

Evaluation of Botulinum Toxin Applications in a Tertiary Cosmetic Department**Bir Eğitim ve Araştırma Hastanesinde Kozmetik Amaçlı Botulinum Toksin Uygulamalarının Değerlendirilmesi**Özge Mine ORENAY¹, Berkay TEMEL¹, Nermin KARAOSMANOĞLU¹**ABSTRACT**

AIM: Botulinum toxin type A (BTX-A) treatment for facial rejuvenation has been started to used widely and become the most common aesthetic procedure. The aim in this study to evaluate the patients features and outcomes who had Onabotulinumtoxin A.

MATERIAL AND METHOD: The data of the BTX-A patient's gender, age, occupation, history of cosmetic procedures, history of disease, doses of the first and control injections, complications and expectations from the therapy collected from the medical records. The patients were divided into two groups as under the age of 45 and age of 45 and older. These groups were compared with each other in terms of mentioned variables.

RESULTS: A total of 200 patients included in this study. The mean botulinum toxin dose was 33.7 units and the mean control dose was 4.5 units. Three (1.5%) of the patients developed a complication, all of them were eyelid ptosis. Most common expectation from the toxin injection was to look more young (69%) and vigorous (75.5%). There were no significant difference between the under the age of 45 and 45 and older group in terms of total BTX-A dose and control dose and complication rate ($p=0.8$, $p=0.5$, $p=0.6$). Expectation of looking less angry and less saggy were significantly higher in the 45 year and older group ($p=0.02$, $p=0.02$).

CONCLUSION: It is important to evaluate the patient's gender, age and expectations from the botulinum toxin injection to get the highest efficiency from BTX-A injection.

Keywords: botulinum toxin, facial rejuvenation, wrinkles

ÖZET

AMAÇ: Botulinum toksin tip A (BTX-A) tedavisi yüz rejuvenasyonunda yaygın olarak kullanılmaya başlanmış ve en yaygın kullanılan kozmetik işlem haline gelmiştir. Bu çalışmanın amacı, Onabotulinum toksin uygulanan hastaların özellikleri ve işlem sonuçlarının değerlendirilmesidir.

GEREÇ ve YÖNTEM: BTX-A uygulanan hastaların dosyaları taranarak; demografik bulguları, kozmetik işlem geçmişleri, uygulanan botoks dozları, kontrol dozu uygulamaları, gelişen komplikasyonlar ve botokstan beklentileri kaydedilmiştir. Ayrıca hastalar 45 yaş altı ve 45 yaş ve üstü olarak iki gruba ayrılarak, iki grubun kozmetik işlem geçmişleri, uygulanan botoks dozları, kontrol dozu uygulamaları, komplikasyonlar ve botokstan beklentileri karşılaştırılmıştır.

BULGULAR: Çalışmaya 200 hasta kabul edilmiştir. Hastaların, ortalama total botoks dozları 33.7 ünite, ortalama kontrol dozları ise 4.5 ünite idi. Hastaların 3'ünde (%1.5) komplikasyon olarak ptosis izlendi. Hastalar en çok fazla daha genç görünme (%69) ve daha dinç görünmek (%75.5) için botoks yaptırdığını bildirmişlerdir. Kırk beş yaş altı ve 45 yaş ve üstü grupta total ve kontrol doz ortalaması, komplikasyon gelişimi açısından istatistiksel olarak anlamlı fark saptanmamıştır ($p=0.8$, $p=0.5$, $p=0.6$). Hastaların botoks işleminden beklentisine bakıldığında ise 45 yaş ve üstü grubun, 45 yaş altı gruba göre daha az öfkeli ve daha az sarkık görünme isteği anlamlı olarak yüksek bulunmuştur ($p=0,018$, $p=0,029$).

SONUÇ: BTX-A enjeksiyonundan en yüksek verimi sağlayabilmek için hastanın cinsiyet, yaş ve beklentilerinin iyi değerlendirilmesi önem kazanmaktadır.

Anahtar Kelimeler: botulinum toksini, kırışıklıklar, yüz rejuvenasyonu

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INTRODUCTION

Facial wrinkles are one of the main signs of aging and also can lead to a negative, unwanted impression of the face such as sadness, anger.^{1,2} Botulinum toxin is a neurotoxin which is produced by gram-negative bacterium named *Clostridium botulinum*. Botulinum toxin paralysis the target muscle by inhibiting the release of acetylcholine at the neuromuscular junction.³

In the recent years, Botulinum toxin type A (BTX-A) treatment for facial rejuvenation has been started to used widely and due to its relatively safeness and effectiveness become the most common aesthetic procedure.⁴ As aesthetic purpose, BTX-A first used to treat glabellar lines and its use extended to many other facial areas. BTX-A applications are considered to have a good safety profile. The use of different formulations (Onabotulinumtoxin A, Abobotulinumtoxin A, Incobotulinum Toxin) with different dilutions and dosage, wide range of anatomical use among practitioners can raise the incidence of side effects. Most common side effects are related to the needle injections (swelling, erythema, edema and bruising). Other complications are due to incorrect dosage practices and misplaced injections.^{5,6}

Although, the BTX -A injections widely used there is no consensus of the applications. In this study, we wanted to evaluate the patient's demographic features, expectations from the treatment and to study the toxin dosage and complications.

MATERIAL AND METHOD

The charts of the patients who received botulinum toxin injection for facial wrinkles between the year of 2019-2020, in the cosmetology department of a Training and Research Hospital were scanned. Informed consent was taken from the patients before the procedure. Ethics approval was obtained from local ethic committee. All of the patients in the study received Onabotulinum toxin type A (Botox, Allergan Inc.) of 100 unit which was reconstituted with 2.5 ml of 0.9% saline to the upper face (glabellar lines, crow's feet lines, forehead lines, bunny lines). Control dose for needed patients was applied on tenth day of the first injection. The data of the patient's gender, age, occupation, history of cosmetic procedures, history of disease, doses of the first and control injections, complications collected from the medical records. The expectations from the therapy questioned with 8 options which contains 'to look more vigorous', 'to look more happy', 'to look more attractive', 'to look more elegant', 'to look more feminine', 'to look more young', 'to look less angry', 'to look less saggy' was also collected from the files. The patients were divided into two groups as under the age of 45 and age of 45 and older. In order to ensure that both groups distributed similarly in number and the patient's median age of was 45, we selected 45 year as threshold. These groups were compared with each other in terms of history of cosmetic procedures, history of disease, doses of the first and control injections, complications and expectations from the therapy.

Statistical Analysis

Descriptive statistics were analyzed in IBM SPSS 22.0 program. Shapiro-Wilk test was applied to reveal whether the data were suitable for normal distribution. For categorical variables, frequency differences between groups were compared using Pearson's chi-square. The t-test was used to compare the means of two independent groups in a normal distribution. The statistical significance was accepted as $p < 0.05$ for this study.

RESULTS

A total of 200 patients included in the study, 97.5% (195) of them were female and 2.5% (5) of them were male. The mean age of the patients was 44.8. Seventy (85%) of the patient were employed, 20 (10%) of the patient were unemployed and 10 (5%) of the patient were retired. One hundred and seven (53.5%) of the patients had botulinum toxin injection before, 93 (46.5%) of them had it for the first time. Only 40 (20%) of the patients had dermal filler before while 160 (80%) of them never had it. Control dose was not needed in 69 (34.5%) of the patients, 131 (65.5%) of the patients had control dose. Patients expectations from the injection were; 151 (75.5%) of them wanted to look more vigorous, 126 (63%) of them to look more happy, 80 (40%) of them to look more attractive, 80 (40%) of them to look more elegant, 55 (27.5%) of them to look more feminine, 138 (69%)

of them to look younger, 91(45.5%) of them to look less angry and 109 (54.5%) of them wanted to look less saggy. Thirty four (17%) of the patients had a comorbidity. The mean botulinum toxin dose that administered to the patients was 33.7 units and the mean control dose was 4.5 units. Three (1.5%) of the patients developed a complication, all of them were eyelid ptosis.

In the group of age under 45 years, there were 101 female and 3 male with a total 104 (52%) patient. In the group of 45 year and older, there were 94 women and 2 men with a total 96 (48%) patient. According to the history of BTX-A injection and dermal filler, there were no statistically significant differences between the two groups. ($p=0.8$, $p=0.06$). Patient's expectations of looking more vigorous, happy, attractive, elegant, feminine and young were similar in both groups with no statistically significant difference. However, expectation of looking less angry and less saggy were significantly higher in the 45 year and older group ($p=0.02$, $p=0.02$). Comparing the both groups in terms of total dose and control dose administered, there were no statistically significant difference ($p=0.8$, $p=0.5$). There was no difference between the groups in terms of complication rate ($p=0.6$)

Table-1: Patient Characteristics

	Patients (n=200)	Under 45 year (n=104)	45 year and older (n=96)	P value
Gender, n(%)				0.7*
Male	5 (2.5)	3 (2.9)	2 (2.1)	
Female	195 (97.5)	101 (97.1)	9 (97.9)	
Age, mean year	44.8	39	51	0.01**
Botulinum toxin history, n(%)	107 (53.5)	55 (52.9)	52 (54.2)	0.8*
Dermal filler history, n(%)	40 (20)	26 (25)	14 (14.6)	0.06*
Patients expectations, n(%)				
Look more vigorous	151 (75.5)	81 (77.9)	70 (72.9)	0.4*
Look more happy	126 (63)	60 (57.7)	66 (68.8)	0.1*
Look more attractive	80 (40)	43 (41.3)	37 (38.5)	0.6*
Look more elegant	80 (40)	39 (37.5)	41 (42.7)	0.4*
Look more feminine	55 (27.5)	30 (28.8)	25 (26)	0.6*
Look younger	138 (69)	75 (72.1)	63 (65.6)	0.3*
Look less angry	91 (45.5)	39 (37.5)	52 (54.2)	0.02*
Look less saggy	109 (54.5)	49 (47.1)	60 (62.5)	0.02*
Botulinum toxin dose, mean Unite				
First	33.7	33.5	34	0.8**
Control	4.5	4	5	0.5**
Complication, n(%)	3 (1.5)	2 (1.9)	1 (1)	0.6*

* Chi-square test, ** t-test

DISCUSSION

The number of people applying for aesthetic procedures is increasing rapidly. The main reason for this can be attributed to the increasing importance given to the perception of beauty and to the desire of aging beautifully. BTX-A injections had been widely used for different indications and variable doses for aesthetic procedures. In this study, we evaluated the patients who had Onabotulinum A toxin injection to the upper face.

The patients mean age was 44.8 which consist with other studies.⁷⁻⁹ American Society for Aesthetic Plastic Surgery statistics reported that 77% of BTX-A procedures were administered to patients of age 35-64, in 2011.¹⁰ BTX-A injections usually preferred between early thirties and fifties before the facial wrinkles become static. It is important to consider the patients age while developing a treatment plan. Wrinkles in older patients are mainly due to the loss of skin elasticity.¹¹ Therefore, BTX-A treatment alone will not provide enough improvement and patient's satisfaction. These patients require additional treatment modalities. Patients 97.5% of them were female which is also similar to other studies.^{8,12} This result can be due to the fact that female seek more aesthetic procedures than men. In a study conducted by Casabona et al.⁶, 40.5% of the patient had a

prior BTX-A injection. In this study, 53.5% of the patients had BTX-A injection before and only 20% of the patients had dermal filler. These rates will increase in the coming years due to rising desire of aging well.

To our knowledge, there was no other study questioning patient's expectations from BTX-A injection. When evaluating the patients it is essential to learn their expectations from the treatment and to clarify the outcomes to avoid unrealistic expectations and disappointments after the treatment. In this study, patient's most common expectations from the BTX-A injections were to look more vigorous and young which is compatible with treatment effects.

There isn't a full consensus on application and doses of BTX-A injection. Recommendations of the BTX-A doses are variable. Doses in the range of 10-30 U for glabellar complex, 6-20 U for horizontal forehead lines and 10-30 U for crow's feet have been recommended.¹³⁻¹⁶ Dose recommendations also vary according to patient characteristics such as race and gender.^{15, 17-18} In a study, a mean total dose of 41.9 U and mean control dose of 12.7 U administered to the patients.⁶ In another single center study¹⁹, the mean quantity of onabotulinumtoxin A injected was 113.8 ± 17.6 units (range: 50-180 units) with touch-ups which was higher than the doses recommended in consensus. In our study, the mean BTX-A dose that administered to the patients was 33.7 units in the first session and the mean control dose was 4.5 units. The doses that administered in this study were lower than other studies.

Many study analyzed the safety of BTX-A injections. Among the studies, the most common side effect reported was headache.^{9, 20} In a multidepartment study, 5310 treatment of BTX-A for multiple indications, 184 (3.73%) adverse events reported. 114 (2.26%) of them were muscle-related and the most common was ptosis.²⁰ In another study, the total complication rate, both muscle-related and muscle-unrelated, was reported as 16%.²¹ In a review of BTX-A complications, the overall incidence of eyelid ptosis was reported as 0.71%.²² In a study conducted by D'Emilio et al.¹¹ a total 189 patient who underwent BTX-A injection 6 patients (3.2%) developed complication; one (0.5%) of them was eyelid ptosis. In this study, we only can report the muscle-related complications due to the retrospective nature of the study. Three (1.5%) of the patients developed a complication, which all of them were eyelid ptosis. This result is lower comparing with the overall complication rate in other studies, however it is similar comparing with the rate of muscle-related complications. Several studies analyzed the correlation between the BTX-A doses and incidence of side effects and found no statistical difference.²³⁻²⁵ This result consist with our study, although we used lower BTX-A doses than recommended, complication rate was similar to other studies.

With aging, skin losses it's elasticity due to the collagen loss. Moreover, muscle contraction decreases with age.⁹ Therefore, BTX-A injections may be less effective in elderly. Also lower doses of BTX-A will be more appropriate due to decrease in the muscle mass.²⁶ In a study, less improvement of wrinkles was seen in patients above 51 years of age, compared with those under 50 years of age.²⁷ In this study, comparing the group of age under 45 years with the group of 45 year and older there were no significant difference in total dose administered and need of control dose. This result was expected due to the low age threshold (45 year) between the groups. Yeslev et al.²⁸ reported that after cosmetic surgery in terms of complication rate there were no statistically significant difference between the patients older than 65 years and the younger patients. In our study, no significant difference was found between the groups in terms of complication rate, which consistent with the above-mentioned study. In the 45 year and older group, expectation of looking less angry and less saggy were significantly higher than the group of age under 45 years which is expected when considering the increase of wrinkles and sagging with aging.

CONCLUSION

BTX-A application techniques and doses vary between injectors. In general, BTX-A injection is a safe and highly effective procedure. However, it is important to evaluate the patients gender, age and expectations from the therapy to get the highest efficiency from BTX-A.

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