Burden of spasticity among patients and caregivers: results of a multinational survey

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Atul Patel,[1] Theodore Wein,[2] Laxman B Bahroo,[3] Ophélie Wilczynski,[4] Carl Rios,[5] Manuel Murie-Fernandez[6]

[1]Kansas City Bone & Joint Clinic, Overland Park, KS, USA; [2]McGill University, Montreal, QC, Canada; [3]Georgetown University, Washington, DC, USA; [4]Carenity, Paris, France; [5]Ipsen Pharma, Boulogne Billancourt, France; [6]Ciudad de Telde Hospital, Las Palmas, Spain

BACKGROUND

- Spasticity is caused by an upper motor neuron lesion leading to intermittent or sustained involuntary activation of muscles,[1] and is a symptom of various disorders, including multiple sclerosis (MS), stroke, traumatic brain or spinal cord injury and cerebral palsy.[2]
- Botulinum toxin type A (BoNT-A) is a recommended pharmacological option for patients with spasticity,[3] and its anti-spastic effects have been demonstrated in stroke and central nervous system lesions,[4–6] MS[7] and cerebral palsy.[8,9]
- However, the impact of spasticity and BoNT-A treatment on the daily lives of real-world patients and caregivers has not been studied widely.
- Carenity,[10] an online social media platform for people with chronic conditions, was used to survey patients and caregivers of patients with spasticity who were receiving BoNT-A treatment for spasticity.

OBJECTIVE

- To understand the burden of spasticity and its treatment from patient and caregiver perspectives, in terms of impact on employment status, activities of daily living and quality of life (QoL).

METHODS

Study design

- An online, cross-sectional survey conducted between 10 November 2017 and 28 February 2018 via the Carenity[10] platform.
- Emails were sent to patients and caregivers from France, Germany, Italy, Spain, the UK and the USA inviting them to complete the online questionnaire.

Inclusion criteria

- Eligible participants were aged ≥18 years old and were either patients self-described as having spasticity and who had received BoNT-A treatment for ≥1 year, or caregivers of such patients.
  - Spasticity had to be due to MS, stroke, traumatic brain injury, spinal cord injury, cerebral palsy, brain tumour or spastic paraplegia.

Assessments/analysis

- The questionnaire (presented in the local language) comprised multiple-choice questions, and Likert scale and free-text responses.
- The following domains were assessed: impact of spasticity on employment status, activities of daily living and QoL; and impact of BoNT-A treatment on employment.
  - Difficulties performing daily activities and impact on QoL were assessed on a Likert scale of 0 ('no difficulty/no impact') to 10 ('great difficulty/a great impact').
- For caregivers, some questions related to their patient, whereas others related to their experience as a caregiver.

Statistical analyses

- Descriptive analyses are presented.

Table 1. Baseline characteristics of all participants (N=615).

Parameter	Patients (n=427)	Caregivers' patients (n=188)	Caregivers (N=188)
Sex, n (%)			
Male	216 (51)	84 (45)	84 (45)
Female	206 (48)	104 (55)	104 (55)
Transgender	5 (1)	0 (0)	0 (0)
Age, n (%)			
18–30 years	72 (17)	24 (13)	49 (26)
31–40 years	127 (30)	15 (8)	63 (34)
41–50 years	134 (31)	25 (13)	45 (24)
51–60 years	66 (15)	35 (19)	25 (13)
>60 years	28 (7)	89 (47)	6 (3)
Mean (95% CI), years	41.7 (40.6–42.8)	57.4 (54.6–60.1)	38.6 (36.9–40.2)
Duration of caregiving, n (%)			
<1 year	–	–	11 (6)
1–3 years	–	–	64 (34)
3–5 years	–	–	46 (24)
5–10 years	–	–	45 (24)
10–15 years	–	–	6 (3)
>15 years	–	–	16 (9)
Mean (95% CI), years			4.9 (4.1–5.7)
Parameter	**All participants***		
Cause of patient spasticity, n (%)			
Multiple sclerosis	256 (42)		
Stroke	122 (20)		
Spastic paraplegia	61 (10)		
Spinal cord injury	60 (10)		
Cerebral palsy	50 (8)		
Traumatic brain injury	48 (7)		
Brain tumour	18 (3)		
Time since patient diagnosis, n (%)			
<3 years	184 (30)		
3–5 years	103 (17)		
5–10 years	136 (22)		
10–15 years	64 (10)		
>15 years	104 (17)		
Not specified	24 (4)		
Mean (95% CI), years	8.1 (7.4–8.9)		
Date of patient's first BoNT-A injection, n (%)			
<2 years ago	271 (44)		
2–5 years ago	186 (30)		
5–10 years ago	101 (16)		
10–15 years ago	37 (6)		
>15 years ago	20 (3)		
Mean (95% CI), years	3.5 (3.1–3.8)		
BoNT-A treatment received by patient†, n (%)			
OnabotulinumtoxinA	338 (55)		
AbobotulinumtoxinA	109 (18)		
IncobotulinumtoxinA	67 (11)		
Other‡	3 (<1)		
Don't know	98 (16)		

*Participants are patient responders and caregivers answering on behalf of their patients; †self-reported; ‡for respondents from Spain only, brand names given were Bocouture, Lantox, Azzalure.
BoNT-A, botulinum toxin type A; CI, confidence interval.

RESULTS

Participants

- In total, 615 participants were included in the analysis (427 patients and 188 caregivers).
- Baseline characteristics for patients, caregivers and caregivers' patients are presented in **Table 1**.
- The most common reason for spasticity was MS, followed by stroke, and most patients were receiving onabotulinumtoxinA as their current BoNT-A treatment.
- Mean time since diagnosis was 8.1 years, compared with a mean time of 3.5 years since first BoNT-A injection **(Table 1)**, suggesting an average delay of 4.6 years between diagnosis and treatment initiation.
- Caregivers had provided care for an average of 4.9 years, and 12% had been caregivers for >10 years.

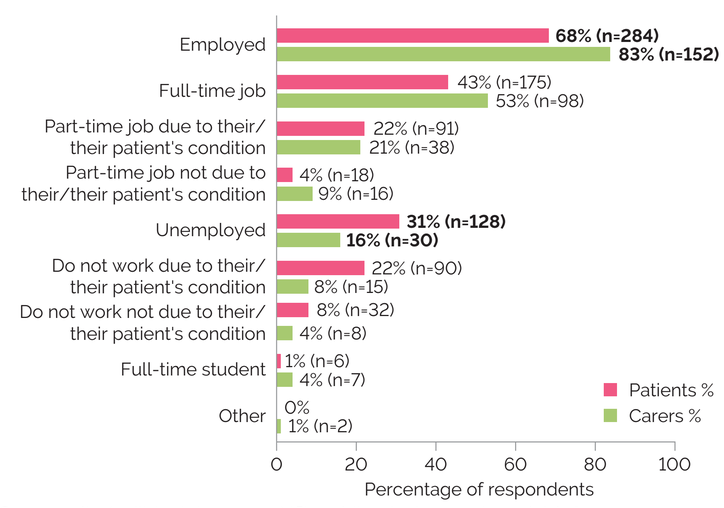
Impact of spasticity on patient/caregiver employment status

- The majority of patients and caregivers were aged <65 years, of whom 70% and 87%, respectively, were employed **(Figure 1)**.
- In total, 181 (44%) patients and 53 (29%) caregivers reported that their/their patient's condition impacted on time spent at work.
- Participants reported that spasticity and their/their patient's condition had a marked impact on employment status **(Figure 1)**.
  - 22% of patients and 8% of caregivers were unable to work.
  - 22% of patients and 21% of caregivers worked part-time.

Impact of spasticity on activities of daily living and QoL

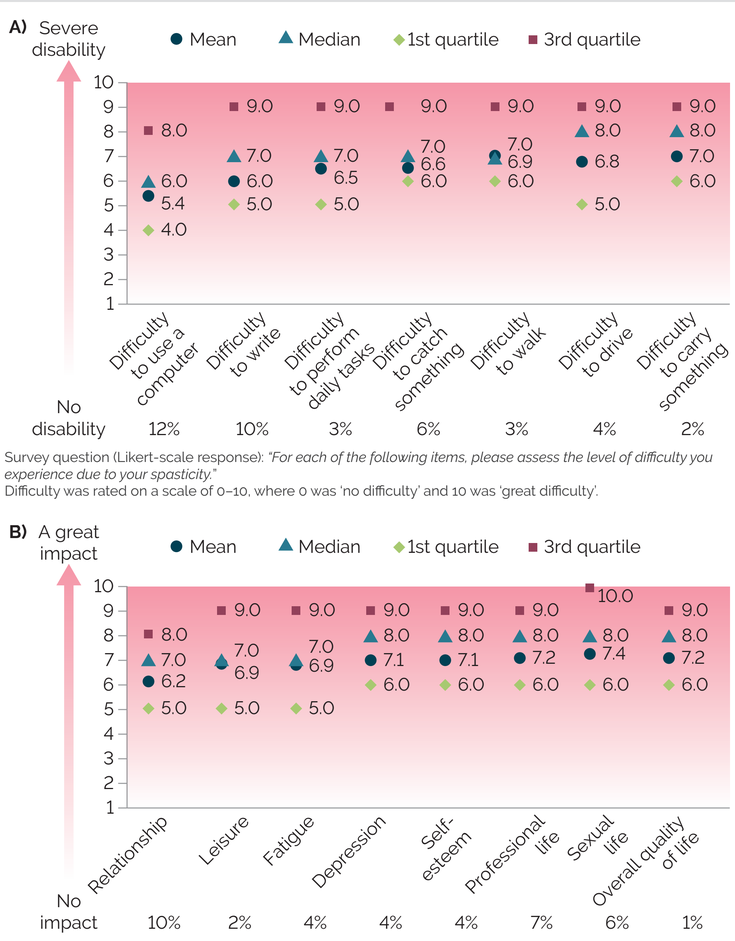
- For each activity of daily living, ≥88% of participants reported that spasticity impaired their/their patient's ability to perform the activity **(Figure 2A)**.
  - For all tasks, mean difficulty scores were ≥5.4, indicating significant impairment.
  - The most affected tasks were carrying things, walking, performing daily tasks and driving.
- At least 90% of participants reported that spasticity affected ≥1 aspect of their/their patient's QoL **(Figure 2B)**.
  - For all areas, mean impact scores were ≥6.2, indicating markedly affected QoL.
  - The most affected areas were overall QoL, leisure, fatigue, depression and self-esteem.

Figure 1. Employment status of participants aged <65 years as reported by patients (n=415) and caregivers (n=184).



Survey question (multiple-choice response): "*Please tell us about your employment status*".
For the category 'Other', one respondent stated 'disabled'; the other respondent did not provide any further details.

Figure 2. Impact of spasticity on A) patients' ability to perform everyday tasks and B) patients' quality of life, as reported by all participants (N=615).



Survey question (Likert-scale response): "*For each of the following items, please assess the level of difficulty you experience due to your spasticity.*"
Difficulty was rated on a scale of 0–10, where 0 was 'no difficulty' and 10 was 'great difficulty'.

Survey question (Likert-scale response): "*Please assess to what extent spasticity affects your life.*"
Impact was rated on a scale of 0–10, where 0 was 'no impact' and 10 was 'a great impact'.

Impact of BoNT-A treatment on employment

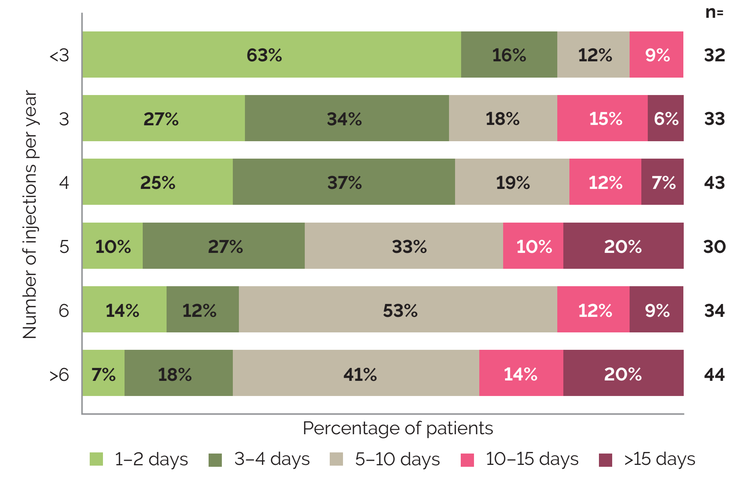
- Most patients (78%) and caregivers (84%) had to take time off work for BoNT-A treatment **(Table 2)**.
  - Half of participants took ≥5 days off per year.
- The number of days patients took off work to receive injections increased with the number of injections received per year **(Figure 3)**.
  - For patients receiving <3 injections per year, 37% required ≥3 days off work, compared with 73–93% for patients who received ≥3 injections per year.

Table 2. Impact of BoNT-A treatment on employment, as reported by patients (n=285) and caregivers (n=156).

	Patients	Caregivers
How often time off work was needed for BoNT-A injections*, n (%)	**n=285**	**n=156**
Never	64 (22)	25 (16)
Sometimes	149 (52)	96 (62)
Often	39 (14)	25 (16)
Always	33 (12)	10 (6)
Number of days taken off work per year due to BoNT-A injections*, n (%)	**n=216**	**n=121**
≤2 days	51 (23)	21 (17)
3–4 days	52 (24)	38 (31)
5–9 days	64 (30)	26 (22)
10–15 days	26 (12)	18 (15)
>15 days	23 (11)	18 (15)

*For patients, this was the time taken off work to receive their BoNT-A injections; for caregivers, this was the time taken off work to accompany their patient to receive their BoNT-A injections.
Survey questions: "*Do you have to take time off work (e.g. full day, half day, several hours) to get your Botulinum Toxin A injections?*" (multiple-choice response) and "*On average, how many days off per year do you have to take to get your Botulinum Toxin A injections?*" (numeric response).
BoNT-A, botulinum neurotoxin type A.

Figure 3. Number of days taken off work each year according to number of BoNT-A injections received, as reported by patients (n=216).



Survey question (numeric response): "On average, how many days off per year do you have to take to get your Botulinum Toxin A injections?"
BoNT-A, botulinum neurotoxin type A.

CONCLUSIONS

- Spasticity has a substantial negative impact on patients' and caregivers' lives, significantly affecting their ability to work, and negatively affecting patients' QoL and ability to perform activities of daily living.
- The burden of spasticity reported in this survey may be improved with BoNT-A treatment; however, QoL is not routinely studied in clinical trials of BoNT-A therapy.

References

1. Pandyan AD. *Disabil Rehabil* 2005.
2. Simon O. *Eur J Phys Rehabil Med* 2010.
3. The Royal College of Physicians of London. 2018 https://www.rcplondon.ac.uk/guidelines-policy/spasticity-adults-management-using-botulinum-toxin.
4. Kaku M. *Drug Des Devel Ther* 2016.
5. Dong Y. *Eur J Phys Rehabil Med* 2017.
6. Rosales RL. *J Neurol Sci* 2016.
7. Dressler D. *J Neurol* 2017.
8. Hoare BJ. *Cochrane Database Syst Rev* 2010.
9. Koman LA. *Paed Drug* 2003.
10. www.carenity.co.uk.

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