

# Quality of Life in Hemifacial Spasm Patient after Treatment with Botulinum Toxin A; A 24-week, Double-Blind, Randomized, Cross-over Comparison of Dysport® and Neuronox® Study

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**Background:** Hemifacial spasm (HFS) is a common movement disorder, presented with unilateral, intermittent, irregular, tonic or clonic contraction of facial expression muscles without any identifiable etiology. Comparison of quality of life (QoL) between Dysport® and Neuronox® has not been studied in HFS patients.

**Objective:** To evaluate the QoL after treatment with botulinum toxin A (Dysport® and Neuronox®) injection in HFS patient.

**Material and Method:** A 24-week, double-blind, randomized, cross-over comparison of QoL in HFS patients after being treated with botulinum toxin A (Dysport®) and botulinum toxin A (Neuronox®) was performed. Assessment of QoL composed of hemifacial spasm-30 (HFS-30), medical outcome study short form 36 items (SF-36), abnormal involuntary movement scale (AIMS) and center for epidemiologic studies-depression (CES-D) questionnaire, were performed at week 0, week 12, and week 24. The 24-hour HFS diary, recorded for 4 weeks after treatment was also evaluated.

**Results:** Total of 26 HFS patients were enrolled between May 2010 and January 2011. The mean HFS-30, AIMS and CES-D were reduced after treatment without any difference between the two groups. The mean SF-36 was not changed in both groups. However, mean HFS-30 ( $p = 0.09$ ), AIMS ( $p = 0.02$ ) and CES-D ( $p < 0.001$ ) of all treated patients were reduced across the treatment period. Total intensity score of HFS, duration of facial muscles spasm per day and duration of functional impairment per day in Dysport® group were significantly lower than the Neuronox® group ( $p < 0.001$ ).

**Conclusion:** There was no difference between Dysport® and Neuronox® in the aspect of QoL in HFS patients. However, there was improvement of QoL after multiple botulinum toxin A injection.

**Keywords:** Hemifacial spasm, Botulinum toxin A Dysport®, Neuronox®, Quality of Life

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Hemifacial spasm (HFS) is a common movement disorder characterized by involuntary, unilateral, intermittent, irregular, tonic or clonic contraction of facial expression muscles without any identifiable etiology. Although most of HFS cases were sporadic, some familial HFS series had been reported<sup>(1)</sup>. Moreover, secondary HFS were associated with an atherosclerotic aberrant or ectatic intracranial artery<sup>(2)</sup>. The prevalence of HFS were approximately 14.5/100

000 in women and 7.4/100 000 in men<sup>(1,2)</sup>. The onset usually begins in adulthood with an average of 45 to 52 years<sup>(2)</sup>. The QoL of HFS patients may be reduced by co-symptoms of vision interference, lacrimation, eye irritation, difficulty in reading and writing, social embarrassment, some dysarthria, and depression<sup>(3)</sup>.

Pharmacological treatment options, such as carbamazepine, clonazepam, and baclofen, are still far from optimum, leaving many patients without being symptom-free or with unpleasant side-effects<sup>(4-6)</sup>. Botulinum toxin A, the most potent neurotoxin, has been used to treat a variety of disorders associated with increased muscle tension, including focal dystonias, spasticity achalasia and HFS<sup>(7,8)</sup>.

The QoL is a subjective evaluation of physical, mental and social general well-being. Commonly, good

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physical health can improve QoL<sup>(9)</sup>. In HFS patients, the instrument used for measurement of general QoL is SF-36 and disease-specific QoL are HFS-30 and AIMS.

Comparison of post treatment QoL between Dysport® and Neuronox® had not been studied in HFS patient, so the authors conducted a 24-week, double-blind, randomized, cross-over study to evaluate the QoL after treatment with botulinum toxin A (Dysport® and Neuronox®) injection in HFS patients.

## **Material and Method**

### **Patients**

Men and women between the ages of 18 and 80 years, who fulfilled the diagnostic criteria for primary HFS, unilateral involuntary facial muscle contraction affecting one or more muscle groups innervated by the ipsilateral facial nerve, during May 2010 to January 2011, were enrolled in the present study if they had normal consciousness and comprehend to the QoL questionnaires and could communicate in and understand Thai language. Patients younger than 18 years old, unable to understand the Thai language, refusing to join the study, pregnant, lactating or not using adequate contraception were excluded. Additionally, clinically significant medical conditions (including blood dyscrasia, thrombocytopenia, rheumatoid arthritis, congestive heart failure, coronary heart disease, dementia, psychosis and major depression), or other conditions that could influence trial results, were criteria for exclusion.

### **Hemifacial spasm-30 (HFS-30) questionnaire (Thai version)**

The HFS-30 questionnaire (Thai version) includes seven subscales (30 items). Mobility (5 items), activity of daily living (5 items) and communication (3 items) are classified as physical health domain. Emotional well-being (7 items), stigma (4 items), social support (3 items) and cognition (3 items) are classified as mental health domain. This questionnaire had been validated and tested for reliability in Thai patients<sup>(9)</sup>.

### **Medical outcome short form 36 items (SF-36) questionnaire (Thai version)**

The medical outcome study short form 36 items (SF-36) is a multipurpose and widely used short-form health survey with 36 questions, which includes eight domains: physical functioning (PF), role limitations due to physical health (RP), role limitations due to emotional problems (RE), vitality (VT), mental health (MH), social functioning (SF), bodily pain (BP),

and general health (GH)<sup>(10)</sup>. Among them, PF, RP, BP and GH are classified as physical health domain, whereas, RE, VT, MH and SF are classified as mental health domain. This questionnaire has been validated, and tested for reliability in Thai patients<sup>(11)</sup>.

### **Abnormal involuntary movement scale (AIMS) (Thai version)**

The abnormal involuntary movement scale (AIMS) consists of rating the severity of movements in 7 regions, each on a 5 points scale and a separate rating of the overall severity of the abnormal movements, judged on the amplitude of movements, incapacitation postures and positions, including sitting in chair, opening the mouth, tapping the thumb against each finger, holding the hand out stretched and standing and walking, are included. Dental status is also rated, as the presence or absence of problems with teeth or dentures. This latter assessment is included because edentulous individuals may sometimes exhibit involuntary movements without exposure to drugs<sup>(12)</sup>. The AIMS (Thai version) had been tested-retested for reliability coefficient with alpha Conbrach > 0.7 in Rajvithi Hospital.

### **CES-D**

The center for epidemiologic studies-depression (CES-D) scale is a self-evaluation instrument to indicate depressive state in adolescence. Thai version CES-D had been validated and tested for reliability in Thai people<sup>(13)</sup>.

### **Study design**

This was a 24-week prospective, double-blind, randomized, cross-over study to evaluate the quality of life after treatment with botulinum toxin A (Dysport® and Neuronox®) injection in hemifacial spasm patients. All HFS patients underwent the questionnaires and diary record training, to ensure they satisfied the inclusion and exclusion criteria. All patients were trained to self-evaluate intensity scoring with a 5 point scale. After enrollment, patients were randomly assigned to receive either botulinum toxin A (Dysport®) or botulinum toxin A (Neuronox®) and then switched to another treatment in the next 12 weeks. All patients and physicians were blinded during the study period. Botulinum toxin A supplied as a freeze-dried powder and reconstituted in saline solution, was used within 2 hours of preparation. All patients received 4 subcutaneous injections into the outer upper and lower orbicularis oculi muscle and outer upper and lower

orbicularis oris muscle at the symptom side (Fig. 1). The unit for each injected site was 15 units Dysport® (0.075 ml) or 3.125 units Neuronox® (0.075 ml), by using the approximately dosage equivalent of Dysport® 4.8 unit per Neuronox® 1 unit. The informed consent was obtained from each patient before enrollment. The study protocol was approved by the independent ethical committee of Rajavithi Hospital.

### Assessments

There were three assessments during the course of the present study, firstly at week 0 (Pre treatment) and then follow-up visits at weeks 12 and 24. At each visit, patients underwent physical and neurological examination, and they were also asked to complete HFS-30<sup>(9)</sup>, SF-36<sup>(11)</sup>, AIMS<sup>(12)</sup> and CES-D<sup>(13)</sup>. All patients had received the botulinum toxin A injection the same day after completing their questionnaires.

After the first and second treatments, patients were asked to record each day when HFS symptoms occurred and their duration, measured over 24 hours per day and documented in 1-hour units. Intensity of spasm was measured in 1-hour units and scored on a 5-point scale (0 = normal, 1 = mild facial muscles spasm, 2 = moderate facial muscles spasm, no functional impairment, 3 = moderate facial muscles spasm, has functional impairment and 4 = severely incapacitated) for 4 weeks after treatment. The total intensity of spasm per day was the summation of the scores over 24 hours. A CES-D score above 22 indicates clinical depression<sup>(14)</sup>. Good functional outcome is indicated by a high score for the SF-36 and a low score for the HFS-30 and AIMS<sup>(14)</sup>.

### Quality of life endpoints

The primary endpoint was the difference of mean HFS-30 between Dysport® and Neuronox®. The secondary endpoints were different means of SF-36, AIMS and CES-D, mean total intensity score, mean duration of facial muscles spasm per day and mean duration of functional impairment per day between Dysport® and Neuronox®. The tertiary endpoints were the comparison of mean change of HFS-30, SF-36, AIMS and CES-D, total intensity score, mean duration of facial muscles spasm per day and mean duration of functional impairment per day, from week 0 to week 12, and week 24.

### Statistical analysis

Descriptive statistic was used for demographic

data. Paired t-tests were used to analyze the different of mean HFS-30, SF-36, AIMS and CES-D, mean total intensity score, mean duration of facial muscles spasm per day, and mean duration of functional impairment per day, by comparison between Dysport® and Neuronox®.

The mean HFS-30, SF-36, AIMS and CES-D at week 0, week 12 and week 24 were compared using the Kruskal-Wallis test. The mean change of total intensity score, mean duration of facial muscles spasm per day, and mean duration of functional impairment per day were compared with paired t-test analysis. The statistical program for social sciences (SPSS) statistical software (version 17.0) (SPSS Inc., Chicago, license serial no. 5066816) was used for data analysis and the significance level was set at  $p < 0.05$ .

### Results

A total of 17 females (65.38%) and 9 males (34.62%), mean age (sd) of 54.8 (12.5) years, range 24 to 75 years, were enrolled from May 2010 to January 2011. The mean (sd) duration of HFS diagnosis was 5.0 (3.1) years, range from 0 to 12 years. There were 12 subjects with right side HFS, and 14 subjects with left side HFS. The mean botulinum toxin A injection administrations before randomization was 8.8 (5.3) times, range from 1 to 22 times (Table 1).

The mean (sd) of HFS-30 was not significantly different between Dysport® and Neuronox® [27.34 (22.8) vs. 27.19 (22.1);  $p = 0.98$ ]. The mean (sd) of SF-36 was not significantly different between Dysport® and Neuronox® [112.07 (8.0) vs. 109.65 (9.9);  $p = 0.34$ ]. The mean (sd) of AIMS was not significantly different between Dysport® and Neuronox® [10.34 (7.5) vs. 10.73 (6.7);  $p = 0.84$ ] and the mean CES-D was not significantly

**Table 1.** Demographic data and clinical characteristics of total hemifacial spasm patients

	(n = 26)
Age (yrs) Mean $\pm$ SD	54.80 $\pm$ 12.50
Gender:	
Female	17
Male	9
Mean duration of disease (yrs)	5.00 $\pm$ 3.10
Mean $\pm$ SD	
Side of spasm: Right	
Right	12
Left	14
Mean BTX injection times	8.90 $\pm$ 5.30

different between Dysport® and Neuronox® [17.19 (7.7) vs. 16.46 (7.4);  $p = 0.73$ ]. There were no significant differences of means (sd) of HFS-30, AIMS and CES-D at week 12 and week 24 between Dysport® and Neuronox® (Fig. 2).

For tertiary outcomes, across the 24-week period, the mean (sd) of HFS-30 was reduced from 34.2 (23.1) at week 0 to 32.7 (20.1) at week 12 and 21.8 (23.3) at week 24 ( $p = 0.09$ ). The mean (sd) of SF36 was changed from 110.7 (12.4) at week 0 to 109.4 (10.5) at week 12 and 112.3 (7.2) at week 24, indicating no significant difference between groups ( $p = 0.60$ ). The mean (sd) of AIMS was reduced from 12.1 (6.1) at week 0 to 11.8 (6.7) at week 12 and 9.3 (7.4) at week 24 ( $p = 0.02$ ). The mean (sd) of CES-D was reduced from 21.7 (7.6) at week 0 to 19.6 (6.9) at week 12 and 14.0 (7.1) at week 24 ( $p < 0.001$ ) (Fig. 3).

The mean (sd) of total intensity score of HFS at 4 week after treatment with Dysport® was significantly lower than Neuronox® [6.62 (0.7) vs. 8.04 (0.2);  $p < 0.001$ ]. The mean (sd) of duration of facial muscle spasm per day at week 4 after treatment with Dysport® was significantly lower than Neuronox® [3.64 (0.4) vs. 4.7 (0.4) hour per day;  $p < 0.001$ ]. The mean (sd) of duration of functional impairment per day at 4 week after treatment with Dysport® was significantly lower than Neuronox® [1.25 (0.1) vs. 1.73 (0.2) hour per day;  $p < 0.001$ ].

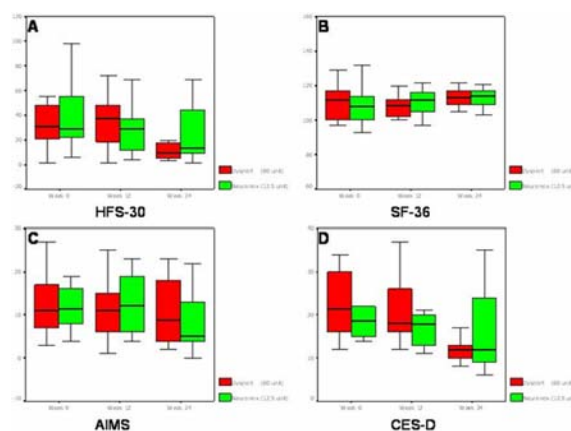
Within 4 weeks after treatment with botulinum toxin A injection, the mean (sd) of total intensity score compared between week 12 and week 24 was reduced from 7.4 (0.8) to 6.7 (0.5) ( $p < 0.001$ ). The mean (sd) duration of facial muscle spasm compared between week 12 and week 24 was reduced from 4.1 (0.5) hour/day to 3.3 (0.3) hour/day ( $p < 0.001$ ). The mean (sd) duration of functional impairment per day compared between week 12 and week 24 was reduced from 1.9 (0.2) hour/day to 1.3 (0.1) hour/day ( $p < 0.001$ ) (Fig. 4) There were no adverse events observed in the present study.

## Discussion

The disease specific QoL questionnaire, HFS-30, has been developed and widely used in HFS patients, validated in English<sup>(15)</sup>, Chinese<sup>(13)</sup> and Thai versions<sup>(9)</sup> and also tested for reliability with these patients. In the previous publications, QoL in HFS patient was analyzed by comparison between pre- and post-treatment in both medical and surgical treatment. In this 24-week, double-blind, randomized, cross-over comparison the QoL in HFS patient study, the primary outcome (HFS-30) and secondary outcome (SF-36,



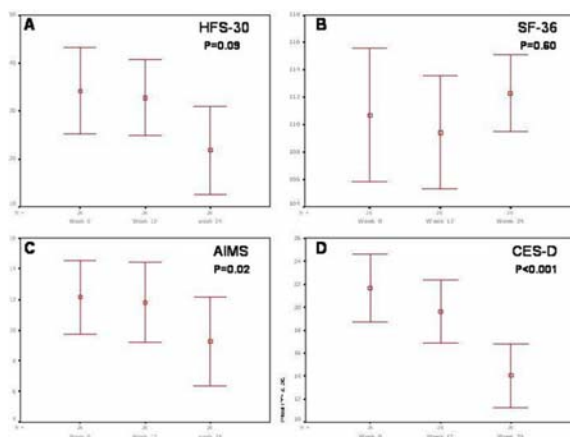
**Fig. 1** Location of injection sites. All patients received 4 subcutaneous injections into outer upper and lower orbicularis oculi muscle and outer upper and lower orbicularis oris muscle in the symptomatic side



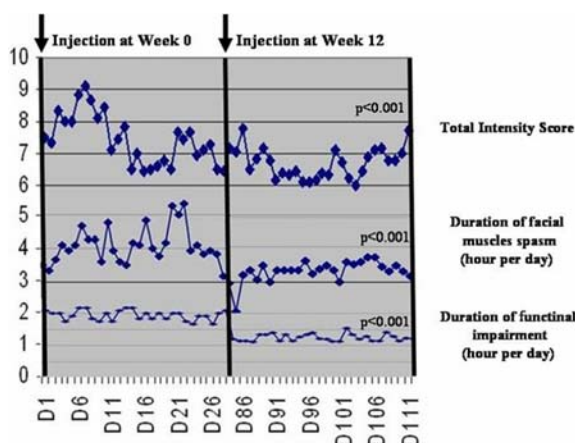
**Fig. 2** A) HFS-30 at week 0, week 12 and week 24, by comparison between Dysport® (red bar) and Neuronox® (green bar). B) SF-36 at week 0, week 12 and week 24, by comparison between Dysport® (red bar) and Neuronox® (green bar). C) AIMS at week 0, week 12 and week 24, by comparison between Dysport® (red bar) and Neuronox® (green bar). D) CES-D at week 0, week 12 and week 24, by comparison between Dysport® (red bar) and Neuronox® (green bar). There was no statistically significant difference between Dysport® (red bar) and Neuronox® in week 0, week 12 and week 24

AIMS and CES-D) showed no significant different between Dysport® and Neuronox®. Interestingly, the effect of treatment after multiple injection, showed improvement of HFS-30 ( $p = 0.09$ ), SF-36 ( $p = 0.60$ ),





**Fig. 3** For all treated HFS patients (n = 26), A) HFS-30 at week 0, week 12 and week 24. B) SF-36 at week 0, week 12 and week 24. C) AIMS at week 0, week 12 and week 24. D) CES-D at week 0, week 12, and week 24. The HFS-30 and SF-36 were not statistically significant in difference after treatment in week 0, week 12 and week 24, whereas AIMS and CES-D showed statistically significant differences after treatment in week 0, week 12 and week 24



**Fig. 4** Mean total intensity score (upper line), mean duration of facial muscles spasm per day (middle line) and mean duration of functional impairment per day (lower line), by comparison between day 0-28 and day 84-112 (28 days after week 0 and week 12 botulinum toxin A injection). All tertiary outcomes showed statistical significance ( $p < 0.001$ )

AIMS ( $p = 0.02$ ) and CES-D ( $p = 0.001$ ), when comparing week 0 to week 12 and week 24. This may support the hypothesis that repeated injection of botulinum toxin A every 12 weeks improve QoL in long term treatment. The present study demonstrated the benefit of

botulinum toxin A substantiating another recent study in HFS that demonstrated a trend of improvement in QoL.

Within 4 weeks after treatment, the mean total intensity score of HFS, mean duration of facial muscle spasm per day and mean duration of functional impairment per day were significantly lower with Dysport® ( $p < 0.001$ ), whereas the overall assessment of QoL in HFS patients were no different between groups. This difference may be due to underestimating the unit dose equivalence of Dysport® versus Neuronox®. Full scale 12-week diary details recorded after each treatment should be investigated in future studies, with a larger sample size, using approximate dosage equivalent of 3.0-4.0 units Dysport® per 1 unit Neuronox®.

The botulinum toxin A is a zinc endopeptidase, which cleaves the structural neurosecretory proteins in the presynaptic nerve terminal. It inhibits the calcium-mediated release of the acetylcholine into synaptic junction resulting in local chemical denervation and loss of activity in the targeted muscles<sup>(2)</sup>. Repeated injection of botulinum toxin A every 12 weeks may change the role of central neurotransmitters such as substance P and glutamate in the trigeminal nucleus in the brainstem, without any changes in dopamine and serotonin systems. Improvement of clinical depression in the present study may be due to the collateral effect of botulinum toxin A, improving physical function by reducing co-symptoms of HFS and depression<sup>(3)</sup>. As showed in the results of the present study, the significant improvements in HFS patients after 3 consecutive injections with botulinum toxin A were in the domain of mental health predominantly compared to physical health. The CES-D questionnaire showed mental health was significantly improved ( $p = 0.001$ ), which may be explained by low sensitivity of the SF-36 and HFS-30 compared to the AIMS and CES-D in HFS patients. The SF-36 may be appropriate for evaluating the general QoL, but may be not sensitive enough to detect disease-specific QoL in HFS patients.

In conclusion, there was no significant difference of QoL between Dysport® and Neuronox® for treatment of HFS. However, there was a trend to improved QoL after multiple botulinum toxin A injections, demonstrating the benefit in both physical health and mental health domains in the present study. Further double-blind, randomized study, with a larger number of subjects and a longer period of diary recording every 12 weeks, to compare the difference of QoL between Dysport® and Neuronox® should be

performed.

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### Potential conflicts of interest

None.

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**คุณภาพชีวิตของผู้ป่วยโรคไบน้ำกระตูกครึ่งซีก ภายหลังการรักษาด้วยโบทูลินัมทอกซิน เอ: การศึกษาแบบสุ่มปกปิดทั้งสองฝ่ายเป็นระยะเวลา 24 สัปดาห์ เพื่อเปรียบเทียบระหว่าง ดิสพอร์ต และ นิวโรน็อกซ์ โดยวิธีการไขว้**

**สืบสาย คงแสงดาว, ศักดิ์สิทธิ์ กฤตลักษณ์กุล**

**ภูมิหลัง:** โรคไบน้ำกระตูกครึ่งซีกเป็นกลุ่มอาการเคลื่อนไหวผิดปกติที่พบได้บ่อย ซึ่งมีอาการไบน้ำกระตูกครึ่งซีกเป็นบางครั้งไม่สม่ำเสมอ โดยมีอาการเกร็งกระตูกของกล้ามเนื้อใบหน้าโดยไม่ทราบสาเหตุ การเปรียบเทียบคุณภาพชีวิตระหว่างรักษาด้วย ดิสพอร์ตและนิวโรน็อกซ์ ไม่เคยได้รับการศึกษามาก่อน

**วัตถุประสงค์:** เพื่อประเมินคุณภาพชีวิตภายหลังการรักษาผู้ป่วยโรคไบน้ำกระตูกครึ่งซีกด้วยโบทูลินัมทอกซิน เอ (ดิสพอร์ตและนิวโรน็อกซ์)

**วัสดุและวิธีการ:** เป็นการศึกษาแบบสุ่มปกปิดทั้งสองฝ่าย เป็นระยะเวลา 24 สัปดาห์ โดยวิธีการไขว้การรักษา ระหว่างโบทูลินัมทอกซิน เอ ชนิดดิสพอร์ตและนิวโรน็อกซ์ เพื่อประเมินคุณภาพชีวิตของผู้ป่วยโรคไบน้ำกระตูกครึ่งซีก โดยแบบสอบถามคุณภาพชีวิตผู้ป่วยโรคไบน้ำกระตูกครึ่งซีก 30 ข้อ แบบสอบถามผลการรักษาแบบสั้น 36 ข้อ มาตรการวัดการเคลื่อนไหวผิดปกติ และแบบสอบถามระดับความวิตกกังวล ซึ่งได้ประเมินที่ก่อนการรักษาสัปดาห์ที่ 0 และสัปดาห์ที่ 12 และ 24 การบันทึกประจำวันตลอด 24 ชั่วโมง สำหรับโรคไบน้ำกระตูกครึ่งซีกได้ถูกประเมินใน 4 อาทิตย์ ภายหลังการรักษา

**ผลการศึกษา:** ผู้ป่วยโรคไบน้ำกระตูกครึ่งซีกจำนวน 26 ราย เข้าร่วมการศึกษาระหว่างเดือนพฤษภาคม พ.ศ. 2553 ถึง มกราคม พ.ศ. 2554 ค่าเฉลี่ยของแบบสอบถามคุณภาพชีวิตผู้ป่วยโรคไบน้ำกระตูกครึ่งซีก 30 ข้อ มาตรการวัดการเคลื่อนไหวผิดปกติ และแบบสอบถามระดับความวิตกกังวล มีผลดีขึ้นหลังจากรักษาโดยไม่มี ความแตกต่างระหว่างการรักษาทั้ง 2 ชนิด อย่างมีนัยสำคัญ แบบสอบถามผลการรักษาสั้น 36 ข้อ ไม่มีการเปลี่ยนแปลงในทั้ง 2 กลุ่ม การรักษาอย่างไรก็ดี ค่าเฉลี่ยแบบสอบถามคุณภาพชีวิตของผู้ป่วยโรคไบน้ำกระตูกครึ่งซีก 30 ข้อ มาตรการวัดการเคลื่อนไหวผิดปกติและแบบสอบถามระดับความวิตกกังวล มีค่าดีขึ้นภายหลังการรักษา ด้วยโบทูลินัมทอกซิน ภายหลังการรักษา 24 สัปดาห์ ( $p = 0.090, 0.020, 0.001$  ตามลำดับ) ค่าคะแนนความรุนแรง ของโรคไบน้ำกระตูกครึ่งซีก, ระยะเวลาไบน้ำกระตูกต่อวันและระยะเวลาการสูญเสียการทำงานต่อวัน ในการรักษา ด้วยดิสพอร์ต ดีกว่าการรักษาด้วยนิวโรน็อกซ์ อย่างมีนัยสำคัญ ( $p < 0.001$ )

**สรุป:** ไม่มีความแตกต่างกันในแง่คุณภาพชีวิตของผู้ป่วยโรคไบน้ำกระตูกครึ่งซีก ระหว่างการรักษาด้วยดิสพอร์ต และนิวโรน็อกซ์ อย่างไรก็ตามคุณภาพชีวิตของผู้ป่วยดีขึ้นภายหลังการรักษาด้วยโบทูลินัมทอกซินซ้ำหลาย ๆ ครั้ง

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