Quality of life in subjects treated with botulinum toxin A for facial wrinkles at return to baseline appearance

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ABSTRACT

Objective: The cosmetic benefit of treatment with botulinum toxin A (BoNT-A) has been associated with an increased quality of life (QoL). This study investigated whether such improvements in QoL were maintained upon return to baseline appearance.

Methods: Consecutive subjects receiving incobotulinumtoxinA treatment for facial wrinkles had their QoL assessed using the Schedule for the Evaluation of Individual Quality of Life Direct-Weighting (SEIQoL-DW) tool pre-treatment and once their appearance had returned to baseline. At each visit, subjects identified the five areas of their life of the greatest importance to them (‘cues’), weighted the areas as to their relative importance (cumulative score = 100), and rated their status in each area on a visual scale (from 0–100). The SEIQoL-DW index score was calculated as the sum of the weighted scores for each cue. At the return visit, QoL was scored on both the pre-treatment (old) cues and the new cues. Subjects also rated their overall QoL on a visual analogue scale (VAS) from 0–100 and satisfaction with their appearance of a scale of 0–10 at both visits.

Results: Fifty subjects (median age 38.5 years; 92% female) with moderate to severe wrinkles to the glabella, forehead or crow’s feet had their QoL assessed. Family, work, finance, relationships, and health were the five most frequently identified cues at both visits. Appearance was weighted the second most important cue (after family) when considering those identified by at least 10 subjects. QoL was significantly higher following a return to baseline appearance than pre-treatment according to the overall VAS score (old cues, P = 0.004; new cues, P = 0.0015), but no difference was apparent according to the SEIQoL-DW index (old cues, P = 0.7622; new cues, P = 0.9568). Satisfaction was significantly lower at the return visit than before treatment (P < 0.0001).

Conclusion: There may be some longer lasting impact of BoNT-A treatment on QoL beyond the period of cosmetic benefit. The results strengthen the notion that satisfaction is not a surrogate for QoL and that the latter should be more routinely assessed in subjects undergoing this procedure.

Keywords: botulinumtoxinA; incobotulinumtoxinA; quality of life; aesthetic; satisfaction

INTRODUCTION

Treatment with botulinum toxin A (BoNT-A) is now a well-established approach to improve cosmetic appearance. Whilst the efficacy and tolerability of BoNT-A treatment is well reported as are the effects on overall satisfaction, few studies have investigated whether improvements in appearance are associated with increased quality of life (QoL). Hexsel et al. reported that subjects treated with full face injections of abobotulinumtoxinA had increased QoL versus baseline, as measured by the WHOQOL-BREF and Satisfaction and Self-assessment Questionnaire. Similarly, Dayan et al. reported that onabotulinumtoxinA treatment of facial wrinkles significantly improved QoL and self-esteem as compared to both treatment with placebo and pre-treatment baseline values using the Quality of Life Enjoyment and Satisfaction Questionnaire – Short Form and the Heatherton and Polivy State Self-Esteem measurement. Research from the Jandhyala Institute has shown that QoL is significantly improved following incobotulinumtoxinA treatment using the Schedule for the Evaluation of Individual Quality of Life Direct-Weighting (SEIQoL-DW) tool. Importantly, this study showed that QoL is not correlated with satisfaction.

Overall, the results of these studies indicate that QoL, as measured by a variety of tools, is improved in subjects receiving BoNT-A during the period of treatment effect (up to 5 months). What is not known is whether these improvements in quality of life are still apparent once the subject has returned to their baseline appearance level and how this interrelates with their satisfaction at this point. To address this key question, an update of the SEIQoL study was conducted to measure QoL and satisfaction at return to baseline appearance and to compare the scores with pre-treatment values.
METHODS

This is an extension of the previously published study by Jandhyala. In the earlier study, QoL was assessed prospectively in 53 consecutive subjects using the SEIQoL-DW tool immediately before and 28 days after treatment with incobotulinumtoxin A (Xeomin®, Merz Pharmaceuticals GmbH, Frankfurt, Germany) for moderate to severe wrinkles in the glabella, forehead, or crow’s feet. At the first, pre-treatment visit, subjects identified the five areas of their life of the greatest importance to them (‘cues’), weighted the cues as to their relative importance (sum of five weightings = 100), and then rated their current status for each cue from worst possible: 0, to best possible: 100. After 28 days, they again rated their current status, this time using the previously defined cues (old cues) and newly defined and weighted cues (new cues). To produce the final SEIQoL index score, which provides an overall measure of QoL for comparison, each of the five cue scores was multiplied by the corresponding cue weight, and the products of these calculations summed together. At both visits, subjects also rated their overall QoL on a visual analogue scale (VAS) (0 being the worst possible, 100 the best possible) and their satisfaction with their appearance on a 10-point scale (0 not satisfied at all, 10 completely satisfied). Overall, treatment with incobotulinumtoxin A was shown to significantly increase QoL according to the SEIQoL-DW indices (old cues: P = 0.0006; new cues: P = 0.0235) and overall QoL on VAS (P = 0.0001 for both old and new cues). Whilst satisfaction increased significantly following treatment (median satisfaction score post vs. pre-treatment: 9.2 vs. 4.3, P < 0.0001), no correlation was found with QoL.

In the present, extension study, all available subjects were asked to define, weight, and score new cues (extension cues), when their wrinkles returned to baseline (pre-treatment) appearance (as judged by photographs). Overall QoL on VAS and satisfaction were also recorded. The extension visit scores were then compared against the original baseline (pre-treatment) visit scores, as defined in the previous study.

This review was necessary, as per the guidelines of the National Research Ethics Service (NRES). Statistical analysis

SEIQoL indices and QoL scores before and at return to baseline were analysed using paired t-tests, whilst the change in patient satisfaction was assessed using the Wilcoxon Rank Sum test. All data were analysed using StatsDirect statistical software (version 2.8.0).

RESULTS

Fifty subjects, aged 22–58 years (median age: 38.5 years; 92% women), had their QoL assessed pre-treatment and following a return to baseline appearance (10–14 weeks after treatment). Family (mean cue weight pre-treatment: 34; extension: 36), work (14; 14), finance (18; 15), relationships (18; 17), and health (19; 18) were the five most frequently identified cues at each assessment. Appearance was weighted the second most important cue when considering those identified by at least 10 subjects (mean cue weight pre-treatment: 22; extension: 19). QoL was not significantly different pre-treatment and post-treatment following a return to baseline appearance according to the SEIQoL-DW index scores using both the old (P = 0.7622) and extension cues (P = 0.9568) (Table 1 and Figure 1). Overall QoL, as measured by VAS, was, however, found to be significantly higher at the extension visit than pre-treatment, when assessed after consideration of both the old (P = 0.004) and extension cues (P = 0.0015). Satisfaction was significantly lower at the extension visit than before treatment (mean score extension vs. pre-treatment: 4.18 vs. 2.65; P < 0.0001).

DISCUSSION

A few studies have now shown that the cosmetic benefit of treatment with BoNT-A is associated with an improvement in QoL. The present study provides further evidence that QoL is increased by BoNT-A treatment and, of potential import, shows that these positive effects might extend beyond the duration of

| TABLE 1. Quality of life scores pre-treatment and at return to baseline appearance |
|---------------------------------|-----------------|-----------------|-----------------|-----------------|-----------------|
| Measure                        | Comparison      | Pre-treatment mean | Return to Baseline mean | P-value*     |
| QoL (VAS)                      | vs. old cues    | 58.2             | 64.0             | 0.004         |
|                                | vs. extension cues |                 | 64.4             | 0.0015        |
| SEIQoLDW indices               | vs. old cues    | 63.4             | 63.9             | NS (0.7622)  |
|                                | vs. extension cues |               | 63.3             | NS (0.9568)  |

*paired t-test; NS: not significant
FIGURE 1. Difference in quality of life (A) and satisfaction (B) scores pre-treatment vs. during the period of treatment effect and at return to baseline appearance. Old: old cues; new: new cues; QoL score on scale of 0–100, satisfaction on a scale of 0–10; *P < 0.0001 vs. pre-treatment; †P = 0.0008 vs. pre-treatment; all other comparisons vs. pre-treatment were not significant (treatment effect index score with new cues vs. pre-treatment: P = 0.0843); P-values derived from pair t-test (QoL/Index) and Wilcoxon Rank Sum test (satisfaction).
cosmetic benefit. Overall QoL, as measured by VAS, was significantly higher at the extension visit than pre-treatment (old cue, P = 0.004; extension cues, P = 0.0015), despite the subjects’ facial appearance having returned to baseline wrinkle severity. Compared to when there was maximal cosmetic effect, as reported previously, overall QoL was not as high at the extension visit (scores: ~71.5 vs. ~64, respectively), indicating that QoL was slowly diminishing or returning to pre-treatment levels (score: ~58). When measured using the SEIQoL-DW index, there was no apparent different in QoL pre-treatment vs. the extension visit (not significant), highlighting again that QoL was falling from the time of peak treatment effect.

Whilst QoL was still improved or at least no worse than pre-treatment levels, satisfaction with appearance was significantly worse at the extension visit compared to baseline (P < 0.0001). It is perhaps not surprising that someone seeking BoNT-A treatment to reduce their wrinkle severity would have an increased satisfaction with their appearance during the period of maximum cosmetic benefit, but then, following a return to baseline appearance, would be even less satisfied than before they had treatment. These results strengthen the argument that satisfaction with appearance is not the overwhelming driver of QoL in those seeking cosmetic treatment and that an improvement in the former does not necessarily mean an improvement in the latter.

Although this study was limited by small subject numbers, recruited from a single centre, and the lack of a control group, it is encouraging to note the consistency of cue areas identified at each visit. Family, work, finance, relationships, and health were the five most frequently identified cues pre-treatment, during peak treatment effect, and at the extension visit. Appearance was also a frequently identified cue and was weighted heavily, which, in people seeking cosmetic treatment, was in line with what would be expected. Overall, the study population appeared relatively stable in terms of non-treatment influences on their QoL.

This study provides further insight into the impact of BoNT-A treatment on QoL and suggests that such assessments should form a more routine part of the management of these subjects, particularly in the absence of any direct correlation with satisfaction.

CONFLICT OF INTEREST STATEMENT

The author has received research funding from Merz Pharma in relation to other studies.

REFERENCES


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