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Uses of botulinum toxin in the management of patients with movement disorders: a national survey from India

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Abstract:

OBJECTIVE: The aim was to assess the opinion of the movement disorder society of India members regarding the uses of botulinum toxin in clinical practice.

METHODS: We developed an online questionnaire covering different aspects of botulinum toxin uses. The questionnaire was sent by email to all members of the movement disorder society of India.

RESULTS: A total of 50 members completed the survey (20%) representing different regions of the country. The average doses of botulinum toxin conform to those mentioned in the literature. Only type A botulinum toxin is available in India. Electromyography was used by 72% of the respondents, however, only 12% of respondents used ultrasonography for muscle localization during botulinum toxin injection. 72% of respondents were using an assessment scale for different types of movement disorders. 76% of the respondents reported adverse effects in their clinical practice, with weakness (69.11%) being the most common. 56% of the respondents reported challenges during the injections with the cost of botulinum toxin being the most common (36%) followed by difficulty in localization of muscles (30%).

CONCLUSION: Our results seem to show that in India, the routine use of botulinum toxin in clinics is far from standardized. Low uses of USG, difficulty in muscle localization and cost of the toxin were important limitations highlighted by the respondents.

Key words:

Botulinum toxin, movement disorders, survey

Key messages:

- An online questionnaire-based survey regarding uses of botulinum toxin in India
- Members of the Movement Disorders Society of India participated in the survey
- The indications and dosage were comparable to the treatment guidelines
- Uses of assessment scale and electromyography were reported by 72% of specialists
- Ultrasound uses were only 12% and the cost of the toxin was the major challenge

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Introduction

U.S. Food & Drug Administration (FDA) first approved botulinum toxin (BTX) in 1989 for the treatment of blepharospasm, strabismus, and hemifacial spasm.[1] Since then, the uses of BTX has expanded for different indications including movement disorders.[2,3] In India, BTX was first used in 1990 by movement disorder specialists.[4] However, only BTX type A (BTX-A) is available here for therapeutic uses. Movement disorders as a subspecialty are new in India and Movement Disorders Society of India (MDSI) was established in 2014.[4,5] Currently, there are 245 members

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(founding members: 19; regular members: 215; student members: 11) registered in the society. Our survey aimed to assess the opinion of MDSI members regarding uses of BTX in India.

Materials and Methods

A survey regarding the clinical practices of BTX was sent to MDSI members via e-mail and responses were accepted for 4 weeks. The survey investigated the following aspects: (i) The uses of BTX in movement disorders and years of clinical experience; (ii) number of movement disorder patients treated with BTX in clinical practice; (iii) types of preparations and doses used; (iv) types of movement disorders treated with BTX; (v) uses of rating scales during pre- and postinjection assessment of patients; (vi) uses of electromyography (EMG) and ultrasonography (USG) as an assistive techniques during injection; (vii) adverse reactions to BTX; and (viii) any specific challenges faced during the injection. The details of the questionnaire are available as online supplementary material. Participation in the survey was voluntary and anonymous.

Statistical analysis: Data were presented as frequencies and percentages for nominal variables, or medians and interquartile ranges for continuous variables. Statistical analysis was performed with Statistical Package for the Social Sciences (SPSS) software program, version 18.0 (IBM, Chicago, USA).

Results

Of the 245 members of the MDSI, 50 members (20.40%) responded to the survey [Table 1]. Responses were generated from different parts of the country (Southern India: 20; Northern India: 17; Western India: 8; Eastern India: 4; and Central India: 1). We received 23 responses from teaching government institutes and 27 responses from private hospitals.

In terms of the experience in treating patients with BTX, 88% specialists (n = 44) had an experience of more than 3 years, including 12 specialists, who had an experience of more than 15 years.

All the specialists (n = 50) reported injecting for blepharospasm and hemifacial spasm. Other indications of injections were cervical dystonia (n = 49), poststroke dystonia (n = 47), focal limb dystonia, including Writer's cramp (n = 45), oromandibular dystonia (n = 42), craniocervical dystonia (n = 40), and spasmodic dysphonia (n = 19). The dosages reported for different indications were comparable to the current treatment guidelines.[1-3]

The majority (36/50; 72%) of the specialists were using scales for assessment and EMG as an assistive device. However, only 12% (6/50) specialists were using USG for muscle localization in their clinical practice.

With regard to the side effects, 76% (n = 38) of the specialists mentioned some adverse effects during their practice, with many of them reporting multiple (n = 68) side effects [Table 2]. The most commonly reported side effects were weakness (69.11%; n = 47/68) followed by injection-related adverse effects (13; 19.11%), syncope (7.35% n = 5/68), and myalgia (1.5%, n = 1/68). Specialists not using scales for assessment and not using EMG accounted for 63.41% of reported weakness, 46% of the injection-related side effects, and the single report of myalgia.

Moreover, 54% of the specialists (n = 27/50) reported the challenges faced by them in their practice. A total of 30 responses were reported, as some specialists had multiple challenges [Table 2]. The cost of injection was the most frequently reported challenge (n = 11/30; 36%) followed by difficulty in muscle localization (n = 9/30; 30%).

Discussion

The main aim of our survey was to provide an overview of some important issues relating to the uses of BTX by movement disorder specialists. We investigated a representative sample of neurologists who are members of MDSI (n = 245) and are more likely to use BTX for movement disorder indications. The survey was conducted in a stipulated time frame of a month and 50 responses (20.40%) were received. This low response even among the select group of participants indicates that the uses of BTX in India as a therapeutic agent for indications in movement disorder are very low. Another important observation was the clustering of responses from the southern and northern parts of the country. The "low representation" from West, East, and Central India is probably because there is a very less number of movement disorder neurologists in these regions and a majority of them are practicing in metropolitan cities and state capitals.[6]

The majority (n = 44; 88%) of the specialists had the experience of using BTX for more than 3 years. In our survey, 72% of specialists used some scale for the evaluation of patients before injections. The remaining clinicians may not be using the scales due to lack of time, as the doctor to patient ratio (either government or private) is very low in India, which curtails the amount of time spent on each patient.

In this survey, EMG was used by 72% of the specialists (n = 36) for muscle localization during injections, but the use of USG was very low (12%). Our results are similar to a survey on practices of BTX in Italy, which showed 68% use of EMG and 11% use of USG in dystonia.[7] The

Table 1: Survey questionnaire and a summary of responses

Questions	Responses	Remark
Institution	50 (government teaching institutes: 27; private hospitals: 23)	50 = (NI-17, SI-20, EI-4, WI-8, CI-1)* *NI = Northern India, SI = Southern India, EI = Eastern India, WI =Western India, CI = Central India
The number of years you have been using botulinum toxin?		*10–14 years = 2
Less than a year	–0	**15 years and above = 12
1 year	1–2 year = 1	
2–3 years	2–3 years = 5	
>3 years	>3 years = 44*,**	
In approximately how many patients have you injected botulinum toxin?	<100 = 13 101–500 = 14 501–1000 = 8 >1000 = 15	
What conditions have you given botulinum toxin for? Please write the approximate number of patients per year and the usual dosage injected.		
Blepharospasm	50 responses. Average dosage = 38.28 U (On/In), 160 U (Ab)	On = onabotulinum Ab = abobotulinum In = incobotulinum
Hemifacial spasm	50 responses. Average dosage = 31.82 U (On/In), 142 U (Ab)	
Cervical dystonia (CD)	49 responses. Average dosage = 159.78 U (On/In), 480 U (Ab)	
Oromandibular dystonia (OMD)	42 responses. Average dosage = 88.83 U (On/In), 281.25 U (Ab)	
Craniocervical dystonia (C-CD)	40 responses. Average dosage = 100.64 U (On/In), 478.75 (Ab)	
Limb dystonia (upper limb, including Writer's cramp and lower limb) (LD)	45 responses. Average dosage = 86.37 U (On/In), 200 U(Ab)	
Spasmodic dysphonia (SD)	19 responses. Average dosage = 6.66 U (On/In), 15 U (Ab)	
Post stroke dystonia (PSD)	47 responses. Average dosage = 293.33 U (On/In), 556.25 U (Ab)	
Are you using any rating scale for the conditions listed below?	Yes =36 (72%) No= 14 (28%)	Multiple responses were ticked
Blepharospasm	17	
Craniocervical dystonia	23	
Writer's cramp	13	
Poststroke spasticity	16	
Other	Not mentioned = 2	
Do you use electromyography (EMG) for botulinum toxin injection?	Yes = 36 (72%) No = 14 (28%)	
If yes, then how frequently?		
<25%	17	
25%–50%	8	
50%–75%	4	
>75%	7	
For what indications, do you use EMG guided injections?		The percentages were calculated by *n*/*N*, where *n* is the number of respondents using EMG and *N* is the total number of respondents injecting for that condition (mentioned above in this table)
Cervical dystonia	21 (42%)	
Oromandibular dystonia	22 (52%)	
Spasmodic dysphonia	18 (94.73%)	
Poststroke spasticity	12 (25.5%)	
Focal hand dystonia (including Writer's cramp)	34 (75%)	
Other	Cerebral palsy = 1	

Table 1: Continued

Questions	Responses	Remark
Have you used ultrasonography (USG) for botulinum toxin injection?	Yes = 6 (12%) No = 44 (88%)	
Have you encountered any side effects during injection, if yes then please name	Yes = 38 (76%) No = 12 (24%)	(Details Table 2)
Any specific challenges you face during the injection?	Yes = 27 (54%) No = 23 (46%)	(Details Table 2)

Table 2: Side effects and challenges reported by the specialists

Serial number	Side effects	No. of responses*
1	Weakness	47
	Ptosis	14
	Weakness in the injected muscle	12
	Facial weakness	4
	Grip weakness	2
	Finger drop	6
	Dysphagia	6
	Diplopia	2
	Difficulty in chewing	1
2	Syncope	5
3	Myalgia	1
4	Lack of efficacy	2
5	Injection-related side effects	13
	Eyelid swelling	1
	Hematoma	1
	Bleeding during injection	1
	Watering of eyes	1
	Dry eyes	1
	Injection site pain	4
	Bruising	2
	Redness	1
	Injection site swelling	1
	Total responses	68

Serial number	Challenges	No. of responses
1	Localizing/poor muscle identification	9
2	Time	2
3	Expensive toxin	11
4	Noncooperation	2
5	Deciding dosage	1
6	Failure/suboptimal response	2
7	Side effects	2
8	Negative second opinions from non-neurologists	1
	Total responses	30

*As there were multiple side effects reported by some respondents, the number of responses is higher than that of respondents

low use of USG is a direct consequence of the lack of specialized training in using the modality. The cost of the equipment and its unavailability may be another reason. The use of EMG or USG helps in localizing deep-seated muscles in cervical dystonia, oromandibular dystonia, and spasmodic dysphonia. These modalities also help in localizing muscles having a common origin or nerve supply like in the case of Writer's cramp where injection for correction of dystonia might cause some unintended weakness due to diffusion of the toxin or spread via the fascial plane along with other factors such as dose, volume, and number of injections per site.[8,9]

Adverse effects were reported by 76% of specialists ($n = 38$) in our survey. Weakness was the most common (69.11%), followed by injection-related side effects. Naumann and Jankovic[10] published a meta-analysis to define the safety and tolerability profile of BTX-A across all common therapeutic indications. They reported mild-to-moderate adverse events in 25% of patients treated with BTX-A (353/1425 patients) compared with 15% in the control group (133/884 patients, $P < 0.001$). The only adverse event that occurred significantly more often with BTX-A treatment than control was a focal weakness. None of the patients in the treated group had any serious adverse events. In our survey also, none of the specialists reported any serious adverse effects. Interestingly, the specialists who did not use EMG or rating scales accounted for 54% of the reported weakness. This points to the fact that proper localization and identification of muscle for accurate injection can help in reducing a substantial amount of side effects.

Approximately 54% ($n = 27/50$) of the specialists had mentioned the challenges faced by them while injecting. A total of 30 responses were indicated as some specialists reported more than one challenges. The most frequently encountered challenge was the cost of the toxin (11/30; 36%). As per the National Health Profile published by the Government of India, in the year 2000, only "437,457" persons in a population of 1.3 billion were covered under insurance.[11] Hence, the majority of the patients bear the cost of the toxin themselves due to a lack of insurance coverage. Apart from these, other challenges reported were difficulty in localizing the muscles or proper identification of muscle for injection, deciding the amount of dosage of toxin, and failure in responses. All these challenges can be tackled to some extent by intensive training. One specialist mentioned about the "negative mindset of referring doctors regarding BTX injections," which dissuades patients from availing treatment. Although this represents a minor percentage of the challenges faced, it highlights the need for spreading awareness regarding the uses of BTX among nonspecialist and neurologists to help more people receive the benefit of the therapeutics.

Our survey has certain limitations, which should be highlighted. First, we did not involve all the neurologists and neurorehabilitation units in our country considering the majority of them are overburdened by providing care to stroke and epilepsy patients with very little exposure to movement disorder patients. Second, there are only 50 responders in the survey with a response rate of only 20%; this may be because many of the MDSI members are either not injecting or they are treating fewer patients. It may be possible that a low response rate may have hindered the results of the survey. However, most of the responders were experienced (88% > 3 years), providing a very robust data. Third, the majority of the MDSI members are adult neurologists, so, our results may have some inherent bias.

Despite all these limitations, our survey has provided some important data regarding the uses of BTX in patients with movement disorders in India. First, the use of BTX is very less considering the large population of the country. Second, the main movement disorders treated and dosage were comparable to the treatment guidelines. Third, the uses of rating scales and EMG as an assistive device for injections are comparable to some other published surveys, but it needs to be encouraged more for the alleviation of adverse effects and to mitigate challenges such as muscle identification or localization. Fourth, the uses of USG in muscle localization are very low, reflecting the lack of resources and specialized training. Fifth, the cost of the toxin is a major limiting factor in the uses of BTX in movement disorder patients.

To conclude, our results seem to show that the uses of BTX in patients with movement disorders in India are far from being standardized.

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Conflicts of interest

There are no conflicts of interest.

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