



## Case Report

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# Effectiveness of Acupuncture in People Affected by Amyotrophic Lateral Sclerosis (ALS): A Quasi-Experimental Study

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## Abstract

Amyotrophic Lateral Sclerosis (ALS) is a fatal disease that triggers a progressive paralysis of the body with very poor prognosis and short life expectancy (3 to 5 years after diagnosis). This research is based on a quasi-experimental study with Acupuncture in people with ALS to know the effectiveness of Acupuncture in relation to the symptoms associated with the disease. We recruited 13 patients, 6 men and 7 women followed Acupuncture treatment. The acupuncture treatments consisted of 10 personalized sessions per person over 3 months. In each session, the pulse and tongue diagnosis of each participant was evaluated for the selection of the Acupuncture points to treat. To know the effectiveness of Acupuncture, patients self-assessed pain with the EVA scale, fatigue with the Borg scale, anxiety with the Hamilton scale, quality of life with the ALSAQ scale and functional status with the ALSFRS scale before and after of the treatments. At a statistical level, the parametric Student test for paired samples was used. The results showed us that Acupuncture was effective in reducing pain, anxiety and fatigue. No significant changes were observed in the ALSAQ and ALSFRS scales.

## Keywords

Acupuncture, Effective treatment, Neurodegenerative disease, Personalized treatments, Quasi-experimental study

## Introduction

ALS is a neurodegenerative disease that affects the body's motor neurons (MT). This neurodegeneration causes irreversible progressive paralysis of the entire body except for the oculomotor nerve. The muscles are weakened and atrophied by nerve-muscle denervation. The etiologies of the disease as well as a curative treatment are unknown. The Conventional Medicine (CM) wanders between multiple hypotheses such as glutamate excitotoxicity, contact with heavy metals, some viral or inflammatory processes, among others [1-6]. Currently, conventional medical treatments indicated to cure or alleviate the symptoms are insufficient [7-11]. Because of this, we try to find new therapeutic answers from Traditional Chinese Medicine (TCM). To do this, we analyse ALS from an energetic perspective where morbid processes are caused by yin and yang disorders. The focus of medical attention of TCM is on the person and all its dimensions while CM focuses its efforts on knowing the biological causes of disorders.

After an extensive bibliographic review of the literature on Acupuncture applied to people with ALS, we find few studies.

The low population incidence of ALS in the world (0.4 and 2.6 per 100,000 people per year and the prevalence is 6 cases per 100,000) makes it difficult to study the disease. In the review we found studies that conclude that Acupuncture has been effective in symptomatic treatment. This fact coincides with the results obtained after the application of Acupuncture in our quasi-experimental study. We conclude (after the statistical analysis by T-Student) that the Acupuncture treatments improved the health status of the participants in relation to pain, anxiety and self-perceived fatigue.

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In recent years, conventional medicine has seen an increase in interest in acupuncture. In part this has been due to the research of Acupuncture using imaging techniques such as Magnetic Resonance Imaging (MRI). These studies concludes that Acupuncture performed at certain points or areas of the body is capable of modulating the function of the nervous system by activating and inhibiting various physiological responses, such as increasing blood flow in certain brain areas, increasing nervous activity in motor areas, the activation of T lymphocytes, the massive release of different neurotransmitters and the moderate inhibition of pro-inflammatory cytokines related to neuronal death. In investigations of specific cases of people affected by strokes, it has been observed that Acupuncture triggers neurogenesis processes, a significant improvement in ischemic synapses and a decrease in neuroinflammation [9,11-14].

Acupuncture causes stimulation of peripheral nerve fibers, sending impulses to the spinal cord and activating various brain centers releasing neurotransmitters that exert a homeostatic effect throughout the body. Furthermore, Acupuncture modulates the neural activity of the diencephalon, exerting an influence on the autosomal, endocrine and immune functions of the hypothalamic-pituitary-adrenal axis, in turn regulating the release of ACTH, vasopressin and cortisol. All of these investigations provide scientific evidence that the acupuncture technique is potentially beneficial in cases of neurodegenerative diseases, such as ALS [15,16].

We know from conventional medicine that the etiology of ALS is caused by the death of motor neurons in the peripheral nervous system. From here, we carry out a bibliographic review and interpretation of the possible energy imbalances that may cause this type of disorder. We found inside the TCM perspective that excessive work, physical exhaustion, little sleep, bad eating habits and excessive thinking and worrying could be the causes of muscle weakness and paralysis. Another factor to take into account in the case of men is the excessive loss of semen. It's considered an essential fluid in Kidney yin energy; this means that the loss of semen causes a significant energy deficiency directly related to the nervous system. This Qi deficiency causes problems of generalized asthenia and mental injury.

The pathophysiology of ALS according to TCM is defined through the differential energetic diagnosis of the affected person. In all of ALS patients of this study have a functional relationship between motor neuron (Kidney yin) and muscle (Liver yin), so a pattern of liver yin deficiency caused by a predominant Yang would mean excessive muscle rigidity, contractions, spasms, numbness of the limbs, muscle cramps, tremors, lack of limb strength and paralysis. This phenomenon can also result in a blood vacuum often preceded by a Blood Stasis (blockage). In diagnostic terms, ALS could be caused by an energetic imbalance caused by an excess of maintained yang that consumes yin. If this energetic situation persists over time, the Qi falls and the body weakens, generating a picture of asthenia and paralysis due to lack of energy, a clinical picture that fits with the manifestations of ALS. That said, ALS is classified by TCM as a "Flaccidity Syndrome", "Wei

Zheng" in Chinese [17] or Atrophy Syndrome [18]. There are different energetic diagnoses that may be compatible with ALS, such as a spleen and kidney yang deficiency associated with phlegm, dampness and Xue Ecstasy. A Kidney yin deficit due to the progressive loss of functional motor neurons [19].

## Materials and Methods

### Study oversight

The research design is longitudinal and experimental study with no control group. To analyse the data, qualitative research techniques such as participant observation, field diaries and semi-structured interviews with patients/relatives are applied, as well as quantitative research techniques such as self-assessment of validated scales EVA (pain), ALSAQ (quality of life), ALSFRS (functionality), Borg (fatigue) and Hamilton (anxiety).

### Patients

Patients were subjected to the following selection criteria:

**Inclusion criteria:** People diagnosed with ALS who voluntarily agreed to be part of the research.

**Exclusion criteria:** Pregnant women, people undergoing active treatment with chemotherapy or radiotherapy, people with cognitive impairment or unaccompanied captivity syndrome, people with other neurodegenerative diseases such as Parkinson's, Alzheimer's or Multiple Sclerosis.

### Materials

For this research we used sterile single-use needles, made of steel and with a silver handle, of two sizes, 0.5 cun and 1 cun. For correct insertion of the needles, material to disinfect the skin: cotton and 95 °C alcohol. Smokeless moxas were also used for moxibustion in cases of great weakness and energy deficit. For contractures we perform Acupuncture with electrostimulation using an electro-stimulator machine.

### Procedures

The Acupuncture treatments lasted 60 minutes. The visit consisted of a medical examination through listening to the explanations, observing the tongue, palpating pulses, performing the energy diagnosis and selecting Acupuncture points.

There is no control group in this research but we do make two differentiated observations based on "the period of active acupuncture" and "the period of no acupuncture" that somehow become control observations. The active acupuncture period consisted of acupuncture applications 1 or 2 times per week. The non-Acupuncture period was 21 days of acupuncture rest but continuation of the usual medical treatments (drugs, rehabilitation, massages...). The patients recorded their health status, symptoms and discomforts via text message or phone calls with the intention of knowing how they were without Acupuncture.

### Research methodology

The research methodology is the sum of quantitative and

qualitative research techniques in order to know the reality of patients with ALS before and after Acupuncture treatments, but in this article, we focus on quantitative methodology. Patients with ALS self-assessed their pain, fatigue, anxiety, functionality and quality of life before and after Acupuncture treatments using the EVA, BORG, Hamilton ALSFRS and ALSAQ scales respectively. Statistical analysis was performed with the PSPP software program. To find out if Acupuncture was being effective, we performed the T-Student test paired data.

There is no control group for ethical reasons. ALS is a fatal disease with a very poor prognosis and short life expectancy (3 to 5 years after diagnosis), so all patients were treated with Acupuncture.

## Results

Thirteen patients participated in the study, 6 men and 7 women. The average age of the patients was 54.76 years, with an age range between 39-69 years. In the case of men, the average age was 52.67 years and the range oscillated between 39-69 years, while in women they had an average of 56.71 years and the age range oscillated between 41-69 years.

Regarding the type of ALS, medullary or spinal ALS predominated, which was diagnosed in 11 patients out of 13 (85% of the sample). Only two patients were diagnosed with familial ALS (15% of the sample).

The average time of diagnosis among patients was 1.46 years once symptoms had been detected, with the minimum time of diagnosis being 1 year to the maximum time of 3 years. Of the patients, 61.53% were diagnosed after one year, while 30.76% were diagnosed after 2 years and only 7.69% after 3 years since the first symptoms.

The most prominent comorbidities of the patients were muscle cramps, insomnia, depressive syndrome, dysphagia and dysarthria. See Table 1 where identifies the clinical comorbidities of the patients in the sample (Table 1).

Following the speeches of the patients and caregivers, certain risk factors that influence the appearance of the disease are also observed. Some of them are already known to the scientific community, such as contact with heavy metals, Traumatic Brain Injuries (TBI), environmental toxins and excessive physical exercise. They are shown below in Table 2.

The statistical analysis is carried out using the PSPP program. The Kolmogorov Smirnov test is carried out on the EVA, Borg, Hamilton, ALSFRS and ALSAQ scales. After knowing the normality, we performed the T student test on paired data on all scales. The following results were then observed:

On the EVA scale, we obtain a significant difference ( $p < 0.05$ ). Changes are observed in the improvement of in pain, obtaining results of 7.08 before and 1.38 after the Acupuncture treatment.

On the BORG scale, we obtain a significant difference ( $p < 0.05$ ). Changes are observed in the improvement of fatigue, obtaining results of 5.62 before and 4.31 after the Acupuncture treatment.

On the Hamilton scale, we obtain a significant difference ( $p < 0.05$ ). Changes are observed in the improvement of anxiety obtaining results of 19.77 before and 11.31 after the Acupuncture treatment.

In the case of “functionality” and “quality life” analysed by the ALSFRS and ALSAQ scales, no differences are observed between applying acupuncture treatment and not applying it.

There were no significant differences between sexes except that women perceived higher levels of fatigue (Borg Scale) than men before the treatments. After Acupuncture treatments both experienced a significant decrease in fatigue.

In the rest periods (21 day of non-Acupuncture), 75% of the patients reported a worsening of their health conditions, experiencing new exacerbations of symptoms and new episodes of loss of strength and weakness.

## Discussion

After analysing the results of our research, we have found similarities with other studies that have applied Acupuncture as a therapy to relieve the symptoms of pain, fatigue and anxiety in ALS and other types of pathologies. In the context of pain, there are numerous studies that prove the effectiveness of Acupuncture. In Haake's research, 1.162 patients with low back chronic pain were analysed. Haake shown that in the short-medium term, the benefits of Acupuncture were superior to Conventional Medicine drugs [20].

**Table 1:** Clinical comorbidities presented by the study population.

Clinical Comorbidities	Frequency (%)
Dysarthria	61.53
Dysphagia	61.53
Muscle Cramps	53.85
Insomnia	53.84
Depressive Syndrome	46.15
Constipation	15.38
Aphasia	7.6

**Table 2:** Possible etiological causes of the disease (risk factors).

Etiological causes of the disease	Frequency (%)
Personality: Nervous and introverted character	100
Stress	84.61
Bad eating habits	84.61
Heavy metals	38.46
Stressful situations in the family	38.46
Environmental toxins	38.46
Excess physical exercise	30.76
Poor oral health	30.76
Tobacco	30.76
Trauma to the brain	23.07
Abuse	23.07
Adverse reactions to anaesthesia	15.38
Familial ALS	15.38

Regarding studies related to pain in people with ALS, we find the research by Ryu. Through the application of multiple TCM techniques, such as moxibustion, cupping, Acupuncture and Chinese herbal decoctions, patients (n = 2) significantly improved their joint and muscle pain [21].

In relation to anxiety, there are multiple studies that affirm the effectiveness of acupuncture [22-24]. In the case of anxiety in people with ALS we hardly find any literature on the matter. Only Zamora's mentions the effectiveness of Acupuncture in a clinical case of spinal ALS [19].

In relation to fatigue, we find different investigations where significant improvements are observed in patients with ALS. The authors of these studies used different Acupuncture points. There is no specific treatment [25-27].

In our research, no significant changes have been observed in the ALSFRS scale or the ALSAQ. As already mentioned in the previous section, both scales measure the degrees of functionality/physical capacity to carry out activities of daily living. Due to the progressive and degenerative nature of the disease, there are no improvements in the post-treatment scores, but it is worth highlighting that in these three months of Acupuncture treatments, the patients have remained stable and free of crises and exacerbations (except for the non-acupuncture period). In general terms the patients have not worsened their physical conditions throughout the treatment. Along these same lines, the research by Kim presents similar results: After the application of Acupuncture to 18 patients with ALS in a period of 3 to 6 months, there are no statistically significant changes in ALSFRS scale so "the treatment suppressing the progression of disease" [28].

## Conclusions

After analysing the results of our research, we conclude that Acupuncture has been an effective therapy to relieve the symptoms associated with ALS and improves the state of health. The effectiveness of acupuncture has been statistically demonstrated through the techniques described. In general terms, Acupuncture has improved pain, fatigue and anxiety, night rest, mood, muscle cramps, stiffness and constipation. Furthermore, we were able to observe that in the rest periods (21 day of non-Acupuncture), 75% of the patients reported a worsening of their health conditions, experiencing new exacerbations of symptoms and new episodes of loss of strength and weakness.

In the analysis of the data, we found that the women in our study perceived themselves to be more fatigued than the men before starting Acupuncture treatments. At the end of the quasi-experimental study, all participants self-filled out a satisfaction questionnaire, and 100% of the patients recommended Acupuncture to other people with ALS and included in the evaluations that Acupuncture has helped them to have a stronger physical state and more mental calm.

## Data Availability

The data used to support the findings of this study are available from the corresponding author upon reasonable request.

## Ethical Approval

The study was approved by the Clinical Research Ethics Committee of the Hospital Universitari de Bellvitge (Code PR233/16).

## Consent

Informed consent was given before enrolment, in accordance with the approved ethics.

## Conflicts of Interest

The authors declare that they have no conflicts of interest.

## Authors' Contributions

Zamora was responsible for the execution of Acupuncture treatments at the Bellvitge University Hospital and PUNT CLINIC center. A total of 130 Acupuncture treatments were offered free of charge. Zamora also designed, wrote and analysed the research. Casadó and Martínez (Directors of her Doctoral Thesis) contributed to the analysis, review and interpretation of the data. All authors have read and approved the manuscript.

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