

Validity and Reliability Assessment of the Siriraj Asthma Control Questionnaire

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Objective: The present study assessed the validity and reliability of the Siriraj Asthma Control Questionnaire in Asthma Clinic, Siriraj Hospital.

Material and Method: The data of the questionnaire responses and spirometric results from 20 randomized asthmatic patients in the clinic including the record of 3 visits for each subject. The validation was performed by Kruskal-Wallis test comparing the scores with the level of asthma control determined by physicians according to GINA guideline. Internal consistency reliability was analyzed by Cronbach's alpha.

Results: Sixty questionnaires from 20 patients with age 29-73 years were analyzed. There were 40 controlled, 7 partly controlled and 13 uncontrolled visits. The scores from 5-items questionnaires and 6-items clinical score were significantly associated with the physician-diagnosed groups (i.e., controlled, partly controlled and uncontrolled groups). Median scores (min, max) were 0 (0, 5), 2 (0, 6), 4 (0, 12) respectively, (5-items, $p < 0.001$) and 2 (0, 7), 3 (1, 7), 6 (2, 15) respectively, (6-items, $p < 0.001$). Internal consistency reliability of both 5-items questionnaire and 6-items clinical score were within the acceptable range (0.829 and 0.708 respectively). 5-items questionnaire is more associated with the physician diagnosed group and more consistent than 6-items clinical score. Further analysis revealed cutoff point at 2.5 to separate uncontrolled from controlled or partly controlled patient with sensitivity 76.9% and specificity 89.4% and cutoff point at 1.5 to separate uncontrolled or partly controlled from controlled patient with sensitivity 70.0% and specificity 85.0%

Conclusion: The validity and reliability of Siriraj Asthma Control Questionnaire is acceptable and might be used in the clinical practice and research in Thai asthmatic patients.

Keywords: Asthma, Control, Questionnaire, Thai

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The prevalence of asthma continues to increase in Thailand and worldwide⁽¹⁾. Many tools were developed to assess asthma control and outcomes in patients. However, most of them are available only in English version⁽²⁻⁶⁾. Additionally, some questionnaires have too many items and some are difficult to score.

Siriraj Asthma Control Questionnaire was thus developed in Thai language in order to assess asthma control and outcomes in Thai patients who attend adult Asthma Clinic in Siriraj Hospital.

The purpose of the present study is to assess the validity and reliability of the Siriraj Asthma Control

Questionnaire in adult Asthma Clinic, Siriraj Hospital.

Material and Method

This validation study recruited 20 patients from the clinic by simple randomization. The data retrieved from medical records included 3 visits by each of the subjects for which the questionnaires as well as spirometric tests were completed.

The questionnaire consists of 5 items representing asthma symptoms during the past week (i.e., day time symptoms, nocturnal symptoms, activity limitation, wheeze and frequency of bronchodilator use). The 6-items clinical score consists of the same 5 items questionnaires and FEV1 measured as % predicted to be scored. The range of the score of each item is 0 to 3 with higher scores indicating worse symptoms. Each questionnaire was completed by Siriraj asthma clinic

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technician by asking each question to the patient. However, spirometry may not be performed in every visit so each questionnaire may be completed by using only 5 items (score 0-15) and some others with all 6 items (score 0-18).

Statistical analysis

The validation was done by Kruskal-Wallis test by comparing the scores with the level of asthma control determined by the physician as stated in medical records. Subjects were then categorized into 3 groups according to the Global Initiatives of Asthma (GINA) guideline (*i.e.*, controlled, partly controlled and uncontrolled groups). Internal consistency reliability was analyzed and presented as Cronbach's alpha.

The correlation between the questionnaire score and number of acute exacerbation within past 2 years (2008-2009) was analyzed by Spearman method. The result was statistically significant if the p-value was less than 0.05

Results

Twenty patients with age ranged from 29-73 years (mean, SD; 56.4, 11.9 years), 50% female, were randomly selected from Siriraj Asthma Clinic. Sixty questionnaires and medical records were analyzed. There were 40 controlled, 7 partly controlled and 13 uncontrolled visits presented in medical records.

The scores from both the 5-items questionnaire and 6-items clinical score were significantly associated with clinical control groups (*i.e.*, controlled, partly controlled and uncontrolled group) as shown in Table 1.

The results from further analyses by multiple

comparisons with Conover-Inman method that the score from 5-items questionnaire in controlled group was different from the partly controlled group ($p = 0.006$) and different from the uncontrolled group ($p < 0.001$). However, the score in the partly controlled group was not different from the uncontrolled group ($p = 0.450$). The analyses of 6-items score revealed a similar pattern.

No linear correlation between questionnaire score and the frequency of acute asthmatic exacerbation presented within the past 2 years (2008-2009) as well as within all of spirometric parameters (*i.e.*, pre-bronchodilator FEV1, post-bronchodilator FEV1, pre-bronchodilator FEV1/FVC) (Table 2).

Internal consistency reliability was within the acceptable range (Cronbach's alpha > 0.7) (5-items 0.829 and 6-items 0.708). 5-items questionnaire is more associated to the physician's diagnosis and more consistent than the 6-items clinical score (Table 3).

Further analysis was done in order to apply the score as a tool for categorization of the level of asthma control (Table 4 and 5).

Receiver-operating characteristic (ROC) curve was performed to analyze the 5-items questionnaires. The cutoff point determined at above or equal to 2.5 to separate uncontrolled from partly controlled or controlled patients yielded sensitivity of 76.9% and specificity of 89.4% (AUC = 0.831, $p < 0.001$) and the cutoff point at above or equal to 1.5 was used to separate uncontrolled or partly controlled from controlled patients and yielded sensitivity of 70.0% and specificity of 85.0% (AUC = 0.844, $p < 0.001$).

For the 6-items clinical score, the cutoff point determined at above or equal to 4.5 to separate uncontrolled from partly controlled or controlled patient

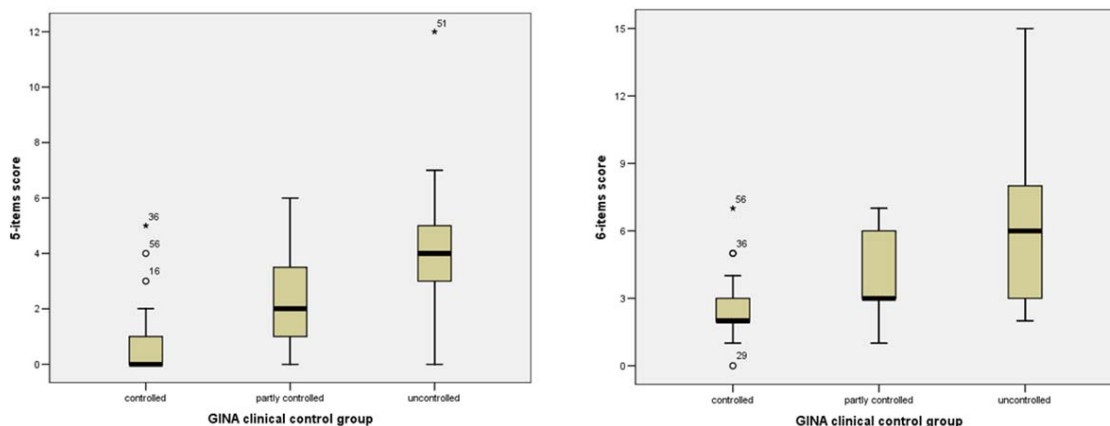


Fig. 1 Distribution of 5-items questionnaires score and 6-items clinical score compared with the level of asthma control determined by physicians according to GINA guideline

Table 1. Validity of Siriraj Asthma Control Questionnaire in Asthma Clinic, Siriraj Hospital compared with the level of asthma control determined by physician according to GINA guideline

| | | Level of asthma control by physicians | | | p-value* |
|-----------------------------|-------------------|---------------------------------------|-------------------|--------------|----------|
| | | Controlled | Partly controlled | Uncontrolled | |
| 5-items score (0-15) | n = 60 | 40 | 7 | 13 | < 0.001 |
| | Mean (SD) | 0.60 (1.17) | 2.43 (2.23) | 4.15 (3.18) | |
| | Median (min, max) | 0 (0,5) | 2 (0,6) | 4 (0,12) | |
| 6-items score (FEV1) (0-18) | n = 54 | 34 | 7 | 13 | < 0.001 |
| | Mean (SD) | 2.44 (1.33) | 4.14 (2.27) | 6.00 (3.56) | |
| | Median (min, max) | 2 (0,7) | 3 (1,7) | 6 (2,15) | |

* Kruskal-Wallis Test

Table 2. Correlation between questionnaire and clinical score compared with frequency of acute asthmatic exacerbation within the past 2 years and spirometric parameters

| | Time of exacerbation per patient per 2 year | Spearman Correlation (p-value) | | | |
|----------------------|---|--------------------------------|--------------------------|---------------------------|------------------------------|
| | | PEF | Pre Broncho-dilator FEV1 | Post Broncho-dilator FEV1 | Pre Broncho-dilator FEV1/FVC |
| 5-items score n = 60 | 0.08 | -0.21 | -0.73 | -0.07 | -0.05 |
| | (0.55) | (0.11) | (0.58) | (0.64) | (0.70) |
| 6-items score n = 54 | 60 | 59 | 60 | 52 | 60 |
| | 0.04 | -0.40 | -0.30 | -0.25 | -0.29 |
| | (0.78) | (0.003) | (0.03) | (0.09) | (0.04) |
| | 54 | 53 | 54 | 47 | 54 |

Table 3. Internal consistency reliability of Siriraj Asthma Control Questionnaire

| | Cronbach's alpha coefficient |
|---------------------------------|------------------------------|
| 5-items questionnaire (n = 60) | 0.829 |
| 6-items clinical score (n = 54) | 0.708 |

yielded sensitivity of 61.5% and specificity of 85.4% (AUC = 0.820, p = 0.001) and the cutoff point at above or equal to 3.5 to separate uncontrolled or partly controlled from controlled patients yielded sensitivity of 60.0% and specificity of 85.3% (AUC = 0.821, p < 0.001).

Discussion

Treatment outcome of asthma should be re-evaluated every visit by clinician. The goal of treat-

ment is that asthma symptoms be controlled. There are many ways to categorize the level of asthma control, *i.e.*, from clinical symptoms directly, which is the current standard, or from the asthma control questionnaires.

According to a previous study in Thai asthma patients⁽⁵⁾, the proportion of controlled, partly controlled and uncontrolled patients after treatment are 57%, 16% and 27%, respectively. These proportions are similar to the present study (66%, 12% and 22%, respectively). It may be inferred that almost 40% of Thai asthma patients still do not achieve controlled criteria which is goal of the treatment.

The present study shows that there is a significant association between the presented Siriraj Asthma Control Questionnaire and the level of asthma control determined by the physician with high reliability. Therefore, this questionnaire can be used as a tool to categorize the asthma control level in Thai patients.

Table 4. ROC curve analysis of 5-items Siriraj Asthma Control Questionnaires and 6-items clinical score for categorization of asthma control

| | Level of asthma control | Area under curve | p-value |
|----------------------|--|------------------|---------|
| 5-items score n = 60 | Uncontrolled vs. controlled or partly controlled | 0.831 | < 0.001 |
| | Controlled vs. partly controlled or uncontrolled | 0.844 | < 0.001 |
| 6-items score n = 54 | Uncontrolled vs. controlled or partly controlled | 0.820 | 0.001 |
| | Controlled vs. partly controlled or uncontrolled | 0.821 | < 0.001 |

Table 5. Coordination of the curve analysis of 5-items Siriraj Asthma Control Questionnaires and 6-items clinical score for categorization of asthma control

| | Level of asthma control | Cutoff value* | Sensitivity (95% CI) | Specificity (95% CI) | PPV (95% CI) | NPV (95% CI) | Accuracy (95% CI) |
|----------------------|--|---------------|----------------------|----------------------|-------------------|------------------|-------------------|
| 5-items score n = 60 | Uncontrolled vs. partly controlled or controlled | ≥ 2.5 | 76.9 (46.2-95.0) | 89.4 (76.9-96.5) | 66.7 (38.4-88.2) | 93.3 (81.7-98.6) | 86.7 (75.4-94.1) |
| | Uncontrolled or partly controlled vs. controlled | ≥ 1.5 | 70.0 (45.7-88.1) | 85.0 (70.2-94.3) | 70.0 (45.7-88.1) | 85.0 (70.2-94.3) | 80.0 (67.7-89.2) |
| 6-items score n = 54 | Uncontrolled vs. partly controlled or controlled | ≥ 4.5 | 61.5 (31.6-86.1) | 87.2 (74.3-95.2) | 57.14 (28.9-82.3) | 89.1 (76.4-96.4) | 81.7 (69.6-90.5) |
| | Uncontrolled or partly controlled vs. controlled | ≥ 3.5 | 60.0 (36.1-80.9) | 87.5 (73.2-95.8) | 70.6 (44.0-89.7) | 81.4 (66.6-91.6) | 78.3 (65.8-88.9) |

*sum score from questionnaire and clinical score

The interview takes only 5 minutes for each patient. Furthermore, the present questionnaires can be used as a tool in the research of the asthma treatment outcomes.

Therefore, the presented questionnaire may not be able to separate partly controlled from uncontrolled group in clinical practice due to the insignificant difference of the scores between the two groups. However, this may not be clinically important because both groups share common plans of management, according to the GINA guideline.

Conclusion

The Siriraj Asthma Control Questionnaire is valid and reliable. Further study is suggested to evaluate test-retest reliability and a prospective study with

larger population should be done.

Potential conflicts of interest

Office of Deputy Dean for Research Faculty of Medicine Siriraj Hospital.

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การประเมินความเที่ยงตรงและความน่าเชื่อถือของแบบประเมินและติดตามการรักษาในคลินิกโรคหืดโรงพยาบาลศิริราช

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วัตถุประสงค์: เพื่อประเมินความเที่ยงตรงและความน่าเชื่อถือของแบบประเมินและติดตามการรักษาในคลินิกโรคหืดโรงพยาบาลศิริราช

วัสดุและวิธีการ: เป็นการศึกษาแบบตัดขวางย้อนหลัง โดยใช้ข้อมูลจากแบบประเมิน และติดตามการรักษา ในคลินิกโรคหืดโรงพยาบาลศิริราช และผลการตรวจสมรรถภาพปอดของผู้ป่วย 20 ราย ที่ได้รับการสุ่มจากผู้ป่วยโรคหืดที่มารับการรักษาต่อเนื่องที่คลินิกโรคหืด โรงพยาบาลศิริราช โดยเลือกศึกษาผลการประเมิน เฉพาะครั้งที่มีการตรวจสมรรถภาพปอดรวมด้วย จำนวน 3 ครั้งต่อราย ความน่าเชื่อถือของแบบประเมินวิเคราะห์โดยใช้ Kruskal-Wallis test เปรียบเทียบคะแนนรวมจากแบบประเมินกับระดับความสามารถในการควบคุมอาการ ตาม GINA guideline ที่ประเมินโดยแพทย์ และบันทึกไว้ในเวชระเบียน ได้แก่ ควบคุมอาการได้, ควบคุมอาการได้บางส่วน และไม่สามารถควบคุมอาการได้ ความเที่ยงตรงของแบบประเมินวิเคราะห์โดยใช้ค่า Cronbach's alpha

ผลการศึกษา: ผลการตรวจติดตามการรักษา จำนวน 60 ครั้ง จากผู้ป่วยโรคหืดไทย 20 ราย อายุ 29-73 ปี พบว่าสามารถควบคุมอาการได้ 40 ครั้ง, ควบคุมอาการได้บางส่วน 7 ครั้ง และไม่สามารถควบคุมอาการได้ 13 ครั้ง คะแนนรวมจากแบบประเมินชนิด 5 ข้อและ 6 ข้อ มีความสัมพันธ์กับระดับความสามารถในการควบคุมอาการที่ประเมินโดยแพทย์ ค่ามัธยฐาน (ค่าต่ำสุด, ค่าสูงสุด) ของคะแนนรวมจากแบบประเมินชนิด 5 ข้อ แยกตามระดับความสามารถในการควบคุมอาการได้, ควบคุมอาการได้บางส่วน และไม่สามารถควบคุมอาการได้ คิดเป็น 0 (0, 5), 2 (0, 6), 4 (0, 12), $p < 0.001$ และจากแบบประเมินชนิด 6 ข้อ คิดเป็น 2 (0, 7), 3 (1, 7), 6 (2, 15), $p < 0.001$ ความเที่ยงตรงภายในของแบบประเมิน ค่า Cronbach's alpha อยู่ในเกณฑ์ที่ยอมรับได้ ทั้งแบบประเมินแบบ 5 ข้อและ 6 ข้อ คิดเป็น 0.829 และ 0.708 ตามลำดับ จากการศึกษพบว่าแบบประเมินชนิด 5 ข้อ มีความสัมพันธ์กับการวินิจฉัยโดยแพทย์และมีความเที่ยงตรงภายในมากกว่าชนิด 6 ข้อ สามารถแบ่งกลุ่ม ผู้ป่วยโดยใช้คะแนนรวมจากแบบประเมินชนิด 5 ข้อ โดยคะแนนรวมมากกว่า 2.5 คะแนน สามารถแยกผู้ป่วย ที่ไม่สามารถควบคุมอาการได้จากกลุ่มอื่นด้วยความไวร้อยละ 76.9 ความจำเพาะร้อยละ 89.4 และคะแนนรวม มากกว่า 1.5 คะแนน สามารถแยกผู้ป่วยที่ไม่สามารถควบคุมอาการได้หรือควบคุมอาการได้บางส่วนจากกลุ่ม ที่สามารถควบคุมอาการได้ ความไว 70.0% ความจำเพาะ 85.0%

สรุป: แบบประเมินและติดตามการรักษาในคลินิกโรคหืดโรงพยาบาลศิริราช มีความน่าเชื่อถือและมีความเที่ยงตรงสามารถนำไปใช้ในการติดตามอาการของผู้ป่วยโรคหืดไทย