Goals Set by Patients Using the *ICF* Model before Receiving Botulinum Injections and Their Relation to Spasticity Distribution

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ABSTRACT

Purpose: Goal Attainment Scaling (GAS) is used to assess functional gains in response to treatment. Specific characteristics of the functional goals set by individuals receiving botulinum toxin type A (BoNTA) injections for spasticity management are unknown. The primary objectives of this study were to describe the characteristics of the goals set by patients before receiving BoNTA injections using the *International Classification of Functioning, Disability and Health (ICF)* and to determine whether the pattern of spasticity distribution affected the goals set. **Methods:** A cross-sectional retrospective chart review was carried out in an outpatient spasticity-management clinic in Toronto. A total of 176 patients with a variety of neurological lesions attended the clinic to receive BoNTA injections and completed GAS from December 2012 to December 2013. The main outcome measures were the characteristics of the goals set by the participants on the basis of *ICF* categories (body functions and structures, activity and participation) and the spasticity distribution using Modified Ashworth Scale scores. **Results:** Of the patients, 73% set activity and participation goals, and 27% set body functions and structures goals ($p < 0.05$). In the activity and participation category, 30% of patients set moving and walking goals, 28% set self-care and dressing goals, and 12% set changing and maintaining body position goals. In the body functions and structures category, 18% set neuromuscular and movement-related goals, and 8% set pain goals. The *ICF* goal categories were not related to the patterns of spasticity (upper limb vs. lower limb or unilateral vs. bilateral spasticity) or type of upper motor neuron (UMN) lesion ($p > 0.05$). **Conclusion:** Our results show that patients receiving BoNTA treatment set a higher percentage of activity and participation goals than body functions and structures goals. Goal classification was not affected by type of spasticity distribution or type of UMN disorder.

Key Words: activities of daily living; botulinum toxin; goals; muscle spasticity; patient participation.

RÉSUMÉ

Objectif : l'échelle de réalisation des objectifs (*Goal Attainment Scaling* ou GAS) est employée pour évaluer les gains fonctionnels en réponse à un traitement. On ne connaît pas les caractéristiques des objectifs fonctionnels établis par les personnes recevant des injections de toxine botulinique de type A (BoNTA) pour la prise en charge de la spasticité. Cette étude vise à décrire les caractéristiques des objectifs établis par les patients avant de recevoir des injections de BoNTA à l'aide de la Classification internationale du fonctionnement, du handicap et de la santé (CIF) et à déterminer si le modèle de distribution de la spasticité avait un effet sur les objectifs établis. **Méthodologie :** on a mené une revue rétrospective transversale des dossiers d'une clinique ambulatoire de prise en charge de la spasticité à Toronto. Au total, 176 patients ayant diverses lésions neurologiques sont venus à la clinique pour recevoir des injections de BoNTA et ont rempli la GAS entre décembre 2012 et décembre 2013. On a recensé les caractéristiques des objectifs en fonction des catégories de la CIF (fonctions organiques et structures anatomiques, activités et participation) et de la distribution de la spasticité à l'aide de l'échelle d'Ashworth modifiée. **Résultats :** de tous les patients, 73 % ont établi des objectifs liés aux activités et à la participation et 27 %, des objectifs liés aux fonctions organiques et aux structures anatomiques ($p < 0,05$). Dans la catégorie des activités et de la participation, 30 % de tous les patients ont établi des objectifs par rapport à « marcher et se déplacer », 28 % ont établi des objectifs par rapport aux « soins personnels » et à « s'habiller », et 12 %, par rapport à « modifier et maintenir sa position corporelle ». Dans la catégorie des fonctions organiques et des structures anatomiques, 18 % des participants ont établi des objectifs liés aux « fonctions de l'appareil locomoteur et au mouvement » et 8 % ont établi des objectifs par rapport à la « douleur ». Les catégories d'objectifs de la CIF n'étaient pas liées aux modèles de spasticité (spasticité des membres supérieurs par rapport aux membres inférieurs ou spasticité unilatérale par rapport à bilatérale) ou au type de lésion des motoneurones supérieurs ($p > 0,05$). **Conclusion :** nos résultats montrent que les patients qui reçoivent un traitement de BoNTA établissent un pourcentage plus élevé d'objectifs liés aux activités et à la participation qu'aux fonctions organiques et aux structures anatomiques. Le type de distribution de la spasticité ou le type de lésion des motoneurones n'a pas eu d'effet sur la classification des objectifs.

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Contributors: All authors designed the study; or collected, analyzed, or interpreted the data; and drafted or critically revised the article and approved the final draft.

Competing Interests: None declared.

This research was completed in partial fulfillment of the requirements for a master's degree in physical therapy at the University of Toronto.

Physiotherapy Canada 2017; 69(2);113–119; doi:10.3138/ptc.2016-25

Spasticity, a velocity-dependent increase in muscle tone, is one of the hallmark clinical signs of upper motor neuron (UMN) syndromes,^{1,2} such as stroke, multiple sclerosis (MS), cerebral palsy (CP), and acquired brain injury (ABI).^{2,3} Spasticity can be present in different parts of the body and can be categorized as either focal (one or more limbs affected unilaterally) or regional (two or more limbs affected bilaterally).⁴ The clinical manifestations of spasticity can be treated with intramuscular botulinum toxin type A (BoNTA) injections, which reduce muscle tone by inhibiting the release of acetylcholine at the neuromuscular junction.⁵

Spasticity management is typically multidisciplinary, involving physical therapy, occupational therapy, and medical care.^{6,7} Each health care professional involved in spasticity management completes an individual assessment and may prescribe interventions such as splinting, stretching, and functional task training as needed to improve function. The treatment goal is to reduce muscle tone and restore function using a combination of BoNTA and therapy.^{3,8} Improvement in function has been shown to improve health-related quality of life (HRQOL) and alleviate caregiver burden.⁹ With multidimensional conditions and impairments, it is critical to have outcome measures that are sensitive and reliable enough to measure the wide-ranging impact of treatment on important areas of a patient's life. Unfortunately, many of the current impairment-based scales cannot measure the multidimensional nature of the impact of neurological conditions and, as such, cannot capture the meaningful changes to a patient's life throughout treatment.

Numerous studies have demonstrated the success of BoNTA injections; it is commonly measured using the Ashworth Scale or Modified Ashworth Scale (MAS), which focuses primarily on impairment and does not measure functional improvements.¹⁰ As a result, health care providers are increasingly using Goal Attainment Scaling (GAS) with individuals with spasticity, in addition to spasticity assessments such as MAS, to provide better patient-centred care and more accurately set goals and measure functional improvements.¹¹ Using GAS in spasticity management is considered best practice on the basis of a consensus statement published in Europe in 2009.¹² GAS measures change in functional ability over time through specific goals set by a patient in conjunction with his or her therapist.⁷

Spasticity is a global phenomenon, and to understand its impact and the goals patients set before using BoNTA to manage it, it is important to categorize goals using a common framework such as the *International Classification of Functioning, Disability and Health (ICF)*.¹³ Goals based on the ICF model that are set by patients after stroke and ABI and before receiving upper limb spasticity treatment with BoNTA are typically in either the body functions and structures category (26% of goals) or the activity and participation category (74% of goals).^{14,15}

The ICF categories of goals set by patients with UMN disorders (other than ABI and stroke), as well as those set by patients for whom treatment with BoNTA is targeted at lower limb spasticity, are not known. The effect of pattern of spasticity on the type of goals set by patients receiving BoNTA for spasticity management is also not known.

The primary objectives of this study were to categorize the goals set by patients receiving BoNTA treatment of spasticity management using the ICF model and to determine whether the pattern of spasticity (upper vs. lower limbs, unilateral vs. bilateral, type of UMN lesion) affected goal characteristics.

METHODS

Study design

A cross-sectional retrospective chart review was conducted for 176 patients admitted to the Spasticity Management Clinic at the West Park Healthcare Centre in Toronto for BoNTA injections who completed GAS between December 2012 and December 2013. This study was approved by the research ethics boards of the West Park Healthcare Centre and the University of Toronto.

Interrater reliability

Four student investigators performed data abstraction, and interrater reliability was assessed with intra-class correlation coefficients (ICCs) using a two-way mixed-effects analysis of variance model for all variables from the data abstraction forms for 10 patients' medical charts. The average ICC and 95% CI were reported; because there were four data abstractors, these values indicate the absolute agreement compared with consistency, which is reported with the single measures.¹⁶ To interpret the ICC values, we set our criteria so that an ICC of 0.80 or more represented excellent agreement.¹⁷

Data collection

Each chart review was completed using a chart abstraction form in Excel (Microsoft Corp., Redmond, WA) on encrypted laptops and desktop computers at the West Park Healthcare Centre. Both paper and electronic medical charts were accessed for data abstraction. Information collected from the charts included demographics (e.g., age, gender) and clinical profile information (e.g., diagnosis, initial appointment date, spasticity distribution, and goals set using GAS). Spasticity distribution was recorded on the basis of whether spasticity was present in only upper or lower limbs and whether it was unilateral or bilateral. The therapists who performed spasticity assessment had more than 5 years' experience.

Patients and therapists determined a primary goal using GAS. The therapists helped the patients to create goals centred on impairments in body functions and structures that patients wanted to reduce as well as activities in which they wanted to participate. Most

patients did not receive physical or occupational therapy intervention post-BoNTA injections, so goals were created on the basis of the expected effect of the BoNTA injection as opposed to complete rehabilitation treatment. After the data were collected, one co-author (a physical therapist), who has experience using the ICF model, categorized the goals on the basis of two ICF categories: body functions and structures (ICF codes b280–b755) and activity and participation (ICF codes d410–d6401).¹⁸

Statistical analysis

We de-identified, organized, and entered the data into IBM SPSS Statistics, version 20 (IBM Corporation, Armonk, NY). We present the continuous variables as descriptive statistics including age (mean, SD). We present all other data as frequencies and percentages. To determine the statistical significance between spasticity distribution and goal characteristics, we performed χ^2 tests¹⁹ ($p < 0.05$ for statistical significance).

RESULTS

Interrater reliability

ICC values for all variables were between 0.90 and 1.00 (95% CI: 0.81, 0.99), which demonstrates excellent agreement among the four student data abstractors. Almost half of the participants were diagnosed with stroke (46%, $n = 80$), and the majority of the sample population were male (58%; $n = 102$) (see Table 1).

ICF goal categories

Patients set a total of 176 personal goals (1 goal per patient). Of these, 73% were activity and participation goals, and 27% were body functions and structures goals ($\chi^2_1 = 11.17$, $p < 0.001$). In the activity and participation category, 12% of patients set changing and maintaining body position goals, 30% set moving and walking goals, and 32% set self-care goals. Table 2 lists number of patients in, as well as the ICF codes for, each goal subcategory. More details on the codes can be found online on the ICF browser provided by the World Health Organization (<http://apps.who.int/classifications/icfbrowser/>).²⁰

In the moving and walking category, the 21 goals in the “walking, other specified” subcategory included increasing ease of walking, reducing discomfort during walking, and increasing ease of ambulation with gait-assistive devices. The 1 goal in the “Moving around, other specified” subcategory was to be more physically active, and the goal in the “walking and moving other specified and unspecified” subcategory was to decrease difficulty going up the stairs. Of those participants who set moving and walking goals, 60% had bilateral lower limb spasticity, and 54% had spasticity in the lower limbs only.

In the self-care subcategory, the majority of goals related to putting on clothes and dressing. In the “dressing, other specified” subcategory, goals included decreasing difficulty in dressing and reducing caregiver burden. Of those who set self-care goals, 57% had spasticity in

Table 1 Demographic Characteristics of the Sample Population

Characteristic	No. (%) of participants* ($n = 176$)
Mean age (SD), y	52 (18)
Gender	
Male	102 (58)
Female	74 (42)
Diagnosis†	
Stroke	80 (46)
MS	20 (11)
SCI	16 (9)
CP	25 (14)
ABI	18 (10)
Other	19 (11)

*Unless otherwise indicated.

†Two patients had multiple diagnoses; thus, percentages total more than 100. MS = multiple sclerosis; SCI = spinal cord injury; CP = cerebral palsy; ABI = acquired brain injury.

the upper limbs only. In the body functions and structures category, 14 goals were pain related, 24 were related to joint mobility, and 7 were related to muscle tone functions. The majority of joint mobility goals were related to preventing contracture in upper and lower limbs.

The ICF goal categories were not related to the patterns of spasticity distribution shown in Table 3—that is, upper limb versus lower limb ($\chi^2_1 = 1.31$, $p = 0.52$), unilateral versus bilateral spasticity ($\chi^2_1 = 0.04$, $p = 0.83$), or type of UMN lesion ($\chi^2_1 = 3.77$, $p = 0.29$).

Exploratory analysis: relationship between spasticity and type of goal set

Of those participants who set moving and walking goals, 60% had bilateral lower limb spasticity, and 54% had spasticity in the lower limbs only. Of those who set self-care goals, 57% had spasticity in the upper limbs only.

DISCUSSION

Activity and participation goals versus body functions and structures goals

Patients in our study set more activity and participation goals than body functions and structures goals, indicating that the majority of patients with spasticity were concerned about improving their activity and participation rather than improving range of motion or pain. Thus, our findings make a threefold contribution to the literature: (1) We confirm previous findings that the majority of the goals set by patients with upper limb spasticity are in the activity and participation category,^{14,15} (2) we show that the majority of the goals set by patients with stroke and ABI who have lower limb spasticity are in the activity and participation category (see Table 3), and (3) our results extend previous findings with patients with stroke^{14,15} to the population of patients with spasticity from other causes, such as spinal cord injury, MS, and CP.

Table 2 Goal Categories and Subcategories

ICF code	Sub-category	No. (%) of participants
Activity and participation goals		
Changing and maintaining body position		
d410	Changing basic body position	2
d415	Maintaining body position	2
d420	Transferring oneself	3
d430	Lifting and carrying objects	2
d440–445	Fine hand and arm use	12
Subtotal		21 (12)
Moving and walking		
d450	Walking	15
d4500	Walking short distances	8
d4508	Walking, other specified	21
d4552	Running	1
d4559	Moving around, other specified	1
d465	Moving around using equipment	5
d469	Walking and moving other specified and unspecified	1
Subtotal		52 (30)
Self-care		
d5	Self-care	1
d510	Washing oneself	1
d5100	Washing body parts	1
d520	Caring for body parts	2
d5201	Caring for teeth	1
d5208	Caring for body parts, others specified	4
d540	Dressing	4
d5400	Putting on clothes	12
d5401	Taking off clothes	1
d5402	Putting on footwear	3
d5408	Dressing, other specified	18
d550	Eating	5
d560	Drinking	1
d6401	(Domestic life) Cleaning cooking area and utensils	2
Subtotal		56 (32)
Total		129 (73)
Body functions and structures goals		
b280–289	Pain	14
b710	Mobility of joint functions	24
b735	Muscle tone functions	7
b4552	Fatigability	1
b755	Involuntary movements	1
Total		47 (27)
Overall total		176

Individuals set activity goals to improve their physical function, which is an important domain in HRQOL.²¹ Crosby and colleagues²² reported that a meaningful change in patients' HRQOL often comes in the form of improvements in function. Patients set goals using GAS in conjunction with a physical or occupational therapist; it is therefore possible that patients were naturally inclined to set activity and participation goals that were more meaningful to them because the results would improve their HRQOL.

Spasticity distribution and goal categories

MS patients with bilateral spasticity have been reported to experience more severe spasticity than stroke patients (with unilateral spasticity).²³ In addition, patients with MS

experience greater worsening of symptoms when exposed to outdoor heat and circadian rhythm-related changes such as worsening of symptoms in the morning and evening.²³ Barnes and colleagues²⁴ found that MS patients with more severe spasticity had more severe disability and that there was an inverse relationship between severity of spasticity and functional independence. Spasticity in patients with MS has been reported to be more severe than that in patients with stroke, and spasticity is commonly seen bilaterally in MS patients compared with the unilateral spasticity seen in patients after stroke.²³ These results support the concept that patients who experience bilateral spasticity are likely to have decreased functional abilities. However, our results indicate that

Table 3 Comparing Spasticity and Lesion Distribution and Goal Characteristics

Spasticity and lesion distribution	No. of participants	Goals set, no. (%) of participants	
		Body functions and structures	Activity and participation
Side of spasticity			
Bilateral	94	24 (26)	70 (74)
Unilateral	82	23 (28)	59 (72)
Limb involvement			
UL only	40	11 (28)	29 (73)
LL only	60	19 (32)	41 (68)
UL + LL	76	17 (23)	59 (77)
Lesion type			
Stroke	80	25 (31)	55 (69)
MS	20	4 (20)	16 (80)
SCI	16	7 (44)	9 (56)
CP	25	5 (20)	20 (80)
ABI	18	5 (28)	13 (72)
Other	19	3 (16)	16 (84)

UL = upper limbs; LL = lower limbs; MS = multiple sclerosis; SCI = spinal cord injury; CP = cerebral palsy; ABI = acquired brain injury.

the types of goal set do not significantly differ on the basis of lesion type.

Previous results showed a similar distribution of *ICF* category goals in patients treated for spasticity in the upper limbs;^{14,15} however, no data for patients with spasticity in the lower limbs were available for comparison, which prompted us to examine whether the goals set for the lower limbs were similar. It appears from our and previous results that, irrespective of location of spasticity (upper vs. lower limbs or bilateral vs. unilateral spasticity), patients set more activity and participation goals than body functions and structures goals. This indicates that activity and participation goals are important for patients irrespective of the distribution of spasticity or lesion characteristics. It is difficult to ascertain whether these results are influenced predominantly by patient choice or by a therapist's guidance in setting feasible and realistic goals. Patients demand and expect benefit in their activity and participation in response to BoNTA injections.

Analysis of goals

In the activity and participation goals category, 30% of all patients set moving and walking goals, 32% set self-care and dressing goals, and 12% set changing and maintaining body position goals. Of those who set moving and walking goals, 60% had bilateral lower limb spasticity, and 54% had spasticity in the lower limbs only, suggesting that patients with bilateral lower limb spasticity (or only lower limb spasticity) are more likely to set walking-related goals. Walking is one of the most important functions of the lower limbs, and our data suggest that patients perceived that lower limb spasticity impairs walking ability; hence, they set walking goals for BoNTA treatment of their lower limb spasticity.

No other study has assessed goals based on *ICF* categories to address impairment in the lower limbs. A previous study of treatment of upper limb spasticity reported

that 11 patients (6%) set walking and balance goals,¹⁴ suggesting the possible impact of upper limb spasticity on walking. Our sample included patients with lower limb spasticity, which explains the much higher occurrence (30%; see Table 2) of gait-related goals in this study. Our results suggest that more studies are needed to understand the nature and impact of BoNTA injections for spasticity on walking goals.

Many self-care activities such as putting on clothes and dressing require the use of the upper limbs. Spasticity in the upper limbs can create movement difficulty and add to the difficulty involved with impaired motor control post-UMN lesion. Of those who set self-care goals, 57% had spasticity in their upper limbs only, indicating that those with upper limb spasticity alone are most likely to set self-care goals. The occurrence of self-care goals found in this study was similar to that found in a previous study in patients post-stroke.¹⁴

Almost one-third (14) of the goals set in the body functions and structures category were related to reducing pain, which indicates that patients expect pain relief from BoNTA injections. This result is similar to that of a previous report showing that patients believed that spasticity was related to pain and that patients also experienced pain relief from a reduction in spasticity with BoNTA injections.²⁵

As expected, more than half the goals in the body functions and structures category were related to joint mobility. It is not possible from the study results to determine why some patients chose body functions and structures goals over activity and participation goals. Because most patients chose prevention of a joint contracture as their primary goal, it is possible that these patients may have experienced difficulty in actively moving their limbs¹⁴ and hence determined that maintaining muscle length was their primary goal. However, data on passive range of motion and motor abilities, for example,

were not available in this study, precluding any further analysis.

This study had several limitations. First, only one therapist was experienced with *ICF* classification and classified the goals on the basis of his or her understanding. Although this therapist was experienced, independent goal classification would ideally have been performed by two investigators, followed by discussion, comparison, and consensus, to ensure proper, unbiased classification. Second, a physical therapist and occupational therapist were equally involved in identifying participants' goals; however, the physical therapist was not available for all clinics, and as a result the goal-setting process may not have been consistent across all patients. Depending on the flow of patients and staff in the clinic on a given day, goals were decided by the patient, the family, the occupational therapist or physical therapist, or all.

CONCLUSION

Our results show that patients receiving BoNTA treatment to manage their spasticity set a higher percentage of goals in the *ICF's* activity and participation category and expected their activity and participation to improve as a result of BoNTA injections. Goal classification was not affected by spasticity distribution or by type of UMN disorder.

KEY MESSAGES

What is already known on this topic

Of patients with stroke who receive botulinum toxin type A (BoNTA) injections for upper limb spasticity, about a quarter select goals from the *International Classification of Functioning, Disability and Health (ICF)* body functions and structures category as their primary goal for treatment, and the majority select goals from the activity and participation category. What goal category is selected by patients with lower limb spasticity is not clear. In addition, it is not clear whether neurological condition or spasticity distribution influences goal category selection.

What this study adds

This study shows that, similar to patients with upper limb spasticity post-stroke, those with lower limb spasticity also predominantly choose *ICF* activity and participation goals for treatment with BoNTA injections. In addition, irrespective of the type of upper motor neuron lesion (stroke, spinal cord injury, cerebral palsy, acquired brain injury, multiple sclerosis) that results in spasticity, patients predominantly choose goals in the activity and participation category. The distribution of spasticity is not associated with the category of goals set.

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