movement kinematics as well as the dynamics and electromyography.

Dynamic electromyography and 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.

6. Conclusions

The available technological investigations for gait that might be useful for the evaluation of improvements in walking impairment in stroke patients are rarely carried out beyond the more common applications in diagnosis and treatment. This study suggests that through its non-invasive, high precision and user friendly characteristics, GA is particularly suited to this purpose. By measuring the movement of the body in space (kinematics) and the forces involved in producing movements (kinetics), GA is very useful to provide 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, and in the final analysis, aid in the future assessment of TCM effectiveness.

By objectively measuring the walking improvements after TCM treatment, the results of this study may justify future randomized controlled studies to demonstrate the effectiveness of the TCM approach for stoke rehabilitation. However, since Western diagnosis can correspond to different Chinese 'syndromes', while a Chinese 'syndrome' in itself might be common to a set of different ailments, as seen, it is important that the WHO recommendations[12] are followed:

"It is important that traditional medical theory is not ignored in the context of a good trial design. In some cases, whilst a modern medical diagnosis may be required for the purpose of screening and including patients for a clinical trial, the trial should be designed to permit a traditional diagnostic and therapeutic approach to practice. Practice is particularly individualized in traditional medicine and a research design that moves too far from traditional medicine practice would no longer achieve its purpose in evaluating traditional medicine."

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[12] WHO *Traditional and Modern Medicine: Harmonizing the Two Approaches* 2000

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