

Clinical Profile and Outcome of Patients using Botulinum Toxin for Cosmetic Purposes: A Cross-sectional Study

RESHMI SUBRAMANIAM¹, VANI VASANTH², BS CHANDRASEKHAR³,
ASIDA MOHAMED ASHRAF⁴, ASHWINI BABU⁵, NEETHA LATHA⁶



ABSTRACT

Introduction: Botulinum toxin injection has become ubiquitous in the treatment of wrinkles. It is less invasive and easy to perform, with almost immediate effects. Although it is the most common non surgical cosmetic procedure performed in many parts of the world, accurate figures of its increasing trend in India need to be unraveled as well.

Aim: To analyse the clinical profile, outcomes, indications, and nature of revisits among patients seeking Botulinum toxin injections for cosmetic indications.

Materials and Methods: A cross-sectional observational study was conducted at a tertiary care centre, Department of Dermatology, Cutis Academy of Cutaneous Sciences, Bengaluru, Karnataka, India, for six months between November 2018 and April 2019 among 80 consecutive patients who received Botulinum toxin injection A for cosmetic purposes. The collected data included age, gender, indication, the number of units of Botulinum toxin used, and the profile of patients seeking revisits. The data was recorded and analysed using Statistical Product and Service Solutions (SPSS) version 23.0.

Results: The average age for treatment among females was 38 years, while among males, it was 35.5 years. Females,

comprising 61 (76%), outnumbered men by a factor of three. The single most common indication for Botulinum toxin injection among females was Crow's feet, accounting for 26 (43%), and among females below 40 years, it was Masseter hypertrophy in 13 (21%). The most common indication among men was Glabellar line correction in 10 (53%). Other indications included the Nefertiti lift, Marionette lines, Popply chin, Brow lift, and Gummy smile. Women revisited the clinic three times more often than men. Among women, Crow's feet correction was the most common reason for revisits. The number of units of Botulinum toxin needed was found to be higher in males for Glabellar lines and in older individuals for Masseter Hypertrophy.

Conclusion: Women are more receptive to cosmetic facial Botulinum toxin injections and revisit more frequently than men. Adverse effects were mild and self-limiting. Upper-face Botulinum toxin injections appear to be the preferred indication in both genders. More epidemiological studies detailing the profile of patients seeking aesthetic Botulinum toxin injections are needed to better understand patients' needs and concerns, offer preprocedure counselling, manage their expectations, and provide customised services.

Keywords: Aesthetics, Cosmetic techniques, Skin aging, Skin wrinkling

INTRODUCTION

From time immemorial, staying young has been an obsession among the aged and aging. The advent of Botulinum toxin has revolutionised this. Emile Van Ermengem (1851-1932) isolated the bacterium *Clostridium botulinum* from ham samples in 1895 and named the toxin "Bacillus Botulinus," which means 'sausage' in Latin [1]. Eight distinct serotypes (A, B, C1, C2, D, E, F, and G) of the neurotoxin have been identified so far. Types A and B of the neurotoxin, known to cause disease in humans, have been used medically and therapeutically. The toxin blocks presynaptic acetylcholine release, preventing nerve impulses responsible for muscle contraction. Recovery from the toxin's effect occurs through the sprouting of nerve terminals and the formation of new synaptic clefts [1].

Botulinum toxin was first approved by the US Food and Drug Administration (FDA) in 1989 for treating blepharospasm and strabismus [1]. However, it was only in 2002 that Botulinum toxin injections were approved by the FDA for correcting Glabellar lines [1]. From being a dreaded and fatal poison found in raw sausages in the 1700s, Botulinum toxin, in its injection form, is now the most common non surgical cosmetic procedure in the USA. It is less invasive, easy, and quick to perform, with almost immediate results [1,2]. A recent review and survey have evaluated the efficacy and dosing patterns of cosmetic Botulinum toxin injections in young adults [3]. Many consensus guidelines for injection strategies for

the Asian face have also been developed [4,5]. While numerous papers discuss the use, common indications, and adverse effects of Botulinum toxin injections, accurate figures on the extent of its use for aesthetic purposes in India are scarce [6].

Therefore, the present study aimed to analyse the clinical profile, outcomes, indications, and nature of revisits among patients seeking Botulinum toxin injections for cosmetic reasons. The present study is one of the first to assess the patient profile of Botulinum toxin users in India and will further assist practitioners in addressing the needs and concerns of patients, deciding on the units' dosing for the Indian context, and providing customised services.

MATERIALS AND METHODS

A cross-sectional observational study was conducted at a tertiary care centre, Department of Dermatology, Cutis Academy of Cutaneous Sciences, Bengaluru, Karnataka, India, over six months from November 2018 to April 2019. Ethical clearance was obtained from the Institutional Ethics Committee, Cutis Academy of Cutaneous Sciences, Bengaluru (letter No. 546 dated 16.10.2018). After obtaining written informed consent, patients were enrolled in the study. Consecutive patients seeking Botulinum toxin injections during the study period were as follows:

Inclusion criteria: Patients seeking Botulinum toxin for aesthetic purposes and giving consent to participate in the study were included.

Exclusion criteria: Patients seeking Botulinum toxin for non aesthetic indications were excluded. Six patients were excluded from the study.

Study Procedure

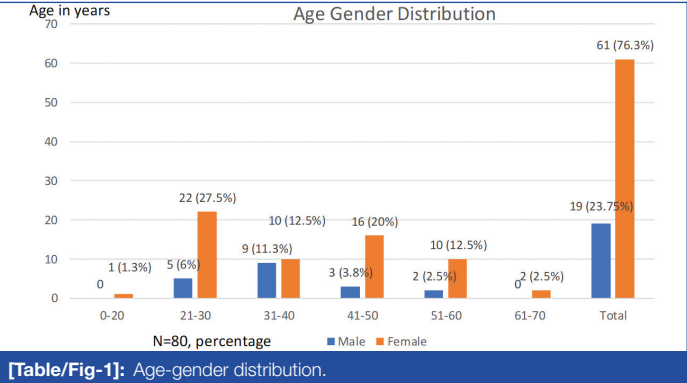
Clinical records of 80 patients were analysed for age, gender, indication for Botulinum toxin injection, dose of Botulinum toxin injected, and profile of revisits. Botulinum toxin is available in single-use 100- and 50-unit vials, which are reconstituted in 2.5 mL and 1.25 mL of 0.9% non preserved saline, respectively, to achieve resulting doses of four units per 0.1 mL. Botulinum toxin was injected using an Insulin syringe of 31 gauge and 6-8 mm length. Initially, patients were given several units of injection based on the indication, muscle mass, previous experience, and available literature. When the patient revisited after two weeks for a touch-up, more units were injected if the response was inadequate.

STATISTICAL ANALYSIS

The data was recorded in Microsoft excel and analysed using Statistical Product and Service Solutions (SPSS) version 23.0 for Windows. All variables were analysed using descriptive statistics. Quantitative variables such as age were expressed as the mean, and results of qualitative variables were expressed as percentages.

RESULTS

Age-gender distribution: Out of the 80 patients, 61 (76.3%) were female. A female preponderance with a female-to-male ratio of 3.2:1 was observed. The youngest and oldest ages among males were 24 and 58 years, respectively, while females' age ranged between 19 and 63 years. The average age for treatment among females was 38 years, while among males, it was 35.5 years. A total of 33 females (54%) were aged 40 years and below, compared to 14 males (74%) [Table/Fig-1].



[Table/Fig-1]: Age-gender distribution.

Indication for Botulinum toxin injection: Among females, 40 (65%) underwent Botulinum toxin injection for more than one indication, compared to 11 (58%) among males. The single most common indication for Botulinum toxin injection among females was for Crow's feet (43% of women), of which 17 (65%) were above 40 years of age. The second most common indication was the correction of forehead lines and Glabellar lines. Of the 13 patients concerned about Masseter hypertrophy, 12 were in the age group 21-30 years, making it the most sought-after indication for women below 40 years of age. The majority (77%) of women who sought the Nefertiti lift were below 40 years of age.

Other indications for Botulinum toxin injections in females were Marionette lines (8), Popply chin (5), Brow lift (4), and gummy smile (2). Seven women above 40 years of age sought Marionette line correction, as opposed to one woman below 40 years of age. The most common indication among men for Botulinum toxin injection was Glabellar complex correction in 10 (53%), followed by Crow's feet 8 (42%). Men below 40 years of age were more concerned about Crow's feet and forehead lines (6 each), compared to those above 40 years of age (2 for Crow's feet, 1 for forehead lines). No such discrepancy was seen regarding Glabellar lines in men. Two male patients in the 31-40 years age group sought correction of Bunny lines and Under-eye wrinkles [Table/Fig-2].

Age group (years)	Crow's feet		Forehead lines		Glabellar complex		Masseter hypertrophy		Others	
	M	F	M	F	M	F	M	F	M	F
11-20	0	0	0	0	0	0	0	0	0	1
21-30	2	4	2	2	1	1	0	12	0	9
31-40	4	5	4	5	4	3	0	0	2	3
41-50	2	11	0	5	1	5	1	1	0	8
51-60	0	5	1	5	4	6	0	0	0	7
61-70	0	1	0	1	0	1	0	0	0	1
Total (% n=80)	8 (10)	26 (32.5)	7 (8.7)	18 (22.5)	10 (12)	16 (20)	1 (1.3)	13 (16.3)	2 (2.5)	29 (36.3)

[Table/Fig-2]: Indications of Botulinum toxin among different age groups in males and females.

Revisits: Out of the total patients, 30 patients (37.5%) revisited, 23 (77%) of whom were females. Among the 23 female patients who revisited, 14 did so for an indication different from the previous visit, often for more than one indication. Crow's feet correction was the most common reason for revisit, made by 17 patients, most of whom (70%) were above 40 years of age. The next common reasons for revisit among women were Glabellar complex correction (12) and forehead lines (10). Only seven men revisited, five of whom revisited for Crow's feet correction.

Units of Botulinum toxin: The number of units of Botulinum toxin needed was found to be higher in males than in females for the same indication. Additionally, it was noted that with increasing age, females required more units for Crow's feet and Masseter Hypertrophy. Above 60 years of age, conservative doses were preferred [Table/Fig-3].

Age group (years)	Units of Botulinum toxin							
	Crow's feet*		Forehead lines		Glabellar complex		Masseter hypertrophy†	
	M	F	M	F	M	F	M	F
0-10							-	
11-20		-		-		-	-	-
21-30	25	10-12	11-18	5-10	15	13	-	28-50
31-40	18-25	16-20	6-18	6-15	14-19	14-20	-	-
41-50	18-20	10-20	-	5-10	12	12-19	-	42
51-60	--	14-20	5-11	5-15	11	11-15	-	-
61-70	--	8-12	-	5	--	12	-	-

[Table/Fig-3]: Number of Botulinum toxin units among males and females. The units for Crow's feet* and Masseter hypertrophy† include both right and left-sides taken together

Adverse effects: The adverse effects of Botulinum toxin injection in the study were few and self-limited, such as headache and heaviness of eyelids observed in one patient each.

DISCUSSION

In the study, more women sought cosmetic Botulinum toxin treatments than men. The most common indications for Botulinum toxin injection among women and men were Crow's feet and Glabellar complex, respectively. Revisits for new indications were more common among women and increased with age. The number of units of Botulinum toxin needed was higher in males, as seen in a previous study [7]. With increasing age, women required more units of Botulinum toxin for indications like Crow's feet and Masseter hypertrophy, as observed in a previous study [7]. The adverse effects of Botulinum toxin injection were mild and often self-limited, as in another study [8].

As mentioned earlier, detailed statistics on the epidemiological trends surrounding aesthetic Botulinum toxin injections in the Indian context are scarce. Women are known to be more concerned about body image than men [9]. However, in Western society, more men

are coming forward to undergo non invasive cosmetic treatments like Botulinum toxin injections in recent years, although this trend may take time to appear in India [10]. Glabellar lines are the most common dynamic lines of the upper face for which Asian patients seek treatment [5]. In the present study, more women 26 (42%) sought treatment for Crow's feet, compared to 16 (26%) women seeking treatment for Glabellar complex, as seen in a previous study [11]. However, among men, more than half sought Glabellar complex correction, making it the most common indication.

Botulinum toxin injections for facial contouring by injecting for Masseter hypertrophy were sought almost exclusively by the 21-30-year-old age group women in this study, as opposed to correction of Marionette lines, which was sought by older women. Facial contouring is a common concern among younger Asian women, unlike Caucasians, who naturally have a narrow face. A square-shaped face among younger Asians is often caused by symmetric or asymmetric increase in the masseter muscle (Masseter hypertrophy) [12]. They prefer Botulinum toxin injection due to its non invasive nature and shorter downtime compared to mandibular resection surgery [13]. Many studies have examined the efficacy of Botulinum toxin injection for this indication [14,15]. Marionette lines increase with age due to the effects of gravity, loss of volume, and repetitive facial expressions on inelastic aging skin, and are a common concern among older women [16].

More younger men sought upper face treatment with Botulinum toxin injections. Among women, the trend is reversed. No definitive conclusion can be drawn from this observation as the total number of patients is biased towards the female gender. Revisits for new indications are common among women and increase with age as they become more comfortable and satisfied with the procedure, and due to the co-existence of more than one type of facial lines with increasing age. The number and nature of revisits among Botulinum toxin injection-seeking patients have not been explored before.

Variations in Botulinum toxin requirements with age and gender help researchers counsel patients accordingly. Treatment indications, strategies, and dosages in Asians differ from those previously described for Caucasians due to distinctions in facial morphotypes, anatomy, and cultural expectations [4]. To bridge this gap, consensus recommendations have been proposed to address the Botulinum toxin dose requirements among Asians [3,9]. Regarding efficacy, and based on limited available data, it is opined that Botulinum toxin is not as effective in individuals above 65 years of age [17].

Adverse effects reported in the literature include mild bruising (10-25%), pain during injection, headache, and altered muscle response due to misplacement of the toxin [18,19]. The present study revealed that adverse events were confined to mild and transient effects.

Limitation(s)

The sample size was not calculated; further studies with a larger sample size can be conducted in the future.

CONCLUSION(S)

Women were found to be more open to cosmetic facial Botulinum toxin injections. Upper-face Botulinum toxin injection seems to be the preferred indication in either gender. Masseter hypertrophy is a common indication among younger women. Revisits indicate the level of satisfaction and comfort with the procedure. Counselling about the transient and benign side-effects helps to encourage revisits.

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PARTICULARS OF CONTRIBUTORS:

1. Associate Professor, Department of Dermatology, Venereology and Leprosy, Sree Uthradom Thirunal Academy of Medical Sciences, Thiruvananthapuram, Kerala, India.
2. Senior Consultant, Department of Dermatology, Cutis Academy of Cutaneous Sciences, Bengaluru, Karnataka, India.
3. Director and Chief Consultant, Department of Dermatology, Cutis Academy of Cutaneous Sciences, Bengaluru, Karnataka, India.
4. Assistant Professor, Department of Pharmacology, Sree Uthradom Thirunal Academy of Medical Sciences, Thiruvananthapuram, Kerala, India.
5. Assistant Professor, Department of Dermatology, Venereology and Leprosy, Sree Uthradom Thirunal Academy of Medical Sciences, Thiruvananthapuram, Kerala, India.
6. Assistant Professor, Department of Dermatology, Venereology and Leprosy, Sree Uthradom Thirunal Academy of Medical Sciences, Thiruvananthapuram, Kerala, India.

NAME, ADDRESS, E-MAIL ID OF THE CORRESPONDING AUTHOR:

Dr. Ashwini Babu,
Assistant Professor, Department of Dermatology, Venereology and Leprosy,
Sree Uthradom Thirunal Academy of Medical Sciences,
Thiruvananthapuram-695028, Kerala, India.
E-mail: resh.sub@gmail.com; ashwinibabu@gmail.com

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