ABSTRACT: Background: Many tools used for recording the response to botulinum toxin treatment are disease-specific, observer-based and cumbersome to implement in service settings, especially where clinics treat a variety of disorders. Physicians, clinics, researchers, and patients themselves could benefit from a practical and generic patient-reported outcome tool. The Liverpool botulinum toxin effects chart (LIVECHART) is a patient-administered questionnaire developed and used informally over 25 years in a major UK botulinum toxin treatment clinic. In preparation for more formal validation studies, this cross-sectional study aimed to understand how well LIVECHART captures the effects of botulinum toxin treatment, using patients with cervical dystonia as exemplars.

Methods: LIVECHART questionnaires were completed by 90 patients with cervical dystonia who had each experienced at least three previous botulinum toxin injection cycles with completed LIVECHARTs.

Results: There were significant positive correlations between Likert scores (major deterioration—major benefit) for botulinum toxin treatment effects, and measures derived from weekly visual analog scale (VAS) scores (0–100), including (1) baseline to peak effect, (2) Area Under the benefit Curve (AUC) of current cycle, (3) peak effect duration, (4) duration of acceptable benefit, (5) time back to baseline. The AUC of the current cycle was positively correlated with (1) VAS change baseline to peak effect, and (2) week worn off completely.

Conclusions: We conclude that LIVECHART has high internal consistency and reliability. It adequately reflects amplitude, duration and overall benefit of botulinum toxin treatment, and is worth further formal evaluation to determine its validity and reliability.
injection cycles in the same patient. Patients find it very difficult to relate their progress over the typical 3–4 months of a toxin injection cycle from memory, and may have only a hazy understanding of this cyclic process, especially in their early treatment cycles. Contemporaneously recorded, flexible and customizable Patient-Reported Outcome Measures (PROMs) would be more appropriate, reliable and informative.

Many BTX clinics treat a variety of disorders. Tools that are disease-specific generate logistical difficulties in training staff and patients, in supply of forms or software, and in interpretation and storage of completed forms. A generic outcome tool simplifies analysis of the performance of the service as a whole, as well as in individual conditions and patients or other subsets of the service, for audit and research.5–7

In order to address these issues, the Liverpool botulinum toxin effects chart LIVECHART (Fig. 1) was developed and adapted from the global clinical rating scale for patient self-reported outcome measures.8 It has been informally used for recording the effects of treatment for over 25 years in the BTX injection clinic at the Walton Centre, Liverpool, United Kingdom. However, this scale has not been formally tested in terms of its reliability and validity. This is an exploratory study prior to a more extensive formal evaluation of the LIVECHART questionnaire, aiming to assess its internal consistency, validity and reliability. As an exemplar, and to minimize heterogeneity, we used cervical dystonia as a well characterized condition that responds reasonably consistently across multiple injection cycles.

Methods

This is a cross-sectional study. The participating patients were recruited for 3 months from BTX injection clinics at the Walton Centre NHS Foundation Trust, Liverpool, United Kingdom. Of the patients attending the clinic, 90% routinely use LIVECHARTs. We included patients with CD, aged more than 18 years, who had a minimum of three previous BTX injection cycles with completed LIVECHARTs. To ensure the patients properly understood how to use the questionnaires, we attempted to minimize any misunderstanding of the use of LIVECHART by re-explaining it to each patient when they entered the study. Patients were given the LIVECHART to take home after their injections and asked to return it at their next appointment, as usual.

The injecting clinician recorded the treatment given on the LIVECHART, and gave the chart to the patient. The questionnaires (Fig. 1) are then self-administered. Through the injection cycle the patient or carer records (1) a weekly visual analog scale (VAS) score from 0 (worst imaginable) to 100 (very good, no problem) for symptoms, (2) a series of questions to clarify the BTX injection effects and minimize any misunderstandings, (3) adverse events, (4) a 7-point Likert scale to report the effect of the current injections (major deterioration—major benefit), (5) a 7-point Likert scale for comparison with previous injections (much worse—much better), and (6) an open patient comment area.

When the forms were returned at the end of the index injection cycle, we also reviewed the case records to find starting Tsui Torticollis severity scale scores from patients’ first ever, and current cycles.4

From the notes and the index cycle LIVECHART, we noted the following VAS scores

1. baseline of symptoms in their first ever and their current BTX treatment cycles
2. their worst ever VAS symptom score
3. as BTX was taking effect in the index cycle, the VAS score from the first week that the patient deemed the injections were working well
4. as BTX was wearing off, score from the first week patient deemed the injections were not working well enough.

We examined and classified the patterns of response seen in the weekly VAS graphs.

For the index cycle, we used the VAS graph to calculate the times in weeks, from BTX injection to

1. onset of (any) effects
2. peak effect
3. starting to wear off
4. worn off completely
5. duration (weeks) of peak effectiveness
6. the area under curve (AUC) of the VAS graph, using the baseline of the current injection cycle

From the questions on section 3 of LIVECHART, we recorded/calculated

7. time to working well (from question b) “How long before it was working reasonably well?”
8. duration (weeks) of “not working well enough” at the end of the cycle (from question e) “for how long has it not been working well enough?”
9. period of adequate benefit (from interval between onset of b) “working well” and e) “not working well enough”
10. the period of inadequate benefit (“interinjection interval” minus “period of adequate benefit”)

Degree of treatment benefit was measured using 7-point Likert scores

11. for effect of the injection cycle (major deterioration–major benefit)
12. to compare with the previous injection cycle (much worse–much better). 

Statistical analysis was done with SPSS version 21.0. Means and proportions were calculated for continuous and discrete variables, respectively. Pearson correlation coefficients (Pearson’s r) and Spearman’s rank correlation coefficient (p) were used for testing the degree of association between two continuous variables.
### LIVECHART
The LIVEpool botulinum toxin effects chart

#### Section 1. To be completed by your doctor

| Name or Label |
|---------------|
| Botox® | Dysport® | Neurobloc® | Xeomin® |

#### Section 2. How well are your symptoms controlled?

| Week | Bad |
|------|-----|
| Start | 0 – 5 – 10 – 15 – 20 – 25 – 30 – 35 – 40 – 45 – 50 – 55 – 60 – 65 – 70 – 75 – 80 – 85 – 90 – 95 – 100 |
| 1    |     |
| 2    |     |
| 3    |     |
| 4    |     |
| 5    |     |
| 6    |     |
| 7    |     |
| 8    |     |
| 9    |     |
| 10   |     |
| 11   |     |
| 12   |     |
| 13   |     |
| 14   |     |
| 15   |     |
| 16   |     |
| 17   |     |
| 18   |     |

#### Section 3.

a. How soon did you feel some effect? ___ days/weeks
b. How long before it was working reasonably well? ___ days/weeks
c. How long did this response last? ___ days/weeks
d. How long ago did it start to wear off? ___ days/weeks
e. For how long has it not been working well enough? ___ days/weeks
f. How long since it wore off completely? ___ days/weeks

#### Section 4. Did you experience any side effects? Please describe these side effects in the boxes below.

| Side effects | Start - days/weeks | End - days/weeks | How long did it last? | Severity - Mild/Moderate/Severe |
|--------------|--------------------|-----------------|-----------------------|----------------------------------|
| 1            |                    |                 |                       |                                  |
| 2            |                    |                 |                       |                                  |
| 3            |                    |                 |                       |                                  |
| 4            |                    |                 |                       |                                  |

#### Section 5. While it was working what was the effect of your injection?

| Major deterioration | Moderate deterioration | Minor deterioration | No effect | Minor benefit | Moderate benefit | Major benefit |
|---------------------|------------------------|---------------------|-----------|---------------|------------------|--------------|

#### Section 6. How did it compare with your previous injection?

| Much worse | Worse | Slightly worse | Same | Slightly better | Better | Much better |
|------------|-------|----------------|------|----------------|--------|-------------|

*Device by Dr AP Moore, The Walton Centre Nuffield Foundation Trust. Presented with compliments by Ipsen Ltd.*

**FIG. 1.** The Liverpool botulinum toxin effects chart (LIVECHART) questionnaire front and reverse.
**How to use**

The LIVEchart is used to record the botulinum toxin treatment you have received and enable you to report on how it is working to help make your future treatment better.

**Section 1**
This section contains the details of your treatment. Your healthcare professional will complete this section for you.

**Section 2**
Please rate how well you think your injection has been working each week byringing a number between 0 (extremely badly) and 100 (extremely well).

**Section 3**
Answer these simple questions about your treatment effects. Ring or underline days or weeks.

**Section 4**
Write down any side effects you experience here.

**Sections 5 and 6**
Put a circle around the statement that best describes:
- the overall effect of your current treatment
- how it compares with previous injections

Ideally it should be the same person who completes the questionnaire each time.

| Week | Bad | Good |
|------|-----|------|
| 19   |     | 0-50-10 | 10-15 | 20-25 | 30-35 | 40-45 | 50-55 | 60-65 | 70-75 | 80-85 | 90-95 | 95-100 |
| 20   |     | 0-50-10 | 10-15 | 20-25 | 30-35 | 40-45 | 50-55 | 60-65 | 70-75 | 80-85 | 90-95 | 95-100 |
| 21   |     | 0-50-10 | 10-15 | 20-25 | 30-35 | 40-45 | 50-55 | 60-65 | 70-75 | 80-85 | 90-95 | 95-100 |
| 22   |     | 0-50-10 | 10-15 | 20-25 | 30-35 | 40-45 | 50-55 | 60-65 | 70-75 | 80-85 | 90-95 | 95-100 |
| 23   |     | 0-50-10 | 10-15 | 20-25 | 30-35 | 40-45 | 50-55 | 60-65 | 70-75 | 80-85 | 90-95 | 95-100 |
| 24   |     | 0-50-10 | 10-15 | 20-25 | 30-35 | 40-45 | 50-55 | 60-65 | 70-75 | 80-85 | 90-95 | 95-100 |
| 25   |     | 0-50-10 | 10-15 | 20-25 | 30-35 | 40-45 | 50-55 | 60-65 | 70-75 | 80-85 | 90-95 | 95-100 |
| 26   |     | 0-50-10 | 10-15 | 20-25 | 30-35 | 40-45 | 50-55 | 60-65 | 70-75 | 80-85 | 90-95 | 95-100 |
| 27   |     | 0-50-10 | 10-15 | 20-25 | 30-35 | 40-45 | 50-55 | 60-65 | 70-75 | 80-85 | 90-95 | 95-100 |
| 28   |     | 0-50-10 | 10-15 | 20-25 | 30-35 | 40-45 | 50-55 | 60-65 | 70-75 | 80-85 | 90-95 | 95-100 |
| 29   |     | 0-50-10 | 10-15 | 20-25 | 30-35 | 40-45 | 50-55 | 60-65 | 70-75 | 80-85 | 90-95 | 95-100 |
| 30   |     | 0-50-10 | 10-15 | 20-25 | 30-35 | 40-45 | 50-55 | 60-65 | 70-75 | 80-85 | 90-95 | 95-100 |
| 31   |     | 0-50-10 | 10-15 | 20-25 | 30-35 | 40-45 | 50-55 | 60-65 | 70-75 | 80-85 | 90-95 | 95-100 |
| 32   |     | 0-50-10 | 10-15 | 20-25 | 30-35 | 40-45 | 50-55 | 60-65 | 70-75 | 80-85 | 90-95 | 95-100 |
| 33   |     | 0-50-10 | 10-15 | 20-25 | 30-35 | 40-45 | 50-55 | 60-65 | 70-75 | 80-85 | 90-95 | 95-100 |
| 34   |     | 0-50-10 | 10-15 | 20-25 | 30-35 | 40-45 | 50-55 | 60-65 | 70-75 | 80-85 | 90-95 | 95-100 |
| 35   |     | 0-50-10 | 10-15 | 20-25 | 30-35 | 40-45 | 50-55 | 60-65 | 70-75 | 80-85 | 90-95 | 95-100 |
| 36   |     | 0-50-10 | 10-15 | 20-25 | 30-35 | 40-45 | 50-55 | 60-65 | 70-75 | 80-85 | 90-95 | 95-100 |
| 37   |     | 0-50-10 | 10-15 | 20-25 | 30-35 | 40-45 | 50-55 | 60-65 | 70-75 | 80-85 | 90-95 | 95-100 |
| 38   |     | 0-50-10 | 10-15 | 20-25 | 30-35 | 40-45 | 50-55 | 60-65 | 70-75 | 80-85 | 90-95 | 95-100 |
| 39   |     | 0-50-10 | 10-15 | 20-25 | 30-35 | 40-45 | 50-55 | 60-65 | 70-75 | 80-85 | 90-95 | 95-100 |

Use this space for additional diagrams, instructions or patient comments.

Devised by Dr AP Moore, The Walton Centre NHS Foundation Trust. Presented with compliments by Ipsen Ltd.

Date of preparation: May 2011 DYS08233
Results

Over a 3 month period, 222 patients with CD received treatment in the toxin clinic. Of these, 132 were ineligible because they had completed fewer than 3 cycles of treatment and/or the records contained fewer than three previously fully completed LIVECTHARTs. Ninety completed LIVECTHART questionnaires and patients’ baseline characteristics were analyzed, and the weekly VAS scores were recorded. Table 1 shows the patients’ baseline characteristics. Table 2 shows the responses to BTX and weekly VAS scores were recorded. Table 1 shows the patients

Using the weekly VAS patterns we classified cycles as

1. **classic**: onset of effects at the 1st week, reaching peak effectiveness in the third or 4th week, onset of wearing off at around the 10th–12th week,
2. **early peak**: peak effectiveness reached before the 3rd week,
3. **late peak**: peak effectiveness commencing after the 6th week,
4. **low and slow**: small effect building slowly over most of the cycle,
5. **fluctuating**: uneven effectiveness,
6. **valley and peak**: initial continuing deterioration after treatment was followed by benefit,
7. **burst response**: high peak effectiveness but short duration (less than 4 weeks),
8. **persistent benefit**: the effectiveness not wearing off throughout the cycle

Discussion

Most methods of measuring patient response to BTX treatment rely on patients’ retrospective reports and “objective” observer-measured scales. LIVECTHART records patient response through mostly contemporaneous self-reported measures. In this study we assessed the internal consistency and reliability of LIVECTHART. Patients were clearly able to distinguish within-cycle milestones such as times of onset of effect, of peak effectiveness, onset of (usually gradual) wearing off, “not working well enough” and of end of benefit (“worn off completely”). Patients can effectively assess between-cycle differences in response, using a Likert scale.
(outcome 8) for coarse grading, and combining a second Likert scale (outcome 9) with VAS charting for fine tuning.

All this information is readily assimilated by the clinician as it is already charted when the patient arrives in clinic. As sections are designed to cross-check each other, any misunderstandings and discrepancies are easily identified and resolved. In busy clinical services, practitioners may be able to extract these distinctions by interrogation at the end of an injection cycle even without LIVECHART, but only if there is time, the patient has been sufficiently observant, and can remember details over several months. Because the pattern and dose of injections given and adverse effects are recorded on the same page, it is easy to match responses with changes of treatment.

LIVECHART relies on the ability of patients to monitor their own results and understand how to use LIVECHART itself. As this was the first formal evaluation of LIVECHART, we enrolled

| TABLE 3 | Subjective treatment benefit |
| --- | --- |
| **Likert scores for the effects of recent injection: number of patients (%)**<sup>a</sup> |  |
| Major deterioration | Moderate deterioration | Minor deterioration | No effect | Minor benefit | Moderate benefit | Major benefit |
| --- | --- | --- | --- | --- | --- | --- |
| 0 | 2 | 0 | 3 | 21 | 41 | 22 |
| (0.0) | (2.0) | (0.0) | (3.0) | (23.0) | (46.0) | (25.0) |

| **Likert scores for comparison with previous injection: number of patients (%)**<sup>b</sup><sup>c</sup> |  |
| --- | --- | --- | --- | --- | --- | --- |
| Much worse | Worse | Slightly worse | Same | Slightly better | Better | Much better |
| 2 | 2 | 14 | 39 | 16 | 12 | 2 |
| (2.0) | (2.0) | (16.0) | (43.0) | (18.0) | (14.0) | (2.0) |

<sup>a</sup>Not recorded 1 (1.0).
<sup>b</sup>Not recorded 3 (3.0).
<sup>c</sup>3 patients were unable to decide on a single Likert category and encompassed two. For statistical purposes the poorer category was used.

| TABLE 4 | Correlations between variables |
| --- | --- |
| Variables | Correlation | P value |
| Tsui score before first BtX treatment |  |
| Baseline VAS | −0.09 | 0.387 |
| VAS change baseline to peak effect |  |
| Duration acceptable benefit | 0.18 | 0.114 |
| Likert score for effect of current injection |  |
| VAS change baseline to peak effect | 0.27 | 0.016 |
| AUC of current cycle | 0.48 | <0.001 |
| Peak effect duration | 0.27 | 0.020 |
| Duration acceptable benefit | 0.26 | 0.024 |
| Adverse effect (any) | −0.02 | 0.864 |
| Week worn off completely | 0.34 | 0.002 |
| AUC of current cycle |  |
| VAS change baseline to peak effect | 0.76 | <0.001 |
| Duration of acceptable benefit | 0.21 | 0.069 |
| Week worn off completely | 0.57 | <0.001 |
| Adverse effects (any) |  |
| VAS change baseline to peak effect | −0.14 | 0.321 |
| AUC of current cycle | −0.10 | 0.500 |
| Likert score for comparison with previous injection | 0.09 | 0.523 |
patients who were already familiar with it, and attempted to further minimize any misunderstandings by having the same practitioner explain it again in the same way to each patient.

Some of the discrepancies between this study and previous literature might lie in the nature of patient self-reported questionnaires as compared to observer-based scores. Examples of discrepancies include the mean time to “Onset of any effect” of 2 weeks (SD 1.18), which is perhaps longer than is commonly reported in the literature.\textsuperscript{10} This may be because time intervals were rounded to the nearest week for the analysis, so that the minimum time to onset was likely to be 1 week, unless onset was within the first 3 days—which is uncommon. In addition, much of the previous literature includes toxin-naïve patients who do not face any trough effect from previous injection cycles. Many experienced patients distinguish between (1) slowing or halting of the “End of Cycle Deterioration,” (2) onset of some improvement from eventual trough level, and (3) rise above the cycle baseline. It can be difficult for them (and for their treating clinicians) to decide which of these events constitutes a clinical effect for the purpose of the specific LIVECHART question. We deliberately do not attempt to predefine this distinction in the patient’s mind as it is likely to complicate matters. Patients are left to develop their own criteria within the wording of the question, which is perhaps the essence of a patient-reported instrument.

Additionally, the mean interval between injections of 23 weeks is perhaps surprisingly long. This was not specifically explored but is likely due to a combination of service capacity problems and some patients who missed appointments or deferred them because of a prolonged response.

The literature generally, and most industry funded studies, tend to assume a standard response perhaps best represented by our VAS pattern “classic response”. The standard response includes a peak effect measured within a pre-defined window, usually at about 6 weeks.\textsuperscript{10–12} Yet, in this study, different response patterns such as “low and slow,” very short peak duration or very short or long time to peak effect were recorded for 50% of cycles, and would easily be missed or misrepresented using pre-defined intervals or windows and single timepoint measures. Our anecdotal experience of using LIVECHART for other conditions suggests these non-standard response patterns occur in many disorders treated with BTX.

Likert scales are one option for measuring the amplitude and/or duration of treatment benefit. They are usually easy for patients to understand and answer correctly.\textsuperscript{13} However, it is important that patients understand which aspect of the benefit is being classified—best effect (amplitude), duration of effect, or a composite. For LIVECHART we ask patients to use the Likert scores to rate best effect (peak effect). This is partly because it is the most informative aspect from the point of view of deciding the best pattern of injections. It can also be difficult for patients to recall or work out duration of effect, and obtain this from the weekly VAS scores.

AUC of current cycle provides a composite measure of benefit. It combines amplitude and duration of treatment benefit, and takes account of non-standard patterns of response. AUC was strongly related to the VAS that change from baseline to peak effect. Calibration of the VAS against their Likert scores differs between patients, but is generally consistent for any individual patient.

Likert scores and the AUC measurement of total patient benefit reflect the patient’s own perception of benefit, which is arguably more important for monitoring a symptomatic treatment than “objective,” observer-based scores. It is possible that the largely observer-based measures currently used in most formal BTX studies are suboptimal, even though some do include (retrospective) patient-reported features.\textsuperscript{7}

In service clinics, any observer-based outcome measures such as the Toronto Western Spasmodic Torticollis Rating Scale (TWSTRS),\textsuperscript{2} Unified Dystonia Rating Scale (UDRS),\textsuperscript{3} or Tsui score\textsuperscript{4} are difficult to apply as they require an extra clinician-patient contact for a peak effect assessment. As we have found, the peak effect timing is highly variable between patients, so that pre-ordained visits risk missing the peak. Nor is it possible for patients to report in at peak, as they cannot know they have reached it until it has passed.

Because of its subjectivity and the ability of most patients to report consistently across cycles, LIVECHART is very helpful for between-cycle comparisons in individual patients. The variability between patients in calibration of VAS scores and Likert scores makes it less easily applied to between-patient comparisons within a single injection cycle, which is the requirement in parallel group randomized controlled trials (RCTs). However, LIVECHART is readily applied and can be a sensitive tool in crossover RCTs,\textsuperscript{14} and further research may yet prove it useful in large enough parallel group studies using aggregated data.

A comprehensive treatment monitoring system might combine patient-based reporting with clinician observations\textsuperscript{11} for every cycle long-term, but would be needlessly complex, inconvenient and expensive for service use, and often unachievable. Intuitively, LIVECHART provides easily accessible and inexpensive monitoring that also improves doctor-patient communication and mutual education. It reflects the treatment response against the patient’s own goals, and doctors can easily refer back to previous injection cycles to optimize treatment.

In conclusion, using the exemplar of cervical dystonia, LIVECHART exhibited internal consistency and reliability. It is a simple, easy to use, self-administered questionnaire. It provides patient-reported outcome measures that (anecdotally) have been applied across multiple conditions. LIVECHART is designed to act as both outcome measure and educational tool. It helps patients to understand the cyclical nature of regular toxin treatment, and this reflects back in their ability to report the effects. It also helps the treating clinician to optimize subsequent injection patterns, as patients become able to distinguish more subtle differences in effect between cycles. LIVECHART reflects amplitude, duration, and overall benefit of treatment.

In this study we have not explored compliance rates in completing the questionnaires. Anecdotally, compliance depends heavily on the way the LIVECHART is explained and promoted to patients, and ensuring that it is used as the basis of clinic discussions so that patients come to realize the benefits. Not every patient answers every question each time, and many
tailor it in some way to suit their own circumstances. The incentive to continue using it is less when their clinical response appears well established and predictable, but most understand that there is a potential “rainy day” benefit in better treatment decisions when a cycle has unexpectedly not worked well. We intend to explore compliance in the next stage of LIVECHART evaluation. Inter-rater reliability was not tested in this study, and the LIVECHART needs further formal evaluation of its validity, reliability and generalizability to other disorders, and its ability to optimize treatment and improve patient and clinician education.

Author Roles

(1) Research Project: A. Conception, B. Organization, C. Execution; (2) Statistical Analysis: A. Design, B. Execution, C. Review and Critique; (3) Manuscript: A. Writing of the First Draft, B. Review and Critique.

C.C.: 1A, 1B, 1C, 2A, 2B, 3A
A.P.M.: 1A, 1B, 1C, 2C, 3B

Disclosures

Ethical Compliance Statement: This study was a part of clinical service evaluation and was approved by the Clinical Audit Committee at the Walton Centre NHS Foundation Trust. It is not defined as research according to the guidelines collated by the NHS Research and Development Forum; it is, therefore, exempted from ethical review by the NHS Research Ethics Committee. All patients consented to take part in the questionnaire assessment and no patient identifiable data has been submitted with this manuscript. We confirm that we have read the Journal’s position on issues involved in ethical publication and affirm that this work is consistent with those guidelines.

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