# Hemifacial Spasm: Results of Treatment with Low Dose Botulinum Toxin Injection

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***Background :*** *Hemifacial Sapsm (HFS) is a common movement disorder in Thailand. Botulinum toxin type A (BTA) is an effective and safe treatment for this condition. The success of BTA treatment depends on the experience of the clinician.*
***Objective :*** *To study the demographic data, efficacy and safety of low dose BTA injection in HFS patients.*
***Setting :*** *The Spastic and Dystonia Clinic, Department of Rehabilitation Medicine, King Chulalongkorn Memorial Hospital.*
***Design :*** *Open-label, prospective case-series study.*
***Patients :*** *All patients with HFS referred for BTA injection from December 1st, 1995 to November 30th, 2003.*
***Method :*** *Sex, age, side of spasm, onset of symptoms before BTA injection, underlying diseases, sites of BTA injection, dose of each BTA treatment, duration of response, efficacy, and side-effects were analyzed. 3-5 units of BOTOX were intramuscularly injected per site to all muscles that had spasm. After injection, a 20-minute cold compression on the first day was followed by 20-minute warm compression with massage at each injection site per day for 14 days.*
***Results :*** *A total of 112 patients with HFS were treated with 874 BTA treatments. There were 71 females (63.4%) and 41 males (36.6%). The mean age was 45 years. 75 patients (67%) were affected on the left side. Mean duration of symptoms was 3.4 years. The sites of injection were orbicularis occuli and orbicularis oris muscles in all 874 treatments (100%). The mean dose of all treatments was 25 units. The mean initial dose was 30.5units.The mean dose for subsequent injection was 23 units. The mean duration between treatments was 4.7 months. The mean initial duration was 3.5 months. The mean duration for subsequent injection was 4.8 months. The outcomes of treatment assessed at 4 weeks after injection classified as excellent (> 80% improvement) were found in 845 treatments (96.7%). Most treatments had no complication (91.9%). Ptosis, facial paresis and double vision were mild and transient, lasting 1-4 weeks. There were no long-term complications of BTA treatment in the present series.*
***Conclusion :*** *Low dose BTA injection is an effective treatment for hemifacial spasm patients. There was a longer duration of response in subsequent injections and a lower complication rate in the present study when compared to others.*

***Keywords :*** *Botulinum toxin, Hemifacial spasm*

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Hemifacial spasm (HFS) is clinically marked by involuntary unilateral contraction of the muscular system innervated by the facial nerve[1]. Its clinical picture may vary substantially. Some patients may merely present with contractions of the orbicularis occuli muscle; in other patients, however, the entire musculature innervated by the facial nerve including platysma may be involved. Mild progression of the symptom is seen in many cases[1]. HFS is often triggered by fatigue, anxiety, stress, reading and driving; it may persist during sleep[2,3]. Rarely, HFS can be bilateral or familial[2]. HFS causes embarrassment and an inferiority complex to the patient. In general, HFS

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is caused by mechanical compression by redundent vessel and distortion of the root exit zone of the facial nerve by an aneurysm which are regarded as idiopathic[2,3]. Lipoma, epidermoid tumor, arterio-venous malformation have been found in less than 1% of the cases[2,3]. Vessel-nerve contact results in mild facial paralysis and may be demonstrated by MRI. Conventional treatment with carbamazepine is only occationally effective, and the side effect is unacceptable to many patients[4]. The surgical treatment is vascular decompression of the facial nerve, which usually gives excellent results (84%)[5]. However, complications are serious, i.e. facial weakness (4.2%), transient facial weakness (3.2%), permanent hearing loss (3.2%), brain stem infarct (0.3%), cerebellar hematoma (0.5%), CSF leak (2.4%) and operative death (0.1%).[5]

Since 1990, many studies have shown that local injection of botulinum toxin is effective for HFS. Different evaluation criteria had been employed in these studies, making comparison difficult. In summary, good to excellent improvements were reported in 76% to 100%[6-8] of these patients. The mean duration of action of each injection ranged between 2.6 and 4[9,10] months. The most common side effects were dry eye 7% to 18.1%[11,12] ptosis 2.8% to 23.3%[12,13] facial weakness 17.6% to 97%[13,14] tearing 5.5%[12] and diplopia less than 1% to 6%[11,15]. All of these undesired effects were transitory, untoward systemic effects were not quoted in any study. The conclusion is that botulinum toxin injections are safe and highly effective treatment of HFS[1].

The authors present here the long-term results of efficacy and safety of low dose botulinum toxin A (BTA) injection in HFS patients over an 8-year period.

## Objective

The objective was to study the demographic data as well as efficacy and safety of low dose BTA injection in HFS patients.

## Study design

Open-label, prospective case-series study.

## Patients and Method

All patients with HFS referred for BTA injection at the Spastic and Dystonia Clinic, Department of Rehabilitation Medicine, King Chulalongkorn Memorial Hospital, Bangkok, Thailand from December 1st 1995 to November 30th, 2003 were analyzed. Demographic data such as sex, age, side of hemifacial spasm, onset of symptoms before BTA injection, underlying diseases (hypertension, diabetes mellitus, heart disease, stroke), history of Bell's palsy, history of head trauma, history of tinnitus, previous surgery (micro vascular decompression of the facial nerve), sites of BTA injection, dose of each BTA treatment, duration of response, efficacy, immediate side-effects, long-term side effects and spontaneous remission (no need for injection over two years) were reported. Data analysis were presented as number (n) and percentage of patients, mean $\pm$ standard deviation (x + SD) and range.

### *Study drug*

Botulinum toxin type A (BOTOX®, 100 unit per vial, Allergan, INC) was reconstituted for injection to yeild 50 unit/ml by 0.9% sterile unpreserved saline solution by the first author.

### *Injection technique and care after injection*

With the patient in a lying position, the injection sites (as shown in Fig. 1) were chosen by clinical assessment of spasm. The injection sites were cleaned with 70% alcohol and BOTOX was injected intramuscularly 3-5 unit each site. A thirty gauge-needle attached to a tuberculin syringe was used for injection. After injection, 20-minute cold compression on the first day and then 20- minute warm compression with massage at the injection sites for 14 days.

### *Assessment and follow-up*

The outcomes of the treatment were assessed by the investigators at 4 weeks after injection. They were classified as excellent (> 80% improvement), good (60-80% improvement), fair (20-60% improvement), poor (1-20% improvement) and no improvement. In

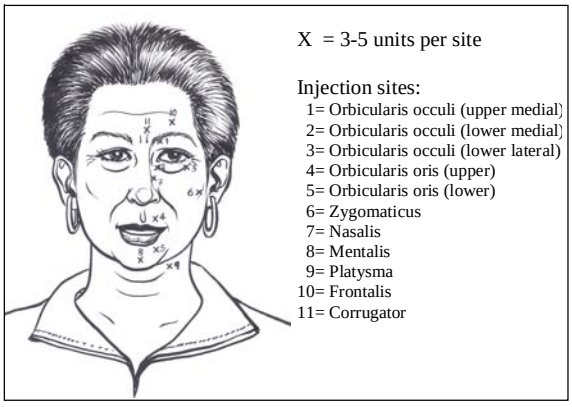



**Fig. 1** Demonstration of injection sites and botulinum toxin usage

addition, complications were assessed by the investigators. Generally, appointment was made every three months for each treatment, but the frequency of their visits were adjusted to accommodate individual needs.

## Results

A total of 112 patients with HFS were treated with 874 BTA treatments during a period of 8 years. The demographic data of all patients are shown in Table 1.

There were 71 females (63.4%) and 41 males (36.6%). The mean age of all patients was 45 $\pm$ 11.1 years (range 24-67 years). Of the 112 HFS patients, 75 (67%) were affected on the left side. Their mean duration of symptoms before treatment was 3.4 $\pm$ 3.1 years (range 1-12 years). The mean follow-up period was 3.5 $\pm$ 2.5years (range 1-8 years). Several patients had underlying diseases: hypertension in 12 patients (10.71%), diabetes mellitus in 8 patients (7.1%), heart disease in 8 patients (7.1%), and stroke in 2 patients (1.8%). History of Bell's palsy in 1 patient (0.9%), tinnitus in 5 patients (4.5%), and history of microvascular decompression of the facial nerve in 1 patient (0.9%) were recorded.

The sites of injection were mostly orbicularis occuli muscle in 874 treatments (100%), orbicularis oris muscle in 874 treatments (100%), zygomaticus muscle in 468 treatments (53.5%), nasalis in 136 treatments (15.6%), mentalis in 168 treatments (19.2%), platysma in 46 treatments (5.3%), frontalis in 42 treatments (4.8%), and corrugator in 34 treatments (3.9%) as shown in Table 2.

The mean dose of BOTOX® of all treatments was 25 $\pm$ 0.6 units (range 10-45 units) per injection. There was decrement in the mean dose for each subsequent injection. The mean initial dose was 30.5 $\pm$ 0.4 units (range 20-45 units), the second 29.5 units, the third 29 units, the fourth 28.5 units, the fifth 28 units, the sixth 28 units, the seventh 28 units, the eight 27 units, the ninth 26 units, and the tenth 25 units. The mean dose of subsequent injection was 27.5 $\pm$ 0.5 units (range 10-35 units) as shown in Table 3 and Fig. 2.

The mean duration of response of all treatments was 4.1 $\pm$ 0.4 months (range 3-6 months). The durations also increased each subsequent injection. The mean initial durations was 3.5 $\pm$ 0.4 months (range 3-5 months), the second 3.8 months, the third 4.0 months, the fourth 4.1 months, the fifth 4.3 months, the sixth 4.3 months, the seventh 4.4 months, the eight 4.5 months, the ninth 4.6 months, and the tenth 4.8 months. The mean duration of subsequent injection was 4.8 $\pm$ 0.4 months (ranged 3-6 months) as shown in Table 3 and Fig. 3. There were 5 patients (8.9%) with spontaneous remission (i.e. injection free interval lasting more than two years).

**Table 1.** Demographic data of the all treatments

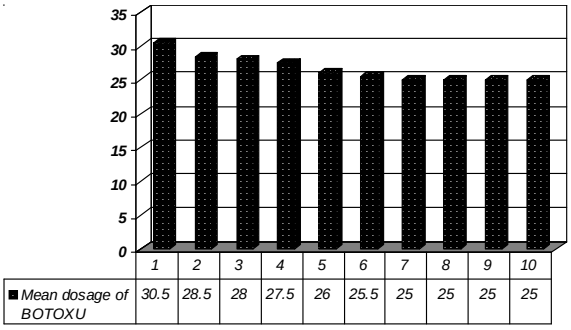
| | | | |
|---|---|---|---|
| Sex: | Male | 41 patients | 36.6% |
| | Female | 71 patients | 63.4% |
| Age (yrs) | | 45 (SD 11.1) range 24-72 | |
| Side of HFS | Right | 37 patients | 33.0% |
| | Left | 75 patients | 67.0% |
| Duration of symptoms before treatment (yrs) | | 3.4 (SD 3.1) range 1-12 | |
| Follow up period (yrs) | | 3.45 (SD 2.45) range 1-8 | |
| Associated conditions | | | |
| History of Bell's palsy | | 1 patient | 0.9% |
| History of tinnitus | | 5 patients | 4.5% |
| History of Microvascular decompression | | 1 patient | 0.9% |
| Underlying diseases | | | |
| Hypertension | | 12 patients | 10.7% |
| Diabetes mellitus | | 8 patients | 7.1% |
| Heart disease | | 8 patients | 7.1% |
| Stroke | | 2 patients | 1.8% |

**Table 2.** The sites of BOTOX injection in 874 treatments

| Muscles | No. of Treatments |
|---|---|
| Orbicularis occuli | 874 (100%) |
| Orbicularis oris | 874 (100%) |
| Zygomaticus | 468 (53.5%) |
| Nasalis | 168 (19.2%) |
| Mentalis | 136 (15.6%) |
| Platysma | 46 (5.3%) |
| Frontalis | 42 (4.8%) |
| Corrugator | 34 (3.9%) |

**Table 3.** Dose of BOTOX and duration of response

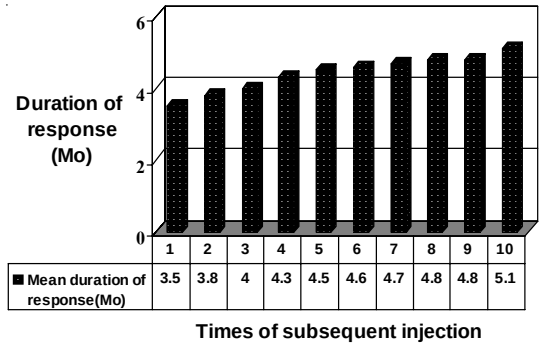
| | n | Mean | range |
|---|---|---|---|
| Dose of BOTOX of all treatment (units) | 874 | 25.0 (SD0.6) | 10-45 |
| Initial dose of BOTOX (units) | 112 | 30.5 (SD0.4) | 20-45 |
| Dose of subsequent injection (units) | 762 | 25.5 (SD0.5) | 10-35 |
| Duration of response of all treatment (months) | 874 | 4.7 (SD0.4) | 3-6 |
| Initial duration (months) | 112 | 3.5 (SD0.4) | 3-5 |
| Duration of subsequent injection (months) | 762 | 4.8 (SD0.4) | 3-6 |




N1=112 patients; N2=105 patients; N3 = 102 patients; N4=99 patients; N5= 98 patients; N6= 95 patients; N7=86 patients; N8= 75 patients; N9= 58 patients; N10= 44 patients

There was continuously decrement in mean dosage of BOTOX® in subsequent injection

**Fig. 2** Mean dosage of BOTOX® in each subsequent injection




N1=112 patients; N2=105 patients; N3 = 102 patients; N4=99 patients; N5= 98 patients; N6= 95 patients; N7=86 patients; N8= 75 patients; N9= 58 patients; N10= 44 patients

There was increment in mean duration of response of BOTOX® in subsequent injection

**Fig. 3** Mean duration of BOTOX® in each subsequent injection

The outcomes of treatment assessed at 4 weeks after injection were classified as: excellent (> 80% improvement) in 845 treatments (96.7%), good (60-80% improvement) in 25 treatments (2.9%), fair (20-60% improvement) in 3 treatments (0.3%), poor (1-20% improvement) in 1 treatment (0.1%) and no case without improvement, as shown in Table 4.

There was no complication in most treatments (91.9%). The immediate complications were ptosis (2.9%), mild facial paresis (3%), double vision (1.7 %), lacrimation (0.6%) and as shown in Table 5. These complications were transient, lasting only 2-4 weeks.

**Table 4.** Outcomes of treatments

| Outcomes | No of Treatments |
|---|---|
| Excellent (> 80%) | 845 (96.7%) |
| Good (60-80%) | 25 (2.9%) |
| Fair (20-60%) | 3 (0.3%) |
| Poor (1-20%) | 1 (0.1%) |
| No improvemt | 0 (0%) |

**Table 5.** Immediate side-effects of Botox injection

| Side-effects | No of Treatments |
|---|---|
| No complication | 803(91.9%) |
| Mild ptosis | 25(2.9%) |
| Mild facial paresis | 26(3%) |
| Double vision | 15(1.7%) |
| Excessive lacrimation | 5(0.6%) |

There was no long-term complication of botulinum toxin treatment in the present series.

## Discussion

HFS usually appears between the fourth and fifth decade of life[16], as found in the present series (i.e. mean age of the onset was 45 yrs). The spasm most notably involves the orbicularis occuli, orbicularis oris, zygomaticus, frontalis and mentalis muscles on one side of the face[16], as in the present series. As the condition progresses, twitching becomes more obvious on involuntary movement all ipsilateral facial as well as the superficial muscles of the neck. Occasionally, the involvement of the stapedius muscle of the middle ear may cause the patients to have auditory symptom characterized by a "thumping" or "clicking" noise associated with the spasm. Occasionally, the patient may complain of tinnitus and hearing loss. In our series, althrough injection at stapedius muscle was not possible, the authors found that tinnitus and clicking in the ear disappeared when injected BTA at zygomaticus.

The response rate of the patients is compared to other series in Table 6[9,11,17-21]. The presented data showed 98% improvement that is also comparable to the other series. The difference between the duration of improvement and the dose are attributed to different types of botulinum toxin (BOTOX vs Dysport), differences in injection sites and techniques, difference in dose per injection site.

The mean dose of all treatments was 25 units, similar to that of Poungvarin et al[19] but lower than

**Table 6.** Long-term results in reported series of botulinum toxin treatment

| Type of BTA | Authors | Follow up (Yrs) | Pts (n) | No of Treatments | Mean dose (Units) | Response rate (%) | Duration of response (Months) | Side effect (%) |
|---|---|---|---|---|---|---|---|---|
| BOTOX | Dutton, et al.[11] | 4 | 60 | 148 | - | 96.8 | 3.6 | 23 |
| | Taylor, et al.[17] | - | 130 | 336 | - | 98 | 4.23 | 32 |
| | Flanders, et al.[18] | 8 | 65 | - | 34 | 100 | 4.06 | 8 |
| | Poungvarin, et al.[19] | 10 | 875 | 3,061 | 25 | 98 | 4.06 | 24.4 |
| | Suputtitada, et al. | 8 | 112 | 874 | 25 | 98 | 4.68 | 8.13 |
| Dysport | Elston [20] | 7 | 73 | - | 120-160 | 75 | 2.8-3.5 | 19-33 |
| | Bergh, et al.[21] | 5 | 40 | 144 | 53 | 100 | 4.93 | 22 |
| | Jitpimolmard, et al.[9] | 7 | 175 | 883 | 92 | 97 | 3.4 | 29 |

that of Flanders et al[18]. At the authors' center, low-dose regimen for every condition treated with BTA is always used[22-27]. The possible explanations were: 1) the smaller muscle mass of Thai patients; and 2) the tropical climate in Thailand may facilitate extensibility of the spastic muscle.

The mean dose in the initial treatment in the present study (30.5 units) was higher than that of subsequent treatments (25 units). The mean duration of the initial treatment (3.5 months) was shorter than that of subsequent treatments (4.8 months). These implied that the severity of the symptoms seem to be lessened with the subsequent treatments. Possible explanation may be that: 1) there were adaptation of receptors of the spastic muscles, 2) there was BTA accumulation at the neuromuscular junction, and 3) there was no clinical resistence over long-term subsequent injection. There was longer duration of response in the present study when compared to others[9,11,17-21].

Also, there was a lower complication rate in the present study when compared to others[9,11,17-21]. These may be due to: 1) lower dose of BTA used per site, 2) different sites of injection were chosen, 3) the cold and hot compression with massage which may cause better diffusion of the toxin after injection.

## Conclusion

Low dose BTA injection is an effective treatment for hemifacial spasm. There was a longer duration of response in subsequent injections and a lower complication rate in the present study when compared to others.

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## *ภาวะใบหน้ากระตุกครึ่งซีก: การรักษาด้วยการฉีดโบทูลินัมทอกซินขนาดน้อย*

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***ปัญหา*** *: ภาวะใบหน้ากระตุกครึ่งซีกเป็นภาวะการเคลื่อนไหวผิดปกติที่พบบ่อยในประเทศไทย การฉีดโบทูลนัมทอกซินมีประสิทธิภาพและปลอดภัยในการรักษาภาวะนี้ ผลสำเร็จของการฉีดโบทูลนัมทอกซินขึ้นกับประสบการณ์ของแพทย์ผู้ทำการรักษา*

***วัตถุประสงค์****: เพื่อศึกษาลักษณะทางคลินิกประสิทธิภาพและความปลอดภัยในการฉีดโบทูลนัมทอกซินขนาดน้อยในการรักษาภาวะใบหน้ากระตุกครึ่งซีก*

***สถานที่ที่ทำการศึกษา*** *: คลินิกลดอาการเกร็งและบิดกระตุกของกล้ามเนื้อ ฝ่ายเวชศาสตร์ฟื้นฟู โรงพยาบาลจุฬาลงกรณ์*

***รูปแบบการศึกษา*** *: แบบไปข้างหน้า ติดตามผลการรักษาระยะยาว โดยไม่มีกลุ่มควบคุม*

***ผู้ป่วยที่ได้ทำการศึกษา*** *: ผู้ป่วยใบหน้ากระตุกครึ่งซีกทุกรายที่ส่งมาเพื่อรับการฉีดโบทูลนัมทอกซิน ระหว่าง 1 ธันวาคม 2538 และ 3 พฤศจิกายน 2543*

***วิธีการศึกษา*** *: เก็บข้อมูลผู้ป่วยด้าน อายุ เพศ ข้างที่มีใบหน้ากระตุก ระยะเวลานานของการมีอาการ โรคประจำตัว ตำแหน่งฉีดยา ขนาดยา และระยะเวลาการออกฤทธิ์ของโบทูลนัมทอกซิน ประสิทธิภาพ และฤทธิ์ข้างเคียง ฉีดยา BOTOX เข้าใต้ผิวหนัง 3-5 ยูนิต ต่อจุด ฉีดทุกจุดของกล้ามเนื้อที่กระตุก หลังฉีดประคบน้ำแข็ง 20 นาที ในวันแรก และน้ำอุ่น 20 นาที ในวันต่อมา ทุกวันจนครบ 14 วัน พร้อมกับนวดคลึงตรงจุดที่ฉีดยาหลังประคบทุกวัน*

***ผลการศึกษา*** *: ผู้ป่วยใบหน้ากระตุกครึ่งซีกทั้งหมด 112 ราย ได้รับการฉีดโบทูลนัมทอกซิน 874 ครั้ง เป็นหญิง 71 ราย (63.4%) ชาย 41 ราย (36.6%) อายุเฉลี่ย 45 ปี มีอาการกระตุกที่ใบหน้าซีกซ้าย 75 ราย (67%) ระยะเวลาเฉลี่ยตั้งแต่ เริ่มมีอาการ 3.4 ปี ตำแหน่งฉีดยาส่วนใหญ่ คือ กล้ามเนื้อ orbicularis occuli และ orbicularis oris ทั้งสองตำแหน่ง ตำแหน่งละ 874 ครั้ง (100%) ขนาดยาเฉลี่ยของการรักษาทั้งหมด 25 ยูนิต ขนาดยาเฉลี่ยของการรักษาครั้งแรก 30.5 ยูนิต ครั้งต่อมา 23 ยูนิต ระยะเวลาเฉลี่ยของการตอบสนองของยาของการรักษาทั้งหมด คือ 4.7 เดือน ระยะเวลาเฉลี่ยของการรักษาครั้งแรก คือ 3.5 เดือน ครั้งต่อมา คือ 4.8 เดือน ผลการรักษาเมื่อประเมิน 4 สัปดาห์หลังฉีดยาพบว่าได้ผลดีมาก (ดีขึ้น >80%) ถึง 845 ครั้งของการรักษา (96.7%) การรักษาส่วนใหญ่ไม่พบฤทธิ์ข้างเคียงอันไม่พึงประสงค์ (91.9%) ได้แก่ อาการหนังตาตก ใบหน้าอ่อนแรง หรือเห็นภาพซ้อน ที่พบจะไม่รุนแรง และอยู่ชั่วคราวเพียง 1-4 สัปดาห์ ไม่พบฤทธิ์ข้างเคียงใด ๆ ระยะยาว*

***สรุป :*** *การฉีดโบทูลนัมทอกซินขนาดน้อยเป็นการรักษาภาวะใบหน้ากระตุกครึ่งซีกที่มีประสิทธิภาพ และพบว่าระยะเวลานาน ในการออกฤทธิ์ของยาเมื่อฉีดครั้งต่อมาจะยาวนานกว่า และฤทธิ์ข้างเคียงอันไม่พึงประสงค์น้อยกว่าเมื่อเทียบกับ การศึกษาอื่น*