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Treatment Satisfaction with Botulinum Toxin Type A in Different Neurological Disorders: A Clinic-based Study

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Abstract

Background: The botulinum toxin type A (BoNT-A) is is safe and effective treatment that is used in diverse range of in neurologic diseases. Patients satisfaction may affect successful treatment outcome.

Objective: To characterize overall patients /caregivers' satisfaction with BoNT-A treatment for symptom control in different neurologic conditions at clinic.

Methods: A cross-sectional study included all patients of both genders and all age groups who had received at least two BoNT-A treatment sessions in our injection clinic. They were asked to rate overall treatment satisfaction at the peak of treatment effect on a 1 to 10 scale (1=not at all satisfied; 10=fully satisfied). Subjects with a rating of 1–3 were classified as not at all satisfied, those with a rating of 4–7 as somewhat satisfied, and those with a rating of 8–10 as very satisfied.

Results: 548 patients were identified for the study with mean age 43.66+14.50. Most of participants 389 (71%) were female. At the end of observational period, the mean satisfaction was 7.28+1.78. Majority of patients 52.9% were very satisfied, while 42.2% of patients were somewhat satisfied and 4.9% of patients were not satisfied at all. There was highly significant difference (p<0.0001) for treatment satisfaction among different neurological disorders. Overall treatment satisfaction with BoNT-A was the highest for axillary HH (9.20 ± 0.86) and the least satisfaction was reported in writer's cramp (4.40 ± 1.67). Overall satisfaction with BoNT-A at beak of treatment effect was very satisfaction among patients with axillary HH (100%), palmar HH (94.4%), other neuropathic pain syndromes (85.7%), planter HH (90), trigeminal neuralgia (80). While somewhat overall satisfaction at beak of treatment effect was more reported among patients with cervical dystonia (86.7%), musculoskeletal pain (80) and 77.8% in headache patients. Not at all satisfaction was more recorded among writer's cramp patients (40%). There was negative significant correlation between BoNT treatment satisfaction and age of patients, (r =-0.099, P=0.022. We reported positive significant correlation between BoNT treatment satisfaction and disease duration and treatment adherence (r =0.185, P=0.0001; r =0.242, P=0.001 respectively).

Conclusion: Patients satisfaction with BoNT-A therapy for different neurological disorders is overall good. The highest patient's satisfaction observed with primary focal HH, and the least satisfaction with cervical dystonia and writer's cramp. Treatment satisfaction improves adherence to treatment.

Keywords: Botulinum toxin type A • Satisfaction • Headache • Dystonia • Hyperhidrosis

Abbreviations: BoNT/A: Botulinum Neurotoxin Type A • CP: Cerebral Palsy • FDA: Food Drug Association • HFS: Hemifacial Spasm • M: Mean • SD = Standard Deviation.

Introduction

Botulinum toxin is the exotoxin of a gram-positive bacteria called clostridium botulinum that blocks the release of acetylcholine into the neural junction and leads to reduced activity of the muscles and glands [1] There are seven antigenically distinct toxins (A, B, C, D, E, F, G) [2]. Among these, type-A toxin is the most stable and commercially used for medical treatment [3]. Botulinum toxin type-A (BoNT-A) is composed of a heavy chain, which is responsible for the specific bindings on the cholinergic fibers' endings, and a light chain which is responsible for its enzymatic activity (zinc-dependent endopeptidase) [4]. It causes presynaptic blockage of the release of acetylcholine at the neuromuscular thereby causing temporary muscle weakness lasting 3–4 months. It is used to treat the clinical disorders characterized by muscle hyperactivity. It has been extensively used for the treatment of different neurological disorders and was found to be well tolerated and highly effective [5,6].

The American Food and Drug Administration (FDA) approved botulinum toxin for the treatment of strabismus, blepharospasm, cervical dystonia, glabellar facial lines, axillary hyperhidrosis, chronic migraine, and lateral canthal lines [7,8]. BoNT-A has been introduced as a useful therapeutic agent for the management of masticatory myofascial pain due to hyperactivity and spasm of the muscles of mastication [9]. It is being used off-label for chronic lower back pain, spasticity due to stroke, traumatic brain injury, cerebral palsy, achalasia, and bruxism [10].

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There is increasing interest in patient satisfaction for their therapies. Patient satisfaction with treatment is a valuable measure of treatment efficacy. The treatment satisfaction is associated with better compliance and adherence. There is need to evaluate and improve patients' treatment satisfaction [11,12].

The satisfaction with BoNT-A treatment among patients with different neurological disorders was found to be variable. Patient satisfaction with medication is affected with several factors as the effectiveness of therapy, convenience of treatment, or side effects of the medication. Satisfaction for therapy is associated with better adherence to, and persistence with, treatment [13].

Many factors affect successful outcome such as injector experience, patients' feedback and satisfaction. It is important to collect information about the satisfaction with BoNT-A treatment because of its widespread use. So the aim of our study is to characterize overall patients /caregivers' satisfaction with BoNT-A treatment for symptom control at our clinic in the only tertiary hospital in Kuwait.

Materials and Methods

This is cross-sectional study included patients with different neurological disorders who review out patient clinic, Ibn Sina hospital, Ministry of health, Kuwait from April 2014 till August 2019. Subjects of both genders at different age groups who had received at least two BoNT-A treatment sessions and were followed up for at least one year were eligible for participation in the study. Patients who were treated with neuroleptics or other drugs that interfere with neuromuscular transmission, pregnant or lactating females were excluded from the study. BoNT-A injection was performed by neurologists (JA, DY) who are expert in BoNT-A treatment. We used 100 IU BoNT/A (Botox®, Allergan) diluted with 2 or 4 mL of sterile saline. The injections in some applications were performed under electromyographic or ultrasonographic guidance whenever necessary. The dose for subsequent injections was modified according to the therapeutic response.

Treating doctor offered the subjects to participate in the study. Informed consent was obtained from each subject prior to enrollment in the study. We recorded and analyzed data for subjects who agreed to participate in the study. Demographic data, detailed medical history, physical and neurologic examination were recorded for participants. Investigations were requested as needed for each patient to confirm their diagnosis.

Treatment satisfaction

We asked all the patients to rate overall treatment satisfaction at the peak of treatment effect on a numerical rating scale ranging from 1 to 10, where 1 was defined as not at all satisfied and 10 as very satisfied. Subjects with a rating of 1–3 were classified as not at all satisfied, those with a rating of 4–7 as somewhat satisfied, and those with a rating of 8–10 as very satisfied [14].

Study protocol and informed consent were reviewed and approved by Ibn Sina Medical Researchs Ethics Committee and the Institutional Review Board Committee of Ministry of health of the state of Kuwait. The study was conducted in accordance with ethical guidelines of the Council for International Organizations of Medical Sciences [15] and principles in the Declaration of Helsinki [16].

Statistical analyses

Statistical analysis was performed using Statistical Package for Social Sciences version 24.0. Descriptive statistics were used to summarize all data. Numerical variables were summarized by mean and Standard Deviation (SD). Categorical variables were summarized as counts and percentages. Categorical variables were compared using the Chi-square test, and continuous variables were compared using Student's t-test. One-Way ANOVA test were used for intergroup comparisons. Pearson's correlations were performed for correlation between treatment satisfaction and disease characters. $P<0.05$ was considered statistically significant.

Results

A total of 548 patients were identified to the study, with mean age 43.66+14.50. Most of participants 389 (71%) were female. At the end of observational period, the mean duration of neurological disorders was 10.61+6.92 years and subjects had been receiving BoNT-A injections for a mean of 39.66 +29.17months.

Table 1 displays Demographic and disease characteristics of patients who received BoNT. Headache disorders were the most prevalent clinical disorder 240 (43.7%) patients and the least frequent was neuropathic pain syndromes 7 (1.3%) (Table 1).

At the end of observational period, we recorded patient satisfaction with BoNT-A therapy for different neurological disorders at the peak of treatment effects. The Mean satisfaction was 7.28+1.78. Majority of patients 52.9 percentage were very satisfied, while 42.2% of patients were somewhat satisfied and 4.9% of patients were not satisfied at all (Table 2).

Overall satisfaction; for axillary HH (9.24 ± 0.77), palmar HH (8.83 ± 0.62), neuropathic pain syndromes (8.57 ± 0.79), blepharospasm (8.50 ± 1.22), planter HH (8.30 ± 0.94), trigeminal neuralgia (8.20 ± 0.84), apraxia of eyelid opening (7.60 ± 1.14), HFS (7.52 ± 1.36), chronic migraine (7.23 ± 1.69), cerebral palsy (7.06 ± 1.66), musculoskeletal pain (6.50 ± 1.17), oromandibular dystonia (6.43 ± 1.99), other headache disorders (6.33 ± 1.17), sialorrhoea (6.25 ± 2.04), spasticity (6.07 ± 1.98), other focal dystonia (6.23 ± 1.53), cervical dystonia (5.53 ± 1.64), and writer's cramp (4.40 ± 1.67). There was highly significant difference ($p<0.0001$) for treatment satisfaction among different neurological disorders. Overall treatment satisfaction with BoNT-A was the highest for axillary HH (9.20 ± 0.86) and the least satisfaction was reported in writer's cramp (4.40 ± 1.67) (Table 2).

Overall satisfaction with BoNT-A at beak of treatment effect was very satisfaction among patients with axillary HH (100%), palmar HH (94.4%), other neuropathic pain syndromes (85.7%), planter HH (90), trigeminal neuralgia (80). While somewhat overall satisfaction at beak of treatment effect was more reported among patients with cervical dystonia (86.7%), musculoskeletal pain (80), and 77.8% in headache patients. Not at all satisfaction was more recorded among writer's cramp patients (40%) (Table 2).

Table 3 shows negative significant correlation between BoNT treatment satisfaction and age of patients. The younger the patients age the more satisfaction with BoNT treatment, (r =-0.099, $P=0.022$). We reported positive significant correlation between BoNT treatment satisfaction and disease duration (r =0.185, $P=0.0001$). The longer the disease duration the more satisfaction to BoNT treatment. Adherence to treatment was significantly correlated with BoNT treatment satisfaction ($r=0.242$, $P=0.001$).

Discussion

Treatment with BoNT-A injections is well tolerated and may improve quality of life [14]. To date, most studies on satisfaction with BoNT-A in neurological disorders have been either small or very focused on specific disorders. We present a tertiary center experience with large number of patients in several neurological disorders. Patients satisfaction generally followed the onset, peak, and trough of efficacy. However, treatment outcome is individual and time to onset, peak, and trough of efficacy varies between patients [17]. This study was conducted to determine the level of overall satisfaction with with BoNT-A treatment at the time of peak effect for different neurological disorders.

Our cohort included 548 subjects. Most of them were womenwith a mean age of 43.66 years.

Most patients were generally satisfied with their therapy at the time of peak effect, 52.9% were very satisfied; 42.2% of patients were somewhat satisfied and 4.9% were not at all satisfied.

In our study, BoNT-A treatment satisfactions were comparable among different diagnoses. All patient groups are satisfied by their treatment. The

Table 1. Deamographgic and characters of patients who received BoNT-A (N=548).

Diagnosis	N (%)	Age M ± SD	Female Gender N (%)	Disease duration in years M ± SD	Treatment duration in months M ± SD
Headache disorders	240 (43.7%)	-	-	-	-
Chronic migraine	213 (38.9%)	45.15 ± 11.47	190	12.02 ± 7.33	30.18 ± 2031
Other headache disorders	27 (4.9%)	44.37 ± 11.15	(48.8) 24 (6.2)	13.22 ± 6.40	28.00 ± 19.45
Hemifacial spasm and related disorders	92 (16.8%)	-	-	-	-
HFS	73 (13.3%)	52.24 ± 13.24	45 (11.6)	9.45 ± 6.54	35.34 ± 33.73
Blepharospasm	14 (2.6%)	50.92 ± 14.16	11 (2.8)	14.14 ± 7.42	74.36 ± 40.39
Eyelid apraxia	5 (0.9%)	27.25 ± 14.93	5 (1.3)	5.60 ± 3.73	47.20 ± 38.48
Primary focal hyperhidrosis	74 (13.5%)	-	-	-	-
Axillary	46 (8.4%)	33.85 ± 12.63	20 (5.1)	11.48 ± 7.42	43.89 ± 31.74
Palmar	18 (3.3%)	31.12 ± 12.93	7 (1.8)	10.67 ± 6.85	4.94 ± 30.18
Planter	10 (1.8%)	32.75 ± 13.92	5 (1.3)	12.80 ± 7.61	50.10 ± 38.16
Focal dystonia	49 (8.9%)	-	-	-	-
Oromandibular dystonia	16 (2.9%)	42.42 ± 8.25	10 (2.6)	4.94 ± 4.15	27.31 ± 24.33
Cervical dystonia	15 (2.7%)	42.86 ± 12.90	7 (1.8)	5.33 ± 3.02	33.33 ± 20.17
Other focal dystonias	13 (2.4%)	65.53 ± 11.54	8 (2.1)	16.62 ± 5.90	85.23 ± 23.80
Writer's cramp	5 (0.9%)	46.40 ± 19.01	3 (0.8)	5.60 ± 2.71	31.20 ± 18.20
Spasticity	47 (8.65%)	-	-	-	-
Adults	29 (5.3%)	43.21 ± 17.18	21 (5.4)	5.86 ± 3.43	40.07 ± 28.76
Children (CP)	18 (3.3%)	15.22 ± 4.03	9 (2.3)	7.5 ± 4.32	60.00 ± 35.08
Sialorrhoea	24 (4.4%)	63.25 ± 13.12	13 (3.3)	10.29 ± 4.11	39.12 ± 17.63
Neuropathic pain disorders	12 (2.2%)	-	-	-	-
Trigeminal neuralgia	5 (0.9%)	30.00 ± 7.97	3 (0.8)	8.80 ± 1.64	27.20 ± 18.36
Other neuropathic pain disorders	7 (1.3%)	36.00 ± 11.02	3 (0.8)	13.00 ± 4.62	46.14 ± 31.75
Musculoskletal pain	10 (1.8%)	50.30 ± 7.17	5 (1.3)	4.4 ± 4.88	27.80 ± 30.93

BoNT/A = Botulinum Neurotoxin Type A; SD: Standard Deviation; HFS: hemiFacial Spasm; CP: Cerebral Palsy; M: Mean, SD: Standard Deviation; *=Significant.

Table 2. BoNT-A satisfaction in different neurological disorders (N=548).

Diagnosis	Satisfaction score Mean (SD)	No Satisfaction N (%)	Somewhat satisfaction N (%)	Very satisfied N (%)
Headache disorders chronic migraine	7.23 ± 1.69	11 (5.2)	91 (42.7)	111 (52.1)
Other headache disorders	6.33 ± 1.18	0	21 (77.8)	6 (22.2)
Hemifacial spasm and related disorders				
HFS	7.52 ± 1.36	0	35 (47.9)	38 (52.1)
Blepharospasm	8.50 ± 1.22	0	3 (21.4)	11 (78.6)
Blepharospasm	7.60 ± 1.14	2	2 (40)	3 (60)
Primary focal hyperhidrosis				
Axillary	9.24 ± 0.77	0	0	46 (100)
Palmar	8.83 ± 0.62	0	1 (5.6)	17 (94.4)
Planter	8.30 ± 0.95	0	1 (10)	9 (90)
Focal dystonia				
Oromandibular dystonia	6.43 ± 1.99	3 (18.8)	7 (43.8)	6 (37.5)
Cervical dystonia	5.53 ± 1.64	2 (13.3)	13 (86.7)	0
Other focal dystonias	6.23 ± 1.54	1 (7.7)	10 (76.9)	2 (15.4)
Writer's cramp	4.40 ± 1.67	2 (40)	3 (60)	-
Spasticity				
Adults	6.07 ± 1.98	5 (17.2)	13 (44.8)	11 (37.9)
Children (CP)	7.17 ± 1.66	0	8 (44.4)	10 (55.6)
Sialorrhoea	6.25 ± 2.04	3 (12.5)	13 (54.2)	8 (33.3)
Neuropathic pain disorders				
Trigeminal neuralgia	8.20 ± 0.83	0	1 (40)	4 (80)
Neuropathic pain disorders	8.57 ± 0.79	0	1 (14.3)	6 (85.7)
Musculoskletal pain	6.50 ± 1.18	0	8 (80)	2 (20)

BoNT/A = botulinum neurotoxin type A; SD = standard deviation; HFS: hemifacial spasm; CP: cerebral palsy; M: mean, SD: standard deviation.

highest patient's satisfaction observed with primary focal HH, and the least satisfaction with focal dystonia, cervical dystonia and writer's cramp. The differences of satisfaction to BoNT-A among different diagnoses could be explained by different injection protocol for the different diagnoses as site of

Table 3. Correlation between satisfaction and disease characters.

Variables	Age	Gender	Disease duration	Treatment Adherence
Satisfaction for treatment	R= -0.99	R=0.018	R=0.185	R=0.242
	P <0.022*	P <0.674	P <0.0001*	P <0.001*

injection, dosing and injection interval or higher expectation by patients or caregivers exceeding what is reasonably possible.

The highest satisfaction among our cohort was seen in HH, either axillary (9.2 ± 0.9), palmar (8.9 ± 1.0), or planter (8.3 ± 1.3), which is in agreement with previous studies. similar to other published data that recorded 50% of patients reported satisfaction within the first week of treatment and increased to 94% after the second week [18,19].

The lowest patient satisfaction for BoNT-A in our study was seen among cervical dystonia patients (5.6 ± 2.4) and writer's cramp patients (4.4 ± 2.7). This could be explained by patient satisfaction may be related to factors other than symptom control as nonmotor symptoms or unrealistic expectations in patients [20]. However, mean satisfaction fort oromandibular dystonia patients was 6.8 which is consistent with previous study of Meral who reported The mean VAS satisfaction score six weeks after injection was 6.74/10 [21].

Chronic migraine was the most common diagnosis in our cohort. A possible reason is that the high prevalence of primary headache, migraine and chronic headache 61%, 23% and 5.6% respectively in Kuwait [22]. Another explanation is that there is specialized headache clinic at same place and schedule time at our center that refer patients with chronic migraine to BoNTA injection. Satisfaction for BoNT-A in chronic migraine patients in our cohort was (7.2 ± 2.0) which was better than other headache disorders (6.5 ± 2.1) including cluster and tension-type headache. BoNT-A injections are effective therapy for chronic migraines and improve patient quality of life [23]. Our results are in line with previous study that reported that 85% of chronic migraine patients reported over all good satisfaction at the end of observational period [24]. Similarly, Cady et al assessed treatment satisfaction using Migraine Impact Questionnaire (MIQ) and found that BoNT-A treated subjects showed improvement in 11 of 13 and 7 of 13 points at months 3 and 6, respectively compared to no improvement in the placebo group [25].

Our study also proved patient satisfaction for BoNT-A in other painful conditions as Trigeminal neuralgia (8.2 ± 1.6) and other neuropathic pain (8.6 ± 1.3).

There is much basic science evidence for an analgesic effect of BoNT-A. Previous clinical trials confirmed its efficacy, safety and tolerability as prophylactic treatment of chronic migraine and also trigeminal neuralgia [26]. BoNT-A is effective at reducing pain in a number of disease states, including chronic migraine, cervical dystonia, neuropathic pain, lower back pain, spasticity, myofascial pain and bladder pain [26]. Our patients with trigeminal neuralgia showed good satisfaction (8.2 ± 1.6) which was in line with a study by Li et al who reported satisfaction in more than 90% of their cohort regarding improvement in the quality of life, emotional function and side effect burden. BoNT-A inhibits neurogenic inflammation and peripheral sensitization, which potentially blocks the development of central sensitization [26].

The second frequent presentation in our cohort was Hemifacial spasm and related disorder 16.8%. BoNT type A plays an important role in the treatment of HFS because the recommended drugs usually have poor, brief, or no effect, and frequent adverse effects. Therefore, BoNT type A should be considered as the first-line therapy in patients with HFS Blepharospasm (BSP) patients were highly satisfied in our cohort with a score of (8.6 ± 0.9) which in agreement with previous results.

In our study, the minority of the patients had spasticity, cerebral palsy and sialorrhea. They had modest satisfactory results.

Most of our patients regular on their visits to BoNT-A injection clinic. We reported significant positive correlation between treatment adherence and satisfaction to treatment. This is explained by the association between satisfaction and adherence and compliance. Improving components of treatment satisfaction, such as treatment convenience or side effects improves compliance and adherence.

Patient satisfaction has has impact on patients health-related decisions and treatment-related behaviors, which affect the success of treatment outcomes. Patients' satisfaction with the services they receive improved treatment success, medical compliance, follow-through with treatment plans, and appropriate use of services.

Treatment satisfaction is an indicator of quality chealth care. Different factors influence treatment satisfaction as participant expectations, treatment procedure and treatment outcome, it remains unclear which factors contribute to satisfaction with each process and outcome attribute.

To improve patients'/ caregivers' treatment satisfaction and optimize treatment outcomes, individualization of the injection protocol (site of injection, dosing and injection interval) should be considered. Ideally, patients should experience only a mild reappearance of symptoms towards the end of their individualized treatment cycle. A good understanding the various factors associated with treatment satisfaction is vital when discussing the goals of treatment with patients and for planning treatment regimens. We should discuss realistic expectations with our patients.

Future research on satisfaction should explore the contribution of BoNT-A protocol and outcome factors on satisfaction to improve understanding of treatment attributes viewed favorably. This understanding optimize treatment effectiveness.

Conclusion

To our knowledge, this study is the only study investigating patients'/ caregivers' treatment satisfaction with BoNT-A treatment for most of neurological indications to date. This study indicate that overall patients satisfaction with BoNT-A injections in is good. The highest patient's satisfaction observed with primary focal HH, and the least satisfaction with focal dystonia, cervical dystonia and writer's cramp. Treatment satisfaction improves adherence to treatment. This study provides useful insight into the real world use and treatment satisfaction with BoNT-A in different neurologic conditions.

Strength and Limitations

Several limitations of the present study should be considered. These include the small number of patients in some neurologic conditions, the satisfaction recorded at one point of treatment cycle (peak of the response). Patients' responses were based on subjective recollections. The lack of routine safety assessment is another limitation. We did not mention the full clinical and injection details because this is beyond the aim of our study. Despite these limitations, we think that the strength of our study that is consisted of a heterogeneous patient group and our results may contribute to the literature.

Availability of Data

Data are available at administrative section, neurology department, Ibn Sina hospital, Kuwait.

Competing Interests

No competing interests.

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Authors' Contributions

JA-H designed the study criticized and reviewed the manuscript. DY and II performed data collection and drafted the manuscript. SFA performed statistical analysis, drafted, criticized and reviewed the manuscript. JA and DY injected the patients with BoNT-A. All authors read and approved the final manuscript.

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