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Original Article

Role of Botulinum toxin injection in the treatment of spasmodic dysphonia: Experience in Bangladesh Medical University

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Abstract

Background: Spasmodic dysphonia (SD) is a focal dystonia and adductor SD is the commonest form. The standard treatment for adductor SD is EMG-guided, transcutaneous injections of botulinum toxin into the thyroarytenoid muscle.

Methods: This is a prospective study on patients with adductor spasmodic dysphonia done in Bangladesh Medical University, Dhaka from January 2020 to January 2023. All of the patients were studied with a complete head and neck and neurologic examination, fiberoptic laryngostroboscopy, and a speech evaluation including the Universal spasmodic dysphonia rating scale and VHI. Proper counselling regarding the results & possible complication was done. All patients received botulinum toxin injections into the thyroarytenoid muscles under fiberoptic laryngostroboscopy guidance, post injections following results were recorded.

Results: The median duration of symptoms prior to diagnosis was 12 months: all were adductor in type. The average age at onset was 44 years. The time for botulinum toxin to take effect averaged 3 days (peak effect, 7 days). The patients received substantial relief from their SD symptoms, an average functional improvement of 40%. Patients' best voice was achieved within one week and persisted for an average of 14 weeks. Side effects from the injections included mild breathiness (68%) and mild choking on

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fluid (56%). After injection, decreased potential for volume was a common complaint. Almost all of the patients returned for repeat injections when the benefit diminished (After 12-16 weeks)

Conclusion: *Botulinum toxin therapy has become the standard care for the treatment of SD. An acceptable and flexible treatment plan to produce a balance between decreased spasms and loss of function must be developed for each patient.*

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Introduction:

Spasmodic Dysphonia is a chronic voice disorder affecting muscles of the larynx or voice box. When we speak air from the lungs is pushed between the two vocal cords with sufficient pressure to cause them to vibrate, producing voice^{1,2}. In Spasmodic Dysphonia the intrinsic muscles of larynx experience sudden involuntary movements' called spasm-which interferes with the ability of the folds to vibrate properly and produce voice^{3,4}. Spasmodic Dysphonia may be Adductor type in which there is strained, strangled type of voice, or may be Adductor type, in which there is breathy, whispering type of voice, or mixed type. Adductor Spasmodic Dysphonia is much more common than the Abductor Spasmodic Dysphonia, accounting for about 90% cases^{5,6}. It is a rare disorder, occurring in roughly 1-4 people per 100000 people^{3,7} or most of the time the disease is undiagnosed. Females are more commonly affected than males. Traube first described Spasmodic Dysphonia in 1871^{1,8}. For many years the disorder was referred to as Spastic Dysphonia, but the term Spasmodic is more widely accepted now a days. Early theories suggested that Spasmodic Dysphonia was a psychoneurosis^{9,10}. It was then determined to be of neurological origin and to represent a focal dystonia. But recent studies have failed to identify any structural defect. Most instances the cause of Spasmodic Dysphonia is idiopathic. Spasmodic Dysphonia is thought to be caused by abnormal functioning in an

area of the brain called Basal Ganglia^{2,11}. In general approximately 8% of patients have a family history of daystonia. Blitzer et al. in 1998 highlights that most cases of Spasmodic Dysphonia are sporadic, although Schweinfurth et al. in 2002 in their case series noted a 20% association with other forms of focal dystonias. Around 13 genes or chromosomal locations have been associated to dystonias and several voice disturbances on the basis of some case reports. The diagnosis of Spasmodic Dysphonia is made on 1) clinical ground, 2) by the listening skill of the experienced clinician, 3) fiberoptic nasopharyngolaryngoscopic examination proper history taking is essential⁶. It may come on suddenly after an illness or stressful event. It may have some aggravating factor (taking on the telephone) or relieving factor (while singing, laughing or after an alcoholic drink) In spasmodic dysphonia, it may be difficult for the patient to say some words than the others. In Adductor Spasmodic Dysphonia, patient will have difficulty with words ending with a vowel and being followed on by a word starting with a vowel (for example we eat) and words with two vowel in tandem (for example eight year)^{1,4}. Nasopharyngolaryngoscopic examination is the gold standard for diagnosing Adductor Spasmodic Dysphonia. Patients are asked to say some sentences and make certain sounds and by fiberoptic nasopharyngolaryngoscopic the motion of the larynx is examined. In Adductor Spasmodic Dysphonia, there is an over closure or

squeezing of the vocal cords which can be seen through the fiberoptic laryngoscope. .

In Bangladesh, although few centers practice this Botulinum Toxin injection on Adductor Spasmodic Dysphonia there is no published data found as yet. So this study was done to assess the outcomes of Botulinum Toxin treatment in patients with Adductor Spasmodic Dysphonia from patients 'perspectives using the VHI as the subjective tool. Patients are investigated by recording their Voice Handicap Index (VHI) scores at five time points: (1) immediately. Prior to injection (baseline), (2) 1-3 days post injection (when least pharmacologic change is expected), (3) 2 weeks post injection (when most pharmacologic change is expected), (4) 8 weeks and (5) 12 weeks post injection time to see the duration and efficacy of treatment. There is significant improvement of voice after Botulinum Toxin Injection, although it lasts for about a period of 2 to 3 months, then it starts to deteriorate again and after a period of about 3-4 months later reinjection is necessary.

Materials & Methods:

Study Procedure: This prospective observational study was conducted in the Department Otolaryngology – Head & Neck surgery, Bangladesh Medical University, Shahbag, Dhaka from January 2020 to January 2023 (3 years).

After obtaining clearance and approval from Institutional Review Board, all patients of Adductor Spasmodic Dysphonia in Department Otolaryngology – Head & Neck surgery BMU who fulfilled the inclusion and exclusion criteria were recruited as subjects in the study. Detail history was taken. Thorough ENT examination and related systemic examinations were done. Diagnosis of Adductor Spasmodic Dysphonia was confirmed by Fiber Optic Laryngoscopy.

Relevant investigations were done. Informed written consent was taken from all patients.

This procedure is simple and was done as an office procedure. For patients with Adductor Spasmodic Dysphonia the Botulinum Toxin Injection was given in the thyroarytenoid muscle transcutaneously under local anesthesia, guide by Fiber Optic Laryngoscopy. Before injecting, hypersensitivity to Botulinum Toxin was tested by Intradermal Skin Test. Dilution was done by 0.9% sodium chloride. 2ml 0.9% NaCl is mixed in 100 unit vial and 4 ml in 200 unit vial, according to Allergens literature, resulting concentration is 5 unit per 0.1 ml. We gave 8 unit (0.16ml) Botulinum Toxin Injection in each patients in one Thyroarytenoid muscle.

Results:

Among 120 patients, the search result was tabulated as follows.

Table-I
Distribution of them patients according to age (N=120)

Age (years)	Frequency (n)
≤30	10 (8.33%)
31-40	25 (20.83%)
41-50	50 (41.67%)
51-60	15 (12.5%)
61-70	20 (16.67%)

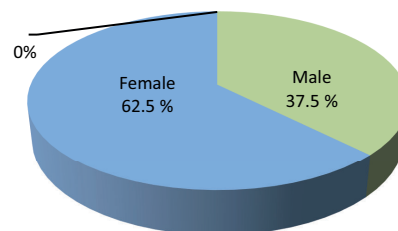


Figure 1: *Distribution of the cases according to gender*

Table-II
Distribution of patients according to occupation (N=120)

Occupation	Number (%)
Housewife	35 (29.16%)
Service holder	25 (20.83%)
Imam	20 (16.66%)
Teacher	15 (12.5%)
Business	15 (12.5%)
Farmer	10 (8.33%)

Table III
Pre and post injection Voice Handicap Index (Functional) (N-120)

Time point	Mean SD (p value, in comparison to pre injection score)	Min- max
Pre injection	25.12 ± 3.48	20-33
1-3 days post injection	25.15 ± 3.44 (0.876)	20-32
2 weeks post injection	11.38 ± 2.41 (<0.001)	7-17
8 weeks post injection	16.88 ± 2.04 (<0.001)	13-20
12 weeks post injection	24.88 ± 3.41 (0.339)	20-32

Table-IV
Pre and post injection Voice Handicap Index (Physical) (N=120)

Time point	Mean SD (p value, in comparison to pre injection score)	Min-Max
Pre injection	31.21 ± 2.11	27-36
1-3 days post injection	31.32 ± 2.17 (0.571)	27-35
2 weeks post injection	11.18 ± 2.75 (<0.001)	1-15
8 weeks post injection	18.74 ± 2.18 (<0.001)	15-24
12 weeks post injection	31.08 ± 3.4 (<0.680)	20-32

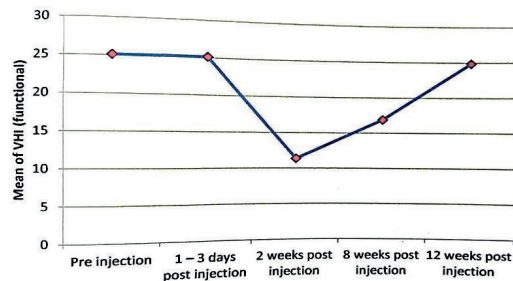


Figure 2: Pre and post injection Voice Handicap Index (Functional)

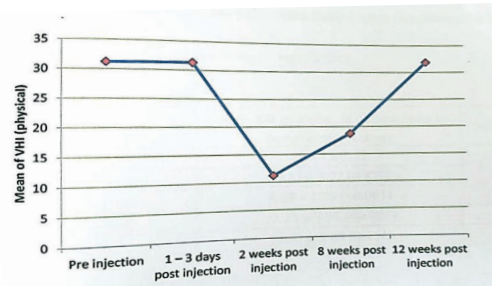


Figure 3: Pre and post injection Voice Handicap Index (Physical)

Table -V
Pre and post injection Voice Handicap Index (Emotional) (N=120)

Time point	Mean SD (p value, in comparison to pre injection score)	Min-Max
Pre injection	23.44 ± 3.32	18-29
1-3 days post injection	23.47 ± 3.22 (0.822)	15-29
2 weeks post injection	8.68 ± 1.79 (<0.001)	6-12
8 weeks post injection	12.26 ± 3.30 (<0.001)	9-27
12 weeks post injection	23.23 ± 2.48 (<0.414)	20-28

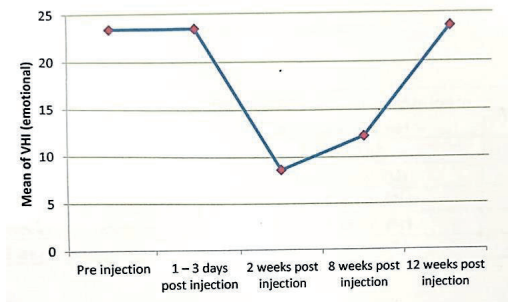


Figure 4: Pre and post injection Voice Handicap Index (Emotional)

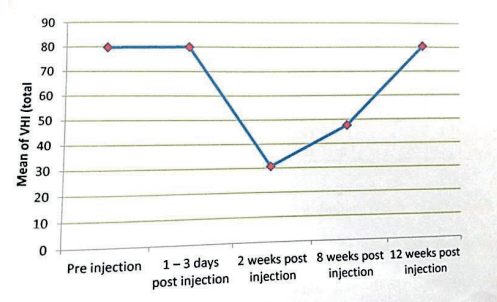


Figure 5: Pre and post injection Voice Handicap Index (Total)

Table VI
Pre and post injection Voice Handicap Index (Total) (N=120)

Time point	Mean SD (p value, in comparison to pre injection score)	Min-Max
Pre injection	79.76 ± 7.97	68-95
1-3 days post injection	80.00 ± 7.74 (0.542)	67-93
2 weeks post injection	30.68 ± 5.09 (<0.001)	22-40
8 weeks post injection	47.56 ± 5.49 (<0.001)	37-59
12 weeks post injection	79.56 ± 7.55 (<0.0652)	65-93

Table VII
Side effects after Botulinum Toxin injection: (N=120)

Side effects	Number of patients %	Duration (days)
No side effects	40 (33.33%)	
Mild pain in the injection site	30 (25%)	1-2
Impaired voice quality	20 (16.66%)	1-3
Reduced speaking volume	15 (12.5%)	1-4
Difficulty in swallowing	15 (12.5%)	1-2

Table VIII
VHI Before and 3 month after Speech Therapy

	VHI before Speech Therapy		VHI 3 month after Speech Therapy		
	Mean±SD	Min-Max	Mean±SD	Min-Max	
Functional	25.12 ± 3.48	20-33	Functional	22.32± 3.69	17-30
Physical	31.21 ± 2.11	27-36	Physical	29.59±2.13	25-32
Emotional	23.44 ± 3.32	15-29	Emotional	22.76±3.13	14-28
Total	79.76 ± 7.97	68-96	Total	74.67± 6.94	65-90

Table IX
Duration after which re- injection became necessary

Number of patients	Time when re- injection required (Weeks)
50	12-13
40	11-12
20	10-11
10	9-10

Discussion:

Present study was undertaken to see the outcomes of Botulinum Toxin injection in Adductor Spasmodic Dysphonia. For this study, a total number of 120 Adductor Spasmodic Dysphonia patients that meet the inclusion criteria were selected. Improvement of voice were assessed by measuring tool Voice Handicap Index (VHI), which is a questionnaire consisting of 30 questions VHI is the most popular and widely used instrument for evaluation of dysphonic patients. It is divided into physical (P), emotional (E) and functional subscales (F). The questionnaire consists of 30 questions (each subscale 10 questions) and total score ranging from 0 to 120 was generated. The questions and answers were rated on a five-point scale "0="never". "1 = almost never," "2= sometimes," "3 ="almost always", "4= always, each of the three parts has a maximum score of 40 points that corresponds to serious

pathological situation. After summing three subscales (Functional, Physical and Emotional), we get the total Voice Handicap Index score. The score between 0-30, 31-60 and 61-120 were regarded as mild, moderate and severe disease respectively. According to the VHI validation study a change of 18 points in total score and 8 points in subscale score was considered statistically significant (Jacobson et al., 1997) All the data were compiled and sorted properly and analyzed statistically by using PASS 14 (Power Analysis Sample Size Software). The statistical significance was set to $p < 0.05$.

Improvements of Voice Handicap Index after Botulinum Toxin Injection were found in this study. It was not so marked in the 1-3 days post-injection time, most marked in 2 weeks post-injection time, and started to deteriorate after 8 weeks post-injection time & became almost similar to pre-injection time in 12 weeks post-injection time.

In this study, the total population was 120. The respondents were between 27-70 years age. Mean age was 48 years (± 11.12). 10 of them (8.33%) were less than 30 years, 25 of them (20.83%) were between 31-40 years, 50 of them (41.67%) were 41-50 years, 15 (12.5%) were 51-60 years and 20 of them (16.67%) were between 61-70 years age. Maximum respondents (50) were between 41-50 years (41.67%).

In the study of Anari et al. in 2007 the age range was 38-89 (± 12), with a mean of 62 years. Benninger et al. in 2001 conducted a study in 22 patients, they found an age range of 20-79, with a mean of 51 years & the highest frequency was between age 50- 59 (10 patients), which was similar to the current study.

According to this study Adductor Spasmodic Dysphonia is more common in female. Out of 120 respondents 75 (62.5%) were female and 45 (37.51%) were male. Male Female ratio is 3:5. However in the study of Anari et al. male female ratio was 0.13:1 and in the study of Benninger et al. male female ratio was 0.25:1. The present series, like the mentioned above shows female predominant, but female predominance is much more in the other studies. This may be due to sociocultural variation between different countries.

According to this study, most number of study subjects 35 was housewife, followed by service holder 25, imam 20, teacher 15, business 15 and farmer 10. Housewife predominates, as most of the respondents were female. Based on the findings we found significant improvement of voice and reflecting it through improvement of Voice Handicap Index after injection of Botulinum Toxin There are three subscale of Voice Handicap Index Functional, Physical and Emotional. We considered both individual (functional, physical & emotional) subscale score and total score. According to the VHI validation study a change of 18 points in total score and 8 points in subscale score was considered statistically significant (Jacobson et al. 1997). It was most marked in 2 weeks post-injection time^{12,13,14}.

In this study, Functional subscale of Voice Handicap Index, pre-injection VHI was 25.12 ± 3.48 (between 20-33), 1-3 days post-

injection VHI was 25.15 ± 3.44 (between 20-32), 2 weeks post-injection VHI was 11.38 ± 2.41 (between 7-17), 8 weeks post- injection VHI was 16.88 ± 2.04 (between 13-20), 12 weeks post-injection VHI was 24.88 ± 3.41 (between 20-32). There were improvement of VHI of 13.74 in 2 weeks post-injection & 8.24 in 8 weeks post-injection (both 8, statistically significant) P value of pre-injection vs 2 weeks post-injection was < 0.05 , & pre-injection vs 8 weeks post-injection was < 0.05 , both of which were statistically significant. But p value of 1-3 days post-injection and 12 weeks post-injection and VHI were statistically not significant. So it shows Botulinum Toxin takes a few days to start its action

In Physical subscale of Voice Handicap Index pre-injection VHI was 31.21 ± 2.11 (between 27-36), 1-3 days post-injection VHI was 31.32 ± 2.17 (between 27-15), 2 weeks post-injection VHI was 11.18 ± 2.75 (between 1-15), 8 weeks post-injection VHI was 18.74 ± 2.18 (between 15-24), 12 weeks post-injection VHI was 31.08 ± 3.40 (between 20-32). There were improvement of VHI of 20.03 in 2 weeks post-injection and 12.47 in 8 weeks post-injection (both > 8 , statistically significant), p value pre-injection vs 2 weeks & 8 weeks post-injection were 0.05, which were statistically significant. But VHI & p value of 1-3 days & 12 weeks post-injection were not statistically significant. These findings were consistent with some other research works^{15,16,17,18}.

In Emotional subscale of Voice Handicap Index, pre-injection VHI was 23.44 ± 3.32 (between 15-29), 1-3 days post-injection VHI was 23.47 ± 3.22 (between 15-29), 2 weeks post-injection VHI was 8.68 ± 1.79 (between 6-12). 8 weeks post-injection VHI was 12.26 ± 3.3 (between 9-27), 12 weeks post-injection VHI was 23.23 ± 2.48 (between 20-28). There were improvement of VHI of 14.76 in 2 weeks post-injection and 11.18 in

8 weeks post-injection (both 8, statistically significant) p value (pre- injection vs 2 weeks & 8 weeks post-injection were 0.05, which were statistically Significant. But VHI & p value of 1-3 days & 12 weeks post-injection were not statistically significant. Novakovic et al had similar outcome in their works ^{19,20,21}.

In Total Voice Handicap Index, pre-injection VHI was 79.76 ± 7.97 (between 68- 95), 1-3 days post-injection VHI was 80.00 ± 7.74 (between 67-93), 2 weeks post- Injection VHI was 30.68 ± 5.09 (between 22-40), 8 weeks post-injection VHI was 47.56 ± 5.49 (between 37-59), 12 weeks post-injection VHI was 79.56 ± 7.55 (between 65-93). There were improvement of VHI of 49.58 in 2 week's post-injection and 32.2 in 8 weeks post-injection (both > 18, statistically significant). p value (pre-injection vs. 2 weeks & 8 weeks post-injection were <0.05, which were statistically significant. But VHI & p value of 1-3 days & 12 weeks post-injection were not statistically significant.

Trial of Speech Therapy was done in all patients before giving Botulinum Toxin injection. We compared VHI (subscale and total) before and 3 months after Speech Therapy. Here we found no significant improvement after 3 months of speech therapy (Mean Functional 2.8, Physical 1.62, Emotional 0.68. Total 5.09, all subscale < 8. Total<18, not significant).

In this study we see that 80 patients needed re-injection after 12-13 weeks, 40 patients needed re-injection after 11-12

In this series, we found that after injection of Botulinum Toxin in patients with Adductor Spasmodic Dysphonia there was significant improvement of voice and it is reflected by our measurement tool Voice Handicap Index in both Total & individual subscale (Functional, Physical & Emotional) But this improvement of voice didn't lasted for long and also it wasn't

immediate. In the first 1 week the voice may even deteriorate and patient may complain some problems like aspiration of liquid and the voice may become a little weak. At 2 weeks after injection, the voice improvement is maximum, reach a steady state and lasted for about 8 weeks. After that the voice deteriorates gradually to pre-injection state and re-injection becomes necessary after 12 weeks of injection.

Conclusion:

In Adductor Spasmodic Dysphonia, injection of Botulinum Toxin provides significant improvement of voice for a period of a period of 2-3 months, with minimum side effects. It may be regarded as an effective treatment option in Adductor Spasmodic Dysphonia patients, although it needs repeated injections.

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