INTRODUCTION

Performing epidemiologic studies for various rheumatic diseases is difficult because of the expense associated with confirming the diagnosis, their low prevalence, lack of specific diagnostic tests, and diverse manifestations (1). To overcome these limitations, various types of questionnaires by postal survey, telephone interview, and direct interview have been developed for many rheumatic diseases, for example, rheumatoid arthritis (RA), systemic lupus erythematosus (SLE), osteoarthritis (OA), spondyloarthropathy, and connective-tissue diseases (1-5), and have proved to be useful instruments for screening potential cases of various rheumatic diseases. After screening via these questionnaires, the second test of a clinical evaluation, laboratory tests, and/or radiologic evaluation can be used in epidemiologic studies for reducing the false-positive rate of misclassifying healthy subjects as having rheumatic diseases (1, 5).

Epidemiologic studies for rheumatic diseases in Korea have been rare. We therefore intended to develop a Korean rheumatic diseases-screening questionnaire (KRSQ) for population studies.

METHODS AND SUBJECTS

Development of the questionnaire

Based on American College of Rheumatology (ACR) criteria for OA of the hand and knee (6, 7), and a connective-tissue disease screening questionnaire (CSQ) for RA, SLE, scleroderma, polymyositis/dermatomyositis (PM/DM), Sjögren’s disease, and mixed connective-tissue disease (MCTD) (1), a Korean rheumatic disease questionnaire was constructed and translated in Korean. The elements in the questionnaire were selected from clinical criteria (7). Among the three questions for estimation of knee pain, the most sensitive but least-specific question was selected for the OA questionnaire: “Have you ever had pain in or around the knee on most days for at least a month? If so, have you experienced any pain during the last year?” Negative predictive values were very high in the general population, from 98.4 to 99.99%. The \( \kappa \) statistic for agreement between laboratory items was 0.22-0.56, except for rheumatoid factor, antinuclear antibody test, and muscle enzyme level. We have developed a simple and sensitive Korean rheumatic diseases-screening questionnaire for the epidemiologic study of rheumatic diseases in Korea.

Key Words: Rheumatic Diseases; Arthritis; Questionnaires; Sensitivity and Specificity; Epidemiology; Korea
Identification of subjects

The case subjects with OA of the hand and/or knee (n=46), RA (n=52), SLE (n=50), scleroderma (n=8), PM/DM (n=7), Sjögren’s disease (n=4), or MCTD (n=9), and the control subjects with fibromyalgia (n=8), were enrolled consecutively from patients attending an outpatient clinic and those admitted to the Hospital for Rheumatic Diseases, Hanyang University, Seoul, Korea. The diagnosis was confirmed by medical record review for classification criteria (6, 7, 9-15). Patients attending the outpatient clinic of family medicine at the same hospital were recruited as another control group. This group was free of rheumatic disease.

Data collection procedure

We used the method of direct interview for completing the questionnaire, since our previous study on the Korean Health Assessment Questionnaire (KHAQ) and the Korean Western Ontario and McMaster University osteoarthritis index found that self-assessed questionnaires may not be accurate when answered by the elderly with poor levels of education (16, 17). Some patients were asked to participate in the second interview at least 6 months after the first one in order to assess the test-retest reliability of the questionnaire. Demographic, socioeconomic, comorbid condition, and functional status (class I includes the patients who can perform usual activities of daily living completely; class II includes the patients who can perform usual self-care and vocational activities but limited in avocational activities; class III includes the patients who can perform usual self-care activities but limited in vocational and avocational activities; class IV includes the patients limited in ability to perform usual self-care, vocational, and avocational activities) (18) were obtained.

Diagnostic criteria for identifying potential rheumatic diseases

An algorithm for identifying potential patients with RA, SLE, scleroderma, PM/DM, Sjögren’s disease, and MCTD was made based on published criteria for connective-tissue diseases (using the CSQ) (1). Our questionnaire was the same as the CSQ except that it was adjusted to achieve the results with a higher sensitivity and more acceptable range of specificity.

The criteria for RA were three (four in CSQ) of the following six symptoms: morning stiffness for at least 1 hr and present for at least 6 weeks; swelling of three or more joints for more than 6 weeks; swelling of wrist, metacarpophalangeal (MCP), or proximal interphalangeal (PIP) joints for more than 6 weeks; symmetric joint swelling; rheumatoid nodules; and positive test results for rheumatoid factor (RF). Radiography findings were not obtained.

The criteria for potential SLE were three (four in CSQ) of the following 12 items: malar rash, discoid rash, photosensitivity, oral ulcers, arthritis, serositis, proteinuria, hematologic disorder (i.e., anemia, leukopenia, or low platelet count), positive antinuclear antibody (ANA) test, seizure, Raynaud’s phenomenon, and hair loss. The last two questions, which have high sensitivity but a lower specificity. Although they were not included in ACR criteria (11), they were included in the KRSQ because the goal of the epidemiologic study was to develop an instrument with a higher sensitivity, rather than a higher specificity.

The criteria for scleroderma included two of the following four items: skin thickening of arm, legs, face, neck, or trunk; sclerodactyly or hand swelling; digital pitting scars; or pulmonary fibrosis.

The criterion for PM/DM was one of the following four items: muscle weakness, upper-extremity proximal muscle weakness, lower-extremity proximal muscle weakness for more than 3 months, or a history of an elevated muscle enzyme level.

Criteria for Sjögren’s disease were dry eyes and mouth, or positive serologic test results (ANA or RF) plus dry eyes or mouth.

Criteria for Raynaud’s phenomenon included white, blue, or purple color changes of the fingers upon exposure to cold.

The classification of MCTD was based on two (four in CSQ) of the following criteria: synovitis as defined by the RA algorithm, hand edema, Raynaud’s phenomenon, myositis, or acrosclerosis.

An algorithm for OA of the hand and knee was constructed based on ACR clinical criteria for OA of hand and knee (6, 7). Criteria for hand OA were hand pain (aching or stiffness) and one of the following features: hand-tissue enlargement at two or more of the hand joints: PIP or distal interphalangeal (DIP) joints, hard-tissue enlargement of two or more DIP joints, fewer than three swollen MCP joints, and deformity of at least one of the ten selected joints (6). Criteria for knee OA were knee pain plus one of the following features (7): age over 50 yr, morning stiffness for less than 30 min, crepitus, bone tenderness, bone enlargement, or palpable warmth.

To confirm the reliability of the patient’s memory regarding the laboratory findings (e.g., anemia, leukopenia, thrombocytopenia, proteinuria, RF, ANA, and muscle enzyme level) and chest radiographic findings, we compared the patient’s answers with actual data from the medical record review.

Statistical methods

A Student’s t-test was performed on the demographic variables of age, education, economy, and number of comorbid conditions. A chi-square test or Fisher’s exact test was performed on the categorized variables such as sex and functional status. The sensitivity (which is the proportion of positive
results from testing a group with a particular disease) and specificity (which is the proportion of negative results in a control group or a group without a particular disease) of the questionnaire were calculated for each rheumatic disease. The specificity of the questionnaire was also calculated for the control group. Likelihood ratios (the ability of the test to distinguish between diseased and nondiseased subjects) for all control subjects combined were calculated as sensitivity/(1-specificity). Positive and negative predictive values were calculated as follows:

Positive predictive value = 
\[
\frac{(\text{prevalence} \times \text{specificity})}{(\text{prevalence} \times \text{sensitivity}) + (1-\text{prevalence}) \times (1-\text{specificity})}
\]

Negative predictive value = 
\[
\frac{(1-\text{prevalence}) \times \text{specificity}}{(1-\text{prevalence}) \times \text{specificity} + \text{prevalence} \times (1-\text{specificity})}
\]

The prevalence data used for the above calculation were from the U.S.A. because no such data were available for Korea (19): 12.1% for OA, 1% for RA, 0.1% for SLE, 0.025% for scleroderma, and 0.006% for PM/DM.

We used kappa (κ) statistics to analyze the agreement between answering results of the laboratory findings and the actual data from the medical record review.

Test-retest reliability was evaluated with a kappa coefficient that quantified the extent of agreement in the classification of a subject as having any disease between two repeated administrations of the questionnaire. Agreement included classification as one type of disease on the first administration and another type of rheumatic disease on the second administration, and also the same rheumatic disease at both administrations.

The results from the kappa analysis were interpreted as follows: 0.00, poor agreement; 0.01-0.20, slight agreement; 0.21-0.40, fair agreement; 0.41-0.60, moderate agreement; 0.61-0.80, substantial agreement; and 0.81-1.00, almost perfect agreement (20).

The specificity of the questionnaire for each rheumatic disease was evaluated for subsets of respondents stratified by age (≤50 yr vs >50), educational (education year ≤12 vs >12), functional status (class I and II vs III and IV), and socioeconomic characteristics (monthly income ≤200×10⁴ vs >200×10⁴ Korean won [=1,670 US $] according to the mean value in study subjects).

**RESULTS**

**Characteristics of the study population**

Subjects participating in the questionnaire interview included the patients with hand and/or knee OA (n=46), RA (n=52), SLE (n=50), scleroderma (n=8), PM/DM (n=7), Sjogren’s syndrome (n=4), MCTD (n=9), fibromyalgia (n=8), and general medical conditions (n=72) (Table 1).

**Test-retest reliability**

Test-retest reliability for detection of any potential rheumatic disease was performed in 12 patients. Eleven (91.7%) of them were classified as having a rheumatic disease at the first and second interview (kappa=0.91).

**Kappa statistic for laboratory questions**

The kappa statistics for questions regarding laboratory and radiographic findings were 0.22-0.56, indicating fair-to-moderate agreement in general. However, some exhibited a poor kappa values: 0.08 for RF, -0.27 for ANA, and 0.18 for CPK (Table 2).

**Sensitivity and specificity**

The sensitivity of the questionnaire ranged from 77.8 to 100%: 91.3% for OA, 78.9% for RA, 88.0% for SLE, 87.5% for SLE, 87.5% for PM/DM.

| Table 1. Characteristics of the study population |
|-----------------------------------------------|
| Characteristics | All rheumatic patients | All control patients | Total |
| | (n=176) | (n=80) | (n=256) |
| Mean age (SD) (yr) | 50.6 (15.2) | 46.4 (10.9) | 49.3 (14.1) |
| Mean education (SD) (yr) | 11.5 (3.9) | 11.7 (3.8) | 11.6 (3.9) |
| Mean number of comorbid conditions (SD) | 2.1 (0.99) | 1.4 (0.79) | 1.87 (0.99) |
| Female, % | 92.6 | 52.5 | 80.1 |

*Includes patients with osteoarthritis (OA), rheumatoid arthritis (RA), systemic lupus erythematosus (SLE), scleroderma, polymyositis/dermatomyositis (PM/DM), Sjogren’s syndrome, and mixed connective tissue disease (MCTD).<ref>Includes patients with fibromyalgia and patients attending an outpatient clinic of family medicine.</ref>

*p<0.05.
Table 3. The sensitivity, specificity, and likelihood ratio of the Korean rheumatic diseases screening questionnaire (KRSQ)

| Rheumatic disease | Sensitivity (%) | Specificity (%) | Likelihood ratio |
|-------------------|----------------|----------------|-----------------|
| OA Hand (n=4)     | 100            | 75.0           | 4.0             |
| Knee (n=23)       | 78.3           | 90.0           | 7.8             |
| Hand and knee (n=46) | 91.3         | 75.0           | 3.7             |
| RA (n=52)         | 78.9           | 95.0           | 15.8            |
| SLE (n=50)        | 88.0           | 72.5           | 3.2             |
| Scleroderma (n=8) | 87.5           | 71.3           | 3.0             |
| PM/DM (n=7)       | 85.7           | 68.8           | 2.7             |
| Sjögren’s disease (n=4) | 100         | 95.0           | 20              |
| MCTD (n=9)        | 77.8           | 91.3           | 8.9             |

Table 5. Prevalence and predictive value (PV) percentages by disease for the general population

| Disease       | Prevalence (%) | Positive PV (%) | Negative PV (%) |
|---------------|----------------|-----------------|-----------------|
| OA            | 12.1           | 33.2            | 98.4            |
| RA            | 1.0            | 13.7            | 99.8            |
| SLE           | 0.1            | 0.32            | 99.98           |
| Scleroderma   | 0.025          | 0.08            | 99.99           |
| PM/DM         | 0.006          | 0.02            | 99.99           |

*These values are based on U.S.A. data (19).

Stratified analysis of specificity by demographic, socioeco- nomic, and functional status was performed (Table 4). We found significantly lower specificity for OA among older subjects (>50 yr), and for RA and SLE among subjects with poor functional status (class=III or IV).

Predictive values

Positive predictive values in the general population ranged from 0.02 to 33.2%: 33.2% for OA, 13.7% for RA, 0.32% for SLE, 0.025% for systemic sclerosis, and 0.02% for PM/DM. Negative predictive values were very high, ranged from 98.4 to 99.99% in the general population: 98.4% for OA, 99.8% for RA, 99.98% for SLE, 99.99% for systemic sclerosis, and 99.99% for PM/DM (Table 5).

DISCUSSION

We have developed the KRSQ based on ACR criteria for various rheumatic diseases and the CSQ, and analyzed the sensitivity, specificity, and positive and negative predictive values of this new questionnaire. The sensitivity and specificity of each disease were found to be high in general. Negative predictive values for any disease were very high, ranging from 98.4 to 99.99%.

Osteoarthritis is the most common type of arthritis, and the second only to chronic heart disease as the primary diagnosis leading to adults receiving social security disability payments in the U.S.A. (19). The prevalence of OA is certain to increase as the number of elderly people increases. In contrast to OA, the other rheumatic diseases were characterized by a low prevalence, and diverse manifestations, and expensive tests (e.g., for ANA) for diagnosis.

Epidemiologic studies on the prevalence of OA and connective tissue diseases have been performed worldwide (21-27). Such studies have used interview and examinational surveys with or without radiographic studies. Radiographic studies provide data that are more precise and useful, but they are more expensive to perform (1). Therefore, it might be difficult to perform this type of expensive and large epidemiologic study in countries such as Korea that have relatively low percapita GDPs. Therefore, the development and application
of a questionnaire with high sensitivity and specificity to epidemiologic studies would be more useful for population studies under these conditions (1, 5). Since the use of the data based on only self-reported cases presents some limitations, we constructed the questions based on the available reports published on this subject. We used the CSQ that was shown to be highly sensitive and specific for screening potential connective-tissue diseases (1), and adjusted the algorithm to Korean circumstances in order to achieve better results.

There have been a few reports validating postal surveys for self-reported OA or asking about the presence of any nodes of the hand joints such as PIP and DIP joints (28-31). Based on these studies and ACR criteria, questions for hand OA in our study included the presence of pain, hard-tissue enlargement, and deformity of hand joints. It is well known that the estimates of knee pain are influenced by even minor changes in question content (8). In one study that compared three questions for knee pain, the ACR-criteria question was relatively insensitive for use in the community, and the following question was found to be the most sensitive but least specific: “Have you ever had pain in or around the knee on most days for at least a month? If so, have you experienced any pain during the last year?” (8). Therefore, we chose this question for verifying the presence of pain, and added the presence of crepitation, bone tenderness, bone enlargement, morning stiffness for less than 30 min, and no palpable warmth in the questionnaire for knee OA based on ACR criteria (7).

The initial results using the original CSQ algorithm and strict criteria for the OA questionnaire showed high specificity rather than high sensitivity (1, 6, 7). Since the goal of this questionnaire was to develop the tools that can find the largest number of cases, we changed the algorithm to get the results with high sensitivity, high negative predictive value, and an acceptable range of specificity.

We investigated the reliability of the questions of laboratory or radiographic findings. Questions for anemia, leucopenia, thrombocytopenia, proteinuria, and pulmonary fibrosis showed fair-to-moderate agreement, but the agreement of questions for RF, ANA, and muscle enzyme level was so poor that these questions were considered not to be useful in Korean population studies. To get more precise results, therefore, it is recommended that KRSCQ should be accompanied with or followed by laboratory tests.

A large national population study into health and nutritional status is conducted by interview survey tri-annually in Korea. According to data from the most-recent study (1998), the prevalence of arthritis in the total population was 8.0% (female 12.9%, male 4.3%), and it occurs in 24.5% of people older than 45 yr. Although that study provided valuable data from a large population, and was certainly a well-designed study, it had some limitations. The study used a self-reported questionnaire asking only about the presence or absence of arthritis: “Have you ever had arthritis?”. It was not considered whether the diagnosis of disease was made by a doctor or not, and what was the disease subcategory (e.g., OA, RA, or SLE). Therefore, future large national population surveys in Korea should be designed to overcome these limitations. Screening the patients with potential disease should be followed by the second step comprising a physician’s physical examination, and laboratory and radiographic tests for reducing false-positive results.

Our study had some limitations, including a small number of patients especially in the case of rare connective-tissue diseases such as scleroderma, PM/DM, Sjogren’s disease, MCTD, and hand OA without knee OA. The number of control patients, especially patients with fibromyalgia, was also small. Furthermore, test-retest reliability was performed on a small number of patients. To obtain precise information and to confirm the usefulness of the KRSCQ in population studies, the continuous enrolling of many more cases is needed.

In summary, we propose this KRSCQ for epidemiologic study of the various rheumatic diseases in Korea. The questionnaire had high sensitivity, moderate specificity, and a high negative predictive value.

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1. 3개월 이상 관절염이 지속된 적이 있었습니까?

2. 아침에 자고 일어났을 때 관절이 뻣뻣한 증상이 6주 이상 지속된 적이 있었습니까?
   1-1 만약 '예'로 답하셨다면 그 증상이 얼마나 지속되었습니까?
   ○ 30분 이내에 좋아진다.
   ○ 1시간 이상 지속된다.
   1-2 어느 관절에 상기 증상이 생겼습니까?

3. 팔꿈치 관절이나 발목 관절 주위의 피부에 약간 튀어 오르거나 혹 같은 절삭이 있었던 적이 있었습니까?

4. 손목 관절, 손가락 관절(단, 손가락 끝마디는 제외), 팔꿈치 관절, 무릎 관절 중에서 6주 이상 붓고 통증이 지속되었던 적이 있으면 다음 그림에 표시를 해주십시오.

5. 류마티스 관절염에 대한 피검사를 해보신 적이 있었습니까?
   5-1 만약 '예'로 답하셨다면 결과가 어떻게 나왔습니까?

6. 루푸스에 대한 피검사를 해보신 적이 있었습니까?
   6-1 만약 '예'로 답하셨다면 결과가 어떻게 나왔습니까?

7. 손가락을 추운 날씨에 노출시키거나 차가운 물에 담겼을 때 피부 색깔이 변합니까?
   7-1 만약 '예'로 답하셨다면 어떤 색깔로 변했습니까?

8. 입안이나 코안이 2주 이상 혀였던 적(궤양)이 있었습니까?

9. 암컷 뿐 위에 붉은 색 발진이 한 달 이상 지속된 적이 있었습니까?

10. 햇볕에 노출 시 남들과는 달리 심하게 피부가 붉게 되거나 물집이 생겨거나 가렵고 쓰라린 적이 있었습니까?

11. 심초손을 할 때 가슴이 결리듯이 아프며 숨쉬기 어려웠던 경험이 한 달 이상 지속되었던 적이 있었습니까?

12. 위안 없이 머리카락이 이전보다 훨씬 심하게 빠졌던 적이 있었습니까?

13. 경기나 간질 등을 한 적이 있었습니까?

14. 건강 검진이나 신체 검사 등을 비롯한 지금까지 했던 피검사에서 다음과 같은 진단을 받은 적이 있었습니까?
   ① 변형이 있다
   ② 백혈구 수가 높아져 있다
   ③ 혈소판 수가 높아져 있다
① 소변에 단백질이 나온다(단백뇨)
② 피부에 원판상 루푸스가 있다
③ 콧속유아로 진단 받았다
④ 근육효소가 상승되어 있다

15. 지금까지 한 번이라도 무릎관절이나 그 주위가 한 달 이상 지속적으로 아픈 적이 있었습니까?
   15-1 만약 '예'로 답하셨다면 최근 1년 사이에도 무릎이나 무릎 주위의 통증이 있었습니까?

16. 무릎을 움직일 때 소리가 난습니까?

17. 무릎관절이 옛날에 비해서 더 딱딱하게 튀어나왔습니까?

18. 무릎관절을 손으로 만져보였을 때 열이 있습니까?

19. 무릎관절을 손으로 놀렸을 때 아픔니까?

20. 손가락 미디가 아랫 적이 있습니까?

21. 손가락 미디 중 딱딱하게 튀어나온 것이 있습니까?
   21-1 만약 있으면 다음 그림에 표시해 주십시오.

22. 손가락 관절 중에서 딱딱하게 튀어나오면서 변형이 된 것이 하나라도 있습니까?
   22-1 만약 있으면 다음 그림에 표시해 주십시오.

23. 한 달 이상 손이 전체적으로 심하게 뿌였던 적이 있었습니까?

24. 팔, 다리, 얼굴, 목이나 또는 흉부가 딱딱해지거나 조이는 듯한 느낌이 있었던 적이 있습니까?

25. 손가락이나 발가락의 피부가 딱딱해진 적이 있습니까?

26. 손가락 끝에 궤양과 함께 그로 인한 상처가 생겼던 적이 있습니까?

27. 3개월 이상 근육의 힘이 없었던 적이 있습니까?

28. 3개월 이상 앉아있다가 일어나기가 힘들 정도로 다리근육의 힘이 없었던 적이 있습니까?

29. 3개월 이상 머리 빗기가 힘들 정도로 팔근육의 힘이 없었던 적이 있습니까?

30. 눈물이 안 나와서 눈이 뻑뻑하고 모래가루가 있는 것처럼 불편한 적이 있습니까?

31. 잠을 자다가 일어나서 물을 마셔야 할 정도로 입이 마른 적이 있습니까?