J Rehabil Med 2014; 46: 864–868

**ORIGINAL REPORT**

# GOAL ATTAINMENT FOLLOWING UPPER-LIMB BOTULINUM TOXIN-A INJECTIONS: ARE WE FACILITATING ACHIEVEMENT OF CLIENT-CENTRED GOALS?

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***Objectives:*** **Evaluate upper-limb goal attainment following botulinum toxin-A, map goals to the International Classification of Functioning, Disability and Health (ICF) and explore associations between client goals, clinical indicators of spasticity and the Botulinum Toxin-A injection strategy adopted by the treating physician.**
***Design:*** **Pre-test/post-test.**
***Participants:*** **Twenty-eight community-dwelling adults with acquired brain injury.**
***Methods:*** **Goal attainment was measured using the Goal Attainment Scale (GAS) 4 weeks post-injection. Goals were linked to the ICF. Clinical measures including the Modified Ashworth Scale (MAS), Tardieu Spasticity Angle (TSA) and Action Research Arm Test (ARAT) were collected pre-injection for determining association with injection strategy.**
***Results:*** **Goals represented the ICF domains of Body Structure/Function and Activity/Participation. Approximately half the goals were achieved 4 weeks post-injection and GAS T-scores improved significantly. Activity/Participation goals were equally likely to be achieved as Body Structure/Function goals. Pre-injection ARAT scores were correlated with GAS change, whereas MAS and TSA scores were not. TSA was a stronger indicator of muscle selection for botulinum toxin-A injections than MAS. Goals were directly associated with botulinum toxin-A injections for distal hand function, but not for proximal upper-limb function.**
***Conclusion:*** **Goal setting and review provides a clinically useful process for measuring upper-limb botulinum toxin-A outcomes.**

*Key words:* stroke; brain injuries; muscle spasticity; botulinum toxins; upper extremity.

J Rehabil Med 2014; 46: 864–868

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Accepted Apr 17, 2014; Epub ahead of print Jul 30, 2014

## INTRODUCTION

Upper limb (UL) muscle spasticity is a well-documented complication of cerebrovascular events and other forms of acquired brain impairment. Spasticity can be defined as "disordered sensorimotor control, resulting from an upper motor neuron lesion" (1) which may reduce functional abilities and contribute to caregiver burden (2, 3). Botulinum toxin-A (BTX-A) has clearly been shown to reduce the clinical symptoms of UL spasticity and improve caregiver ability to manage everyday UL tasks such as dressing, hygiene and cutting fingernails (4). In addition to these symptom and impairment outcomes, literature is emerging to support functional level outcomes following UL BTX-A injections.

Meta-analytical findings (5) indicate a clear and statistically significant association between changes in spasticity following BTX-A and arm function during everyday tasks such as dressing, eating and grooming. The timing of maximal reduction in spasticity coincided with maximal improvement in arm function at 4 weeks post-injection for 34% of the cases in the Francis et al. (5) pooled analysis; in contrast, 19% achieved maximal hand function well after achieving maximal spasticity reduction, suggesting that for some individuals, functional gains may be missed if outcome is only measured at one time point, early post-injection. A double-blind randomised crossover trial, published subsequent to the above meta-analysis, provides further evidence of functional improvement during activities of daily living when UL BTX-A injections are combined with occupational therapy and splinting (6). In an additional large ($n = 333$) randomised controlled trial, basic function for hand hygiene and facilitated dressing improved for up to 12 months following UL BTX-A injections (7).

International consensus focuses on functional, goal directed spasticity management practices (4). This creates opportunities for patients and their caregivers to be more involved in the team process of goal setting, promoting cooperation, improving motivation and favourably impacting on rehabilitation outcomes (8). Allied health professionals report goal setting to be a regular part of their spasticity management practice (9). Goals related to UL spasticity reduction typically focus on 4 key areas (4): relief from symptoms such as pain or involuntary movements (10–12); avoiding progression of impairments through improved posture or prevention of UL deformity through splint use (10); improving passive function and reducing caregiver burden (10–12); and finally increasing active UL function for reaching and grasping, and use during activities of daily living (11, 12). The Goal Attainment Scale (GAS) has been increasingly used to evaluate outcomes from BTX-A intervention (10–13). The GAS method (14), initially developed for evaluating outcomes


 doi: 10.2340/16501977-1853
 ISSN 1650-1977

from complex mental health interventions, has been adapted to evaluate passive and active functional outcomes following BTX-A injections for UL spasticity (12, 13, 15, 16).

The purpose of this study was to examine the effect of BTX-A injections for treatment of UL spasticity in a cohort of community dwelling adults by evaluating individual goal achievement and group goal attainment. In addition, this study mapped individual goals to the International Classification of Functioning, Disability and Health (ICF) and evaluated the associations between client goals, clinical indicators of spasticity and the BTX-A injection strategy adopted by the treating physician.

## METHODS

This pre/post-test study was approved by the local Institution Human Research Ethics Committee. Participants provided written informed consent prior to study involvement.

### *Participants*

Consecutively referred community dwelling adult participants who met the following inclusion criteria: age >17 years, first onset of acquired brain impairment (ABI), exhibiting positive upper-motor neuron (UMN) features of greater than three months duration. Exclusion criteria included: bilateral UL neurological disease, other causes of UL weakness and inability to understand instructions.

### *Data collection measures and procedures*

Data were collected by two experienced occupational therapists, who attended 3 outpatient spasticity management clinics. Pre-injection data were collected on the day of injection and post-injection data were collected 4 weeks post-injection at the clinical review appointment. Expected treatment outcomes and associated goal setting for one or two goals was facilitated by an occupational therapist and communicated to the rehabilitation physician. BTX-A injections were designed around maximising the likelihood that these goals would be achieved. The injection strategy (muscle selection, BTX-A product type and dose) was recorded for each participant on the day of injection. Injectors were asked to follow their usual practice with regards to choice of BTX-A formulation, with muscle selection and dosing aimed to maximise the chance of attaining each participant's personal GAS goals. Targeting of the selected muscles was confirmed through muscle stimulation. Group frequencies for individual muscle selections were calculated and mean dose (using BOTOX or Dysport) was calculated for each muscle.

The GAS was used to index goal attainment on a 5-point ordinal scale, in relation to a specific goal negotiated between the patient and the therapist. Baseline performance was routinely set at -1. When pre-intervention function could not deteriorate any further, baseline was set at –2. Standardised GAS-T scores were calculated and included weighting for importance and difficulty (15).

The Modified Ashworth Scale (MAS) and Tardieu Scale were administered pre- and post-injection using standardised methods (17, 18) to evaluate resistance to passive movement at the elbow, wrist and fingers. Tardieu spasticity angle was calculated as the difference in degrees between angle of arrest at V1 and V3. In addition to individual UL segment scores, composite summed MAS (5) and Tardieu spasticity angle scores were calculated using methods previously described.

A standardised UL measure, the Action Research Arm Test (ARAT), was administered to evaluate grasp, grip, pinch, and gross movements. ARAT scores range from 0–57 with higher scores indicting more ability to perform UL tasks (19).

### *Data analysis*

Goals were mapped to the ICF using linking rules established and later refined by Cieza et al. (20, 21). The ICF provides a common language for categorising goals into different domains of personal experience (12). Goals were classified retrospectively (by first author) to the ICF category that best matched the meaningful concept representing the aim with which the intervention was applied e.g. "Move right arm away from body to wash armpit" was categorrised as *d510 – Washing oneself*. Second-level categories (3-digit codes) were used as they are considered to provide ideal balance between breadth and depth of coding (12). Comparable linking procedures have been previously reported for classification of Botulinum toxin goals and outcomes in adults (12) and children (13).

Change in GAS-T scores following BTX-A injections were analysed using Wilcoxon sign-ranks test (z) as data were not normally distributed. Normality was tested using Kolmogorov-Smirnov Test of Normality. Effect size (ES) was calculated using $ES = z/\sqrt{n}$ (where $n$ = number of matched pairs) as described by Corder & Foreman (22, p. 39). Effect size was interpreted as per Cohen 1988 (cited in 23, p. 40) where 0.1 represents a small ES, 0.3 represents a medium ES and 0.5 represents a large ES.

Individual goals were categorised as achieved when the GAS ordinal score ≥ zero at 4 week follow-up. Factors potentially mediating goal attainment were examined using several analytic approaches. Likelihood of goal attainment was determined using chi-square analysis for different levels of the ICF Classification structure ('Body Structure and Function' vs 'Activity and Participation') and MAS score at each UL segment (elbow/wrist/fingers). Participant scores on the MAS were grouped into high = MAS score 2–4 or low = MAS score 0–1+. Non-parametric correlations, Spearman's rho, were calculated between GAS-T change scores and several pre-injection clinical measures: muscle overactivity (composite MAS score), Tardieu spasticity angle (composite score) and ARAT score. Correlations greater than 0.75 were considered strong, between 0.50 and 0.75 considered moderate to good, and fair if between 0.25 and 0.50 (23).

Several factors that potentially influenced the BTX-A injection strategy were examined. First, the association between presence of UL goal (proximal/distal) and receiving BTX-A injection to regionally associated muscles (proximal/distal) was tested using chi-square analysis. Second, the likelihood of BTX-A injection to elbow flexors/wrist flexors/finger flexors for participants with high vs low MAS scores at each UL segment (elbow/wrist/fingers) was tested using chi-square analysis. Differences between the Tardieu spasticity angle of participants who were/were not injected at each joint (elbow/wrist/fingers) were examined using independent group *t*-tests for each muscle group: elbow flexors/wrist flexors/finger flexors. *T*-tests were chosen following normality checking with Kolmogorov-Smirnov Test of Normality. All analyses were considered significant when $p < 0.05$.

## RESULTS

Mean age of the 28 adults with UL spasticity included in this cohort was 51 years (standard deviation (SD) 17). Approximately half were male ($n$ = 15/28) and mean time since onset of ABI was 6.4 years (SD 8.5). Most had sustained a cerebrovascular accident (CVA = 22; TBI = 6). All demonstrated 'positive' features of the upper motor neuron syndrome (i.e. spasticity), for which they received BTX-A injections (BOTOX, $n$ = 13, mean UL dose = 200 u; Dysport, $n$ = 15, mean UL dose = 740 u). Distal UL muscles were more frequently injected than proximal UL muscles (refer to Table I for muscle injection frequency and dose). Modified Ashworth Scale scores indicated a cohort with moderate resistance to passive movement: median (IQR) elbow = 1.0 (1.3); wrist = 1.5 (1.5); fingers = 1.5 (2.0). Tardieu spasticity angles at each UL joint were large: mean (SD) elbow = 51° (28°); wrist = 28° (24); fingers/MCP = 29° (26°). Baseline active UL function was limited (mean ARAT score 14 (SD 17)).

### *Goal mapping*

Fifty-five individual goals were set by the 28 participants with guidance by an occupational therapist. Goals were discussed

Table I. *Botulinum toxin-A (BTX-A) intervention – muscle injection frequency and dose*

| Muscle | Injection frequency *n* (%) | BOTOX dose Median (IQR) | Dysport dose Median (IQR) |
|---|---|---|---|
| *Flexor Digitorum Superficialis* | 21 (75%) | 50 (25) | 190 (88) |
| *Flexor Digitorum Profundus* | 19 (68) | 40 (14) | 100 (125) |
| *Flexor Pollicis Longus* | 19 (68) | 25 (13) | 75 (0) |
| Thumb intrinsic muscles[a] | 17 (61) | 15 (9) | 37.5 (56) |
| *Flexor Carpi Radialis* | 13 (46) | 40 (34) | 150 (88) |
| *Flexor Carpi Ulnaris* | 13 (46) | 40 (19) | 150 (63) |
| *Biceps Brachii* | 13 (46) | 50 (15) | 188 (50) |
| Hand intrinsic muscles[b] | 11 (39) | 40 (45) | 100 (255) |
| *Brachioradialis* | 8 (29) | 50 (38) | 100 (63) |
| *Pronator Teres/Quadratus* | 8 (29) | – | 87.5 (91) |
| *Brachialis* | 6 (21) | 27.5 (5) | 75 (88) |
| *Pectoralis Major* | 3 (11) | – | 150 (50) |
| *Subscapularis* | 2 (7) | 60 (0) | 150 (0) |

[a]*Adductor Pollicis, Flexor Pollicis Brevis.*
[b]*Lumbricals, Interossei, Abductor Digiti Minimi.*
IQR: interquartile range.

with the treating physician prior to BTX-A injections. One-quarter (24%) of goals were categorised at the ICF level of *Body Structure and Functions*, reflecting impairments such as pain, muscle tone and involuntary reactions. The remaining 76% of goals were related to the *Activity and Participation* domains, broadly divided into communication, arm mobility, self-care, domestic and community participation goals. Detailed ICF mapping is shown in Table II.

### *Goal attainment*

Standardised GAS T-scores increased by 10 points from pre-injection (median 37.6; IQR 0.1) to post-injection (median 47.6; IQR 17.3). Standardised GAS-T scores improved significantly ($z = 4.02$; $p < 0.001$); with an associated large ES (0.76). Approximately half the set goals were achieved ($n = 27/55$; 49%) in the 4-week post-injection review time frame.

Factors potentially mediating goal attainment were examined. Goals were equally likely to be achieved irrespective of ICF level i.e. Body structure and function vs Activity and Participation ($\chi^2 = 1.1$; $p = 0.30$). Similarly, goals were equally likely to be achieved by participants with high or low MAS scores (elbow: $\chi^2 = 0.53$, $p = 0.47$; wrist: $\chi^2 = 0.53$, $p = 0.47$; fingers: $\chi^2 = 0.02$, $p = 0.88$). Level of muscle overactivity, measured using composite MAS was not correlated with GAS change score (rho = –0.21; $p = 0.28$), nor was composite Tardieu spasticity angle (rho = –0.24; $p = 0.21$); however, level of pre-injection active hand function, measured by the ARAT, demonstrated a moderate positive correlation with GAS change score (rho = 0.39; $p = 0.047$).

### *Injection strategy*

Factors potentially influencing the BTX-A injection strategy were evaluated. First, the association between type of client goal and muscle selection was examined. Presence of a client identified goal primarily involving the proximal UL (e.g. reaching to sink) did not increase the likelihood of receiving injections in muscles of the proximal UL ($\chi^2 = 0.05$; $p = 0.82$). In contrast, over 90% of participants identified goals primarily involving distal UL musculature and all of these participants received BTX-A injections to muscle of the distal UL. Further statistical analysis was not possible due to the small number of participants who did not have distal UL goals ($n = 2$) nor received distal UL injections ($n = 1$).

Next, clinical measures of muscle overactivity (MAS and Tardieu spasticity angle) were examined for potential association with muscle selection. Tardieu spasticity angle appeared to be a stronger indicator of muscle selection for BTX-A injections. When considering the elbow, Tardieu spasticity angle varied considerably between injected and non-injected participants (injected group = 61°, non-injected group = 40°, mean difference = 21° (95% CI = –0° to 41°);

Table II. *Mapping of participant goals to the World Health Organisation International Classification of Functioning, Disability and Health (ICF) codes*

| ICF Domain and participant goal examples | ICF Chapter | ICF Code | Frequency |
|---|---|---|---|
| *Body Structure and Functions* | | | |
| Pain | 2 – Sensory & Pain | b280 – Pain | 2 |
| Splint wear/tolerance | 7 – Neuromusculoskeletal | b735 – Muscle tone | 4 |
| Arm position during ambulation | | b755 – Involuntary movement reactions | 4 |
| Stretches/home exercises | | b760 – Control of movements | 3 |
| *Activities and Participation* | | | |
| Greeting hand gestures (shaking hands) | 3 – Communication | d335 – Communicating | 1 |
| Handwriting | | d345 – Writing | 2 |
| Keyboard use | | d360 – Using communication device | 2 |
| Use upper limb during transfers | 4 – Mobility | d410 – Changing basic body position | 1 |
| Grasp/release objects/equipment | | d440 – Fine hand use | 1 |
| Stabilising objects | | d445 – Hand and arm use | 1 |
| Wash/dry body | 5 – Self Care | d510 – Washing oneself | 3 |
| Cut nails, clean teeth | | d520 – Caring for body parts | 6 |
| Upper and lower extremity dressing | | d540 – Dressing | 8 |
| Eating with cutlery | | d550 – Eating | 4 |
| Drinking from a cup | | d560 – Drinking | 7 |
| Meal preparation tasks | 6 – Domestic Life | d630 – Preparing meals | 2 |
| Household tasks | | d640 – Doing housework | 2 |
| Artistic and civic tasks | 9 – Community/social | d920 – Recreation and leisure | 2 |
| *Total* | | | 55 |

$t = 2.1$, $p = 0.051$); whereas higher MAS score was not associated with increased likelihood of receiving elbow flexor muscle injections ($\chi^2 = 0.53$; $p = 0.47$). A similar pattern was evident at the wrist. Participants were equally likely to receive injection to one or more wrist flexor muscles irrespective of high/low MAS category ($\chi^2 = 1.26$; $p = 0.26$); whereas Tardieu spasticity angle varied significantly between injected and non-injected participants (injected group = 43°, non-injected group = 14°, mean difference = 29° (95% CI = 12°–45°); $t = 3.6$, $p = 0.001$).

Both clinical scales appeared to be associated with the decision to inject extrinsic and intrinsic finger flexors. Tardieu spasticity angle was significantly higher in participants receiving injections (injected group = 34.1°, non-injected group = 0.0°, mean difference = 34.1° (95% CI = 23.6°–44.6°); $t = 6.7$, $p < 0.001$); and participants with high MAS scores were more likely to receive injection to one or more finger flexor muscles ($\chi^2 = 4.04$; $p = 0.04$).

## DISCUSSION

This consecutively referred cohort of community dwelling adults received BTX-A injections for treatment of UL spasticity. All participants were able to set goals when assisted by an experienced occupational therapist. Individual participant goals were mapped against 7 different chapters of the ICF; two from the domain of 'Body Structures and Functions' and 5 from the 'Activity and Participation' domains. Goal areas previously identified in the literature (10–12) were well represented in this study including relief from pain (ICF Chapter b2), prevention of UL deformity through splint use (ICF Chapter b7), improving passive function (ICF Chapter d5), increasing active UL function for reaching and grasping (ICF Chapter d4), and active use during activities of daily living (ICF Chapters d3, d4, d5, d6 & d9). The goals identified by this cohort reflected a more varied occupational profile of adults with spasticity than previously depicted. Goals included typical areas of self-care and mobility; however, additional areas related to use of communication devices, engagement in social and cultural activities and community participation were also identified. This cohort of adults, on average 6 years post ABI, continued to have high expectations for treatment outcomes related to UL spasticity management.

Approximately half the set goals were achieved within 4 weeks of BTX-A injections. The ES associated with positive GAS-T change was large and supports the clinical significance of this outcome. The timing of follow-up coincided with established clinical practices of one month post-injection review. In light of Francis et al. (5) meta-analytic findings, achievement of functional goals may have been under-estimated at this time point, as outcome was only measured once and this occurred relatively early post-injection. The timing of maximal reduction in spasticity coincided with maximal improvement in arm function at 4 weeks post-injection in only 34% of the cases in Francis et al's pooled analysis; in contrast, 19% achieved maximal hand function well after achieving maximal spasticity reduction. In this study, many participants who benefited from an immediate reduction in spasticity following BTX-A injection, may have required more than 4 weeks to achieve similar functional benefits. This lag between the reduction in spasticity and observed functional benefits may reflect the time needed to adapt and learn new motor plans in the presence of less muscle overactivity (24).

Level of goal attainment appeared to be associated with pre-injection level of UL active use. A moderately strong correlation was identified between pre-injection ARAT scores and GAS-T change scores. These findings reiterate those by Chang et al. (25), who reported that adult stroke patients with less baseline hand impairment gained larger functional improvements than those with more impairment following a treatment programme that combined BTX-A injections with functional electrical stimulation and repetitive task training. In combination, these findings support the hypothesis that people with milder baseline hand impairments have the potential to attain greater functional recovery compared to those with severe baseline hand impairments.

In this study, clinical measures of muscle overactivity including the MAS and Tardieu Spasticity Angle had no association with goal attainment. Participants with high MAS scores and large spasticity angles were equally likely to achieve their goals when compared to participants with low MAS scores or smaller spasticity angles. This may be a critical finding for determining the 'achievable' and 'realistic' aspects of goal setting, and raises questions about the use of these parameters when determining "best responders" to BTX-A (24).

Another factor that potentially mediates goal achievement is the specificity of the provided intervention. While individual goals were communicated to the treating rehabilitation physician, it remains unclear to what extent, or how, knowledge of these goals was used to formulate an injection strategy. Findings from this study were ambiguous. Injections for clients with an identified goal primarily involving use of the proximal UL (e.g. reaching) were not associated with receiving BTX-A injections to proximal UL muscles. Muscle overactivity in *Teres Major* or *Latissimus Dorsi* may inhibit forward reach; however, neither of these muscles were targeted for injection. *Pectoralis Major* and *Subscapularis* were injected in 3 and two participants respectively, to reduce the typical shoulder deformity involving adduction and internal rotation (26). In contrast, over 90% of participants identified goals that primarily involved use of distal UL muscles and all of these participants received BTX-A injections to muscles of the distal UL. The most frequently injected muscles were *Flexor Digitorum Superficialis* and *Profundus*, *Flexor Pollicus Longus* and intrinsic thumb muscles, *Flexor Carpi Radialis* and *Ulnaris*. This injection strategy was similar to the injection strategy reported previously by Baguley et al. (27), but included thumb injections on a more regular basis. The large number of active function goals that included object grasp and manipulation may have increased the frequency with which extrinsic and intrinsic thumb muscles were selected for injection. To this end, the injection strategy for distal musculature, appeared to be more closely aligned with participant goals, and may reflect a progressive shift in the specificity of BTX-A injections.

### *Study limitations*

The authors recognise some clear limitations to this study, primarily related to sample size and study design. The sample

($n = 28$) is relatively small and goal areas were diverse. As such, achievement of specific types of goals should be interpreted with caution. ICF linking was conducted retrospectively and the first author (MN) who conducted the linking procedure was required to infer the meaningful concepts of goals set by participants. In future, prospective linking could improve accuracy. This study was conducted in a clinical setting and was intended to interfere minimally with clinical practice; therefore strict controls were not in place. The research was designed as a pre-test/post-test cohort study and did not include a control group. Measures of change following intervention were not blind.

### *Conclusion*

In summary, the process of goal setting and review was a clinically useful practice in the context of UL spasticity management. Goals were set that reflected a wide range of anticipated outcomes, and approximately half the participants achieved their goals when reviewed 4 weeks post-injection. Future research examining goal attainment in this area would be enhanced by follow-up at multiple time points rather than a single time point. Level of pre-injection hand function was associated with goal attainment, while MAS and Tardieu spasticity angles were not. Clear identification of predictive factors may assist in future development of an "optimal responder" profile.

## ACKNOWLEDGEMENTS

This paper is derived from data collected as part of an investigator initiated study supported by Ipsen Australia. The funding body had no influence on the interpretation of data nor the conclusions drawn.

*Conflicts of interest*: Nott: Advisory Board for Ipsen and Allergan, Honoraria from Ipsen and Allergan – Modest; Barden: Honoraria from Ipsen and Allergan – Modest; Baguley: Research Grant from Ipsen – Significant, Advisory Board for Ipsen and Allergan, Honoraria from Ipsen and Allergan – Modest.

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