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SHORT COMMUNICATION

SHORT FORM 36 ASSESSED HEALTH-RELATED QUALITY OF LIFE AFTER FOCAL SPASTICITY THERAPY

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Objective: **Analysis of the impact of an individualized comprehensive focal spasticity management on health-related quality of life.**
Design: **Prospective observational and interventional 12-week trial in a single-centre rehabilitation outpatient clinic.**
Patients: **Forty-one adult patients with upper motor neurone lesions (23 men), mean age 52 (standard deviation 13) years; 27 stroke, 7 cerebral palsy and 7 miscellaneous diagnoses.**
Methods: **Patients were assessed using the Short Form 36 (SF-36) Questionnaire before and after intramuscular injections of botulinum toxin type A combined with physical interventions. Spasticity was assessed with the Ashworth Scale (0–4). A verbal scale for patients' self-report of therapy effect was also used.**
Results: **Significant improvement was found in 3 of 8 SF-36 health scales: social ($p = 0.008$) and physical functioning ($p = 0.026$), and role physical ($p = 0.048$). Spasticity improved significantly (mean 1.1, $p < 0.001$). Improvement according to the verbal scale was observed for 57 (86%) indications (overall improvement in 36 patients, 88%).**
Conclusion: **Comprehensive focal spasticity management with botulinum toxin type A intramuscular injections and physical interventions can improve patients' perceived health-related quality of life in addition to objectively and subjectively measured motor functions.**

Key words: health-related quality of life, Short Form 36, spasticity, botulinum toxin type A, physical therapy.

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INTRODUCTION

Rehabilitation is by definition a goal-oriented and time-limited process aimed at enabling a disabled person to reach an optimal level of physical, mental and social functioning (1). A relevant part in the evaluation of physical rehabilitation is therefore its impact on health-related quality of life (HRQL), defined as "a combination of an individual's physical, mental and social well-being; and not merely the absence of disease" (2).

In upper motor neurone syndrome (UMNS) spasticity frequently causes symptoms related to motor dysfunction, pain, contractures, etc. Spasticity therapy is therefore often applied and usually combines pharmacological and physical interventions (3–4).

In a recent study on 100 consecutive patients we observed ≥ 90% improvement after focal spasticity reduction with botulinum toxin type A (BoNT-A) combined with physical interventions. A simple and robust verbal scale and the Ashworth scale were used (5). The aim of the present study was to analyse the patients' own perspective. The aim was therefore to evaluate the impact of the individual treatments on HRQL as an outcome, following focal spasticity therapy, about which little information is available, in a new patient cohort.

PATIENTS AND METHODS

This is an observational and interventional cohort study applying the Short Form 36 (SF-36) (6). The same management strategy was used as in our earlier study, details of which, including criteria for focal spasticity therapy, have been published previously (5).

Patients

Forty-one patients (23 men) were enrolled, mean age 52 years (standard deviation (SD) 13, range 21–79). All patients fulfilled the clinical criteria for focal spasticity therapy and consented to participate. In addition no previous focal spasticity treatment, no noticeable cognitive impairment, and ability to communicate independently were required. Out of 132 consecutive first referrals 9 did not fulfil the clinical criteria, 33 were excluded due to cognitive problems, 32 because of impaired communication, 13 for administrative reasons, and 4 declined to participate. The diagnosis was stroke in 27 (all patients were hemiparetic), cerebral palsy in 7, traumatic brain injury and hereditary spastic paraplegia in 2 each, and multiple sclerosis, spastic paraplegia (aetiology unknown), and spastic diplegia (post-lumbar spinal injury) in one each. In all acquired disorders onset was > 6 months prior to the study. Approximately 50% of the patients received oral anti-spasticity therapy, which was unchanged during the study.

Protocol

The study included 4 visits. At the first visit the therapy targets were defined by the patient, who was then assessed by a multidisciplinary clinical team, which decided whether clinical criteria for focal spasticity therapy was present (5). Following the therapeutic decision, target muscles for BoNT-A injections were selected, and the verbal and Ashworth scales were applied. The patients were then asked about their participation in the study. This procedure was approved by the local ethics committee. At the second visit intramuscular injections of BoNT-A (Botox® Purified Neurotoxin Complex, Allergan, Inc., Irvine, CA, USA) were administered. Electromyography (EMG) was used to

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confirm the presence of abnormal muscle activity and to guide the injections. Dosing was based on the 2002 guidelines (7). In the treatment of spastic lower limb muscles the substance was used off-label at the discretion of the responsible physician and with patient consent. The patient was then interviewed following the SF-36 (6). A physiotherapist who was not otherwise involved organized the distribution and management of the questionnaires on this occasion and at follow-up. The third visit was scheduled for 6 weeks after the injections, when patient status and treatment effects, as well as any adverse events, were assessed by the clinical team together with the referring therapist and/or the patient's physician. The SF-36 assessment was performed at a fourth follow-up visit 3 months after the injections. The verbal and Ashworth scales were applied again. This time interval was chosen in order to cover delayed effects of therapy.

Therapeutic interventions

The mean BoNT-A dose in one set of injections was 236 U Botox (SD 97; range 75–400). A total of 154 muscles (1–9 per patient) were injected. The upper and lower extremities were treated in 24 and 23 cases, respectively, both in 6 patients. The team discussed physical interventions with the external therapist in charge of the subsequent therapy. Altogether 105 physical interventions were provided, on average 2.6 per patient, 69 of them were physical therapy, 26 orthoses, and 10 orthopaedic shoes and footwear corrections.

Evaluation methods

The SF-36 questionnaire is considered a reliable and valid measure of perceived physical and mental health, and includes a reference population consisting of a sample of 8930 persons from the general Swedish population (6, 8). SF-36 is grouped in 8 multi-item health scales measuring physical functioning (PF, 10 items), role limitations due to physical health problems (RP, 4 items), bodily pain (BP, 2 items), general health perceptions (GH, 5 items), vitality (VT, 4 items), social functioning (SF, 2 items), role limitations due to emotional problems (RE, 3 items), and mental health (MH, 5 items). There is also a transition item (question 1 and 2) on overall evaluation of health that provides a summary indicator and captures the impact of health problems not directly included in the other questions. For each item the response ranges from 2 to 6. The scores for items on each health scale are added and then linearly transformed to obtain a mean value ranging from 0 to 100. "0" indicates extreme problems and "100" no problems; the higher score the better perceived health. PF, RP, BP and GH scales are aggregated to a physical health index, while RE, MH, SF, SF and VT provides a mental health index (6).

Spasticity was assessed by the Ashworth Scale (0–4); efforts were made to optimize the subject's testing position, control of velocity of passive stretching, and the range of movement. In the 6 patients treated in both upper and lower extremities an average Ashworth score based on the evaluation of both extremities was calculated.

A verbal scale was used to document patients' self-report of therapy effect, and was comparative in the form of "worse – the same – better" (3–5).

The patients' principal therapy target/s were categorized according to the International Classification of Functioning, Disability and Health (ICF) (9).

Statistics

Mean and SD and/or median and range were used for descriptive purposes. SF-36 was expressed on an ordinal scale and the Wilcoxon matched pairs signed-rank test was used for the comparison of baseline and follow-up scores, as well as for change in scores on the Ashworth scale. However, by convention the SF-36 is usually treated as a nominal scale. In order to allow comparisons with other studies we therefore also used parametric statistics with mean values. A significance level of $p < 0.05$ was used.

RESULTS

Principal therapeutic targets

There were 66 therapy targets, on average ~1.6/patient (range 1–3). In 50% of the patients there was one indication. The 2 main targets in patients with stroke were within the ICF component "Activities and participation". In patients with cerebral palsy it was within the component "Body functions", and in patients with miscellaneous diagnoses within "Activities and participation".

Treatment effects

A statistically significant improvement was found in the SF-36 health scales PF, RP and SF (Fig. 1). Among patients after stroke significant improvements were found in the same health scales. The individual changes varied considerably, as shown by the 95% confidence intervals of the mean values (Fig. 1). The statistical significances were therefore due to relative large improvements in 21 patients. Assessment of spasticity according to the Ashworth Scale gave a median score of 2 (mean 2.5; range: 2–4) before intervention. After intervention the median was 1 (mean 1.4; range: 0–3), with an average improvement of 1.1 ($p < 0.001$). Spasticity improved in 38 patients (93%), and was unchanged in 3. Improvement according to the verbal scale ("better") was observed for 57 (86 %) therapeutic targets and unchanged ("the same") for 9 (14 %), corresponding to an overall improvement in 36 patients (88%), and 5 unchanged.

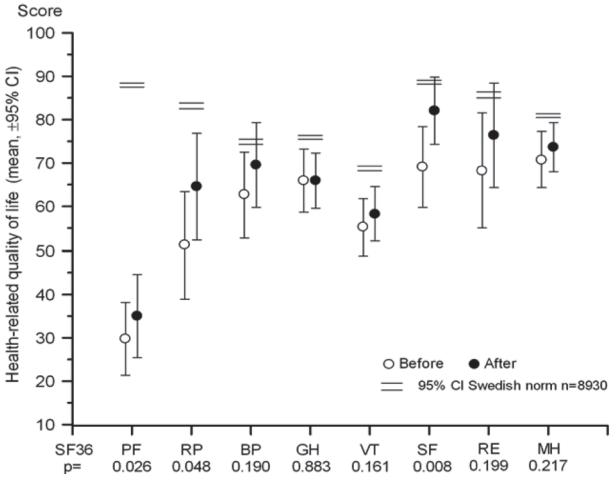

Fig. 1. Results of the Short Form 36 (SF-36) mean scores and 95% confidence interval (CI) for all 8 health-scales before and 3 months after therapy in all patients ($n = 41$). Norms for the general Swedish population ($n = 8930$) (6) are provided for comparison (shown as 2 horizontal lines). PF: physical functioning; RP: role physical; BP: bodily pain; GH: general health; VT: vitality; SF: social functioning: RE; role emotional; MH: mental health.

Safety

Three patients treated for wrist and finger spasticity after stroke reported transient moderate to severe muscular weakness in injected muscles. Inter-current diseases/diagnoses not considered to be related to the present therapy occurred during the 3-month follow-up period in 2 patients after stroke; seizure and a new stroke, in one patient each.

DISCUSSION

The impact on HRQL of a comprehensive strategy for focal spasticity therapy was assessed by SF-36 in a consecutive series of 41 patients. Statistically significant improvements were seen in 3 out of 8 health scales 3 months after initiation of therapy. These results were obtained by combining the BoNT-A injections with on average 2.6 physical interventions. In approximately 90% of cases and targets improvements were observed both according to the Ashworth spasticity scale and patients' self-report of therapy effects (verbal scale).

The most significant improvement was seen in the health scale SF. According to Sullivan et al. (6) this sub-scale has a moderate hypothesized correlation ($0.30 < r < 0.70$) to the physical dimension but a strong correlation ($r \geq 0.70$) to the mental dimension. Patients and their relatives also frequently reported on patients taking up contacts with old friends and started participating in social activities. The 2 other significantly improved sub-scales PF and RP have a strong correlation ($r \geq 0.70$) to the physical dimension in the SF-36 measure. These 2 sub-scales reflect daily physical activities such as activities in daily living, walking, stair-climbing, sports, and performing work or other regular daily activities, respectively (6).

To our knowledge there is only one prior report on HRQL after BoNT-A therapy, a dose-response (placebo, 90, 180 and 360U) study using SF-36 in 91 stroke patients, with 21 to 26 in each sub-group. There was a dose-dependent effect on muscular tone in the upper extremities, but no overall effect on HRQL (10). However, in the subgroup of 21 patients receiving 90 U there was, at 6 weeks, a statistically significant improvement in the health scale SF.

Methodological aspects and limitations

We did not observe any significant improvement in 5 of 8 SF-36 subscales. There might be different explanations, including lack of statistical power. However, 4 of these 5 subscales have a moderate – strong association to the mental dimension (GH, VT, RE, MH), but the 2 first only a moderate and the 2 latter only a weak association to the physical dimension (6). The remaining scale is BP, which has a strong association to the physical dimension, but was not a problem in 32 of our patients.

One of the major advantages in using a generic instrument, such as SF-36, is that comparisons can be made with other populations with and without disease (11). Such a reference population is included in Fig. 1. In addition, SF-36, like the Sickness Impact Profile, is a multidimensional comprehensive instrument addressing social and community life in conjunction with physical function, in contrast to a one-dimensional instrument like the Barthel Index, primarily addressing physical function.

This open study had a limited sample with inherent problems such as the possibility of a placebo effect and the risk of evaluation bias. The results require confirmation through a study with a placebo-controlled design.

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