

VALIDITY AND RELIABILITY OF RADAR QUESTIONNAIRE FOR PATIENTS WITH RHEUMATOID ARTHRITIS

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ABSTRACT

Rheumatoid arthritis (RA) is a chronic debilitating autoimmune disease modifying anti-rheumatic drugs (DMARDs) are needed to modify the progression of RA. Therefore, a practical tool to monitor disease activities of RA is needed. The objectives of this study were to determine physician-patient agreement, and patient-patient reliability of RADAR questionnaire translated to Bahasa Indonesia. Twenty two patients who fulfilled The ACR Revised Criteria 1987 for RA, not illiterate, and understand Bahasa Indonesia were included in this study. To determine the agreement, questionnaire A is firstly completed by the physician, on only for questions 6, then compared to question no 6 of questionnaire B which is completed by the patient. To determine the reliability, all questions of questionnaire B is blindly compared to all questions of questionnaire C. Without knowing by the patients, questionnaire C is completed 2 hours afterwards. ICCs were used to measure agreement and reliability. The results showed that more than 60% of the ICC values of physician-patient agreement were > 0.65 and more than 90% of the ICC values of patient-patient reliability were > 0.65. In conclusion, RADAR questionnaire translated to Bahasa Indonesia showed substantial validity and reliability.

Keywords: agreement, reliability, RADAR questionnaire, Rheumatoid Arthritis

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INTRODUCTION

Rheumatoid arthritis (RA) is a chronic debilitating autoimmune disease with a high psycho-socio-economic burden (Wolfe et al 1994). High intensity pain and progressive destruction of cartilage, bones and joint structures in RA may cause disability and premature mortality. The prevalence of RA is between 0.5-2.0 % (WHO 1992; Lawrence et al 1994). Among 3700 patient's visits at the Dr. Soetomo Hospital Rheumatology Outpatient Unit, AR ranked second after osteoarthritis (Kusmartatmo et al. 1992). Disease modifying anti rheumatic drugs (DMARDs) is a group of drugs which are able to modify the progression of AR and other autoimmune diseases. This includes chloroquine, hydroxychloroquine, methotrexate, sulfasalazine, leflunomide, cyclosporine, gold compounds etc (Wijnands et al. 1992; Platt et al. 1993). In order to improve the health status of AR patients, there must be an instrument for disease activity monitoring in RA patients receiving DMARDs (Taal et

al. 1989). The instrument (e.g. a questionnaire) is supposed to be practical and concise. This concept is preferable for Indonesian patients, since they may have lower education attainment. Measuring signs and symptoms of AR which mostly consist of subjective components such as pain, stiffness, tenderness through traditional collecting method may be costly. Whilst the use of a questionnaire can be time and cost saving, particularly for laboratory tests (Mason et al. 1992). However, we have to be sure regarding the validity and reliability of a questionnaire applied in the different settings (Fuch et al. 1989; Stewart et al. 1990). Therefore, we were trying to determine the agreement (can a surrogate for validity) and reliability of the Rapid Assessment of Disease Activity in Rheumatology (RADAR) questionnaire for AR patients translated to Bahasa Indonesia. RADAR questionnaire is a short, concise, and self assessing which has been validated for RA patients at Boston University, USA (Mason et al. 1992).

MATERIALS AND METHODS

The study which was done between 1 May 1995 up to 31 December 1995 included 22 RA patients fulfilled The 1987 ACR Revised Criteria for classification of AR. The location of study was at The Rheumatology Out-patient Unit, Dr. Soetomo Hospital, Surabaya,

Indonesia. The patient must not be illiterate and understand Bahasa Indonesia. A physician specialized in internal medicine (dr. JS) who has been working at The Rheumatology Outpatient Unit for 3 years, undertook history taking and physical examination on every single RA patient to establish the diagnosis of AR.

Table 1. 1987 American College of Rheumatology (ACR) revised criteria for the classification of RA (Arnett et al. 1988)

Criteria	Definition
1. Morning stiffness	Morning stiffness in/around the joints, lasting at least 1 hour before maximal improvement
2. Arthritis of three or more joint areas	At least three joint areas simultaneously with soft tissue swelling or joint fluid observed by a physician; the 14 possible areas are (right or left): PIP, MCP, wrist, elbow, knee, ankle, and MTP joints
3. Arthritis of hand joints	At least one area swollen in a wrist MCP, or PIP joint
4. Symmetric arthritis	Simultaneous involvement of the same joint areas on both sides of the body (bilateral involvement of PIP, MCP, or MTP acceptable without perfect symmetry)
5. Rheumatoid nodules	Subcutaneous nodules over bony prominences or extensor surfaces, or in juxtaarticular regions, observed by a physician
6. Serum rheumatoid factor	Abnormal amount of serum rheumatoid factor by any method for which the result has been positive in < 5% of control subjects
7. Radiographic changes	Erosions or unequivocal bony decalcification localized in or most marked adjacent to the involved joints (osteoarthritis changes excluded), typical of rheumatoid arthritis on posteroanterior hand and wrist radiographs

For classification purposes, a patient is said to have rheumatoid arthritis if four of seven criteria are satisfied. Criteria 1-4 must have been present for at least 6 weeks. Patients with two clinical diagnoses are not excluded. MCP, metacarpophalangeal; MTP, metatarsophalangeal; PIP, proximal inter-phalangeal.

The Instrument

To determine the agreement and reliability of the RADAR questionnaire for RA patients in Indonesian setting, this was firstly translated from the original RADAR questionnaire (Figure 1) to Bahasa Indonesia by Dr. JS. To assess the language appropriateness, The RADAR Bahasa Indonesia (Figure 2) was blindly retranslated to English by another physician (Dr. CE). The RADAR questionnaire consists of 6 questions. Among them, there are 3 quantitative scaled questions with 3 anchored 10 cm visual analog scales (VAS) where the patients put, such as their response to disease activity levels over the previous 6 months, disease activity on the day the patient completed the form, and arthritic pain on the day the form is completed.

The other questions are in ordinal manners, such as duration of morning stiffness, patient’s functional

capacity according to Steinbrocker Criteria, the presence of pain and tenderness in respective joint represented joint counts on 9 joints. There are 3 versions of one page questionnaire, namely questionnaire A, questionnaire B and questionnaire C. To determine the agreement, questionnaire A is firstly completed by the physician, on only for questions 6, then compared to question no 6 of questionnaire B which is completed by patients. To determine the reliability, completed questionnaire B is compared to questionnaire C which is blindly completed by the same patient 2 hours afterwards, without knowing that she/he will complete the second questionnaire (questionnaire C). The blinding completion is applied to minimize recall bias. The 2 hour interval was chosen to avoid changes in signs and symptoms of RA (Figure 3).

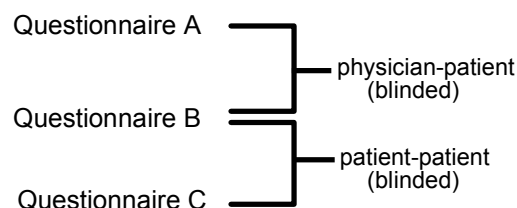


Figure 3. The protocol of the study.

Analysis

To determine the reliability, questions number 1,2,3 (in continuous scale) were assessed through ICCs (intraclass correlations coefficient) with mixed model-agreement type available in SPSS version 9.0. While for variables with dichotomous and ordinal scales of questions no 4,5,6 were assessed through ICCs with parallel model-reliability type. The values of agreement of 0.0 – 0.20 is considered as slight agreement, 0.20-0.40 is considered as fair agreement, 0.40-0.60 is considered as moderate agreement, 0.60-0.80 is considered as substantial agreement, and 0.80-1.0 is considered as almost perfect agreement (Sacket et al. 1991). The 95% level of confidence was used.

RESULTS

Patients' Characteristics

The number of patients fulfilled the 1987 ACR criteria for classification of RA were 26. Four patients were excluded from the study, since 1 patient did not understand the questions of the questionnaire, 1 patient did not understand Bahasa Indonesia, and 2 patients did not fill the second questionnaire (questionnaire C). The patients included in this study were 20 females and 2 males. The mean of age was 38.14 years (± 11.44). The mean of education attainment was 9.73 years (± 5.32). All 22 patients (100%) presented morning stiffness >1 hour, arthritis of three or more joint areas, arthritis of hand joints, and symmetric arthritis. No patients presented rheumatoid nodule. Nine patients (40.9%) showed positive serum rheumatoid factor, and 20 patients (90.9%) showed radiographic specific changes, such as osteoporotic bones around the joints, and joint erosion (Table 2). The results of agreements and consistencies are shown in Table 2 and Table 3.

Table 2. Clinical characteristics of RA patients.

Criteria (N=22)	Patient's presentations	%
Morning stiffness > 1 hour	22	100
Arthritis of three or more joint areas	22	100
Arthritis of hand joints	22	100
Symmetric arthritis	22	100
Rheumatoid nodule	0	0
Positive rheumatoid factor	9	40.9
Radiographic changes	20	90.9

Table 3. The Physician-patient agreement for question no 6.

Joints	ICC value	95% CI	p-value
Shoulders			
Right	0.67	0.38 - 0.85	0.000
Left	0.72	0.44 - 0.87	0.000
Elbows			
Right	0.67	0.35 - 0.85	0.000
Left	0.55	0.18 - 0.78	0.003
Wrists			
Right	0.77	0.60 - 0.85	0.000
Left	0.76	0.50 - 0.89	0.000
Hand knuckles			
Right	0.72	0.57 - 0.93	0.000
Left	0.62	0.28 - 0.82	0.000
Finger knuckles			
Right	0.48	0.11 - 0.74	0.008
Left	0.50	0.10 - 0.75	0.009
Knees			
Right	0.84	0.67 - 0.93	0.000
Left	0.74	0.50 - 0.81	0.000
Ankles			
Right	0.48	0.10 - 0.84	0.009
Left	0.63	0.31 - 0.83	0.003
Ball of foot			
Right	0.73	0.45 - 0.88	0.000
Left	0.83	0.64 - 0.92	0.000
Toe knuckles			
Right	0.83	0.64 - 0.95	0.000
Left	0.70	0.40 - 0.86	0.000

DISCUSSION

RADAR questionnaire is another alternative for physician to measures disease activity in RA. This one page questionnaire is understandable, only 5 to 10 minutes to fill up, requires no special instructions and self-assessing. The "agreement" between physician and patient was quite substantial, showed by around 60% of the ICC values was more than 0.65. The percentages of physician-patient agreement were lower compared to the results of a study done by Mason et al (1992). Mason et al. (1992), in the same study using RADAR questionnaire, found that 75% of the questions had Ices more than 0.65. Lower education attainment of the patients (9.73 \pm 5.32 years) was probably related the lower percentage of physician patient-agreement in this study. In this study, the Ices of patient-patient reliability was found to be substantial as well. This was showed by > 90% of the Ices of all questions were more than 0.65. Some clinicians also developed simplified questionnaires to assess disease activities in RA. Egger et al. (1985).

Table 4. The Patient-patient reliability for all questions

Variables	ICC value	95% CI	p-value
Disease activity during 6 months	0.82	0.62 – 0.92	0.000
Disease Activity today	0.88	0.74 – 0.95	0.000
Tenderness today	0.67	0.35 – 0.85	0.000
Functional status	0.89	0.67 – 0.93	0.000
Shoulders			
Right	0.81	0.59 – 0.91	0.000
Left	0.67	0.37 – 0.85	0.000
Elbows			
Right	0.84	0.65 – 0.93	0.000
Left	0.74	0.47 – 0.88	0.000
Wrists			
Right	0.79	0.56 – 0.90	0.000
Left	0.78	0.54 – 0.93	0.000
Hand knuckles			
Right	0.92	0.82 – 0.97	0.000
Left	0.73	0.45 – 0.88	0.000
Finger knuckles			
Right	0.80	0.57 – 0.91	0.000
Left	0.86	0.68 – 0.84	0.000
Knees			
Right	0.82	0.76 – 0.96	0.000
Left	0.78	0.54 – 0.90	0.000
Ankles			
Right	0.68	0.68 – 0.85	0.000
Left	0.74	0.47 – 0.88	0.000
Ball of foot			
Right	0.85	0.65 – 0.94	0.000
Left	0.85	0.67 – 0.93	0.000
Toe knuckles			
Right	0.71	0.40 – 0.81	0.000
Left	0.76	0.50 – 0.91	0.000

proposed a joint count index by which the clinician evaluates 36 joints. Fuchs et al (1989), also developed a simplified joint index on 28 joints. Proponents of both questionnaires are easier to use and provide information similar with previous indices used for the evaluation of disease activity. Stewart et al (1990), proposed a self-report particular index that depicts body diagram of 36 joints that presently tender and inflamed. A separated score must then assign weights, ranging from 3 to 95. However, their initial testing did not indicate how such designations would affect their weighing⁸. Those questionnaires would be good for evaluating disease activity in rheumatic diseases. However, those may not reduce the cost and time burden, both for the clinicians and the patients, since the number of joints to be evaluated is quite numerous. The RADAR questionnaire tends to evaluate joints which are involved most in RA. Therefore, less number of joint is examined.

A questionnaire such as the RADAR, when applied alone or in conjunction with a functional status measure, may also provide the information gathered by the clinician in a clinical trial. RADAR can also be frequently administered at minimum burden to the patient. For example, RADAR does not need to evaluate laboratory parameters, which may cost more. The RADAR can also be used as a take home questionnaire to self-observe the disease activities of RA for specific periods. This study showed that Translated RADAR questionnaire is able to represent what the patients' feel about the disease suffered. However, there are some weakness and limitations committed in this study. The interval of filling the questionnaire B and C was only about 2 hours. We have some reasons of this problem such as if the patients fill up the question more than 2 hours, the signs and symptoms may have already been changed. We believe that the blinded strategy of filling the questionnaire C can reduce recall bias. Besides showed substantial physician-patient agreement (validity) and patient-patient reliability, this translated RADAR questionnaire to Bahasa Indonesia is practical, concise in gathering disease activity data in patients with RA. We hope this translated questionnaire can be applied for evaluation and monitoring of disease activities particularly among RA patients in Indonesian setting. This study did not evaluate the *sensitivity to change* of the questionnaire. Therefore, we would integrate translated RADAR questionnaire to Bahasa Indonesia in any clinical trial in RA to determine the *sensitivity to change*.

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