Acupuncture treatment on gait problems in multiple sclerosis: a preliminary study

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Abstract
Multiple sclerosis (MS) is considered a disease of the central nervous system, complex and heterogeneous from the clinical point of view. The underlying aetiology and pathogenesis of the disease is not completely elucidated. The clinical manifestations of MS are highly variable and unpredictable but gait dysfunction is one of the most debilitating symptoms. Approximately 85% of patients indicate impaired gait as one of the major limitations in their daily life.

Acupuncture, as a therapeutic form of Traditional Chinese Medicine (TCM), regulates the vegetative functions to maintain homeostasis by stimulating self-regulation mechanisms. Acupuncture studies found a reduction of spasticity and improvement of fatigue and imbalance in MS patients, but there is a lack of studies regarding gait.

Based on the Heidelberg model of TCM, an acupuncture prospective, randomized and controlled study in cross-over design was design in order to investigate if it is useful on gait problems in patients with MS. The sample consisted of 20 individuals with diagnosis of MS of relapse-remitting type (RRMS). Gait impairment was evaluated by the T25FW and Tandem walking test (TWT). It was also asked to all patients to answer the survey Multiple Sclerosis Walking Scale 12 (MSWS-12).

The preliminary results obtained in the present study could support the idea that T25FW and TWT tests are sufficiently sensitive to changes that occurred as a result of treatment and can therefore be a useful tool as a clinical measure of gait in studies involving acupuncture. Also, preliminary results presented here could point out that acupuncture treatment, according to Heidelberg model of TCM, can result in improvements in mobility in MS population.

Keywords: Multiple sclerosis, gait dysfunction, acupuncture, Heidelberg model, T25FW test, effective therapy

Introduction
Multiple sclerosis (MS) is an inflammatory, demyelinating neurodegenerative disease of the central nervous system, considered as the most common cause of chronic neurological disability in young adults1. MS affects more than 2.5 million people worldwide2. Although important advances in our understanding of the cellular and molecular aspects of MS have been achieved, there is still a long way to elucidate the underlying aetiology and pathogenesis of the disease.

The clinical manifestations of MS are highly variable and unpredictable. There are no clinical findings that are unique to MS, but some are highly characteristic of the disease. In this sense, gait dysfunction represents one of the most debilitating symptoms experienced by MS patients. Gait is a complex process involving coordination of multiple systems within the body (central nervous, musculoskeletal and cardiovascular systems) 3. 85% of individuals with MS report gait impairment as a major limitation of their lives4. Gait impairment in MS is believed to be linked to leg strength, spasticity, aerobic capacity and fatigue. Also, there are increasing evidences that cognitive functions are also involved 5,6,7. Although assessing gait disability is of great importance, there is no consensus regarding the most appropriate tool for characterization of gait dysfunction5. Timed walking over a fixed distance has been extensively used as a clinical measure of gait in a variety of neurological conditions and forms part of a recommended outcome measure for clinical trials.
in multiple sclerosis. The most common of timed performance tests is the 25-foot walk test (T25FW). Acupuncture, as a therapeutic form of Traditional Chinese Medicine (TCM), aims to normalize the vegetative functions to maintain homeostasis of the organism by stimulating self-regulation mechanisms. Acupuncture is considered to be effective in several diseases and further research is likely to uncover additional areas where acupuncture interventions will be useful. Literature regarding the application of acupuncture in neurological diseases has reported reduction of pain, numbness and tingling, significant improvement in sensory and motor function, less spasticity, enhanced motor function, and significant improvement in fatigue. However, literature regarding gait impairment is scarce.

Taking this into account, we present the design and preliminary results of a study of acupuncture treatment, according to the Heidelberg model of TCM, with the aim to investigate if acupuncture can be a useful therapeutic strategy in patients with gait impairment in multiple sclerosis of relapse-remitting type.

Material and Methods
This study had the collaboration of the two associations of patients with MS with facilities in Oporto region: the "National Association for Multiple Sclerosis" (ANEM) and the "Portuguese Multiple Sclerosis Society" (SPEM). The criteria for inclusion/exclusion of the patients in the study are shown in Table 1

<table>
<thead>
<tr>
<th>Inclusion criteria</th>
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<td>Patients with diagnosis of MS of Relapse-Remitting type</td>
<td>Patients with diagnosis of other pathologies.</td>
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<td>18-70 years of age</td>
<td>Patients with psychiatric diseases.</td>
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<td>Stable symptoms in last two months</td>
<td>Patients with severe cognitive deficiencies.</td>
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<td>EDSS (Expanded Disability Status Scale) between 3 and 7.</td>
<td>EDSS (Expanded Disability Status Scale) higher than 7.</td>
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After applying these criteria, 20 patients were selected (12 females and 8 males). Figure 1 represents the flow chart of the intervention process.

Evaluation of gait impairment was done by the 25-foot walk test (T25FW). The following instructions were given to patients for the completion of the test: "walk, as fast and safely as you can, across a clear marked linear 25 feet course. There are no turns, start is static and assistive device can be used". After that, the same test was done but in a tandem walking way. Tandem gait is a method of walking where the toes of the back foot touch the heel of the front foot at each step. Tandem gait is a test for unsteady gait to bring out abnormalities in gait and balance.

It was also asked to all patients to answer the survey Multiple Sclerosis Walking Scale 12 (MSWS-12). This survey consists of 12 questions that assess gait impairment impact perceived by the patient. The MSWS-12 has been validated as a measure of walking function for Portuguese language.

Acupuncture treatments were administered only by one acupuncturist. For the study, a standardized acupuncture protocol was developed, based on the Heidelberg Model of TCM. True acupuncture was done using acupuncture points, anatomically located in the lower extremities: ST34, BL40, BL57. Sham acupuncture was done using points located 2 cun laterally to the ulnar border of the leg, out of any meridian. Acupuncture technique called "Leopard spot technique" was used in the study. In this technique some drops of blood let out from peripheral points by quickly stabbing the skin with the needle. For this technique, sterile disposable needles with a size of 30G, 0.30x8mm were used (BD Micro-Fine®).

Preliminary results
The study sample consisted of 20 individuals recruited from the two MS associations that are operating in Oporto region, ANEM and SPEM. All the individuals had the diagnosis of multiple sclerosis of relapse-remitting type (RRMS), without any relapse in the previous two months. From the 20 patients, 12 were females (60%) and 8 males (40%). These results correspond to a female-male ratio of 1.5. With respect to quantitative variables, the mean age of the sample was 46.3±11 years, the mean time from diagnosis was 11.4±8 years and a mean age at diagnosis of 35±12 years. Taking males and females separately we observed that according to our data, both, the mean age and the mean age at diagnostic, were lower in males than in females. Tiredness and misbalance was pointed out by females as the main complain (30% and 25%, respectively). In the male sample, fatigue, tiredness and misbalance had the same importance (10% each). The use of assistive devices was only observed in the female sample.

Results of the 25-Foot Walk test (T25FW) were measured in seconds. Table 2 shows the preliminary results obtained before and after each true acupuncture and sham acupuncture treatment in
Among clinical manifestations of MS, gait dysfunction represents one of the most weakening symptoms considered by most of the MS patients as a major limitation of their lives. Several factors, such as weakness and spasticity from pyramidal lesions, loss of co-orientation from dorsal column, and cerebellar lesions, together with visual and cognitive dysfunction, pain, and also environmental and personal factors can contribute to walking disability. One of the priorities managing with MS is to define strategies to control the symptoms and to prevent secondary complications and increased disability associated with the disease. It must take into account that the resulting limitations of the disease are associated with strong social and economic impacts. Symptomatic treatment must be carefully planned and suitable for each patient.

Acupuncture represents a potential useful therapeutic option to consider within the overall management of individuals with MS. Scientific literature regarding the application of acupuncture in neurological diseases has been reported. However, literature regarding gait impairment is scarce, and therefore additional studies using appropriated outcome measures are required. Also, it is important to point out that according to several authors one of the advantages of acupuncture is that the occurrence of adverse side effects is very low.

Taking this into account, we present the design and preliminary results of a study of acupuncture and preliminary results of a study of acupuncture. Taking this into account, we present the design and preliminary results of a study of acupuncture and preliminary results of a study of acupuncture.

Our results will refer to paired samples. The use of paired samples offers the benefit of controlling extraneous factors that can influence the results. The time interval between the first and the second treatment was, at least, of two weeks. This period of time is important to avoid that results from the first treatment interfere in the second one. For the evaluation of the treatment, in terms of gait improvement, we used the 25-Foot test and the Tandem walking test. They represent a good measure of overall gait ability and balance. The preliminary results obtained in the present study can support the idea that these tests are sufficiently sensitive to changes that occurred as a result of treatment and can therefore be a useful tool as a clinical measure of gait in studies involving acupuncture. This is an important aspect as well designed research is required to guide practice more effectively, and appropriated outcome measures (objective and measurable parameters) need to be carefully considered in order to contribute to the credibility of the effectiveness of acupuncture treatments.

With respect to the evaluation of the acupuncture treatments, our results seem to point out to a reduction in the time spent to perform the tests with true acupuncture treatment. If these observations were confirmed in the whole sample it could mean that the treatment protocol used in our study for true acupuncture is significantly more effective in improving gain impairment than sham acupuncture. In summary, the protocol used and preliminary results presented here could point out that acupuncture treatment, according to Heidelberg model of TCM, can result in improvements in mobility in MS population.

Acknowledgements

The authors thank the “Sociedade Portuguesa de Esclerose Múltipla” (SPEM) and “Associação Nacional de Esclerose Múltipla” (ANEM) for their collaboration in this study.

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