Rheumatoid Arthritis Disease Activity Index-5: an easy and effective way of monitoring patients with rheumatoid arthritis

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Objective
To study the utility of the Rheumatoid Arthritis Disease Activity Index-5 (RADAI-5) as a valid tool for daily rheumatoid arthritis (RA) monitoring and to compare its predictability to assess RA activity with respect to Disease Activity Score 28 (DAS28) and Clinical Disease Activity Index (CDAI).

Patients and methods
A total of 100 patients with RA (diagnosed as per American College of Rheumatology 1987 criteria) were enrolled in the study group. Each patient was assessed two times with 3-month interval for disease activity (DA) using DAS28, CDAI, and RADAI-5. Spearman's correlation coefficient (ρ) for correlation and kappa for agreement between different activity measures were assessed.

Results
In our study group, 19% patients were men and 81% patients were women, with male to female ratio of 1 : 4.3. Their mean age was 44.4±11.8 years, and their mean disease duration was 67.5±59.8 months. On initial visit, that is, baseline, mean DA as per RADAI-5, DAS28, and CDAI were 5.14±2.17, 5.58±1.55, and 27.96±15.46, respectively, and on follow-up visit, the readings were 3.76±1.92, 4.54±1.41, and 17.67±12.46, respectively. The mean changes in DA at follow-up visit were –1.37 ±2.15 by RADAI-5, –1.04±1.58 by DAS28, and –10.29±15.75 by CDAI. Changes in DA indices correlated significantly with each other with ρ ranging from 0.8 to 0.9 ($P<0.001$). An average agreement was found among all three measures at different DA level.

Conclusion
RADAI-5 seems to be an effective tool with high tendency to assess the changes in RA DA in routine patient care in hospital settings as well as in home-based settings.

Keywords:
Clinical Disease Activity Index, Disease Activity Score 28, Rheumatoid Arthritis Disease Activity Index-5

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Introduction

Rheumatoid arthritis (RA) is a chronic systemic inflammatory disease characterized by persistent synovitis of diarthrodial joints often symmetrical in distribution, resulting in pain, stiffness, and loss of function [1]. Apart from joint involvement, a wide variety of extra-articular features like rheumatoid nodules, vasculitis, lymphadenopathy, serositis, neuropathies, episcleritis, anemia, and amyloidosis may also develop [2]. Management of RA often involves repetitive assessment of disease activity (DA) by using activity measures and initiation of disease modifying anti-rheumatic drugs [3]. Several widely used indices [Disease Activity Score (DAS28) and Clinical Disease Activity Index (CDAI)] and activity measures like number of swollen joint count (SJC) and tender joint count (TJC) requires physician's intervention (to perform joint counts), and hence, cannot be used by patient himself/herself at home-based settings. Most practicing rheumatologists either do not have sufficient time to perform joint counts at every patient visit or they do not measure them otherwise [4,5], which is a prerequisite for the calculation of the respective indexes. However, data from patients only can be as useful as any other information to assess and monitor the disease [6]. It has been seen that for prognosis and monitoring the disease, patient questionnaire's score for functional status appeared to be equally or even more informative than even a full joint count [7]. Rheumatoid Arthritis Disease Activity Index-5 (RADAI-5), a newly developed activity assessment tool, has been evaluated in various studies for DA, and it relies on patient-reported outcomes only [8–11]. We performed an observational and follow-up study to

evaluate its effectiveness in monitoring the RA DA and to compare its utility with the well-known DA measures (i.e. DAS28 and CDAI).

Patients and methods

Patients and data collection

This prospective and observational study was conducted at Rheumatology outdoor of our institute. The ethical committee of the institution approved the study, and a written informed consent was obtained from each patient before enrollment in the study. A total of 100 patients with RA, diagnosed as per American College of Rheumatology 1987 revised criteria [12], were enrolled as patients in the study. Those patients who were experiencing hypothyroidism, severe anemia, and renal, cardiac, liver, or pulmonary disease were excluded from the study group because all these can affect the nonspecific symptoms of RA, and second, they may alter the patient's perception of general health as well as acute-phase reactants [erythrocyte sedimentation rate (ESR) and C-reactive protein)]. All patients were assessed two times during the study (first assessment was done at the time of enrollment and second assessment was done at 3-month follow-up visit). Each patient was first assessed for core data set measures, that is, TJC and SJC, patient's global health assessment [patient's global assessment (PGA) or general health), and evaluator's global health assessment (EGA) as per visual analog score (VAS) scale, as well as acute-phase reactant – ESR, and then the DA measures (DAS28 and CDAI) were assessed by using these core data set measures. All patients were asked to complete the RADAI-5 questionnaire (Table 1) at the same visit. Total RADAI-5 score is calculated as a mean of nonmissing items, which ranges from 0 to 10 [8].

Table 1 Rheumatoid Arthritis Disease Activity Index-5 questionnaire [8]

RADAI-5 items	Possible range
1. How active was your arthritis in general during the past 6 months?	0–10
2. How active is your arthritis today in terms of pressure sensitivity and swelling of the joints?	0–10
3. How severe is your arthritis pain today?	0–10
4. How would you describe your general health?	0–10
5. Were your joints stiff when you woke up today? If so, how long did this stiffness last?	0–10
Total RADAI-5 score	0–10

RADAI-5, Rheumatoid Arthritis Disease Activity Index-5. Adapted with permission from Leeb Burkhard.

DAS28 was calculated by using following formula [13]:

$$\mathrm{DAS28} = 0.56\sqrt{\mathrm{TJC}} + 0.28\sqrt{\mathrm{SJC}} + 0.70(\log \mathrm{ESR}) + 0.014(\mathrm{GH}).$$

where TJC=tender joint count (0–28).

SJC=swollen joint count (0–28).

ESR=erythrocyte sedimentation rate.

GH=global health on VAS (0–100 mm).

CDAI was calculated by using following formula [14]:.

$$\mathrm{CDAI} = \mathrm{TJC} + \mathrm{SJC} + \mathrm{PGA} + \mathrm{EGA}$$

where

TJC=tender joint counts (0–28).

SJC=swollen joint counts (0–28).

PGA=patient's global assessment of DA (as per VAS scale: 0–10 cm).

EGA=evaluator's global assessment of DA (as per VAS scale: 0–10 cm).

Statistical analysis

The statistical analysis was performed using Statistical Package for Social Sciences (version 20; SPSS, Chicago, Illinois, USA). Descriptive statistics were done by number and percentage as well as mean and SD. Correlations were calculated using Spearman's correlation coefficient (ρ), which ranges from −1 to +1; a positive value indicates a proportional relationship between the two variables, a value of 1 indicates a perfect correlation, a value of 0 indicates no correlation, and a negative value indicates an inversely proportional relationship between the two variables [9]. The level of statistical significance was set at a P value less than 0.05. The study group was categorized into four groups as per the level of DA. The various categories of disease severity according to the various scales were defined as follows: remission like state: $0.0<\mathrm{RADAI\text{-}5}\leq 1.4$, $0.0<\mathrm{DAS28}\leq 2.6$, and $0.0<\mathrm{CDAI}$ 0–2.8; mild: $1.6\leq \mathrm{RADAI\text{-}5}\leq 3.0$, $2.6<\mathrm{DAS28}\leq 3.2$, and $2.8<\mathrm{CDAI}\leq 10.0$; moderate: $3.2\leq \mathrm{RADAI\text{-}5}\leq 5.4$, $3.2<\mathrm{DAS28}\leq 5.1$, and $10<\mathrm{CDAI}\leq 22.0$; and severe: $5.6\leq \mathrm{RADAI\text{-}5}\leq 10.0$, $5.1<\mathrm{DAS28}\leq 9.4$, and $22.0<\mathrm{CDAI}\leq 76.0$ [13–16]. All patients were then distributed into aforementioned categories and cross-tabulation was done, and kappa statistics was applied for agreement

analysis between RADAI-5 and composite indices. Kappa values define the following categories of agreement: less than 0.20=poor; 0.21–0.40=fair; 0.41–0.60=average; 0.61–0.80=good, and more than or equal to 0.81=very good [9].

Results

A total of 100 patients with RA were included in the present study. Their mean age was 44.4±11.8 years, and their mean disease duration was 67.5±59.8 months. In the study group, 19 (19%) were men and 81 (81%) were women, with male to female ratio of 1 : 4.3. Rheumatoid factor (RF) positivity in the study group was 76%. Values for the core data set measures and DA indices are given as means and are shown in Table 2. Distribution of patients according to the activity level (individual tool wise assessment) is shown in Table 3 (Figs 1, 2). The correlation of RADAI-5 with various activity parameters at both visits is shown in Table 4.

At both the assessments, RADAI-5 was found to be correlated significantly with DAS28-ESR, CDAI, and core data set measures (all $\rho>0.5$; all $P<0.001$) (Table 4). The mean differences for the DA scales between the first and second assessment in the study population were as follows: ΔRADAI-5=−1.37; ΔDAS28=−1.04, and ΔCDAI=−10.29. These changes were significantly intercorrelated, with a *P* value less than 0.001 (Table 5; Figs 3, 4).

Table 2 Mean values of various rheumatoid arthritis core data set measures and disease activity assessment tools at baseline and at 3-month follow-up

Variables	Mean±SD	
	At baseline	At 3-month follow-up
PGA (0–10 cm)	5.81±2.49	4.23±2.12
EGA (0–10 cm)	5.16±2.29	3.88±2.02
TJC (0–28)	12.30±8.34	6.57±5.90
SJC (0–28)	4.75±4.83	3.07±3.36
ESR (0–100 mm/h)	37.41±17.64	28.04±14.88
Pain score (0–10)	5.66±2.54	4.34±2.18
RADAI-5 (0–10.0)	5.14±2.17	3.76±1.92
CDAI (0–76)	27.96±15.46	17.67±12.46
DAS28-ESR	5.58±1.55	4.54±1.41

CDAI, Clinical Disease Activity Index; DAS28, Disease Activity Score 28; EGA, evaluator's global health assessment; ESR, erythrocyte sedimentation rate; PGA, patient's global health assessment; RADAI-5, Rheumatoid Arthritis Disease Activity Index-5; SJC, swollen joint counts; TJC, tender joint counts.

For agreement analysis, kappa was calculated. For the relationship between the RADAI-5 and DAS28, it appeared to be 0.563 at baseline and 0.411 at 3-month follow-up assessment, which can be regarded as average and significant agreement ($P<0.001$). Kappa for the relationship of RADAI-5 with CDAI was in the same range (0.595 at baseline and 0.574 at 3-month follow-up; all $P<0.001$).

Discussion

RA is a noncurable but treatable chronic inflammatory systemic disease associated with progressive joint damage and disability, which is directly related to the duration of active disease. Consistent and frequent DA evaluation followed by consequent treatment adjustment is needed to improve outcome in patients with RA, as shown in the short-term perspective of clinical trials [3]. Various measures to assess the DA have been developed, but no single measure can reliably capture DA in all patients. This may be owing to the high variability of the presentation and course of RA as well as the reflection of different disease characteristics.

While assessing RA, most clinicians or rheumatologists focus on joints rather than functional status and pain as important measures of DA [17]. Second, they do not even perform quantitative joint counts at most visits [5]. Composite indices such as DAS28 and CDAI have been successfully used to express RA activity fluctuations [18], but as both require joint counts, which is not generally done by most rheumatologist in most patients on their every visit, thus are not suitable for daily-basis DA assessment in routine outdoors [15].

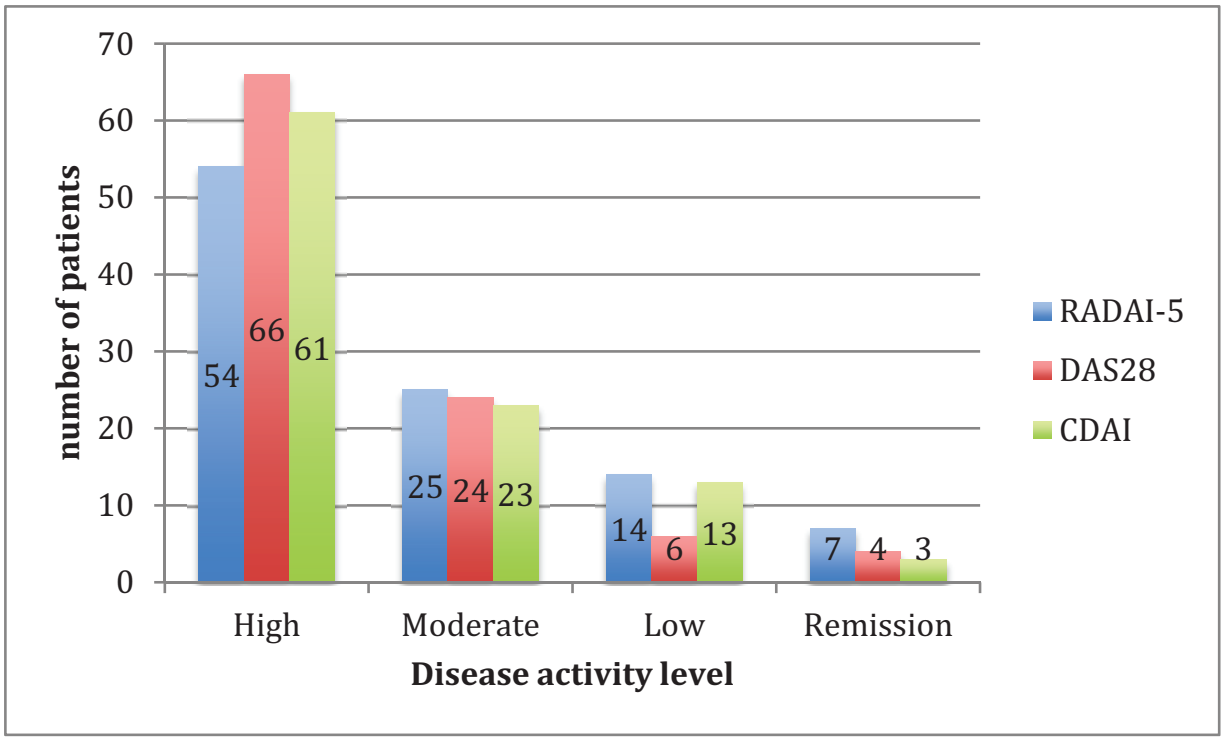
Moreover, besides DAS28 and CDAI, radiographs and other imaging modalities such as MRI and ultrasound (US) may also be appropriate to measure RA DA. The sensitivity of US is greater than that of

Table 3 Numbers of patients as per disease severity by using various assessment tools

Activity/severity	At baseline			3-month follow-up		
	RADAI-5	DAS28	CDAI	RADAI-5	DAS28	CDAI
High	**54**	**66**	**61**	30	18	25
Moderate	25	24	23	**53**	**44**	**46**
Low	14	6	13	8	26	25
Remission	7	4	3	9	12	4

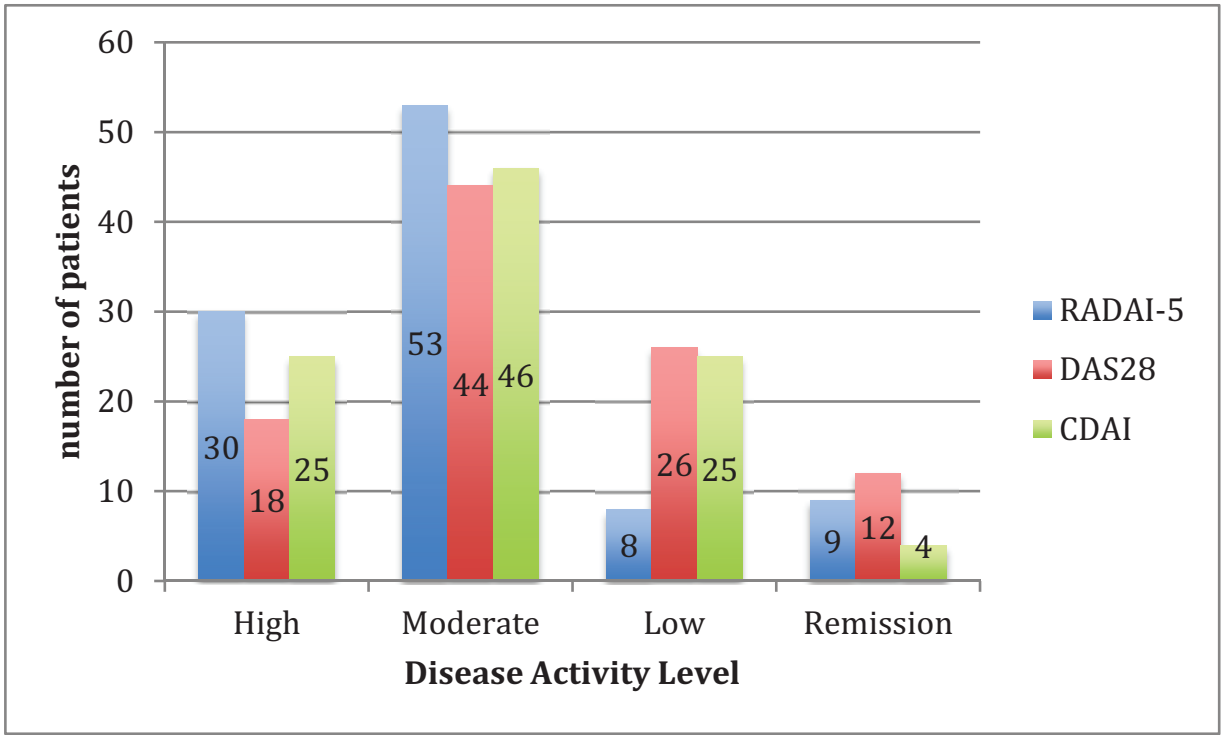
CDAI, Clinical Disease Activity Index; DAS28, Disease Activity Score 28; RADAI-5, Rheumatoid Arthritis Disease Activity Index-5. Bold letters signify the most number of patients in both assessments.

Figure 1



Distribution of patients according to the various assessment tools at baseline (first visit). CDAI, Clinical Disease Activity Index; DAS28, Disease Activity Score 28; RADAI-5, Rheumatoid Arthritis Disease Activity Index-5.

Figure 2



Distribution of patients according to the various assessment tools at follow up (second visit). CDAI, Clinical Disease Activity Index; DAS28, Disease Activity Score 28; RADAI-5, Rheumatoid Arthritis Disease Activity Index-5.

other imaging techniques in the early detection of aggressive arthritis and surveillance of DA [19]. US7 score is simple and practical sum scoring system for use in the detection of synovitis in patients with RA [20].

In addition, various trials have shown that patient self-reported measures appear more reliable (reproducible) than joint count measures [21], and also more likely to be abnormal in patients with RA than an ESR and C-reactive protein in RA [22]. Pincus and colleagues suggested that three patient measures only (i.e. physical function, pain, and global status) of the seven American College of Rheumatology core set measures are as reliable as the whole core set measures for describing RA activity changes and can constitute the basis for therapeutic decisions [7]. Moreover, patient self-administered tools such as RADAI-5 and Routine Assessment of Patient Index Data 3 appeared to be equally or even more informative than even a full joint count with respect to prognosis and monitoring of RA [6,7,23]. RADAI-5 is a physician independent and patient self-administered activity assessment tool which hardly takes 20–30 s in contrast to 2–3 min for a CDAI, and 3–5 min for a DAS28 and does not include any laboratory measurement and therefore all variables are easily available at point of care in the clinical setting, which can in turn produce more consistency in timing and completeness of disease measurement [8]. RADAI-5 does not include an item directly targeting physical function that is known to be a strong predictor of disability and mortality in patients with RA [4,24] but in support, it comprises questions targeting patient's pain perception and global health estimate, which can be seen as surrogates for

Table 4 Correlation of Rheumatoid Arthritis Disease Activity Index-5 with various disease activity parameters at baseline and at 3-month follow-up

Parameters	At baseline		At 3-month follow-up	
	Spearman's ρ	*P* value	Spearman's ρ	*P* value
PGA	0.928	<0.001	0.969	<0.001
EGA	0.925	<0.001	0.959	<0.001
TJC	0.746	<0.001	0.825	<0.001
SJC	0.512	<0.001	0.745	< 0.001
Pain VAS	0.934	<0.001	0.967	<0.001
CDAI	0.856	<0.001	0.938	<0.001
DAS28	0.862	<0.001	0.942	<0.001

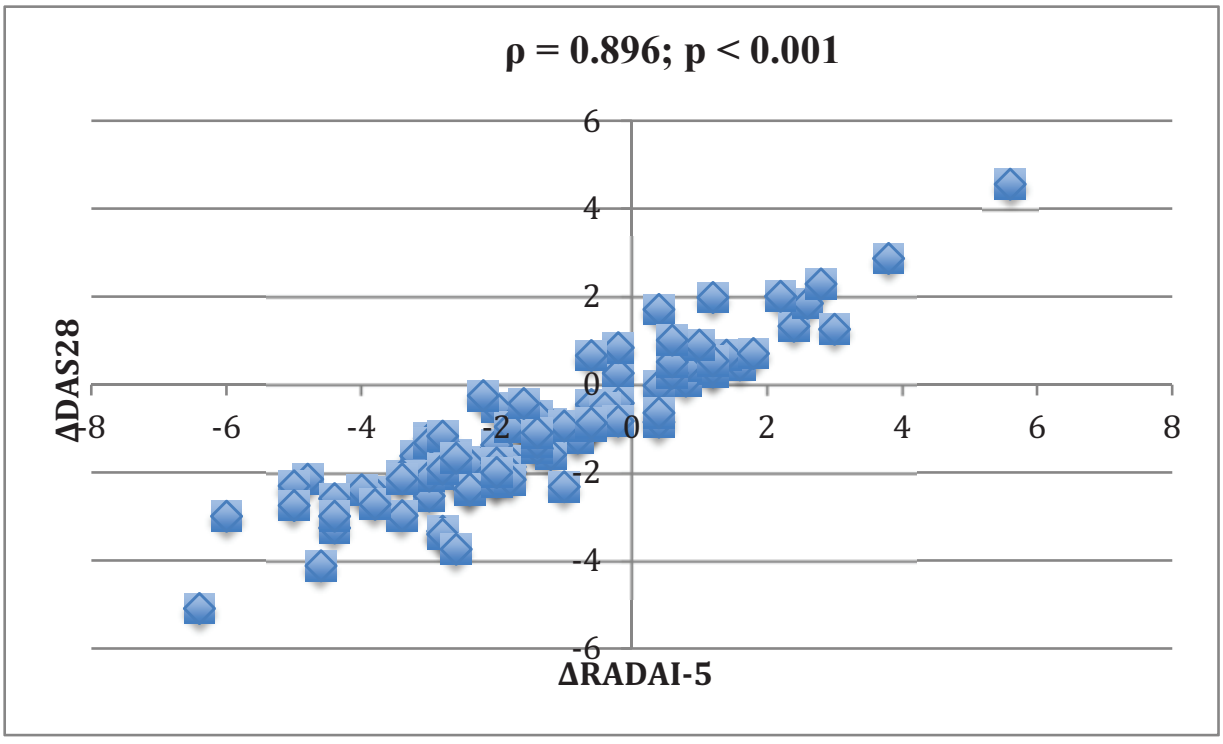
CDAI, Clinical Disease Activity Index; DAS28, Disease Activity Score 28 using erythrocyte sedimentation rate; EGA, evaluator's global health assessment; PGA, patient's global health assessment; SJC, swollen joint counts; TJC, tender joint counts; VAS, visual analog score.

Table 5 Correlation of Rheumatoid Arthritis Disease Activity Index-5 change (ΔRheumatoid Arthritis Disease Activity Index-5)[a] with change in other activity measures

Activity measures	Mean change±SD	Spearman's ρ	*P* value
ΔDAS28	−1.04±1.58	0.896	<0.001
ΔCDAI	−10.29±15.75	0.837	<0.001

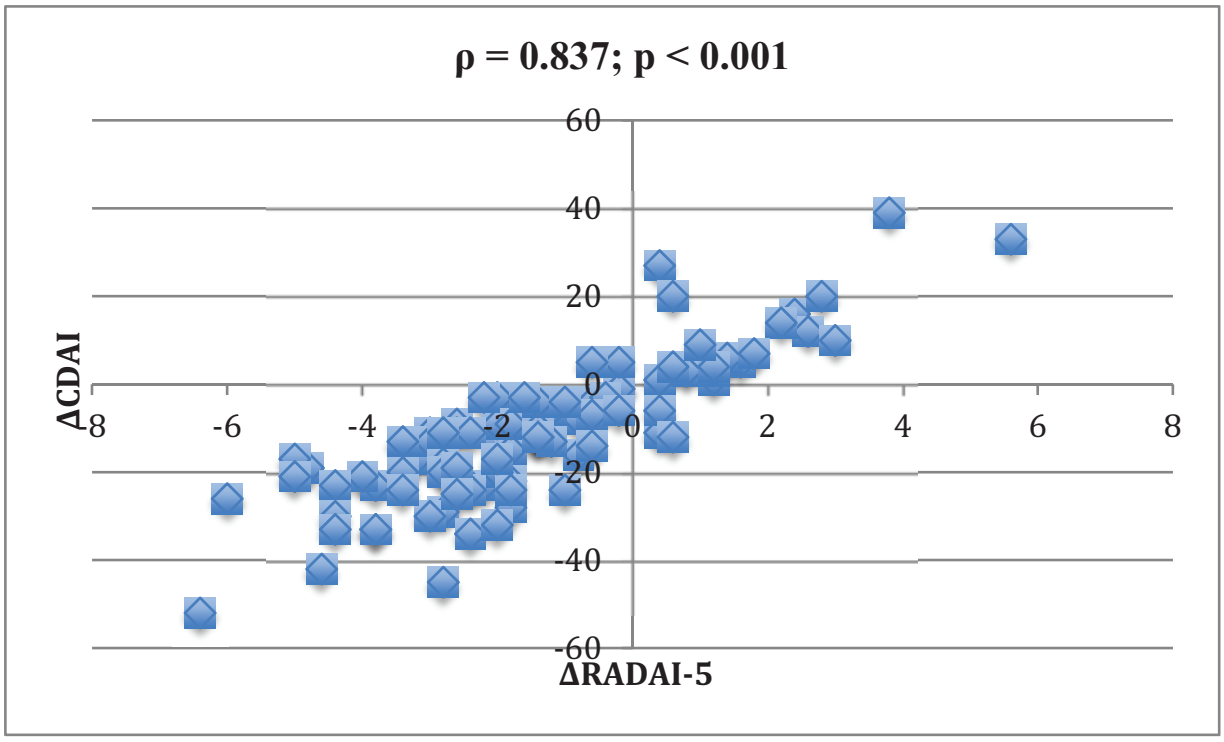
CDAI, Clinical Disease Activity Index; DAS28, Disease Activity Score 28. [a]−1.37±2.15; ΔDAS28, change in DAS28 score; ΔCDAI, change in CDAI

Figure 3



Significant correlation between change in RADAI-5 (on *x* axis) and change in DAS28 (on *y* axis) at follow-up visit. ρ, Spearman's correlation coefficient; ΔDAS28, change in Disease Activity Score 28; ΔRADAI-5, change in Rheumatoid Arthritis Disease Activity Index-5.

Figure 4



Significant correlation between change in RADAI-5 (on *x* axis) and change in CDAI (on *y* axis) at follow-up visit. ρ, Spearman's correlation coefficient; ΔCDAI, change in Clinical Disease Activity Index; ΔRADAI-5=change in Rheumatoid Arthritis Disease Activity Index-5.

functionality [8]. The present study was planned to assess whether RADAI-5 could be used as a valid tool for daily RA monitoring, to assess its sensitivity to improvement or flare-up of RA disease, and to compare its predictability to assess RA activity with respect to DAS28 and CDAI.

Demographic profile of our study group is almost similar to that of previous studies. Malaviya *et al.* [25] had studied the prevalence of RA in Northern India and showed a prevalence of RA approximately three to four times higher in females than males. In a study by Leeb *et al.* [8], the mean age of the patients was 57 years (higher than the mean age of our study group), and almost 80% of the patients were women (as in our study). In another study done by Rintelen *et al.* [26], the study group had 78% women, and the mean duration of disease was 62 months (as in our study). In a study done by Bossert *et al.* [9], 200 patients were included as patients in which 154 (78%) patients patients were RF positive (as in our study). In another study done by Rintelen *et al.* [26], RF positivity of the study group was 59.4%.

At the first assessment, the means for the RADAI-5, DAS28, and CDAI were 5.14, 5.58, and 27.96, respectively (Table 2), which indicate high DA, on average, for the entire patient population. At the second assessment after 3 months, the mean for RADAI-5 was 3.76, for DAS28 was 4.54, and for CDAI was 17.67, indicating a moderate DA (Table 2). Thus, the aforementioned findings indicate that RADAI-5 assessment was very close to or almost similar to DAS28 and CDAI assessment.

The study population was then distributed into four groups according to the level of DA. At the first visit, most patients were found to have high DA, whereas on subsequent second visit, moderate activity was found in most patients (Table 3; Figs 1,2). This means RADAI-5 assesses RA as efficiently as DAS28 and CDAI at individual activity level. However, it was also seen that RADAI-5 assessment was not similar to DAS28 and CDAI at remission and low disease activity state (Table 3; Figs 1, 2).

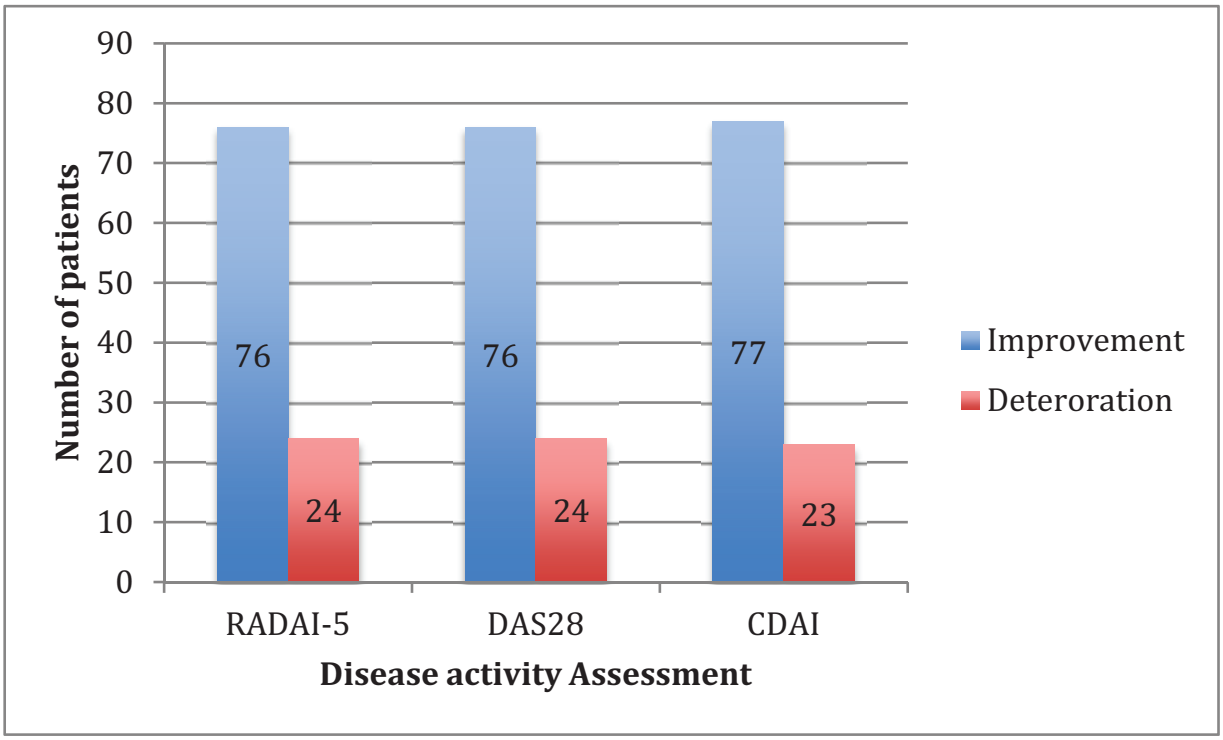
In the present study, RADAI-5 was correlated significantly with CDAI (at first visit ρ=0.856; at second visit ρ=0.938; all P<0.001) and DAS28 (at first visit ρ=0.862; at second visit ρ=0.942; all P<0.001). In a study done by Leeb *et al.* [8], ρ between RADAI-5 and CDAI was 0.740 and between RADAI-5 and DAS28 was 0.638. Bossert *et al.* [9] also found RADAI-5 correlated with CDAI (ρ=0.743) and with DAS28 (ρ=0.662) significantly

Table 6 Number of patients and their mean values for improvement and deterioration in disease activity as assessed by different assessment tools at follow-up visit

DA measures	Improvement		Deterioration	
	Number of patients	Mean	Number of patients	Mean
RADAI-5	76	−2.31	24	1.58
DAS28	76	−1.73	24	1.16
CDAI	77	−16.65	23	11.00

CDAI, Clinical Disease Activity Index; DAS28, Disease Activity Score 28 using erythrocyte sedimentation rate; RADAI-5, Rheumatoid Arthritis Disease Activity Index-5.

Figure 5



Distribution of patients according to the improvement and deterioration in RA disease as assessed by various scales at follow-up (second visit). CDAI=Clinical Disease Activity Index; DAS28, Disease Activity Score 28; RA, rheumatoid arthritis; RADAI-5, Rheumatoid Arthritis Disease Activity Index-5.

($P<0.01$) in their study. In another study by Sunar *et al.* [10], RADAI-5 was correlated with DAS28, with $r=0.81$; P value less than 0.001. In an Egyptian study, correlation between RADAI-5 and DAS28 was also significant ($r=0.90$; $P<0.001$) [11].

At the second assessment, mean RADAI-5, mean CDAI, and mean DAS28 changed by −1.37, −10.29, and −1.04, respectively. All these values indicate improvement in DA, which may be owing to that patients were taking treatment. The change in RADAI-5 score (ΔRADAI-5) was significantly correlated with change in DAS28 (ΔDAS28) ($\rho=0.896$; $P<0.001$), as well as with change in CDAI (ΔCDAI) ($\rho=0.837$; $P<0.001$) (Table 5; Figs 3, 4). Leeb *et al.* [8] also found a strong positive correlation for RADAI-5 change with respect to change in DAS28 ($\rho=0.589$; $P<0.001$) and CDAI ($\rho=0.569$; $P<0.001$) in their study.

Reduction in DA at second visit was considered as improvement and flare-up of DA at second visit considered as deterioration. Improvement was noted in total 76 patients, whereas deterioration was noted in 24 patients when assessed by using RADAI-5 and DAS28-ESR (Table 6). Almost similar results were found when assessment was done by using CDAI (77 improved, 23 deteriorated) (Table 6). This means RADAI-5 is as sensitive as DAS28-ESR and CDAI for assessing any change in DA (Fig. 5).

On agreement analysis between two measures, we found an average although statistically significant agreement between RADAI-5 and DAS28 (kappa

0.563 at first visit; 0.411 at second visit) and CDAI (kappa 0.595 at first visit; 0.574 at second visit). In a study by Leeb *et al.* [8], kappa between RADAI-5 and DAS28 was 0.290 and kappa between RADAI-5 and DAS28 was 0.369, suggestive of a fair but statistically significant agreement. In another study done by Rintelen *et al.* [26], RADAI-5 had a fair relationship with DAS28 (kappa 0.236; $P<0.001$) and CDAI (kappa 0.280; $P<0.001$).

However, the limitations of our study include the following: first, the study was performed in a single center within a relatively small region; second, the study group, although representative of the center's entire RA patient population, in general had moderate to severe DA; third, fibromyalgia that coexists in 15–20% of patients with RA could have exerted an influence on RADAI-5 [27]; and fourth, increased self-efficacy as member of study group constitutes a factor possibly influencing a patient's self-assessment [28].

The observations of our study are in well consonance with the previous studies, which favors the use of RADAI-5 for routine clinical settings as well as home-based settings. It is also suggested that RADAI-5 has a high reliability, high acceptability, good feasibility, and high sensitivity for assessment of any improvement or deterioration in RA DA.

Conclusion

In our study, RADAI-5 is found to be compatible with physician-derived tools, which are developed mainly for research purposes, and seems a valid instrument for measuring and monitoring of RA DA and hence is capable of substituting the use of other tools in routine patient care.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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