Validation of the Thai Version of a Screening Questionnaire for Detection of Systemic Lupus Erythematosus

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Objective: *The present study was performed to assess the sensitivity and specificity of the translation questionnaire for Systemic Lupus Erythematosus (SLE) in Thai speaking populations.*
Material and Method: *The 10- item questionnaire was applied to out-patients at the rheumatology clinic of the Chiang Mai University Hospital. One hundred and thirty-nine SLE, 109 Rheumatoid Arthritis (RA), and 35 Scleroderma (Scl) patients, as well as 88 Healthy Controls (HC) were enrolled into the present study.*
Results: *All subjects completed the questionnaire within 2 minutes. A positive response to three or more questions of the questionnaire gave a sensitivity and specificity of 92.81% and 76.39%, respectively, and was comparable to the original version.*
Conclusion: *This Thai-version of the screening questionnaire should be applied in the general population to determine the prevalence of SLE.*

Keywords: *Systemic lupus erythematosus, SLE, Screening, Questionnaire*

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Systemic Lupus Erythematosus (SLE) is an inflammatory multi-system disease of unknown etiology. The disease has protean clinical manifestations and laboratory findings, with a variable course in prognosis[1]. The disease occurs worldwide, and is 10 times more common in women than men. The prevalence of SLE varies widely, depending on the race and country of the patients studied, and the method used to determine the prevalence. In the United States, a study in San Francisco during the late 1960s found a lupus prevalence in white and black women of 90.50 and 280 per 100,000 individuals, respectively[2]. A more recent study in America found a prevalence of physician-diagnosed SLE in women's age ≥ 17 years of 241 per 100,000 individuals[3]. The prevalence of SLE in Thailand has never been studied systematically. However, one epidemiological study found a prevalence of connective tissue diseases of 40 per 100,000 individuals. Unfortunately, the actual prevalence of SLE was not determined[4]. There has been no available data on the prevalence of SLE in other Southeast Asian countries.

As SLE is a serious disease and can be fatal, early diagnosis and appropriate treatment is crucial. The criteria for the diagnosis of SLE developed by the American College of Rheumatology are used for an individual diagnosis purpose[5,6]. The diagnosis of SLE is rarely made by the first onset of symptoms. Immunologic testing, particularly the ANtinuclear Antibody (ANA) test is often used to screen the diagnosis, as this antibody is found in more than 90% of patients with SLE. This test is now available in many hospitals and laboratories, but it is not specific and it can be found in various conditions[7]. Therefore, the presence of ANA is useful to support the diagnosis of SLE, but not as the marker of the diagnostic test. The absence of ANA, without the clinical characteristic of SLE suggests that a diagnosis of SLE is unlikely. A subset of SLE patients, with a negative ANA test (ANA negative lupus), usually presents with subacute cutaneous skin rashes and a positive test for antiRo/SSA antibody[1].

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To determine the prevalence of a disease with a protean clinical manifestation in populations like SLE, a simple, accurate and in-expensive tool is required. In 1980, Liang et al. developed a 10-item screening questionnaire for screening SLE[8]. This screening questionnaire was simple, with a high sensitivity and specificity, and it was useful for selecting patients who were highly probable of having SLE and referring them to specialists. This screening questionnaire was translated into the Spanish language for Spanish-speaking populations, and found to be as valid as the original one[9].

In Thailand, there was no similar instrument for Thai-speaking populations. The authors, therefore, translated this instrument and assessed its sensitivity and specificity for further use in the Thai population.

Material and Method

The original questionnaire for screening SLE developed by Liang et al was translated into Thai[8].

The screening questionnaire consisted of 10-item questions, to be answered in the form of "yes or no". Back translation was carried out by an English and a Thai speaking physician, who did not know the original English version. This process was performed until the back translated version had no different meanings from the original.

This Thai-version screening questionnaire was applied to out-patients with a definite diagnosis of SLE, Scleroderma (Scl), and Rheumatoid Arthritis (RA) in the Rheumatology Clinic at Chiang Mai University Hospital. The diagnosis of SLE[5,6], Scl[10], and RA[11] was based on the diagnostic criteria developed by the American College of Rheumatology. RA and Scl were used as a control for chronic arthritis and other connective tissue diseases, as these 2 diseases have arthritis and multiple organ system manifestations that could mimic SLE. Healthy (Control) medical personnel (HC), who did not have musculoskeletal problems, were used as a control for the general population.

Statistical analysis

The results were calculated for sensitivity and specificity. Sensitivity was the proportion of individuals who tested positive out of all those who actually had the disease. Specificity was the proportion of individuals who tested negative out of all those who actually did not have the disease. A ROC curve was used to define the best cut-off point and distinguish between SLE and other conditions.

Results

There were 139 SLE, 109 RA, and 35 Scl patients and 88 HC who completed the questionnaire. The mean $\pm$ standard deviation (SD) of duration for completing the questionnaire was 1.31 ± 0.56 minutes. Their mean $\pm$ SD of age and disease duration is shown in Table 1.

Table 2 shows the Thai version of the screening questionnaire and the response rate of the patients studied. One hundred and thirty seven SLE patients (98.56%) responded to at least 2 questions, and the highest response rate was 8 questions. None of the RA and Scl patients had more than 4 positive questions response. Nine HC (10.22%) had 2 positive questions response, and none had $\geq$ 3 positive questions response. The sensitivity and specificity of the Thai version screening questionnaire are shown in Table 3. According to the ROC generated, 3 or more positive questions response was the best cut-off point for this screening questionnaire.

Discussion

In the present study, the authors found that the Thai version of Liang's screening questionnaire for SLE had the same sensitivity and specificity as the original version[8]. The response rate to 3 or more questions gave a sensitivity of 92.81% and specificity of 76.39%. Thirty-four of the 144 RA and Scl patients (23.61%) responded to more than 3 questions, and only 11 RA and Scl patients (7.63%) responded to more than

Table 1. Demographics of the individuals studied

Diagnosis	N	Age (yr)	Duration of disease (yr)
Systemic lupus erythematosus	139	37.45±11.11	7.34±5.83
Rheumatoid arthritis	109	50.82±12.51	7.33±6.33
Scleroderma	35	50.06±10.24	5.91±4.31
Healthy controls	88	40.71±9.80	-

Data are expressed in mean ± SD

Table 2. Questionnaire items and response rate

Questionnaire items	Responses %			
	SLE (n = 139)	RA (n = 109)	Scl (n = 35)	HC (n = 88)
1. Have you ever had joint or muscle pain lasting over three months	36.69	97.25	31.43	12.50
2. During the cold weather, have your fingers ever turned pale, numb or painful?	59.71	14.68	97.14	14.77
3. Have you ever had pain or sores in your oral cavity lasting over two weeks?	43.88	11.01	5.71	4.54
4. Have your doctors ever told that you have low blood counts, for instance, you are anemic, you have low white blood cell count or low platelet count?	72.26	41.28	20.00	0
5. Have you ever had a prominent rash on you cheeks lasting over one month?	54.68	1.83	2.86	0
6. After sun exposure, have you ever had any unusual skin rash which is not caused by sun burn?	52.52	4.59	17.14	4.54
7. Have you ever have pain over your rib cage while taking deep breath that lasted for days?	31.65	9.17	17.14	0
8. Have your doctors ever told you that you had a higher than normal level of protein in your urine?	69.06	5.50	0	0
9. Have you ever had hair loss that is more than usual?	76.26	10.09	22.86	2.27
10. Have you ever had a seizure, convulsion or become unconscious?	22.30	0.92	2.86	1.14

Table 3. The questionnaire response levels and the screening parameter estimation

Positive question response	SLE (n = 139)	RA + Scl (n = 144)	Sensitivity, %	Specificity, %
≥ 2	137	90	98.56	37.50
≥ 3	129	34	92.81	76.39
≥ 4	111	11	79.86	92.36

4 questions. None of the HC responded to more than 3 questions. Therefore, despite the positive response to 3 or more questions, SLE could still be misdiagnosed. Although 3 or more positive questions response is the most appropriate cut-off point (according to ROC) for the screening of Thai lupus patients, it should be realized that RA and Scl must be excluded. Patients with a positive response to 4 or more questions should have a complete history; take a physical examination, and laboratory tests that include ANA to confirm the diagnosis of SLE. The cut-off point of 3 positive responses in the Thai version screening questionnaire was similar to the results in the Spanish version, where a positive response to 3 or more questions gave a sensitivity and specificity of 95.00% and 84.00% respectively[9]. The cut-off point was also similar to the original English version, which had a sensitivity and specificity of 95.00% and 94.00%, respectively[8].

There were several limitations in the present study. Firstly, it was conducted in a rheumatology clinic, where all patients had well-defined SLE, RA and Scl, with rather long disease duration. This tended to make all the patients give a more positive response to the questionnaire. The positive and negative predictive value was not able to determine, as it was not done in the general population. Secondly, the one hundred and thirty nine SLE patients (37.46%) of the study could be a result of the high sensitivity and specificity of this instrument. Thirdly, this instrument was applied to patients with well-defined diseases; therefore, patients with early SLE, in whom the disease had not been fully developed, might have been missed. Lastly, it should be remembered that this is only a screening instrument; thus, suspected cases should undergo history taking, a physical examination and appropriate laboratory tests for a definite diagnosis.

It should also be noted that both RA and Scl patients, who were used in the present study as representatives of chronic arthritis and connective tissue diseases, could respond to 3 or more questions, and only 7.63% gave a positive response to more than 4 questions. Therefore, this instrument is still valid for screening SLE from other musculoskeletal diseases. However, it needs to be cross-validated in the general population where the prevalence of SLE is much lower.

Finally, this Thai version of the screening questionnaire is easy, quick and inexpensive to apply. It took less than 2 minutes to complete. It can also be used by self-responding or telephone interview. Thus, it can be used in field surveys where there are many population samples. The results obtained from this method could be extrapolated to estimate SLE prevalence in populations.

Conclusion

The Thai-version screening questionnaire for SLE was valid, quick, inexpensive and easy to use. It took less than 2 minutes to complete. It could, therefore be used for an SLE field survey.

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แบบทดสอบภาษาไทยสำหรับการคัดกรองผู้ป่วยโรคลูปุส

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การศึกษานี้ทำขึ้นเพื่อศึกษาความไวและความจำเพาะของแบบทดสอบภาษาไทยสำหรับการคัดกรองผู้ป่วยโรคลูปุสที่แปลมาจากภาษาต่างประเทศในคนไทย แบบทดสอบประกอบไปด้วยคำถาม 10 คำถาม ซึ่งถูกนำไปทดสอบกับผู้ป่วยโรคลูปุส 139 ราย, โรคข้ออักเสบรูมาตอยด์ 109 ราย, โรคผิวหนังแข็ง 35 ราย ที่ห้องตรวจผู้ป่วยนอกคลินิกโรคข้อและรูมาติสซั่ม โรงพยาบาลนครเชียงใหม่ และได้ทดสอบในผู้มีสุขภาพสมบูรณ์ 88 ราย ทุกรายสามารถตอบแบบสอบถามเสร็จภายในเวลา 2 นาที พบว่าการตอบรับเท่ากับหรือมากกว่า 3 คำถามขึ้นไปให้ความไวและความจำเพาะต่อการวินิจฉัยโรคลูปุสเท่ากับร้อยละ 92.81 และ 76.39 ตามลำดับ ซึ่งมีค่าใกล้เคียงกับต้นฉบับภาษาอังกฤษ แบบทดสอบภาษาไทยสำหรับการคัดกรองผู้ป่วยโรคลูปุสนี้ควรนำไปทดสอบในชุมชนเพื่อหาความชุกของโรคลูปุสต่อไป

ตารางที่ 2. คำถามและอัตราการตอบสนอง

คำถาม	อัตราการตอบสนอง (%)			
	SLE (n = 139)	RA (n = 109)	Scl (n = 35)	HC (n = 88)
1. ท่านเคยมีอาการปวดข้อ หรือกล้ามเนื้อนานเกิน 3 เดือนหรือไม่	36.69	97.25	31.43	12.50
2. ท่านเคยมีอาการปลายนิ้วมือซีด ชา หรือปวดเมื่อถูกอากาศเย็นหรือไม่	59.71	14.68	97.14	14.77
3. ท่านเคยมีอาการเจ็บหรือมีแผลในปากเป็นเวลานานกว่า 2 สัปดาห์หรือไม่	43.88	11.01	5.71	4.54
4. แพทย์เคยบอกท่านว่าท่านมีจำนวนเม็ดเลือดต่ำกว่าปกติ เช่น ซีด เม็ดเลือดขาวต่ำ หรือเกล็ดเลือดต่ำ หรือไม่	72.26	41.28	20.00	0
5. ท่านเคยมีผื่นที่เห็นชัดบริเวณแก้มนานกว่า 1 เดือนหรือไม่	54.68	1.83	2.86	0
6. ท่านเคยมีผื่นผิดปกติที่ผิวหนังหลังถูกแสงแดดที่ไม่ใช่ผื่นไหม้จากตากแดดเป็นเวลานานหรือไม่	52.52	4.59	17.14	4.54
7. ท่านเคยมีอาการเจ็บบริเวณทรวงอกเวลาหายใจลึก ๆ เป็นเวลาติดต่อกันหลายวันหรือไม่	31.65	9.17	17.14	0
8. แพทย์เคยบอกท่านว่าท่านมีโปรตีนออกมาทางปัสสาวะมากกว่าปกติหรือไม่	69.06	5.50	0	0
9. ท่านเคยมีผมร่วงผิดปกติหรือไม่	76.26	10.09	22.86	2.27
10. ท่านเคยมีอาการชัก อาการกระตุกของแขนขา หรือหมดสติหรือไม่	22.30	0.92	2.86	1.14