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# EVALUATION OF VOICE HANDICAP INDEX AND VOICE RELATED QUALITY OF LIFE IN SPASMODIC DYSPHONIA FOLLOWING BOTULINUM TOXIN ADMINISTRATION IN 29 PATIENTS

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*Botulinum toxin, spasmodic dysphonia, ADDSD, ABSD, spasm, VHI and VRQOL.*

## *Abstract*

Spasmodic dysphonia (SD) is a voice disorder of uncertain etiology characterized by 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 intervention is by unilateral sectioning of recurrent laryngeal nerve and partial thyroarytenoid resection. Speech therapy is ineffective in spasmodic dysphonia, especially in moderate and severe cases. The aim of the present study was to determine the effect of Botulinum toxin type A injections for adductor type of SD on duration of benefit, perceived voice related quality of life.

**MATERIALS AND METHODS:** 29 patients treated with Botulinum Toxin A injected into thyroarytenoid muscles on both sides. Pre and Post treatment Subjective assessment by Voice-Related Quality of Life (V-RQOL) scoring during the follow up for 18 months.

**RESULTS:** There was improvement after injection in quality of life as indicated by the Voice-Related Quality of Life (V-RQOL). The average cycle of remission dysphonia was six months on average.

**CONCLUSIONS:** Botulinum is effective in giving a 50 to 100% VRQOL to the patients with SD. Per cutaneous route of injection showed statistically significant results than intra oral route. Results suggested significant effects on participants' perceived quality of life and acoustic variables, over time, for all participants..

## 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 Spasmodic Dysphonia 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 out bursts with sudden initiation and cessation of speech. The diagnosis usually made by hearing to the speech, aided by fibreoptic laryngoscopy. The findings are normal, but few patients show hyper adduction 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 and range and biofeedback technique. Treatment consists of Botox injection into intrinsic muscles of larynx, anterior laryngoplasty, selective denervation of adductors of larynx and using implantable stimulator. Presently chemodenervation of thyroarytenoid muscle with the help of Botox is the Gold standard care of Adductor type of SD (³). It is commonly seen in women around the age of 30 years (4). 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 (5). 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 effect of Botulinum type A toxin injected into intrinsic muscle of larynx of patients with Spasmodic dysphonia. 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.

## MATERIALS AND METHODS

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. 29 patients presenting with hoarseness of voice, at the ENT department of General Hospital / Prathima Medical College, Karimnagar, Telangana, between June 2011 and September 2012 were included in the present study. Demographic details recorded and patients were subjected to ENT examination including voice recording the speech. Diagnosis was made on history taking, hearing to the speech and video-laryngoscopy examination. Only Adductor type of spasmodic dysphonia was included. Ten questions of VHI of Jacobson et al (5), used to assess pre treatment voice status. First six questions were related to the physical functioning in production of speech and the last four questions were related to effect of voice on social-emotional aspects of life as shown in Appendix I. After the treatment the response expressed as V-RQOL score (Appendix II) is used. Freshly constituted commercially available Botulinum toxin type A was used. 1.5 Units were used initially for the injection and the dose was titrated by increasing or decreasing the dose by 1 unit depending upon the period of remission and development of aspiration. 16 patients were administered Botulinum toxin in to the vocal cords bilaterally visualizing the larynx through fiber optic Nasopharyngoscope under local anesthesia and Alprazolam sedation. 13 patients were administered Botox injection through percutaneous route by point- touch technique described by S. Morzaria, E.J Damrose (6). 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. 7 patients received single injection, 10 patients received two injections (3 within 1 week 7 after 6 months). 12 patients received 3 injections at 6 months interval. Follow up was at 6 months interval for 18 months. All the data was analyzed using standard statistical methods using Single sample T test, Z score for single sample and Student T test for two independent Means.

## OBSERVATIONS

29 patients attending the ENT OPD with complaints of Hoarseness of voice were included in the study. Patients belonged to the age group of 37 years to 60 years. The youngest patient was a female aged 37 year and the eldest patient was aged 58 years male. The mean age was 47.62 and standard deviation was 6.62. Twelve of 29 of the patients (41.37%) belonged to the age group between 45 and 52 years **(Table 1)**. 18 patients (62.06%) were females and 11 (37.93%) were males **(Table 1).** The duration of symptoms ranged between 3 years to 7 years and the mean duration was 5.68 years with Standard deviation of 1.56. 12 (41.37%) patients belonged to the lower middle class, 9

(31.03%) were from middle class and 8 (27.58%) were from the Upper middle class of socio economic groups. 23 (79.31%) of the 29 patients belonged to the responsible position either in the family or at work place. 16 (55.17%) patients belonged to the habitual voice users; hawkers. 14 (48.27%) of the patients showed emotional stress during the past 3 years. 6 (20.68%) patients showed signs of mood swings. The ENT examination and video laryngoscopy showed no demonstrable organic changes in the vocal cord or their movement.

| Age Group | Male-11 (37.93%) | Female-18- (62.06%) | Percentage % |
|---|---|---|---|
| 37 to 44 | 3 | 8 | 37.93 |
| 45 to 52 | 5 | 7 | 41.37 |
| 53 to 60 | 3 | 3 | 20.68 |

**Table 1: Showing the age incidence and sex incidence (n=29).**

Patients were assessed with VHI score and VRQOL scores. 17 patients (58.62%) had their VHI score at 40 with VRQOL score at 25%, 8 patients (27.58%) had their VHI score at 50 with VRQOL score at 0% and 4 (13.79%) with 30 VHI and 50% VRQOL score before treatment. Assessment after 6 weeks showed 3 patients (10.34%) showing complete relief from dysphonia and these patients had their VRQOL score as 0%. Twelve patients (41.37%) showed VRQOL score at 75% and 14 patients (48.27%) 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 three (3) patients continued to show no recurrence in dysphonia, 12 (41.37%) patients showed VRQOL score at 75% and 7 patients (24.13%) 50% response on VRQOL score. & 6 patients (20.68%) showed little (25%) and poor response (0%) in one patient **(Table 2).** The overall efficacy of treatment was seen in 22 (84.61%) out of 29 patients which was statistically significant.

| | | | Post treatment patients | | | | |
|---|---|---|---|---|---|---|---|
| VHI score | VRQOL score-% | Pre treatment patients | 6 Weeks | 12 Weeks | 6 Months | 12 Months | 18 Months |
| 0 | 100 | Nil | 03 | 03 | 03 | 03 | 03 |
| 20 | 75 | Nil | 12 | 12 | 10 | 08 | 12 |
| 30 | 50 | 04 | 14 | 14 | 11 | 09 | 07 |
| 40 | 25 | 17 | Nil | Nil | 03 | 08 | 06 |
| 50 | 0 | 08 | Nil | Nil | 02 | 01 | 01 |

**Table 2: Showing the response to treatment during follow up and related VBI & VRQOL scores (n=29).**

Out of 7 patients who were given single injection 3 did not require further injections in 18 months and showed VRQOL 100% recovery. Out of 10 patients who received two injections VRQOL was 75 to 50% and 7 out of 12 patients who received three injections showed 75% to 50%VRQOL. The remaining 7 patients showed little (25%) or no (0%) VRQOL score **(Table 3).**

| Number of Injections | Number of patients | Total Dose of Botulinum Toxin | VRQOL 100% | VRQOL 75% | VRQOL 50% | VRQOL 25% | VRQOL 0% |
|---|---|---|---|---|---|---|---|
| 1 | 7 | 3 Units | 3 | 3 | 1 | - | - |
| 2 | 10 | 5 Units | - | 5 | 4 | 3 | - |
| 3 | 12 | 7 units | | 4 | 3 | 3 | 1 |

**Table 3: Showing the total dose of Toxin and its correlation with VRQOL score (n=29).**

Mean value of VHI score prior to treatment was 42.13 with VRQOL score 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.**

| | Pre | Post treatment 6 Wks | Post 12wks | Post 6 months | Post12 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** |

**Table 4: showing the Mean VBI and VRQOL scores during the follow up of treatment.**

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

| Route of Administration | Pre treatment Mean VHI score | Post treatment Mean VRQOL score |
|---|---|---|
| **Intra laryngeal- 16** | **41.68** | **28.70** |
| **Per cutaneous-13** | **42.69** | **18.15** |
| | | |

**Table 5: Showing the significance administration of the Botulinum toxin by two different routes (n=29).**

A student T test for 2 independent Means was used to calculate the T-value and P-value to know the significance between the two routes of administration of the drug. The T-value was 2.8521 and the _p-value was 0.004. The test was significant at P-value <0.05 (Table 5).

## DISCUSSION

Spasmodic Dysphonia is a disease of uncertain etiology. It is commonly seen in the females (3, 4); present study shows the incidence to be common in the females. 62.06% of the present sample was of females with a female to male ratio of 1: 1.63. 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 psychogenic basis (5). The present study showed incidence of emotional stress in 48.27%, mood swings in 20.68%. In a similar study by LIU et al showed the incidence of anxiety, depression and somatization among the patients of SD in higher level (6). Recently few authors have hypothesized that SD is a dysfunction of basal ganglia resulting in focal laryngeal dystonias and similar to blepharospasms and torticollis (7). Demonstration of electro myographic tracings recorded from 90% of the 10 patients with SD by Behlau Robe in 1990 changed the concept of the disease pointing towards its neurological nature (8). Murry et al concluded that there is no evidence to show the effectiveness of speech therapy in SD treatment; it only improves effectiveness of other treatments to minimize the hyper functional state of the larynx (9). 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 (10). 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 to 4 months and requires repeat administration of the toxin (11). In the present study patients had improved VRQOL from 50 to 7% lasting at an average of 24.5 weeks per cycle. The present study with a follow up of 18 months duration, 10 patients (34.48%) out of 29 required two injections, 12 patients (41.37%) of them required three injections and the remaining patients required one injection of the Botulinum toxin. Three (24.13%) 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 (12). Blitzer et al 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, 14, and 15). The overall efficacy of treatment was seen in 22 (84.61%) out of 29 patients which was statistically significant in the present study.

Various surgical procedures are attempted to achieve a long term result from spasms of larynx but do not offer great advantages than Botulinum toxin injections. (3,16and17). To know the significance of the present study Z test for single sample was used and the Z score was -30.77. The P-value was 0 and hence the result was significant at P <0.05. A student T test for 2 independent Means was used to calculate the T-value and P-value to know the significance between the two routes of administration of the drug. The T-value was 2.8521 and the _p-value was 0.004. The test was significant at P-value <0.05. To know the significance of the study Z test for single sample was used and the Z score was -30.77. The 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 to 100% VRQOL to the patients even though for a short period. The average period of remission is about 24 weeks in the present study. Per cutaneous route of injection showed statistically significant results than intra oral route; P-value 0.004.

## ANNEXURE I

| | | 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.**

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