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ORIGINAL ARTICLE

Translation and validation of the Turkish language version of the Rheumatoid Arthritis Disease Activity Index-5

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Abstract

Aim: The purpose of this study was to translate the Rheumatoid Arthritis Disease Activity Index-5 (RADAI-5), which is a tool for measuring disease activity in rheumatoid arthritis (RA) patients, into Turkish language and prove its validity, reliability and sensitivity to changes.

Methods: Translation from the original German version was performed according to the standardized methods. One hundred and two patients with RA completed in the Turkish RADAI-5 twice within 3 days interval. Internal consistency and test–retest reliability was investigated by calculating Cronbach's alpha and intra-class correlation coefficients (ICC), respectively. Validity was assessed by analyzing the correlations between the Turkish RADAI-5 and some measurement tools evaluating the disease activity, functional status and quality of life. To test the scale's responsiveness to the changes, another 23 patients with uncontrolled disease activity and three newly diagnosed RA patients completed the RADAI-5 before and after a biologic agent or methotrexate treatment.

Results: There were no floor or ceiling effects. Cronbach's alpha (0.91) and ICC (0.997) values certified the Turkish version's reliability. Strong correlations between the Turkish questionnaire and Disease Activity Score-28 (DAS28), DAS28-CRP, DAS28-three variables, Health Assessment Questionnaire, Rheumatoid Arthritis Quality of Life questionnaire, patient's and doctor's global assessments, tender joint count proved the convergent validity of the scale. Effect size (3.08) demonstrated that the Turkish RADAI-5 is sensitive to the changes.

Conclusion: The Turkish RADAI-5 is a feasible, reliable and valid questionnaire and sensitive to changes; thus it can be used to monitor disease activity in Turkish RA patients.

Key words: RADAI-5, rheumatoid arthritis, Turkish, validation.

INTRODUCTION

Rheumatoid arthritis (RA) is a systemic autoimmune disease characterized by chronic inflammation of the synovial joints. Disease activity varies greatly between patients. Some patients have a mild disease activity, whereas in the majority of patients, the disease leads to progressive joint destruction and disability. Various questionnaires are used for monitoring patients to assess disease activity and treatment effectiveness.

Disease activity scales may be long, tedious and may interfere with the flow of patient visits rather than contributing information to clinical care.[1] A simplified version of the Rheumatoid Arthritis Disease Activity Index questionnaire (RADAI) was developed specifically for busy clinical settings by Leeb *et al.* and called Rheumatoid Arthritis Disease Activity Index-5 (RADAI-5). RADAI-5 is a patient self-assessment questionnaire that was improved by subtracting one of the questions of the RADAI and adding a question regarding patient's global assessment. Excluding the joint examination which takes place in the original RADAI, the RADAI-5

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enables the physician to gain time while assessing RA activity in daily routines. Its validity, reliability and responsiveness have been proven.[2] It has five questions which ask about global disease activity in the last 6 months and current disease activity with respect to joint swelling and tenderness, arthritis pain, duration of morning stiffness and general health. The answers range from 0 to10 on a visual analogue scale (VAS). The total score is the average of five questions. Values of 0.0–1.4 correspond to remission, 1.6–3.0 to low disease activity, 3.2–5.4 to moderate disease activity and > 5.6 to high disease activity.[3]

Our aim in this study was to adapt the RADAI-5 to Turkish language and test its validity, reliability and responsiveness to change.

METHODS

Before the study we obtained permission from Dr. Burkhard Leeb who developed the RADAI-5 for adaptation of it to Turkish language. The protocol of this study was approved by the Local Ethics Committee of Ankara Numune Training and Research Hospital that conforms to the provisions of the World Medical Association's Declaration of Helsinki. All of the participants signed informed consent forms.

Translation procedure

The steps in the American Association of Orthopedic Surgeons (AAOS) guideline was followed in the translation process of the questionnaire.[4] Three bilingual translators (a medical doctor, a translator and interpreter and a bureaucrat who lived in Germany for a while) independently translated the original RADAI-5 to Turkish. The medical doctor was aware of the aim of translation while the others were not. Then they prepared a single text together. This form was retranslated to German by a translator and interpreter and a German language teacher. The retranslated form was compared with the original form by two German language teachers of German origin. They stated that these two forms matched up with each other. After that the Turkish text was presented to 25 physiatrists and their opinion was asked about cross-cultural differences and any difficulty they anticipated in using this form in daily practice. They found the questions clear and understandable. Finally, a Turkish language teacher controlled the Turkish form regarding sentence structure and grammar rules. Then pre-test stage was started and 23 patients with RA (other than the study sample) diagnosed according to 1987 American College of Rheumatology (ACR) criteria were asked to fill in the Turkish form and to tell if they experienced any difficulty in understanding and replying to the questions. Since there was no negative feedback, the test stage was started.

Patients and setting

One hundred and twenty-five patients with RA diagnosed according to the 1987 ACR criteria applying to the outpatient clinic of the Numune Training and Research Hospital between October 2011 and July 2012 participated in the study. After they signed the informed consent form they were asked to fill in the Turkish RADAI-5 twice within a 3-day interval. The literate patients filled in the questionnaire themselves and the same investigator (SI) interviewed the illiterate patients. She read the questions to them and noted their answers. All the patients were also asked to fill in the Health Assessment Questionnaire (HAQ) and the Rheumatiod Arthritis Quality of Life questionnaire (RAQoL) along with the RADAI-5 in the first visit.

The HAQ was developed to evaluate the functional status of patients with arthritis.[5] There are 20 questions in eight categories of functioning – dressing, rising, eating, walking, hygiene, reach, grip and usual activities. There is a four-level difficulty scale for each item. The choices are normal (no difficulty) (0), some difficulty (1), much difficulty (2) and inability to perform (3). The total possible score ranges from 0 to 3. Its adaptation to Turkish language and validation were proven by Kucukdeveci *et al.*[6] The RAQoL is a disease-specific measure that assesses self-reported quality of life in patients with RA.[7,8] It is composed of 30 questions which assess specific activities of daily living. Each item is answered with yes or no. The number of items answered 'yes' are summed up, giving the final score which ranges from 0 to 30. Higher scores indicate worse quality of life. The RAQoL has consistently shown good responsiveness and validity as a quality of life measure in RA patients.[9–11] A validated Turkish version of the RAQoL is available.[12]

In addition, tender and swollen joint counts (out of 28 joints), erythrocyte sedimentation rate (ESR), C-reactive protein (CRP), patient's general health assessments (according to the VAS 0–100 mm) and physician's global assessment of disease activity (according to the VAS 0–100 mm) were recorded. Joint assessments were performed by the same experienced physician.

Twenty-six patients other than the 120 patients previously enrolled were evaluated to determine the scale's sensitivity to changes. Twenty-three of these patients were the ones with uncontrolled disease activity, who were determined to be given an anti-tumor necrosis

factor (TNF) or other biologic agent treatment, while three of them were newly diagnosed with RA and initiated on methotrexate 15 mg/week. Six of these 23 patients were initiated on etanercept 50 mg/week, seven on rituximab two infusions of 1000 mg, five on adalimumab 80 mg/month and the rest on infliximab 3 mg/kg treatment. These 26 patients filled out the Turkish RADAI-5 before and a month after the first biologic drug or methotrexate usage.

Feasibility

Feasibility was assessed by evaluating the floor and ceiling effects. A floor effect occurs when the majority of the scores are at the minimum possible score for the variable that the health status survey instrument is measuring. Floor effects can be determined by examining the proportion of subjects with the lowest possible scores. A ceiling effect occurs when the majority of the scores are at the maximum possible score for the variable that the health status survey instrument is measuring. Similarly, ceiling effects are calculated by determining the proportion of subjects who achieved the highest possible score. Floor and ceiling effects were considered to be present if 15% of patients scored the lowest or highest possible scores.[13]

Reliability

Reliability was investigated by measuring the internal consistency and assessing the test–retest reliability. Cronbach's alpha and intra-class correlation coefficient (ICC) were calculated for determining the internal concistency and test–retest reliability, respectively.

Construct validity

Convergent validity method was used and correlations between the RADAI-5 and the Disease Activity Score 28 (DAS28), DAS28-CRP, DAS28 with three variables (DAS28–3), ESR, CRP, HAQ, RAQOL scales and some clinical parameters that were reported to be related with the disease activity in RA (patient's global assessment, doctor's global assessment, swollen/tender joint count) were all investigated for this purpose.

Responsiveness

Responsiveness was evaluated by paired samples *t*-test and effect size. The formula Effect size = Dx/SD (Dx) was used to determine the effect size.[14]

Statistical analysis

The data analysis was made with the Statistical Package for the Social Sciences (SPSS) Windows version 11.5 (SPSS Inc., Chicago, IL, USA). The quantitative data were stated as the mean ± standard deviation or median (minimum–maximum), while the qualitative data were stated as frequency (percent).

Feasibility was assessed by evaluating the floor and ceiling effects. While reliability in terms of internal concistency was determined by calculating Cronbach's alpha coefficient, in terms of test–retest reliability it was analyzed by intra-class correlation coefficient. ICC values > 0.7 was accepted as satisfactory. The minimum acceptable value for Cronbach's alpha coefficient was 0.7.[15] Construct validity was investigated using the 'convergent' validity method. Spearman's correlation coefficient (r) was used for analysis. $r > 0.6$ was accepted as strong correlation, $0.3 < r < 0.6$ was accepted as moderate correlation and $r < 0.3$ was accepted as weak correlation.[16] Internal responsiveness was evaluated by paired samples *t*-test and effect size, external responsiveness was assessed with correlation between changes in RADAI-5 scores and DAS28.[14] A value of $P < 0.05$ was accepted as statistically significant.

RESULTS

Eighteen patients were excluded from the study since they did not attend the second visit (3 days after the first visit). There were missing items in the forms of five patients and they were also excluded from the study for this reason. Therefore 102 patients' data were incorporated into the statistical analysis. The demographic characteristics of the patients are presented in Table 1.

Sixty-seven percent of the patients were using methotrexate while on other medications and their usage rates in the study group were as follows: 50% glucocorticoids, 11.8% leflunomide, 22.5% hydroxychloroquine, 8.8% sulfasalazine, 16.7% biologic agents, 65.7%

Table 1 Demographic characteristics of the study group

Age (mean ± SD)	56.2 ± 11.7
Gender, F/M, *n* (%)	80 (80.4%)/20 (19.6%)
Educational status	
Illiterate	28 (27.5%)
Primary school (5 years)	59 (57%)
Middle school (8 years)	8 (7.8%)
College (11 years)	7 (6.9%)
Disease duration (years) (mean ± SD, min–max)	13.6 ± 8.1 (0.8–35.3)
RF+/RF−, *n* (%)	82 (80.4%)/20 (19.6%)

F, female; M, male; max, maximum; min, minimum; RF, rheumatoid factor; SD, standard deviation.

non-steroidal anti-inflammatory drugs. Descriptive statistics of clinical and laboratory measures are presented in Table 2.

Mean RADAI-5 score of the study group was 4.3 ± 2.4, whereas question-based scores for the 1st–5th questions were as follows: 4.98 ± 2.6; 4.25 ± 3.1; 4.62 ± 3.2; 4.65 ± 2.5; 2.9 ± 2.6, respectively. In three patients maximum (2.94%) and in one patient minimum (0.98%) RADAI-5 scores were obtained. Hence ceiling and floor effects were not seen. Therefore, it may be proposed that feasibility of the Turkish RADAI-5 is good.

Cronbach's alpha of the Turkish RADAI-5 was 0.91, greatly above the bound value of 0.7, demonstrating that the internal consistency of the Turkish form is sufficient.

ICC of the Turkish RADAI-5 was 0.997, indicating a good test–retest reliability. Moreover; question-based ICC values were also greatly above the bound value of 0.7. They were 0.994, 0.997, 0.972, 0.978 and 0.876 for the 1st–5th questions, respectively.

Illiterate patients responded similarly compared to literate ones. They had similar disease acitivity according to DAS28. Median DAS28 values of illiterate versus literate persons were 3.6 (1–7.5) and 3.1 (0.8–7.1); $P = 0.131$. They had also similar RADAI-5 scores at both first and second examinations. Illiterate patients' mean RADAI-5 scores were 4.97 ± 2.7 and 4.96 ± 2.7 at the first and second examinations, respectively. Corresponding values for literate patients were 4 ± 2.2 and 3.96 ± 2.2. ICC for illiterate persons was 0.999 and it was 0.995 for literate ones.

There were strong correlations between the Turkish RADAI-5 and some other disease activity indices, DAS28, DAS28-CRP, DAS28–3, proving the convergent validity of the Turkish form. There were also strong correlations between HAQ, RAQoL, patient's and doctor's global assessments, tender joint count and the RADAI-5. Swollen joint count, CRP and ESR were found to be moderately correlated with RADAI-5. All these correlations demonstrated the construct validity of the Turkish RADAI-5. Correlation coefficients are presented in Table 3.

Mean RADAI-5 of 26 patients with high disease activity before and 1 month after starting a biologic agent treatment or methotrexate was 7.4 ± 1.5 and 3 ± 1.6, respectively. The difference was statistically significant ($P < 0.0001$). Effect size was found as 4.40/1.43 = 3.08. While testing external responsiveness, the change in DAS28 was evaluated as well as RADAI-5. Mean DAS28 value was 4.5 ± 1.1 before the treatment and 2.99 ± 2.9 after 1 month of therapy. The change in DAS28 was statistically significant ($P < 0.0001$). Before and after biologic agent and methotrexate treatment there was a same-direction relationship between changes of the DAS28 and the RADAI-5; however, it was not statistically significant ($P = 0.87$). Having a same-direction relationship indicates that RADAI-5 has

Table 2 Clinical and laboratory assessments of the study group

Tender joint count (out of 28 joint), mean ± SD (min–max)	4.7 ± 7.1 (0–28)
Swollen joint count (out of 28 joint), mean ± SD (min–max)	0.6 ± 1.2 (0–9)
Physician's global assessment, VAS 0–100 mm, median (min–max)	33 (10–92)
Patient's global assessment, VAS 0–100 mm, median (min–max)	42 (7–100)
ESR, mm/h, mean ± SD, (min–max)	24.8 ± 18.5 (0–83)
CRP, mg/L, mean ± SD, (min–max)	9.3 ± 13 (0.2–70.3)
RADAI-5, mean ± SD, (min–max)	4.3 ± 2.4 (1–10)
DAS28, mean ± SD, (min–max)	3.6 ± 1.6 (0.8–7.5)
DAS28-CRP, mean ± SD, (min–max)	3.2 ± 1.5 (1.2–7.5)
DAS28–3, mean ± SD, (min–max)	3.4 ± 1.4 (0.7–7)
HAQ, mean ± SD, (min–max)	1.1 ± 0.9 (0–3)
RAQoL, mean ± SD, (min–max)	14.9 ± 9.6 (0–30)

CRP, C-reactive protein; DAS28, Disease Activity Score of 28 joints; ESR, erythrocyte sedimentation rate; HAQ, Health Assessment Quenstionnaire; Min, minimum; max, maximum; RAQoL, Rheumatiod Arthritis Quality of Life questionnaire; RADAI-5, Rheumatoid Arthritis Disease Activity Index-5; SD, standard deviation; VAS, Visual Analog Scale.

Table 3 Correlations of the Turkish RADAI-5 proving its construct validity

Parameter	*r*
DAS28	0.86**
DAS28-CRP	0.84*
DAS28–3	0.79**
Physician's global assessment	0.72**
Patient's global assessment	0.84**
Tender joint count	0.75**
Swollen joint count	0.56**
ESR	0.48**
CRP	0.31**
HAQ	0.71**
RAQoL	0.69**

*$P < 0.001$; **$P < 0.0001$. CRP, C-reactive protein; DAS28, Disease Activity Score of 28 joints; ESR, erythrocyte sedimentation rate; HAQ, Health Assessment Quenstionnaire; RADAI-5, Rheumatoid Arthritis Disease Activity Index-5; RAQoL, Rheumatiod Arthritis Quality of Life questionnaire.

external validity with DAS28 and statistical significance of the relationship may be proven by increasing the number of subjects. Questions of the RADAI-5 and the Turkish RADAI-5 are presented in Appendices 1 and 2.

DISCUSSION

Our study results revealed that the Turkish RADAI-5 is a feasible, reliable and valid instrument and can be used to detect the disease activity of Turkish patients with RA. We intended to translate the RADAI-5 to our language because of its accessibility in daily routine as well as its accuracy in detecting RA activity levels. Further, it helps physicians save time by excluding the joint examination. It is reported to take < 1 min for the patient to fill in the questionnaire and < 30 seconds for the physician to calculate.[17,18] The deficient side of the scale may be obtaining patient-derived data only and thus leading to some individual disease perception differences. Moreover, not including acute phase reactants in the calculation may be an advantage in crowded outpatient clinics, but this may also be evaluated as a lacking in the scale.

Internal concistency of the Turkish RADAI-5 was high with a Cronbach's alpha of 0.911, very close to the Cronbach's alpha of the original RADAI-5 which was 0.917.[2] This result shows that the Turkish questionnaire is as internally consistent as the original form and proves the Turkish form's reliability. Leeb *et al.*[18] reported Cronbach's alpha of the RADAI-5 as 0.906 in a study in which they compared the composite indexes and patient questionnaries in routine care of RA patients and this value is also similar to the Turkish form's Cronbach's alpha value.

According to the literature, the periods between the administration of scales vary from hours to several months. The period is advised to be long enough for the patient not to remember the former reply and short enough not to be affected by any change in disease activity status.[15] We arranged the visits with a 3-day interval for test–retest reliability evaluation. Our purpose was to make this period long enough that the patient could not remember his or her former answers, but short enough that his or her disease activity and clinical status would not change. In the literature we did not encounter any cultural adaptation studies for the RADAI-5 but in the study of RADAI's translation to Thai language the patients also answered the questionnaire with 3 days interval.[19]

The correlation coefficients between the original German RADAI-5 and DAS28, DAS28-CRP were reported as 0.638 and 0.719, respectively, while they were found as 0.86 and 0.84 in our study. Both of the study groups had moderate disease activity according to DAS28 and DAS28-CRP and the mean scores of these composite indices were very similar (3.51 *vs*. 3.6 for DAS28 and 3.19 *vs*. 3.2 for DAS28-CRP in German and Turkish patients, respectively). They also had moderate disease activity according to the RADAI-5 but mean scores of the Turkish study group were higher than the German group (4.27 *vs*. 3.07). The study groups were also similar regarding mean age (57/56.2) and gender distribution (female proportion of 79.9% *vs*. 80.2%). Patient's self-health assessment may differ between cultures for the same disease. Turkish patients with RA may feel themselves more disabled than German RA patients with similar disease activities. This may explain why mean RADAI-5 scores of the Turkish group were found to be higher than the German group. Additionally, the Turkish group had longer disease duration than the German group (13.6 *vs*. 7.2 years). Living with a chronic, painful disease for a long time may affect patients' perceptions of her/his health status. This may also explain why Turkish patients found their health status worse than that of German patients with similar disease activity according to DAS28.[2]

Responsiveness to changes of the RADAI-5 has not been proven to date. Our study is the first one that assessed responsiveness of RADAI-5 by a standardized method. In the study developing the RADAI-5, the scale's sensitivity to changes was not investigated with standard methods and this situation was stated as a limitation of the study. Moreover it has been reported that sensitivity to changes may be demonstrated ideally in patients who failed with the former treatments and new therapies were initiated.[2] The discovery and utilization of the biologic disease-modifying anti-rheumatic drugs (DMARD) is a cornerstone in RA management. In patients resistant to conventional DMARDs, disease control may be achieved by these drugs. Their effects are rapid. In a group of 23 patients having failed with the conventional DMARD therapies whom various biologic agent treatments were initiated for the first time and three patients having just been diagnosed with RA and methotrexate was initiated, we observed that disease activity assessed by DAS28 decreased significantly, as well as the RADAI-5 scores.

A limitation of our study was the illiterate patients in a remarkably high ratio. The scale is developed to be replied by patients on their own. However the Austrian population's educational level where the scale was created is different from the Turkish population's. Since

the illiterate patients would not read and answer the questions on their own, the investigator read the text and noted the answers. Why we did not exclude these patients from the study is that illiteracy is common in Turkey in elderly patients so we thought that illiterate people should be represented in this validation study. The illiterate patients did not have difficulty in understanding and replying to the questions. Therefore, Turkish RADAI-5 can also be applied in uneducated patients.

Another limitation of this study is the shortness of the period between the visits which is not enough for evaluating methotrexate's effect. If the patients in whom methotrexate was initiated for the first time had filled in the Turkish RADAI-5 within a 2-month interval (instead of one) the scale's responsiveness to changes would have been found to be stronger.

The original RADAI-5 is in German. In the literature in studies which RADAI-5 is involved, its English form is also available. No other adaptation studies were encountered.

In conclusion, the Turkish RADAI-5 is a feasible, reliable and valid questionnaire and sensitive to changes; thus it can be used to monitore RA activity in busy clinical care settings.

DISCLOSURE

The authors declare that they have no any conflict of interest.

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APPENDIX I
Questions of the RADAI-5

1 How active was your arthritis in the last 6 months? (0 = completely inactive to 10 = extremely active)
2 How active is your arthritis today with respect to joint tenderness and swelling? (0 = completely inactive to 10 = extremely active)
3 How severe is your arthritis pain today? (0 = no pain to 10 = unbearable pain)
4 How would you describe your general health today? (0 = very good to 10 = very bad)
5 Did you experience joint (hand) stiffness on awaking yesterday morning? If yes, how long was this stiffness? (0 = no stiffness to 10 = stiffness to whole day)

APPENDIX II
RADAI-5 (Turkish Form)

Hasta ismi:

Sayın hasta;

Bu anket romatizmal hastalığınızın boyutunu tam olarak tespit etmek amaçlıdır. Lütfen romatizmal şikayetlerinize ilişkin aşağıdaki soruları cevaplayınız. Lütfen hiçbir soruyu cevapsız bırakmayınız.

Lütfen aşağıdaki 5 soru için 0 ile 10 arasındaki bir sayıyı işaretleyiniz.

1 Son 6 ay boyunca iltihaplı eklem hastalığınız (artritiniz) ne kadar aktifti?

Hiç aktif değildi	0	1	2	3	4	5	6	7	8	9	10	Son derece aktifti

2 Eklemlerinizin basıya hassasiyeti ve şişliği açısından eklem hastalığınız (artritiniz) bugün ne kadar aktif?

Hiç aktif değil	0	1	2	3	4	5	6	7	8	9	10	Son derece aktif

3 Bugün eklem ağrınız (artritiniz) ne kadar şiddetli?

Ağrı yok	0	1	2	3	4	5	6	7	8	9	10	Dayanılmaz ağrı

4 Şu anki sağlık durumunuzu nasıl tarif edersiniz?

Çok iyi	0	1	2	3	4	5	6	7	8	9	10	Çok kötü

5 Dün sabah uyandığınızda eklemleriniz (elleriniz) tutulmuş muydu? Cevabınız evet ise bu tutukluk ne kadar sürdü?

Tutukluk yoktu	0	1	2	3	4	5	6	7	8	9	10	Bütün gün sürdü