Frequency and characteristics of goal attainment following BoNT-A injection for management of spasticity

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Abstract

Purpose: To determine which Goal Attainment Scale (GAS) goals are commonly achieved in patients with upper limb and/or lower limb spasticity following Botulinum Neurotoxin Type A (BoNT-A) injection.

Method: Adults who attended a Spasticity Management Clinic for upper and/or lower limb BoNT-A injection were included in this prospective cohort study. Goals were set by participants and/or carers in conjunction with the therapist using the GAS, prior to injection and reviewed at one month following the injection. Three out of the five categories of goals were passive. Goals were categorised into: mobility/transfers, pain/comfort, upper limb use, hygiene, and cosmesis. The number of responders for the GAS total score, and in each of the GAS categories, was calculated.

Results: Sixty-seven participants were recruited (mean age 51 ± 16 years; range 18–85), 70% had a stroke. Responders for mobility and transfer goals were further post injury or disease onset than non-responders (median 5.9 vs. 1.2 years, \( p = 0.03 \)). Clients with stroke were less likely than other participants to achieve mobility and transfer goals (\( p = 0.02 \)). There was a trend for those who achieved mobility and transfer goals to be younger (mean 49 years vs. 55 years, \( p = 0.06 \)). Although active goals are more commonly identified, passive goals were more likely to be achieved.

Conclusions: Although active goals are commonly identified by people with spasticity, passive goals were more likely to be achieved following BoNT-A injection. A long duration of spasticity does not preclude patients from achieving mobility and transfer goals. Non-stroke participants were more likely to achieve mobility and transfer goals.

Implications for Rehabilitation

- Patients with chronic spasticity should be considered for BoNT-A as clinically meaningful outcomes can be achieved.
- When spasticity is present in multiple muscles, the GAS can be an assistive tool to guide clinicians in determining which muscles are a priority for injection, because the client will be more motivated to improve those specific goals.
- Although carers and patients are more willing to set active goals, these are more difficult to achieve possibly because follow up intervention or independent practise is required.

Introduction

Spasticity is a physiological consequence of an insult to the brain or spinal cord, which can have devastating effects on individuals’ lives, impacting on all aspects of impairment, activity and community participation.[1] This typically occurs following stroke, brain injury (trauma or other causes), spinal cord injury, multiple sclerosis, cerebral palsy and other disabling neurological diseases. It is estimated that 19% of hospitalised stroke survivors will experience spasticity [2] and at one year the number is thought to be approximately 38%. [3] The management of spasticity has advanced considerably over the last 10 years, with physical therapies and the use of Botulinum Neurotoxin Type A (BoNT-A).

Many attempts have been made to define spasticity; however, Lance’s definition continues to be the most widely accepted, classifying spasticity as one of the features of the upper motor neurone syndrome.[4] It is also widely accepted within rehabilitation that there are both positive features (e.g. exaggerated tonic and...
phasic stretch reflexes) and negative features (such as muscle weakness) of the upper motor neurone syndrome.[5–7] Essentially, if positive features (including spasticity) are left untreated following damage to the central nervous system, they will lead to muscle and soft tissue contracture.[7]

Treatment of spasticity is clinically indicated when it is causing harm and interferes with active or passive functioning. There is strong evidence to support the use of BoNT-A injections to reduce focal spasticity in a variety of neurological diagnoses,[1,8,9] which can reduce carer burden during self-care.[1,10,11] Whilst it is widely accepted that BoNT-A can produce improvement in passive functional goals, achievement of active goals, such as handwriting and improved walking speed, has been more difficult to demonstrate.[1] Tools commonly used to measure clinical improvement after BoNT-A injection are thought to lack sensitivity since they often need to be broad enough in concept to be applicable to a widely varied client group.[10] Goal achievement is considered to be more sensitive and clinically relevant than observational measures of motor performance.[10,12] The Goal Attainment Scale (GAS), as one standardised measure of goal achievement, has been demonstrated to be useful in measuring change after BoNT-A injections for spasticity management.[13] The GAS evaluates longitudinal change in an individual and additionally permits service evaluation of the clinic.[14] Goals are set with the client and may be weighted for importance and degree of difficulty. The therapist predicts a range of outcomes. The GAS score is determined at the follow-up interview. The interviewer assigns scores depending on the level achieved (+2 = much better than expected, +1 = better than expected, 0 = as expected, –1 = less than expected, –2 = much less than expected).[12] The scores are then converted to a GAS t-score [15] using the Conversion Key tables.[16] GAS is as sensitive to change as other outcome measures such as the FIM and Barthel.[13] The GAS is particularly useful in spasticity management as it often involves development of goals prior to injection and can aid in optimal identification of muscles for injection.

In 2010, Turner-Stokes et al. retrospectively placed goals set during spasticity management programmes into categories.[13] They found that active goals were not often achieved and had hypothesised that this was due to the chronicity of their cohort. Passive goals were more likely to be achieved but less likely to be set by the patient. The authors identified that a limitation to their study was that the goal categories were set retrospectively and that goals often fell into more than one category, making them challenging to categorise. In order to verify these goal categories and determine whether there are differences between them in the frequency of goal attainment according to the nature of the goals or patient characteristics, the authors felt this study needed to be replicated with prospective goal setting.

The aim of this study was to determine which GAS goals are most commonly achieved in patients with upper limb and/or lower limb spasticity. By identifying categories of goals that are most likely to be achieved, we hope to be able to target the clients who are likely to respond positively to BoNT-A. We also hypothesised that understanding which goals are not often achieved would allow us to improve our service delivery in terms of injection frequency, dosage and follow-up therapies.

Methods

Design and setting

A prospective cohort study was undertaken in the setting of an inpatient and ambulatory specialist rehabilitation service for adult patients with neurological impairment in a large metropolitan public sub-acute hospital in Melbourne, Australia. Data were gathered from patients attending the Spasticity Management Clinic at Caulfield Hospital, Alfred Health between June 2008 and March 2011. Ethics approval was obtained from the Alfred Human Research Ethics Committee and La Trobe University Human Research Ethics Committee.

Participants

The study sample consisted of consecutive adults treated with BoNT-A injections at our centre from 2008 to 2011. Patients were eligible for inclusion if they were aged 18 years or older and had been referred to the Spasticity Management Clinic for BoNT-A injection in their upper and/or lower limb. Patients were excluded if they were assessed by the treating clinician as unsuitable for BoNT-A injection (e.g. fixed contracture), or if neither the patient nor the carer could identify GAS goals. Informed, written consent was obtained from all 67 participants or their carer.

Procedure

In the Spasticity Management Clinic, patients are seen by the rehabilitation physician and allied health staff (physiotherapists and occupational therapists), all of whom were specialised in neuromuscular disorders. In addition to the GAS findings, physical examination for range of movement in the involved limbs is routinely
recorded at each visit, spasticity is rated using the Tardieu Scale,[17] and a suite of measures of physical function (which includes 10 Metre Walk Test, Timed Up and Go Test, Six Minute Walk Test), Visual Analogue Pain Scale and/or the Patient Disability and Carer Burden Scale are completed for pre and post injection.[18] The objective gait measures were only included for patients receiving lower limb injections, as long as they could ambulate independently \( n = 36 \). Treatment objectives are discussed before the treatment session with both patients and their caregivers to ensure that expectations are realistic and that the patients’ post-injection therapy programme can be optimised for treatment objectives. Some patients have more than one indication for treatment and may receive injections to more than one muscle group in the same injection appointment. Follow-up visits are scheduled at one month, at which time all assessments are repeated and the GAS score was obtained.

Prior to injection the individualised goals for the GAS were set in conjunction with the patient and/or family or carers. Patients and/or carers were invited to express their most important goals. After discussion with the patient and/or carer, therapists only assisted to modify the goals if they appeared to be unrealistic. The level of importance for each goal was determined by the patient and/or carer, thus eliminating observer bias. Therapists suggested which specific muscles should be injected according to the goals clients wanted to achieve and which muscles were identified with spasticity according to the Tardieu Scale.

Goals were allocated to one of five categories, determined by therapists and rehabilitation physicians who were involved in the Spasticity Management Clinic. These categories were identified prospectively by clinicians with extensive clinical experience in spasticity management. The five categories of goals were: mobility and transfers e.g. improve walking quality/speed; upper limb use in occupational performance e.g. increase ease of dressing my arm; positioning/cosmesis e.g. to relax arm by side when walking to look normal; pain and comfort e.g. improve comfort with sleeping position; and hygiene e.g. to be able to open fingers to wash hand properly. In order to facilitate analysis, broad categories were required. Individual goals were weighted in terms of their importance to the patient on a scale of 0–3.[12] Baseline scores for goals were allocated – 1 however, a score of – 2 was given if the patient’s status was the worst it could be in relation to the goal. Between one and three goals were set for each client.

Goal achievement was rated on the GAS by physiotherapists or occupational therapists. Optimally the baseline and review assessments were performed by the same clinician, however, there were occasions when this was not possible. The degree of difficulty of each goal for each client was set by the clinician when the client was well known to the clinician. When the client was not known to the clinician the degree of difficulty was determined in collaboration with the client and/or carer. If the difference between the two t-scores was 10 or greater in a positive direction, the goal was considered to have been achieved.[19] For the purpose of this study the patients whose goals were achieved were classified as ‘responders’. The number of responders for the GAS total score, and in each of the GAS categories, was calculated.

**Injection technique**

BoNT-A in the form of either Botox (Allergan, Inc., Irvine, CA) or Dysport (Ipsen Biopharm, Wrexham, UK), was used according to the manufacturer’s instructions. The dose for Botox was between 20 mouse units (UL) and maximum of 600 mouse units (LL) distributed to target muscles. The dose for Dysport was between 30 mouse units and maximum of 400 mouse units distributed to target muscles (Table 1). The targeted muscles were identified by palpation in conjunction with Electrical Low Frequency stimulation.

**Statistical analyses**

The proportion of participants achieving goals in each category was expressed as a percentage. Z scores were calculated from these percentages with confidence intervals. The influence of demographic and baseline features on goal attainment was assessed using Pearson’s Chi Square test for categorical data and Mann–Whitney U-test for continuous data, where

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**Table 1. Dosage per muscle of dysport or botox.**

<table>
<thead>
<tr>
<th></th>
<th>Upper limb</th>
<th></th>
<th>Lower limb</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>Range of dose</td>
<td>Mean dose (SD)</td>
<td>Range of dose</td>
<td>Mean dose (SD)</td>
</tr>
<tr>
<td>Dysport</td>
<td>128</td>
<td>50–400</td>
<td>154 (72)</td>
<td>30–150</td>
<td>84 (29)</td>
</tr>
<tr>
<td>Botox</td>
<td>12</td>
<td>20–80</td>
<td>63 (17)</td>
<td>100–600</td>
<td>283 (120)</td>
</tr>
</tbody>
</table>
significant predictors were found, receiver operating characteristic (ROC) curves were used to identify relevant clinical cut offs. Alpha was set at 0.05.

Results

Participants

All 67 participants gave informed consent. These participants were all included in the study. Refer Table 2 for full baseline demographic and gait data description. Forty percent ($n = 27$) had only their upper limb injected, 39% ($n = 26$) had only their lower limb injected and 21% ($n = 14$) had both upper and lower limb injected. All participants who received upper limb injections ($n = 41$), had their wrist and finger flexors injected (flexor digitorum superficialis and/or profundus, flexor carpi ulnaris and/or flexor carpi radialis), 21 had their elbow flexors injected (biceps and/or brachialis and/or brachioradialis), 15 had their forearm pronators injected (pronator teres and/or pronator quadratus), 2 had their pectoralis major injected, 2 had their triceps injected, 2 had posterior deltoid injected, 1 had flexor pollicis longus injected, 1 had subscapularis injected and 1 had teres major injected. For those participants who received lower limb injections ($n = 40$), 33 injections were in to calf muscles (gastrocnemius and/or soleus), 17 injections were into foot invertors (predominantly tibialis posterior, but occasionally tibialis anterior), 11 injections were into rectus femoris, 8 injections were into the toe flexors, 5 injections were into flexor hallucis longus and 2 injections were in to extensor hallucis longus.

A total of 6 of the 67 (9%) participants were wheelchair bound and unable to ambulate. No gait data is presented for the 40% ($n = 27$) of participants who only had upper limb injections as these measurements were not taken. Of the 40 participants who had lower limb injections only 34 could ambulate independently and had their gait measures taken at baseline (Table 2).

Goals

The mean $Z$ score was 48.95 across all goal domains with a standard error of 2.01 (Figure 1). A total of 115 goals were set by the 67 participants (Figure 2). All those with mobility and transfer goals had their lower limb injected and all hygiene goals were related to the upper limb. Thirty-five mobility and transfer goals were set with 19 responders (54%). For upper limb use in occupational performance, there were a total of 24 goals with 10 responders (42%). Thirty-three positioning/cosmesis goals were set with a total of 28 responders (85%). In the pain and comfort category, a total of 15 goals were set. Twelve responders (80%) were identified. Eight hygiene goals were established and all of these were achieved (100%).

Effect of demographic characteristics on goal attainment

Responders for GAS total score tended to be further post injury or disease onset than those who did not respond (median 3.5 years vs. 1.8 years $p = 0.06$). For mobility and transfer goals, responders had a median of 5.9 years since onset, compared to 1.2 years in non-responders ($p = 0.03$). The ROC analysis indicated that the best threshold for distinguishing responders from non-responders was 1.22 years, with a sensitivity of 83% and a specificity of 56%. There was no significant difference between responders and non-responders for time since onset in the categories of upper limb use in occupational performance ($p = 1.0$), positioning/cosmesis ($p = 0.64$), and pain and comfort ($p = 0.77$).

Participants with a diagnosis of stroke were less likely to achieve their mobility and transfer goals than those with other diagnoses ($p = 0.02$). Fourteen out of 24 participants with stroke did not achieve their mobility and transfer goals, compared to 2 out of 11 with other diagnoses. There were no differences in the proportion

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Number ($n$)</th>
<th>Percentage (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex</td>
<td>Male/female</td>
<td>37/30 55/45</td>
</tr>
<tr>
<td>Spasticity aetiology</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stroke</td>
<td>46</td>
<td>69</td>
</tr>
<tr>
<td>MS/TBI/adult CP/brain tumour</td>
<td>21</td>
<td>31</td>
</tr>
<tr>
<td>UL and/or LL injected</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unilateral LL</td>
<td>26</td>
<td>39</td>
</tr>
<tr>
<td>Unilateral UL</td>
<td>27</td>
<td>40</td>
</tr>
<tr>
<td>Both UL and LL</td>
<td>14</td>
<td>21</td>
</tr>
<tr>
<td>Naive to BoNT-A</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Naive</td>
<td>32</td>
<td>48</td>
</tr>
<tr>
<td>Not Naive</td>
<td>28</td>
<td>42</td>
</tr>
<tr>
<td>Unknown</td>
<td>7</td>
<td>10</td>
</tr>
<tr>
<td>Gait measures for LL injected</td>
<td>40</td>
<td>100</td>
</tr>
<tr>
<td>Non-ambulant</td>
<td>6</td>
<td>15</td>
</tr>
<tr>
<td>Gait aid used ($n = 34$)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nil</td>
<td>20</td>
<td>59</td>
</tr>
<tr>
<td>Single point stick</td>
<td>9</td>
<td>26</td>
</tr>
<tr>
<td>Four wheeled frame</td>
<td>2</td>
<td>6</td>
</tr>
<tr>
<td>Four point stick</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Forearm crutch</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Gutter frame</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Orthotic/AFO/none ($n = 34$)</td>
<td>AFO – 10</td>
<td>30.3</td>
</tr>
<tr>
<td>Soft ankle brace – 2</td>
<td>6</td>
<td>63.7</td>
</tr>
<tr>
<td>No orthotic – 22</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 2. Demographic and gait date for participants at baseline.
of responders related to diagnosis for GAS total score ($p = 0.89$), upper limb use in occupational performance ($p = 0.44$), positioning/cosmesis ($p = 0.10$) or pain and comfort ($p = 0.74$).

There was a trend for those who achieved mobility and transfer goals to be slightly younger (mean age of responders: 49 years vs. non-responders: 55 years, $p = 0.06$). Age did not influence goal attainment for GAS total score ($p = 0.15$) or any other GAS category. There was no influence of gender on goal attainment for GAS total score.

**Effect of treatment characteristics on goal attainment**

Participants who were having upper limb injections were equally likely to achieve their goals as those having lower limb injections (GAS total score $p = 0.40$). There was no difference in the proportion of responders amongst those who were naive to BoNT-A injection compared to those with previous BoNT-A injections for GAS total score ($p = 0.70$) or any GAS category. The total BoNT-A dose injected was analysed for the Dysport product as it was more frequently used and was found not to affect response (responders median 1000 mouse units compared to non-responders 650 mouse units, $p = 0.93$). The number of muscles injected (median four muscles in both responders and non-responders) was also found not to affect response.

**Discussion**

Results of this study confirm that passive goals such as those surrounding hygiene, pain and comfort, were less likely to be set by patients and/or family or carers but more likely to be achieved after BoNT-A injection and
therapy, compared to active goals, such as improved walking and use of upper limb in occupational performance. Whilst therapists may have modified some of the goals with patients and/or carers, they did not change the goals from active to passive or vice versa. These prospectively collected results mirror those of the retrospective chart audit conducted by Turner-Stokes et al. which examined goal achievement in upper limb spasticity post stroke.[13] Whilst both studies have found that goals concerning passive tasks or impairments are more likely to be achieved than those related to activity and participation goals, the present study has also highlighted that active goals are more commonly identified by patients and their carers and that mobility and transfers goals were more likely to be achieved by participants who had a longer duration of spasticity.

The achievement of active goals is complex and may be influenced by a range of factors including severity of disability, presence of comorbidities and psychosocial factors. Chan et al. have found that objective gait outcome measures (such as 10 Metre Walk Test, Timed Up and Go Test, 6 Minute Walk Test) are not necessarily sensitive to the improvements people perceive they have made post BoNT-A injection, which illustrates the complex nature of the improvements that are required in order to achieve active goals.[20] For this reason, the focus of this paper was on goal achievement and not improvement in objective measures.

It is possible that passive goals are easier to achieve within a spasticity management programme because they require less physical rehabilitation than active goals. For example in achieving the goal of hygiene, if spasticity is reduced in the hand muscles, the fingers will open more easily for cleaning. Alternatively, in order to achieve active goals such as hand grip, spasticity needs to be eliminated or reduced via BoNT-A injection concurrent to antagonist muscle strengthening via motor training and specific activity retraining. Whilst predicting a response to BoNT-A injection has been made more likely through research,[1,7] predicting a response to physical therapy is less straightforward. Whilst antispasticity drugs (including BoNT-A) reduce spasticity, this does not directly lead to hemiplegic limbs regaining function in daily tasks.[6] Thus, the achievement of active goals requires significant commitment from the patient, their caregiver and the interdisciplinary rehabilitation team. Active goals are unlikely to be achieved by purely reducing spasticity but require attention to improving motor control and strength to enable the active functional goal to be reached. Patients’ motivation to practise specific tasks associated with the goal that has been set will also influence the outcome. This is not to intimate that either goal type (active or passive) is any more important than the other, since both remain valid indications for injecting BoNT-A as both may potentially improve quality of life of the patients and reduce carer burden.

It is widely acknowledged that more research needs to be undertaken to determine the effects of follow-up therapy.[1,7,21] It has even been suggested that home exercise programmes do not provide a sufficient dose of therapy, and that they may require supervision to be effective.[22] This suggests that patients may need adequate information prior to BoNT-A injection, emphasising their participation both in attending therapy appointments and practise in the home or community environment, in order to assist achievement of active goals.

A limitation of the GAS is the capacity of patients to set realistic and valid goals and likewise, for therapists to guide patients in goal setting.[12] We acknowledge that this is a potential source of bias in the goal setting process. For example, it has been shown in the literature that there is a window of opportunity to make change post BoNT-A injection. Ward suggests this time frame is approximately 3–4 months.[6] Clinicians should guide patients and carers in the goal setting process to assist in identifying appropriate goals to be achieved within this time frame.[12] An additional reason for a lower rate of achievement for active goals is possibly that in this study the participants were setting goals for the first time using the GAS and may have had unrealistic expectations.

Turner-Stokes et al. propose that chronicity of injury impacts negatively on ability to achieve active goals.[13] In contrast, this study demonstrates that people who are at a greater time post injury still have the ability to achieve their goals and were able to achieve them more readily than the more acute participants. This was particularly significant in the mobility/transfer category of goals, suggesting that BoNT-A may still have benefits for chronic populations with active goals such as transfers. The higher rate of goal achievement in the chronic population may be partially attributed to more experience in realistic goal setting and achievable outcomes. In addition, another possible explanation may be that clients with more chronic neurological conditions may not have received active treatment for a long time. Many of these patients, once assessed and receiving BoNT-A, participated in therapy that specifically targeted the goals they had set. This should be a consideration for future research and clinical practise.

**Limitations**

A limitation of this study is that the only reassessment of measures was one-month post injection. The literature regarding optimal time for reassessment is limited. Based
on the Dysport and Allergan studies when this current
research commenced, one-month post injection was
considered best practise. Further research is warranted to
definitely find the optimal time or times for re-
evaluation, where possible clinicians conducting baseline
assessments completed reassessment post injection,
however, this was not always possible. The investigators
determined that it was preferable to include all the data
despite the confounding factor of different assessors. In
order to minimise this limitation, staff attended a training
regarding a consistent implementation of the Tardieu
Scale and GAS, to enhance inter-rater reliability.

It is possible that therapists can influence the goal
setting process, which is a potential source of bias. Ideally
patient GAS goals are derived from a predetermined
suite of SMART (SMART = specific, measurable, achiev-
able, realistic and timed) goals.[13] However, this study
relied on clinicians developing goals with patients indi-

cidually. An additional challenge during the goal setting
process was that clinicians were at times working with

unfamiliar patients. These challenges may have resulted
in clinicians and/or patients setting unrealistic goals.

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Declaration of interest

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Appendices

1. GAS formula

\[ P_i = \frac{10 \sum (w_i x_i)}{\sqrt{0.7 \sum w_i^2 + 0.3(\sum w_i^2)^2}} \]