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ABSTRACT

- Aim:** To determine disease characteristics, severity of spasticity and functional impairment in a large cohort of patients with multiple sclerosis (MS) in Spain.
- Methods:** Approximately 8,500 MS patients >18y old from the two main Spanish MS patients’ societies, FELEM and AEDEM, were contacted to complete a web-based questionnaire.
- Results:** 2029 (77%) respondents provided valid data for analysis. Women comprised 2/3 of the cohort which had a mean age of 40.2y and a mean MS duration of 8.7y. MS spasticity (MSS) was present in 65.7%, absent in 20.1% and the diagnosis was unclear in 14.2%. The severity of MSS was rated as minimal/mild by 59.9%, moderate by 17.4% and severe/total by 22.7%. MSS patients had more spasticity related signs and symptoms, and resource use compared with non-MSS patients as highlighted by: greater difficulty in walking; more spasms; greater difficulty in sleeping; more frequent urinary dysfunction; need for care and rehabilitation sessions; and officially notified of their disability. The degree of disability was also rated as higher yet 56.8% of patients did not take any medication for their MSS symptoms. There was a positive correlation between worsening of symptoms and daily activities with increasing severity of spasticity ($p<0.001$).
- Conclusions:** This survey shows that 2/3 of MS patients in Spain have MSS, and in 40% it was of moderate to high severity. A direct correlation between MSS severity and walking ability, spasms, urinary dysfunction and sleep disturbances was observed. Patients with MSS used more health resources but, surprisingly, many of them were not treated for this symptom.

INTRODUCTION AND PURPOSE

Spasticity is a common symptom in Multiple Sclerosis (MS) which was reported by 84% of respondents in one large survey, and it contributed to the level of MS disability^[1]. Older age, male gender, and longer disease duration were associated with increased severity of spasticity. Over time, intensification of MS spasticity (MSS) symptoms can have a marked negative impact on the quality of life (QoL) of patients and their carers, including family and friends^[2]. Therefore, correct diagnosis and management are priorities of the care process to help minimise the pain and disability that are attendant risks of MSS^[3]. Information relating to the epidemiology and consequences of MSS in general is limited^[4] and in Spain, where more than 40 000 patients suffer from MS, details are scarce. In a recent retrospective study it was shown that MSS diagnosis, reporting and management were not consistent^[5] and that available guidelines^[6] were not followed.

The aim of this survey is to define the epidemiology, severity and consequences of MSS in Spain, and to monitor what resources are used to manage this disabling symptom.

SURVEY METHODOLOGY

Spanish MS patients aged ≥ 18 years, or their carers/family, were contacted to participate in this web-based survey through the 3 following methods: via e-mail, via the web sites of the main Spanish MS patients’ associations (FELEM or AEDEM), and via social network links of FELEM or AEDEM.

Main parameters surveyed

- Respondent:** patient, carer or other.
- Sociodemographic details:** age, gender, educational level, province, and working/living situation.
- MS-related parameters:** age MS diagnosed, MS type, number of relapses in the last 12 months, change of disease status in the last 6 months, and walking ability.
- MS Spasticity:** which was defined as **“An unusual tightening of muscles that feels like leg stiffness, jumping of legs, a repetitive bouncing of the foot, muscle cramping in the legs or arms, legs going out tight and straight or drawing up”**^[8]. The following questions were then posed: spasticity presence, years with spasticity, severity of spasticity (Table 1).

Table 1. Spasticity intensity definitions

Score	Label	Definition
1	Minimal	Spasticity is felt, but does not affect daily activities
2	Mild	Spasticity forcing once a week to change/renounce to activities
3	Moderate	Spasticity forcing some days a week to change / renounce to activities
4	Severe	Spasticity forcing to change / renounce every day to activities
5	Total	Spasticity forbidding to implement any activity every day

- Spasticity-related symptoms:** spasms, presence and frequency; urinary dysfunction presence and nocturnal urgency; sleep disruption, presence and features.
- Spasticity management:** drug treatment, presence, number of medicines and duration of treatment; physiotherapy, number of sessions and duration; alternative therapies used; requirement for a carer and features; visits to a specialist; disability pensions received.

It was calculated that a sample size of 2000 MS persons surveyed was sufficient to detect differences at the 2% level with 95% CIs. Statistical comparisons were generally performed between MS patient groups with and without spasticity.

SURVEY RESULT

Survey sample and patient characteristics/demographics

8463 forms were distributed and 2627 subjects answered the questionnaire; 2029 (77%) respondents provided valid data for analysis (Table 2). Women comprised 2/3 of the cohort which had a mean age of 40.2y and a mean MS duration of 8.7y. Demographically the MSS and non-MSS groups had some differences: 36.9% vs. 25.8% male; mean age 41.8y vs. 36.9y; disease duration 9.5y vs. 6.3y and a greater proportion were retirees (34.7% vs. 8.6%; $p<0.001$).

Table 2. Survey of MS patients in Spain: baseline characteristics

Survey sample	8463 forms distributed 2627 responses received 2029 valid questionnaires
Age	≤ 30 years 19.0%; 31- ≤ 50 years 63.7%; 51- >60 years 17.3%
Gender	66.7% female 33.3% male
MS type	Relapsing-remitting 60.1%; Primary progressive 6.9%; Secondary progressive 11.7%; Not known 21.2%
MS Spasticity	Yes 65.7% with a mean age of diagnosis of 32.5 \pm 9.6 years versus 30.7 \pm 8.6 years for those without MS spasticity
MS Spasticity severity	Minimal/mild 59.9%; moderate 17.4%; severe or total 22.7%
Living details	Alone 11.1%; Couple 29.4%; Family 54.2%; Carer/other 5.2%
Working details	Active (including housewives) 57.9%; Student 3.7%; Retired 26.3%; Unemployed 12.1%

The impact of MS spasticity on signs and symptoms

MSS patients had more spasticity-related signs and symptoms compared with non-MSS patients as highlighted by:

- More spasms (66% vs. 5.4%; $p<0.001$), which were generally more painful.
- Greater difficulty in walking (69.5% vs. 16.5%; $p<0.001$) (Figure 1).
- Greater difficulty in sleeping (50.9% vs. 26.1%; $p<0.001$) (Table 3).
- More frequent urinary dysfunction (70.4% vs. 29.2%; $p<0.001$) (Table 3).

Figure 1. Impact of MS spasticity on walking ability

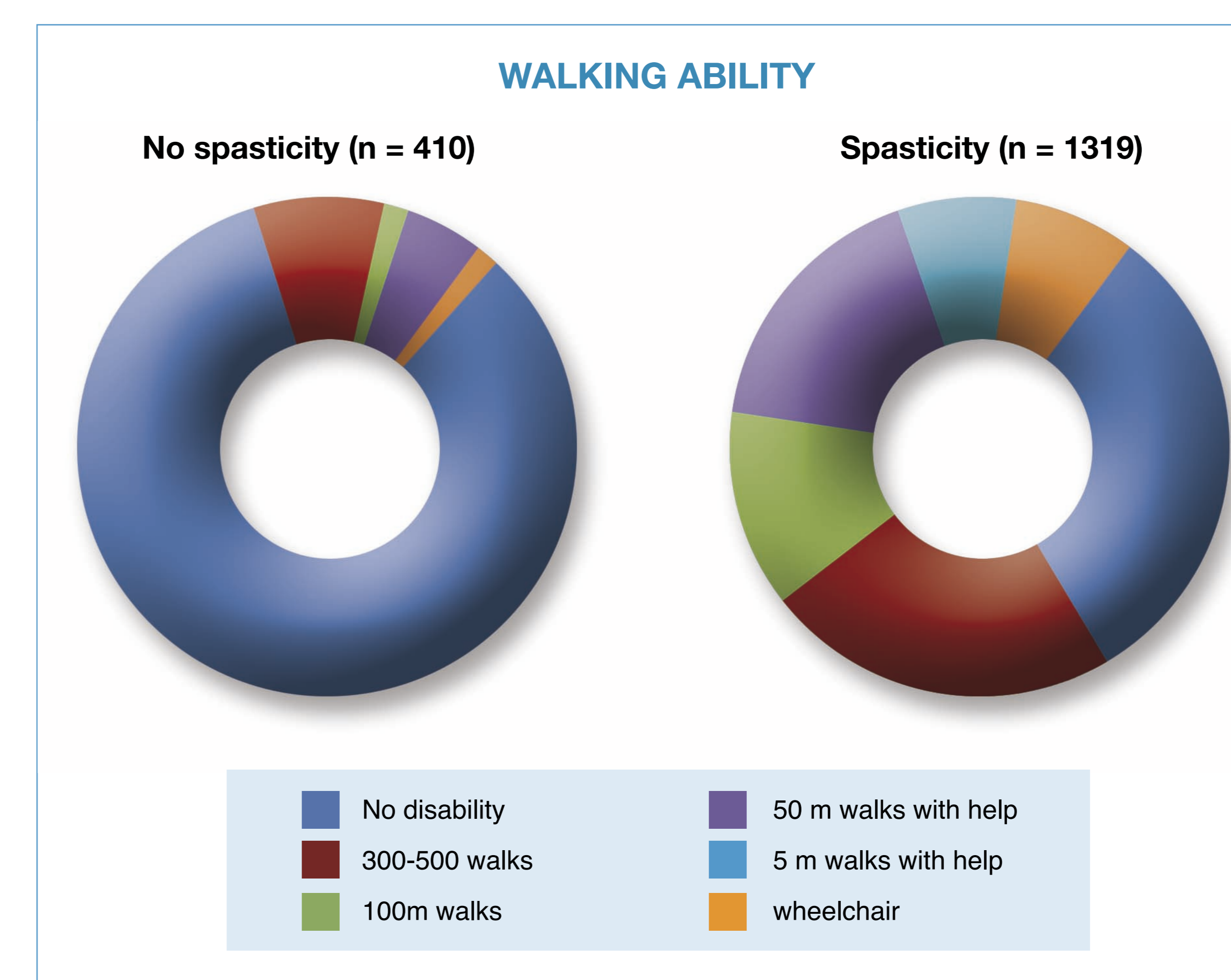


Table 3. Other symptoms associated with MS in patients with and without spasticity

MS Symptom	No Spasticity	Spasticity	P value
Urinary dysfunction	29.2%	70.4%	<0.001
Require incontinence pads	10.4%	19.7%	0.016
Sleep disturbances	26.1%	50.9%	<0.001
Woken by urinary urgency (> 2 times per night)	7.0%	13.7%	<0.001
Woken by spasms (1->5 times per night)	1.9%	51.7%	<0.001

The impact of MS spasticity on use of resources

On a daily basis, 16.8% of MSS patients required a carer vs. only 4.4% of the non-MSS group ($p<0.001$) (Table 4). 40.8% of MSS patients undertook rehabilitation sessions vs. 10.6% of the non-MSS group ($p<0.001$). 59.6% of MSS patients were officially notified of their disability vs. 26.5% in the non-MSS group ($p<0.001$). The degree of disability was also rated as higher ($p<0.001$).

56.8% of patients did not take any medication for their MSS symptoms, and those that did took an average of 1.58 \pm 0.91 drugs. There was a positive correlation between worsening of symptoms and daily activities with increasing severity of spasticity ($p<0.001$).

Table 4. Use of resources in MS patients with and without spasticity

Resource	No Spasticity	Spasticity	P value
Requires a carer	4.4%	16.3%	<0.001
Requires rehabilitation sessions	10.6%	40.8%	<0.001
Requires MS disability subsidies	26.5%	59.6%	<0.001
Visits to specialist on demand	10.0%	16.6%	0.002
Taking MS spasticity medications	Not applicable	30.2%	Not applicable

CONCLUSION

This survey showed that 2/3 of patients with MS in Spain indicated that they suffered from typical symptoms of spasticity and 40% of them rated it to be of moderate to high intensity. A direct correlation was found between MS severity and MS symptoms such as spasms, poor mobility, urinary dysfunction and sleep disturbances. MS patients with spasticity used more health resources including, support/care, rehabilitation sessions, medical attention and subsidies but, surprisingly, only one-third of them reported that they had received drug therapy for MSS. Given the marked negative impact that spasticity can have on day-to-day functioning and QoL, greater attention and tracking of its presence and evolution, as well as the success of management initiatives are clearly desirable to improve patient outcomes and well-being.

Disclosure

The 6E study was sponsored by Almirall.

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