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Clinical Study and Evaluation of Botulinum Toxin Type-A in the Management of Oro-Facial Aesthetics

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ABSTRACT

AIM: To evaluate the efficacy of BOTULINUM TOXIN TYPE – A in the management of hyper dynamic forehead wrinkles.

MATERIALS AND METHODS: Patients within the age group of thirty to sixty years irrespective of sex who presented with dynamic wrinkles of the upper two thirds of the face.

RESULTS: In the present study there was a significant difference in the total number of wrinkles pre and post Botulinum toxin-A injection and considerable change in wrinkles was noticed when assessed at 1st month, 4th month, 7th month, 8th month shows statistically significant change which shows the efficacy of Botulinum toxin – A for treatment of forehead wrinkles with rapid onset of action and effect lasting for more than 4 months.

CONCLUSION: Treatment with Botulinum toxin-A is a simple, safe and effective modality to reduce wrinkles through the transitory and reversible paralysis of the treated muscles. The significant result achieved in this study provides scope for wider and increasingly targeted use of Botulinum toxin-A for the management of facial wrinkles.

Keywords: Botox, Aesthetics, Wrinkles.

I. INTRODUCTION

Invasive and non invasive facial aesthetic procedures are becoming common in Oral and Maxillofacial Surgery. Apart from invasive surgical procedures many patients choose rejuvenation with injections such as Botulinum toxin type A. Surgical procedures are invasive which requires skill, expertise of the operator and extensive clinical training with prediction of future after surgery. In the expanding era of non surgical treatment modalities, Botox has emerged as a boon for both clinician and patient[1]. Botulinum toxin is the preferred treatment for upper facial lines which occur in 20 - 40 years old Indians. Botox doses required to treat upper static forehead lines is higher in men than women. It is stated that the most common requests for treatment are glabella, forehead, lateralcanthal lines in 41% of upper facial lines; out of which 35% most commonly requested for treatment of glabellar and forehead lines, and 17% are for lateral canthal lines[2]. Botox represents one of the most important contributions to the approach of the aging face in the recent years.

II. MATERIALS AND METHODS

The prospective clinical study was conducted in the Department of Oral and Maxillofacial Surgery, Kamineni Institute of Dental Sciences, Narketpally, Telangana, India, during 2016-19. Total number of 10 patients were included in this study. The patients who visited the department during the study period were included according to below mentioned inclusion and exclusion criteria.

Healthy volunteers of either gender between the age group of 30-50 years with moderatr (2-3 wrinkles) and severe (≥4 wrinkles) wrinkling at maximum contraction were involved for the treatment. The patients were self motivated, cooperative, aesthetically conscious and who were willing to come for regular follow-up Inclusion criteria was Patients within the age group of thirty to sixty years irrespective of sex, Patients presenting with wrinkles of the upper two thirds of the face. Exclusion criteria was Patients who have unrealistic goal and reasons, Psychologically unstable patients, History of neuromuscular disorders: Myasthenia gravis, Eaton-Lambert syndrome etc, Reported allergy to components of the drug, On medication like aminoglycosides, quinine, pencillamine and calcium channel blockers that would interfere with the

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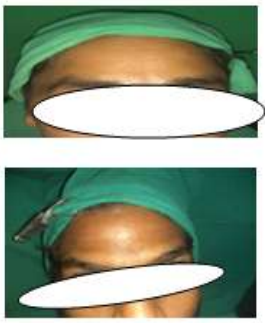
neuromuscular function,Pregnancy, lactation during the study period. Written consent were taken for the procedure.

Evaluation criteria: Patients were observed both rest and at maximum contraction of muscles and the underlying facial anatomy was analyzed. The depth and lateral extent of the forehead creases were evaluated. Subjectively to allot the number of units of Botox to be injected in each patient. Brow asymmetry, if recognized, was brought to the patient's attention. All patients were photographs where the forehead was in a dynamic state.

Pre operative

Post operative

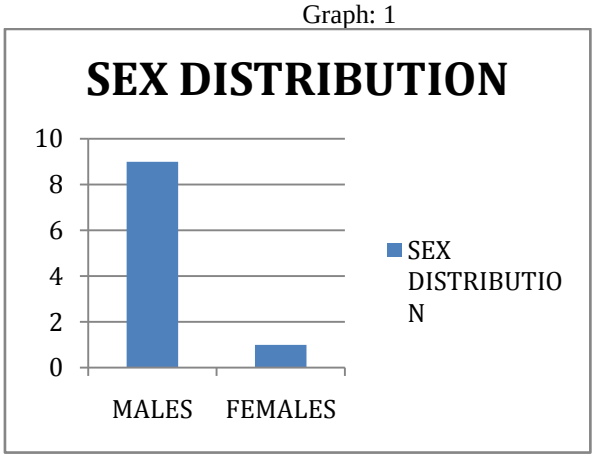


Procedure: The Botulinum toxin was procured as a 100 units vial. It was reconstituted with 4ml of 0.9% normal saline to a concentration of 25U Botox per 1ml. BTX- A is considered to be safe and effective for 3 to 6 weeks after reconstitution. Reconstituted BTX A vials were kept refrigerated at 2-8 centigrade at all times after reconstitution. Patient was seated in a dental chair with a raised head support. Asepsis of the skin was carried out using 70% isopropyl alcohol. The dynamic wrinkles were identified for treatment. The lowest crease was identified and marked. The distance from the orbital rim and brow was noted along with the 1 cm point above the brow. Injection points were marked at 1.5 to 2.5 cm intervals on either side of deep crease in a ''V" or horizontal configuration, starting approximately 2cm above and at the medial side of the eyebrows and finishing at the hairline 5 units of Botox was injected intramuscularly at each site, entering perpendicular to the skin. Care was taken to deposit Botox into the frontalis muscle. Postoperatively, ice compress were used to decrease the pain and edema. Patients were instructed to remain in the vertical position and avoid intense physical exercise and manipulation of the injected area for at least 4 hours after injection. The patients were reviewed periodically at 1st month, 4th month, 7th month and 8th month post operatively.

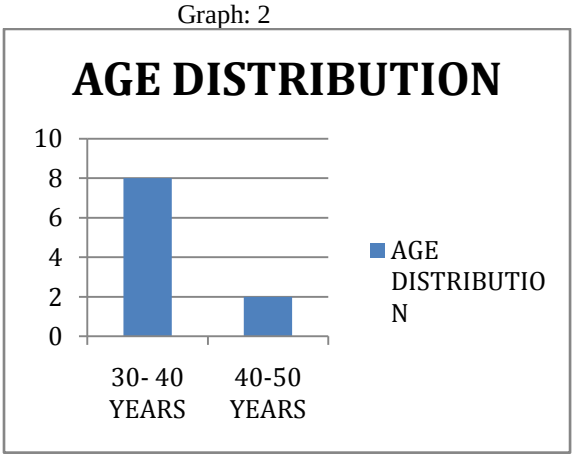
STATISTICAL ANALYSIS

The scoring was tabulated using Microsoft Excel and statistical analysis was done using statistical package for the social sciences. Mean, mode, standard deviation, Wiicoxon signed rank test and p-value were calculated to assess significant results pre and post-operatively.

Graph: 1



Graph: 2



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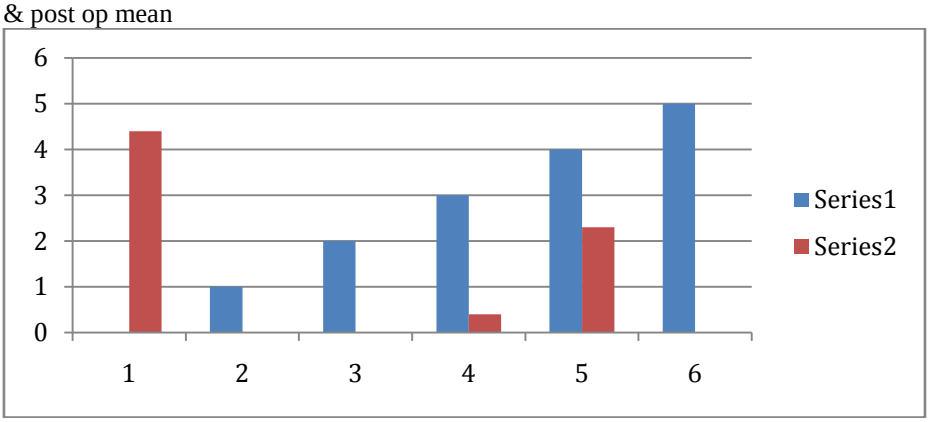
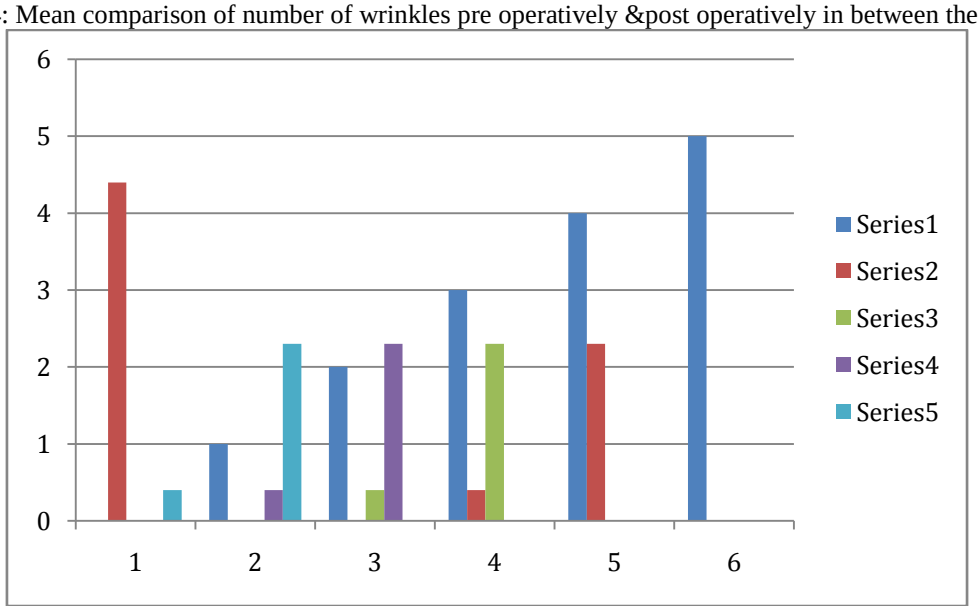
Graph 3: Mean comparison of number of wrinkles pre operatively and post operatively
Series 1 – MEAN
Series 2- pre & post op mean



Graph 4: Mean comparison of number of wrinkles pre operatively &post operatively in between the groups



Series 1- Mean
Series 2- pre op comparison with 1st, 4th, 7th, 8th months
Series3- 1st month comparison with 4th, 7th, 8th months
Series 4- 4th month comparison with 7th and 8th months
Series 5- 7th month comparison with 8th month

III. RESULTS

Total number of nine males and one female were enrolled with age range of 30- 50 years. The wrinkles comparison showed significant reduction at pre operative and post-operative 1st month, 4th month, 7th month and 8th month. The mean wrinkle numbers at rest preoperatively were 4.40 with a standard deviation of 1.578 and 1st month and 4th month postoperatively mean is .00 with a standard deviation .00. Postoperatively 7th month mean is .40 with standard deviation .699. 8th moth post operatively mean is 2.30 with standard deviation .675. This shows significant improvement in number of wrinkles with P value .005. Wilcoxon signed ranks test. Statistically significant if P less than 0.005.

IV. DISCUSSION

The forehead is the upper third of the face defined as extending from the hairline to the glabella and the supra orbital ridge, extending laterally till the temporal ridges[1]. However since the eyebrows and eyes along with the forehead and glabella, play a role in forming facial expressions and conveying emotions, in terms of rejuvenate procedures, they are often considered as a unit[2].

Tsukahara et al[3] described a five-grade wrinkle scale for the outer eye corners and forehead using a five-point descriptive scale (defined as follows: 1 = none, 2 = mild, 3 = mild/moderate, 4 = moderate, 5 = severe) by using predetermined photos and they compared the other photographs. However, their study was not reliable as it assessed the photo-damage to the skin and fine static wrinkles and not the dynamic wrinkles. **Carruthers, A et al**[4], in his dose-comparison, pilot study of botulinum neurotoxin type A in female patients with upper facial rhytids, described a scale of assessment of facial rhytids as 0 = none; 1 = mild; 2 = moderate; and 3 = severe. They did an assessment of the efficacy based on a nine point PGA scale ((+4 = 100% improvement; +3 = 75% improvement; +2 = 50% improvement; +1 = 25% improvement; 0 = no change; -1 = 25% worsening; -2 = 50% worsening; -3 = 75% worsening; -4= 100% worsening) at 4 weeks, measured both by patient and by a trained observer. In this study assessment of postoperative results was done by noting the number of major horizontal wrinkles present, their disappearance and the duration and number of their reappearance. They concluded that objective assessment of the number of wrinkles, was found to be a reliable and reproducible method of assessment of efficacy compared to subjective and patient dependent methods. Most literature describes the average duration of action of BTX-A as approximately 4 months[5,6]. A study conducted by **Carruthers et al**[4] evaluated the efficacy of Botulinum toxin for the treatment of glabellar lines. The investigators determined that the rate of response at maximal frown lasted 3 months for most patients, and as long as 4 months in 25% of the patients. In another paper describing the consensus recommendations on the use of Botulinum toxin type A in facial aesthetics, **Carruthers et al**[7] noted that 80 percent of the panel members observed benefits to last for 4 to 6 months. In a paper comparing the efficacy of Type A and type B Botulinium toxin the duration of action of BTX A was found to be 16 weeks (4 months) on an average[8].According to **Paulo Keiki et al**[9]**,** the complete efficacy of toxin was observed within 24-48 hours after injection and lasted for approximately 5-6 months**. Joseph Niamtu**[10] observed subtotal paralysis within seven days and finishing injections were given 7 days later. In this study the duration of paralysis has persisted up to 6 months. Few patients had regain of muscle function within 4 months which required reinjection. In the present study the post-operative assessment was done on the 1st month, 4th month, 7th month and 8th month. Preoperatively, one patient had 2, 2 patients had 3, 3 patients had 4, 1 patient had 5, 2 had 6 and one had 7 deep wrinkles at rest. Most of the patients had no wrinkles a from 1st post-operative month to 7th post-operative month, but 3 patients reported back with mild reappearance of wrinkles at rest. One patient reported with the reappearance of wrinkles at the 7th post-operative month. At the 8th post-operative month all the patients showed wrinkles at rest. However the number of wrinkles was found to be lesser compared to preoperative assessment. Thus, in our study the duration of action was 6-7 months which was found to be slightly more than that reported in the literature. **Flynn et al**[11] has conducted a systemic review and noted that duration of response varies and may depend on the area treated, differences in patient populations, formulation, dosing, and specific endpoints assessed. They also noted that repeated treatments may increase the response rate and/or duration of response. In 2000, the FDA published data documenting 1437 adverse events associated with the toxin; 1031 of these were associated with cosmetic use. Thirty-six were serious adverse events (death, hospitalization, disability, congenital abnormality); 995 were no serious adverse events, including loss of effect in 623 patients (63%), injection site reaction in 190 patients (19%), ptosis in 111 patients (11%), muscle weakness in 51 patients (5%), and headache in 46 patients (5%). For 124 of the 995 reports, more than one adverse event was reported. There were no deaths from cosmetic use.[11]

V. CONCLUSION

Botox is targeted for aesthetic improvement. The scope of Botox is increasing day by day with its safety, efficacy and range of applications. The use of Botox to improve the aesthetic appearance of horizontal forehead lines is optimized when taken into account the variations in frontalis muscle function and position, anatomy of brow, proper injection technique, volume of diluents and the size of the doses when devised individualized treatment regimens.

An understanding of the anatomy and physiology of the frontalis muscle and its intricate interactions with the surrounding muscles allows more precise treatment and effect for the patient and decreases the chance of esthetically undesirable results.

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