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ORIGINAL ARTICLE

Treatment of masseter muscle hypertrophy with botulinum toxin type A injection: A review of adverse events

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Abstract

Background: The popularity of noninvasive botulinum toxin type A (BTX-A) injections for masseter muscle hypertrophy is increasing among Asian individuals with a square-shaped lower face.

Aims: This study aimed to analyze the adverse events (AEs) caused by BTX-A injections into the masseter muscle.

Patients/Methods: This observational study retrospectively evaluated 46 250 patients who underwent BTX-A injections into the masseter muscle in 2022. The inclusion criteria were the diagnosis of an AE by the physician at the return visit and subsequent follow-up of progress ($n = 223$). The patients who were lost to follow-up ($n = 40$) were excluded from the study.

Results: Among the 223 patients with AEs, the most common AE was paradoxical bulging (88.3%, $n = 197/223$). The average period from treatment until confirmation of improvement was 159.6 ± 113.6 days (range 13–667 days) for all AEs, all of which were temporary. The period until improvement was 166.1 days in the intervention group ($n = 122$) and 151.9 days in the observation group ($n = 101$) ($p = 0.24$). As the period until improvement of AEs included the period until the patients visited the clinics and the improvements were confirmed by physicians, the actual period was likely to have been shorter.

Conclusions: (1) All AEs were temporary. (2) All AEs improved within 22.2 months (within 5.3 ± 3.8 months on average). (3) There was no significant difference between the intervention and observation groups in the period until the improvement of AEs.

KEYWORDS
adverse events, Asian patients, botulinum toxin type A injection, masseter muscle, risorius muscle

1 | INTRODUCTION

A square-shaped lower face due to masseter hypertrophy is a common facial feature among Asian individuals that is considered esthetically unpleasing by many women.[1–3] In the past, the main option for contouring the lower face involved surgical excision of the masseter muscle.[4] However, due to the invasiveness and risks associated with surgery, noninvasive alternative treatments have

recently become more popular and safer options.[2,5] In particular, botulinum toxin type A (BTX-A) injection into the masseter muscle has gained popularity among patients seeking a noninvasive treatment to achieve a smaller face appearance.[6] Recent trends have demonstrated a steady increase in the annual number of BTX-A injection procedures conducted in Japan (excluding injections into the breast), with a temporary decrease in 2020 that was likely due to the impact of the COVID-19 pandemic.[7–9] However, some patients have reported esthetic adverse events (AEs) after BTX-A injections, such as paradoxical bulging, swelling, sagging, difficulty in smiling, and sunken cheeks. Although these AEs are usually temporary, they can reduce patient satisfaction and trust in the procedure. Therefore, physicians need to be well-acquainted with these potential AEs.

The movement of the jaw during chewing involves a group of masticatory muscles, namely the masseter, temporalis, medial pterygoid, and lateral pterygoid muscles. Among them, the masseter muscle is the largest.[1] The masseter muscle arises from the zygomatic arch, extending downward and posteriorly, ultimately attaching to the ramus of the mandible and mandibular angle. Additionally, the masseter is composed of three distinct layers: superficial, middle, and deep.[10]

There are many studies on the techniques used to inject BTX-A into the masseter muscle and Kundu et al. performed a comprehensive review of these studies.[11] The BTX-A injection methods include two-point, three-point, and five-point techniques. The two-point technique comprises injections spaced 1 cm apart along a line from the tragus to the corner of the mouth, while the three-point method entails positioning one injection point below the tragus-mouth line at the thickest part of the muscle, accompanied by two injection points situated 1 cm away from the anterior and posterior borders of the masseter. An alternative approach is the five-point injection technique, which focuses on the areas of maximum bulging in the masseter muscle.[11]

The aim of this study was to analyze the AEs caused by BTX-A injections for treatment of masseter muscle hypertrophy and to discuss their prevention and countermeasures.

2 | MATERIALS AND METHODS

This was an observational, descriptive, multicenter study that retrospectively evaluated the medical records of 46 250 patients (61 341 procedures) who received BTX-A injections into the masseter muscle from January to December 2022 in 107 clinics.

We explained to the patients in advance about possible AEs and encouraged them to return to the clinic if they experienced these symptoms. Patients returned on their own initiative if they felt their treatment was not progressing well or if they experienced symptoms of potential AEs. When the treatment course deviated from the typical progression, the physician diagnosed it as an AE. A total of 453 patients returned to the clinics, 263 of whom were diagnosed by a physician as having an AE. The study inclusion criteria were a diagnosis of an AE by a physician at the time of the return visit and follow-up of the subsequent progress ($n = 223$). The remaining patients were lost to follow-up ($n = 40$) because we were unable to contact these patients after the return visit.

Details of the AEs were documented in the patients' medical records when they revisited the clinic. The following items were retrospectively analyzed: patients' background characteristics (age and sex), number of procedures and number of BTX-A units, duration from the procedure to the revisit date, level of the masseter muscle at the revisit date and diagnosis and treatment methods for any AEs.

The following five members were involved in this work during the study period from January 2022 to February 2024 and during the study period that was needed to review the analyzed data in this study: the principal author (A.N.), two members of the department to which AEs must be reported and two members of the department who were responsible for data management in this study.

The injectable product that was used in this study was BOTOX Vista® Injection (Allergan Aesthetics, AbbVie, Irvine, CA, USA), which has been approved by the Ministry of Health, Labour and Welfare in Japan. The dosage of BTX-A was determined at the discretion of each physician, along with input from the patient after pretreatment counseling. At our facility, internal trainers conduct lectures on botulinum toxin, followed by injection training sessions, to ensure uniformity in the technique. The recommended injection method is to divide an appropriate amount of BTX-A into five injection points on each side of the lower face, located posterior to the line connecting the corner of the mouth to the earlobe, targeting the posterior area relative to the line connecting the corner of the mouth to the earlobe. However, the actual injection techniques may vary among physicians due to individual perspectives.

We used the *t*-test with Microsoft® Excel® MSO (version 2209 Build 16.0.15629.20196) 32-bit to assess the statistical significance of the difference in the period from treatment until confirmation of improvement of AEs between the intervention group and follow-up observation group. $p < 0.05$ was considered statistically significant.

3 | RESULTS

3.1 | Patient demographics

There were 4885 males (10.6%) and 41 365 females (89.4%). The average age was 33.3 years (range: 15–78 years). The proportion of patients who received BTX-A injection for the first time was 20% ($n = 46\,250$). The age distribution is shown in Figure 1. Patients in their 20s were the most common age group. Regarding the ethnic distribution of patients among the total study cohort, 95.3% were Japanese and 99.7% were of Asian ethnicity.

3.2 | Patients who were diagnosed by physicians with AEs at the revisit ($n = 263$)

Of the 263 patients who were diagnosed by physicians with AEs at the revisit, 27 were males (10.3%) and 236 were females (89.7%).

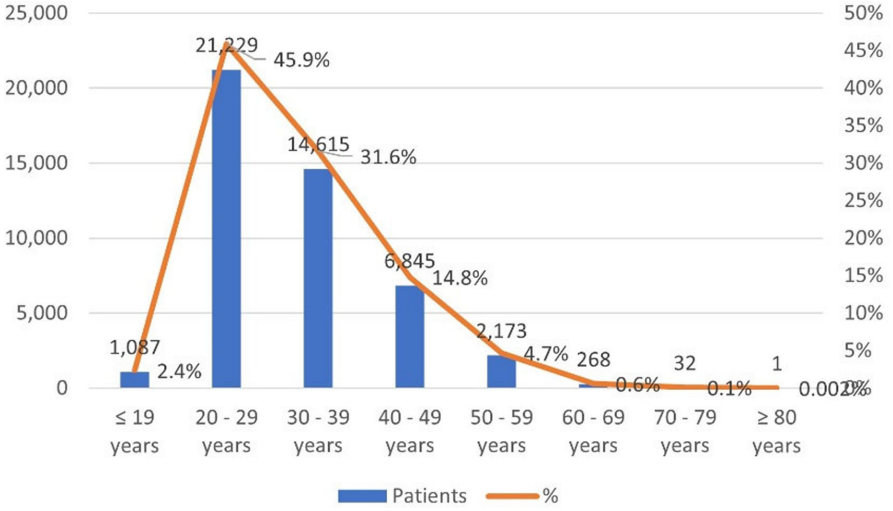

FIGURE 1 Age distribution in the total study cohort in 2022 ($n = 46\,250$).

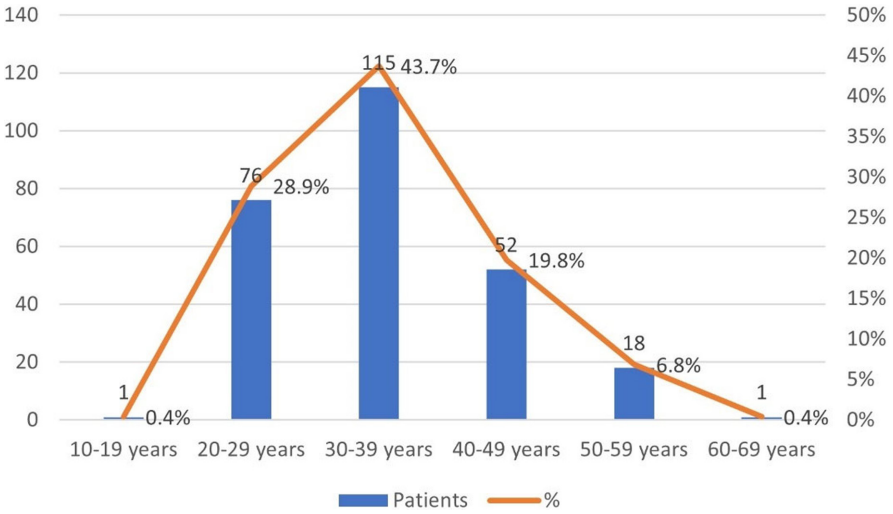

FIGURE 2 Age distribution of the patients with physician-diagnosed AEs ($n = 263$).

The average age of patients with AEs was 35.2 ± 8.6 years (range: 17–62 years). The age distribution of patients with physician-diagnosed AEs is shown in Figure 2. Patients in their 30s were the most common age group. The average number of days from the first treatment to the revisit was 35.1 ± 44.8 days (range: 1–353 days). The average number of times each patient had received BTX-A injections prior to the current treatment was 1.8 ± 2.9 (range: 0–24). Regarding the ethnic distribution of patients with physician-diagnosed AEs, 95.1% ($n = 250$) were Japanese and 100% ($n = 263$) were Asian.

The average number of days from treatment until confirmation of improvement of AEs was 159.6 ± 113.6 days (range: 13–667 days). All AEs were temporary rather than permanent. Therefore, the improvement rate for AEs was 100%.

3.3 | Analyses of patients with AEs

The most common AE was paradoxical bulging ($n = 230$), followed by pain ($n = 12$). Forty patients were lost to follow-up. Among the patients with AEs, 54.0% ($n = 142$) received intervention comprising additional injections of BTX-A, whereas 46.0% ($n = 121$) received follow-up observation (Table 1).

As described above, there were 40 patients lost to follow-up; therefore, the remaining 223 patients were included in the study. Among the 223 patients, the average period from treatment until confirmation of improvement was 159.6 ± 113.6 days (range: 13–667 days) for all AEs and all AEs were temporary. The average period from treatment until confirmation of improvement was 166.1 days in the intervention group ($n = 122$) and 151.9 days in the follow-up observation group ($n = 101$) (Table 2). There was no significant difference between the intervention group and the follow-up observation group in the period until confirmation of improvement of AEs ($p = 0.24$).

3.4 | Case series

Data S1 summarizes the characteristics of the 61 of 263 patients with AEs. The criteria for inclusion in Data S1 were as follows:

TABLE 1 Numbers and management of each AE ($n = 263$).

AEs	Patients			
		Management afterward		
	Total	Intervention group	Follow-up observation group	Lost to follow-up
Paradoxical bulging	230	132	98	33
Pain	12	3	9	4
Sunken cheeks	7	2	5	1
Sagginess	5	1	4	1
Asymmetry	3	2	1	0
Loss of full smiling	2	0	2	0
Poor effect due to antibody	2	2	0	1
Headache	1	0	1	0
Wrinkling	1	0	1	0
Total	263	142	121	40

TABLE 2 Period from treatment until AE improvement ($n = 263$).

AEs	Average period from treatment until confirmation of improvement		
	Total ± SD (range)	Intervention group	Follow-up observation group
Paradoxical bulging	161.6 ± 114.8 (13–667)	164.7	157.3
Pain	176.5 ± 132.5 (15–375)	200.0	173.1
Sunken cheeks	83.0 ± 60.6 (23–184)	86.0	81.5
Sagginess	130.5 ± 52.1 (78–198)		130.5
Asymmetry	189.3 ± 117.0 (113–324)	227.5	113
Loss of full smiling	137.5 ± 161.9 (23–252)		137.5
Poor effect due to antibody	332.0	332.0	
Headache	55.0		55.0
Wrinkling	95.0		95.0
Total	159.6 ± 113.6 (13–667)	166.1	151.9

- All patients with AEs excluding paradoxical bulging.
- Patients with paradoxical bulging treated with some type of intervention and patients with special notes noted in the medical record.

The aim of creating this table (in other words, case series) was to share our practical clinical data for readers as reference material.

Data S1 also includes the results of the survey about the injection procedure completed by the clinicians administering the injections (injectors). The injectors reported that the AEs comprised paradoxical bulging ($n = 13$), pain ($n = 8$), sunken cheeks ($n = 3$), asymmetry ($n = 3$), loss of ability to smile fully ($n = 2$), and headache ($n = 1$), comprising 30 cases in total. Fifteen of the 30 patients received a bolus injection of BTX-A only in the deep layer of the masseter muscle, while 15 of the 30 patients received BTX-A at different depths from the deep layer to the superficial layer.

4 | DISCUSSION

The most common AE was paradoxical bulging ($n = 230$). In patients with significant masseter muscle hypertrophy, the muscle may have excessive contractions and a bulky appearance. BTX-A is used to reduce muscle activity by blocking nerve signals to the

muscle; however, in some cases, it may not adequately weaken the muscle, thus leading to paradoxical bulging.[12] In such cases, under normal circumstances, the analysis should have been performed by comparing the control group and the paradoxical bulging group. However, this was not possible in the present study because the grades of masseter muscle hypertrophy were not clearly differentiated.

Paradoxical bulging is considered to originate from the deep inferior tendon (DIT), which is located within the superficial layer of the masseter muscle.[13] When BTX-A is injected underneath the DIT, the toxin is blocked from diffusing into the more superficial muscle fibers, thus creating a discrepancy between the contractile capabilities of the deep and superficial layers. In some cases, overcompensation by nonparalyzed superficial muscle fibers creates prominent bulging. As reported by Rice et al., paradoxical bulging may also occur if a more superficial BTX-A injection fails to penetrate through the DIT, or if deeper fibers remain unaffected by the toxin.[14] It is important that injections must be precisely demarcated throughout the muscle and evenly spaced above and below the DIT for prevention the paradoxical bulging.[14] And it was reported by Bae et al. that the results of a study showing that the US-guided injection method, which visualizes the masseter muscle, is more effective in preventing paradoxical bulging that can occur with conventional blind injections.[15]

The masseter consists of three layers: superficial, middle, and deep.[16,17] The deep and middle layers of the masseter are basically vertical in direction and contraction, whereas the superficial layer is diagonal in direction and contraction, and many cases of paradoxical bulging represent this scenario.[18] Paradoxical bulging is caused by overcompensation of masseter muscle fibers in the superficial layer due to the neurotoxic weakness of the deep layer.[13]

Paradoxical bulging is more likely to occur in patients with high-grade masseter muscle hypertrophy. Therefore, to prevent this AE from occurring, it is important to inject a sufficient amount of BTX-A above and below the DIT at even intervals and to accurately demarcate and treat the entire muscle. Future studies are warranted to investigate this issue.

The duration of the effect of BTX-A is generally 6–12 months.[11] However, although the symptoms of AEs after BTX-A injections gradually improved, there were more patients ($n = 138$) that physicians considered as needing interventions for AEs than there were patients who only needed follow-up observation ($n = 122$). Herein, we discuss the preventions and countermeasures for these AEs.

Paradoxical bulging typically disappears within 1 week without any management; thus, this AE usually only requires follow-up observation. However, if the symptoms persist for 1–2 weeks, additional BTX-A injections into the superficial layer of the masseter muscle are recommended.[18]

BTX-A injections into other non-masseteric muscles, the parotid gland, and the marginal mandibular nerve can cause other AEs such as a loss of ability to fully smile, an asymmetric smile, sunken cheeks, difficulty in opening the mouth, xerostomia, and neurapraxia.[18] Kim[19] classified the anatomical arrangement of the risorius muscle fibers into the zygomaticus risorius, platysma risorius, and triangularis risorius. The risorius muscle is related to the depressor muscle of the oral commissure and inserts at the tubercle of the oral commissure in the following three layers: superficial, flush, and deep. The risorius muscle rises from 1/3 (or rarely 2/3) anterior to the masseter surface on the superficial muscular aponeurotic system. A well-developed risorius passes the fascia of the masseter and covers the lateral face superior to the parotid gland.[20] However, the bulging type (I–V) of the masseter muscle cannot be confirmed without ultrasonography.[11]

Currently, there is no standardized injection point or recommended dosage for administering BTX-A to the masseter muscles. Yi et al.[10] extensively analyzed studies investigating the anatomy of the masseter and proposed recommendations for effective and safe injection sites and techniques for BTX-A administration in the masseter (particularly in the context of facial contouring), with the aim of offering anatomical guidelines. Bae et al.[21] classified the masseter into four types and suggested that the medial part of the masseter is a hazardous zone into which the injection of BTX-A may affect the risorius, thus potentially resulting in iatrogenic unnatural facial expressions.

It is important for physicians to have accurate knowledge regarding the safety zone and masseter muscle layers before injecting BTX-A into the masseter.[2,18,22–25] It is also important for physicians to know how to identify and manage AEs of BTX-A injections into the masseter.

It is crucial to note that there were no permanent AEs in the present study, as all AEs were temporary. Furthermore, as the period from treatment until improvement of AEs included the time until the patients visited the clinics and the improvements were confirmed by a physician, the actual period is likely to be shorter than the recorded period. To clarify the period until improvement of AEs, we are planning to implement a more detailed follow-up study in the future. There was no significant difference in the period from treatment until confirmation of the improvement of AEs with versus without intervention, which shows that physicians must have adequate diagnostic ability to determine whether intervention is necessary or not.

Only one of the 61 341 procedures resulted in an AE due to the spread of BTX-A through the risorius muscle. Once BTX-A has spread through the risorius, it is usually recommended that the patient waits until the symptoms disappear on their own without administering additional injections. However, in this case, after the physician confirmed that BTX-A had been spread through the risorius, another 20 U was injected into the masseter. The reason for this decision was that the previous injection site was too medial in the masseter; therefore, there was no effect on the lateral part of the masseter muscle. Thus, an additional 20 U of BTX-A was injected to compensate for the contralateral effect in the lateral part of the masseter muscle.

AE management by physicians is generally divided into two main types: follow-up observation and intervention (Table 2). As mentioned above, the effect of BTX-A lasts for 6–12 months.[15]

Therefore, if the patient is observed as is without intervention, the symptoms of the AE will diminish over time. Thus, follow-up observation is the best management option in terms of both positive improvement and safety. However, another option for the management of AEs is additional BTX-A injections. Depending on how the initial BTX-A injection was performed, the value of further injections will vary. Poor management based on inaccurate diagnosis must be avoided as much as possible.

In the cases in which paradoxical bulging disappeared within 1 week and the cases in which it persisted for more than 1 week, the BTX-A worked only in the deep layer of the masseter muscle. Furthermore, even in the four patients who were injected at different depths (from the deep to the superficial layers), there was a tendency for the BTX-A to work only in the deep layer of the masseter muscle; in all these cases (#39, 46, 59, and 61 in Data S1), the time from the treatment until the revisit was more than 1 week.

5 | LIMITATIONS

This study had several limitations.

1. It is possible that some patients who received BTX-A injections may have visited other hospitals when the symptoms occurred. Consequently, these patients were not included in this study.
2. The masseter volume and morphological alterations of the masseter muscle in each case were not recorded, so we are not able to show these data.
3. It was impossible to record quantitative data regarding the grade of masseter muscle hypertrophy. Therefore, we were unable to perform quantitative analyses such as evaluating the post-treatment reduction in muscle volume or muscle force.
4. We were unable to identify which percentage of the cases with each AE disappeared within 1 week because some cases had missing data regarding the date of disappearance of the AE.

6 | CONCLUSIONS

1. All AEs were temporary rather than permanent.
2. All AEs improved within 22.2 months (within 5.3 ± 3.8 months on average).
3. There was no significant difference between the intervention group and follow-up observation group in the time from treatment until the improvement of AEs.

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DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the principal author (A.N.). The data are not publicly available due to their containing information that could compromise the privacy of research participants.

ETHICS STATEMENT

The study was approved by the Medical Corporation Shoubikai Ethics Committee (approval number 5-001) and conducted in accordance with the Declaration of Helsinki. All patients provided written informed consent for study inclusion.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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