



Clinical Study

Botulinum toxin injections for the treatment of hemifacial spasm over 16 years



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ABSTRACT

The aim of this study was to investigate the efficacy and side effects of botulinum toxin (BTX) in the treatment of hemifacial spasm (HFS). We also focused on the divergence between different injection techniques and commercial forms. We retrospectively evaluated 470 sessions of BTX injections administered to 68 patients with HFS. The initial time of improvement, duration and degree of improvement, and frequency and duration of adverse effects were analysed. Pretarsal and preseptal injections and Botox (Allergan, Irvine, CA, USA) and Dysport (Ipsen Biopharmaceuticals, Paris, France) brands were compared in terms of efficacy and side effects, accompanied by a review of papers which reported BTX treatment of HFS. An average of 34.5 units was used per patient. The first improvement was felt after 8 days and lasted for 14.8 weeks. Patients experienced a 73.7% improvement. In 79.7% of injections, no adverse effect was reported, in 4.9% erythema, ecchymosis, and swelling in the injection area, in 3.6% facial asymmetry, in 3.4% ptosis, in 3.2% diplopia, and in 2.3% difficulty of eye closure was detected. Patients reported 75% improvement on average after 314 sessions of pretarsal injections and 72.7% improvement after 156 sessions of preseptal injections ($p = 0.001$). The efficacy and side effects of Botox and Dysport were similar. BTX is an effective and safe treatment option for HFS. No difference was determined between Botox and Dysport, and pretarsal injection is better than preseptal injection regarding the reported degree of improvement.

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1. Introduction

Hemifacial spasm (HFS) is characterised by involuntary paroxysmal clonic or tonic contractions of muscles innervated by the facial nerve on one side of the face [1]. Generally, it is caused by axonal–axonal ephaptic transmission and ectopic excitation due to vascular cross-compression at the root exit zone of the facial nerve [2]. HFS seems more common in females than males with a prevalence of 14.5/100,000 and 7.4/100,000, respectively [3]. Regarding causality of HFS, hypertension is related to vascular tortuosity in the cerebellopontine angle [4].

A combination of mild facial palsy and mild narrowed palpebral fissure are characteristic of HFS. Differential diagnoses of HFS include facial myokymia, facial tics, blepharospasm, synkinesis and aberrant regeneration after Bells' palsy and psychogenic facial movements [5]. Anticonvulsants such as carbamazepine or

gabapentin have been shown to be effective in the symptomatic treatment of HFS [6,7] and selected patients are treated by microvascular decompression [8]. For the symptomatic treatment of HFS, injections of botulinum toxin (BTX) have been proven effective and are increasingly used worldwide. Here, we report our own experience in addition with a review of the literature for the past 30 years.

2. Patients and methods

Between July 1996 and July 2012, 113 patients (68 women, 45 men) with HFS were retrospectively analysed. The mean age of patients was 63.1 years. Forty-five patients had only one injection per session in a total number of 514 sessions. Data for the 68 patients who had at least two injections per session were further analysed. The latency, duration and degree of improvement (assessed by the visual analogue scale [VAS]: subjective evaluation of degree of amelioration of spasms from 0 to 100% by the patient with 0% being no effect and 100% being asymptomatic), and

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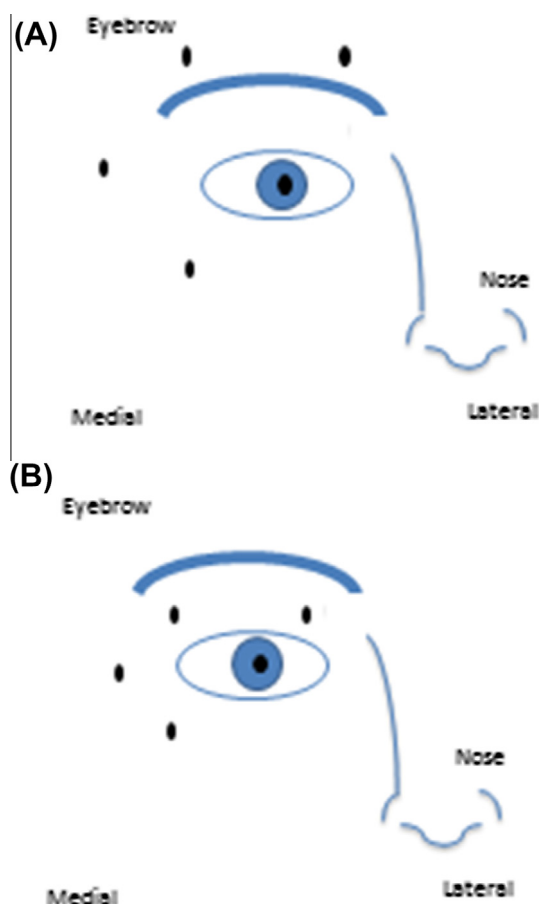


Fig. 1. Schematic representations of (A) preseptal and (B) pretarsal injection techniques. The black oval dots indicate the injection points.

frequency and duration of the side effects were analysed. Pretarsal and preseptal injections and the commercial brands Botox (Allergan, Irvine, CA, USA) and Dysport (Ipsen Biopharmaceuticals, Paris, France) were compared in terms of the parameters mentioned above (Fig. 1). The dose equivalence of Botox and Dysport was calculated as 1/5. We did not use a strength conversion ratio between Botox and Dysport in accordance with the results of previous reports [9].

For the first session, all patients were injected with 5 units of Botox or 15 units of Dysport per site as shown in Figure 1. Doses were adjusted in upcoming sessions in accordance with the effectiveness and side effects of the previous session. Perioral muscles

were never injected in the first session and were only injected afterwards if the patient still complained of perioral spasms.

3. Results

In our cohort, 470 sessions of BTX injections were applied to 68 patients with a mean of 6.9 sessions per patient (range: 2–27). An average value of 34.5 units (range: 19.5–85; Botox equivalent dose) were used. On average, patients felt the first improvement after 8 days (range: 1–40) and they returned to their pre-injection condition after 14.8 weeks (range: 1–22). Patients expressed a 73.7% (range: 0–100) improvement on average in the VAS. No adverse effects were observed in 79.7% of injections. Detected side effects were 4.9% erythema, ecchymosis, and swelling in the injection area, 3.6% facial asymmetry, 3.4% ptosis, 3.2% diplopia, and 2.3% difficulty of eye closure. Ocular pain, blurred vision, nasal bleeding, temporary increase in spasms, conjunctival hyperaemia on the injection side, conjunctival hyperaemia on the non-injected eye, and dry eyes were reported in less than 1% of the sessions (Table 1).

With regard to the injection site, our patients reported 75% improvement on average after 314 sessions of pretarsal injections and 72.7% improvement after 156 sessions of preseptal injections (Student's *t*-test $p = 0.001$). Adverse effects were seen in 19.7% of pretarsal injections and 16.7% of preseptal injections (chi-squared test $p = 0.42$; Table 2).

When comparing commercial brands, the average improvement was 74.3% with Botox in 460 sessions and 76.3% with Dysport in 10

Table 1
Adverse effects of botulinum toxin in hemifacial spasm patients

Adverse effect	Frequency, %
None	79.7
Erythema, ecchymosis, and swelling in the injection area	4.9
Facial asymmetry	3.6
Ptosis	3.4
Diplopia	3.2
Difficulty of eye closure	2.3
Other effects	
Ocular pain	0.3
Blurring in vision	0.3
Prickling in forehead	0.3
Nasal bleeding	0.3
Temporary increase in spasms	0.3
Conjunctival hyperaemia on the injection side	0.8
Conjunctival hyperaemia on the non-injected eye	0.3
Dry eyes	0.3

Table 2
Efficacy and adverse effects of pretarsal versus preseptal botulinum toxin injection applications and Botox versus Dysport brand

	Patients with HFS, n = 68 Total sessions, n = 470					
	Botox ^a	Dysport ^b	<i>p</i> value	Pretarsal	Preseptal	<i>p</i> value
Age, year, mean \pm SD	63 \pm 14.4	64 \pm 7.2	0.13	64 \pm 14.3	62 \pm 14.1	0.92
Sex, n (%)			0.45			0.84
Female	36 (55.4)	1 (33.3)		17 (53.1)	20 (55.6)	
Male	29 (44.6)	2 (66.7)		15 (46.9)	16 (44.4)	
Total sessions, n (%)	460 (97.9)	10 (2.1)	NC	314 (66.8)	156 (33.2)	NC
Doses as units, mean \pm SD	33.8 \pm 13.5	49.7 \pm 21.9	0.19	39.1 \pm 18.3	30.4 \pm 6.9	<0.0001
First improvement (days), mean \pm SD	8.1 \pm 7.0	1.0 \pm 0.0	NC	8.6 \pm 8.8	7.5 \pm 4.9	0.21
Improvement on VAS, %	74.3	76.3	0.86	75	72.7	0.001
Adverse effects, %	18.7	20	0.92	19.7	16.7	0.42

^a Allergan, Irvine, CA, USA.

^b Ipsen Biopharmaceuticals, Paris, France.

HFS = hemifacial spasm, NC = not calculated, SD = standard deviation, VAS = visual analog scale.

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