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The validity and reliability of a Thai version of the Angioedema Control Test: Which recall period is preferable?

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Abstract

Background: The Angioedema Control Test (AECT) is a questionnaire that monitors disease control in patients with angioedema, with a recall period of 4 weeks (AECT-4wk) or 3 months (AECT-3mo).

Objective: This study investigated the psychometric properties of a Thai version of the AECT.

Methods: Of 54 patients, 46, 5, 2, and 1 had recurrent angioedema with chronic spontaneous urticaria, hereditary angioedema, idiopathic histaminergic angioedema, and acquired angioedema due to C1 esterase inhibitor deficiency, respectively. The AECT, Angioedema Activity Score (AAS), Dermatology Life Quality Index (DLQI), Angioedema Quality of Life Questionnaire (AE-QoL), and anchors for disease control (numeric rating scale [NRS] and patient global assessment-Likert scale [PatGA-LS]) were used. The patients rated the efficacy of their treatment.

Results: Fifty-four and 47 patients completed the AECT-4wk and AECT-3mo, respectively. Both AECT versions showed significant correlations with disease activity (AAS, r = 0.6–0.8), disease control (NRS and PatGA-LS, r = 0.7–0.9), and quality of life impairment (DLQI and AE-QoL, r = 0.6–0.8). Higher correlations were found for the AECT-4wk than for the AECT-3mo. Excellent internal consistency (alpha = 0.98 and 0.97, respectively) and intraclass correlation (0.96 and 0.94, respectively) were found. A cutoff ≥ 10 was confirmed to identify patients with well-controlled disease for both AECT versions (AUCs = 0.89 and 0.97).

Conclusion: The Thai version of the AECT is a valid and reliable tool for clinical practice. Due to the shorter recall period, the AECT-4wk may be more accurate than, and preferable to, the AECT-3mo. A cutoff ≥ 10 should be used to identify patients with well-controlled disease.

Key words: Angioedema Control Test, Validity, Reliability, Screening accuracy, 4-week

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Introduction

Angioedema is a sudden, localized, self-limited, and often recurrent swelling of the mucous membrane or the deep layers of the skin, including the lower dermis and subcutis. Symptoms include tingling, burning, tightness, and sometimes pain rather than itch. The resolution of an individual lesion can take up to 72 hours, which is usually slower than for hives and wheals. The typical locations are the eyelids, lips, tongue, larynx, extremities, and genitalia.[1,2] Recurrent angioedema (RAE) can be classified as bradykinin-mediated and mast cell mediator-mediated. When RAE occurs without wheals,

bradykinin-mediated RA (such as angiotensin-converting enzyme inhibitor-related RAE or hereditary angioedema [HAE]) must be excluded. On the other hand, mast cell mediator-mediated RAE occurs in patients with chronic spontaneous urticaria or chronic inducible urticaria.[3,4]

Due to the unpredictability of angioedema outbreaks, the disfiguring nature of the swellings, and a potentially life-threatening course, RAE can cause a significant burden for patients, families, societies, and healthcare systems. Evidence shows that understanding patients' perspectives using patient-reported outcome measures (PROMs) leads to better communication between physicians and patients and shared decision-making.[5] Moreover, PROMs may help personalize and reduce treatment costs.[6] The use of PROMs for patients with RAE is also recommended by the international HAE guidelines of the WAO/EAACI (World Allergy Organization/European Academy of Allergy and Clinical Immunology).[1]

The Angioedema Control Test (AECT) is a PROM that aims to capture disease control of patients with RAE.[7] It was initially developed in German. An American English version was subsequently developed using a structured translation process. The AECT comprises 4 questions addressing angioedema frequency, angioedema-related quality of life impairment, and angioedema control by current treatment. Each question has 5 answer options. Two AECT versions are available, one with a recall period of 4 weeks (AECT-4wk) and the other with a recall period of 3 months (AECT-3mo). Apart from the recall period, the question and answer options of the 2 versions are identical. Both versions are easy to administer, complete, and use in routine clinical practice.

The AECT-4 weeks and AECT-3mo have been proven to be valid and reliable instruments for monitoring disease control in patients with RAE.[4,8] Nevertheless, it is still questionable which recall period (4 weeks or 3 months) is preferable. In addition, the AECT must be translated and culturally adapted for use in countries other than Germany and the United States to achieve valid outcomes.[8] Doing so also makes it possible to pool or directly compare data from research projects conducted in different countries or geographic regions.

This study aimed to develop a Thai-language equivalent of the AECT and to investigate the validity, reliability, and screening accuracy of the 4-week and 3-month versions of the Thai AECT.

Methods

This study was conducted at the Siriraj Urticaria and Angioedema Center of Reference and Excellence, Bangkok, Thailand, which is certified by the Global Allergy and Asthma European Network (GA^{2}LEN) and HAE International. The investigation consisted of 2 phases: the generation of a Thai version of the AECT and the validation of the Thai version using Thai patients with RAE. The Siriraj Institutional Review Board approved the protocol (Si756/2020).

Translation phase—generation of the Thai version of the AECT

In the first phase, the German AECT-4wk and AECT-3mo versions were translated into Thai using a structured forward-backward translation process per the MOXIE protocol (https://moxie-gmbh.de). Briefly, 2 independent forward translations to Thai were performed, a reconciliation of both versions by a Thai healthcare professional was undertaken, and a back-translation to German was done. A discussion between the Thai research team and the original authors then occurred to identify potential misconceptions or misinterpretations that may have been inadvertently introduced during the translation process. After a consensus on the final Thai language versions was achieved, cognitive debriefing interviews were performed with 1 male and 9 female Thai patients with RAE and chronic spontaneous urticaria. Their mean age was 36.9 ± 15.04 years, and the mean disease duration was 15.2 ± 11.49 months. As no changes in the wording of the Thai AECT versions were identified as being needed, they were deemed final and used in the subsequent validation study. **Figure 1** demonstrates the Thai AECT-4wk and AECT-3mo versions.

Validation phase—anchor outcomes

The following 3 validated Thai versions of PROMs were used as anchors in the validation phase:[9-11]

- **Angioedema Activity Score (AAS) questionnaire.** This diary-type document prospectively assesses daily angioedema activity. In a daily opening question, the AAS asks if angioedema was present on that day. Patients answering "Yes" are requested to answer 5 AAS questions that are scored from 0 to 15.[9,12] Patients were instructed to complete the AAS for 4 consecutive weeks and 3 consecutive months.
- **Dermatology Life Quality Index (DLQI) questionnaire.** This simple, self-administered tool measures the health-related quality of life (HRQoL) impairment of adult patients with skin diseases. It has 10 questions scored from 0 to 30, with higher scores indicating a higher level of HRQoL impairment.[11,13]
- **Angioedema Quality of Life (AE-QoL) questionnaire.** This angioedema-specific 17-item instrument assesses HRQoL in patients with RAE. It uses a recall period of 4 weeks and scores from 0 to 100, with higher scores indicating a higher degree of RAE-related HRQoL impairment.[3,7,10]

In addition, patients were asked to rate their disease control using a numeric rating scale (NRS) and a patient global assessment-Likert scale (PatGA-LS). In the case of the NRS, the scores 0 and 10 represented "not at all" and "complete control," respectively. As for the PatGA-LS, patients were asked to rate their angioedema control as "not at all," "hardly controlled," "moderately controlled," "well controlled," or "completely controlled," with a score ranging from 0 to 4. For both scales, higher scores signified better levels of disease control.

(a)

ใบประเมินการควบคุมโรคแองจิโออีดีมา
(AECT)

ชื่อ :_____ **วันที่:**_____._____._____

วันเดือนปีที่เกิด: _____._____._____

คำอธิบาย: ท่านมีอาการบวมเป็นๆ หายๆ หรือเรียกว่าแองจิโออีดีมา ภาวะแองจิโออีดีมาจะทำให้มีอาการบวมชั่วคราวของผิวหนังชั้นลึกหรือเยื่อบุ ซึ่งอาจเกิดที่บริเวณส่วนใดของร่างกายก็ได้ แต่พบบ่อยที่บริเวณริมฝีปาก เปลือกตา ลิ้น มือและเท้า และสามารถจะคงอยู่เป็นเวลาหลายชั่วโมงจนถึงหลายวัน คนไข้บางคนอาจมีอาการแองจิโออีดีมาในช่องท้องได้ด้วย ซึ่งจะมองไม่เห็นแต่ทำให้มีอาการปวดท้องได้บ่อย ในบางคนอาการบวมอาจเกิดร่วมกับผื่นลมพิษ

คำถาม 4 ข้อต่อไปนี้จะเป็นการประเมินระดับอาการในปัจจุบันของท่าน ในแต่ละคำถามกรุณาเลือกคำตอบจาก 5 ตัวเลือกที่ตรงกับอาการของท่านมากที่สุด กรุณาตอบให้ครบทุกคำถามและโปรดเลือกเพียงหนึ่งคำตอบในแต่ละคำถาม

1. ในช่วง 4 สัปดาห์ที่ผ่านมา ท่านมีอาการแองจิโออีดีมาบ่อยมากเพียงใด

O บ่อยมาก O บ่อย O เป็นครั้งคราว O น้อยครั้ง O ไม่มีเลย

2. ในช่วง 4 สัปดาห์ที่ผ่านมา ภาวะแองจิโออีดีมาส่งผลกระทบกับคุณภาพชีวิตของท่านมากเพียงใด

O มากที่สุด O มาก O ปานกลาง O เล็กน้อย O ไม่มีเลย

3. ในช่วง 4 สัปดาห์ที่ผ่านมา ท่านรู้สึกวิตกกังวลมากน้อยแค่ไหนจากการเกิดขึ้นโดยไม่สามารถคาดเดาได้ของภาวะแองจิโออีดีมา

O มากที่สุด O มาก O ปานกลาง O เล็กน้อย O ไม่มีเลย

4. ในช่วง 4 สัปดาห์ที่ผ่านมา การรักษาสามารถควบคุมภาวะแองจิโออีดีมาของท่านได้ดีเพียงใด

O ไม่ได้เลย O ได้เล็กน้อย O ปานกลาง O ดี O ดีมาก

Figure 1. (a) The Thai versions of the Angioedema Control Test with a recall period of 4 weeks. (b) The Thai versions of the Angioedema Control Test with a recall period of 3 months.

(b)

ใบประเมินการควบคุมโรคแองจิโออีดีมา
(AECT)

ชื่อ :_____ **วันที่:**_____._____._____

วันเดือนปีที่เกิด: _____._____._____

คำอธิบาย: ท่านมีอาการบวมเป็นๆ หายๆ หรือเรียกว่าแองจิโออีดีมา ภาวะแองจิโออีดีมาจะทำให้มีอาการบวมชั่วคราวของผิวหนังชั้นลึกหรือเยื่อบุ ซึ่งอาจเกิดที่บริเวณส่วนใดของร่างกายก็ได้ แต่พบบ่อยที่บริเวณริมฝีปาก เปลือกตา ลิ้น มือและเท้า และสามารถจะคงอยู่เป็นเวลาหลายชั่วโมงจนถึงหลายวัน คนไข้บางคนอาจมีอาการแองจิโออีดีมาในช่องท้องได้ด้วย ซึ่งจะมองไม่เห็นแต่ทำให้มีอาการปวดท้องได้บ่อย ในบางคนอาการบวมอาจเกิดร่วมกับผื่นลมพิษ

คำถาม 4 ข้อต่อไปนี้จะเป็นการประเมินระดับอาการในปัจจุบันของท่าน ในแต่ละคำถามกรุณาเลือกคำตอบจาก 5 ตัวเลือกที่ตรงกับอาการของท่านมากที่สุด กรุณาตอบให้ครบทุกคำถามและโปรดเลือกเพียงหนึ่งคำตอบในแต่ละคำถาม

1. ในช่วง 3 เดือนที่ผ่านมา ท่านมีอาการแองจิโออีดีมาบ่อยมากเพียงใด

O บ่อยมาก O บ่อย O เป็นครั้งคราว O น้อยครั้ง O ไม่มีเลย

2. ในช่วง 3 เดือนที่ผ่านมา ภาวะแองจิโออีดีมาส่งผลกระทบกับคุณภาพชีวิตของท่านมากเพียงใด

O มากที่สุด O มาก O ปานกลาง O เล็กน้อย O ไม่มีเลย

3. ในช่วง 3 เดือนที่ผ่านมา ท่านรู้สึกวิตกกังวลมากน้อยแค่ไหนจากการเกิดขึ้นโดยไม่สามารถคาดเดาได้ของภาวะแองจิโออีดีมา

O มากที่สุด O มาก O ปานกลาง O เล็กน้อย O ไม่มีเลย

4. ในช่วง 3 เดือนที่ผ่านมา การรักษาสามารถควบคุมภาวะแองจิโออีดีมาของท่านได้ดีเพียงใด

O ไม่ได้เลย O ได้เล็กน้อย O ปานกลาง O ดี O ดีมาก

Figure 1. (Continued)

Patients rated the efficacy of their RAE treatment during the preceding 4 weeks and 3 months as "insufficient" or "sufficient."

Validation phase—participants and study design

Patients with RAE attending the Siriraj Urticaria and Angioedema Center who had or did not have hives or wheals were asked to participate in the study. The patients needed to be adults (18 years or older) to participate. Patients were excluded if they could not read or understand questionnaires or had mental or psychological diseases. All participants provided written informed consent. Throughout the 3-month study period, the participants received appropriate RAE treatment according to their disease severity and per the EAACI/GA²LEN/EDF/WAO guidelines.[1,2]

At Visit 1 (Day 0), the patients were instructed how to complete the various instruments (AAS, DLQI, AE-QoL, NRS, and PatGA-LS) and to rate their treatment efficacy. Once the instructions were satisfactorily comprehended, the patients were asked to complete the AAS questionnaire for 4 consecutive weeks before their second visit to the Siriraj Urticaria and Angioedema Center. The AAS questionnaire was collected on the morning of Visit 2 (4 weeks). The patients completed the AECT-4wk, DLQI, AE-QoL, NRS, and PatGA-LS, and they were requested to rate the efficacy of the treatment given during the preceding 4 weeks. In the afternoon, they again completed the AECT-4wk in the same room and environment as in the morning. Subsequently, the patients were asked to record their angioedema activity with the AAS for 2 more consecutive months. At Visit 3 (3 months), the procedures used in Visit 2 were repeated, except that the AECT-3mo questionnaire was used instead of AECT-4wk.

Validation phase—determination of validity, reliability, and screening accuracy

Validity

Convergent validity: Spearman's correlation was used to determine the convergent validity of the AECT-4wk and the AECT-3mo with disease activity (AAS), disease control (NRS and PatGA-LS), and HRQoL impairment (DLQI and AE-QoL) serving as anchors. No or negligible, weak, moderate, strong, and very strong correlations were defined as 0.01 to 0.19, 0.20 to 0.29, 0.30 to 0.39, 0.40 to 0.69, and ≥ 0.70, respectively.[14] We expected the highest correlation between AECT and the anchors for disease control as these measures assess the same concept.

Known-group validity: PatGA-LS angioedema control and the patients' rating of their treatment efficacy were used to categorize the patients. The Kruskal–Wallis test was used for known-group validity.

Reliability

Internal consistency reliability: Cronbach's alpha reliability coefficient was computed to assess the internal consistency of the Thai version of the AECT. Cronbach's alpha values ≥ 0.9, 0.7 to < 0.9, and 0.6 to < 0.7 were deemed to indicate excellent, good and acceptable reliability, respectively.[8,15,16]

Test-retest reliability: Stable patients should have comparable AECT scores across 2 independent administrations (in the morning and afternoon). Intraclass correlation coefficient values > 0.75 denoted excellent reliability.[15,17]

Screening accuracy

The AECT should be able to identify patients with poorly controlled and well-controlled disease. The PatGA-LS angioedema control was used as an anchor to define patients with poorly controlled and well-controlled disease. Patients were regarded as "poorly controlled" if they selected the PatGA-LS answer options not at all, hardly controlled, or moderately controlled. In contrast, patients who chose well controlled or completely controlled were regarded as having "well-controlled" disease. Receiver operating characteristic (ROC) and area under the curve (AUC) were used to analyze the screening accuracy of the Thai version of the AECT, ie, its ability to identify and distinguish between patients with poorly controlled and well-controlled disease. AUC values > 0.8 signified excellent screening accuracy.[15,18]

Validation phase—sample size calculation and statistical analysis

A sample size of 54 was computed to achieve 80% power to detect a difference in correlation of 0.2 between the null and alternative hypothesis correlation (0.6 vs. 0.8), using a 2-sided type I error of 0.05. PASW Statistics for Windows, version 18.0 (SPSS Inc, Chicago, IL, USA) was used to analyze the study data. Probability (*P*) values < 0.05 were considered statistically significant.

Results

Fifty-four patients with RAE (mean age 45.1 ± 16.1 years; 45 women) were enrolled. Of these patients, 46 had RAE with chronic spontaneous urticaria, 5 had HAE, 2 had idiopathic histaminergic acquired angioedema, and 1 had acquired angioedema due to C1 esterase inhibitor deficiency (multiple myeloma). The questionnaires assessing the validity and reliability of the Thai versions of the AECT-4wk and AECT-3mo were completed by 54 and 47 patients, respectively.

Convergent validity and known-group validity

The AECT-4wk showed very strong and significant correlations with disease activity, disease control, and HR-QoL impairment (all correlations > 0.7; **Table 1**). Similarly, the AECT-3mo showed very strong and significant correlations with disease control (NRS-3 months and PGA-LS-3 months) and DLQI. There were strong relationships between AECT-3mo and disease activity (r = 0.56) and between AECT-3mo and AE-QoL (r = 0.64). Nevertheless, the AECT-3mo was less correlated with all aspects of angioedema including disease activity, disease control and QoL impairment than the ACET-4wk. For known-group validity, patients were categorized into 3 groups using their PGA-LS responses (not at all or hardly controlled; moderately controlled; and well controlled or completely controlled; **Table 2**). There were significant differences in the median AECT scores for the different levels of angioedema control (P < 0.001). Regarding the patients' ratings of their treatment efficacy at 4 weeks, 8 and 46 patients provided a rating of insufficient and sufficient, respectively. There was a significant difference in the median AECT scores of the insufficient and sufficient groups (P = 0.001). As only 2 patients rated their treatment as insufficient at 3 months, the known-group validity of the AECT-3mo was not investigated.

Table 1. Convergent validity of the Thai version of the Angioedema Control Test (AECT), with recall periods of 4 weeks (AECT-4wk) and 3 months (AECT-3mo)

Concept	Assessment	AECT-4wk (n = 54)	AECT-3mo (n = 47)
Disease activity	AAS (last 4 weeks)	-0.78* (P < .001)	–
	AAS (last 3 months)	–	-0.56* (P < .001)
Disease control	NRS-angioedema control (last 4 weeks)	0.86* (P < .001)	–
	NRS-angioedema control (last 3 months)	–	0.72* (P < .001)
	PatGA-LS angioedema control (last 4 weeks)	0.86* (P < .001)	–
	PatGA-LS angioedema control (last 3 months)	–	0.70* (P < .001)
QoL impairment	DLQI	-0.73* (P < .001)	-0.72* (P < .001)
	AE-QoL	-0.78* (P < .001)	-0.64* (P < .001)

Abbreviations: AAS, angioedema activity score; AE-QoL, Angioedema Quality of Life Questionnaire; DLQI, Dermatology Life Quality Index; NRS, numeric rating scale; PatGA-LS, Patient Global Assessment-Likert Scale
*Spearman's correlation coefficient

Table 2. Known-group validity of the Thai version of the Angioedema Control Test (AECT), with recall periods of 4 weeks (AECT-4wk) and 3 months (AECT-3mo)

Using the Patient Global Assessment-Likert Scale				
AECT	**Level of angioedema control**	**AECT score, mean ± SD (median)**	**Interquartile range**	**Number of patients**
AECT-4wk	Not at all to hardly controlled	4.5 ± 2.6 (5)	3.0–5.8	6
	Moderately controlled	7.5 ± 2.6 (7.5)	4.5–9.0	12
	Well- to completely controlled	13.6 ± 2.4 (14)	11.0–16.0	36
AECT-3mo	Not at all to hardly controlled	7.8 ± 2.3 (8)	5.3–9.8	8
	Moderately controlled	8.5 ± 1.8 (8.5)	6.0–9.3	10
	Well- to completely controlled	13 ± 3.2 (14)	11.0–16.0	29
Using the Patient Global Rating of the efficacy of treatment				
AECT	**Evaluation of current treatment efficacy**	**AECT score, mean ± SD (median)**	**Interquartile range**	**Number of patients**
AECT-4wk	Insufficient	6 ± 4.1 (5)	4.0–10.5	8
	Sufficient	12.1 ± 3.6 (12)	9.8–16.0	46

Abbreviation: SD, standard deviation

Internal consistency and test-retest reliability

The Cronbach's alpha values for the AECT-4wk and the AECT-3mo were 0.98 and 0.97, respectively, which indicated excellent internal consistency reliability for both versions. Two assessment time points (morning and afternoon, in the same room and environment) were available for the AECT-4wk and the AECT-3mo. The intraclass correlation coefficients were 0.96 (95%CI, 0.92–0.97) and 0.94 (95%CI, 0.89–0.97) for the AECT-4wk and the AECT-3 months, respectively.

Screening accuracy

At 4 weeks, there were 36 cases with well-controlled disease and 18 with poorly controlled disease, as defined by PatGA-LS. At 3 months, 29 and 18 cases had well-controlled and poorly controlled disease, respectively, for the AECT-3mo. The AUCs of the ROC analysis for the AECT-4wk and the AECT-3mo were 0.97 (95%CI, 0.93–1.0) and 0.89 (95%CI, 0.80–0.98) (**Figure 2**), respectively, indicating excellent screening accuracy for each. **Table 3** lists the sensitivities and specificities for different AECT cutoffs to identify patients with well-controlled and poorly controlled disease. For the AECT-4wk, the cutoff of ≥ 10 had high sensitivity (97.2%) and specificity (88.9%) for identifying patients with well-controlled disease. Similarly, for the AECT-3mo, the cutoff of ≥ 10 demonstrated high sensitivity (82.8%) and specificity (77.8%); at the cutoff of ≥ 11, it had the same sensitivity (82.8%) but a higher specificity (88.9%).

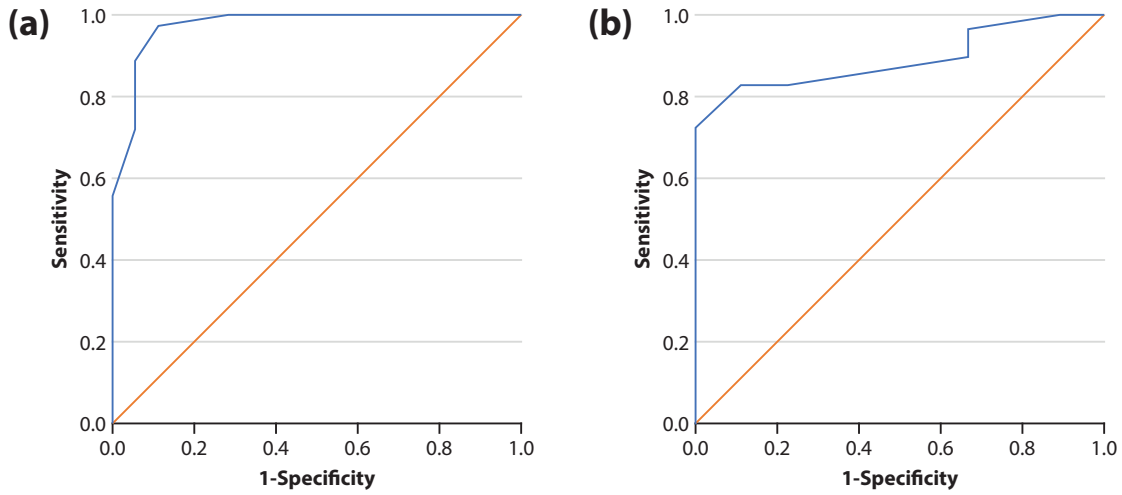

Figure 2. The area under the curves (AUCs) of the receiver operating characteristic (ROC) analysis for the Angioedema Control Test (AECT).

The AUCs of the ROC analysis for the AECT-4wk and the AECT-3mo were 0.97 (a) and 0.89 (b), respectively.

Table 3. Sensitivity and specificity for different cutoffs of the Thai version of the Angioedema Control Test (AECT), with recall periods of 4 weeks (AECT-4wk) and 3 months (AECT-3mo).

Cutoff values AECT-4wk	Sensitivity	Specificity
≥ 4	1.000	0.056
≥ 5	1.000	0.278
≥ 6	1.000	0.444
≥ 7	1.000	0.500
≥ 8	1.000	0.611
≥ 9	1.000	0.722
≥ 10	0.972	0.889
≥ 11	0.889	0.944
≥ 12	0.722	0.944
≥ 13	0.556	1.000
≥ 14	0.556	1.000
≥ 15	0.472	1.000
≥ 16	0.389	1.000

Cutoff values AECT-3mo	Sensitivity	Specificity
≥ 4	1.000	0.000
≥ 5	1.000	0.000
≥ 6	1.000	0.111
≥ 7	0.966	0.333
≥ 8	0.897	0.333
≥ 9	0.862	0.556
≥ 10	0.828	0.778
≥ 11	0.828	0.889
≥ 12	0.724	1.000
≥ 13	0.586	1.000
≥ 14	0.552	1.000
≥ 15	0.448	1.000
≥ 16	0.310	1.000

Discussion

Over the last 3 decades, there has been an increasing focus on PROMs in recognition of their usefulness in facilitating and enhancing the individualized treatment of patients. A literature review in 2021 showed that there are 9 PROMs for angioedema and HAE. They are AAS, AECT, AE-QoL, Hereditary Angioedema Activity Score, Hereditary Angioedema Quality of Life, Hereditary Angioedema Patient Reported Outcome, Hereditary Angioedema Association Questionnaire, Mean Symptom Complex Severity, and Treatment Outcome Score.[6,19-22] Five (AAS, AECT, AE-QoL, Hereditary Angioedema Activity Score, and Hereditary Angioedema Quality of Life) are easy to administer and suitable for routine clinical practice.[6] The AAS, AECT, and AE-QoL can be used for adult patients with RAE, including HAE. It should be noted that no disease-specific PROMs are available for pediatric patients with RAE.[6]

An investigation of the original German version of the AECT showed that it had the highest correlation with angioedema frequency and VAS angioedema control (disease control), both of which are close to the concept of the AECT.[8] Our study complemented that study by showing that the AAS (indicating disease activity) was also strongly correlated with the AECT-4wk and the AECT-3mo. Higher correlations were found for the AECT-4wk than for the AECT-3mo. This may be because the shorter recall period makes the AECT-4wk more accurate than the AECT-3mo. The higher correlations therefore suggest that the AECT-4wk may be preferable to the AECT-3mo.

The AECT-4wk and the AECT-3mo had high reliability, reproducibility, and screening accuracy. The original study showed that a cutoff of ≥ 10 had the best balance for identifying patients with well-controlled disease (≤ 9, poorly controlled RAE; ≥ 10, well-controlled RAE). Our study showed that a cutoff of 10 or 11 should be used. We have opted for the cutoff of ≥ 10 to identify patients with well-controlled disease as it is easier in clinical practice to have the same cutoff as in the original study.

Our study supports that the AECT can be used in an Asian country with a very different language and culture from Western countries. Further studies with more patients are required to investigate the sensitivity to change and the minimal clinically critical differences between the Thai and German versions of the AECT. Several reasons explain the limited number of our patients and the inability to investigate known-group validity for the AECT-3mo in our study. First, few patients with HAE were included as this condition is relatively rare in the Asian population. The Asian prevalence of HAE ranges from 0.1 to 8.2 per 10 million people, in contrast to 1:50,000–100,000 in the Caucasian population.[23-26] Most of our patients had RAE with chronic urticaria. Generally, RAE with urticaria (histaminergic angioedema) is less severe than HAE as it usually resolves within 24 to 48 hours and responds to antihistamine treatment.[27] Accordingly, we had only 2 patients who reported having insufficient treatment after 3 months.

Conclusion

Our study shows that the Thai versions of the AECT-4wk and the AECT-3mo are valid and reliable PROMs for clinical practice. Due to its shorter recall period, the AECT-4wk may be more accurate than, and preferable to, the AECT-3mo. A cutoff of ≥ 10 points can be used to identify patients with well-controlled disease.

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Conflicts of interest

The authors have no conflicts of interest to disclose.

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