

# Efficiency of ultrasound and water capsule-guided local injection of *botulinum* toxin type A treatment on patients with facial spasm

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**Abstract. – OBJECTIVE:** To study the efficacy of ultrasound and water capsule-guided local injection of botulinum toxin type A (BTX-A) treatment on patients with facial spasm.

**PATIENTS AND METHODS:** One hundred and fifty-seven cases of facial spasm were randomly divided into oral drug treatment group (group A) (78 cases) and ultrasound and water capsule-guided local injection of botulinum toxin type A treatment group (group B) (79 cases). Cohen, Acbert spasm strength grade scores in each case with facial spasm were recorded. Therapeutic effect, duration, significant efficiency, and muscle spasm strength were compared before and three after treatment.

**RESULTS:** The muscle spasm strength showed no significant change in group A after the treatment. However, the muscle spasm strength was decreased significantly in group B after treatment ( $p < 0.01$ ).

**CONCLUSIONS:** Ultrasound and water capsule-guided local injection of botulinum toxin type A treatment is a safe, effective, and simple treatment for patients with facial spasm.

*Key Words:*

Color Doppler ultrasound, Water capsule, Facial muscle, Dystonia, Botulinum toxin type A.

limited<sup>5,6</sup>. Local injection of *botulinum* toxin type A (BTX-A)<sup>7,8</sup> is used widely at home and abroad by the way of unarmed injection, but with lots of side effects such as keratitis, difficulty in swallowing, weakness of facial muscles, incensement of tears, or dry eyes. It is of great importance to find out an effective injection method, and this study that adopted ultrasound and water capsule-guided local injection of *botulinum* toxin type A (BTX-A) treatment on patients with facial spasm achieved satisfactory results.

So we consider that adopted ultrasound and water capsule-guided local injection of BTX-A is an effective way to treat hemifacial spasm. It is convenient operation and can be carried out at a clinic. It has no systemic complications, less local complications and natural elimination within a short time and it is also rapid for patients with pain. It is easy accepted by patients and worthy of clinical use. Attention should be paid to individual treatment process. Intramuscular injection and injection site should be correctly chosen and the complications like lower eyelid with ptosis back, blink less, lagophthalmos and facial muscle weakness should be decreased. BTX-A is a safe and effective biological agent, as long as the injection method and position is correct, it can reduce the pain of the patients and can be applied in the primary hospital.

## Introduction

Facial spasm<sup>1,2</sup> is a chronic progressive neuromuscular dysfunction, often characterized by intermittent or continuous involuntary spasm or twitch on partial muscle, which brings adverse effect on the patients' physical and mental health.

Microvascular decompression<sup>3,4</sup> is a therapy to remove the compression and stimulation of facial nerve from the local blood vessels currently with 80-90% cure rate, but there are some risks and complications so that its extensive application is

## Patients and Methods

### General Information

From January 2009 to July 2011, there were 157 cases of patients (95 men and 62 women) with facial spasm in our department including outpatients and inpatients at the age of 20-62 years old and with the course of disease from 6

months to 12 years, excluding patients who were with systemic muscle weakness such as secondary dystonia, myasthenia gravis, Eaton-Lambert syndrome, motor neuron disease and so on, allergic constitution, pregnant women, patients with serious abnormal heart, liver, kidney and other important viscera, with severe cognitive dysfunction, mental disorders, asthma history, fever, infectious disease, and once took drugs that exacerbated the transmission disorder of neuromuscular junction. This study was approved by the hospital Ethics Committee and lasted for 15 months. All of the patients signed the informed consent and then registered to their groups, with the examination of blood routine, urine routine, liver and kidney functions, electrocardiogram and electroencephalogram before treatment. These patients were divided into groups A (78 cases) and B (79 cases) by the method of random number table choice. The general information of these two groups was without any significant differences in statistics.

### **Methods**

Group A was given unarmed injection of BTX-A, while B group was given ultrasound and water capsule-guided injection of BTX-A. BTX-A was produced by Lanzhou Institute of Biological Products, the Ministry of Health, as a form of dry and cold crystallizing agent, with 100 U per ampoule.

BTX-A injection required patients supine with the preparation of normal saline as 25 U/ml 1 finishing the injection within 1 h (longest 4 h or less) after the preparation as far as possible; each locus was injected 5 U BTX-A with 1 mL syringe for skin test, No. 4.5 or No. 5 needle (No. 6 needle for deep muscle)<sup>9</sup>. The locus and dose of injection were determined by two chief physicians, from the Department of Neurology according to the size and amount of muscle, facial spasm type, degree of spasm, who did not know this experiment design; Choose muscle: unilateral orbicularis oculi muscle, levator labii superior alaeque nasi, levator labii superior, zygomatic major, musculus risorius, orbicularis oris, platysm, and levator anguli oris were chosen, respectively. If tinnitus happened, posterior auricularis muscle should also be injected. We adopted multipoint and layered injection method with 1.5 cm locus separation, and injection into blood vessel is prohibited strictly<sup>10-12</sup>. People with poor curative effect were supposed to be injected once more after a week. After 1 and 4 weeks, the patients were checked; then, reexamination could carry out once a

month, to observe the situation of facial spasm, which was executed by two physical therapists who were ignorant of this experiment design on the basis of unified table independently, and the result depended on the average. One chief physician who did not know this experiment design from department of neurology recorded the details of evaluation results, time of function, time of top efficacy, time of duration for efficacy, side effects, adverse reactions, blood routine, urine routine, liver and kidney function, electrocardiogram, electroencephalogram, and so on<sup>13,14</sup>.

Color ultrasound guidance was using portable ultrasound, and the operation steps were as follows: Patients lied on their backs. We disinfected injection skin with iodophor and smeared couplant on the probe of color ultrasound device when the skin is dry<sup>15</sup>; siphoned about 20 mL normal saline with syringe into water capsule, which were placed between the probe and skin to improve the resolution of ultrasonic image. With the direction of location map of color ultrasound, we cleared out the muscle and cross-sectional area to inject and made sure the locus and dose; and we injected BTX-A beside the water capsule into the selected muscle<sup>16</sup>. Under the visual image of ultrasound, we could carry out layered injection (two layers or three layers) in terms of the depth of muscle. In addition, we should pay attention to avoid blood vessels and nerves<sup>17</sup>.

### **Evaluation of Efficacy**

The degree of muscle spasm is classified by Cohen and Albertc spasm strength: level 0 stands for no spasm; level I stands for the increment of blinking stimulated by external; level II stands for mild blepharospasm and facial spasm without dysfunction; level III stands for moderate spasm, with spasm and mild dysfunction; level IV stands for severe serious spasm and dysfunction, with small eyelid fission, affecting work, walk, drive, reading, etc. The efficiency of these two groups was evaluated by Cohen and Albert spasm strength grade according to before and after treatment, respectively. After treatment, reduction from level II-IV to level 0 means complete remission; from level II-III to level I or from level IV to I-II means remission; from level III to level II or from level IV to level III means partial remission; no reduction means invalidity. The sum of complete remission and obviously remission is marked improvement.

### Statistical Analysis

We adopted statistical software to process these data, and the results were shown as  $\pm s$ ,  $t$ -test, and  $p < 0.05$  as difference with statistical significance.

### Result

The curative effect, marked improvement rate, and side effect incident rate of group A are higher than group B, with significant difference ( $p < 0.05$ ), and the durations of group A and group B were compared, without significant difference ( $p > 0.05$ ), which is shown in Table I.

The muscle spasm strength of group A is higher than that of group B, with significant difference ( $p < 0.01$ ), which is shown in Table II.

### Discussion

The etiology of facial spasm is unknown, which is often treated by pharmaceutical, acupuncture, physical therapy, etc., but the efficacy is unsatisfactory<sup>18-20</sup> and with some risks. Since the introduction of BTX-A to neurology treatment of focal dystonia<sup>21</sup>, it became the first-line drug for its good efficacy, little serious side effects, easy operation, etc. BTX-A that belongs to anaerobic *Clostridium* is a kind of macromolecular protein toxin produced by *Clostridium botulinum*<sup>22</sup>. After local injection, BTX-A diffuses in muscle and acts on peripheral cholinergic nerve endings, to control the release of acetylcholine from nerve endings through blocking calcium influx, leading to the relaxation of contractile muscle fibers<sup>23</sup>.

This research shows that the total effective rate of group B is 100%, and the marked improvement is 85.1%, similar with related reports<sup>24-26</sup>. The curative effect of *botulinum* toxin injections is closely associated with accurate muscle position. Electromyogram guide is direct, but the large motor units shown by electromyography with bleep only can prove the proximity of needle to contractile muscle fiber, which cannot indicate that the pinpoint lies in the target muscle. It also requires for special instrument and great operation skill<sup>27</sup>. Facial muscle is relatively shallow and bumpy with loose structure, with unarmed injection at home and abroad at present. We take use of water capsule to make up for the disadvantage of electromyography-guide and ultrasound-guide effec-

Table I. Clinical classification, injection dosage, efficacy, duration, marked improvement rate, and incident rate of side effect.

Groups	Classification	n	Injection dosage ( $\mu$ )	Efficacy (case)					Duration (w)	Marked improvement rate (%)	Incident rate of side effect (%)
				Complete remission	Obviously remission	Partial remission	Invalidity				
Unarmed	Blepharospasm	25	30-35	5	8	9	3	14.2 $\pm$ 1.3	52	32	
	Facial spasm	28	35-40	8	7	10	3	15.1 $\pm$ 1.1	55.6	30	
	Hybrid	26	55-75	9	6	9	2	13.9 $\pm$ 1.4	53.8	31	
Ultrasound	Blepharospasm*	24	25-35	12	7	5	0	14.3 $\pm$ 3.6	79.1	6	
	Facial spasm*	27	30-35	14	8	5	0	16.4 $\pm$ 5.3	85.1	7	
	Hybrid*	27	50-70	13	10	3	1	13.6 $\pm$ 4.2	85.1	9	

\*Represents the comparison with corresponding group  $p < 0.05$ .

**Table II.** Spasm strength and change of two groups before and after treatment.

Projects		Level 0-1	Level 2	Level 3	Level 4
Unarmed	Before treatment	0	15	25	39
	After treatment	22	21	19	17
Ultrasound	Before treatment	0	16	27	35
	After treatment <sup>#</sup>	39	25	11	3

<sup>#</sup>Represents the comparison with corresponding group  $p < 0.01$ .

tively, as a result, the surface becomes smooth, so that we can take the advantage of ultrasound fully. As a new technology of intramuscular positioning, ultrasound has no trauma, no pain, high resolution that targets muscle, and its surrounding nerve blood vessels can display clearly. Under ultrasound, muscles are characterized by hypoechoic, tendons by tubular hyperechoic line (fibrous), and muscle fascia is characterized by hyperechoic; the resolution of high frequency ultrasound is high so that the target muscle and its peripheral nerve blood vessels are visible.

Water capsule can reduce the influence of probe on the needle point and fix the positions of skin and needle, and the ultrasonic image resolution can be improved at the same time, with easy production that can be widely used in clinic. This study, which was guided by color Doppler ultrasound instrument, not only can position the needle to reach the target muscle accurately, but also can avoid the peripheral blood vessels and nerves; it can reduce drug consumption without affecting the curative effect and guarantee the accuracy of the drug to the action part. The results of this research show that the duration of these two groups has no comparison difference in statistic, which means *botulinum* toxin has efficacy for this disease but only can last for some time<sup>28</sup>, so it can be injected repeatedly. The comparison difference of marked improvement rate, incident rate of side effect and spasm strength for these two groups has statistical significance. It shows that ultrasound and water capsule can avoid inaccurate positioning due to fast speed, hard strength, or lower injection point of unarmed injection that can result in reduction of efficacy and increment of side effects. It was reported that the side effect can reach 31-53%; however, there was not any allergic reaction and severe side effects, impaired swallowing, choke, and cough for drinking, with related reports as 12-80%<sup>29,30</sup>.

### Conflict of Interest

The Authors declare that they have no conflict of interests.

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