Original Article

Reliability and Validity of the Rhinitis Control Assessment Test (Thai Version) in Patients with Rhinitis

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Objective: To assess the reliability and validity of the Rhinitis Control Assessment Test (RCAT) (Thai version) in patients with rhinitis.

Materials and Methods: This is a questionnaire-based research, cross-sectional study. The researchers had asked permission from the developer to translate the RCAT into Thai based on the international standard of translation method. Validity test was evaluated by the expert looking at the items in the questionnaire and agreeing that the test is a valid measure of the concept. Fifty patients with allergic and non-allergic rhinitis were recruited into the present study and completed the RCAT, total nasal symptom scores (TNSS) and skin tests were measured at the same time. Cronbach's coefficient alpha and Pearson correlation were evaluated for its reliability.

Results: The RCAT (Thai version) have a good reliability and validity with Cronbach's coefficient alpha 0.73 and Pearson correlation 0.74 in correlation analysis with TNSS ($p<0.01$). The aspect of content validity was evaluated by three specialists, and they agreed to all six questions of RCAT (Thai version).

Conclusion: The researchers have demonstrated that the RCAT (Thai version) have a good reliability and validity and is suitable for clinical application to evaluate the rhinitis symptoms.

Keywords: Rhinitis; Allergic rhinitis; Non-allergic rhinitis; RCAT

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Allergic Rhinitis is a disease caused by immune system disorders that shows symptoms at the nasal passages, causing itch, runny nose, sneezing, and stuffy nose. Rhinitis is a common disease in Thailand and other countries. The incidence of disease could be found in 10% to 25% of the population and tends to increase. Even though rhinitis usually does not show severe symptoms, it may affect the quality-of-life, study, and work performance of the patient. If it is not treated correctly, complications may occur such as otitis media, asthma, rhinosinusitis, nasal polyp, snoring, and obstructive sleep apnea.

There are many ways to treat rhinitis, such as giving instructions to patients on how to care for themselves, elimination or avoidance of allergens and irritants, environmental control, medications, immunotherapy, and endoscopic sinus surgery in patient who has nasal polyp or rhinosinusitis as comorbidity. Therefore, evaluation and control of rhinitis symptoms are important for treatment methods and helping patients to be aware of their conditions as well.

In 2013, the Rhinitis Control Assessment Test (RCAT)[1] was created in English with six questions and in the range of 6 to 30 points. The questions are about the frequency of rhinitis symptoms and other allergy symptoms within the past week. The patient may conduct the test to assess their own rhinitis symptoms. The study showed that the RCAT was an assessment that had reliability and validity in the assessment of rhinitis[1]. However, this test has not been translated into Thai. Therefore, the present study was conducted to find the reliability and validity of the RCAT (Thai version) for controlling rhinitis in Thai people and further used for monitoring rhinitis patients.

Materials and Methods

To develop the Thai version of the RCAT, the

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authors requested and received from the developer's permission to translate the original English RCAT into Thai version. The translation followed the standards by two independent translators with a subsequent back-translation to English and final conciliation of the versions and Local sign-off by the two local external experts, which were one pulmonologist and one family doctor.

The present study was approved by the Ethic Committee of Faculty of Medicine, Chiang Mai University (No. 052/2018). The sample size was calculated based on Formula by Bonett as below, which result in 47 patients. Therefore, 50 patients were included in the present study.

$$n = \frac{2k/(k-1)(Z_{\alpha/2}+Z\beta)^2}{\ln(\delta)}$$

$\delta = (1-c)/(1-P_k)$

According to k=number of questions

c=the value of Cronbach's alpha at null hypothesis=0.77 according to RCAT by Meltzer et al[1]

P_k=the expected value of Cronbach's alpha=0.85

α=type I error=0.05

β=type II Error=0.20

Between March 1, 2018 and September 1, 2018, the patients who had appointment for a skin allergy test and stopped using antihistamine drugs for seven days, age 18 years and over, and having rhinitis within the past 12 months were recruited in the study. The researchers excluded the patients who had infectious rhinitis, rhinitis medicamentosa, rhinosinusitis, severe nasal obstruction due to septal deviation, schizophrenia or dementia, and pregnancy.

Patients were having nasal examination, rhinohygrometry and were instructed to do a self-rating Thai version of the RCAT questionnaire on nasal symptoms and allergy symptoms, as well as directional adjusted the total nasal symptom scores (TNSS), to be in the same direction of RCAT response for participants' understanding.

The data collected were statistically analyzed with SPSS Statistics, version 16 (SPSS Inc., Chicago, IL, USA).

Content Validity

Content validity was conducted by experts' consideration.

1. Each question or text in the questionnaire was brought to at least three experts for consideration.

2. Summarized the verdicts of all experts by breaking down the frequency of each question.

3. Decided the content validity of each question using the criteria of at least two out of three experts.

Reliability

1. Checked for internal consistency using Cronbach's coefficient alpha.

2. Parallel forms method: Used the Parallel forms method by two instruments, RCAT and TNSS, that have similar characteristics of assessing the same content and having the same difficulty and discriminatory power to the samples to answer together. Then, find the Pearson correlation coefficient of the scores of the two questionnaires.

Results

The RCAT version was translated into Thai (Figure 1). There were no significant differences between the two translations into Thai, and therefore the final consolidation of the translated RCAT and the English version did not result in any changes to the original tool.

Content validity

The three experts agreed that the questions of the RCAT are valid for assessing the control of rhinitis (Table 1).

Patient Sample

The collected data of 50 patients diagnosed with rhinitis at the Department of Otolaryngology, Chiang Mai University Hospital revealed 23 males (46%) and 27 females (54%), age from 18 to 77 years old with an average of 37.34±16.17 years. Skin test was positive in 29 patients (58%).

The physical examination[2] of the patients participating in the present study, by using the modification of the Lund-Kennedy endoscopic scoring system, showed that most of the patients did not have nasal polyp, mild inferior turbinate congestion, or rhinorrhea (Figure 2). The level of rhinohygrometry was categorized into four levels, with 0 as no, 1 as mild, 2 as moderate, and 3 as severe decrease of airflow. The relationships were calculated with Spearman's rank-order correlation between RCAT score and nasal polyp, inferior turbinate, rhinorrhea, and rhinohygrometry, which found to have r=–0.60, –0.51, –0.27, and –0.15 accordingly ($p>0.05$).

The mean score of RCAT, TNSS, and visual analog scale (VAS) (mean ± SD) of the 50 patients were 18.42±3.96, 16.06±3.61, and 5.48±1.97, accordingly. High RCAT and TNSS scores reflected that the patients had good control of rhinitis.

Reliability

The analysis of the consistency within the

1. ใน 1 สัปดาห์ที่ผ่านมา ท่านมีอาการคัดจมูกบ่อยแค่ไหน?

ไม่เคย	น้อยมากแทบจะไม่มี	มีบ้างบางครั้ง	บ่อย	บ่อยมาก
5 ☐	4 ☐	3 ☐	2 ☐	1 ☐

2. ใน 1 สัปดาห์ที่ผ่านมา ท่านจามบ่อยแค่ไหน?

ไม่เคย	น้อยมากแทบจะไม่มี	มีบ้างบางครั้ง	บ่อย	บ่อยมาก
5 ☐	4 ☐	3 ☐	2 ☐	1 ☐

3. ใน 1 สัปดาห์ที่ผ่านมา ท่านน้ำตาไหลบ่อยแค่ไหน?

ไม่เคย	น้อยมากแทบจะไม่มี	มีบ้างบางครั้ง	บ่อย	บ่อยมาก
5 ☐	4 ☐	3 ☐	2 ☐	1 ☐

4. ใน 1 สัปดาห์ที่ผ่านมา อาการทางจมูกหรืออาการภูมิแพ้อื่นๆรบกวนการนอนหลับของท่านในระดับใด?

ไม่มีเลย	เล็กน้อย	มีบ้าง	มาก	ตลอดเวลา
5 ☐	4 ☐	3 ☐	2 ☐	1 ☐

5. ใน 1 สัปดาห์ที่ผ่านมา ท่านสามารถควบคุมอาการทางจมูกหรืออาการภูมิแพ้อื่นๆของท่านได้ดีเพียงใด?

ได้อย่างสมบูรณ์	อย่างมาก	ค่อนข้างได้	ได้เล็กน้อย	ไม่ได้เลย
5 ☐	4 ☐	3 ☐	2 ☐	1 ☐

6. ใน 1 สัปดาห์ที่ผ่านมา ท่านหลีกเลี่ยงกิจกรรมต่างๆ (เช่น การไปบ้านที่มีสุนัขและแมว การทำสวน) เนื่องจากอาการทางจมูกหรืออาการภูมิแพ้อื่นๆ ได้บ่อยเพียงใด?

ไม่เคย	น้อยมากแทบจะไม่มี	มีบ้าง บางครั้ง	บ่อย	บ่อยมาก
5 ☐	4 ☐	3 ☐	2 ☐	1 ☐

Figure 1. RCAT (Thai version) which the translation followed the standards by two independent translators with a subsequent back-translation to English and final conciliation of the versions and Local sign-off by two local external experts after received the developer's permission.

Table 1. Content Validity from the consideration of 3 experts

Number question of RCAT	Expert 1	Expert 2	Expert 3	Opinion agreement	Item CVI
1	1	1	1	3	1
2	1	1	1	3	1
3	1	1	1	3	1
4	1	1	1	3	1
5	1	1	1	3	1
6	1	1	1	3	1
Proportion relevant	6/6=1	6/6=1	6/6=1	S-CVI 6/6=1	Ave I-CVI=1
Average proportion relevant (1+1+1)/3=1					

CVI=content validity index S-CVI=scale content validity index; Ave I-CVI=average item content validity index; 0=content invalidity;, 1=content validity

Expert 1: Pulmonologist, Expert 2: Family doctor, and Expert 3: Otolaryngologist

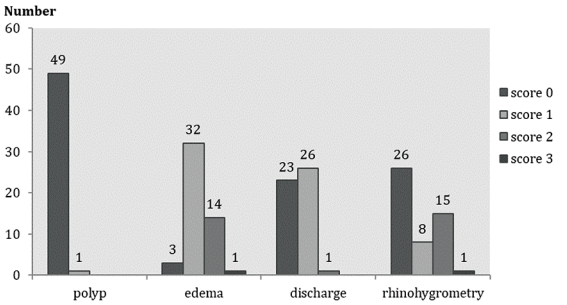

Figure 2. Endoscopic examination and rhinohygrometry score of rhinitis patients.

questions of the Thai version of the RCAT questionnaire was assessed using Cronbach's coefficient alpha to compare the six questions in the questionnaire. The resulting value was at an acceptable level (r=0.73, acceptable). The reliability of the TNSS questionnaire was at an acceptable level (r=0.72, acceptable). When analyzing the RCAT and TNSS questionnaires with parallel forms method using Pearson's correlation coefficients, the resulting value was at an acceptable level (r=0.74, acceptable; p<0.01).

Cut-point score for the disease control

From the present study, mean scores of the RCAT questionnaire divided by VAS symptom severity with a reference point that if the VAS score was greater than or equal to 5, it means poor disease control or severe nasal symptoms[3] was found to have significant difference (Table 2) and the cut-point score for the disease control using Receiver Operating Characteristic Curve (ROC Curve) was at 20 points (Figure 3).

From the presented, it was found that the area under the curve (AUC) was 0.75 (Table 3) and the cut-off scores for the disease control are RCAT score equal or lower than 19 for poor rhinitis control and RCAT score equal or higher than 20 for good rhinitis control with a sensitivity of 63% and a specificity of 84%.

Analyzed from AUC, if AUC was greater than 0.7, it would be considered accurate enough and it was closer to 1, displaying an increase of accuracy. From Table 2, the authors chose the cut-off point at 20 points because of high AUC, high specificity, and good sensitivity to do not make unnecessary treatment. If the cut-off point was chosen at 22 points as suggested by Meltzer et al[1] with sensitivity 47% and specificity 90%, it may cause false negative in patients who can control the symptoms, leading to inappropriate treatment.

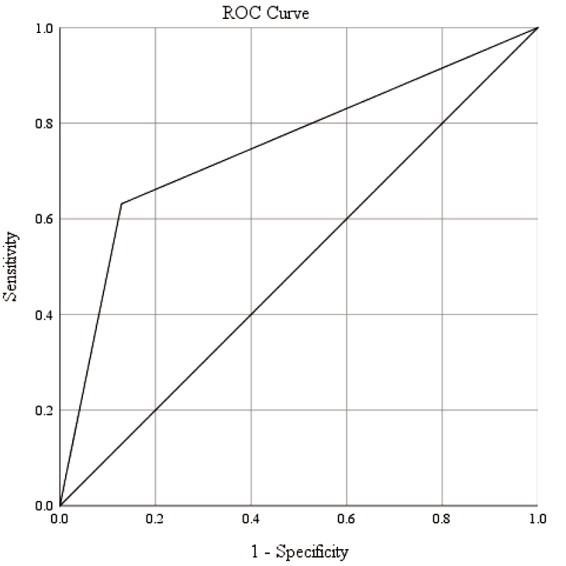

Figure 3. ROC curve of cut-off RCAT at 20 points.

Table 2. The mean score of the RCAT questionnaire divided by VAS symptom severity

VAS	n	RCAT score; mean±SD	95% CI	p-value
Less than 5	19	21.47±3.37	19.88 to 23.10	<0.001*
More or equal to 5	31	16.55±3.05	15.43 to 17.67	

VAS=visual analog scale; RCAT=Rhinitis Control Assessment Test; SD=standard deviation; CI=confidence interval

* Independent t-test

Table 3. Scores of RCAT and VAS to find the cut-point score for the disease control

RCAT score	Sensitivity (%) (95% CI)	Specificity (%) (95% CI)	AUC (95% CI)
>15	100 (82.3 to 100)	32 (16.7 to 51.4)	0.73 (0.63 to 0.81)
>16	100 (82.3 to 100)	45 (27.3 to 64.0)	0.76 (0.67 to 0.85)
>17	100 (82.3 to 100)	52 (33.1 to 69.84)	0.73 (0.61 to 0.85)
>18	84 (60.4 to 96.6)	61 (42.2 to 78.1)	0.72 (0.59 to 0.85)
>19	74 (48.8 to 90.8)	71 (52.0 to 85.8)	0.74 (0.61 to 0.86)
>20	63 (38.3 to 83.7)	84 (66.3 to 94.5)	0.75 (0.62 to 0.88)
>21	63 (38.3 to 83.7)	87 (70.2 to 96 .4)	0.69 (0.56 to 0.81)
>22	47 (24.4 to 71.1)	90 (74.2 to 97.9)	0.71 (0.60 to 0.82)
>23	42 (20.2 to 66.5)	100 (88.8 to 100)	0.63 (0.53 to 0.73)

RCAT=Rhinitis Control Assessment Test; AUC=area under the curve; CI=confidence interval

Discussion

At present, rhinitis could be frequently found in Thailand and the other countries. The incidence of

the disease tends to increase. Even if the symptoms were not severe, they affect the quality of life. If the symptoms cannot be controlled, it may lead to morbidity and complications. The present study wanted to study the reliability and validity of the Thai version of the RCAT. The present study found that the Thai version of RCAT had the level of reliability and validity that could be used for assessing rhinitis with the cut-off point at 19 or lower means a poor rhinitis control, and the cut-off point at 20 or higher means a good rhinitis control with a sensitivity of 63%, a specificity of 84%, and an AUC of 0.75. The cut-off points are not at the same level of the original RCAT by Meltzer et al[1] because the researchers referenced the VAS score greater than 5 from MACVIA clinical decision algorithm[3], different from Meltzer et al[1] that found the cut-off point of RCAT referencing the physician's ratings. If a more accurate assessment of the control of symptoms was required, the evaluation should be performed before and after the treatment by the physician and patient to obtain definite changes in value.

The Thai version of the RCAT is beneficial for making the patients aware of their conditions and able to monitor their disease and cooperate with the treatment more when the severity of the symptoms do not correlate with the physical examination results such as the size of nasal polyp, swelling of the inferior turbinate, the amount of mucus, and the level of airflow by rhinohygrometry.

At present, the RCAT has been widely translated into many languages. Many countries have studied and confirmed that the RCAT has the reliability and validity for assessing the control of rhinitis[4]. From the present study results of the Thai version of RCAT, it shows the reliability and validity of the assessment. The researchers have their opinion that the Thai version of RCAT could be used for monitoring the rhinitis patients and if there is a significant change in value, it could be used to further treat the patients.

Conclusion

The RCAT (Thai version) has good reliability and validity. It is suitable for clinical application in evaluating the rhinitis patient because of its simplicity. Furthermore, patient can evaluate themselves using this assessment.

What is already known on this topic?

RCAT in English version showed good reliability and validity in the assessment of rhinitis.

What this study adds?

RCAT (Thai version) has good reliability and validity that could be used for assessing rhinitis. With a cut-off point at 19 or lower means a poor rhinitis control and a cut-off point at 20 or higher means a good rhinitis control. This is not at the same level as the original RCAT by Meltzer et al[1] because the researcher referenced the VAS score at greater than 5 from MACVIA clinical decision algorithm.

Conflicts of interest

The authors declare no conflict of interest.

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