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ORIGINAL REPORT

INFLUENCE OF PHYSICIAN EMPATHY ON THE OUTCOME OF BOTULINUM TOXIN TREATMENT FOR UPPER LIMB SPASTICITY IN PATIENTS WITH CHRONIC STROKE: A COHORT STUDY

Alessandro PICELLI, MD, PhD[1], Gabriella VALLIES, MD[1], Elena CHEMELLO, MD[1], Alessandro GAVRAS, MD[1], Paola CASTELLAZZI, MD[1], Andrea MESCHIERI, MD[1], Anna SERINA, MD[1], Marialuisa GANDOLFI, MD, PhD[1], Alessio BARICICH, MD[2], Andrea SANTAMATO, MD[3], Carlo CISARI, MD[2] and Nicola SMANIA, MD[1,4]

From the [1]Neuromotor and Cognitive Rehabilitation Research Centre, Department of Neurosciences, Biomedicine and Movement Sciences, University of Verona, Verona, [2]Health Sciences Department, Università del Piemonte Orientale, Novara, [3]Physical Medicine & Rehabilitation Section, 'OORR' Hospital, University of Foggia, Foggia, [4]Neurorehabilitation Unit, Department of Neurosciences, Hospital Trust of Verona, Verona, Italy

Objective: **To examine the relationship between patient-rated physician empathy and outcome of botulinum toxin treatment for post-stroke upper limb spasticity.**

Design: **Cohort study.**

Subjects: **Twenty chronic stroke patients with upper limb spasticity.**

Methods: **All patients received incobotulinumtoxinA injection in at least one muscle for each of the following patterns: flexed elbow, flexed wrist and clenched fist. Each treatment was performed by 1 of 5 physiatrists with equivalent clinical experience. Patient-rated physician empathy was quantified with the Consultation and Relational Empathy Measure immediately after botulinum toxin treatment. Patients were evaluated before and at 4 weeks after botulinum toxin treatment by means of the following outcome measures: Modified Ashworth Scale; Wolf Motor Function Test; Disability Assessment Scale; Goal Attainment Scaling.**

Results: **Ordinal regression analysis showed a significant influence of patient-rated physician empathy (independent variable) on the outcome (dependent variables) of botulinum toxin treatment at 4 weeks after injection, as measured by Goal Attainment Scaling ($p < 0.001$).**

Conclusion: **These findings support the hypothesis that patient-rated physician empathy may influence the outcome of botulinum toxin treatment in chronic stroke patients with upper limb spasticity as measured by Goal Attainment Scaling.**

Key words: botulinum toxins; muscle spasticity; rehabilitation; treatment outcome, empathy.

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Correspondence address: Alessandro Picelli, Neuromotor and Cognitive Rehabilitation Research Centre, Department of Neurosciences, Biomedicine and Movement Sciences, University of Verona. P.le L.A. Scuro, 10. IT-37134 Verona, Italy. E-mail: alessandro.picelli@univr.it

Stroke is a leading cause of adult disability (1, 2). Damage to the descending tracts and sensory-motor networks results in the positive and negative signs of the upper motor neurone syndrome (UMNS) (1–3). The upper limb is commonly involved after stroke, with up to 69% of patients having arm weakness on admission to hospital (4). Recovery of upper limb function has been found to correlate with the degree of initial paresis and its topical distribution according to the cortico-motoneuronal representation of arm movements (5–9).

Spasticity is a main feature of UMNS. It is defined as a state of increased muscle tone with exaggerated reflexes characterized by a velocity-dependent increase in resistance to passive movement (10). Upper limb spasticity has been found to be associated with reduced arm function, low levels of independence and high burden of direct care costs during the first year post-stroke (11). It affects nearly half of patients with initial impaired arm function, with a prevalence varying from 17% to 38% of all patients at one year post-stroke (11). Up to 13% of patients with stroke need some form of spasticity treatment (drug therapy, physical therapy or other rehabilitation approaches) within 6–12 months post-onset (11, 12). Botulinum toxin type A (BoNT-A) has been proven safe and effective for reducing upper limb spasticity and improving arm passive function in adult patients (13, 14). While current literature reports highly patient-specific potential gains in function after BoNT-A treatment, there is inadequate evidence to determine the efficacy of BoNT-A in improving active function associated with adult upper limb spasticity (13).

Empathy refers to the ability to understand and share the feelings, thoughts or attitudes of another person (15). It is an essential component of the physician-patient relationship and a key dimension of patient-centred care (15, 16). This is even more important in rehabilitation medicine, where persons with disabilities often report encountering attitudinal and environmental barriers when trying to obtain rehabilitative care and express the need for better communication with their healthcare providers (17).

To the best of our knowledge, no previous research has investigated the influence of physician empathy on patient outcome after spasticity treatment. The aim of this study was to examine the relationship between

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patient-rated physician empathy and clinical outcome of BoNT-A treatment for upper limb spasticity due to chronic stroke.

METHODS

This was a single-centre cohort study. Inclusion criteria were as follows: age greater than 18 years; upper limb spasticity resulting from ischaemic or haemorrhagic stroke (documented by a computerized tomography or magnetic resonance imaging scan; subarachnoid haemorrhage and transient ischaemic attack excluded); elbow, wrist and finger flexors tone grade of at least 1+ on the Modified Ashworth Scale (MAS) (18); time since stroke onset at least 6 months and time since last BoNT-A treatment at least 5 months. Exclusion criteria were as follows: participation in other clinical trials; depression (Beck Depression Inventory II score > 13) (19); fixed contractures (tone grade of 4 on the MAS) or bony deformities in the affected upper limb; previous treatment of the affected upper limb spasticity with neurolytic or surgical procedures; other neurological or orthopaedic conditions involving the upper limbs. Participants were recruited from among the outpatients consecutively admitted to the spasticity service our clinical unit during the period from October 2015 to June 2016.

Written informed consent for participation in the study was obtained from all participants. The study was carried out according to the tenets of the Declaration of Helsinki and approved by the local ethics committee. Participants were not allowed to take part in any type of physical rehabilitation during the 3 months before entering the study (as certified by the participant's general practitioner) or home exercise programme for the duration of the study. Moreover, to minimize potential confounding factors, participants were requested to avoid stretching for the duration of the study. When appropriate, participants were referred to an intensive rehabilitation programme on completion of the study according to the recommendations of the local ethics committee.

IncobotulinumtoxinA (Merz Pharma GmbH, Frankfurt, Germany) was injected into at least one muscle for each of the following upper limb spasticity patterns: flexed elbow (biceps brachii; brachialis; brachioradialis), flexed wrist (flexor carpi radialis; flexor carpi ulnaris), and clenched fist (flexor digitorum superficialis; flexor digitorum profundus). The incobotulinumtoxinA dose (dilution 100 U/2 ml in saline 0.9%) was 100 U for the biceps brachii, 75 U for the brachialis, 50 U for the brachioradialis, 50 U for the flexor carpi radialis, 50 U for the flexor carpi ulnaris, 75 U for the flexor digitorum superficialis and 75 U for the flexor digitorum profundus. B-mode real-time ultrasonography was performed using a MyLab 70 XVision system (Esaote SpA, Genoa, Italy) interfaced with a linear transducer (scanning frequency 13 MHz) to guide needle positioning into the targeted muscle at each injection site. The transducer was positioned in the transverse view, perpendicular to the affected upper limb surface and the needle was inserted into the targeted muscle at a 30° angle to the transducer (20, 21). Immediately after BoNT-A administration, all patients received a 60-min session of electrical stimulation of the injected muscles (rectangular current pulses, 4 Hz, 0.2 ms, intensity adjusted to elicit visible muscle contraction) (22). No other physical therapy, casting, taping or stretching procedures were done during the study period.

Each treatment was performed by 1 of 5 physiatrists (who were unaware of the study aims and protocol) with equivalent experience (more than 3 years) in spasticity management with BoNT-A. According to their routine clinical practice, they evaluated the outcome of BoNT-A treatment immediately before and at 4 weeks after injection. Outcome measures were: the MAS (18), the Wolf Motor Function Test – Functional Ability Scale (WMFT-FAS) (23), the Disability Assessment Scale (DAS) (24) and the Goal Attainment Scaling (GAS) (25). The MAS is a 6-point scale that grades the resistance of a relaxed limb to rapid passive stretch (0: no increase in muscle tone; 1: slight increase in muscle tone at the end of the range of motion; 1+: slight increase in muscle tone through less than half of the range of motion; 2: more marked increase in muscle tone through most of the range of motion; 3: considerable increase in muscle tone; 4: joint is rigid) (18). For statistical purposes, a score of 1 was considered as 1, a score of 1+ as 2 and so on up to a score of 4, which was considered as 5 (26). Fifteen function-based tasks on the WMFT-FAS were used to assess the functional ability of the affected arm as follows: forearm to table (side); forearm to box (side); extend elbow (side); extend elbow (weight); hand to table (front); hand to box (front); reach and retrieve; lift can; lift pencil; lift paper clip; stack checkers; flip cards; turn key in lock; fold towel; lift basket. The quality of movement for each task was rated on a 6-point scale from 0 (does not attempt) to 5 (movement appears to be normal). Scores range from 0 to 85 (23). The DAS evaluates the extent of functional impairment in the areas of patient hygiene, dressing, limb position, and pain according to the following scale: 0 = no disability; 1 = mild disability; 2 = moderate disability; 3 = severe disability (24). The GAS is a method for scoring the extent to which a patient's individual goals are achieved during the course of an intervention (25). For the purposes of this study, the main problem areas before BoNT-A treatment were identified, then the patient weighted 2 goals on a 4-point scale, where 0 = not at all important; 1 = slightly important; 2 = moderately important; 3 = very important. Similarly, the physician weighted the goals in terms of the anticipated difficulty to achieve them on the same 4-point scale. The goal weight was importance × difficulty. At 4 weeks after treatment, each goal was rated on a 5-point scale according to the degree to which it was attained: –2 = much less than the expected outcome; –1 = somewhat less than the expected outcome; 0 = expected level of outcome; 1 = somewhat more than the expected outcome; 2 = much more than the expected outcome. The goal attainment "T-score" was calculated using a spreadsheet calculator (25).

Immediately after BoNT-A treatment, another examiner, who was not involved in the treatment, evaluated all patients, recording the office waiting time to see the physician (time elapsed from front office registration until the attending physician entered the room), the duration of the visit, and the time from submitting a consultation request to receiving an appointment. In addition, the examiner measured patient-rated physician empathy by means of the Consultation and Relational Empathy Measure (CARE), which is a validated 10-item questionnaire that investigates the patient's perception of the physician's empathic understanding and behaviour during the visit (Appendix I). Each response is marked on a 5-point scale, where responses range from 1 (poor) to 5 (excellent). The score was obtained from the sum of all items (maximum score 50; minimum score 10) (27).

Statistical analysis was carried out using the Statistical Package for Social Science for Macintosh, version 20.0 (IBM Corp., Armonk, NY, USA). Pre-study power calculation estimated that a total of 13 patients would provide 95% power to detect a difference of one point on the MAS (SD = 0.9) after

Table I. Demographic and clinical features of patients

Variables	
Age of patients, years, mean (SD)	64.8 (11.8)
Sex of patients, male/female	16/4
Time from stroke, years, mean (SD)	6.1 (3.6)
Age of physicians, years, mean (SD)	41.1 (7.9)
Physicians' years of practice, years, mean (SD)	14.1 (7.8)
Time from request, days, mean (SD)	36.5 (13.1)
Waiting time, min, mean (SD)	9.8 (3.8)
Duration of consultation, min, mean (SD)	42.3 (14.9)

SD: standard deviation.

treatment (28). Ordinal regression analysis was performed to evaluate the influence of patient-rated physician empathy (independent variable) on the improvements found at 4 weeks after BoNT-A treatment, as measured on the MAS, the WMFT-FAS, the DAS and the GAS (dependent variables). The Spearman rank correlation test was performed to assess the association between patient-rated physician empathy and demographic/organizational characteristics (age of patients and physicians, physicians' years of practice, time since stroke onset, office waiting time to see the physician, duration of consultation and time from consultation request to actual appointment). Within-group comparisons were performed with the Wilcoxon signed-rank test. The alpha level for significance was set at $p<0.05$ with no correction for multiple comparisons.

RESULTS

Seventy-five potentially eligible, consecutive outpatients were examined. Fifty-five patients met the exclusion criteria and were not included in the study. Twenty chronic stroke patients (16 men and 4 women; mean age 64.8 years) with upper limb spasticity (mean time since stroke onset 6.1 years) were confirmed eligible and included in the study. No adverse events occurred during the study. All patients included in the study completed all evaluations and were analysed. Tables I and II present the patients' demographic and clinical features.

The ordinal regression analysis showed a significant influence of patient-rated physician empathy, as measured by the CARE (independent variable) on the GAS ($p<0.001$) but not on the MAS (elbow: $p=0.324$; wrist: $p=0.506$; fist: $p=0.720$), the WMFT-FAS ($p=0.476$) and the DAS (hygiene: $p=0.453$; dressing: $p=0.453$; limb position: $p=0.233$; pain: $p=0.935$). As reported in Table III, the Spearman correlation showed a significant direct association between the CARE score and patients' age ($p=0.016$; $\rho=0.532$).

Table II. Goal Attainment Scaling choose according to the World Health Organization (WHO) International Classification of Functioning, Disability and Health (ICF) classification

WHO ICF classification		Total goals set (*n*)
Domain and goal area	Primary code	
Body Functions		
Pain	b280	1
Passive movement/range	b735/b710	8
Reducing associated reactions	b755	2
Simple hand/arm movements	b760	5
Activities and Participation		
Upper limb activities		
Lifting and carrying objects	d430	2
Fine finger use/dexterity	d440	4
Holding, grasping objects	d445	2
Self care		
General independence	d500	2
Hygiene/skin integrity	d520/d510	3
Dressing	d540	3
Eating/drinking	d550/d560	2
Domestic		
Meal preparation/cooking	d630	2
Household tasks	d640	2
Community		
Recreation/leisure/hobbies	d920	2

Within-group comparisons showed significant improvements on the MAS after BoNT-A treatment at the affected elbow ($p=0.003$; $Z=-3.002$), wrist ($p=0.007$; $Z=-2.714$) and fist ($p=0.001$; $Z=-3.250$). Within-group comparisons showed significant improvements in the WMFT-FAS scores after BoNT-A treatment at the affected upper limb ($p=0.003$; $Z=-2.937$). Within-group comparisons showed significant improvements in the DAS scores after BoNT-A treatment at the affected upper limb in the areas of hygiene ($p=0.046$; $Z=-2.000$), dressing ($p=0.046$; $Z=-2.000$) and limb position ($p=0.011$; $Z=-2.530$). Table IV presents the data on patient performance at pre-treatment and post-treatment evaluations and the results of the within-group comparisons.

Table III. Spearman's rho correlation matrix

Outcome measures	Age of patients	Time from stroke onset	Age of physicians	Physicians' years of practice	Time from request	Waiting time	Duration of consultation	CARE
Age of patients	1.000							
Time from stroke onset	0.074	1.000						
Age of physicians	0.106	0.178	1.000					
Physicians' years of practice	0.106	0.178	1.000*	1.000				
Time from request	–0.278	0.166	0.189	0.189	1.000			
Waiting time	0.271	–0.081	0.063	0.063	0.301	1.000		
Duration of consultation	0.057	0.182	–0.317	–0.317	–0.137	–0.198	1.000	
CARE	0.532*	–0.239	–0.017	–0.017	–0.216	0.079	–0.101	1.000

*$p<0.05$.
CARE: Consultation and Relational Empathy Measure.

Table IV. Within-group comparisons of treatment effects in all outcome measures

Parameter	Before treatment Median (IQR)	After treatment Median (IQR)	Within-group comparisons: After treatment vs before treatment *p*-value (z)
MAS elbow (0–5)	2.00 (1.25; 3.00)	1.00 (1.00; 2.00)	0.003 (–3.002)*
MAS wrist (0–5)	2.00 (1.00; 3.00)	1.00 (1.00; 2.00)	0.007 (–2.714)*
MAS fist (0–5)	3.00 (2.25; 3.75)	2.00 (1.00; 2.75)	0.001 (–3.250)*
WMFT – FAS (0–85)	16.50 (1.25; 28.28)	22.50 (1.25; 35.75)	0.003 (–2.937)*
DAS hygiene (0–3)	1.00 (0.00; 2.00)	1.00 (0.00; 2.00)	0.046 (–2.000)*
DAS dressing (0–3)	1.50 (0.25; 2.00)	1.00 (0.00; 2.00)	0.046 (–2.000)*
DAS limb position (0–3)	1.00 (0.00; 2.00)	0.50 (0.00; 1.75)	0.011 (–2.530)*
DAS pain (0–3)	0.00 (0.00; 0.00)	0.00 (0.00; 0.00)	0.180 (–1.342)
CARE (10–50)	49.50 (40.00; 50.00)		
GAS (T-score), mean (SD)		52.55 (9.38)	

*$p < 0.05$. MAS: Modified Ashworth Scale; IQR: interquartile range; WMFT-FAS: Wolf Motor Function Test – Functional Ability Scale; DAS: Disability Assessment Scale; CARE: Consultation and Relational Empathy Measure; GAS: Goal Attainment Scaling; SD: standard deviation.

DISCUSSION

Consistent with the aim of this single-centre cohort study, our findings support the hypothesis that patient-rated physician empathy (as measured on the CARE) may influence the outcome of BoNT-A treatment for upper limb spasticity in chronic stroke patients, as measured on the GAS. Measurement of spasticity is an important part of stroke patient care (29). Guidelines for the management of upper limb spasticity have highlighted the importance of measuring the impact of interventions at the level of improved function and care needs (30). Unfortunately, obtaining accurate measurements of spasticity is challenging because the nature of spasticity may be quite elusive and assessment is frequently subjective, including evaluation of passive and active function and self-efficacy measures (13, 24, 25, 29, 31). In clinical practice as in scientific research, the MAS (or its original version) is the most commonly used method for measuring spasticity (32, 33). However, because of its methodological limitations, it has been suggested that the MAS should not be applied as a single outcome measure. Instead, newer methods that take into account the needs of patients with upper limb spasticity should be used in the evaluation of limb function, not only during clinic attendance, but also within the context of everyday real-life activities (30, 32, 34). On this basis, we employed 3 main categories of methods to evaluate (active or passive) function as follows: the patient report on some upper-limb items (including the DAS), the composite measure of function (incorporating patient-reported items) and the GAS that sets goals for intervention involving patients, carers and clinicians (30).

Botulinum toxin demonstrated a clinically significant effect on goal attainment for the real-life management of upper limb spasticity following stroke (33). When interpreting this observation, however, we should remember that goal attainment depends not only on the patient's ability to meet the goal, but also on the accuracy of expected outcomes prediction and the ability to negotiate treatment objectives, which, in turn, relies upon high-level negotiating skills to establish realistic expectations and set (challenging but) achievable goals (35). Good interpersonal communication skills are critical for negotiating and agreeing on realistic treatment goals with the patient. In this context, physician empathy may be considered a key determinant of goal attainment after BoNT-A treatment in adults with upper limb spasticity due to stroke. Our findings are in keeping with these concepts. Indeed, we observed a significant relationship between patient-rated physician empathy (CARE) and the GAS score. From this perspective, in order to critically discuss our results, we have to consider that one of the main limitations of the GAS is that pessimistic goals might be more susceptible to obtain higher gains than optimistic ones. Furthermore, some patients may often be unable to recognize and rate their pre-defined goal achievements, providing "desirable" answers rather than those that reflect their actual level of goal attainment (36). In addition, we have to take into account that each goal defined by the GAS should be of interest and relevant to the patient reflecting his/her reflect expectations, wishes and priorities, as well as those of carers and family members (36, 37). Thus, it is likely that some goals defined by the patients involved in this study would not be SMART ones (specific, measurable, achieveable, realistic/relevant and timed) and, consequently, their attainment was evaluated by means of subjective opinion (37). In our view, considering the great empathic load required, not only by the clinical management of chronic stroke patients with upper limb disability, but also in order to obtain the effective collaborative involvement of both the patients and carers during the goal-setting and follow-up processes, it is highly plausible that the positive relationship with the physician would have influenced the BoNT-A treatment outcome as measured by the GAS. On this basis, the GAS should not be considered as a clinical measure focused on spasticity assessment, but instead as a gauge of those symptoms, behaviours, feelings, skills or achievements that a specific therapeutic intervention is designed to change in order to organize, focus and clarify the aims of treatment (38).

As to the other outcomes evaluated in the current study, we failed to find significant relationships with the CARE. This was probably because passive soft-tissue stretching, functional ability and functional

impairment are less influenced by physician empathy because of their focal evaluation (see the MAS and the WMFT-FAS) as well as the definition of SMART evaluation criteria (see the MAS, the WMFT-FAS and the DAS). Interestingly, we also observed a significant direct association between patient-rated physician empathy and patient age. This observation is shared by findings in the general emotion literature, which showed that older adults have better emotion regulation abilities than young adults according to self-report data, which suggests that older adults may have better empathic understanding than young people (39).

The current study has several limitations. First, this was a single-centre study. This may have reduced the impact of some organizational aspects (such as office waiting time, visit duration, and the time from consultation request to actual appointment), as well as may relate to the high CARE score obtained, given that the 5 physicians involved in this study work in the same clinical service and might have similar attitudes. In this respect, we also exclude the risk that the targeted muscles were not chosen in relation with the GAS because, according to their clinical service routine, the GAS is taken into account to choose the target muscles of BoNT-A treatment. Secondly, no long-term (more than 1 month) follow-up was planned. Thirdly, lower limb spasticity was not evaluated. Fourthly, we did not include paediatric patients and so we cannot draw conclusions about the influence of patient-rated physician empathy on the outcome of BoNT-A treatment in children.

In conclusion, the findings of this study support the hypothesis that patient-rated physician empathy may influence the outcome of BoNT-A treatment in chronic stroke patients with upper limb spasticity. In order to further validate our findings, future larger studies should address these issues and the role of empathy during post-injection rehabilitation treatment (40).

The authors declare no conflicts of interest.

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Appendix I. The Consultation and Relational Empathy Measure

How the doctor was…	Poor	Fair	Good	Very good	Excellent
1) Making you feel at ease… (being friendly and warm towards you, treating you with respect; not cold or abrupt)	1	2	3	4	5
2) Letting you tell your "story"… (giving you time to fully describe your illness in your own words; not interrupting or diverting you)	1	2	3	4	5
3) Really listening… (paying close attention to what you were saying; not looking at the notes or computer as you were talking)	1	2	3	4	5
4) Being interested in you as a whole person… (asking/knowing relevant details about your life, your situation; not treating you as "just a number")	1	2	3	4	5
5) Fully understanding your concerns… (communicating that he/she had accurately understood your concerns; not overlooking or dismissing anything)	1	2	3	4	5
6) Showing care and compassion… (seeming genuinely concerned, connecting with you on human level; not being indifferent or "detached")	1	2	3	4	5
7) Being positive… (having a positive approach and a positive attitude; being honest but not negative about your problems)	1	2	3	4	5
8) Explaining things clearly… (fully answering your questions, explaining clearly, giving you adequate information; not being vague)	1	2	3	4	5
9) Helping you take control… (exploring with you what you can do to improve your health yourself; encouraging rather than "lecturing" you)	1	2	3	4	5
10) Making a plan of action with you… (discussing the options, involving you in decisions as much as you want to be involved; not ignoring your views)	1	2	3	4	5