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The validity and reliability of the Thai-version of 5-D itch scale

Papapit Tuchinda, Kanokvalai Kulthanan, Leena Chularojanamontri, Chuda Rujitharanawong, Chanika Subchookul, Suphattra Trakanwittayarak

Abstract

Background: Pruritus is commonly associated with skin disorders. The 5-D itch scale was developed as a specific questionnaire for pruritus.

Objective: This study aimed to evaluate the validity, reliability, and sensitivity to change of the Thai 5-D itch scale in Thai patients.

Methods: The Thai Dermatology Life Quality Index (DLQI), patient's global assessment of disease severity (PatGA-VAS), Chronic Urticaria Quality of Life Questionnaire (CU-Q_2oL), and seven-day urticaria activity score (UAS7) were evaluated as correlation with Thai 5-D itch scale. Seventy-five stable patients (42 chronic urticaria patients and 33 eczema patients), who had no change in disease severity after 4-weeks were assessed for test-retest reliability.

Results: Of 130 pruritus patients who were treated at Department of Dermatology, Siriraj Hospital, 65 patients were diagnosed with chronic urticaria. The others were diagnosed with eczema. The validity of Thai 5-D itch scale correlated strongly with Thai DLQI total score (r = 0.76, p < 0.0001) and PatGA-VAS (r = 0.79, p < 0.0001). The strong reliability of Thai 5-D itch scale was demonstrated as intraclass correlation coefficient of 0.90. The changes in Thai 5-D itch scale was correlated with the changes in PatGA-VAS and UAS7 which indicated that the Thai 5-D itch scale had good sensitivity to change (r = 0.66) and (r = 0.67), respectively.

Conclusion: The Thai 5-D itch scale is a questionnaire with good validity, reliability and sensitivity to change to evaluate pruritus in Thai patients. This will support the use of 5-D itch scale in practice, in other languages.

Key words: 5-D itch scale, Questionnaire, Clinimetric properties, Validity, Reliability, Interpretability, Patient reported outcome

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Introduction

Pruritus, or itch is defined as a displeasing sensation that arouses the desire to scratch. This symptom is commonly associated with primary skin disorders, for example, xerosis, atopic dermatitis, arthropod assault, psoriasis, urticaria.[1,2] Moreover, a systemic or neuropathic cause of pruritus including renal, cholestatic, malignancy, hypothyroidism, iron deficiency anemia, and idiopathic generalized pruritus may be the cause of pruritus.[3,4] The intensity of pruritus ranges from a mild annoyance to a severe, disabling condition.

Although itch symptoms are commonly found in general practice, a specific questionnaire to evaluate itch symptoms is quite limited. In 2010, the 5-D itch scale has been developed by Elman S, *et al* in English language.[5] The 5-D itch scale consists of 8 items in 5 domains as follows: duration, degree, direction, disability, and distribution. The domains of duration, degree, and direction contain 1 item whereas there are 4 items for determining the disability. The items of 4 domains are assessed by a 5-point Likert scale.

The distribution domain includes 16 potential itch areas, including 15 body parts and 1 area with clothing or bandages contact. The score of distribution is determined based on the number of areas: 0-2 areas = score of 1, 3-5 areas = score of 2, 6-10 areas = score of 3, 11-13 areas = score of 4, 14-16 areas = score of 5.[5,6] The 5-D itch scale is a short questionnaire which is easy to complete. It can be used to assess the multidimensional nature of pruritus and its impact on health-related quality of life (HRQoL). This scale is applicable to several diseases including renal pruritus, cholestatic pruritus, pruritus related to skin diseases, and burn. The 5-D itch scale has been translated into various different languages including Arabic, Malay, and Urdu.[7-9] At present, the validated patient-reported outcome (PRO) measurement for assessing pruritus in Thai patients is still necessary. This study aimed to investigate the validity, reliability, and sensitivity to change of the Thai version of the 5-D itch scale among patients with chronic urticaria (CU) and eczema.

Methods

Generation of the Thai 5-D itch scale

Formal permission was given by Marlyn J. Mayo to translate the original English version of 5-D itch scale into Thai, and to validate the translated instrument.[5] This English version was translated into Thai by those who spoke both Thai and English languages with native proficiency. The first draft of Thai version of the questionnaire was reviewed for comprehensibility of items by two dermatologists. After these physicians reached consensus, the Thai version was back-translated into English by a native speaker of English. The original and back-translated English versions were reviewed by the original English authors and the Thai research team to detect any misconceptions or misinterpretation. After a consensus conference, the Thai version of the 5-D itch scale (**Figure 1**) was tested with 10 chronic pruritus patients, and no points of misunderstanding were detected. Subsequently, the final Thai 5-D itch scale was interviewed to chronic pruritus patients for the study.

Patients and conduct of study

This study was approved by the Siriraj Institutional Review Board (SIRB), Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok, Thailand (COA no. Si464/2018). Data were collected from November 2018 to August 2019 at Department of Dermatology at Siriraj Hospital. The target sample size for validation was 130 who were 65 patients of CU and 65 patients of eczema. All the patients who were interviewed to join in this study were over 18 years of age and had the ability to complete questionnaires in Thai. Written informed consent was obtained from all participating patients.

Patient HRQoL questionnaires used to evaluate the clinimetric properties of the Thai version of the 5-D itch scale

The validated Thai version of the Dermatology Life Quality Index (DLQI) questionnaire

In 1994, the DLQI questionnaire was developed by Finlay, *et al* for assessing HRQoL of general dermatologic diseases.[10] Dr. Kulthanan got the formal permission to validate and use the Thai version of the DLQI questionnaire.[11] There are 10 questions according to 6 domains: symptoms and feeling, daily activities, leisure, work and school, personal relationships, and treatment. The range of total score is from 0 to 30. Total DLQI scores are grading into five groups as follows: 0-1 = no effect, 2-5 = small effect, 6-10 = moderate effect, 11-20 = very large effect, and 21-30 = extremely large effect.

Patient's Global Assessment of Visual Analog Scale (PatGA-VAS)

The PatGA-VAS is a patient-based outcome measurement for assessing severity of itch during 4 weeks. The participant uses abstract thought processes to convert their itch severity to a mark on a continuum, and the scoring requires manual measuring of the mark with a ruler. The total score ranges from 0 to 10.[12]

The validated Thai version of Chronic Urticaria of Life Questionnaire (CU-Q_2oL)

The CU-Q_2oL is the first urticaria-specific questionnaire to evaluate HRQoL in CU patient. It consisted of 23 items, classified into 6 domains: pruritus (2 items), swelling (2 items), limitations (3 items), sleep problems (5 items), look (5 items), impact on daily activities (6 items). The total score ranges from 0 to 100. Dr. Kulthanan got the formal permission to validate and use the Thai version of the CU-Q_2oL questionnaire.[13]

Standard seven-day urticaria activity score (UAS7)

The UAS7 is a specific instrument to assess the disease severity of CU patients over 7 days. It evaluates intensity of pruritus and numbers of wheals. The total score ranges from 0 to 42.[14]

On the 1st visit (baseline), informed consent was obtained and a complete history and physical examination were performed in all patients. The patients were informed how to fill the Thai 5-D itch scale, the Thai DLQI, and the PatGA-VAS by themselves. Regarding to patients with CU were also asked to fill extra questionnaires including the Thai CU-Q_2oL and the UAS7. After 4-weeks of treatment, all of the questionnaires were completed again by them in the clinic at the 2nd visit.

Statistical analysis

Consensus-based Standards for the Selection of Health Measurement Instruments (COSMIN), a standard protocol for determining the methodologic quality of health measurement instrument study, was used in this study.[15] The data analysis used Statistical Package for the Social Sciences for Windows, Version 18 (SPSS Inc., Chicago, IL, USA). Two-sided *P*-values of less than or equal to 0.05 were considered to be statistically significant.[16]

Assessment of the Thai 5-D Itch scale validity

Validity is a measurement of the accuracy of research instrument especially questionnaire.

5-D ระดับความคัน

1. <u>ระยะเวลา</u>: ในระยะเวลา 2 สัปดาห์ที่ผ่านมา ท่านมีอาการคันวันละกี่ชั่วโมง

น้อยกว่า 6 ชั่วโมงต่อวัน	6-12 ชั่วโมงต่อวัน	12-18 ชั่วโมงต่อวัน	18-23 ชั่วโมงต่อวัน	ตลอดวัน
❑ 1	❑ 2	❑ 3	❑ 4	❑ 5

2. <u>ความรุนแรง</u>: กรุณาประเมินระดับความรุนแรงของอาการคันของท่านในช่วง 2 สัปดาห์ที่ผ่านมา

ไม่มีอาการ	คันน้อย	คันปานกลาง	คันมาก	คันมากจนไม่สามารถทนได้
❑ 1	❑ 2	❑ 3	❑ 4	❑ 5

3. <u>ความเปลี่ยนแปลง</u>: อาการคันของท่านในช่วง 2 สัปดาห์ที่ผ่านมามีแนวโน้ม ดีขึ้น หรือ แย่ลง เมื่อเทียบกับอาการคันในเดือนที่ผ่านมา

อาการคันหายสนิท	ดีขึ้นมาก แต่ยังมีอาการคันอยู่	ดีขึ้นเล็กน้อย และยังมีอาการคันอยู่	คันเท่าเดิม ไม่เปลี่ยนแปลง	อาการคันแย่ลง
❑ 1	❑ 2	❑ 3	❑ 4	❑ 5

4. <u>ผลกระทบ</u>: อาการคันของท่านในช่วง 2 สัปดาห์ที่ผ่านมา มีผลกระทบต่อกิจกรรมในการดำเนินชีวิตประจำวันอย่างไร

	ไม่มีผลกระทบต่อการนอนหลับ	ทำให้หลับช้าลงบางครั้ง	ทำให้หลับช้าลงบ่อยครั้ง	ทำให้หลับช้าลงและตื่นตอนกลางคืนบางครั้ง	ทำให้หลับช้าลงและตื่นตอนกลางคืนบ่อยครั้ง
การนอนหลับ	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5

	ไม่มีความเกี่ยวข้อง	ไม่มผลกระทบ	แทบจะไม่มีผลกระทบ	มีผลกระทบบ้าง	มีผลกระทบบ่อยๆ	มีผลกระทบเสมอ
การผ่อนคลาย/การเข้าสังคม	❑	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5
งานบ้าน/กิจธุระ	❑	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5
การทำงาน/การเรียน	❑	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5

5. <u>บริเวณที่มีอาการ</u>: กรุณาเลือกส่วนของร่างกายที่มีอาการคันในระยะเวลา 2 สัปดาห์ที่ผ่านมา ถ้าส่วนที่มีอาการไม่อยู่ในรายการ โปรดเลือกส่วนที่ใกล้เคียงที่สุด

ศีรษะ/หนังศีรษะ	❑	หลังเท้า/นิ้วเท้า	❑
ใบหน้า	❑	ฝ่าเท้า	❑
หน้าอก	❑	ฝ่ามือ	❑
ท้อง	❑	หลังมือ/นิ้วมือ	❑
หลัง	❑	แขนท่อนล่าง	❑
ก้น	❑	ต้นแขน	❑
ต้นขา	❑	บริเวณที่สัมผัสกับเครื่องนุ่งห่ม (เช่น ขอบกางเกง, ชุดชั้นใน)	❑
ขาส่วนล่าง (น่อง)	❑	ขาหนีบ	❑

Figure 1. The Thai version of 5-D itch scale

- **Construct validity** defines the degree to which a relevance is measured. The correlation between the Thai 5-D itch scale and other standard instruments for HRQoL including the Thai DLQI, the PatGA-VAS, the Thai CU-Q_2oL and the UAS7 were assessed by Spearman's rank correlation coefficient. Weak, moderate, and strong correlations were identified as correlation coefficient values of < 0.3, 0.3-0.6, and > 0.6 respectively.[17]

- **Known-group validity** is demonstrated when a questionnaire can discriminate groups that is different on the variable of interest. For disease activity of pruritus, the capacity of the Thai 5-D itch scale was tested to classify 5 groups of patients according to the PatGA-VAS score. The PatGA-VAS score of = 0, 0 < score < 4, 4 ≤ score < 7, 7 ≤ score < 9, score ≥ 9 indicated no pruritus, mild pruritus, moderate pruritus, severe pruritus, very severe pruritus, respectively.[12] For disease activity of CU patients, the UAS7 scores of 0, 1-6, 7-15, 16-27, and 28-42 were used to categorize patients into 'no activity', 'minimal disease activity, 'mild disease activity', 'moderate disease activity', and 'severe disease activity', respectively.[14] For HRQoL, patients were classified into 5 groups by using the DLQI scores, as follows: (i) 'no effect' (DLQI scores of 0-1); (ii) 'small effect' (DLQI scores of 2-5); (iii) 'moderate' (DLQI scores of 6-10); (iv) 'very large effect' (DLQI scores of 11-20); and (v) 'extremely large effect' (DLQI scores of 21-30).[18] Kruskal Wallis test was used to determine known-group validity.

Assessment of the Thai 5-D Itch scale reliability

Reliability is the ability of an instrument to get stable scores over a short period of time.

- **Internal consistency** is typically used to measure the homogeneity of questionnaire based on the correlations between different items on the same test. It was measured using Cronbach's alpha reliability coefficient to analyze internal consistency and interpret. Excellent, good, and acceptable reliability were defined as $\alpha \geq 0.9$, $0.7 \leq \alpha < 0.9$, and $0.6 \leq \alpha < 0.7$, respectively.[19]

- **Test-retest reliability** measures the consistency of scores that assesses the different administrations of the same test over period of time change. Stable patients were patients in the same disease severity group according to the PatGA-VAS score over 4-weeks interval (stable in disease severity), the total score of the Thai 5-D itch score at baseline and at follow-up. Intraclass correlation coefficient (ICC) values of < 0.4, 0.4-0.75, and > 0.75 represented poor, average, and strong reliability, respectively.[20]

Assessment of the Thai 5-D Itch scale sensitivity to change

The ability of a questionnaire is to detect significant change over time, regarding a meaningful change. Correlation coefficients of < 0.3, 0.3-0.5, and > 0.5 were considered weak, moderate, and large correlations, respectively.[21] At least moderate correlation between a questionnaire and a standard comparative measurement was required. A correlation between score changes in the Thai 5-D itch scale and the PatGA-VAS was performed in this study.

Results

Patient characteristics

Of 130 patients with pruritus (mean ± SD age = 44.5 ± 16 years), 65 (50%) patients were diagnosed with CU. The remaining patients were diagnosed with eczema. Of those, 85 (65.4%) were female and 45 (34.6%) were male. The average duration of disease was 24 months (range 1-240 months). The average frequency of symptom was 4.9 days. (range 0-7 days). The most common patients were employed occupation 90 (69.2%). The median, minimum, and maximum of the Thai 5-D itch scale, the PatGA-VAS, the DLQI, the UAS7, and the CU-Q_2oL were 13 (min 5 - max 23), 4 (min 0 - max 10), 6.5 (min 0 – max 23), 10 (min 1 - max 42), and 16 (min 1 - max 53), respectively. The majority of pruritus according to the PatGA-VAS, the DLQI, and the UAS7 were 47 (36.2%) mild pruritus (0 < score < 4), 45 (34.6%) very large effect (score 11-20), and 25 (19.2%) minimal disease activity (score 1-6), respectively. Demographic data and scores at baseline are demonstrated in **Table 1**.

Table 1. Demographic data of 130 patients with chronic pruritus, including chronic urticaria (65 patients) and eczema (65 patients)

Characteristics	N (%)		
	Total N = 130	Chronic urticaria N = 65	Eczema N = 65
Age, mean ± SD, year	44.5 ± 16	42.4 ± 14	46.6 ± 17
Sex			
Male	45 (34.6)	18 (27.7)	27 (41.5)
Female	85 (65.4)	47 (72.3)	38 (58.5)

Table 1. (Continued)

Characteristics	N (%)		
	Total N = 130	Chronic urticaria N = 65	Eczema N = 65
Duration of disease, mean ± SD, month	24.0 ± 32.7	27.8 ± 36.2	20.3 ± 28.6
Frequency of symptom, mean±SD, day	4.9 ± 2.3	4.0 ± 2.3	5.8 ± 1.9
Occupation			
Employed	90 (69.2)	42 (64.4)	48 (73.8)
Housewife	13 (10)	8 (12.3)	5 (7.7)
Student	13 (10)	5 (7.7)	8 (12.3)
Doctor/scientist/nurse/dentist	7 (5.4)	6 (9.2)	1 (1.5)
Retired	5 (3.8)	3 (4.6)	2 (3.1)
Unemployed	2 (1.5)	1 (1.5)	1 (1.5)
Score of 5-D itch scale, median, (min-max)	13 (5-23)	11 (5-23)	14 (8-22)
Score of PatGA-VAS, median, (min-max)	4 (0-10)	3 (0-10)	6 (0.8-10)
Score of DLQI, median, (min-max)	6.5 (0-23)	5 (0-22)	10 (1-23)
Score of UAS7, median, (min-max)	10 (1-42)	10 (0-42)	N/A
Score of CU-Q_2oL (%), median, (min-max)	16 (1-53)	16.3 (0-57.61)	N/A
Pruritus according to PatGA-VAS			
No pruritus (score = 0)	3 (2.3)	3 (4.6)	0
Mild pruritus (0 < score < 4)	47 (36.2)	32 (49.2)	15 (23.1)
Moderate pruritus (4 ≤ score < 7)	40 (30.8)	16 (24.6)	24 (36.9)
Severe pruritus (7 ≤ score < 9)	33 (25.4)	11 (16.9)	22 (33.8)
Very severe pruritus (score ≥ 9)	7 (5.4)	3 (4.6)	4 (6.2)
Pruritus according to DLQI			
No effect (0-1)	21 (16.2)	14 (21.5)	7 (10.8)
Small effect (2-5)	39 (30)	24 (36.9)	15 (23.1)
Moderate effect (6-10)	22 (16.9)	11 (16.9)	11 (16.9)
Very large effect (11-20)	45 (34.6)	15 (23.1)	30 (46.2)
Extremely large effect (21-30)	3 (2.3)	1 (1.5)	2 (3.1)
Pruritus according to UAS7			
No activity (0)	3 (2.3)	3 (4.6)	N/A
Minimal disease activity (1-6)	25 (19.2)	25 (38.5)	N/A
Mild disease activity (7-15)	16 (12.3)	16 (24.6)	N/A
Moderate disease activity (16-27)	8 (6.2)	8 (12.3)	N/A
Severe disease activity (28-42)	13 (10.0)	13 (20)	N/A

Abbreviations: CU-Q_2oL, chronic urticaria quality of life; DLQI, dermatology life quality index; PatGA-VAS, patient's global assessment of disease severity; UAS7, seven-day urticaria activity score; N/A, not available

Table 2. Construct validity by spearman's rank correlation coefficient (*r*)

Questionnaires	Construct validity		
	The correlation coefficient between the Thai 5-D itch scale and other standard instruments for HRQoL		
	All patients	CU patients	Eczema patients
Patient's global assessment of disease severity (PatGA-VAS)	0.79 (0.72-0.85)	0.81 (0.71-0.88)	0.68 (0.52-0.79)
Validated Thai version of DLQI total score	0.76 (0.68-0.82)	0.76 (0.63-0.85)	0.72 (0.58-0.81)
Validated Thai version of CU-Q_2oL total score	N/A	0.65 (0.48-0.77)	N/A
UAS7 score	N/A	0.73 (0.59-0.83)	N/A

Correlation coefficient (95 % confident interval), $r > 0.6$ (strong correlation)
Abbreviations: CU, chronic urticaria; CU-Q_2oL, chronic urticaria quality of life; DLQI, dermatology life quality index; HRQoL, health-related quality of life; PatGA-VAS, patient's global assessment of disease severity; UAS7, seven-day urticaria activity score; N/A, not available

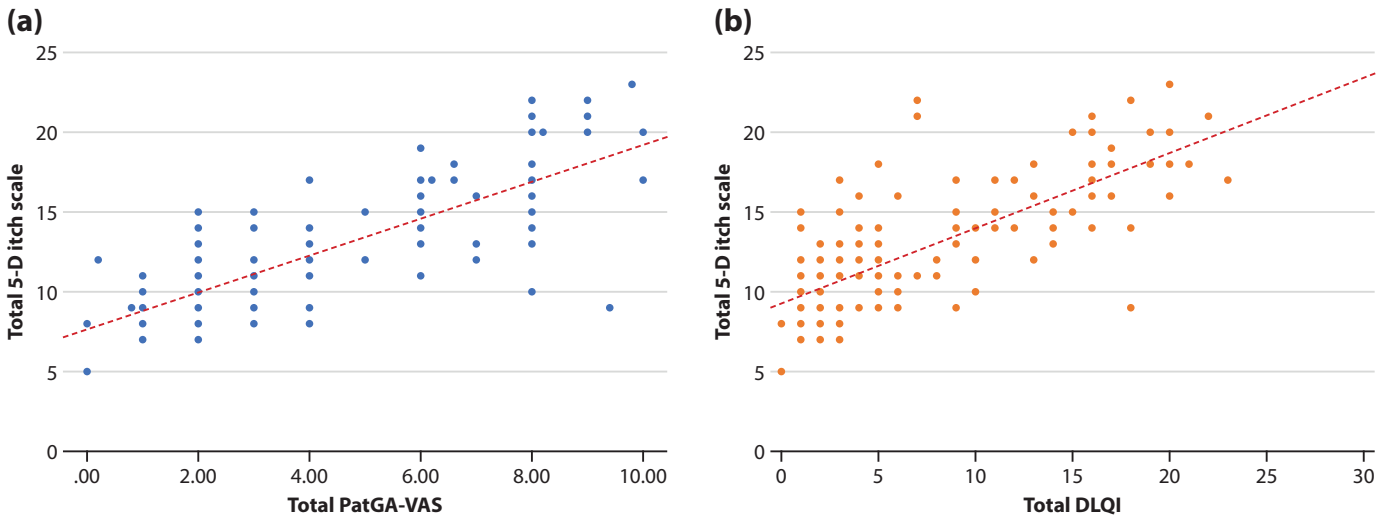

Figure 2. Scatter plot of the Thai 5-D itch scale
(a) The total 5-D itch scale and the total PatGA-VAS in all patients
(b) The total 5-D itch scale and the total DLQI score in all patients
Abbreviations: DLQI, dermatology life quality index; PatGA-VAS, patient's global assessment of disease severity

The 5-D itch scale is a valid instrument for determining severity of pruritus

Of the 130 patients, the total Thai 5-D itch scale correlated strongly with the total PatGA-VAS (disease severity) and the total DLQI score (HRQoL impairment) as shown in **table 2** and **figure 2**. Moreover, the significant differences in the total Thai 5-D itch scale among the 5 PatGA-VAS groups and the 5 DLQI groups were found by Kruskal–Wallis test (**Figure 3**, $p < 0.0001$).

In CU patients, there were a strong correlation between the Thai 5-D itch scale and the PatGA-VAS ($r = 0.81$, 95% CI: 0.71-0.88, $p < 0.0001$). Correlations between the Thai 5-D itch scale and the DLQI were found to be strong ($r = 0.76$, 95% CI: 0.63-0.85, $p < 0.0001$). In addition, there were significant differences of the Thai 5-D itch scale among the 5 PatGA-VAS groups, the 5 DLQI groups, and the 5 UAS7 groups by Kruskal–Wallis test ($p < 0.0001$).

In eczema patients, the Thai 5-D itch scale correlated strongly with the PatGA-VAS ($r = 0.68$, 95% CI: 0.52-0.79) and the DLQI ($r = 0.72$, 95% CI: 0.58-0.81), ($p < 0.0001$), respectively. Furthermore, the 5-D itch scale significant differences with the 5 PatGA-VAS groups and the 5 DLQI groups by Kruskal–Wallis test ($p < 0.0001$).

The 5-D itch scale demonstrated high internal consistency and test-retest reliability

Of the 130 patients, the Cronbach's α value of the Thai 5-D itch scale was 0.75 that implied good to excellent internal consistency. Seventy-five patients with no change in the severity group according to the PatGA-VAS score during the four-weeks interval were recruited to analyze the test-retest reliability. The ICC was 0.90 (95% CI: 0.85-0.94) for the 5-D itch score, which indicated strong intra-rater reliability.

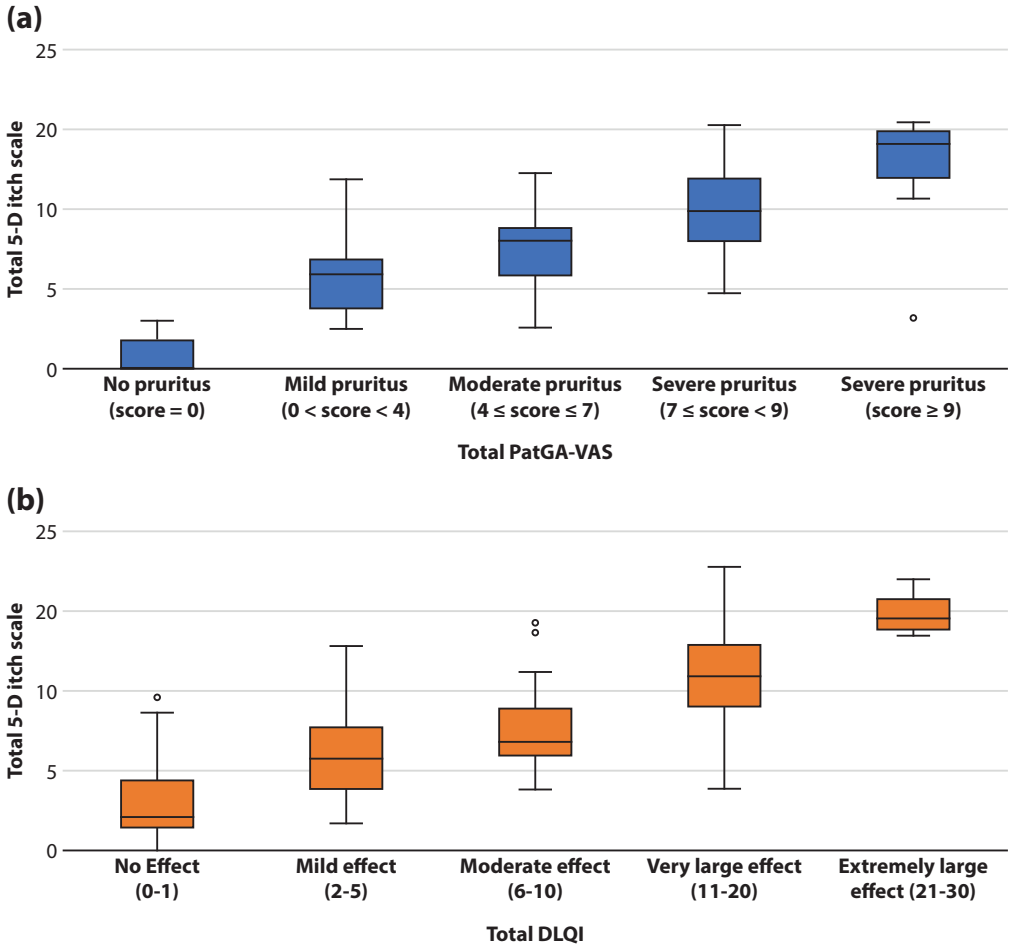

Figure 3. The significant differences in the Thai 5-D itch scale among the five PatGA-VAS groups and the five DLQI groups of all patients
(a) Correlation between the Thai 5-D itch scale and the five PatGA-VAS groups
(b) Correlation between the Thai 5-D itch scale and the five DLQI groups
Abbreviations: PatGA-VAS, patient's global assessment of disease severity, DLQI, dermatology life quality index

Table 3. Sensitivity to change

	Baseline	Follow up at week 4	Median change in score	Correlation between the change of the 5-D itch scale and the change of PatGA-VAS r, 95% CI, (*p* value)
All patients				0.66, 95% CI: 0.55-0.73, (< 0.0001)
5-D itch scale, median, (min-max)	13 (5-23)	11 (1-22)	2	
PatGA-VAS, median, (min-max)	4 (0-10)	3 (0-9)	1	
CU patients				0.60, 95% CI: 0.42-0.74, (< 0.0001)
5-D itch scale, median, (min-max)	11 (5-23)	10 (5-19)	1	
PatGA-VAS, median, (min-max)	3 (0-10)	2 (0-8.6)	1	
Eczema patients				0.72, 95% CI: 0.58-0.82, (< 0.0001)
5-D itch scale, median, (min-max)	14 (8-22)	12 (1-22)	2	
PatGA-VAS, median, (min-max)	6 (0.8-10)	5 (0.8-9)	1	

$r > 0.5$ (large correlation), Correlation coefficient (95 % confident interval), p value = < 0.0001
Abbreviations: CU, chronic urticaria; PatGA-VAS, patient's global assessment of disease severity

In CU patients, the internal consistency of the Thai 5-D itch scale was excellent, with Cronbach's α value of 0.83. Furthermore, the reliability of ICC, that was calculated in 42 CU patients, was 0.94 (95% CI: 0.88-0.96) indicating strong reliability.

In eczema patients, the internal consistency of the Thai 5-D itch scale was respectable with Cronbach's α of 0.70. Moreover, the ICC that was calculated in 33 patients with the unchanged severity group of the PatGA-VAS score was 0.84 (95% CI: 0.70-0.92) for the 5-D itch scale, that indicated excellent intra-rater reliability.

The 5-D itch scale demonstrated good sensitivity to change

The correlations between the difference of 5-D itch scale and the difference of the PatGA-VAS in all patients, CU patients, and eczema patients were large (r = 0.66, 95% CI: 0.55-0.73, $p < 0.0001$), large (r = 0.60, 95% CI: 0.42-0.74, $p < 0.0001$), and large (r = 0.72, 95% CI: 0.58-0.82, $p < 0.0001$), respectively as shown in **table 3**. Interestingly, the correlations between the change of 5-D itch scale and the change of the UAS7 was strong (r = 0.67, 95% CI: 0.51-0.79, $p < 0.0001$) in CU patients.

Discussion

In order to improve an evaluation of pruritus in skin conditions, physicians should assess both disease severity and impact on HRQoL in each patient. This study was the first study to validate the patient-report outcome instrument of pruritus, the 5-D itch scale, that was applied in dermatologic diseases. In previous studies, the 5-D itch scale was validated and used in patients with chronic kidney disease in Malaysia, Taiwan, and Pakistan and patients under targeted anticancer therapy in Korea.[7,9,22,23]

Our study demonstrated that the 5-D itch scale was a valid instrument for assessing impairment in Thai patients with pruritus. The strong construct validity was shown by the correlations between Thai 5-D itch scale and Thai DLQI, and between Thai 5-D itch scale and PatGA-VAS. Moreover, the positive strong correlations of Thai 5-D itch scale with Thai CU-Q_2oL and UAS7 were also demonstrated in CU patients. It illustrated that the higher 5-D itch scale was, the more severe of pruritus was in each patient. The known-group validity of Thai 5-D itch scale showed a statistically significant difference for each different level of DLQI and PatGA-VAS. The reliability of 5-D itch scale was analyzed by Cronbach's α, revealing excellent reliability. The good test-retest reliability was supported by the ICCs values of Thai 5-D itch scale that was consistent across multiple administrations for stable patients.

The sensitivity to change of Thai 5-D itch scale was assessed in this study. We found the linear correlations between the difference of the Thai 5-D itch scale and self-rated HRQoL impairment, PatGA-VAS were well-demonstrated in all patients, CU patients, and eczema patients. Moreover, the correlation of the difference of Thai 5-D itch scale with UAS7 was also in straight-line relationship in CU patients. It was an important measurement quality to determine treatment outcomes. However, the minimal clinical importance difference (MCID) and the categorization of the 5-D itch scale were unable to be investigated in this study due to our limitations including the relatively small number of patients and the restricted range of 5-D itch scale in our patients. Further studies with larger participants that enrolled patients with high disease activity are necessary to interpret the MCID and categorization of 5-D itch scale. Nevertheless, this study demonstrated the 5-D itch scale as a valid and reliable instrument for both Western and Asian patients to measure pruritus activity in skin diseases.

Limitation

Selection bias

The 5-D itch scale can be applied in previous studies involving different etiologies of pruritus. However, this study has evaluated the 5-D itch scale among CU and eczema patients only. Further studies should validate other dermatological conditions including psoriasis, atopic dermatitis, and xerosis.

Measurement error

There was no the measurement error for systematic error in this study because the Thai 5-D itch scale was interviewed by Thai research team who has trained.

There was no measurement error for random error in this study because all the patients had the ability to complete questionnaires in Thai. Written informed consent was obtained from all participating patients.

External validity, generalizability, and transportability

The patients were recruited in a single center within a limited time period of cross-sectional study. Therefore, our results may be not generalizable.

Conclusion

Our study is the first to investigate the measurement properties of the 5-D itch scale including validity, reliability and sensitivity to change in Asian patients with skin diseases. Based on standard methodologies, the results of our study are convinced that the 5-D itch scale is a reliable patient reported outcome instrument for applying in routine clinical practice and clinical trial researches.

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Conflict of interest

The authors declare that they have no competing interests.

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