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Original (translation)

Characterization and Physiotherapy Evaluation of Patients with Amyotrophic Lateral Sclerosis in Costa Rica

Karla Abadia-Cubillo[1], Mariana Azofeifa-Segura[2], Luis Benavides-León[3], José Andrés Rojas-Varela[4], Carlo Magno Araya-Alpízar[5], Catalina Saint-Hilaire-Arce[6]

Authors' affiliation:
[1]Universidad de Costa Rica, Escuela de Tecnologías de la Salud. San José, Costa Rica. Caja Costarricense de Seguro Social, Centro Nacional de Control del Dolor y Cuidados Paliativos, Departamento de Terapia Física y Rehabilitación. San José, Costa Rica.
0009-0005-1276-4635
[2]Caja Costarricense de Seguro Social, Centro Nacional de Control del Dolor y Cuidados Paliativos, Departamento de Terapia Física y Rehabilitación. San José, Costa Rica. Caja Costarricense de Seguro Social, Hospital San Francisco de Asís, Departamento de Terapia Física y Rehabilitación. Alajuela, Costa Rica.
0009-0001-3480-2867
[3]Caja Costarricense de Seguro Social, Centro Nacional de Control del Dolor y Cuidados Paliativos, Departamento de Terapia Física y Rehabilitación. San José, Costa Rica.
0009-0005-7344-789
[4]Caja Costarricense de Seguro Social, Centro Nacional de Control del Dolor y Cuidados Paliativos, Departamento de Terapia Física y Rehabilitación. San José, Costa Rica.
0009-0005-3449-9078
[5]Universidad de Costa Rica, Escuela de Estadística. San José, Costa Rica.
0009-0008-1279-1651
[6]Caja Costarricense de Seguro Social, Centro Nacional de Control del Dolor y Cuidados Paliativos, Departamento de Medicina. San José, Costa Rica.
0000-0002-2896-7171

Abbreviations:
ALS; Amyotrophic Lateral Sclerosis.
CNCDYCP; Centro Nacional de Control del Dolor y Cuidados Paliativos [National Center for Pain Management and Palliative Care]
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kabadiac@ccss.sa.cr

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Abstract

Aim: To characterize the profile of individuals with amyotrophic lateral sclerosis treated at the National Center for Pain Control and Palliative Care during the 2020-2022 period, through an analysis of clinical and sociodemographic assessments.

Methods: A descriptive, cross-sectional study was conducted with a retrospective review of the medical records of patients treated in the outpatient and home care programs of the physical therapy service. All variables analyzed were related to the physiotherapy evaluation and demographic characteristics. Various tests were used to assess the patient's physical and functional status (body composition assessment using electrical bioimpedance, muscle strength measurement, and the revised Amyotrophic Lateral Sclerosis Functional Rating Scale). The presence of pain and risk of falls were also assessed. Data were obtained from the start of follow-up at the health center.

Results: The analyzed population consisted of 200 patients, 61.5% of whom were male. Patient ages at the time of assessment ranged from 30 to 89 years, although the majority were between 55 and 59 years old. Distributed by province, 44.5% of users were from San José, followed by 15.8% from Alajuela, 11.4% from Puntarenas, 7.9% from Cartago, 7.4% from Heredia, 6.4% from Guanacaste, and 6.4% from Limón. Regarding the clinical characteristics of the study population, the spinal phenotype represented the majority of cases (72%). The average time elapsed from symptom onset to diagnosis was 21 months. 62.8% of patients reported no falls. Regarding painful symptoms, 61.4% indicated that they experienced pain in some anatomical area. Using the revised amyotrophic lateral sclerosis functional rating scale, 37% of patients had involvement in all four domains (stage 5), followed by 17.4% with involvement in three domains (stage 4), 16.4% were determined to be stage 3, 16.9% were stage 2, and only 10.9% were stage 1.

Conclusion: Establishing patient profiles is important, and this study found that patients treated in the physical therapy department of this specialized national center present with advanced stages of the disease, with significant impairment in function. Furthermore, pain is a common symptom, and its location depends on the type and underlying mechanisms.

Keywords: Amyotrophic Lateral Sclerosis, Physical Therapy Services, Physical Therapy, Symptom Assessment, Demography.

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Amyotrophic Lateral Sclerosis (ALS) is a progressive neurological disease characterized by the degeneration of upper and lower motor neurons.[1-3] Clinically, it manifests as progressive muscle weakness; the median survival time from onset to death ranges from 20 to 48 months, but up to 10-20% of people with ALS survive for more than 10 years. It has been consistently reported that onset at an advanced age and with bulbar-onset involvement is associated with a poorer prognosis.[4] In addition, approximately 35-50% of patients experience cognitive impairment or behavioral changes.[5]

The cause of ALS remains unknown.[6] However, recognition of the disease's phenotypic heterogeneity, global dysfunction of the central nervous system, genetic architecture, and the development of new diagnostic criteria are clarifying the spectrum of clinical presentation and facilitating diagnosis.[5] Insights into the pathophysiology of ALS, the identification of disease biomarkers and modifiable risk factors, along with new predictive models, scales, scoring systems, and a series of clinical trials of mechanism-based therapies, are changing the landscape of its prognosis. Although the most recent advances have not yet translated into benefits for patients, the concept of ALS as a complex syndrome is already having noticeable effects in clinical practice.[5]

The diagnosis of the disease remains clinical, following the exclusion of other possible causes.[5] This disease is classified based on the site of symptom onset: it is spinal ALS when symptoms begin in the extremities, bulbar ALS if it presents with speech and swallowing difficulties, or respiratory ALS if it begins with dyspnea. Diagnostic criteria have evolved since their first version in 1994. In 2019, new and simplified criteria for the diagnosis of ALS (Gold Coast criteria) were introduced, which include magnetic resonance imaging (MRI), biomarkers in blood and cerebrospinal fluid, and genetic testing.[7]

Treatment for ALS must be comprehensive and multidisciplinary. Since there is no curative treatment, management should focus on early intervention, preventing premature deterioration, and better coping with the process of becoming dependent.[8] Physical therapy plays a fundamental role in the overall treatment of patients with ALS, as it is tailored to the needs and goals of each individual. It focuses on addressing symptoms, maximizing function, and enabling patients with ALS to live their lives to the fullest and with quality.[9] While the inevitable functional decline associated with ALS must be accepted, the best available evidence indicates that therapeutic physical exercise in its various forms produces positive or neutral effects on outcome measures and is not associated with serious adverse events.[10]

There are various tools for assessing patients, such as the Revised Amyotrophic Lateral Sclerosis Functional Rating Scale (ALSFRS-R), which evaluates functional decline and changes associated with the disease. The main components of this tool are: assessment of bulbar function through speech, salivation, and swallowing; assessment of fine motor skills through writing, use of utensils, dressing, and personal hygiene; assessment of gross motor function through analysis of bed transfers, walking, and going up and down stairs; and assessment of respiratory function through evaluation of dyspnea, orthopnea, and respiratory failure. Currently, this is the most widely used scale for assessing the functional status of patients with ALS.[11]

Within the framework of individualized care for comprehensive and multidisciplinary treatment, it is important for physical therapists to clarify needs and establish individualized goals to guide appropriate interventions; which is why this study was conducted. Its objective was to characterize the profile of people with ALS treated at the National Center for Pain Management and Palliative Care (CNCDYCP) during the 2020–2022 period, through an analysis of clinical and sociodemographic assessments at the time of initiation of care at this specialized national center.

Methods

This is a descriptive, cross-sectional study. A retrospective review was conducted of all patient records from patients seen in the outpatient and home visit programs of the Physical Therapy Service at the CNCDYCP who had been diagnosed with ALS. To facilitate the collection of information for each patient, the records of the physical therapy consultations during which the clinical data were obtained were analyzed. The inclusion criteria were: adult patients with a definitive diagnosis of ALS. The exclusion criteria were: patients without a digital medical record and pregnant women.

This study was approved by the center's ethics and scientific committee (protocol number CCSS 02-2022, resolution 016-2022, September 2022—resolution 5).

The ALS patients included in this study were diagnosed in the neurology departments of various national hospitals and referred to the CNCDYCP during the period from January 2020 to December 2022.

General data (age, gender, and place of residence) were obtained from the Single Digital Health Record (EDUS) after verifying that the patients had their diagnosis formally recorded under ICD-10 code G-122 (motor neuron disease). To determine the onset date of the symptoms reported by the patient, the first day of the month in which the symptoms began was used as a refer-

ence (if the exact date could not be recalled), and the first day of the month in which the individual received their diagnosis from a neurologist was used as the diagnosis date. Likewise, the phenotype with which the disease presented at the onset of clinical manifestations (spinal ALS or bulbar ALS) was recorded from the medical records.

For this study, all variables analyzed were related to the specific characteristics of the physical evaluation. As part of the physical therapy assessment, various evaluations were conducted upon admission to objectively assess the patient's physical and functional status. Body composition was assessed using electrical bioimpedance analysis; muscle strength was measured; the ALSFRS-R functional scale was applied; and the presence of pain and the risk of falls were assessed.

Regarding bioimpedance, the InBody→Model 770 (InBody Co., Korea) was used to evaluate patients; this device determines body composition values (phase angle (°), body mass index (BMI, kg/m^2), and muscle mass index (kg/m^2)). The body composition analyzer provided measurements and evaluations based on patient data, specifically age and height, detailing the results of the measurements by body segment. These data could only be obtained from patients who retained sufficient muscle strength and postural control to stand independently and voluntarily hold the handheld sensor; the results from the first assessment for each patient were used for the analysis in this study. Body composition analysis was performed on only 46 patients, as documented in the records.

Muscle strength was assessed through a manual muscle examination, using the Daniels and MRC (modified Medical Research Council) scales, which rate muscle function from absence of movement (zero) to normal muscle strength with strong resistance (five).[12]

The ALSFRS-R scale has been proposed as a basic tool for functional assessment. It was developed and is used to measure function in daily activities in patients with ALS. This scale is widely accepted for monitoring functional status and disease progression, both in clinical practice and in research. With its 12 observer-administered items, scored from 0 (unable to attempt the task) to 4 points (normal function), and a maximum score of 48 achieved by summing these 12 items, it provides information on the impact of the disease on patients based on the level of motor and respiratory impairment, which are also presented as an instrument with sufficient clinimetric support.[13] It assesses the degree of disability in patients with ALS based on their functional status across four domains: bulbar function, fine motor function, gross motor function, and respiratory function. Depending on the impairment in these domains, the condition is classified into 5 stages: Stage 1: functional impairment, but with independence in all domains. Stage 2: dependence in one domain; Stage 3: dependence in two domains; Stage 4: dependence in three domains; Stage 5: dependence in all four domains. The Spanish version of the ALSFRS-R scale was used.[14-15]

Pain was assessed using the Numerical Pain Scale (NPS). This is a tool for assessing pain on a subjective basis, in which the patient rates their pain level on a scale from 0 (no pain) to 10 (maximum or unbearable pain).[16]

Fall risk was assessed using the "up and go" test; in addition, participants reported their personal history of falls during the month prior to the assessment. In the "up and go" test, the subject is asked to sit in a chair without armrests but with a backrest, stand up from it, walk briskly a distance of 3 m, turn around, return to the chair, and sit down again, while the time is measured with a stopwatch.[17–18] During the administration of this test, it was agreed that patients who required an assistive device (cane, walker, or brace) could use it for their safety.

To ensure consistency in patient assessment and standardized data presentation, a standardized assessment tool was first developed for use by the physical therapists on staff. Additionally, a single computer and an electronic platform were used to store, organize, and share information among researchers, thereby reducing the risk of errors or unintentional data loss.

The study data were analyzed using the IBM SPSS Statistics software program, employing univariate descriptive statistics by organizing the results for analysis through frequency distributions, measures of central tendency, and measures of variability.

Results

The study population consisted of 207 active patients in the EDUS registry; 6 patients were excluded due to imprecise diagnoses or because they were under observation for a possible other neurodegenerative disease; in addition, the case of a pregnant woman was excluded because she might have presented symptoms associated with her condition.

The sample used for this study consisted of 200 patients; 61.5% were male and 38.5% were female. The patients' ages at the time of assessment ranged from 30 to 89 years, although most patients fell within the 55–59 age range (Figure 1).

By place of residence, 44.5% (89 cases) of the patients were from the province of San José, followed by 15.8% (32 patients) from the province of Alajuela; the remainder were from other provinces, as shown in Figure 2.

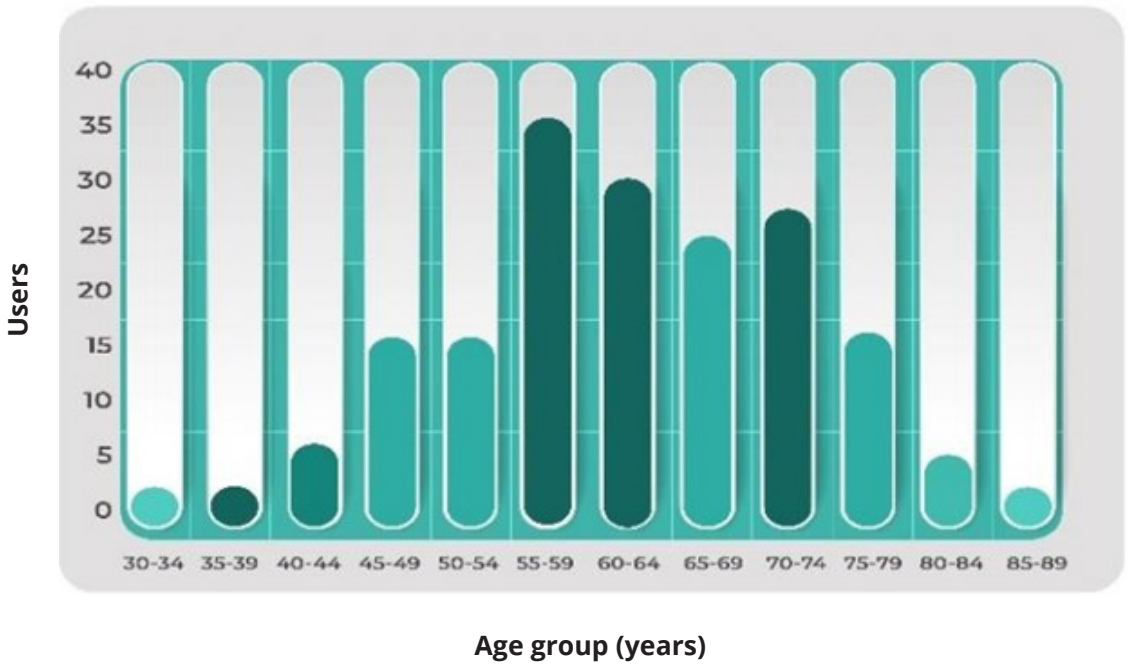

Figure 1. Distribution of patients diagnosed with amyotrophic lateral sclerosis by age, grouped into five-year intervals (range 30 to 89 years); it can be seen that most patients were between 55 and 59 years of age when they began receiving care as patients at the National Center for Pain Management and Palliative Care, n=200, Costa Rican Social Security Fund, 2020–2022.

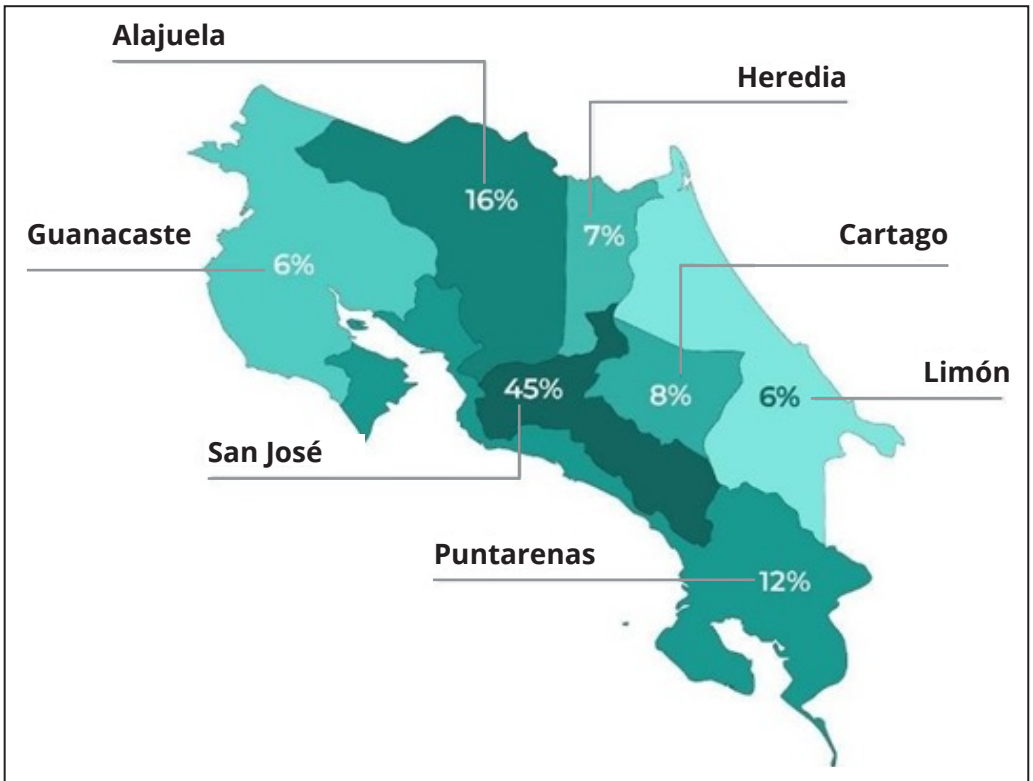

Figure 2. Distribution of patients diagnosed with amyotrophic lateral sclerosis (ALS) by province of residence at the time of the physical therapy evaluation, at the start of their care at the National Center for Pain Management and Palliative Care, n = 200, Costa Rican Social Security Fund, 2020–2022.

The time elapsed from the onset of initial symptoms to the definitive diagnosis of ALS was approximately 21 months. 72.2% presented with a spinal onset; the remainder were distributed as follows: 22.4% with a bulbar onset and 5.4% with a mixed onset. No patients were recorded with a respiratory onset. 42.2% of patients presented with weakness in the upper extremities, of whom 24.1% had bilateral involvement; meanwhile, 41.5% presented with involvement of the lower extremities, and of these, 31.8% had bilateral involvement.

Using the ALSFRS-R scale, varying degrees of impairment were observed among the 200 patients evaluated. The most severe impairment was observed in 37.0% of patients, who presented with impairment in all four domains: bulbar function, fine motor function, gross motor function, and respiratory function (stage 5), followed by 17.4% with impairment in three domains (stage 4); in addition, it was determined that 16.4% corresponded to stage 3, 16.9% were at stage 2, and only 10.9% were at stage 1.

The average BMI was found to be 23.5 kg/m², which falls within the normal range, while the average total body phase angle was 4.2° below the standard for body composition. These results were obtained from only 23% of the sample, due to the inherent requirements of the test and individual ability to perform it.

It was documented that 38.6% of the patients were pain-free; conversely, 61.4% of the patients reported pain, specifically in the region with the most physical impairment. 62.8% of the patients reported no falls during the past month; in contrast, 19.8% reported at least one fall in the past month.

Discussion

Based on the results of this study, the clinical characteristics identified during the physical therapy evaluation of 200 patients with ALS who received specialized care at this center are described; these patients were referred by the Neurology Department and came from all over the country.

It is noteworthy that patients from the provinces of San José and Alajuela predominated. These demographic data are consistent with those presented in a previous study conducted in Costa Rica by Abadía et al. in 2015.[19] This finding can be explained by the fact that these are the provinces with the largest populations in the country.

The disease was more prevalent among men, which is consistent with most of the results reported in other studies where the prevalence of the disease is higher in men.[20] The age group with the highest number of patients aligns with data from previous studies, where the highest prevalence is found among those in their 60s.[20] The age reported in this study corresponds to the patient's age at the time the information was collected, not at the time of diagnosis or the onset of symptoms.

In most of the studies reviewed, the median time from symptom onset to diagnosis is reported as approximately 14.8 months.[21] In this study, that time interval was longer, reaching 21 months. In this regard, one of the hypotheses put forward is that patients are initially evaluated at primary care levels, where other conditions must be ruled out; consequently, they are referred later to specialized neurology or physiatry services for diagnosis. In this same vein, the issue of access to timely specialized care is a cause for concern, since, by the time care began at this qualified center, more than half of the patients evaluated were already in the most advanced stages of the disease (37.0% and 17.4% in stages 5 and 4, respectively) and, as discussed below, this also limits functional assessment by restricting mobility or due to a complete inability to stand independently.

Based on the patients' clinical characteristics regarding the onset of their disease, the spinal phenotype of ALS accounts for approximately 72.2%; this is consistent with other studies that have reported similar findings.[22]

On the other hand, assessing body composition in patients with ALS can be complex due to limitations related to impaired mobility and muscle strength in advanced stages of the disease.[23] A limitation of the present study was that the bioimpedance test could only be performed on a minority of patients, since only 23% were able to stand independently on the device and had sufficient handgrip strength to hold the sensors.

Furthermore, specifically regarding the phase angle, this is an established bioimpedance parameter for diagnosing malnutrition and predicting clinical outcomes, as it is considered a marker of health and a direct indicator of cellular integrity and quality in healthy patients, ideally ranging between 5° and 7°.[24] This study found that the group of patients evaluated had an average of 4.5°, which is below the reference range. This confirms that patients are being admitted to the palliative care unit at advanced stages of the disease.

While it is true that people with ALS often have neurological deficits that predispose them to repeated falls and associated adverse consequences, there is little available literature evaluating the risk of falls in this population.[25] In this regard, falls are considered a manifestation of physical decline and are reported in 33-46% of patients undergoing a clinical evaluation.[26] One factor that may explain our low rate of reported falls is that the majority of the population was in ad-

vanced stages of the disease, where they exhibit motor impairments that restrict their mobility; consequently, they were already using assistive devices such as wheelchairs or were bedridden.

Studies assessing the presence and distribution of pain in ALS patients have not identified a specific location for the symptoms, as pain may affect different limbs or be widespread.[27] Evidence shows that pain is a common symptom in ALS patients; however, it may be underestimated due to the misconception that ALS is a purely motor syndrome. This symptom can occur at all stages of the disease and in any anatomical area. It is important to note that, for the purposes of this study, we determined only whether or not the patient experienced pain, regardless of its location or characteristics.

Finally, establishing the patients' profile is important, and this study found that patients treated in the physical therapy department of this specialized national center present with advanced stages of the disease and marked functional impairment; furthermore, pain is a common symptom, and its location depends on the type of disease and the underlying mechanisms. It can also be concluded that, due to the diversity of prognoses, physical therapists must develop a treatment plan tailored to each patient's clinical condition at the time of evaluation. Although the ALSFRS-R functional scale is one of the most widely used in clinical trials for ALS, physical therapy assessments require the use of additional tests to characterize each case. Based on clinical experience working with ALS patients, there is a direct relationship between muscle weakness and the number of falls; therefore, preventive measures to minimize muscle mass loss are considered essential. Furthermore, based on this study, the identification and assessment of pain are considered paramount, as it has detrimental effects on the quality of life of both patients and their caregivers.

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