RESEARCH ARTICLE

Factors Affecting Compliance with Botulinum Toxin Injection in Spasmodic Dysphonia Patients

Nupur K Nerurkar[1], Manisha Sharma[2], Deepak Singhal[3]

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Abstract

Background: Spasmodic dysphonia (SD) is a focal laryngeal dystonia where there is an involuntary contraction of adductors, abductors, or both groups of muscles during phonation. Consequently, the voice is strained or breathy with spasms. The gold standard treatment for SD is considered to be injection of botulinum toxin (BTX) into the affected group of muscles, which is the thyroarytenoid muscle in adductor SD and the posterior cricoarytenoid muscle in abductor SD under the guidance of laryngeal electromyography (EMG). However, as this provides temporary relief for 4–6 months till the toxin is metabolized, the patient needs regular follow-up injections. Thus, it is essential that the patient follows up regularly for the treatment to be effective.

Objective: Since BTX injection needs to be repeated every 6 months, it is important that the patient follows up. Our aim is to study the demographics of SD in the Indian population, compliance with BTX treatment by patients, and factors affecting it.

Materials and methods: A retrospective study was performed on SD patients who presented to the voice clinic over a period of 5 years from January 2018 to January 2023. From the SD registry, details of the type of SD, gender, age, residence, total number of diagnosed SD patients, number of patients who opted for the initial dose of BTX, and those who took a subsequent dose were noted. A comparison with international studies was performed.

Results: A total number of 88 patients were diagnosed with SD at our voice clinic during our study period. Out of 88 patients, 46 (52%) were males and 42 (48%) were females. Among the diagnosed cases, 76 out of 88 (86%) patients opted for the initial dose of BTX, in whom 41 out of 76 (54%) were males and 35 out of 76 (46%) were females. However, only 37 out of 76 (49%) opted for a subsequent dose of BTX, in whom 21 out of 37 (57%) were males and 16 out of 37 (43%) were females. With respect to age, out of 88 patients who were diagnosed with SD at our center, age distribution was 0–20 years (1%), 21–40 years (10%), 41–60 years (73%), and above 60 years (16%). Out of 76 patients who opted for BTX, age distribution was 0–20 years (1%), 21–40 years (9%), 41–60 years (73%), and above 60 years (17%). On geographical analysis, out of the total patients who were diagnosed with SD, 30 out of 88 (34%) were from the city, and among those, 16 out of 30 (53%) were females compared to 14 out of 30 (47%) males. Out of the remaining 58 patients, 34 (59%) were males and 24 (41%) were females. Out of 76 patients who opted for the initial dose of BTX, 21 (28%) were from the city and 55 (72%) were out of the city. Among patients from the city, 12 out of 21 (57%) were females and 9 out of 21 (43%) were males. From out of the city, 23 out of 55 (42%) were females and 32 out of 55 (58%) were males. Out of 37 patients who opted for a subsequent dose, 22 out of 37 (59%) were out of the city, and 15 out of 37 (41%) were from the city. Among those from the city, 9 out of 15 (60%) were females and 6 out of 15 (40%) were males. From out of the city, 15 out of 22 (68%) were males and 7 out of 22 (32%) were females.

Conclusion: Our study observed that not only is there a statistically significant male preponderance in SD seen at our voice clinic, but there is also a significant male predominance at every level of seeking care, both of which are in contrast to the international literature. This observation points toward a deep-rooted socioeconomic and gender bias. However, there is a significant female predominance in the presentation of SD within the city. We have attributed this to the cosmopolitan culture of the city, ease of access to healthcare, and follow-up being in the same city.

Keywords: Botulinum toxin, Dysphonia, Laryngeal electromyography.

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Introduction

Spasmodic dysphonia (SD) is a focal laryngeal dystonia where there is involuntary contraction of the adductor or abductor muscles during phonation. Consequently, the voice is strained or has breathy spasms. Occasionally, the patient may have a combination of both, resulting in mixed SD.

Adductor spasmodic dysphonia (ADSD) patients have a typical choking voice with spasms prominent on vowels. Thus, sentences with more vowels can highlight this voice disorder.[1] The adductor type is more common than the abductor type, with the former affecting around 80% of people with SD.[2] In the case of abductor spasmodic dysphonia (ABSD), a typical breathy spasm is observed on voiceless consonants which is often accompanied by flaring of the ala nasi.[3] The gold standard treatment for ADSD is considered to be injection of botulinum toxin (BTX) into the affected group of muscles, such

[1–3]Bombay Hospital Voice and Swallowing Centre, Bombay Hospital & Medical Research Center, Mumbai, Maharashtra, India

Corresponding Author: Nupur K Nerurkar, Bombay Hospital Voice and Swallowing Centre, Bombay Hospital & Medical Research Center, Mumbai, Maharashtra, India, Phone: +919821034085, e-mail: nupurkapoor@yahoo.com.

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as the thyroarytenoid muscle in adductor SD.[4] However, as BTX injection only provides temporary relief for 3–6 months, the patient needs regular injections. Thus, it is essential that the patient follows up regularly for this treatment to be effective in improving the quality of life. In India, BTX injection for SD is not currently covered by insurance, posing another challenge. Our aim is to study the demographics of SD in the Indian population, compliance with BTX treatment by patients, and factors affecting it.

Materials and Methods

This retrospective study has received ethical clearance from our institutional ethics committee. A study was performed on our SD patients over a period of 5 years from January 2018 to 2023. From the SD register, details of the type of SD, gender, age, profession, residence, number of patients who opted for BTX, and who took subsequent doses were noted. We studied male and female distribution geographically in patients who opted for the initial as well as the subsequent dose.

Patients presenting to the voice clinic were diagnosed with SD based on hearing the quality of their voice, response of voice to various tasks, and flexible videostroboscopy. All patients who underwent injection of BTX were advised prior neurology clearance to rule out any other neurological condition.

Results

A total number of 88 patients were diagnosed with SD at our voice clinic during our study period. Out of 88 patients, 46 (52%) were males and 42 (48%) were females. Among the diagnosed cases, 76 out of 88 (86%) patients opted for BTX, in whom 41 out of 76 (54%) were males and 35 out of 76 (46%) were females. However, only 37 out of 76 (49%) opted for a subsequent dose of BTX, in whom 21 out of 37 (57%) were males and 16 out of 37 (43%) were females (Fig. 1). With respect to age, out of 88 patients who were diagnosed with SD at our center, age distribution was 0–20 years (1%), 21–40 years (10%), 41–60 years (73%) and above 60 years (16%). Out of 76 patients who opted for BTX, age distribution was 0–20 years (1%), 21–40 years (9%), 41–60 years (73%), and above 60 years (17%) (Fig. 2).

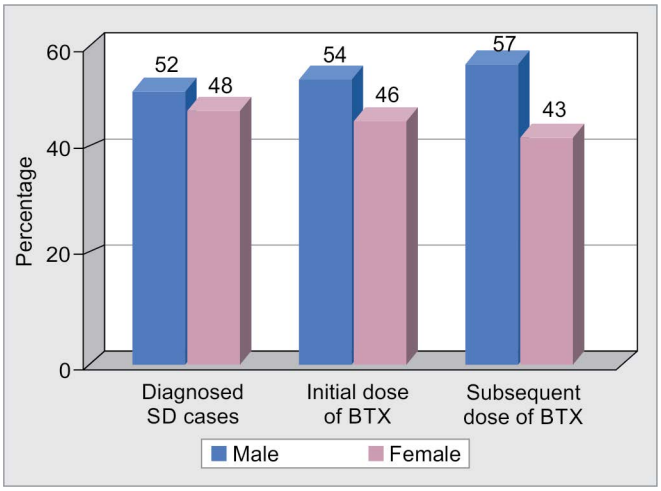

Fig. 1: Male preponderance at the time of diagnosis of SD, initial and subsequent dose of BTX

On geographical analysis, out of total patients who were diagnosed with SD, 30 out of 88 (34%) were from the city, and among those, 16 out of 30 (53%) were females compared to 14 out of 30 (47%) males. Out of the remaining 58 patients, 34 (59%) were males and 24 (41%) were females. Out of 76 patients who opted for the initial dose of BTX, 21 (28%) were from the city and 55 (72%) were out of the city. Among patients from the city, 12 out of 21 (57%) were females and 9 out of 21 (43%) were males. From out of the city, 23 out of 55 (42%) were females and 32 out of 55 (58%) were males. Out of 37 patients who opted for a subsequent dose, 22 out of 37 (59%) were out of the city, and 15 out of 37 (41%) were from the city. Among those from the city, 9 out of 15 (60%) were females and 6 out of 15 (40%) were males. From out of the city, 15 out of 22 (68%) were males and 7 out of 22 (32%) were females (Figs 3 and 4). We observed 12 out of 88 (14%) patients who were diagnosed with SD but did not opt for BTX, and among them, 5 out of 12 (42%) were males and 7 out of 12 (58%) were females.

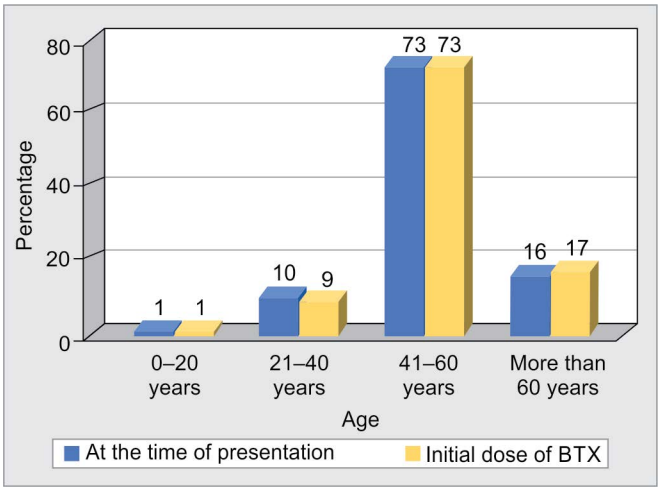

Fig. 2: Percentage distribution of age-groups at the time of presentation and initial dose of BTX

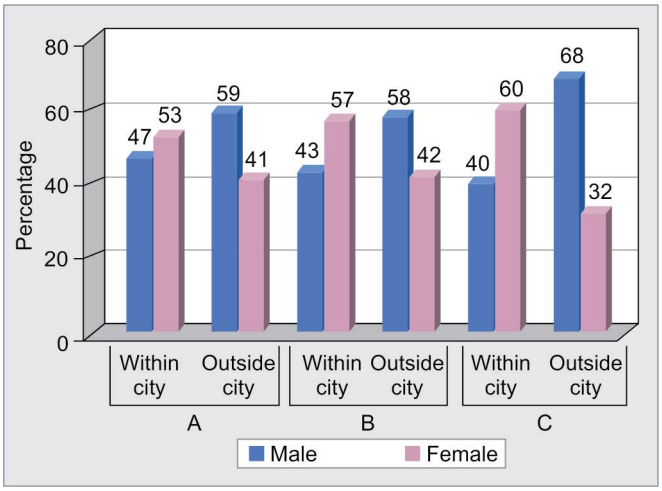

Fig. 3: (A) Geographical distribution of diagnosed SD cases with respect to gender; (B) Geographical distribution of SD cases who opted for initial dose of BTX with respect to gender; (C) Geographical distribution of SD cases who opted for subsequent doses of BTX with respect to gender

Category	Total number of SD patients (n = 88)	Patients opted for BTX (n = 76)	Patients opted for subsequent dose (n = 37)
(A) Gender			
- Male	46 (52%)	41 (54%)	21 (57%)
- Female	42 (48%)	35 (46%)	16 (43%)
(B) Geographical distribution			
From the City	30 (34%)	21 (28%)	15 (41%)
- Male	14 (47%)	9 (43%)	6 (40%)
- Female	16(53%)	12(57%)	9 (60%)
Out of the city	58 (66%)	55 (72%)	22 (59%)
- Male	34 (59%)	32 (58%)	15 (68%)
- Female	24 (41%)	23 (42%)	7 (32%)

Fig. 4: Male preponderance at all levels of care except within the city

Discussion

International studies such as "Risk factors and demographics in patients with spasmodic dysphonia" found a 79% female predominance in SD.[5] A study performed by Aronson and Bless[6] demonstrated 81% females. In a review by Blitzer et al. of 900 patients with laryngeal dystonia, 63% female predominance was observed.[2] A patient profile of 200 cases of SD published by Izdebski et al.[7] demonstrated 70% females. "Spasmodic dysphonia: clinical features and effects of botulinum toxin therapy in 169 patients—an Australian experience" by Tisch et al. observed that females (62%) outnumbered males (38%).[8] "The prevalence and clinical features of spasmodic dysphonia: a review of epidemiological surveys conducted in Japan" by Hyodo et al. observed 75% females.[9] A questionnaire conducted by Yamazaki in 81 university hospitals in Japan observed 81.6% females.[10] In our present study, we observed 52% male patients diagnosed with SD compared to 48% females. Among the patients who were diagnosed with SD, 86% opted for the initial dose of BTX, in which 54% were males and 46% were females. The odds ratio is 1.37, which is statistically significant. Similarly, 57% male preponderance was observed in patients who followed up for subsequent doses compared to 43% females. For the subsequent dose, the odds ratio is 1.72, which is also statistically significant. In our current study, both the above data suggest male preponderance is statistically significant in opting for initial and subsequent doses of BTX. Also, we observed that among the 59% of patients who were from outside the city and who opted for the subsequent dose of BTX, 68% were males compared to 32% females. In our previous study of "Spasmodic dysphonia: a seven-year audit of dose titration and demographics in the Indian population", a similar high male preponderance was found to the tune of 80%.[11] We have postulated that possibly social factors are responsible for gender bias in both presentation and subsequent seeking of treatment and follow up. As per the Periodic Labor Force Survey (PLFS) Annual report, labor force participation rate (LFPR) for males in India is 77.4% in 2022–23 and for females it is 31.6%.[12] Primarily males remain the earning members in the family and heads of the household in India and consequently the primary decision makers, so they are more likely to seek treatment as BTX is both expensive and temporary; thus, repeated injections are required and hence the recurring cost. An effort should be made to sensitize the community as voice is important not only for vocational purposes but also for overall mental and emotional well-being of the individual. We also observed that geographically, out of a total of 88 patients who were diagnosed with SD, 34% were from the city, and among those patients, 53% were females compared to 47% males. Similarly, from the city, 57% of females compared to 43% of males opted for the initial dose, while 60% of females and 40% of males opted for the subsequent dose of BTX. This trend of female predominance was only observed in patients from the city at both stages of diagnosis and care in the form of initial and subsequent treatment with BTX. In our study, the odds ratio for the presentation of SD in females within the city is 1.62, which is statistically significant. This could be attributed to many factors such as the cosmopolitan nature of the city where more women are in the workforce, where decisions regarding healthcare are in the hands of women. There is more ease of access to the hospital as travel and repeated follow-up were possible being in the same city. As per latest PLFS data,[12] female labor force participation rate (FLFPR) is 25% in Mumbai compared to 18.8% in Delhi, 21% in Chennai, and 20% in Kolkata. As SD is predominantly

found in females in all the international literature we reviewed, this could be the true representation. Currently, treatment with BTX is not covered by insurance in India, unlike in the West,[13] which is a deterrent as it is costly and needs subsequent injections every 6–8 months. The COVID-19 pandemic has proved to be a game changer for the health insurance segment in India. The global health emergency has been a wake-up call for both the general public and Indian authorities to take health insurance coverage more seriously. The surging working population, increasing disposable income, and rising awareness about policies offered by health insurance companies are some of the major factors driving the country's health insurance market. Additionally, the mandatory provision of providing health insurance for both private and public sector employees is further anticipated to fuel the growth of the health insurance market in India through 2025. As per a study by Reshmi et al., the healthcare insurance in India increased by 34.2% in 2022, compared to 9.9% growth in 2021.[14] Thus, it is prudent that BTX for SD should be considered under the umbrella of health insurance, thereby encouraging more patients to opt for it and reducing dropout rates. In our study, we observed only 37 out of 76 patients (49%) opted for the subsequent dose who took the initial dose suggesting that cost and need for repeated injections could be the reason for this trend.

The mean age of onset of SD was observed as 36.7 years by Hyodo et al.[9] Yanagida et al conducted a survey in Japan and demonstrated that the most common decade of onset was 20–29 years.[15] The National Spasmodic Dysphonia Association of the US[13] in their study observed that the mean age of onset ranged from 35–50 years. Tisch et al. observed the mean age at diagnosis was 56 years.[8] Similar trend such as most of the international studies was observed in our study in which 73% of patients were in the age-group of 41–60 years reiterating the fact that this is the primary age-group engaged in the workforce; hence, they are more likely to seek the treatment. Approximately half of the patients are dropping out from taking subsequent doses possibly due to cost and travel ramifications. Chemodenervation with BTX injection remains the gold standard for the management of vocal symptoms.[4] There are three office-based techniques described for accessing the laryngeal musculature. Apart from the laryngeal EMG-guided BTX injection, which we follow at our center, other modalities are laryngoscopic visualization and percutaneous or oral injections or injection via the side channel of the flexible laryngoscope.[16] A total of 47% patients followed up for the subsequent dose in our study, suggesting that they were satisfied with the treatment. In a study by Blitzer titled "Spasmodic dystonia and botulinum toxin: experience from the largest treatment series," the results of the abductor group showed the average best voice at 70.3% of normal as rated by patients and at 91.2% in the adductor group.[17] As there were 14% of patients who did not opt for BTX and 53% of patients who did not opt for subsequent doses in our study, we can offer surgeries such as surgical management of ADSD by selective laryngeal adductor denervation and reinnervation (SLAD-R) or thyroarytenoid myoneurectomy.[18–22]

In our study, we observed that there is a significant male preponderance in presentation and subsequent treatment, possibly due to gender and social bias toward women. The majority (73%) of patients who presented were in the age-group of 41–60 years, and as this is the critical age-group for generating income, it is important to be able to address their vocal needs. BTX, being the gold standard, should be made affordable for all by bringing it under the ambit of insurance and subsidized treatment in government institutions, for which national bodies should make a representation to the government and insurance companies.

Awareness should be increased among general practitioners also, so as to guide patients with voice problems toward a specialist. Regular training and teaching should be imparted to ENT surgeons to correctly diagnose SD and perform BTX injections, so that patients do not need to travel long distances to get proper treatment.

Conclusion

Our study observed that there is a statistically significant male preponderance in presentation, subsequent seeking of treatment, and follow-up, possibly due to gender and social bias toward women. There is a significant female predominance in the presentation of SD within the city. We have attributed this to the cosmopolitan culture of the city, ease of access to healthcare, and follow-up being in the same city.

Orcid

Nupur K Nerurkar https://orcid.org/0000-0002-4127-1590
Manisha Sharma https://orcid.org/0009-0006-8710-6984

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