

Voice Handicap Index and Voice-related Quality of Life after Botulinum Toxin Injection for Spasmodic Dysphonia Patients

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Abstract

Background: Spasmodic dysphonia (SD) is not an uncommon voice disorder defined as a condition of uncertain etiology with uncontrolled, intermittent, and speech induced spasms of intrinsic muscles of the larynx resulting in strangled, strained, and breathy voice commonly seen in women. Botulinum injection into the thyroarytenoid muscle is the standard treatment in controlling the disorder. Surgical procedures include unilateral sectioning of recurrent laryngeal nerve and partial thyroarytenoid resection. Speech therapy is good in mild cases but not in moderate and severe cases.

Aim of the Study: The aim of the study was to determine the effect of botulinum toxin type A injections for adductor type of SD on the duration of benefit, perceived voice-related quality of life (V-RQOL).

Materials and Methods: A total of 46 patients treated with botulinum Toxin A injected into thyroarytenoid muscles on both sides were selected. Pre- and post-treatment subjective assessment was done by V-RQOL scoring and during the follow-up for 18 months done.

Observations and Results: There was an improvement after injection in the quality of life as indicated by the V-RQOL evaluation. The mean period of remission from dysphonia was 9.30 ± 1.75 .

Conclusions: Botulinum is effective in giving a 65–100% VRQOL to the patients with SD. Percutaneous route of injection showed statistically significant results and better acceptance than intraoral route. Results suggested significant effects on participants' perceived quality of life and acoustic variables, over time, for all participants.

Key words: Abductor spasmodic dysphonia, Adductor spasmodic dysphonia (ADDSD), Botulinum toxin, Spasm, Spasmodic dysphonia, Voice handicap index, Voice-related quality of life

INTRODUCTION

Spasmodic dysphonia (SD) is a voice disorder of unknown etiology. Many authors consider it as a psychogenic disorder because it is worse under emotional stress and better in the morning hours and under alcoholic effect.^[1] The term SD is coined by Traube 1871. It is a disorder of voluntary muscles

of larynx that manifests during speech and four types are described Adductor type, Abductor type, mixed type and Adductor Laryngeal breathing type, and Adductor type accounts for 80% of all types. The patient tries to overcome excessive spasm of adductors causing closure of vocal cords during speech.^[2] Typically, the patients have strained voice with short outbursts with sudden initiation and cessation of speech. The diagnosis usually made by hearing to the speech, aided by fiber-optic laryngoscopy. The findings are normal, but few patients show hyperadduction of false vocal cords. Treatment is aimed at reducing the tension in the vocal cords without affecting the vibration. Voice therapy is part of surgical and medical treatments in SD which helps the patients to relax the laryngeal muscles with the help of breathe support, inverse phonation, altering one's pitch level,

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and range and biofeedback technique. Treatment consists of Botox injection into intrinsic muscles of larynx, anterior laryngoplasty, and selective denervation of adductors of larynx and using implantable stimulator. The prevalence rate of SD varies from 3 to 732 per 1, 00, 000 population worldwide.^[3-5] In India a crude prevalence rate is placed as 43.9 per 1, 00, 000 population. In an Indian study by Das *et al.* shows that writer's cramp and blepharospasms are the most common focal dystonia.^[6] Even though SD does not reduce the life expectancy, it may be responsible for considerable morbidity in terms of pain, low self-esteem, depression, embarrassment, and poor social interaction. Health-related quality of life is a multi-dimensional concept that encompasses the subjective assessment of the impact of illness or treatment across the physical, psychological, and social and somatic domains of functioning and the well-being.^[7] At present, chemodenervation of thyroarytenoid muscle with the help of Botox is the Gold standard care of Adductor type of SD.^[8] Similar to other pharmaceutical agents Botox also gets washed out of the muscle after sometime requiring ongoing re-injection to maintain the patient's improvement in voice production.^[9] The expected duration of benefit ranges from 3 to 12 months and the subjects requiring ongoing re-injections to maintain an easy, efficient manner of phonation.^[10] Usually, the patients decide when it is time to seek reinjection, but the criteria for their decision remain unclear.^[11] SD is commonly seen in women around the age of 30 years.^[12] There is no universal index of vocal function to quantify the degree of dysphonia, and the decision to intensify the treatment is usually based on the magnitude of the voice-related problems experienced by the patients and its importance in his life. That is expressed as voice-related quality of life (V-RQOL). Similarly, post-treatment assessment is also not standardized and hence is measured in terms of patient's perception of improvement related to the quality of his life.^[13] Studies in literature have employed voice handicap index (VHI) and V-RQOL score as standard methods of assessing patient's subjective perception of the condition. The present study was a prospective study on the effect of botulinum type A toxin injected into the intrinsic muscle of larynx of patients with SD. The patient's perception of improvement in speech and VRQOL score following treatment was analyzed. The clinical significance of using two different routes of administration of the toxin is reviewed in the face available literature.

Type of Study

This was a prospective, random cross-sectional analytical study.

Institute of Study

This study was conducted at the Department of Ear, Nose, and Throat (ENT) and Head and Neck Surgery, Kakatiya Medical College and MGM Hospital, Warangal, Telangana.

Period of Study

This study was from August 2013 to July 2015.

MATERIALS AND METHODS

A total of 46 patients with SD were included in this study for evaluation. After obtaining approval by the Ethical Committee of the institute as no life-threatening events were predicted during the procedure, the patients were informed, and due consent was taken. 46 patients presenting with hoarseness of voice, at the ENT Department of Kakatiya Medical College and MGM Hospital Warangal Telangana, between August 2013 and July 2015 were included in the present study.

Inclusion Criteria

1. Patients aged >37 years and <60 years were included.
2. Patients belonging to both the genders were included.
3. Patients with signs and symptoms of SD for >6 months were included.
4. Patients with previous treatment with botulinum toxin injections were also included.
5. Patients with dissatisfaction with voice therapy were included.

Exclusion Criteria

1. Patients aged <37 years and >60 years were excluded.
2. Patients with history of upper respiratory infection were excluded.
3. Patients with surgical procedures on larynx, thyroid were excluded.

Patient's demographic details were recorded and patients were subjected to ENT examination including voice recording of the speech. Diagnosis was made on history taking, hearing to the speech, and video-laryngoscopy examination. Only adductor type of SD was included. 10 questions of VHI of Jacobson^[13] were used to assess pre-treatment voice status. First six questions were related to the physical functioning in the production of speech and the past four questions were related to effect of voice on social-emotional aspects of life as shown in Annexure I. After the treatment the response expressed as V-RQOL score (Annexure II) was used. Freshly constituted commercially available botulinum toxin type A was used. Botulinum toxin type A 1.5 units were used initially for the injection and the dose was titrated by increasing or decreasing the dose by 1 unit depending on the period of remission and development of aspiration. 26 patients were administered botulinum toxin into the vocal cords bilaterally visualizing the larynx through fiber-optic nasopharyngoscope under local anesthesia and Alprazolam sedation. 20 patients were administered Botox injection through a percutaneous route by point touch technique described by Morzaria and

Damrose.^[14] Each cycle of injection was supplemented by another injection depending on the patient's perception of difficulty in speech. All the patients were cautioned about the possibility of aspiration of liquids and difficulty in breathing. 11 patients received single injection, 16 patients received two injections (3 within 1 week 7 after 6 months). 19 patients received 3 injections at 6 months interval. Follow-up was at 6 months interval for 18 months. All the data were analyzed using standard statistical methods using single sample *t*-test, Z score for single sample, and student *t*-test for two-independent means.

Observations

A total of 46 patients attending the ENT outpatient department with complaints of hoarseness of voice were included in the study. Patients belonged to the age group of 37–60 years. The youngest patient was a female aged 37 years, and the eldest patient was aged 58 years male. The overall mean age was 45.35 ± 4.10 years. The mean age in males was 46.20 ± 3.80 years and 41.95 ± 4.70 years in females. There were 29 (63.04%) female patients and 15 (32.60%) male patients with a female to male ratio of 1.93:1. 22/46 (47.82%) patients belonged to the age group between 45 and 52 years [Table 1]. The duration of symptoms ranged between 9 months and 7 years, and the mean duration was 5.68 years with standard deviation of 1.56. 16/46 (34.78%) patients belonged to the lower middle class, 19 (41.30%) were from middle class, and 11 (23.91%) were from the upper middle class of socioeconomic groups. 33/46 (71.73%) of the 46 patients belonged to the responsible position either in the family or at workplace. 36/46 (78.26%) patients belonged to the habitual voice users; hawkers. 24 (52.17%) of the patients showed emotional stress during the past 3 years. 16 (34.78%) patients showed signs of mood swings. The ENT examination and video laryngoscopy showed no

demonstrable organic changes in the vocal cord or their movement.

Patients were assessed with VHI score and VRQOL scores. 26/46 patients (56.52%) had their VHI score at 40 with VRQOL score at 25%, 11/46 patients (23.91%) had their VHI score at 50 with VRQOL score at 0% and 09/46 (19.56%) with 30 VHI and 50% VRQOL score before treatment. Assessment after 6 weeks showed 07/46 patients (15.21%) showing complete relief from dysphonia and these patients had their VRQOL score of 0%. 21/46 patients (45.65%) showed VRQOL score at 75% and 18 patients (39.13%) showed 50% VRQOL score [Table 2]. Even though the patients participated in the study at different points of time, the calculation of scores was done at fixed time intervals to observe the significance of the injection Botulinum in our institute. After 18 months of follow up 07/46 (15.21%), patients continued to show no recurrence in dysphonia, 16/46 (34.78%) patients showed VRQOL score at 75%, and 13/46 (28.26%) patients had 50% response on VRQOL score. 08/46 (17.39%) patients showed 25% VROL score and 02/46 patients (04.34%) showed 0% VROL scores in this study [Table 2]. The overall efficacy of treatment was seen in 36/46 (78.26%) patients who had at the end of 18 months a VRQOL of 50% and above, which was statistically significant (*P* = 0.018; *P* taken significant at <0.05), [Table 2].

Out of 11 patients who were given single injection 05 did not require further injections in 18 months, and 06/46 (13.04%) showed VRQOL 100% recovery. Out of 16 patients who received two injections 13/46 (28.26%) patients had their VRQOL between 75 and 50% and all the 19 patients who received three injections 16/46 (34.78%) showed 75–50% VRQOL. The remaining 04 (08.69%) patients showed little (25%) or no 0% VRQOL score [Table 3].

The mean value of VHI score before treatment was 42.13 ± 6.15 with VRQOL score of 25% in the sample studied. The same values calculated at the end of 6 weeks, 12 weeks, 6 months, 12 months, and 18 months of follow-up was observed is shown in Table 4.

Table 1: The age incidence and sex incidence (n=46)

| Age group | Male -15 (32.60%) | Female - 29 (63.04%) | Percentage |
|-------------|-------------------|----------------------|------------|
| 37 to 44–11 | 03 | 08 | 23.13 |
| 45 to 52–22 | 08 | 14 | 41.37 |
| 53 to 60–13 | 04 | 07 | 23.13 |

Table 2: The response to treatment during follow-up and related VBI and VRQOL scores (n=46)

| VHI score | VRQOL score% | Pre-treatment patients | Post-treatment patients | | | | | Total | P value |
|-----------|--------------|------------------------|-------------------------|----------|----------|-----------|-----------|-------|---------|
| | | | 6 Weeks | 12 weeks | 6 months | 12 months | 18 months | | |
| 0 | 100 | Nil | 07 | 07 | 07 | 07 | 07 | 36 | 0.018 |
| 20 | 75 | Nil | 21 | 19 | 17 | 16 | 16 | | |
| 30 | 50 | 09 | 18 | 16 | 15 | 13 | 13 | | |
| 40 | 25 | 26 | Nil | Nil | 03 | 04 | 08 | 10 | |
| 50 | 0 | 11 | Nil | Nil | 01 | 01 | 02 | | |

VHI: Voice handicap index, VRQOL: Voice-related quality of life

To know the significance of the study Z test for single sample was used and the Z score was -30.77. P-value was 0, and hence the result was significant at $P < 0.05$.

A student t-test for two-independent means was used to calculate t-value and P-value to know the significance between the two routes of administration of the drug. t-value was 2.8521 and P-value was 0.004. The test was significant at P-value < 0.05 [Table 5].

DISCUSSION

SD is a disease of uncertain etiology. It is commonly seen in the females;^[1,3,4] present study shows the incidence to be common in the females. 63.04% of the present sample was of females with a female to male ratio of 1:1.93. SD is characterized by irregular, intermittent and uncontrollable spasms within the laryngeal muscles as the person starts to speak. It is exaggerated by emotional stress, fatigue, and absent after a good sleep. Few authors support that it can be treated by itself on the psychogenic basis^[13] The present study showed 24 (52.17%) of the patients showed emotional stress during the past 3 years and 16 (34.78%) patients showed signs of mood swings. In a similar study by Liu *et al.* showed the incidence of anxiety, depression, and somatization among the patients of SD in a higher level.^[10] Recently few authors have hypothesized that SD is a dysfunction of the basal ganglia resulting in focal laryngeal dystonias and similar to blepharospasms and torticollis.^[15] Demonstration of electromyographic tracings recorded from 90% of the 10 patients with SD by Behlau Robe in 1990 changed the concept of the disease pointing toward its neurological nature.^[16] Murray *et al.* concluded that there is no evidence to show the effectiveness of speech therapy in SD treatment; it only improves the effectiveness of other treatments to minimize the hyperfunctional state of the larynx.^[17] Speech therapy was not given to the patients in the study. Since 1988 Botulinum toxin injection has become

the mainstay of treatment of SD following the use and demonstration of Botulinum toxin by Blitzer *et al.*^[18] The mode of action of botulinum toxin is to reduce the release of acetylcholine at the neuromuscular junctions. This has an effect to reduce the paralysis of adductor spasm and in speech production. The effect may last for 3–4 months and requires repeat administration of the toxin.^[19] In the present study patients had improved VRQOL from 50 to 75% lasting at an average of 24.5 weeks per cycle. The present study with a follow up of 18 months duration, 16/46 patients (34.78%) required two injections, 19/46 patients (41.30%) of them required three injections, and the remaining 11/46 (23.91%) patients required one injection of the botulinum toxin. 07/46 (15.21%) of the patients showed VRQOL 100% improvement of voice during the period. Subjective assessment of the improvement in voice and quality of life is an appropriate mode of assessment, as the treatment used is only an attempt to achieve symptomatic relief rather than cure.^[20] Blitzer *et al.*^[21] published a study of 900 patients over a period of 12 years of follow-up wherein there was 90% improvement in patients with Adductor type of SD with a mean duration of 15.1 weeks (4 and 1/2 months). Effect of botulinum toxin on Abductor type of SD in their study showed an improvement in 66% with a mean duration of normal voice being 10.5 weeks.^[13-15] The overall efficacy of treatment was seen in 36/46 (78.26%) patients which were statistically significant in the present study with P value of 0.018 [Table 2]. Various surgical procedures are attempted to achieve a long-term result from spasms of the larynx but do not offer great advantages than botulinum toxin injections.^[3,16,17] To know the significance of the present study Z test for the single sample was used and the Z score was 30.77. P-value was 0, and hence the result was significant at $P < 0.05$. A student t-test for two-independent means was used to calculate t-value and P-value to know the significance between the two routes of administration of the drug. t-value was 2.8521 and P-value was 0.004. The test

Table 3: The total dose of Toxin and its correlation with VRQOL score (n=29)

| Number of injections | Number of patients | Total dose of Botox (units) | VRQOL 100% | VRQOL 75% | VRQOL 50% | VRQOL 25% | VRQOL 0% |
|----------------------|--------------------|-----------------------------|------------|-----------|-----------|-----------|----------|
| 1 | 11 | 3 | 06 | 04 | 1 | - | - |
| 2 | 16 | 5 | - | 09 | 04 | 03 | - |
| 3 | 19 | 7 | | 14 | 02 | 02 | 02 |

VRQOL: Voice-related quality of life

Table 4: The mean VBI and VRQOL scores during the follow-up of treatment

| Voice parameter | Pre-treatment | Post-treatment 6 weeks | Post 12 weeks | Post 6 months | Post 12 months | 18 months |
|-----------------|---------------|------------------------|---------------|---------------|----------------|-----------|
| Mean VHI | 42.13 | 23 | 28.41 | 27.20 | 31.93 | 32.17 |
| SD | 6.15 | 5.64 | 5.85 | 5.75 | 6.00 | 6.4 |
| VRQOL score | 25 | 75 | 50 | 50 | 50 | 50 |

VHI: Voice handicap index, VRQOL: Voice-related quality of life, SD: Standard deviation

Table 5: The significance administration of the botulinum toxin by two different routes (n=29)

| Route of Administration | Pre-treatment mean VHI score | Post-treatment mean VRQOL score |
|-------------------------|------------------------------|---------------------------------|
| Intra laryngeal- 26 | 41.68 | 28.70 |
| Percutaneous-20 | 42.69 | 18.15 |

VHI: Voice handicap index, VRQOL: Voice-related quality of life, SD: Standard deviation

was significant at P -value <0.05 . To know the significance of the study Z test for the single sample was used and the Z score was -30.77 . P -value was 0, and hence the result was significant at $P < 0.05$.

CONCLUSIONS

Botulinum toxin injection into intrinsic laryngeal muscle in the treatment of SD is effective in giving a 50–100% VRQOL to the patients even though for a short period. The average period of remission is about 24 weeks in the present study. Percutaneous route of injection showed statistically significant results than intraoral route; P value 0.004.

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ANNEXURE

Annexure I

| Symptom | 1 | 2 | 3 | 4 | 5 |
|--|---|---|---|---|---|
| 1 I run out of Air when I talk | | | | | |
| 2 The sound of my voice varies throughout the day | | | | | |
| 3 My voice sounds dry and creaky | | | | | |
| 4 I feel that I have to strain to produce speech | | | | | |
| 5 I use a great deal of effort to speak | | | | | |
| 6 My voice worsens in the evening | | | | | |
| 7 People have difficulty in understanding my voice in noisy surroundings | | | | | |
| 8 My voice difficulties restrict my personal and social life | | | | | |
| 9 I feel tense when talking to people because of my voice | | | | | |
| 10 I am losing my income due to my voice | | | | | |

Table showing the 10 Questions related to voice problem; VHI index. 1 - None, Not a Problem, 2 - A small amount, 3 - A moderate amount (Medium), 4 - A Lot, 5 - Problem is as bad as it can be

Annexure II

| Questionnaire score | VRQOL score |
|---------------------|--------------------|
| 0 | 100 (excellent) |
| 20 | 75 (fair to good) |
| 30 | 50 (poor to fair) |
| 40 | 25 (poor) |
| 50 | 0 (worst possible) |

Table showing the VRQOL scores and interpretation of the score form Annexure I