การศึกษาเปรียบเทียบผลการรักษาการฉีดโบทูลินัมท็อกซินระหว่างการฉีดกล้ามเนื้อใบหน้าด้านล่างและไม่ฉีดในการรักษาโรคใบหน้ากระตุกครึ่งซีก

The Effect between Botulinum Toxin Injection and Non-injection into the Lower Facial Muscles in Treatment of Hemifacial Spasm

ปิลันธนา สายเชื้อ
Pilantana Saichua

บทคัดย่อ

วัตถุประสงค์: เพื่อศึกษาเปรียบเทียบผลการรักษาการฉีดโบทูลินัมท็อกซินระหว่างการฉีดกล้ามเนื้อใบหน้าด้านล่างและไม่ฉีดในการรักษาโรคใบหน้ากระตุกครึ่งซีก และศึกษาผลข้างเคียงที่อาจเกิดขึ้นจากการฉีดยาโบทูลินัมท็อกซิน ในกล้ามเนื้อใบหน้าด้านล่าง

วิธีการศึกษา: การศึกษานี้เป็นการวิจัยเชิงทดลองแบบ randomized controlled trial โดยแบ่งผู้ป่วยโรคใบหน้ากระตุกครึ่งซีกออกเป็น 2 กลุ่ม ได้แก่ กลุ่มที่ได้รับการฉีดโบทูลินัมท็อกซินที่กล้ามเนื้อใบหน้าด้านล่าง (กลุ่ม A) และกลุ่มที่ไม่ได้รับการฉีด (กลุ่ม B) ผู้ป่วยทั้งหมดได้รับการประเมินผลการรักษาด้วย Hemifacial Spasm Grading Scale (HSGS) ที่ 4 เดือนหลังการรักษา รวมถึงประเมินผลลัพธ์รอง ได้แก่ ระดับการตอบสนองที่ดีที่สุด (peak improvement), ระยะเวลาที่โบทูลินัมท็อกซินออกฤทธิ์ (duration of response), และระดับความพึงพอใจของผู้ป่วย

ผลการศึกษา: ผลการวิจัยไม่พบความแตกต่างอย่างมีนัยสำคัญทางสถิติระหว่างกลุ่ม A และกลุ่ม B ทั้งในด้านผลลัพธ์หลัก (HSGS ที่ 4 เดือน) และผลลัพธ์รอง ได้แก่ ระดับการตอบสนองสูงสุด ระยะเวลาที่โบทูลินัมท็อกซินออกฤทธิ์ และระดับความพึงพอใจของผู้ป่วย อย่างไรก็ตาม กลุ่ม A มีอัตราการเกิดภาวะใบหน้าไม่สมมาตรสูงกว่ากลุ่ม B (ร้อยละ 33.33 เทียบกับร้อยละ 8.33) แม้จะไม่มีนัยสำคัญทางสถิติก็ตาม

สรุป: การฉีดโบทูลินัมท็อกซินในกล้ามเนื้อใบหน้าด้านล่างไม่ได้แสดงให้เห็นถึงผลการรักษาที่แตกต่างอย่างมีนัยสำคัญเมื่อเปรียบเทียบกับการไม่ฉีด แต่พบแนวโน้มการเกิดผลข้างเคียง โดยเฉพาะภาวะใบหน้าไม่สมมาตรในอัตราที่สูงกว่า

คำสำคัญ: โรคใบหน้ากระตุกครึ่งซีก, โบทูลินัมท็อกซิน, การฉีดกล้ามเนื้อใบหน้าด้านล่าง, Hemifacial Spasm Grading Scale, ภาวะใบหน้าไม่สมมาตร

ปิลันธนา สายเชื้อ
Pilantana Saichua
นายแพทย์ชำนาญการ กลุ่มงานอายุรกรรม โรงพยาบาลร้อยเอ็ด

ผู้รับผิดชอบบทความ:
พญ.ปิลันธนา สายเชื้อ
กลุ่มงานอายุรกรรม โรงพยาบาลร้อยเอ็ด
111 ถนนรณชัยชาญยุทธ ตำบลในเมือง
อำเภอเมืองร้อยเอ็ด จังหวัดร้อยเอ็ด 45000
Email: Looktanpilan@gmail.com โทรศัพท์ 084-6033455

รับต้นฉบับ 20 กุมภาพันธ์ 2568, ปรับปรุงต้นฉบับ 8 มีนาคม 2568, ตอบรับต้นฉบับตีพิมพ์ 11 มีนาคม 2568

Abstract

Objective: To compare treatment outcomes between lower facial muscle botulinum toxin injection and non-injection in hemifacial spasm patients, and to study potential side effects of botulinum toxin injection in lower facial muscles.

Methods: This randomized controlled trial divided hemifacial spasm patients into two groups: those receiving botulinum toxin injection in lower facial muscles (Group A) and those not receiving the injection (Group B). All patients were evaluated using the Hemifacial Spasm Grading Scale (HSGS) at 4 months post-treatment. Secondary outcomes included peak improvement, duration of response, and patient satisfaction.

Results: No statistically significant differences were found between Group A and Group B in the primary outcome (HSGS at 4 months) and secondary outcomes, including peak improvement, duration of response, and patient satisfaction. However, Group A showed a higher rate of facial asymmetry compared to Group B (33.33% vs 8.33%), although this difference was not statistically significant.

Conclusion: Lower facial muscle botulinum toxin injections did not demonstrate significantly different treatment outcomes compared to non-injection, but showed a trend toward higher incidence of side effects, particularly facial asymmetry.

Keywords: Hemifacial spasm, Botulinum toxin, Lower facial muscle injection, Hemifacial Spasm Grading Scale, Facial asymmetry

Introduction

Hemifacial spasm is a movement disorder characterized by involuntary tonic or clonic contractions of facial muscles, typically affecting one side of the face. The condition usually begins around the eye area and may progress to involve lower facial muscles, including those around the mouth, platysma, and other facial muscles[1]. The incidence rate is approximately 11 per 100,000 population[2], with a mean age of onset of 60.8 years, ranging from 20-75 years[3]. The primary cause is typically compression of the seventh cranial nerve (facial nerve) at its root exit zone, often due to vascular abnormalities in the posterior fossa[4]. According to Wang A. et al., symptoms initially appear in the orbicularis oculi muscle in 90% of cases, before spreading to other muscles on the same side of the face. The most significant impact on patients' daily lives is involuntary eye closure, which affects vision and leads to decreased social confidence[5]. Hemifacial spasm can significantly reduce social interaction, potentially leading to isolation and depression, thereby affecting the overall quality of life[6].

Botulinum toxin injection is one of the most effective and safe treatments for hemifacial spasm[7] Botulinumtoxin, a neurotoxin produced by Clostridium botulinum bacteria[8], works by inhibiting acetylcholine release, a neurotransmitter responsible for nerve-muscle signal transmission. This inhibition targets specific muscle contractions. The toxin can be injected directly into target muscles or subdermally, with its effects primarily localized to the injection site and surrounding tissues, showing minimal systemic distribution[9]. The muscle-inhibiting effects of botulinum toxin typically last for 2.6-4 months[10] after which muscle function returns to normal[11]

However, currently, there is no standardized injection technique for treating hemifacial spasm patients with botulinum toxin. The benefits and side effects of injecting specific sites remain debatable,

particularly regarding lower facial muscle injections. While these injections can reduce the severity and frequency of spasms, they may cause facial asymmetry due to lower facial muscle weakness, reported in up to 97% of cases[12] (94.7%). Furthermore, studies have shown that injecting botulinum toxin only into the orbicularis oculi muscle can also reduce lower facial muscle spasms[13,14]. Therefore, this study aims to evaluate the efficacy of botulinum toxin injection techniques in lower facial muscles for treating hemifacial spasm, specifically comparing whether it provides better spasm reduction than non-injection, with the ultimate goal of improving treatment effectiveness for hemifacial spasm patients.

Objective

To compare treatment outcomes between lower facial muscle botulinum toxin injection versus non-injection in hemifacial spasm treatment and to evaluate potential adverse effects.

Methods

This study was designed as a single-blind randomized controlled trial. Participants were divided into two groups: Group A received botulinum toxin injections in the lower facial muscles, while Group B received no injections in this area. The study population consisted of hemifacial spasm patients who received treatment at the Neurology and Epilepsy Clinic, Roi Et Hospital. The study was approved by the Human Research Ethics Committee of Roi Et Hospital, project code: RE 107/2567, approval date: July 19, 2024.

Sample size calculation was performed using the formula for experimental studies with continuous data. The calculation referenced a study by Colakoglu BD et al. in Turkey, which examined 23 volunteers comparing botulinum toxin injections for hemifacial spasm treatment, with and without lower facial muscle injections[15], closely resembling our study design.

Based on these calculations, the required sample size was determined to be 10 participants per group (treatment and control). To account for potential data loss, an additional 20% was added, resulting in a total sample size of 24 participants.

Inclusion Criteria:

- Patients diagnosed with hemifacial spasm by a neurologist
- Age 18 years or older
- Severity of hemifacial spasm:
  - Moderate: Orbicularis oculi spasms causing eyelid closure 10-50% of visual field, or simultaneous eye and mouth spasms
  - Severe: Orbicularis oculi spasms causing eyelid closure 50-100% of visual field, or presence of tonic spasms

Exclusion Criteria:

- Mild severity cases (isolated orbicularis oculi muscle spasms with upper eyelid twitching only, without lid closure)
- Pre-existing facial asymmetry from previous botulinum toxin injections
- History of botulinum toxin allergy
- Botulinum toxin resistance
- Pregnancy or breastfeeding
- Neurological conditions that may be adversely affected by botulinum toxin type A injection (e.g., Myasthenia gravis)

Participants were divided into two groups (Group A and Group B) using stratified randomization.

The stratification factors included age and pre-treatment hemifacial spasm severity. Baseline data was collected using questionnaires. The study employed the Hemifacial Spasm Grading Scale[16] as the primary tool for measuring treatment efficacy, evaluating both frequency and severity of facial muscle spasms, as detailed in Figure 1.

Hemifacial spasm	Yes–no
Localization	
- Isolated upper face (e.g., orbicularis oculi)/lower face muscles	1
- Involvement of both the upper and lower face muscles	2
Intensity	
- Single jerks	1
- Sub-continuous jerks (spasm)	2
Frequency	
- Muscular contractions provoked by motor activation	1
- Spontaneous contractions	
< 50% the time	3
> 50% the time	5
Total	____/9

Figure 1 Hemifacial spasm grading scale

Both groups of patients received injections of onabotulinumtoxinA (Botox®, Allergan). The Botox® was reconstituted with 2.5 mL of normal saline per 100 units and administered at a dose of 2 units per injection site. Group A receiving injections at two points in the central and lateral parts of the upper eyelid (pretarsal part of the orbicularis oculi), another two points in the central and lateral parts of the lower eyelid, and one additional point in the lower facial muscles in the zygomaticus group. The injection site for the zygomaticus group was determined by drawing an imaginary line from the lateral canthus to the corner of the mouth, with the injection administered at the midpoint of this line. Group B received injections only in the orbicularis oculi muscle (Figure 2)

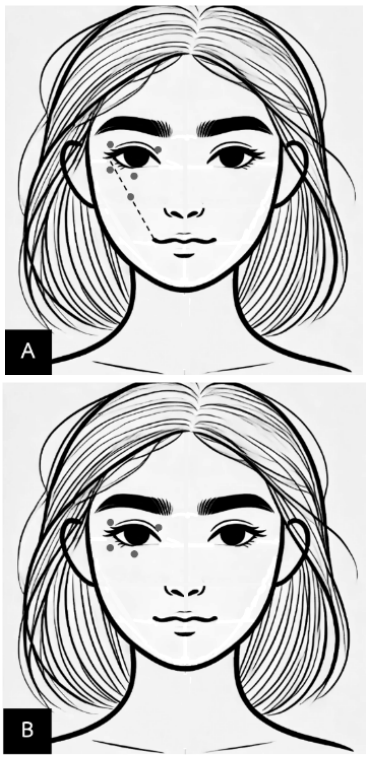

Figure 2 Site of injection
(A. lower facial injection, B. Non-injection)

Primary outcome were assessed using the HSGS at 4 months post-treatment. Secondary outcomes included peak improvement, duration of response, patient satisfaction, and side effects. These were evaluated at 6 weeks via telephone and at 4 months through an in-person assessment at the hospital, as shown in Figure 3.

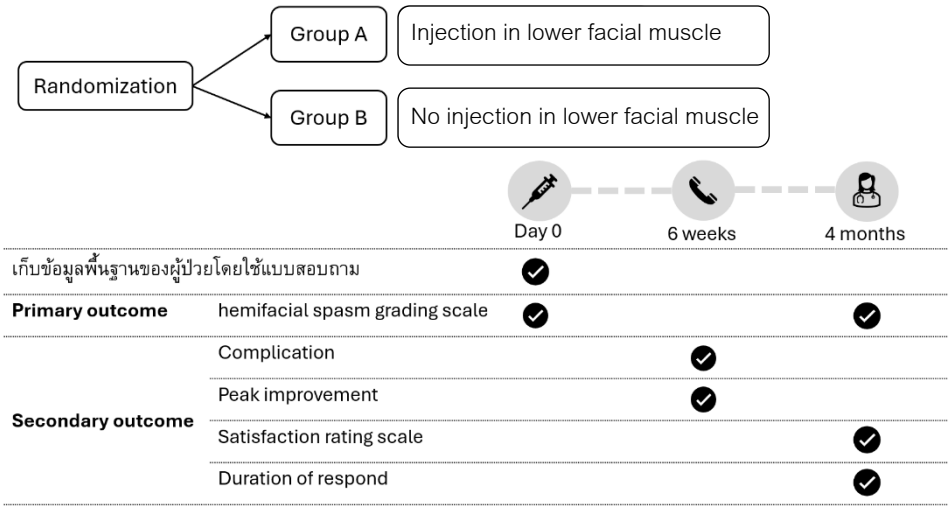

Figure 3 Study protocol

This study utilized STATA version 17 for data analysis. Descriptive statistics were used to explain the characteristics of the sample population. Categorical data were presented as frequencies and percentages, while numerical data were presented as means and standard deviations. For inferential statistics, comparison between two groups (mean difference) was analyzed using T-test, with statistical significance set at P-value of 0.05.

Results

In this study, there were 24 hemifacial spasm patients who received treatment at the Neurology and Epilepsy Clinic at Roi Et Hospital, meeting the research criteria and consenting to participate. The baseline characteristics of all participants are shown in Table 1, with a mean age of 57.63 ± 11.44 years. The majority were female (83.33%) and had right-sided symptoms (75%). Before treatment, most patients (70.83%) had moderate severity. Of the total population, 7 patients had severe symptoms - 3 in Group A and 4 in Group B. For HSGS scores, Group A had a mean pre-treatment score of 6.58 ± 1.83, while Group B had a mean score of 7.5 ± 2.07.

Table 1 Demographic data and clinical characteristics

Demographic data	Total (N=24)	Group A (N=12)	Group B (N=12)	p-value
Age (years), Mean (SD)	57.63(11.44)	56.08(10.27)	59.17(12.77)	0.521
Sex (Female), N (%)	20(83.33)	10(83.33)	10(83.33)	1.000
Symptomatic side, N (%)				
Right	18(75.00)	7(58.33)	11(91.67)	0.155
Left	6(25.00)	5(41.67)	1(8.33)	
Duration of disease (years), Median (IQR)	9.5(4.5-10)	10(6.5-10)	6.5(4.5-10)	0.228
Duration of previous treatment(yrs), Mean(SD)	4.83(3.23)	4.5(3.37)	5.17(3.17)	0.624
Pretreatment severity of symptom, N (%)				
Moderate	17(70.83)	9(75.00)	8(66.67)	1.000
Severe	7(29.17)	3(25.00)	4(33.33)	
Pretreatment HSGS, Mean (SD)	7.04(1.97)	6.58(1.83)	7.5(2.07)	0.263

Participants received botulinum toxin injections from the same treating physician. Group A received lower facial muscle injection, while Group B did not. At 4 months post-treatment, the primary outcome was evaluated using the HSGS tool, as shown in Table 2. There was no statistically significant difference between Groups A and B in HSGS scores at 4 months post-treatment (6.00 ± 1.48 vs 5.92 ± 2.20, p=0.914).

Table 2 Clinical outcomes

Clinical outcomes	Total	Group A (N=12)	Group B (N=12)	P-value
Posttreatment HSGS at 4 months, Mean (SD)	5.96(1.83)	6(1.48)	5.92(2.20)	0.914
Posttreatment severity at 4 months, N (%)				
Mild	8(33.33)	6(50.00)	2(16.67)	0.301
Moderate	10(41.67)	4(33.33)	6(50.00)	
Severe	6(25.00)	2(16.67)	4(33.33)	
Peak improvement (%), Mean (SD)	78.25(13.09)	78.58(10.29)	77.92(15.88)	0.904
Latency to respond (Days), Mean (SD)	8.08(5.60)	8.25(3.89)	7.91(7.10)	0.888
Satisfaction rating scale at 4 months (0-10), Mean (SD)	7.96(1.36)	8.01(1.14)	7.88(1.60)	0.771
Duration of response (months), Median (IQR)	3(2.25-3.5)	3.25(2.5-3.5)	3(2.25-3.25)	0.210

For secondary outcomes, there were no significant differences between Groups A and B in terms of peak improvement (78.58 ± 10.29% vs 77.92 ± 15.88%, p=0.904), duration of respoond (3.25 months vs 3 months, p=0.210), and patient satisfaction score (8.01 ± 1.14 vs 7.88 ± 1.60, p=0.771). Regarding post-treatment severity of hemifacial spasm, Group A had 6 mild, 4 moderate, and 2 severe cases, while Group B had 2 mild, 6 moderate, and 4 severe cases. Compared to pre-treatment, where patients only had moderate and severe symptoms, this suggests that most patients experienced reduced severity.

Table 3 shows the statistical analysis comparing treatment outcomes between the two groups using HSGS. Group B, which did not receive lower facial muscle botulinum toxin injection, showed a greater reduction in HSGS post-treatment compared to Group A, with a difference of 1 (p=0.352), though not statistically significant. The difference was greater in the severe group compared to the moderate group, at 1.25 and 0.806 respectively (p=0.478, 0.566).

Table 3 Comparison of treatment outcomes for lower facial muscles (Assessed by HSGS)

Severity	Group A			Group B			Different Between Group	P-value
	Pre HSGS	Post HSGS	Diff.	Pre HSGS	Post HSGS	Diff.		
Total, Mean (SD)	6.58(1.83)	6(1.48)	0.58	7.5(2.07)	5.92(2.19)	1.58	1	0.352
Moderate, Mean (SD)	6.22(1.92)	5.78(1.64)	0.44	6.75(2.19)	5.5(2)	1.25	0.806	0.566
Severe, Mean (SD)	7.67(1.15)	6.67(0.58)	1	9(0)	6.75(2.63)	2.25	1.25	0.478

Side effects from botulinum toxin treatment are shown in Table 4. Facial asymmetry was higher in Group A compared to Group B (33.33% vs 8.33%) but not statistically significant (p=0.317). Eye irritation was found in 5 cases in each group. Diplopia was found in 1 and 3 cases, ptosis in 2 cases (Group A only), and bruising in 1 case (Group B only).

Table 4 Complications

Complications N(%)	Group A (N=12)	Group B (N=12)	P-value
Facial asymmetry	4(33.33)	1(8.33)	0.317
Irritation	5(41.67)	5(41.67)	1.000
Diplopia	1(8.33)	3(25.00)	0.590
Ptosis	2(16.67)	0(0.00)	0.478
Bruising	0(0.00)	1(8.33)	1.000

Discussion

A comparative study of the effectiveness of lower facial muscle botulinum toxin injection versus non-injection in hemifacial spasm patients at the Neurology and Epilepsy Clinic, Roi Et Hospital, found that when evaluating treatment outcomes using the Hemifacial Spasm Grading Scale (HFGS) at 4 months post-treatment, botulinum toxin injection in lower facial muscles did not result in statistically significant differences in treatment efficacy compared to non-injection, both in patients with moderate and severe disease severity. However, there is an important observation from this study: the HFGS score evaluation was conducted at 4 months post-treatment, while the average duration of botulinum toxin's effective control of muscle spasms in this study was approximately 3 months. Therefore, HFGS scores assessed at 4 months post-treatment may reflect reduced outcomes compared to the period when botulinum toxin was at its peak effectiveness.

This finding aligns with the study by Mami Ishikawa et al., who investigated the effects of botulinum toxin injection only in the orbicularis oculi muscle in hemifacial spasm patients. Their evaluation using electrophysiologic study at 2 and 6 weeks showed that besides reducing orbicularis oculi muscle activity, the treatment also decreased mentalis muscle activity. This phenomenon may be explained by the mechanism where orbicularis oculi muscle spasms cause hyperexcitability in the facial motor fibers innervating these muscles, which then signals to the facial motor nucleus. This signaling propagates within the facial motor nucleus to other facial motor fibers, leading to subsequent spasms in other facial muscles innervated by the facial nerve[17]. This mechanism explains why botulinum toxin injection targeting only the orbicularis oculi muscle can effectively reduce lower facial muscle spasms as well.

Similarly, a 2011 study by Colakoglu BD et al. in Turkey found that botulinum toxin injections effectively reduced facial spasms in both methods, and lower facial muscle injections might be unnecessary, particularly in mild cases. However, their subgroup analysis of severe cases showed that additional lower facial muscle injections yielded better treatment outcomes[15]. This differs from our study, which found no significant difference in treatment outcomes between lower facial muscle injection and non-injection across all severities.

Secondary outcomes showed no significant differences between groups with and without lower facial muscle injections. The peak improvement were similar at 78.58±10.29% and 77.92±15.88% (p=0.904) respectively, which aligns with previous studies reporting best response rates of 75-100%[7]17 were lost to follow up and were excluded. 855 treatments were injected in the remaining 158 patients with a median of 4 treatments. The response rate was 97%. Of 855 treatments, the adjusted mean peak and duration of improvement was 77.2 (95% confidence interval (95%CI. Similarly, patient satisfaction scores were comparable between both groups.

Side effects are another factor affecting patients' quality of life, such as facial asymmetry, which impacts patients' social embarrassment. This study found a higher incidence of facial asymmetry in the group receiving lower facial muscle botulinum toxin injections at 33.33%. This may be due to the diffusion of the medication into the zygomaticus group and levator labii superioris muscles, resulting in weakness of these muscle groups and subsequent facial asymmetry. This finding is consistent with Chen R-S et al.'s study of botulinum toxin injection into the lower facial muscle, which reported facial asymmetry in 39% of cases[18].

Therefore, this study found that botulinum toxin injection in lower facial muscles, when evaluated using HSGS at 4 months, showed no significant difference in treatment outcomes compared to non-injection. Similarly, other outcomes including peak improvement, duration of respond, and patient satisfaction score showed no significant differences. Meanwhile, important side effects, particularly facial asymmetry, were found more frequently in the group receiving lower facial muscle injections, although this difference was not statistically significant.

This study has several limitations that should be considered. First, as a single-blind randomized controlled trial where the treating physician was not blinded, researcher bias could have occurred. However, to minimize this limitation's impact, treatment outcome assessments were

conducted by a specialized research assistant rather than the treating physician directly. Second, the relatively small sample size used in this study may affect the accuracy and ability to draw broad conclusions. Finally, the timing of HSGS outcome assessment extended beyond the period of botulinum toxin's peak effectiveness, which could potentially lead to misinterpretation of treatment outcomes.

Conclusion

This study demonstrates that injecting botulinum toxin into the lower facial muscles does not result in a statistically significant difference in treatment outcomes compared to not injecting, both in terms of the severity of spasms and the patient satisfaction. However, the group that received botulinum toxin injections in the lower facial muscles exhibited a higher tendency for facial asymmetry, which may impact patients' confidence in social interactions. Therefore, careful consideration of the benefits and potential side effects when selecting injection sites is crucial in the treatment of patients with hemifacial spasm.

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