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Diagnostic Methods

Responsiveness of the Persian health assessment questionnaire measures in differentiating among disease activity levels in rheumatoid arthritis patients

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ABSTRACT

Objectives: Evidence suggests that inflammation has a harmful effect on muscle strength as well as on functional disability. The purpose of the present study was to examine the association of objectively measured disease activity levels and functional disability among Iranian patients with Rheumatoid Arthritis (RA), and to analyse whether a Persian version of the health assessment questionnaire-disability index (PHAQ-DI) can distinguish between RA patients at different stages of the disease progression.
Materials & methods: 198 RA patients were requested to complete the PHAQ-DI. The disease activity score for each patient was evaluated using the disease activity score (DAS-28). The association analysis between the PHAQ-DI scores and the four levels of disease activity was measured using a Spearman correlation coefficient. A Kruskal-Wallis analysis was utilized to determine differences in PHAQ-DI scores among the levels of disease activity. The Receiver operating characteristic (ROC) curve was also utilized to determine the PHAQ-DI total score cut-off for predicting the level of disease activity.
Results: Spearman's correlation coefficients between the PHAQ-DI and the disease activity level ranged between 0.59 and 0.75. There were significant differences in the PHAQ-DI total score among known groups with various disease activity levels ($P = 0.001$); However, HAQ-DI total score could not differentiate the remission phase from low disease activity levels in patients with RA ($p = 0.37$). The PHAQ-DI total score cut-off for distinguishing remission-low disease activity from moderate-high disease activity was 1.19, with a specificity of 0.91 and a sensitivity of 0.615.
Conclusion: The present findings provide evidence for the degree to which the PHAQ-DI measures identify and distinguish disease activity levels in patients with rheumatoid arthritis. The PHAQ-DI questionnaire, as a patient-administered, non-invasive, fast, inexpensive and available tool, can be used in the rheumatologist's office as a substitute for determining disease activity in patients with active RA.

1. Introduction

Rheumatoid arthritis (RA) is an inflammatory chronic systemic disease that affects 0.37% of Iran's population (Davatchi et al., 2016). The highest incidence of RA has been observed to be in the fourth and fifth decades of a person's life. Relevant studies have demonstrated that 80% of RA patients aged 35–50 years (Wolff, 2007). Functional disability, pain, fatigue, depression, and anxiety are considered as symptoms of this disease. Previous studies indicate that functional disability is much more irritating than the pain in RA patients (Lubeck, 2004).

There are four quantitative measures available for diagnosis, prognosis, and management of rheumatoid arthritis (RA). These included number of affected joints, x-ray, laboratory findings, and questionnaires. Counting the number of tender and swollen joints is the specific measure for diagnosis of patients with RA.

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Unfortunately, this is not a reproducible measure. X-ray measures the number of damaged joints objectively but has little value for predicting disability and mortality and is usually used in clinical research. Biomarkers such as erythrocyte sedimentation rate (ESR), c-reactive protein (CRP), and rheumatoid factor (RF) are popular methods, but findings reveal that they have poor prognostic values as a result of “false negative” and “false positive” results (Pincus, 2006). The past three decades have seen a dramatic shift in the assessment of patient health status towards health outcomes based on the patient's personal beliefs (Bruce and Fries, 2003), hence the necessity of developing a simple, safe, but reliable and valid tool is pervasive. This need led to the creation of numerous questionnaires for patients with RA including Arthritis Impact Measurement Scales 2 (AIMS2), Rheumatoid Arthritis Quality of Life (RAQOL), McMaster Toronto Arthritis patient preference questionnaire (MACTAR), Health Assessment Questionnaire Disability Index (HAQ −DI) and rheumatoid and arthritis outcome score (RAOS) (Bremander et al., 2003; Bruce and Fries, 2003; Cox et al., 2007; Salaffi et al.; Verhoeven et al., 2000). Among such questionnaires, the most common instrument for the assessment of RA patients is the Health Assessment Questionnaire-Disability Index (HAQ-DI). HAQ-DI was originally developed by Fries in 1980. HAQ-DI evaluates functional disability through items regarding upper extremity fine movements, lower extremity locomotion or both (Bruce and Fries, 2003; Ji et al., 2017). HAQ-DI has been commonly used in clinical trials as well as clinical practice because it is self-reported, concise, and take less time to complete (MacFarlane and Todd, 2014; Tammaru et al., 2007). The Persian version of HAQ-DI is mostly similar to original version. The differences between two versions is related to some items (items 5, 11, and 13) make it compatible with Iranian culture (Nazary-Moghadam et al., 2017b). Most rheumatologists have long relied on disease activity to enhance patients' outcome or to estimate the effect of treatments (Anderson et al., 2012). These assessments should be an algorithm combining signs and symptoms, such as; ESR, CRP, number of tender and swollen joints mostly related to inflammatory activity; and self-reported measures such as pain and global assessment of health status (Smolen and Aletaha, 2010). Disease activity score (DAS) is one of the most popular outcomes for measuring disease activity. The DAS28 is a composite score and is a simplification of the original DAS score, which requires 44 joints to be counted. Since the DAS28 measurement requires laboratory findings, it has disadvantages due to the time-consuming processes of blood testing, and the discomfort produced by needle penetration; in addition to raising the risk of spreading infection.

In a 20-year prospective study it has been demonstrated that the HAQ-DI is able to predict mortality as compared to other self-report questionnaires. The laboratory, radiographic, and physical examination data were substantially weaker in predicting mortality; thus it seems that using HAQ-DI as a self-report questionnaire produces more valuable clinical outcome information than any other available clinical measures (Kosinski et al., 2000; Wolfe et al., 2003). With due regard to this fact, in addition to the development of patient-administered tools for RA patients, the question that arises is whether the Persian version of HAQ-DI (PHAQ-DI) questionnaire can provide an appropriate alternative to estimate disease activity in RA patients. Therefore, the purpose of the present study was to investigate the correlation between the PHAQ-DI and disease activity in RA patients. In addition, the present study aimed to evaluate whether PHAQ-DI can differentiate among patients at various stages of disease progression.

2. Materials and methods

2.1. Patients

198 Iranian RA patients who had referred to Tehran's Firouzgar Hospital as well as to the National rheumatology centre both located in Iran participated in the present study. The RA patients met the American College of Rheumatology (ACR) 1987 criteria for RA diagnosis. Rheumatoid arthritis was included by the presence of 4 or more out of the following criteria. 1) morning stiffness in and around joints lasting at least 1 h before maximal improvement; 2) soft tissue swelling (arthritis) of 3 or more joint areas observed by a physician; 3) swelling (arthritis) of the proximal interphalangeal, metacarpophalangeal, or wrist joints; 4) symmetric swelling (arthritis); 5) rheumatoid nodules; 6) the presence of rheumatoid factor; and 7) radiographic erosions and/or periarticular osteopenia in hand and/or wrist joints (Anderson et al., 2012).

The exclusion criteria for the present study were any deformity of the upper and lower extremities, except for deformities caused by RA, cognitive problems, severe neurological, cardiovascular and respiratory diseases diagnosed by the physician, severe addiction to drug and alcohol, a history of being overweight, a history of falling, and a history of vertigo (Nazary-Moghadam et al., 2017b). This study was approved by the Ethics Committee of Mashhad University of Medical Sciences, Mashhad, Iran (IR.MUMS.REC.1398.025). The anonymity of the RA Patients has been maintained throughout the study.

2.2. Procedures

The HAQ-DI questionnaire was used to assess the disability in RA patients. HAQ-DI is a 20-item patient-administered questionnaire with eight subscales including dressing & grooming, arising, eating, walking, hygiene, reaching, gripping, and activities (Wolfe et al., 2003). A four-point Likert scale ranging from 0 (without difficulty) to 3 (with much difficulty) has been used for scoring each item. The total score ranges from 0 to 3 where 0 indicates no disability and 3 indicates the most disability (Bruce and Fries, 2005). The total score has been calculated by summing the greatest item scores in subscales divided by eight (Bruce and Fries, 2003). The HAQ-DI is one of the most widely used instruments. The HAQ-DI has satisfactory psychometric properties in terms of reliability and validity and responsiveness (Bruce and Fries, 2003; Smolen and Aletaha, 2010). HAQ-DI has been translated and culturally adapted into more than 60 different languages and dialects that is supported by a bibliography of more than 500 references (Bruce and Fries, 2005; Wells et al., 2009). The HAQ-DI has been translated, and culturally adapted into the Persian language; PHAQ-DI has proved to be as reliable and valid as the original questionnaire (Nazary-Moghadam et al., 2017b).

DAS 28 is a measure to estimate disease activity in RA patients in research and clinical rheumatologic settings (Wells et al., 2009). DAS-28 is a modified version of the DAS scale that uses 28 joints for detecting disease activity. Fuchs and Pincus demonstrated that the measurement of disease activity using joint counts consisting of 28 joints is as reliable and valid as 44 joint counts (Wells et al., 2009). DAS 28 is calculated using tender joint count (0–28), swollen joint count (0–28), ESR (mm/hr), and VAS general health (mm). The present study used DAS-28 based on ESR since the validity of (DAS-28 (ESR)) has been approved for use in clinical studies in different investigations (Prevoo et al., 1995; van Riel and Renskers, 2016;

Table 1
Demographic characteristics of RA* patients (N = 198).

Demographic Data	Minimum	Maximum	Mean (SD)
Age (Year)	18	85	48.44 (14.11)
Sex			N (%)
Male			42 (21.2)
Female			156 (78.8)
Education (Year)			N (%)
0-6			86 (43.4)
6-8			24 (12.1)
9-12			49 (24.7)
>12			39 (19.7)
Tender Joint Number	0	20	2.27 (3.48)
Swollen Joint Number	0	14	1.26 (2.26)
Morning Stiffness Time (min)	0	290	25.11 (43.55)
Ritchie Articular Index (RAI)	0	42	4.49 (7.98)
Disease Activity			N (%)
Remission			66 (33.3)
Low			24 (12.1)
Moderate			77 (38.9)
High			31 (15.7)
Rheumatoid Factor			N (%)
Positive			142 (71.7)
Negative			51 (25.8)
Missing			5 (2.5)

• RA: Rheumatoid arthritis.

Wells et al., 2009). For measuring DAS-28 score, online computing, available on https://www.das-score.nl/das28/DAScalculators/dasculators.html has been used. An RA patient with a DAS-28 < 2.6 indicates remission phase, 2.6≤DAS-28 ≤ 3.2 indicates low activity; 3.2≤DAS-28 ≤ 5.1 indicates moderate activity and DAS-28 > 5.1 indicates high activity (Ishiguro et al., 2018).

Prior to the study all participants were made familiar with the research process and were requested to sign an informed consent form. Demographic data of RA patients including age, gender, and educational level were recorded. The RA patients were then requested to fill out the PHAQ-DI questionnaire. Physical and clinical findings, including the number of tender joints, number of swollen joints, morning stiffness time, Ritchie articular index (RAI), and VAS general health were recorded by a certified rheumatologist. At the end of the study, the RA patients were referred to the laboratory of The National Rheumatology Center for ESR and rheumatoid factor measurements.

2.3. Statistical analysis

In order to examine the correlation between the HAQ-DI scores and DAS-28, the Spearman correlation coefficient was used. The Spearman correlation coefficient strength is interpreted based on Munro's classification (Domholdt, 2005). Based on this classification, the correlation coefficient between 0.00 and 0.25 shows little if any correlation, 0.26 to 0.49 shows a low correlation, 0.50 to 0.69 indicates a moderate correlation, 0.70 to 0.89 shows a high correlation and 0.90 to 1.00 indicates a very high correlation (Nazary-Moghadam et al., 2017a). All statistical tests were performed using SPSS software (version 23, SPSS Inc., Chicago, IL, USA). The alpha level was considered to be 0.05 in the statistical tests. To determine whether there are any differences between the four stages of disease activity (remission, low disease activity, moderate disease activity, and high disease activity), the Kruskal-Wallis test has been used. In addition, the receiver operating characteristics (ROC) curve has been utilized to determine cut off for discriminating two determined levels of disability (remission-low vs. moderate-high disease activity) (Hoo et al., 2017). The ROC curve is an important tool for diagnostic test examination. The true positive rate is plotted in function of the false positive rate (100-Specificity) for various cut-off points of a parameter in the ROC curve. The area under the ROC curve (AUC) is a tool for measuring that how well a factor can differentiate between two groups. In addition, linear regression, adjusting for age and sex, and education was conducted to determine the confounding variables.

Table 2
Linear regression modelling disability and disease activity level and age and sex and education in patients with rheumatoid arthritis.

	HAQ-DI Total Score		
	Estimated β (SE)	Standardized β	P-Value
Constant	−0.68	0.32	0.03
Disease Activity Level	0.52 (0.04)	0.68	<0.001
Age	0.01 (0.003)	0.14	0.008
Sex	0.10 (0.32)	0.05	0.30
Education	−0.06 (0.04)	−0.09	0.11

Table 3
Spearman's correlation coefficient (0.95 CI) between DAS-28 and PHAQ-DI subscales, Pain, health status, (N = 198).

PHAQ-DI[a] Subscales	DAS-28 (Correlation Coefficient (rs) (95% CI)	P-values *
Dressing	0.64 (0.55–0.71)	**P<0.001**
Arising	0.65 (0.55–0.72)	**P<0.001**
Eating	0.63 (0.54–0.71)	**P<0.001**
Walking	0.56 (0.46–0.65)	**P<0.001**
Hygiene	0.64 (0.54–0.73)	**P<0.001**
Reaching	0.62 (0.53–0.70)	**P<0.001**
Gripping	0.59 (0.49–0.68)	**P<0.001**
Other Activities	0.60 (0.50–0.69)	**P<0.001**
Total Score	0.69 (0.61–0.76)	**P<0.001**

All correlation coefficients are Positive.
*Significant correlations (p < 0.01) are in bold.
[a] PHAQ-DI: Persian version of Health Assessment Questionnaire-Disability Index.

3. Results

The demographic characteristics of the RA participants in the present study are portrayed in Table 1. The linear regression model for perceived disability revealed that controlling for sex, and level of education were not significant predictors of perceived disability level. The age and disease activity level significantly associated with perceived disability. Older RA patients reported significantly higher perceived disability. In addition, higher disease activity level reported significantly higher perceived disability (Table 2). The results of the current study further indicate that there is a significant correlation (Spearman's correlation coefficient ranged from 0.56 to 0.75) between the PHAQ-DI questionnaire and disease activity scale. The details of this correlation coefficients are shown in Table 3 (Fig. 1). The results of the Kruskal-Wallis test demonstrate that the obtained PHAQ-DI scores (PHAQ-DI total score and PHAQ-DI subscales) differed significantly among the four stages describing disease activity level (Table 4). Additionally, pairwise comparison analysis show that the HAQ-DI total score increased significantly from low disease activity to moderate disease activity; from moderate disease activity to high disease activity, and from low disease activity to high disease activity. There is no statistical difference in the PHAQ-DI total score among the remission phase and low disease activity (Table 5). As demonstrated in Fig. 2, PHAQ-DI total score cut off is 1.19 as determined by the Receiver operating characteristic (ROC) curve. The HAQ-DI total score of 1.19 has a sensitivity of 0.615 and a specificity of 0.91.

We also reported the AUC for all participants (0.81), young (18–35 years old) (0.86), middle (0.73), (36–55 years old) and older adults (>55 years old) (0.856). As the findings demonstrated, the

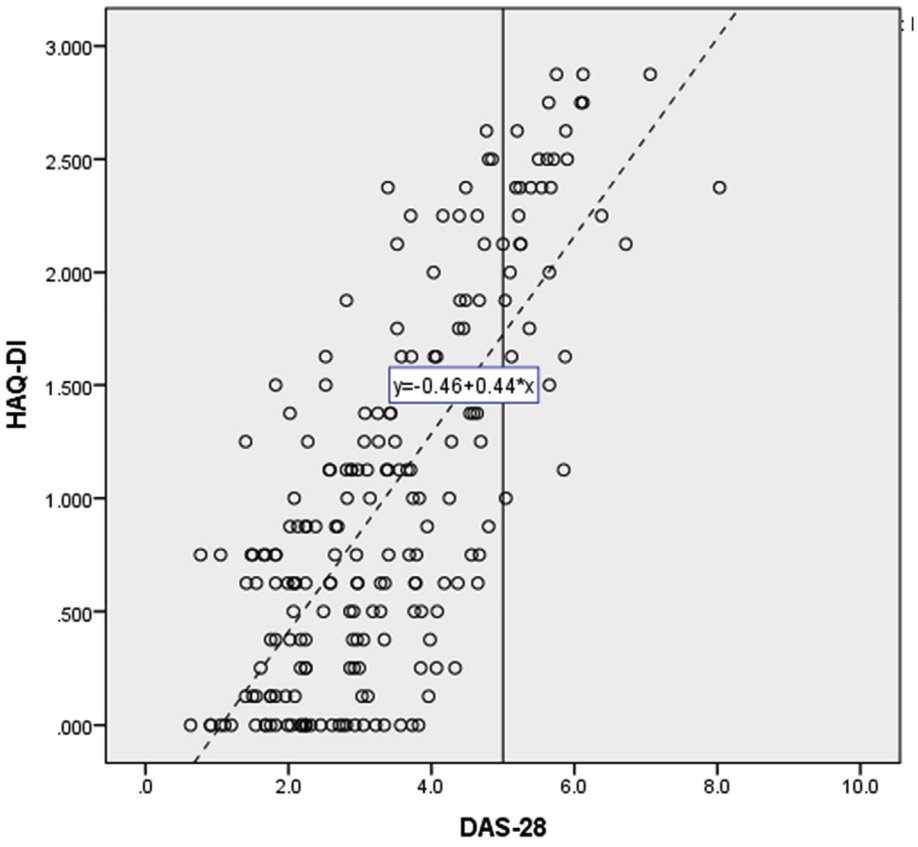

Fig. 1. Scatter plot demonstrating correlation between HAQ-DI* and DAS-28**
*Persian version of Health Assessment Questionnaire-Disability Index
**DAS-28: Disease activity score 28.

Table 4
Comparison of PHAQ-DI scores at different disease activity level: Results of one-way analyses of variances (ANOVAs) (N = 198).

PHAQ-DI[a] Subscales	Disease Activity Level					
	Sum of Squares		Mean Square		F ratio	P-Value
	Between Group	Within Group	Between Group	Within Group		
Dressing	90.23	98.57	30.07	0.51	59.19	**<0.001**
Arising	60.10	61.39	20.03	.032	63.30	**<0.001**
Eating	88.87	93.51	29.62	0.48	61.46	**<0.001**
Walking	58.01	97.25	19.33	0.50	38.57	**<0.001**
Hygiene	76.25	88.51	25.41	0.46	55.70	**<0.001**
Reaching	96.66	126.99	32.22	0.65	49.22	**<0.001**
Gripping	92.98	104.99	30.99	0.54	57.26	**<0.001**
Other Activities	100.35	131.82	33.45	0.67	49.23	**<0.001**
Total Score	79.42	60.97	26.47	0.31	84.22	**<0.001**

**Significant differences ($p < 0.01$) are in bold.
[a] PHAQ-DI: Persian version of Health Assessment Questionnaire-Disability Index.

Table 5
Pairwise comparisons of disease activity level using PHAQ-DI[a] total score.

Disease Activity Level	Mean Difference	Standard Error	P-Value**
Remission-Low	0.19	0.13	0.87
Remission-Moderate	0.76	0.09	**P<0.01**
Remission-High	1.86	0.12	**P<0.01**
Low-Moderate	0.56	0.13	**P<0.01**
Low- High	1.67	0.15	**P<0.01**
Moderate- High	1.10	0.11	**P<0.01**

**Significant differences ($p < 0.01$) are in bold.
[a] PHAQ-DI: Persian version of Health Assessment Questionnaire-Disability Index.

accuracy of the PHAQ-DI total score among disease activity levels was different among rheumatoid arthritis patients with different ages. However, it seems that the age could be considered as a confounder.

4. Discussion

The results of the study showed that there were significant moderate to high correlations between PHAQ-DI questionnaire and disease activity level; moreover, the results of this study indicate

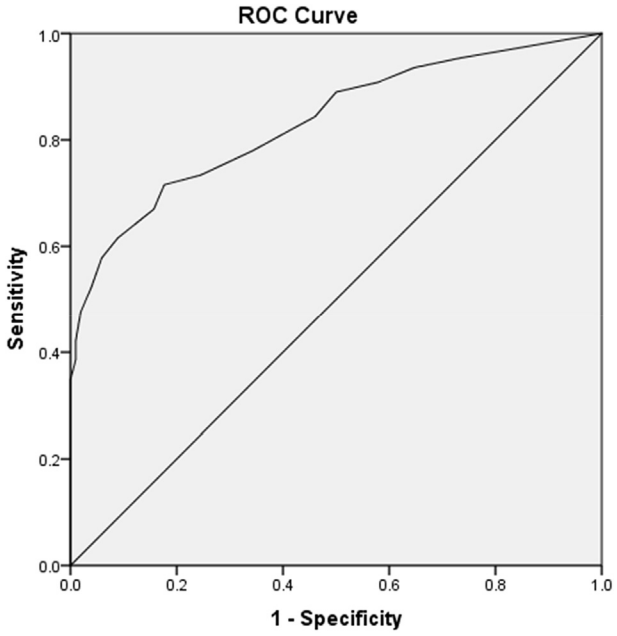

Fig. 2. The receiver operating characteristics (ROC) curve[11] for PHAQ-DI total score for predicting disease activity (binary including remission-low and moderate-high). The area under the ROC curve curve = 0.83 (95% confidence interval 0.78–0.89).

that the PHAQ-DI (subscales and total scores) differed significantly at three stages of disease activity (low, moderate, and high disease activity). The PHAQ-DI total score is not significantly different among the remission phase and low disease activity. Furthermore, the results of the study indicated that HAQ-DI total score had discriminating ability (AUC = 0.83) to differentiate RA patients with higher disease activity.

To the knowledge of authors, this is the first work to examine the accuracy of disease activity, categorised by disability measures, for discriminating between remission-mild from moderate to high levels of disease activity. As Table 2 demonstrates, the result of the present study showed that functional disability is not confounded by level of education and sex.

Moderate to high correlation between the HAQ-DI (subscales and total scores) and disease activity level is clinically important. These results provide evidence that those who have a higher questionnaire score have a higher disease activity level. Our findings were supported with the results of previous studies. For example, the HAD-DI questionnaire showed a significant correlation with disease activity in Iraqi patients with active RA (Mikhael and Gorial, 2013). Uutela et al. stated that disease activity is clearly correlated with muscle performance (Uutela et al., 2018). This finding agrees with our result because functional disability can originate from muscle weakness. Welsing found that the functional disability is highly correlated with disease activity in early stages of RA (Welsing et al., 2001). The present results also support the hypothesis that the PHAQ-DI is also able to differentiate among disease activity only in patients with active RA (AUC>0.70). As Table 4 demonstrates, there is not any statistical difference of PHAQ-DI (total and subscales) between two states of remission and low disease activity. Similar to the results of this study, Sontichai and Vilaiyuk found that there is a good correlation between disease activity and childhood HAQ-DI in active juvenile idiopathic arthritis (JIA), but this correlation is weak in inactive stages of JIA (Sontichai and Vilaiyuk, 2018). The relevant studies found significant correlations between the disability originated from RA and the number of swollen joints as well as the number of tender joints (Bae et al., 1998; El Meidany et al., 2003).

The PHAQ-DI questionnaire is a commonly used instrument for the measurement of functional disability. The present study provides evidence that the PHAQ-DI is a safe, inexpensive, and available instrument for differentiating remission-low from moderate-high disease activity in RA patients. Overall, our findings suggest that HAQ-DI total score was valuable clinically for including and excluding remission-mild from moderate-high disease activity. It seems that a total score lesser than 1.19 could be a good cut off for determining remission-low disease activity in RA patients. This could be important upon the completing of the PHAQ-DI questionnaire in rheumatologists' office in order to prevent time–consuming blood testing along with its complications including needling discomfort and infection.

4.1. Limitations

The most important limitations of the present study is the small sample size (n = 198). In addition, this study was performed on local RA patients in Iran, using PHAQ-DI. However, the present findings might not be generalized into another translated version of the HAQ-DI. The findings also suggest performing multicentre studies with a larger sample size in order to achieve better estimation about the responsiveness of translated versions of HAQ-DI to differentiate disease activity levels in rheumatoid arthritis patients. An additional limitation was the generalizability of the findings based on our study sample. Because all the participants were referred from hospital and rheumatology clinics, it appears that these individuals may have more severe RA. As such, these findings may not apply to those with less severe RA. It suggests to include RA patients with different disease activity levels even the RA patients who have less disability.

5. Conclusion

It can be concluded that the PHAQ-DI questionnaire, as a patient-administered and inexpensive tool, can be used as an appropriate substitute for determining disease activity in active RA patients.

5.1. Clinical relevance

- The PHAQ-DI questionnaire is a commonly used instrument for the measurement of functional disability.
- PHAQ-DI is a safe, inexpensive, and available instrument for differentiating remission-low from moderate-high disease activity level in RA patients.
- A PHAQ-DI total score lesser than 1.19 could be a good cut off for determining remission-low disease activity in RA patients.

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Ethical approval

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent

Informed consent was obtained from all individual participants included in the study.

Declaration of competing interest

None.

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[1] For more information, please see the link "https://www.medcalc.org 〉 Manual 〉 ROC curve analysis".