The Validation of the Disease-Specific Questionnaire for Health-Related Quality of Life in Thai Patients with Hemifacial Spasm

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Objective: *To investigate the reliability and validity of the Thai version of disease-specific health-related quality of life instrument for patients with hemifacial spasm (HFS) as well as their response to botulinum toxin treatment.*
Material and Method: *A Thai version of HFS-30 has been developed with the permission of the author. Thirty patients with HFS were asked to complete this Thai HFS-30, the 6-point disability scale before treatment and between four and six weeks after botulinum toxin injections. Peak improvement (0-100%) was subjectively assessed by each patient between four and six weeks after injection. They were also asked to answer the existing Thai SF-36 questionnaire before treatment to test its correlation with Thai HFS-30. Another group of ten patients completed the questionnaire and then a second identical copy after a 2-week interval. The reliability, validity, and responsiveness were subsequently analyzed.*
Results: *The Thai HFS-30 showed a Cronbach's alpha coefficient of 0.78 and no significant difference of a test-retest reliability. The total content validity was 0.88 (range 0.5-1.0). There were good correlations between both the Physical and Mental Health parts of the Thai HFS-30 and Thai SF-36 ($p < 0.05$ and $p < 0.01$, respectively). The Thai HFS-30 also demonstrated a response to treatment similar to the 6-point disability scale and the peak improvement.*
Conclusion: *The Thai version of HFS-30 is a valid, reliable, and sensitive to change instrument for disease specific health-related quality of life assessment.*

Keywords: *Hemifacial spasm, Thai HFS-30, Quality of life, Validity*

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Hemifacial spasm (HFS) is a chronic disease characterized by a unilateral tonic and clonic contraction of facial muscles innervated by the facial nerve[1]. Microvascular compression of the root exit zone of the facial nerve is the most likely cause[2]. Treatment with botulinum toxin is widely accepted as an alternative to surgery. Although HFS is not a life threatening condition, it is a chronic and possibly progressive illness that frequently affects the quality of a patient's life[3].

Quality of life (QOL) is a subjective multidimensional evaluation of a person's perception and satisfaction of various aspects of their life[4]. Since good health contributes to the quality of life the term "health related quality of life" (HRQOL) is frequently used. The assessment of HRQOL can be measured with

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generic and disease specific instruments. The generic HRQOL instruments, such as medical outcome study-short form 36, compare the outcome across different diseases. These instruments do not measure specific problems of that disease compared to disease-specific instruments, which better refer impact of that disease to a particular patient[5].

To the best of the authors' knowledge, there is no validated disease-specific HRQOL instrument for hemifacial spasm in Thailand. Therefore, the authors have investigated the reliability and validity of a Thai version of the disease-specific HRQOL questionnaire specifically for patients with hemifacial spasm and their response to botulinum toxin treatment.

Material and Method

Questionnaires

With the kind permission of Tan EK, et al[6] a bilingual person translated the hemifacial spasm questionnaire-30 item version (HFS-30) into Thai and then a second, independent, bilingual person retranslated the document back into English. The final step involved making corrections found from the differences between the original translated version and the retranslated version. The questionnaire consisted of seven subscales (30 items): mobility (5 items), activity of daily living (5 items), emotional well-being (7 items), stigma (4 items), social support (3 items), cognition (3 items), and communication (3 items) (see Appendix 1: Thai version of the HFS-30). All the items were scored on a 5-point scale ranging from 0 (never) to 4 (always). For each subscale, a total subscore (the sum of each item scores) was rescaled from 0 (the best) to 100 (the worst possible QOL) in order to make a comparison of the score for all subscales.

The medical outcome study 36-item short form health survey (SF-36)[7] is a widely used generic HRQOL questionnaire containing eight domains and can be divided into two parts: Physical Health (physical functioning, role physical health, bodily pain, and general health) and Mental Health (vitality, social functioning role, emotional and mental health). The Thai version of the SF-36 has now been developed, validated and tested for reliability in Thai patients with mental disorder[8].

Subjects

The present study has been approved by the Institutional Ethics Committee and the written informed consent was obtained from each patient prior to testing. Two groups of patients were used to test validity and reliability. The first group contained 30 patients with primary hemifacial spasm attending the out-patient botulinum-toxin clinic at Songklanagarind Hospital. The second group was 10 patients also with primary hemifacial spasm attending the same clinic as the first group. All patients had been diagnosed using standard criteria[9]. The exclusion criteria were: 1) concomitant with chronic debilitating illness or other movement disorders and 2) unable to read or understand Thai.

For the first group, all participants independently completed the self-rating questionnaire of the Thai HFS-30 before having the botulinum toxin injection and another identical copy of the questionnaire between four and six weeks after the injection to assess their response to treatment. They were also asked to answer the Thai SF-36 version before any treatment commenced to test the construct validity of the Thai HFS-30 version.

The second group of patients did not have any injections and were asked to answer the self-rating questionnaire of the Thai HFS-30 version twice (at the start and after two weeks) to assess the test-retest reliability.

Assessment of severity and response to treatment

The severity of hemifacial spasm was examined by a neurologist and graded from five predetermined and universally accepted levels before the injection[10], which are: 0 = no spasms; 1 = mild, barely noticeable; 2 = mild without functional impairment; 3 = moderate spasm, moderate functional impairment; 4 = severe, incapacitating spasm. The response to treatment with botulinum toxin between four and six weeks after the injections was subjectively assessed by the patients in terms of peak improvement (0-100%) and the 6-point disability rating scale[11] identified as 0 = normal; 1 = mild discomfort or functional impairment; 2 = mild to moderate discomfort or functional impairment; 3 = moderate discomfort or functional impairment; 4 = moderate to severe discomfort or functional impairment; 5 = severe discomfort or functional impairment; 6 = completely disabled or incapacitated. Any side effects after treatments were also recorded. All patients were examined by a neurologist who was blinded to the patient's questionnaire answers.

Statistical analyses

The reliability of the questionnaire was tested with test-retest and internal consistency. These two methods were measured using Wilcoxon Signed Ranks

test and Cronbach's Alpha Coefficients of total score respectively. A Cronbach's alpha coefficient of greater than 0.7 and no significant difference between initial and follow up scores were considered as giving a good reliability.

The Thai HFS-30 was evaluated by neurological content experts for its relevance to the specific domain and validity across culture. Each item had been graded as three levels (0 = no relevance, 0.5 = moderate relevance, 1 = very relevance). After evaluation, the Total content validity was demonstrated using mean score of all items scores. A mean score greater than 0.5 was considered as an acceptable content validity.

All the subscales in the Thai HFS-30 were grouped under two headings: Physical Health (mobility, activity of daily living, and communication) and Mental Health (emotional well-being, social support, stigma, and cognition). The correlation between the score of Physical and Mental Health of the Thai HFS-30 and those of the SF-30 were tested with Spearman rank correlation coefficient to assess the construct validity.

The mean scores of each subscale in the questionnaire as well as the 6-point disability rating scale both before and after botulinum toxin injections were compared using the Wilcoxon Signed Ranks test to evaluate the degree of patient responsiveness. Statistical significance was defined at $p < 0.05$. All the data analysis was performed by computer with SPSS for window (version 11.5).

Results

There were 30 patients in the first group who had completed the entire questionnaire. This group consisted of 22 females (73.3%) and 8 males (26.7%). Twenty-one patients (70%) were newly diagnosed and had never received botulinum toxin injection (De-novo patients). Nine of thirty patients (30%) had previously had multiple injections. The mean age was 51 $\pm$ 9.7 years. The duration of the symptoms was 6.2 $\pm$ 5.9 (SD) years. The disease severity was at three (range from 1 to 4). Other background information is shown in Table 1. The treatment side effects occurred in 16 patients (53.3%) including tearing and eyelid weakness. Almost all the side effects occurred in the De-novo patients but were very mild and only transient lasting for only a few days to a week.

The reliability evaluation of Thai HFS-30 carried out by the 10 patients in the second group with mean age of 59 $\pm$ 11.1 years and consisting 70% of females. The Cronbach's alpha coefficient was 0.78 and the test-retest reliability using Wilcoxon Signed Ranks test was not significantly different.

The content validity was 0.88 (range 0.5-1.0). There was a strong correlation between the Physical and the Mental Health parts of the Thai HFS-30 and Thai SF-36 respectively (Table 2).

For the first group, all the patients showed improvement after injections and had a mean peak improvement score of 80.7%. The six-point disability rating scale also improved significantly after treatment (3.15 $\pm$ 1.5 *cf.* 0.58 $\pm$ 0.7, $p = 0.000$). The mean score of emotional well-being showed a significant change between the before and after injection state (28.2 $\pm$ 18.5 (SD) *cf.* 17.1 $\pm$ 13.2 (SD), $p = 0.004$). The mean scores of other subscales between the before and after injection state did not differ significantly (Table 3).

Subgroup analysis for the De-novo patients (n = 21), the mean scores of emotional well-being, stigma, social support and communication between before and after injections were significantly different (Table 4). The mean peak improvement was 77.9% and the 6-point disability rating scale before and after treatment was 3.35 $\pm$ 1.4 *cf.* 0.85 $\pm$ 0.79, $p = 0.000$. Nine patients who had previously had multiple injections showed no significant change in any domain between

Table 1. Patient group 1 characteristics at baseline

Number		30
Age (mean $\pm$ SD, year)		51 $\pm$ 9.7
Gender:	female	22 (73.3%)
	male	8 (26.7%)
Mean duration of disease (year $\pm$ SD)		6.2 $\pm$ 5.9
Disease severity (range)		3 (1-4)
De-novo patients		21 (70%)
Married		24 (80%)
Employment rate (only patients < 60 years)		23 (76%)
Education:	< 7 years	15 (50%)
	$\geq$ 7 years	15 (50%)

Table 2. Spearman rank correlation between the Thai HFS-30 and Thai SF-36

Thai HFS-30	Thai SF-36	
	Physical health	Mental health
Physical health	-0.39*	-0.62**
Mental health	-0.59**	-0.78**

* $p < 0.05$, ** $p < 0.01$

Table 3. Mean scores of each subscale before and after botulinum toxin injections (n = 30)

Domains	Before injection (mean ± SD)	After injection (mean ± SD)	p-value
Mobility	30.17 ± 21.0	24.0 ± 22.3	0.06
Activity of daily living	33.33 ± 20.5	28.83 ± 22.5	0.24
Emotional well-being	28.21 ± 18.5	17.14 ± 13.0	0.004
Stigma	28.33 ± 23.7	22.29 ± 20.7	0.14
Social support	11.94 ± 19.9	5.83 ± 9.3	0.14
Cognition	35.28 ± 20.7	28.61 ± 20.7	0.10
Communication	21.67 ± 20.0	16.11 ± 21.9	0.16

Significance defined at $p < 0.05$

Table 4. Mean scores of each subscale before and after botulinum toxin injections in De-novo patients (n = 21)

Domains	Before injection (mean ± SD)	After injection (mean ± SD)	p-value
Mobility	30.48 ± 19.6	24.05 ± 21.4	0.13
Activity of daily living	32.38 ± 18.8	29.52 ± 21.6	0.57
Emotional well-being	31.29 ± 17.3	17.35 ± 13.7	0.003
Stigma	31.55 ± 24.1	19.05 ± 20.2	0.008
Social support	15.01 ± 22.9	5.56 ± 10.0	0.048
Cognition	36.51 ± 19.6	28.57 ± 18.5	0.17
Communication	21.82 ± 18.9	10.71 ± 15.8	0.026

Significance defined at $p < 0.05$

the before and after injections except for social support ($p = 0.04$). The mean score of each subscale before injections for these patients was lower than the De-novo patients (data not shown).

Discussion

Many reports from Thailand have confirmed[12-15] that the widely accepted belief of the effectiveness of botulinum toxin in the treatment of hemifacial spasm is true. However, the assessment of its value has been clinically based; for example, the peak improvement in contraction, duration of treatment and side effects. The authors' previous report assessed the condition by duration of treatment, side effects, peak improvement, and the 6-point disability scale[15]. The 6-point disability scale is an accepted measure of how much overall discomfort is felt or function is impaired[11]. However, it could not show the consequence of hemifacial spasm in detail. HRQOL is an important outcome in the evaluation of multiple dimensions of life in patients with chronic diseases such as hemifacial spasm, which should be assessed especially disease-specific HRQOL.

The Thai version of the HFS-30 demonstrated a Cronbach's alpha coefficient of 0.78 for the total scale and no significant difference between the initial and the follow up scores; indicating a good reliability.

The content validity of the Thai HFS-30 was 0.88 (range 0.5-1.0). Moreover, there was a significant correlation between Physical Health part and Mental Health part of the Thai HFS-30 and Thai SF-36. Thus, the content and the construct validity were well accepted.

The present study examined the sensitivity to change of the Thai HFS-30 by comparing each of the subscale scores before and after treatment. These showed a significant change in the emotional well-being domain for the present study population. However, the De-novo patients did show a significant change in four domains namely: emotional well-being, stigma, social support, and communication. Nine of the patients from the present study population had had previous multiple injections and; therefore, had experience of the treatment response. That is why only one domain (social support) showed a significant change between the before and after injections for this group. Moreover, the mean score of each subscale for this group was lower than the De-novo group. These results imply that patients who had had previous multiple injections had a better QOL than did the De-novo patients. They received repeated injections to maintain the efficacy of the drug.

The presented De-novo patients did show a significant change in emotional well-being, stigma, and social support domains after receiving treatment, which has been similarly described by Tan EK, et al[6]. This indicates that HFS has more of an effect on mental than on physical health.

Some patient factors have been observed that influence the overall answers to the questionnaire. First, as mentioned earlier in the present study, patients previously receiving multiple injections did not readily notice any changes after injections, which lead to a small change in each subscale. Although the side effects in the present study were common to all and occurred in most De-novo patients, nonetheless they were still satisfied with the treatment. Third, 50% of the present study population had no more than seven years of education. Therefore, it is probable they did not fully

understand the questionnaire and thus gave the wrong score.

Conclusion

The present study has demonstrated that the Thai version of the HFS-30 is reliable, valid, and responsive. It is a very practical, self-rating questionnaire over a short period of time. The instrument should be future tested in both the local community and other regions of Thailand. It may also have applications to other chronic intermittent contractions such as blepharospasm.

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Appendix 1.

ภาคผนวก 1 แบบสำรวจสุขภาพสำหรับโรคใบหน้ากระตุกครึ่งซีก

แบบสอบถามนี้เป็นแบบสอบถามที่สำรวจความคิดเห็นของท่านที่มีต่อสุขภาพของท่านเองในช่วง 2-3 สัปดาห์ที่ผ่านมาว่าโรคของท่านทำให้ท่านมีสุขภาพเป็นอย่างไร (วงกลมหนึ่งคำตอบ)

1. ฉันทำกิจกรรมยามว่างด้วยความลำบาก

   0. ไม่เลย 1. นาน ๆ ครั้ง 2. บางครั้ง

   3. เกือบตลอดเวลา 4. ตลอดเวลา
2. ฉันดูแลบ้านด้วยความลำบาก เช่น ทำสวน, ทาสีบ้าน, ซ่อมบ้าน, จัดบ้าน
3. ฉันทำงานด้วยความลำบาก
4. ฉันขับรถ

   1. เป็น 2. ไม่เป็น..... ข้ามไปข้อ 5

   4.1. ฉันขับรถด้วยความลำบาก
5. ฉันข้ามถนนด้วยความลำบาก
6. ฉันอ่านหนังสือด้วยความลำบาก
7. ฉันดูทีวี, ภาพยนตร์ด้วยความลำบาก
8. ฉันใช้คอมพิวเตอร์

   1. เป็น 2. ไม่เป็น..... ข้ามไปข้อ 9

   8.1. ฉันใช้คอมพิวเตอร์ด้วยความลำบาก
9. ฉันเขียนหนังสือด้วยความลำบาก
10. ฉันทำงานบ้านด้วยความลำบาก เช่น ล้างจาน,กวาดบ้าน, ซักผ้า
11. ฉันรู้สึกซึมเศร้า
12. ฉันรู้สึกอยากร้องไห้
13. ฉันรู้สึกโกรธ หรือขมขื่น
14. ฉันกังวลว่าจะมองไม่เห็น (ตาบอด)
15. ฉันรู้สึกกลัวการรักษา
16. ฉันกังวลว่าจะเป็นอัมพาต
17. ฉันกังวลว่าจะสูญเสีย “ งานประจำ” (ถูกให้ออกจากงาน)
18. ฉันหลีกเลี่ยงการสบตาผู้อื่น
19. ฉันหลีกเลี่ยงการรับประทานอาหารหรือดื่มเครื่องดื่มในที่สาธารณะ
20. ฉันรู้สึกเขินอายกับสภาพตัวเอง
21. ฉันรู้สึกกังวลกับปฏิกิริยาของบุคคลอื่นที่มีต่อตัวเรา
22. ฉันมีปัญหาเกี่ยวกับความสัมพันธ์กับผู้ใกล้ชิด
23. ฉันไม่ได้รับการดูแลสนับสนุนจากคู่ครอง
24. ฉันไม่ได้รับการดูแลสนับสนุนจากครอบครัวและเพื่อน
25. ฉันมีปัญหาเรื่องสมาธิ
26. ฉันมีปัญหาเรื่องปวดศีรษะ
27. ฉันมีปัญหาเรื่องมึนงง, วิงเวียน
28. ฉันพูดด้วยความลำบาก
29. ฉันรู้สึกไม่สามารถติดต่อสื่อสารได้อย่างเหมาะสม
30. ฉันรู้สึกถูกละเลยไม่ใส่ใจจากบุคคลทั่วไปในการติดต่อสื่อสาร

ความแม่นยำของแบบสำรวจคุณภาพชีวิตเฉพาะโรคสำหรับผู้ป่วยไทยที่มีโรคใบหน้ากระตุกครึ่งซีก

สุวรรณา เศรษฐวัชราวนิช, นิพัฒน์ เอื้ออารี, กิตติ ลิ่มอภิชาต, พรชัย สถิรปัญญา, คณิตพงษ์ ปราบพาล

วัตถุประสงค์: *เพื่อทดสอบความน่าเชื่อถือ และความแม่นยำของแบบสำรวจคุณภาพชีวิตเฉพาะโรคฉบับภาษาไทยสำหรับผู้ป่วยโรคใบหน้ากระตุกครึ่งซีก รวมถึงการตอบสนองต่อการรักษา*

วัสดุและวิธีการ: *แบบสำรวจคุณภาพชีวิตเฉพาะโรคใบหน้ากระตุกครึ่งซีก-30 ฉบับภาษาไทยได้รับการพัฒนาโดยขออนุญาตจากผู้คิดสร้าง จากนั้นผู้ป่วยโรคใบหน้ากระตุกครึ่งซีกจำนวน 30 ราย ได้ตอบคำถามในแบบสำรวจคุณภาพชีวิตเฉพาะโรคใบหน้ากระตุกครึ่งซีก-30 ฉบับภาษาไทย, ประเมิน 6-ระดับความพิการ (6-point disability scale) ก่อนและระหว่าง 4-6 สัปดาห์หลังการฉีดยาโบทูลินั่มท็อกซิน ประเมินอาการดีที่สุด (peak improvement) เป็นร้อยละ โดยผู้ป่วยระหว่าง 4-6 สัปดาห์หลังการฉีดยา นอกจากนี้ผู้ป่วยยังได้ตอบแบบสำรวจสุขภาพทั่วไป-36 ฉบับภาษาไทยก่อนการรักษา เพื่อทดสอบความสัมพันธ์กับแบบสำรวจคุณภาพชีวิตเฉพาะโรคใบหน้ากระตุกครึ่งซีก-30 ฉบับภาษาไทย ผู้ป่วยอีกกลุ่มจำนวน 10 รายจะตอบแบบสำรวจคุณภาพชีวิตเฉพาะโรคใบหน้ากระตุกครึ่งซีก-30 ฉบับภาษาไทย 2 ครั้งห่างกัน 2 สัปดาห์ วิเคราะห์ความน่าเชื่อถือ ความแม่นยำ และการตอบสนองต่อการรักษาของแบบสำรวจ*

ผลการศึกษา: *การทดสอบแบบสำรวจคุณภาพชีวิตเฉพาะโรคใบหน้ากระตุกครึ่งซีก-30 ฉบับภาษาไทย พบว่ามีค่า Cronbach's alpha เท่ากับ 0.78 ความน่าเชื่อถือเมื่อทำซ้ำ (Test-retest reliability) มีค่าไม่ต่างกัน ค่าความถูกต้องของเนื้อหาเท่ากับ 0.88 (0.5-1.0) และพบว่ามีความสัมพันธ์อย่างมีนัยสำคัญทางสถิติ ระหว่างกลุ่มสุขภาพทางกาย (Physical Health part) และสุขภาพทางจิตใจ (Mental Health part) ของแบบสำรวจคุณภาพชีวิตเฉพาะโรคใบหน้ากระตุกครึ่งซีก-30 ฉบับภาษาไทย และแบบสำรวจสุขภาพทั่วไป-36 ฉบับภาษาไทย ($p < 0.05$ และ $p < 0.01$ ตามลำดับ) นอกจากนี้ แบบสำรวจคุณภาพชีวิตเฉพาะโรคใบหน้ากระตุกครึ่งซีก-30 ฉบับภาษาไทยยังแสดงให้เห็นถึงการตอบสนองต่อการรักษาที่ให้ผลดีขึ้น คล้ายคลึงกับการวัดโดย 6-ระดับความพิการ และอาการดีที่สุดภายหลังการฉีดยา*

สรุป: *แบบสำรวจคุณภาพชีวิตเฉพาะโรคใบหน้ากระตุกครึ่งซีก-30 ฉบับภาษาไทย เป็นเครื่องมือที่มีความน่าเชื่อถือ ความแม่นยำ และไวต่อการเปลี่ยนแปลง สำหรับการประเมินคุณภาพชีวิตเฉพาะโรค*