Patient-Reported Goal Achievement Following OnabotulinumtoxinA Treatment in Patients With Neurogenic Detrusor Overactivity

Emmanuel Chartier-Kastler,1* Eric Rovner,2 Zsolt Hepp,3 Kristin Khalaf,3,4 Quanhong Ni,3 and Michael Chancellor5

1Department of Urology, Pitié-Salpêtrière Academic Hospital, University Paris 6, Paris, France
2Department of Urology, Medical University of South Carolina, Charleston, South Carolina
3Global Health Outcomes Strategy and Research, Allergan, Inc., Irvine, California
4Department of Pharmaceutical Sciences, University of Arizona, Phoenix, Arizona
5Neurourology Department, Beaumont Hospital, Royal Oak, Michigan

Aims: To identify the self-reported treatment goals of patients with urinary incontinence (UI) due to neurogenic detrusor overactivity (NDO), determine whether patients achieved their goals following onabotulinumtoxinA treatment, and assess impact of neurogenic disease (multiple sclerosis or spinal cord injury) and/or clean intermittent catheterization (CIC) on goal achievement. Methods: Data from two Phase III studies of onabotulinumtoxinA 200U (n = 227) or placebo (n = 241) in NDO patients (≥14 UI episodes/week; inadequately managed by anticholinergics) were pooled for analysis. At baseline, patients listed their top two qualitative treatment goals, which were distributed into eight subcategories. Six weeks post-treatment, patients rated whether they achieved their goals (5-point Likert scale). The frequency distribution of goals, the proportion of patients who achieved their goals, and goal achievement by etiology and use/non-use of CIC were assessed. Results: At baseline, the most common goals were “be dry” (37.9%), “reduce other urinary symptoms” (26.4%), and “improve quality of life/sleep/emotions” (21.4%). Significantly higher proportions of onabotulinumtoxinA-treated patients achieved their overall goals versus placebo (62.0% vs. 17.2%; P < 0.001). OnabotulinumtoxinA treatment resulted in higher goal achievement in all goal categories, regardless of etiology. CIC use did not negatively impact patients’ overall goal achievement; significantly higher proportions of onabotulinumtoxinA-treated patients versus placebo achieved their goals regardless of baseline catheterization use or de novo CIC during the first 6 weeks of the study. Conclusions: The majority of patients with UI due to NDO achieved their self-determined treatment goals following onabotulinumtoxinA 200U therapy, regardless of etiology or CIC use. Neurourol. Urodynam. 35:595–600, 2016.

Key words: botulinum toxin A; multiple sclerosis; spinal cord injury; urinary incontinence

INTRODUCTION

Patients with neurologic conditions such as multiple sclerosis (MS) and spinal cord injury (SCI) often suffer from neurogenic detrusor overactivity (NDO), which is characterized by involuntary detrusor contractions that may lead to urinary incontinence (UI) and can negatively impact their health-related quality of life (HRQoL).1–4 In patients with NDO who were not adequately managed with an anticholinergic, onabotulinumtoxinA (BOTOX®, Allergan, Inc., Irvine, CA) has been shown to significantly reduce weekly UI episodes (−21.3 vs. −10.5 for onabotulinumtoxinA 200U and placebo, respectively), improve maximum cystometric capacity (+153.6 ml vs. +11.9 ml, respectively), and reduce maximum detrusor pressure (−32.4 cm H2O vs. +11.1 cm H2O, respectively) at week 6 following treatment.5–8 OnabotulinumtoxinA has also been shown to improve HRQoL in these patients, with high proportions of onabotulinumtoxinA-treated patients indicating they were satisfied with treatment.9,10 Although the clinical assessments used to capture symptom improvement provide objective and quantitative evidence of treatment efficacy for physicians, they do not necessarily capture information that is of importance to patients. Conversely, while patient-reported outcomes (such as HRQoL measures) capture information that is important to patients, they are often standardized and do not account for individual symptoms and concerns, nor do they document patient-reported goals and expectations for treatment. Identification of individual treatment goals and assessment of the degree to which they are achieved following treatment can potentially help optimize treatment benefit and enhance patient satisfaction. The objectives of the present analysis were to identify the self-reported treatment goals of patients with UI due to NDO, to determine whether patients achieved their goals following onabotulinumtoxinA treatment, and to assess whether disease etiology and/or use of clean intermittent catheterization (CIC) influenced goal achievement.

Christopher Chapple led the peer review process as the Associate Editor responsible for the paper.

Potential conflicts of interest: This study was funded by Allergan. Dr. Chartier-Kastler reports personal fees from Allergan, American Medical Systems, Wellspect, Coloplast, Astellas, Pfizer, Lilly, Myopowers, and Laborie outside the submitted work. Dr Chancellor, Dr. Hepp, Dr. Khalaf, and Dr. Rovner report personal fees from Allergan outside the submitted work. Dr Hepp is an employee of Allergan, Inc. Dr Khalaf was an employee of Allergan, Inc. when the work was conducted.

Grant sponsor: Allergan, Inc.

*Correspondence to: Emmanuel Chartier-Kastler, Pitié-Salpêtrière Academic Hospital, University Paris 6, Paris, France.
E-mail: emmanuel.chartier-kastler@psl.aphp.fr
Received 3 October 2014, Accepted 30 January 2015
Published online 6 April 2015 in Wiley Online Library (wileyonlinelibrary.com).
DOI 10.1002/nau.22757
METHODS

Study Design

Data from two Phase III studies were pooled for analysis; details regarding study design and patient selection for the individual studies have been described in detail elsewhere. Briefly, the Double-blind InvestiGation of purified Neurotoxin complex In neurogenic detrusor overactivity (DIGNITY) studies (ClinicalTrials.gov identifier NCT00461292 and NCT00311376) were multinational, double-blind, placebo-controlled, randomized studies that included patients with urodynamically confirmed NDO due to MS (clinically stable for ≥3 months prior to enrollment and with an Expanded Disability Status Score of ≤6.5) or SCI (T1 or below, with injury ≥6 months before enrollment), and ≥14 UI episodes/week. Patients were either using CIC prior to study entry or, if they were not, had to be willing to initiate CIC if necessary. CIC in this multi-center, multinational study was performed per local site practice using single-use self-catheters, therefore reflecting what would be expected in clinical practice. Local sites were not asked to practice one technique or another (e.g., touch vs. non-touch). Patients had to be inadequately managed by or intolerant of at least one anticholinergic. If patients were on anticholinergic therapy on study entry, they were allowed to continue it at a stable dose if the physician felt it was clinically warranted. Patients were randomized to receive placebo (n = 241), onabotulinumtoxinA 200U (n = 227), or onabotulinumtoxinA 300U (n = 223) administered as 30 intradetrusor injections (1 ml each) via cystoscopy, avoiding the trigone. The analyses presented herein focus on the approved 200U dose; however, because the trials included a 300U dose arm, a summary of the results for this dose is also included and relevant corresponding data are presented in Supporting Information. Dosing and results reported in this study are specific to onabotulinumtoxinA, which is not interchangeable with other botulinum toxin products and units cannot be converted using a dose ratio. Therefore, the results of this study cannot be extrapolated to other formulations of botulinum toxins.

Treatment Goal Assessments

At study entry, patients were asked to list their top one or two goals for treatment of their detrusor overactivity symptoms. Patients’ verbatim qualitative responses were then categorized by two independent raters into eight categories (Table I), which included “be dry,” “reduce incontinence,” “reduce other urinary symptoms” (e.g., urgency, frequency, and nocturia), “reduce activity limitations” (role/physical/social limitations), “improve bladder control,” “improve quality of life (QoL)/sleep/emotions,” or “reduce number of oral medication therapies.” The responses that did not fit the above categories were grouped as “other” (general positive treatment results, reduce or stop infections [urinary tract infection or pyelonephritis], or save money). A patient with two goals was counted in each of the categories for which they listed a goal. If both goals happen to fall in one category, the patient would be counted only once in that category. At 6 weeks following onabotulinumtoxinA treatment, patients were asked to rate how effectively treatment helped them achieve their stated goals on a 5-point Likert scale (no progress toward, some progress toward, moderate progress toward, significant progress toward, or complete achievement of primary treatment goals). Respondents were considered to have met their treatment goal if they reported “significant progress toward” or “complete achievement” of their goal. A patient was considered as an overall responder if one of the goals was achieved.

Statistical Analyses

Analyses were conducted using the intent-to-treat (ITT) population (all randomized patients). Differences in baseline characteristics between the placebo and onabotulinumtoxinA groups were assessed using one-way analysis of variance for continuous variables and Pearson’s chi-square test or Fisher’s exact test for categorical variables. Pearson’s chi-square test or Fisher’s exact test were also used to analyze between-group comparisons of the proportion of patients in each goal category at baseline and at week 6. The proportions of patients within each patient subgroup (etiology or CIC use) who achieved their overall goal following treatment were also analyzed using the same statistical tests; however, statistical analyses within each goal subcategory were not performed in these patient subgroups due to small sample sizes.

RESULTS

Baseline Demographics and Characteristics

Of the study population that included the 200U and placebo groups (N = 468), 261 (55.8%) had MS and 207 (44.2%) had SCI. Baseline patient demographics and disease characteristics were generally similar across treatment groups when stratified by disease etiology (Table II). The MS population was comprised of

| Table I. Treatment Goals at Baseline |
|-------------------------------------|
| Goal category, n (%)               | ITT population | MS subpopulation | SCI subpopulation |
|                                    | OnabotA 200U (n = 218) | Placebo (n = 217) | Total (N = 435) |
|                                    | OnabotA 200U (n = 126) | Placebo (n = 119) | Total (N = 245) |
|                                    | OnabotA 200U (n = 92)  | Placebo (n = 98)  | Total (N = 190) |
| Be dry                             | 80 (36.7)        | 85 (39.2)        | 165 (37.9)        |
| Reduce incontinence                | 28 (12.8)        | 26 (12.0)        | 54 (12.4)         |
| Reduce other urinary symptoms      | 58 (26.6)        | 57 (26.3)        | 115 (26.4)        |
| Reduce activity limitations        | 27 (12.4)        | 24 (11.1)        | 51 (11.7)         |
| Improve bladder control            | 32 (14.7)        | 41 (18.9)        | 73 (16.8)         |
| Improve QoL, sleep, and emotions   | 44 (20.2)        | 49 (22.6)        | 93 (21.4)         |
| Reduce no. of oral medication therapies | 43 (19.7)    | 36 (16.6)        | 79 (18.2)         |
| Other                              | 24 (11.0)        | 32 (14.7)        | 56 (12.9)         |

Percentages (%) represent the proportion of patients who identify with the category (n) out of the total number (N) of patients in that respective patient population. Note: Patient with two goals is counted in both categories.

ITC, intent-to-treat; MS, multiple sclerosis; OnabotA, onabotulinumtoxinA; QoL, quality of life; SCI, spinal cord injury.

Neurourology and Urodynamics DOI 10.1002/nau
a greater proportion of female patients than the SCI population, while a higher proportion of the SCI population was using CIC and/or anticholinergic medications in comparison to the MS population. Greater proportions of patients using CIC at baseline reported anticholinergic use and were found to be generally younger than patients who were not using CIC. In addition, patients using CIC at baseline were found to have lower daily UI episodes and a higher volume per void. Among those who were not using CIC at baseline (N = 104, 47.7%), 29 patients (27.9%) initiated de novo CIC during the first 6 weeks of treatment onabotulinumtoxinA 200U.

**Treatment Goals at Baseline**

Of the 468 patients who were randomized to receive onabotulinumtoxinA 200U or placebo, 435 (92.9%) enumerated their treatment goals at baseline (Table I). Among this population, baseline treatment goals did not differ significantly among the placebo- and onabotulinumtoxinA-treated groups. The most common treatment goals at baseline were “be dry” (37.9%), “reduce other urinary symptoms” (26.4%), and “improve QoL/sleep/emotions” (21.4%). In addition, 18.2% of patients indicated a goal of “reduce number of oral medication therapies” and 12.9% chose goals that fell into the “other” category. Higher proportions of patients in the MS population chose goals associated with “reduce urinary symptoms” and “improve QoL/sleep/emotions” in comparison to the SCI population. Conversely, a higher proportion of SCI patients chose “be dry” as a goal in comparison to MS patients. The choice of treatment goals was similar among patients regardless of whether or not CIC was used at baseline, and in patients spontaneously voiding at baseline, regardless of whether or not it had to be initiated during the first 6 weeks of the study.

**Goal Achievement Following Treatment**

Significantly higher proportions of patients receiving 200U onabotulinumtoxinA achieved their treatment goals in comparison to placebo-treated patients (Fig. 1). Overall, 62.0% of patients in the onabotulinumtoxinA group achieved at least one of their goals compared with only 17.2% of patients in the placebo group (P < 0.001). A similar trend was noted for each of the eight categories of treatment goals, where a greater proportion of onabotulinumtoxinA-treated patients achieved their goals compared with placebo (Fig. 1).

**Impact of Disease Etiology and CIC Use on Goal Achievement**

Patients with MS or SCI reported significantly greater overall goal achievement with onabotulinumtoxinA 200U treatment compared with placebo (P < 0.001 for each; Table III). Patients with MS or SCI who received onabotulinumtoxinA 200U also reported greater achievement of goals in each category compared with those treated with placebo. Overall goal achievement was similar in NDO patients, regardless of disease etiology.

The impact of CIC on goal achievement was also assessed. Overall goal achievement was significantly higher in patients treated with onabotulinumtoxinA 200U compared with placebo; regardless of CIC use at baseline (70.9% vs. 14.8% with CIC and 52.0% vs. 20.9% without CIC; P < 0.001 for both). In addition, initiation of de novo catheterization during the first 6 weeks of the study did not impact patients’ overall goal achievement; the proportion of onabotulinumtoxinA 200U-treated patients who achieved at least one of their overall treatment goals was 46.4% for patients who initiated de novo CIC versus 54.2% for patients who did not.

**Treatment With 300U OnabotulinumtoxinA**

Overall, the results for patients who received 300U onabotulinumtoxinA were similar to those in the patients who received 200U. Treatment goals at baseline in the 300U group were similar to those in the placebo and 200U arms of the study (Table I and Supporting Information Table S1). A significantly higher proportion of patients treated with 300U onabotulinumtoxinA group achieved their overall treatment goals (63.9%) versus placebo (17.2%; P < 0.001; Supporting Information Figure S1), and the proportion did not differ significantly from the proportion of patients in the 200U group who achieved their goals (62.0%; P = 0.693). Significantly greater proportions of patients in the 300U onabotulinumtoxinA group achieved their overall treatment goals versus placebo regardless of disease etiology or CIC use (data not shown).

**DISCUSSION**

In the current study, patients assessed achievement of their predefined treatment goals following treatment with 200U or 300U onabotulinumtoxinA or placebo. Significantly greater proportions of patients in the onabotulinumtoxinA groups reported making significant progress toward, or complete achievement of, their goals in comparison to placebo. These differences were observed regardless of disease etiology or CIC use.

**TABLE II. Baseline Demographics and Disease Characteristics**

| Characteristic          | ITT population     | MS subpopulation | SCI subpopulation |
|-------------------------|--------------------|------------------|-------------------|
|                         | Onabota 200U (n = 227) | Placebo (n = 241) | P-value | Onabota 200U (n = 130) | Placebo (n = 131) | P-value | Onabota 200U (n = 97) | Placebo (n = 110) | P-value |
| Age (years), mean ± SD  | 45.9 ± 13.3        | 46.2 ± 13.3      | 0.774   | 49.7 ± 12.1        | 50.2 ± 10.7      | 0.712     | 40.7 ± 13.1        | 41.5 ± 14.5     | 0.709   |
| Female gender, n (%)    | 134 (59.0)         | 125 (51.9)       | 0.119   | 104 (80.0)         | 100 (76.3)       | 0.474     | 30 (30.9)          | 25 (22.7)       | 0.183   |
| Anticholinergic use, n (%) | 120 (52.9)       | 140 (58.1)       | 0.255   | 64 (49.2)          | 67 (51.1)        | 0.757     | 56 (57.7)          | 73 (66.4)       | 0.201   |
| UI episodes/day, mean ± SD | 4.6 ± 3.0          | 4.5 ± 3.3        | 0.632   | 4.8 ± 3.0          | 4.6 ± 3.4        | 0.652     | 4.4 ± 3.1          | 4.4 ± 3.2       | 0.864   |
| Using CIC, n (%)        | 119 (53.1)         | 139 (58.2)       | 0.276   | 41 (32.0)          | 42 (32.1)        | 0.996     | 78 (81.3)          | 97 (89.8)       | 0.080   |

Percentages (%) represent the proportion of patients who identify with the category (n) out of the total number (N) of patients in that respective patient population. Statistical tests for differences within populations (total, MS, or SCI) were assessed using one-way analysis of variance for continuous variables and Pearson’s chi-square test or Fisher’s exact test. N represents the total number of patients within each patient population.

CIC, clean intermittent catheterization; ITT, intent-to-treat; MS, multiple sclerosis; Onabota, onabotulinumtoxinA; SCI, spinal cord injury; SD, standard deviation; UI, urinary incontinence.
results were seen ubiquitously among all categories in our analyses, some of which included some ambitious goals. In particular, the goal of being dry may be considered overly optimistic for an incontinent patient with NDO who has already failed at least one anticholinergic; however, onabotulinumtoxinA 200U resulted in greater proportions of patients reporting achievement of this substantial goal in comparison to placebo (55.4% vs. 16.3%, respectively). These results support the clinical efficacy of onabotulinumtoxinA 200U, as measured with diary-documented changes in daily UI episodes and improvements in urodynamic parameters,5–8 and further extend these findings by providing evidence of improvements in parameters that are important to patients. This is particularly important because while physician-rated assessments

![Fig. 1. Goal achievement following treatment. The proportions of patients in the ITT population who received onabotulinumtoxinA 200U (black bars) or placebo (white bars) and reported significant progress toward or complete achievement of goals at week 6. n/N represents the number of patients who achieved goal/number of patients reporting category as a goal. Each patient would specify up to two treatment goals. Patient is considered as an overall responder if one of the goals is achieved. *P < 0.001; statistical analyses within each goal subcategory were not performed in this population due to small sample size. QoL, quality of life.](image)

**TABLE III. Goal Achievement by Disease Etiology**

| Goal category, n/N (%) | MS subpopulation | SCI subpopulation |
|------------------------|------------------|------------------|
|                        | OnabotA 200U     | Placebo          | OnabotA 200U     | Placebo          |
| Overall                | 79/125 (63.2)   | 25/115 (21.7)*  | 53/88 (60.2)    | 11/94 (11.7)*   |
| Be dry                 | 15/35 (42.9)    | 7/31 (22.6)     | 26/39 (66.7)    | 6/49 (12.2)     |
| Reduce incontinence    | 12/16 (75.0)    | 2/14 (14.3)     | 8/11 (72.7)     | 0/12 (0.0)      |
| Reduce other           | 24/37 (64.9)    | 13/38 (34.2)    | 5/16 (31.3)     | 1/11 (9.1)      |
| urinary symptoms       | 10/14 (71.4)    | 0/13 (0.0)      | 7/11 (63.6)     | 1/9 (11.1)      |
| Reduce activity        | 12/18 (66.7)    | 5/27 (18.5)     | 9/11 (81.8)     | 1/11 (9.1)      |
| limitations            | 18/26 (69.2)    | 3/33 (9.1)      | 7/12 (58.3)     | 1/12 (8.3)      |
| Improve bladder control| 12/23 (52.2)    | 3/12 (25.0)     | 7/15 (46.7)     | 1/22 (4.5)      |
| Improve QoL, sleep,    | 7/14 (50.0)     | 3/13 (23.1)     | 3/9 (33.3)      | 2/16 (12.5)     |
| and emotions           |                  |                  |                  |                  |
| Reduce no. of oral     |                  |                  |                  |                  |
| medication therapies   |                  |                  |                  |                  |
| Other                  | 7/14 (50.0)     | 3/13 (23.1)     | 3/9 (33.3)      | 2/16 (12.5)     |

Percentages (%) represent the proportion of patients who identify with the category (n) out of the total number (N) of patients in that respective patient population. Note: Patient with two goals is counted in both categories. Patient is considered as an overall responder if one of the goals is achieved. Statistical tests for differences across populations were assessed using Pearson’s chi-square test or Fisher’s exact test; statistical analyses within each goal subcategory were not performed in these patient subgroups due to small sample sizes.

*P < 0.001.

Neurourology and Urodynamics DOI 10.1002/nau
provide valuable clinical evidence of treatment efficacy for physicians, they do not necessarily align with patient-rated assessments and often do not provide information on improvements in disease conditions that may be more important and relevant to individual patients. In order to better understand the impact of treatment from the patients’ perspective, patient-reported outcomes data, including characterization of treatment effects on HRQoL and satisfaction, are necessary. The current study is the first to use patient-selected goals to demonstrate efficacy and satisfaction with onabotulinumtoxinA treatment in NDO patients, supporting the positive clinical efficacy of onabotulinumtoxinA in previous studies.

Patient-reported treatment goals are an aspect of treatment efficacy that has not been well documented in patients with UI due to NDO, either at baseline or following treatment, although such measures have been described and utilized previously in other aspects of pelvic floor disorders. In the current study, patients’ individual goals for their treatment of UI due to NDO were recorded before treatment with onabotulinumtoxinA or placebo. Patients’ goals fell into two broad categories that focused on reducing symptoms and improving HRQoL. Although HRQoL impact and bother of urinary symptoms among patients with NDO have been documented previously, the authors’ knowledge, this is the first report to document treatment goals in this population. This comprehensive review of patients’ goals for therapy is a valuable approach that will aid in initiating a dialogue between physicians and NDO patients in order to set realistic goals for therapy, allow physicians to effectively evaluate therapies, and ultimately lead to improved patient outcomes.

As the population in these studies was comprised of patients with both MS and SCI, we wanted to investigate whether there were any differences in baseline goals or goal achievement by disease etiology. Overall, treatment goals were similar in patients with MS versus those with SCI, although there were a few differences. For example, higher proportions of MS patients than SCI patients had the goal of reducing symptoms and improving QoL/sleep/emotions. This finding is not entirely surprising, as the onset of urinary symptoms in MS patients is an indication that their disease is progressing and is associated with depression and poorer HRQoL. Conversely, a higher proportion of SCI patients had the goal of “be dry,” which is not unexpected given that they have a fixed, usually non-progressive neurological lesion and are already experiencing incontinence. Differences in baseline goals may also be attributed to the more active lifestyle of MS versus SCI patients. Regardless of these slight differences in baseline goals, patients of both etiologies reported significantly greater overall goal achievement following onabotulinumtoxinA treatment compared with placebo. This observation is in line with results demonstrating that onabotulinumtoxinA was significantly more effective than placebo at improving urinary symptoms and QoL, regardless of disease etiology. These results suggest that disease etiology has no impact on overall goal attainment following treatment.

More than 50% of the ITT population was already regularly performing catheterization when they enrolled in the study. Goal achievement among patients who were catheterizing at baseline versus those who were not was similar. We found that initiation of de novo CIC during the first 6 weeks following onabotulinumtoxinA treatment did not negatively impact overall goal achievement. These results are in line with previous findings, which indicate that patients were satisfied with onabotulinumtoxinA 200U treatment regardless of whether they had initiated CIC and are in line with the previous findings that patient HRQoL following onabotulinumtoxinA treatment is not significantly impacted by the initiation of CIC.

There are limited reports on patient-reported goals amongst patients with urinary symptoms. In a study of patients with idiopathic overactive bladder (OAB) and urinary urgency incontinence (UUI), patients listed up to two treatment goals at baseline before receiving a single onabotulinumtoxinA or placebo injection; however, the categorization of patient goals was not characterized in this publication. In a study of patients with interstitial cystitis/painful bladder syndrome, 37 patients reported 140 separate goals, with the majority of goals centered around pain reduction, followed by goals focused on the urinary symptoms of frequency and nocturia. Lee et al. assessed patient-reported goals and goal achievement amongst patients experiencing OAB symptoms who were treated with anticholinergics. Similar to our analysis, patients’ goals at baseline were stratified into subcategories, and the majority of patients chose goals related to reducing urinary symptoms, with the next largest percentage of patients choosing goals that were quality-related. While the patient populations were different and the number of goals chosen by patients varied, all studies suggest that reducing symptoms is a primary concern for patients with detrusor overactivity symptoms, regardless of whether they are idiopathic or neurogenic, and are in line with reduction in clinical symptoms following treatment.

The literature documenting goal achievement following onabotulinumtoxinA treatment is sparse. Brubaker et al. used the Patient Global Impression of Symptom Control tool to assess patients with refractory non-NDO incontinence and found that onabotulinumtoxinA significantly improved patient perception of improvement in symptom control. Using a modified OAB-Patient Satisfaction with Treatment Questionnaire, onabotulinumtoxinA at doses of ≥100U resulted in patient-reported progress of “significant progress” or “complete achievement” of their primary goals in patients with idiopathic OAB or UUI. In addition, onabotulinumtoxinA at doses of ≥100U resulted in significantly greater proportions of patients reporting that they were “very satisfied” or “somewhat satisfied” with treatment in comparison to patients receiving placebo. Our study corroborates these findings and further supports the benefit of onabotulinumtoxinA for patients with detrusor overactivity beyond reduction in clinical endpoints, but is also the first study to document onabotulinumtoxinA treatment-associated goal achievement in the NDO population.

Our study had several limitations. First, the categorization of patient goals was a qualitative and subjective process, and thus is open to interpretation; similarly, patient-rated assessment of goal achievement was subjective and may have varied between patients. Second, the subanalyses that examined the effect of disease etiology or the impact of CIC use on goal achievement were limited to small numbers of patients and thus should be interpreted with caution. Finally, there exist several opportunities for future analyses from this study or other studies, such as evaluating goal achievement at longer timepoints post-treatment; determining whether certain variables, such as baseline severity of symptoms, affect goal achievement; and assessing physician-rated goal achievement and the concordance between physician-and patient-rated goal achievements.

**CONCLUSION**

Treatment goals for patients with UI due to NDO focus on reducing urinary symptoms and improving HRQoL. NDO patients experience greater goal achievement following treatment with onabotulinumtoxinA, regardless of disease etiology or CIC status. These results suggest that MS and SCI patients...
experience similar levels of satisfaction following treatment and show that the need to self-catheterize does not impact patient satisfaction with onabotulinumtoxinA treatment. The identification and characterization of individual treatment goals may allow clinicians to more effectively evaluate therapy and inform patient treatment decision making, thus leading to enhanced patient satisfaction and treatment benefit following onabotulinumtoxinA injection.

ACKNOWLEDGMENTS

This study and its analysis were sponsored and supported by Allergan, Inc., Irvine, CA. The authors would like to thank Catherine Corbell and Denise Globe for independently rating patient goals for stratification into goal categories and Shula Pollard and Brenda Jenkins of Allergan, Inc. for critical review of the manuscript. Assistance with the writing and development of the manuscript was provided by Jessica Deckman, Ph.D. and Linda Wychowski, Ph.D., of Evidence Scientific Solutions and was funded by Allergan, Inc.

DISCLOSURES

This study and its analysis were sponsored by Allergan, Inc., Irvine, CA. Emmanuel Chartier-Kastler is an advisor/consultant, meeting participant/lecturer, and has received research funding for a scientific study from Allergan, Inc. He is an advisor/consultant for Medtronic, Coloplast, Astellas, Pfizer, Lilly, and Wellspect. He was an investigator for Ipsen Biotech and AB Sciences, and also received travel funds from Apothecon. Eric Rovner is an advisor/consultant, scientific study/trial investigator, and has received research funding for an investigator-initiated trial from Allergan, Inc. He was also compensated as the central urodynamics reader for the Phase III onabotulinumtoxinA development program. Zsolt Hepp and Quanhong Ni are employees of Allergan, Inc.; Kristin Khalaf was an employee of Allergan, Inc. at the time of study completion and is currently a Ph.D. student at the University of Arizona. Michael Chancellor has consulted for, conducted studies funded by, or received honoraria from Allergan, Inc.

REFERENCES

1. Hollingworth W, Campbell JD, Kowalski J, et al. Exploring the impact of changes in neurogenic urinary incontinence frequency and condition-specific quality of life on preference-based outcomes. Qual Life Res 2010;19:323–31.
2. Clanet MG, Brassat D. The management of multiple sclerosis patients. Curr Opin Neurol 2000;13:263–70.
3. Hicken BL, Putzke JD, Richards JS. Bladder management and quality of life after spinal cord injury. Am J Phys Med Rehabil 2001;80:916–22.
4. Westgren N, Levi K. Quality of life and traumatic spinal cord injury. Arch Phys Med Rehabil 1998;79:1439–9.
5. Ginesberg D, Gousse A, Keppenne V, et al. Phase 3 efficacy and tolerability study of onabotulinumtoxinA for urinary incontinence from neurogenic detrusor overactivity. J Urol 2012;187:2131–9.
6. Cruz F, Hershorn S, Allofta F, et al. Efficacy and safety of onabotulinumtoxinA in patients with urinary incontinence due to neurogenic detrusor overactivity: A randomised, double-blind, placebo-controlled trial. Eur Urol 2011;60:742–50.
7. Rovner E, Dmochowski R, Chapelle C, et al. OnabotulinumtoxinA improves urodynamic outcomes in patients with neurogenic detrusor overactivity. Neurourology Urodyn 2013;32:1109–15.
8. Ginesberg D, Cruz F, Hershorn S, et al. OnabotulinumtoxinA is effective in patients with urinary incontinence due to neurogenic detrusor overactivity (corrected) regardless of concomitant anticholinergic use or neurologic etiology. Adv Ther 2013;30:819–33.
9. Chancellor MB, Patel V, Leng WQ, et al. OnabotulinumtoxinA improves quality of life in patients with neurogenic detrusor overactivity. Neurology 2013;81:841–8.
10. Sussman D, Patel V, Del Popolo G, et al. Treatment satisfaction and improvement in health-related quality of life with onabotulinumtoxinA in patients with urinary incontinence due to neurogenic detrusor overactivity. Neurourology Urodyn 2013;32:242–9.
11. BOTOX. Irvine, CA: Allergan, Inc; 2014.
12. Brin MF, James C, Maltman J. Botulinum toxin type A products are not interchangeable: A review of the evidence. Biologics 2014;8:227–41.
13. Information for Healthcare Professionals: OnabotulinumtoxinA (marketed as Botox/Botox Cosmetic), AbobotulinumtoxinA (marketed as Dysport) and RimabotulinumtoxinB (marketed as Myobloc). www.fda.gov 2013 [cited 2014 November 26]. Available from: http://www.fda.gov/Drugs/ DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ DrugSafetyInformationforHealthcareProfessionals/ucm174949.htm.
14. Lee KS, Lee YS, Kim JC, et al. Patient-reported goal achievement after antimuscarinic treatment in patients with overactive bladder symptoms. Int J Clin Pract 2012;66:663–70.
15. Cartwright R, Srikrishna S, Cardozo L, et al. Validity and reliability of patient selected goals as an outcome measure in overactive bladder. Int Urogynecol J 2011;22:841–7.
16. Choo MS, Doo CK, Lee KS. Satisfaction with tolterodine: Assessing symptom-specific patient-reported goal achievement in the treatment of overactive bladder in female patients [STARGate study]. Int J Clin Pract 2008;62:191–6.
17. Cartwright R, Srikrishna S, Cardozo L, et al. Patient-selected goals in overactive bladder: A placebo controlled randomized double-blind trial of transdermal oxybutynin for the treatment of urgency and urge incontinence. BJU Int 2011;107:70–6.
18. Lowenstein L, FitzGerald MP, Kenton C, et al. Patient-selected goals: The fourth dimension in assessment of pelvic floor disorders. Int Urogynecol J Pelvic Floor Dysfun 2008;19:81–4.
19. Khalaf KM, Coyne KS, Globe DR, et al. Lower urinary tract symptom prevalence and management among patients with multiple sclerosis. Int J MS Care 2015;17:14–25.
20. Khan S, Game X, Kalai V, et al. Long-term effect on quality of life of repeat detrusor injections of botulinum neurotoxin-A for detrusor overactivity in patients with multiple sclerosis. J Urol 2011;185:1344–9.
21. Khalaf KM, Coyne KS, Globe DR, et al. The impact of lower urinary tract symptoms on health-related quality of life among patients with multiple sclerosis. Neurourology Urodyn 2014 [Epub Oct 18]. doi: 10.1002/nau.22670.
22. Kessler TM, Khan S, Panicker J, et al. Clean intermittent self-catheterization after botulinum neurotoxin type A injections: Short-term effect on quality of life. Obstet Gynecol 2009;113:546–51.
23. Brubaker L, Gousse A, Sand P, et al. Treatment satisfaction and goal attainment with onabotulinumtoxinA in patients with incontinence due to idiopathic OAB. Int Urogynecol J 2012;23:1017–25.
24. Payne C, Allee T. Goal achievement provides new insights into interstitial cystitis/painful bladder syndrome symptoms and outcomes. Neurourology Urodyn 2009;28:13–17.
25. Brubaker L, Echter HE, Visco A, et al. Refractory idiopathic urge urinary incontinence and botulinum A injection. J Urol 2008;180:217–22.

Supporting Information

Additional supporting information may be found in the online version of this article at the publisher’s web-site.